

[{"file\_name": "FSIS\_GD\_1995\_0001", "title": "Labeling and Consumer Protection: Proprietary Mixture Suppliers and Manufacturers Questions and Answers", "num": "FSIS-GD-1995-0001", "id": "5e518f264996163d5bd4b99f66b5b973cd48d8f4437ba83618170fcf78659aa1", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/documents/FSIS-GD-1995-0001\_0.pdf", "type": "pdf", "n\_pages": 15, "word\_count": 5896, "text\_by\_page": ["Proprietary Mixture Suppliers and Manufacturers - FAQ's  
http://www.fsis.usda.gov/OPPDE/larc/Ingredients/PMC\_QA.htm 1 of 15 10/6/2005  
1:40 PM United States Department of Agriculture Food Safety and Inspection Service Office of Policy and Program Development Washington, D.C. 20250-3700 Labeling and Consumer Protection Proprietary Mixture Suppliers and Manufacturers Questions and Answers March 17, 1995 To: Proprietary Mixture Suppliers and Manufacturers This letter is intended to supplement the previous letter to the Proprietary Mixture Suppliers and Manufacturers (dated November 1, 1990), and FSIS Directive 7237.1 (Rev. 1), by conveying a compilation of updated questions and answers (Enclosure) pertaining to ingredient review, use, and labeling. The questions and answers are those frequently posed regarding current Agency issuance's on ingredient policies, e.g., proprietary mixes and reaction flavors, and are updated to reflect rule changes promulgated on January 6, 1993, by the Food and Drug Administration on ingredient labeling. Questions regarding ingredient mix formulation review, use, and labeling may continue to be sent to the Labeling and Additives Policy Division (LAPD) at the following address: Robert C. Post, Ph. D., Director USDA, FSIS, OPPD Labeling and Consumer Protection Staff 1400 Independence Avenue, SW, Room 602 - Annex Building Washington, DC 20250-3700 As always, proprietary ingredient mix formulations that are submitted by companies to the Agency for review in order to respond to questions are exempt from mandatory disclosure under the Freedom of Information Act, 5 U.S.C. 552 (b) (4), and will only be used to determine proper listing of the ingredients on meat and/or poultry product labels.", "Proprietary Mixture Suppliers and Manufacturers - FAQ's  
http://www.fsis.usda.gov/OPPDE/larc/Ingredients/PMC\_QA.htm 2 of 15 10/6/2005  
1:40 PM Sincerely, Robert C. Post, Ph. D., Director Labeling and Additives Policy Division Enclosure [return to top of page] QUESTIONS AND ANSWERS RELATING TO USE AND LABELING OF INGREDIENTS, INCLUDING FLAVORINGS, PROPRIETARY INGREDIENT MIXES, INGREDIENTS IN STANDARDIZED AND NON-STANDARDIZED FOODS, AND PROTEIN HYDROLYSATES Table of Contents I. Labeling of Flavorings II. Proprietary Ingredient Mixtures and Ingredients in Standardized and Non-Standardized Foods III. Labeling of Reaction Flavors IV. Labeling of Protein Hydrolysates I. LABELING OF FLAVORINGS 1. Question: What commonly used ingredient may be designated as \"flavors,\" \"flavorings,\" \"flavoring,\" or \"flavor?\"", "Proprietary Mixture Suppliers and Manufacturers - FAQ's  
http://www.fsis.usda.gov/OPPDE/larc/Ingredients/PMC\_QA.htm 3 of 15 10/6/2005  
1:40 PM 2. 3. 4. 5. 6. 7. 8. Answer: Spices, spice extractives, essential oils, oleoresins, onion powder, garlic powder, celery powder, onion juice, and garlic juice. Spices, oleoresin, essential oils, and spice extractives are listed in 21 CFR 172.510, 182.10, 182.20, 182.40, 182.50, and 184. Question: What commonly used ingredients, which have been designated as \"flavors\" prior to March 1990, must be designated by their common or usual name? Answer: Hydrolyzed (source)"]

proteins (e.g., hydrolyzed corn gluten, hydrolyzed casein, hydrolyzed wheat protein, and hydrolyzed milk protein), gelatin, hydrolyzed meat and meat by-products (i.e., \"hydrolyzed [species and tissue of origin]\"), autolyzed yeast, and autolyzed yeast extract are some examples. Question: Can dry meat or poultry stocks, dried broth, extracts, and dried beef plasma be designated as \"flavors?\" Answer: No, because dried stocks, dried broths and extracts, and blood fractions are of animal origin, they must be designated as dried (species) stock, dried (species) broth, (species) extract, or dried (species) plasma. Question: Can commonly used organic acids be designated as flavors? Answer: No, because they have restricted uses and use levels, commonly used acids must be designated by their specific name (e.g., ascorbic, citric, lactic, phosphoric, etc.). Question: Can fruit (or vegetable) juices, purees, powders, and similar ingredients be designated as \"flavors?\" Answer: No, with very few exceptions, these ingredients are foods that have nutritional value and may not be designated as \"flavor\" and must be listed by their common or usual name, e.g., tomato powder and lemon juice. However, powdered onion, powdered garlic and powdered celery, as specifically cited in the regulations (9 CFR 317.2 (f) (1) (i) and 381.118 (c) (2)), may be labeled as \"flavor,\" \"natural flavors,\" or similar terms. Onion juice and garlic juice, according to FDA, may also be termed \"flavor,\" etc. Question: Must specific ingredients that meet the definition of \"flavor,\" e.g., rosemary, and are not proteinaceous, be identified on the label application form? Answer: No. Spices, oleoresins, essential oils, and spice extractives may be grouped together and listed as \"spices\" or \"flavor\" or similar terms without specific names. If color is imparted, they must be designated as, for example, \"spice and coloring\" or by their specific name(s), e.g., turmeric. Question: Can the use of mustard as part of the ingredient mix be designated in the label application as \"spice?\" Answer: Yes, mustard may be listed in the ingredient statement on the label of a meat or poultry product as \"mustard,\" \"spice,\" or \"flavoring\" (see 9 CFR 317.2 (f) (1) (i)). Question: Can \"deflavored\" or \"decharacterized\" mustard (or other spices) be used as an ingredient in meat or poultry products? If so, how should it be designated in the ingredient statement? Answer: Deflavored (or decharacterized) mustard is an acceptable ingredient in the preparation of meat or poultry products, under the conditions of use that are acceptable for spices or flavorings.", "Proprietary Mixture Suppliers and Manufacturers - FAQ's

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1:40 PM \u2022 9. 10. 12. 13. 14. 15. including level of use. When used in a meat or poultry product, deflavored mustard may be designated as \"deflavored mustard,\" \"deheated mustard,\" or \"deactivated mustard.\" According to FDA, deflavored mustard, however, may not be designated as \"mustard,\" \"spice,\" or \"flavoring.\" The same would hold true for other spices. Question: If the processor declares spice(s) or spice extractive(s) on the meat or poultry product label, is it necessary to identify the specific spice(s) and spice extractive(s) on the label application form? Answer: Generally, the processor need not identify each spice or spice extractive and the quantity of each on the label application form. As always, the total quantity of all spices versus all spice extractives will need to be indicated on the label application form to determine order of predominance for the different terms, i.e., spice(s) and spice extractive(s). In addition, if the label is submitted by an establishment in a foreign country, each spice and spice extractive must be identified on the label application form by name because of differences between countries in regulations for these ingredients. Question:

Can paprika, saffron, and turmeric be designated as \"spice\" or \"flavoring\" on meat and poultry product labels? Answer: No. Paprika, saffron, turmeric, and extractives of these, according to FDA, are both spices and coloring, or flavoring and coloring and should be declared as \"spice and coloring\" or \"flavoring and coloring\" unless the specific spice or spice extractive is named in the ingredients statement. Question: Can annatto be designated as \"spice\" or \"flavoring\" on meat and poultry product labels? Answer: No. Annatto may be called either \"annatto\" or \"artificial color\" or \"artificial coloring\" but may not be labeled as spice or flavoring. Question: Does each constituent of ingredients designated, as \"artificial flavor(s)\" have to be identified on the label application form? Answer: No. It is not necessary to identify the specific components of artificial flavors when the substances meet the definition in 21 CFR 172.515 and 182.60. Question: Do ingredients that are designated as \"spice(s),\" \"flavor,\" etc., in FDA-regulated foods that are used as components in meat and poultry products need to be identified on the label application form as to the specific spices or flavors used? Answer: No, foods produced under FDA jurisdiction (e.g., sauces, vegetable mixes, baked beans) that are purchased and used as components of meat or poultry products need not identify the flavors on the label application. The ingredients listed on the label of the FDA regulated product may be listed as such on the label of the meat or poultry product because it is expected they will be in conformance with FDA ingredient labeling rules. Question: When does a processor need to provide specific \"flavor\" component information on purchased products? Answer: Specific information need only be provided if the product is a seasoning ingredient or if there is reason to suspect that the purchased product contains ingredients that are inappropriately designated as \"flavor,\" etc. Question: Does the Agency recognize a de minimis (minimal) level below, which a flavoring ingredient need not be declared?", "Proprietary Mixture Suppliers and Manufacturers - FAQ's

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1:40 PM Answer: No, there is no de minimis level at which a flavoring ingredient need not be declared by its common or usual name. 16. Question: How much information must suppliers of natural flavors, such as \"tomato flavor\" or \"egg flavor,\" provide? Answer: Suppliers of these types of ingredients must supply FSIS, at the time of label approval, with the identification of all constituents (ingredients) of that flavor. 17. Question: Can natural smoke flavoring be listed as natural flavor? Answer: No, the labeling of natural smoke flavorings is covered by 9 CFR 317.2 (j) (3) and 381.119 (a) and by Policy Memo 117, \"Smoke Flavoring.\" Natural smoke flavoring may not be listed as \"natural flavor\" or \"flavor\" in the ingredients statement. It may be declared as \"natural smoke flavoring\" or \"smoke flavoring.\" Artificial smoke flavoring must be labeled as such. 18. Question: Would a distillate of acid, alcohol, or food be considered \"flavor?\" Answer: Yes, distillates from acid, alcohol, or food that are the result of a distillation process, can be designated as \"flavor,\" if they contain solely the flavoring constituents that are not of nutritional consequence. That is to say, no components of the substrate are present \u2013 only the chemical constituents that provide flavor, e.g., aldehydes, ketones, etc. 19. Question: Can cultured, fermented, or enzyme-modified products be designated as \"flavorings?\" Answer: No. According to FDA, these ingredients must be designated by their common or usual name, e.g., \"cultured whey\" and \"enzyme modified cheddar cheese (sublisted ingredients).\" 20. Question: Can flavoring compounds which are separated from fermented products be designated as \"flavors\" (e.g., aldehydes, ketones, diacetyl, etc.)?

Answer: Yes, provided the mixture contains only the flavoring compounds and does not contain the substrate from which the flavoring compounds were removed.

21. Question: How would the "natural" versus "artificial" status of a flavoring compound be verified and by whom?

Answer: FSIS regulations do not provide criteria for differentiating between "natural" and "artificial" flavoring compounds (e.g., "natural" diacetyl). Determination for proper nomenclature can be obtained from the FDA.

22. Question: Can sandalwood extract or yellow sandalwood may be designated as "flavor" on labels of meat and poultry products?

Answer: White sandalwood extract or yellow sandalwood may be designated as "flavor" in the ingredients statement. FDA does not permit the use of red sandalwood extract in food, with the exception of alcoholic beverages.

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1. Question: Does a proprietary ingredient mix formula have to be reviewed approved by FSIS, LAPD, before it can be used in meat or poultry products?

Answer: No. Prior review and approval of proprietary ingredient mixes intended for use in meat or poultry products have never been required by the Agency. A letter of guaranty and a complete bulk label that lists all ingredients of the mix in descending order by common or usual name have always been a means of confirming the identity of ingredient mixes and assuring compliance with FDA ingredient rules and the rules of this Agency.

Percentages of individual constituents of a mix may appear on bulk labels depending on whether the ingredient is restricted in meat or poultry products and\or the meat or poultry manufacturer intends to use a composite approach to listing ingredients on the meat and poultry product label.

2. Question: Can processors submit their proprietary ingredient mix formulas to FSIS, LAPD, to be kept in confidential files for reference before or during the label approval process?

Answer: Yes. Processors may submit the proprietary ingredient mix formulas to FSIS. The formulas will remain I confidential files, as in the past, and will be used for the purpose of verifying the ingredients statements on labels for meat and poultry products.

3. Question: What proprietary mix formulas can be submitted to FSIS?

Answer: The formulas for mixtures of non-meat and\or non-poultry ingredients, e.g., breading mixes, seasonings, spices, marinades, flavorings, cures, and antioxidants, may be voluntarily submitted.

4. Question: Is there a prescribed format required for submission of proprietary mix formulas?

Answer: The suggested format for submission is a list of the following:

- (1) date of submission,
- (2) company name and mailing address,
- (3) technical contact person,
- (4) telephone number,
- (5) name of proprietary mixture (brand name, code, or other designation under which ingredient mix is marketed),
- (6) intended use and level of use,
- (7) statement of composition (list of the quantitative formula with percentages of each ingredient in descending order of predominance \u2013 provide a sublisting of any ingredients used to formulate another ingredient),
- (8) a description of the manufacturing process used to formulate the ingredient mix, including temperatures and time,
- (9) the proposed labeling of the mix in the meat\poultry ingredients statement, and
- (10) certification by a company representative (including name, signature, title, and date) that the description of the mix is accurate and complete, and that it is in accordance with FSIS guidelines and rules."

," "Proprietary Mixture Suppliers and Manufacturers - FAQ's [http://www.fsis.usda.gov/OPPDE/larc/Ingredients/PMC\\_QA.htm](http://www.fsis.usda.gov/OPPDE/larc/Ingredients/PMC_QA.htm) 7 of 15 10\6\2005 1:40 PM

5. Question: Does FSIS provide advisory letters to manufacturers who voluntarily

submit their ingredient mix formulas? Answer: FSIS will issue letters conveying labeling advice when specifically requested.

6. Question: When spices, such as rosemary and thyme, are listed on a proprietary mix label, must they be listed separately on the meat or poultry product label or can they be termed as spices or flavorings? Answer: Ingredients that are spices can be listed by their names, e.g., rosemary and thyme, or as "spices," "flavorings," or similar terms, regardless of the wording on the ingredient mix bulk label.

7. Question: If an ingredient mix is to be used in a product such as "Italian sausage," which must contain the spices, pepper and anise or fennel, as required by 9 CFR 319.145, should the label application list the total amount of spices and sublist each with its percentage? Answer: While it is not necessary to list separately or provide the percentage of each spice on the label submittal form nor to sublist each spice by common or usual name on the proprietary mix label, it would be useful to identify the required spices by name on the label application or on the ingredient mix label because labels for an "Italian sausage" in which the mix is used will not be approved unless the label application shows the mix contains the required spices.

8. Question: Is it necessary to disclose the individual percentage of each proteinaceous ingredient in a mix on the label? Answer: No, while each percentage disclosure for ingredient mixes that are allowed in moisture controlled products has been a practice in the past, we have reconsidered this requirement since publication of the "flavoring" and "added water" regulations (9 CFR 317.2 (f) (1) (i), 318.22, and 381.118) (c) (2)) in March 1990.

9. Question: When are ingredients considered incidental additives? Answer: Ingredients that are present in a meat or poultry product in an insignificant amount and have no functional or technical effects in the finished meat or poultry product may be considered incidental additives. The definition of incidental additives provided by FDA (21 CFR 101.100 (a) (3)) is applied to meat or poultry products. Compliance with these conditions is determined by the Agency (LAPD\FSIS) on a case-by-case basis by considering the use of the proposed incidental additive and the specific meat or poultry product formulation to which it is added.

10. Question: Are incidental additives declared in the ingredient statement? Answer: No, incidental additives are not required to be listed in the ingredients statement of meat and poultry product labels. Anticaking substances, as defined by FDA, such as silicon dioxide (used at less than 2 percent of a spice and seasoning blend), are examples of incidental additives frequently used in spices and seasoning blends. When meat and poultry processors use such spices in their products, they are not required to list the anticaking agent in the ingredients statement because it is present in insignificant amounts and because it no longer serves an anticaking function.

11. Question: What are "carriers?" Answer: Carriers are substances that are, in and of themselves, non-functional (i.e., inert) but which are used to carry and distribute functional additives added to meat and poultry product.","Proprietary Mixture Suppliers and Manufacturers - FAQ's [http://www.fsis.usda.gov/OPPDE/larc/Ingredients/PMC\\_QA.htm](http://www.fsis.usda.gov/OPPDE/larc/Ingredients/PMC_QA.htm) 8 of 15 10\6\2005 1:40 PM Functional additives which are frequently added to formulations through the use of carries are flavorings, antioxidants, and other substances which are used in very small quantities. The use of carriers assists in accurate quantitative measurement and in uniform distribution of the functional additive.

12. Question: Are carriers considered incidental additives? If not, how should carriers be labeled on meat and poultry labels? Answer: A carrier may be required to be designated in the ingredients statement of the product to which it is added unless it is determined to be an incidental additive. If the carrier is determined to be an incidental additive, it need not be designated on the finished product label. There is no precise

level at which the carrier becomes an incidental additive and the issue is handled on a case-by-case basis. 13. Question: Under what circumstances is the listing of carriers on the meat or poultry product ingredients statement required? Answer: In cases where the carrier performs a functional role in the product, the carrier is not an incidental additive and must be declared on the label of the finished meat or poultry product in accordance with labeling rules. However, when lactose, salt, and proteinaceous substances are used as carriers, they are not considered to be incidental additives and must be designated by their specific common or usual names on the meat or poultry product label. 14. Question: When is dextrose or sugar considered a carrier of spices? Answer: Dextrose and\or sugar are commonly used as carriers for spice extracts and resins of spices. The carrier must be declared in the ingredients statement of the meat or poultry product, except in those cases where a sweetening agent is used separately in formulating the meat or poultry product and the use of the spice mixture will not result in the quantity of the carrier being more than 0.75 percent of the product. When a determination cannot be made from the information on a label application, declaration is required. 15.

Question: Are there any situations when the label declaration of monosodium glutamate (MSG) as an added ingredient is not required? Answer: No, there is no established limit, below which, monosodium glutamate does not need to be declared on the label of a product to which it is added. Therefore, when monosodium glutamate is used as an ingredient it must be identified on the finished product label regardless of the amount used. 16. Question: Do FDA certified color additives and their lakes have to be individually declared in the ingredients statement? Answer: Yes. According to FDA rules (21 CFR 101.22 (K) (1), certified color additives and their lakes are distinct ingredients and, thus, must be declared individually, e.g., \"FD&C Red #40\" or \"Red 40,\" in the ingredients statement and not by a grouped term such as \"coloring.\" 17.

Question: Do FDA certified color additives and their lakes have to be individually declared when added to the casings for sausage products and the casings are removed but the surface color effect remains? Answer: Yes. Certified colors must be declared whenever used. In situations where colored casings on sausage products impart a color to the product, the manufacturer must continue to apply", "Proprietary Mixture Suppliers and Manufacturers - FAQ's

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1:40 PM the product name qualifier \"Casing Colored,\" and may either include the name of the certified color in the qualifier (e.g., \"Artificially Colored with FD&C Red #40,\") or may include it in the ingredients statement of the sausage product. 18. Question: Does an FD&C color, e.g., Red #3 or Red #40, have to be declared in the ingredients statements of meat and poultry products when it is added to cure mixes as a tint to distinguish nitrite from salt? Answer: No. The policy has always been that since the color does not function as a color additive in the meat or poultry product, it is considered to be incidental and does not require declaration. 19.

Question: How are non-certified color additives identified? Answer: Color additives not subject to certification may continue to be declared as \"artificial color,\" \"artificial color added, \" or \"color added.\\" Alternatively, such color additives may be declared as \"colored with , \" or \" color,\\" with the blank space filled in with the name of the color additive listed in 21 CFR 73, e.g., \"colored with annatto,\\" or \"caramel color.\\" 20. Question: When used as ingredients in meat or poultry products, do the common or usual names of ingredients of standardized FDA-foods and ingredients have to be listed? Answer: Yes. According to FDA rules (21 CFR 130.11), the ingredients of standardized foods must be (1) declared parenthetically following the name

of the standardized ingredient (i.e., \"component\" labeling), e.g., \"cheddar cheese (milk, enzymes, salt)\" or (2) declared by dispersing each ingredient in its order of predominance in the ingredients statement of the product in which it is used without naming the standardized food specifically (i.e., \"composite\" labeling). 21. Question: When used as ingredients in meat or poultry products, do the ingredients of non-standardized FDA-foods and ingredients have to be listed? Answer: Yes. FDA has always required the ingredients in non-standardized FDA-foods, e.g., egg products and Ricotta cheese, to be listed when used as ingredients in other foods. In the past, FSIS has allowed limited exceptions to the rule, however, after August 8, 1995, all meat and poultry products containing FDA components as ingredients must list all ingredients in those components. 22. Question: What non-standardized foods will require full declaration of ingredients after August 8, 1995? Answer: Soy sauce and Worcestershire sauce are examples of the non-standardized items used as ingredients in meat and poultry products that will need full disclosure of ingredients. 23. Question: What is the policy for declaring ingredients in cured meat products that are used as ingredients in other meat and poultry items? Answer:

Consistent with the recent FDA rule changes requiring the declaration of ingredients in all foods, FSIS is changing its policy on the use of cured meat products as ingredients to require the declaration of ingredients regardless of the use level. 24. Question: How would vegetable oils be listed in an ingredients statement in regard to source material? Answer: FDA regulations require that the source of specific fats or oils be identified. This provision is different with regard to Federal meat inspection regulations which permit the use of a general term such as \"vegetable oil\" (9 CFR 317.2 (f) (1) (iii), 317.8 (b) (21), 319.701). Therefore, \"vegetable oil\" is acceptable as an ingredient declaration and will continue to be acceptable until", "Proprietary Mixture Suppliers and Manufacturers - FAQ's

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1:40 PM the meat and poultry products inspection regulations are amended accordingly.

25. Question: What is the acceptable designation of vegetable starches and starchy vegetable flours? Answer: In some cases, USDA regulations (e.g., the Tables of Approved Substances) require a specific source disclosure, e.g., \"pea flour.\" In many cases, however, the regulations use general terms, e.g., \"vegetable starches\" and \"starchy vegetable flour.\" Unless specified in FDA regulations, source labeling of starches is not required by FDA and, therefore, is not required by FSIS. Thus, terms like \"modified food starch\" are acceptable. 26. Question: Is it acceptable to use an \"and/or\" (or \"may contain\") approach to declare the ingredients of a FDA-foods or ingredient, e.g., ketchup, that is purchased from different manufacturers?

Answer: The use of \"and/or\" labeling will be permitted for the declaration of ingredients in purchased FDA-foods and ingredients in accordance with FDA\u2019s regulations, only if they are listed as components in the ingredients statements of meat and poultry products in which they are used. 27. Question: Can the use of \"and/or\" (or \"may contain\") labeling be applied to minor ingredients, i.e., those present at 2 percent or less, of products such as cured meat or poultry products or such products that are further processed (i.e., sliced, diced, etc.) and packaged? Answer: The use of \"and/or\" labeling will be permitted for minor ingredients of a component of meat or poultry products in accordance with Policy Memo 072, \"Composite Ingredient Labeling.\" Thus, the use of \"and/or\" labeling will be permitted for cured meat components, such as bacon ends and pieces, and ham, as well as for non-meat components, such as soy sauce. Additionally, cured meat poultry items, e.g., ham, with variations in minor

ingredients in their formulations, can be sliced, diced, etc., and bear a label containing an \"and\or\" or \"may contain\" statement in the ingredients listing. 28. Question: Is the term \"seasoning\" an acceptable ingredient designation on meat and poultry product labels? Answer: No. \"Seasoning\" is not established by FDA as a common or usual name. Because it is a very general term, whenever \"seasoning\" is used in the ingredients statement, its components must be identified as a sublisting. 29. Question: Can approved phosphates be collectively designated as \"sodium phosphates\" or \"potassium phosphates,\" as the case may be? Answer: Yes. As a convenience to meat and poultry processors, we are continuing to allow these substances to be declared on labels of meat and poultry products simply as \"sodium phosphates\" or \"potassium phosphates.\" However, if the processor chooses to use a more specific name, the phosphates can be declared by their accepted chemical names.

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1:40 PM III. LABELING OF REACTION FLAVORS 1. Question: What are \"reaction flavors?\"

Answer: During the heating process, chemical reactions occur between reducing sugars and amino acids or proteins. This process conforms to what is commonly understood in chemistry to be the \"Maillard reaction.\" End products of Maillard reactions are referred to as Maillard reaction flavors, \"processed flavors,\" or as \"reaction flavors.\" 2. Question: What processing procedures must be used for reaction flavors? Answer: Presently, reaction flavor products must be processed by heating the reactant mixes at not less than 100\u00b0 C for not less than 15 minutes. 3. Question: Are reaction flavors \"flavoring?\" Answer: Yes. According to FDA\u2019s advisory opinion, the reaction mixture of free amino acid(s) (e.g., cysteine) and reducing sugar(s) (e.g., xylose) in a Maillard reaction system may be termed \"flavor,\" etc. 4. Question: If other substances are added to make a reaction flavor, when should the reactants in a reaction system be listed in the ingredients statement? Answer: The following label guidelines apply to ingredients that are part of a reaction system: a. All ingredients that are of animal origin must be identified by species and tissue, if appropriate, e.g., beef fat, chicken broth, gelatin, and must be listed in descending order of predominance. b. Complex carbohydrates, e.g., modified food starch and maltodextrin, must always be declared because they are not totally consumed (i.e., used up) under most reaction conditions. c. All non-animal proteinaceous substances, e.g., autolyzed yeast extract, hydrolyzed (source) protein, monosodium glutamate, soy sauce, whether totally consumed or not, must be declared. d. All ingredients that are of seafood origin, e.g., Bonito fish extract and shrimp must be listed. e. All ingredients that are foods, meat food products or poultry products, e.g., fruit or vegetable juice, cheddar cheese, beef extract or broth, pepperoni, and bacon must be declared by their standardized names. f. Thiamine hydrochloride, phosphates, salt, and vegetable oil must always be listed because they are not consumed in reaction process.", "Proprietary Mixture Suppliers and Manufacturers - FAQ's

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1:40 PM --- g. Reducing sugar(s) and amino acid(s) that produce a flavor when treated with heat for at least 15 minutes at 100\u00b0 C may be grouped together and labeled as \"flavors.\" 5. Question: Is there a standard of composition or identity for reaction flavor? Answer: No, there is no standard of composition or identity for reaction flavor products; they are merely required to bear non-misleading descriptive names that comply with the established labeling guidelines.

6. Question: How would a reaction flavor be labeled? Answer: The Agency has established specific guidelines for labeling of reaction flavors. Example: a. If 40 percent water, 40 percent chicken meat, 10 percent hydrolyzed soy protein, 5 percent chicken broth, and 5 percent sugar were reacted with sufficient time and heat for a reaction to take place (100°C and 15 minutes), the product name would be Chicken Flavor (contains hydrolyzed soy protein and chicken broth). b. If 30 percent water, 30 percent beef extract, 20 percent xylose, 10 percent cysteine, 5 percent thiamine, and 5 percent salt were reacted with sufficient time and heat, the product would be labeled Beef Flavor (contains beef extract, thiamine, and salt). c. If a chicken "type" flavor was produced from a reaction without chicken as a substrate, using 40 percent water, 20 percent beef extract, 20 percent bacon fat, 10 percent dextrose, 5 pepperoni and 5 percent cysteine, the resulting product would be called Chicken Type Flavor (contains beef extract, bacon fat, and pepperoni). d. If the substrate is 90 percent chicken meat and 10 percent sugar, under the prescribed reaction conditions, the label would state "Chicken Meat and Chicken Flavor," unless it can be shown that the chicken meat is broken down in the reaction to yield only amino acids. In this case, the label would state "chicken flavor" or "flavor (contains chicken)." e. If the substrate is 50 percent pork trimmings, 30 percent xylose, 10 percent cysteine hydrochloride, 5 percent onion powder, 3 percent clove oil, and 2 percent rosemary extract, the label would state "pork flavor" or "flavor (contains pork)." 7.

Question: Are the labeling guidelines for reaction flavors intended to encompass ingredients with a separate identity as a meat food product or poultry product, e.g., dried beef plasma or pork stock? Answer: No. 8. Question: Can reaction flavors be labeled as "natural flavor?" Answer: No. The reaction mixture does not come from a natural source, as such, but is carefully formulated in specific proportions to ensure a product mixture of desired flavor characteristics.", "Proprietary Mixture Suppliers and Manufacturers - FAQ's

[http://www.fsis.usda.gov/OPPDE/larc/Ingredients/PMC\\_QA.htm](http://www.fsis.usda.gov/OPPDE/larc/Ingredients/PMC_QA.htm) 13 of 15 10/6/2005  
1:40 PM \u2022 9. Question: Do processors have to declare water as an ingredient in a reaction flavor? Answer: No. Water that is needed in order for the Maillard reaction to take place does not have to be declared. 10. Question: Can ingredients that are precluded by regulations from use in any meat or poultry product, e.g., sorbates, be used in the preparation of a reaction flavor? Answer: No. 11. Question: What is the appropriate labeling for a reaction mix that is not heat processed? Answer: The labeling guidelines for reaction flavors are not applicable to a mix of reactants (e.g., amino acids and reducing sugars) where heat has not been applied. Each ingredient, including amino acid(s) and reducing sugar(s), in the mix must be individually identified just as ingredients are listed in a seasoning or spice blend. [return to top of page] IV.

LABELING OF PROTEIN HYDROLYSATES 1. Question: Can protein hydrolysates be grouped in the ingredients statement, e.g., "hydrolyzed vegetable protein (corn, soy, wheat)"? Answer: No, "hydrolyzed vegetable protein" is not established by FDA as a common or usual name, nor is it established as an appropriate collective name for a variety of different protein hydrolysates. The common or usual name of a protein hydrolysate should be specific to the ingredient and shall include the identity of the source from which the protein was derived. Hydrolyzed soy protein, hydrolyzed corn gluten, and hydrolyzed casein are examples of acceptable names. The acceptable FDA designation is hydrolyzed corn protein, hydrolyzed soy protein, and hydrolyzed wheat protein. Question: What is the rule of thumb when the identity and function of a hydrolyzed substance is in question? Answer: According to FDA, appropriate standards exist to

allow a distinction between commercially available "highly" hydrolyzed protein hydrolysates and those variously termed "partially," "mildly," or "lightly" hydrolyzed that are not used for flavor-related purpose. According to the FDA, "highly" hydrolyzed proteins are declared as "hydrolyzed (source protein)", "Proprietary Mixture Suppliers and Manufacturers - FAQ's [http://www.fsis.usda.gov/OPPDE/larc/Ingredients/PMC\\_QA.htm](http://www.fsis.usda.gov/OPPDE/larc/Ingredients/PMC_QA.htm) 14 of 15 10/6/2005 1:40 PM and can be defined as those whose ratio of alpha-amino nitrogen (AN) to total nitrogen (TN) is greater than 0.62 (AN:TN > 0.62). Proteins that are not highly hydrolyzed would have AN:TN of less than 0.62 (AN:TN < 0.62) and may be declared by using such terms as "partially," "mildly," or "lightly," e.g., "partially hydrolyzed (source protein)." When a problem arises regarding whether a hydrolyzed substance used in the formulation of a meat or poultry product is accurately identified and serving the primary function of flavoring, we consider these definitions and the level of use of the substance in question. In our experience, substances that have AN:TN > 0.62 would be used at less than 2 percent of the meat or poultry product formulation when used for the primary purpose of flavoring.

3. Question: What is the proper nomenclature of hydrolyzed protein derived from an animal source when utilized as an ingredient in meat or poultry products? Answer: The hydrolyzed protein of slaughtered animal species and tissue of origin, other than gelatin, must be indicated, e.g., "hydrolyzed beef plasma," "hydrolyzed pork stock," and "hydrolyzed pork skin."

4. Question: What are the acceptable declarations for protein hydrolysates that are made of blends of proteins, i.e., the proteins from different sources are hydrolyzed together or individually? Answer: According to FDA rules, for proteins that are blended prior to being hydrolyzed, an appropriate name for the hydrolyzed protein must be sufficiently descriptive of the product and must include all of the various proteins that were used to make the hydrolyzed protein. For example, a hydrolyzed protein made from a blend of corn protein, soy, protein, and wheat gluten would be "hydrolyzed corn, soy, and wheat gluten protein." If proteins are hydrolyzed individually prior to blending, then the common or usual name of each protein hydrolysate must be indicated, e.g., "hydrolyzed corn protein, hydrolyzed soy protein, and hydrolyzed wheat gluten."

5. Question: Is "hydrolyzed gelatin" an acceptable common or usual name? Answer: No. According to a FDA decision, "hydrolyzed gelatin" falls within the standard for Type B gelatin and, therefore, would be declared as "gelatin." [return to top of page]

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For Additional Information Contact: U.S. Department of Agriculture Food Safety and Inspection Service", "Proprietary Mixture Suppliers and Manufacturers - FAQ's [http://www.fsis.usda.gov/OPPDE/larc/Ingredients/PMC\\_QA.htm](http://www.fsis.usda.gov/OPPDE/larc/Ingredients/PMC_QA.htm) 15 of 15 10/6/2005 1:40 PM 1400 Independence Ave. Room 602 - Annex Building Washington, DC 20250 Telephone: 202-205-0279 Fax: 202-205-3625 Email: [FSIS.Labeling@fsis.usda.gov](mailto:FSIS.Labeling@fsis.usda.gov) Please include your name and/or company name, phone number and complete e-mail address so that we may promptly reply to your inquiries."]}, {"file\_name": "FSIS\_GD\_1996\_0001", "title": "Guidelines for Escherichia coli Testing for Process Control Verification in Cattle and Swine Slaughter Establishments", "num": "FSIS-GD-1996-0001", "id": "2abf39a3c5374105e5b9b7c1de624c2949a5ea09895773d3d1673aff5def0318", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Guideline\_for\_Ec

oli\_Testing\_Cattle\_Swine\_Estab.pdf", "type": "pdf", "n\_pages": 22, "word\_count": 7444, "text\_by\_page": [{"Guidelines for Escherichia coli Testing for Process Control Verification in Cattle and Swine Slaughter Establishments INTRODUCTION Under the Pathogen Reduction\HACCP Regulation, slaughter establishments are required to test carcasses for generic E. coli as a means of verifying process control. This document outlines sampling and microbial testing procedures that would meet this requirement. These guidelines may be helpful to your company microbiologist or analytic laboratory. This document is a supplement to the Regulation but not a substitute; in-depth details of microbial sampling and testing may be found in the Regulation. Background These guidelines describe a nondestructive sponge technique for sample collection from raw cattle and swine carcasses. The Pathogen Reduction\HACCP Regulation anticipated that this nondestructive technique would be used with samples taken from the same point in the slaughter process as were the samples in the FSIS Nationwide Microbiological Baseline Data Collection Programs. It was envisioned that a conversion factor would correlate sample results from the sponge method to results from the excised-tissue method used in the baseline studies. Performance criteria derived from the baseline studies - with acceptable, marginal, and unacceptable ranges - would then be applied to establishment sample results obtained by the sponging method. Analysis of recent data, however, has not been able to determine such a conversion factor for the two methods. For this reason, the regulatory criteria described in the Regulation remain relevant only to excised-sample results, upon which they were based. Consequently, the Agency is requiring that establishments test for generic E. coli and employ standard statistical process control measures to demonstrate that their operations are in control, until such time as new baselines are established with the sponging method. Also provided here in an Addendum are the sampling and analytical techniques, using excised tissues, that were employed in the FSIS baseline studies; establishments may use the excised-tissue technique and apply the performance criteria originally defined for their specific operations. Statistical Process Control - An Overview The statistical process control approach required by the Agency is based on the principle that every product is produced by a process. All processes are subject to variation, which should be", "understood and controlled by statistical methods. A process that is in control is stable in terms of average level and degree of variation, i.e., it is predictable within limits and is thus \"doing its best.\\" Processes that have not been subjected to analysis are not likely to be in control. Control is attained, often by degrees, by detecting and eliminating special causes of variation, those not present all the time or not affecting all product output. This involves initially evaluating data to determine process capability (the typical process performance level), and then checking subsequent data to see if they are consistent with this baseline level, i.e., the process is in control and variations are within normal and acceptable limits. This is accomplished by checking for unreasonably high results, trends, etc., and looking for and correcting problems in the process when these signals occur. It is important to recognize that an in-control process may not necessarily result in product of the desired quality improvements may be needed or the entire process may require reconsideration. Problems in a process may stem from many sources, for example: inadequate knowledge of how a process should work or how a specific process is performing; errors or deficiencies in executing procedures; failure to recognize the need for preventive measures; unnecessary complexity in the process; and uncontrolled variation among inputs. Specific techniques of statistical process control include

the time plot, which charts measurements over time; this is the first technique to use with data collected over time and analyzed for patterns. A further development is the control chart, which plots data over time but also displays an upper control limit for specific measurements, and a centerline, above and below which there is an equal number of sample results (the centerline is in effect a median average). A sample result above the upper control limit would indicate the likely presence of a special cause of variation that should be addressed. Results within control limits indicate simply that the process is in control. Control charts have two essential uses: after-the-fact analysis of process performance and gaining and maintaining control of a process. In most situations more than one type of control chart would be applicable; detailed information can be found in texts on statistical quality control, under the topic "control charts." In general, statistical process control techniques help to provide experience in "process thinking" (a central tenet of HACCP), develop an historical record of performance, evaluate the long-term stability of a process and determine process capability (i.e., how it is actually working), and judge the effectiveness of process improvement actions.

Generic E. coli testing conducted as part of statistical process control will not be directly useful for attaining and maintaining control of a process, as test results will come from the end of the process and in any case would not be timely enough; observations made earlier in the process would be more useful for attaining and maintaining control. Rather, E. coli testing would serve to verify process control. Process control techniques, applied and verified in this manner, would accomplish the essential intent", "of the Regulation by integrating process control and microbial testing into slaughter operations.

**GUIDELINES FOR SAMPLE COLLECTORS\ MICROBIOLOGISTS**

Pre-sampling Preparation Sample collection shall be conducted by the individual(s) designated in the establishment's written procedures for microbiological sampling, as required by 9 Code of Federal Regulations (CFR) Part 310.25(a)(2)(i). These procedures shall also specify the location of sampling, the random sample selection method chosen by the establishment, and sample handling procedures that will ensure sample integrity. Before beginning sample collection, assemble sampling supplies, such as sterile gloves, sterile sampling solutions, hand soap, and sanitizing solution, as well as specific materials needed for sampling different carcass types (i.e., specimen sponges in bags and template for sampling cattle or swine carcasses). For cattle and swine carcass sampling, a template is recommended to mark off the area to sample. The template can be made of any suitable material, such as metal or aluminum foil, brown paper, or flexible plastic. Some disposable templates may be sterilized and individually prepackaged. To make a reusable template, cut out a 10 centimeters (cm) x 10 cm (3.94 inches x 3.94 inches) square from a sheet larger than the area to be sampled. (See Figure 1). If a reusable template is used, it will need to be sanitized with an approved sanitizing solution [e.g., hypochlorite (bleach) solution or alcohol]; however, the template needs to be dry before it is placed on the carcass. Aluminum foil or paper templates can be used once and discarded; foil or paper used for the template should be stored so as to prevent contamination. Since the area enclosed by the template will be sampled, take care not to touch this area with anything other than the sampling sponge. Using dirty or contaminated material may lead to nonrepresentative results. If an autoclave is available, paper or aluminum foil templates can be wrapped in autoclavable paper and sterilized. Sterile sampling solutions, such as Butterfield's phosphate diluent (BPD) or buffered peptone water (BPW), can be stored at room temperature; however, at least the day before sample collection, check such solutions for cloudiness and do not use

solutions that are cloudy or turbid or that contain particulate matter. Place the number of containers of sampling solution that will be needed for the next day's sampling in the refrigerator. To obtain the most accurate results, samples should be analyzed as soon after collection as possible. If samples must be transported to an off-site laboratory, they should be refrigerated and then shipped refrigerated, on the same day they were collected, via an overnight delivery service to the laboratory. A sample should arrive at the laboratory and be analyzed no later than the day after it is collected. If sample collection, pick-up or shipment, and laboratory analysis cannot be carried out within this timeframe, the carcass selected for sampling", "should be held until the process can be accomplished in the appropriate span of time. The same principle applies for samples that are analyzed in-plant: If a carcass cannot be sampled and the sample analyzed by the day after it is taken, the carcass should be held until this is possible. A collected sample should not be held; it should be either analyzed in-plant by the next day or immediately shipped for overnight delivery to the laboratory that will conduct the analysis. The Sample Shipment section below gives information on shipping containers and transporting samples to off-site facilities. Sampling frequency Sampling frequency for E. coli testing is determined by production volume. The required minimum testing frequencies for all but very low production volume establishments are shown in Table 1 by type of livestock. An establishment need sample only the predominant species when two or more species are slaughtered. Table 1. E. coli Testing Frequencies Cattle 1 test per 300 carcasses, or at least 1 test per week Swine 1 test per 1,000 carcasses, or at least 1 test per week NOTE: These testing frequencies do not apply to very low volume establishments. See Table 2. Very low volume establishments Some establishments may be classified as very low volume establishments. The maximum yearly slaughter volumes for very low volume establishments are described in Table 2. An establishment need sample only the predominant species when two or more species are slaughtered. Table 2. Maximum Yearly Livestock Slaughter Volumes for Very Low Volume Establishments Type of Criteria (Yearly Slaughter Volume) Livestock Cattle not more than 6,000 head Swine not more than 20,000 head Cattle and not more than 20,000 total, with not more Swine than 6,000 cattle A very low volume establishment will sample the predominant species once per week beginning the first full week of operation after June 1, until at least 13 test results have been obtained or the following June 1, whichever", "is first. The establishment will repeat the same sampling regime once per year, beginning the first full week of operation after June 1. If a very low volume establishment is using the excised-sample technique and is slaughtering a type of livestock for which performance criteria have been determined, the establishment must continue sampling once per week until results show that it has met the m\l/M criteria outlined in the Pathogen Reduction\HACCP Regulation. See Addendum below. Random selection of carcasses Samples are to be taken randomly at the required frequency. For example, given that the frequency of testing for cattle is one test per 300 cattle slaughtered, if a plant slaughters 150 head of cattle an hour, one sample will be taken every two hours. Note: If more than one shift is operating at the plant, the sample can be taken on any shift. Cattle and swine carcass selection Different methods of selecting the specific carcass for sampling could be used, but all require the use of random numbers. Examples of methods include random number tables, calculator- or computer-generated random numbers, or drawing cards. The carcass for sampling should be selected at random from all eligible carcasses of the predominant species. If there are multiple lines or chillers, randomly select the line or

chiller for sample collection for that interval; each line or chiller should have an equal chance of being selected at each sampling interval. Both the \"leading\" and \"trailing\" sides of a carcass should have an equal chance of being selected within the relevant time frame (based on the sampling frequency for the plant). Cattle and swine carcasses may be designated for sampling at any time, but samples should be collected at the end of the slaughter process after chilling for at least 12 hours; hide-on or hotboned swine or cattle samples should be collected after the final wash. Aseptic techniques\sampling Extraneous organisms from the environment, hands, clothing, sample containers, sampling devices, etc., may contaminate samples and lead to non-representative analytical results. It is necessary to use aseptic sampling techniques and clean, sanitized equipment and supplies. An area should be designated for preparing sampling supplies. A stainless steel, wheeled cart or table would be useful during sampling. A small tote or caddy could be moved to the location of sampling and used for carrying supplies; sample bags could be placed on the tote or caddy when sterile solutions are added to the bags. Sterile gloves should be used for collecting samples. Nothing should contact the external surface of the glove except the exposed sample being collected or the sterile sample utensil (specimen sponge). Keep in mind", "that the outside surfaces of the sample container are not sterile. The following procedure for putting on sterile gloves can be followed when collecting samples: a) Peel open the package of sterile gloves from the top without contaminating (touching, breathing on, contacting) the exterior of the gloves. b) Remove a glove by holding it by the inner surface of the wrist-side opening. Avoid any contact with the outer surface of the glove. Insert the washed and sanitized hand into the glove, taking care not to puncture the glove. c) Taking care not to contaminate the exterior surface of the glove, repeat the above step for the hand you will use to physically handle the sample. d) If at any time you are concerned that a glove may be contaminated, begin again with step a) above.

Preparation for Sample Collection

On the day of sampling, gather all sample collection bags, sterile gloves, sanitizer, hand soap, sterile solutions for sampling, and specific materials needed. Ensure that all sampling supplies are on hand and readily available before beginning sample collection. Label the sample bags before starting the sampling procedure. Use permanent ink. If you are using paper labels, it is important that the label be applied to the bag at normal room temperature; it will not stick to the sample bag if applied in the cooler. Outer clothing such as frocks, gloves, or head gear worn in other areas of the plant should be removed before entering the sampling area or preparing to collect samples. Replace outer clothing with clean garments, such as a laboratory coat, that have not been directly exposed to areas of the plant outside of the sampling area. Sanitize the sample work area surfaces by wiping with a clean disposable cloth or paper towel dipped in a freshly prepared 500 ppm (parts per-million) sodium hypochlorite solution (0.05% sodium hypochlorite) or other approved sanitizer that provides an equivalent available chlorine concentration. The sample work area surfaces must be free of standing liquid before sample supplies or product containers are placed on them. Before sampling, thoroughly wash and scrub hands to the midforearm. Use antibacterial hand soap. This procedure should include a sanitizer at 50 ppm equivalence available chlorine, if available. Dry the hands using disposable paper towels.", "Cattle and Swine Surface Sponge Sample Collection Procedure Materials: 1. Sterile specimen sponge in sterile Whirl-Pak\u00ae-type bag or equivalent[approximately 1 1/2\" x 3\" x 5/8\" after hydration) 2. 25 ml sterile sampling solution (e.g., Butterfield's phosphate diluent [BPD] or sterile buffered peptone water [BPW]) 3. Sterile ziplock-type or

stomacher bag 4. Template for 100 CM<sup>2</sup>sampling area 5. Sterile gloves 6. Sanitizing solution 7. Small tote or caddy for carrying supplies 8. Wheeled ladder, platform, or step ladder Collection A sterile (non-latex, non-bactericidal) sampling sponge, which is usually dehydrated and prepackaged in a sterile bag, will be used to sample all sites on the carcass. The sites are for cattle: flank, brisket, and rump see Figure 2 (for hide-on calves: inside the flank, inside the brisket, and inside the rump); for swine: belly, ham, and jowl - see Figure 3. It is important to sponge the areas in the order of least to most heavily contaminated in order to avoid spreading any contamination. Therefore, sponge the areas in the sequence indicated in this sampling protocol. Nondestructive surface sampling should be conducted as follows: 1. Ensure that all supplies are on hand, including the sampling template, and that all bags have been pre-labeled. The information needed for each sample includes the type of livestock sampled, the date and time of sample collection, and, if there is more than one slaughter line, the slaughter line from which the sample was collected. (An assistant may be helpful during the sampling process.) 2. If a reusable template is used, immerse the sampling template in an approved sanitizing solution for at least 1-2 minutes. Just before sponging the first sample site on the carcass, retrieve the sampling template from the sanitizing solution (step 12). Shake excess solution from the template and let dry, then protect the portion of the template that will contact the carcass from contamination. 3. For cattle: Locate the flank, brisket, and rump sampling sites using illustrations and directions in Figure 2 (cattle carcass sampling locations).,"For swine: Locate the belly, ham, and jowl sampling sites using illustrations and directions in Figure 3 (swine carcass sampling locations). 4. While holding the sponge bag at the top corner by the wire closure, tear off the clear, perforated strip at the top of the bag. Open the bag. 5. Remove the cap from the sterile BPD\BPW bottle, being careful not to touch the bottle opening. Do not contaminate the lid. 6. Carefully pour the entire contents of the sterile BPD\BPW bottle (25ml) into the sponge bag to moisten the sponge. 7. Close the top of the bag by pressing the wire closures together. Use hand pressure from the outside of the bag and carefully massage the sponge until it is fully hydrated (moistened). 8. With the bag still closed, carefully push the moistened sponge to the upper portion of the bag, orienting one narrow end of the sponge up toward the opening of the bag. Do not open the bag or touch the sponge with your fingers. Hold the bag and gently squeeze excess fluid from the sponge using hand pressure from the outside. The whole-moistened sponge should still be in the upper portion of the bag, with the excess BPD\BPW in the lower portion. 9. Open the bag containing the sponge, being careful not to touch the inner surface of the bag with your fingers. The wire closure at the top of the bag should keep the bag open. Set bag aside. 10. Put on a pair of sterile gloves (use procedure on pp. 6-7). 11. Carefully remove the moistened sponge from the bag with the thumb and fingers (index and middle) of your sampling hand. 12. With the other hand, retrieve the template by the outer edge, taking care not to contaminate the inner edges of the sampling area of the template. 13. For cattle: Locate the flank sampling area (Figure 2). Place the template over this location. For swine: Locate the belly sampling area (Figure 3). Place the template over this location. 14. Hold the template in place with one gloved hand (Remember, only the sponge should touch the sampling area. Take care not to contaminate this area with your hands.) 15. With the other hand, wipe the sponge over the enclosed sampling area (10 cm x 10 cm) for a total of approximately 10 times in the vertical and 10 times in the horizontal directions. The pressure for sponging would be as if you were removing dried blood from the

carcass;","however, the pressure should not be so great as to crumble or destroy the sponge. (Note: The template may need to be \"rolled\" from side to side during sponging since the surface of the carcass is not flat. This ensures that the 100 cm<sup>2</sup> area is enclosed while sponging.) 16. For cattle: Repeat steps 14-15 for the brisket area, using the same side of the sponge used for the flank. Then, repeat steps 14-15 for the rump area, using the side of the sponge opposite that used for the flank and brisket. For swine: Repeat steps 14-15 for the ham area, using the same side of the sponge used for the belly. Then, repeat steps 14-15 for the jowl, using the side of the sponge opposite that used to sponge the belly and ham. 17. For cattle: After sponging the brisket and rump areas, carefully place the sponge back in the sponge sample bag, taking care not to touch the sponge to the outside of the sample bag. For swine: After sponging the ham and jowl areas, carefully place the sponge back into the sponge bag. Do not touch the surface of the sponge to the outside of the sponge bag. 18. Press wire closures of the sponge bag together, expel excess air, then fold down the top edge of the bag 3 or 4 times. Secure the bag by folding the attached wire tie back against the bag. Place the closed sponge bag into the second bag and close the second bag securely. 19. a) If samples are to be analyzed at an on-site laboratory, begin sample preparation (Analytical Methods section) b) If samples are to be analyzed at an outside (off-site) laboratory, follow procedure in the Sample Shipment section. Sample Shipment If on-site facilities are not available, samples should be shipped to an outside laboratory the same day they are collected. Samples should be analyzed no later than the day after collection. Shipping containers and coolant packs It is important that samples fit easily into the shipping containers so that the sample bags do not break. Correct use of coolant gel-ice packs and proper packing of the shipping container are necessary so that samples arrive at the laboratory at an acceptable temperature (0-10\u00b0C). Maintaining samples at improper temperatures may cause inaccurate results. The sample should be kept refrigerated, not frozen, in the shipping container before it is picked up. The shipping container itself should not be used as a refrigerator; however, multiple samples (if needed) for that","day may be stored in the open shipping container in the cooler or refrigerator. Recommended Procedure 1. Prechill shipping container by placing the open shipping container in the refrigerator at least the day before sampling. 2. Place the appropriately-labeled, double-bagged sample(s) in the prechilled shipping container in an upright position to prevent spillage. Newspaper may be used for cushioning the sample and holding it in the upright position. If more than one sample is collected during the day, take steps to ensure that samples are maintained at refrigeration temperature, as this helps limit multiplication of microorganisms. 3. Place a corrugated cardboard pad on top of sample(s). This corrugated cardboard pad prevents direct contact of frozen gel packs with the samples. Next place the frozen gel pack(s) on top of the corrugated pad. Use sufficient frozen coolant to keep the sample refrigerated (0-10\u00b0C) during shipment to the designated laboratory. Insert foam plug and press it down to minimize shipper head space. 4. Ship samples to the laboratory via overnight delivery or courier. Suggested Criteria for Microbiological Laboratories These suggestions are not meant to be exhaustive. Specific needs will vary from one processor to another. Personnel Both laboratory analysts and supervisors must have education, training, and experience in food microbiology. Specific familiarity with meat slaughter operations would be desirable. Personnel should be well versed in methods of analysis for meat samples and the organisms associated with meat products. Facilities Laboratory facilities should be suitable for conducting routine and specialized

microbiological analyses and should provide adequate bio-safety precautions. It is crucial that the laboratory maintain separate, defined areas for sample receipt, preparation, and analytic work. Equipment The laboratory should have suitable equipment, appropriate preventive maintenance programs, readily available equipment manuals, and log books for documentation. Specialized equipment may be necessary for some applications.", "Operations The laboratory should have in place a written quality assurance (QA) program that is available to all employees. The QA program should include bio-safety equipment, media preparation, microbiological methods and procedures, control programs, equipment control, culture maintenance, sample receipt, handling, result reporting, and record keeping. Records Records should contain a complete sample description, including condition, source, lot code, date, quantity, etc. Results should be reported promptly and all data and summaries permanently recorded with the results. Analytical Methods All sample analyses must begin the day after collection. Samples must be analyzed using one of the E. coli (Biotype I) quantitation methods found in the Official Methods of AOAC International, 1611 edition, 3rd revision, 1997. Or, by any method that is validated by a scientific body in collaborative trials against the 3-tube Most Probable Number (MPN) method and that agrees with the 95% upper and lower confidence limits of the appropriate MPN index. The following methods for generic E. coli quantitation in foods have been AOAC-approved: 1) 3-tube MPN method - AOAC 17.2.01-17.2.02 2) Modified 3-tube MPN method - AOAC 17.3.07 - Substrate Supporting Disc Method (ColiComplete\u00ae). ColiComplete\u00ae Substrate Supporting Discs are available from BioControl Systems, Inc., 19805 North Creek Parkway, Bothell WA 98011. 3) Modified 3-tube MPN method - AOAC 17.4-01 - Fluorogenic Assay for Glucuronidase. Lauryl sulfate tryptose broth with added 4-methylumbelliferyl-B-D-glucuronide (MUG) is used in a 3-tube MPN method. 4) Plating Method - AOAC 17.3.04 - Dry Rehydratable Film (Petrifilm E. coli Count Plate) Method. Medical-Surgical Division\3M, 275-5W 3M Center, St. Paul MN 55144. 5) Filtration\Plating Method - AOAC 17.3.09 - Hydrophobic Grid Membrane Filter\MUG (ISO-GRID) Method. QA Life Sciences, Inc., 6645 Nancy Ridge Dr., San Diego CA 92121. Note: For most quantitative assays, weekend laboratory work can be kept to a minimum by refrigeration of incubated plates\tubes until Monday. A programmable refrigerated incubator is useful in such cases. For commercially available methods follow manufacturer's recommendations.", "Suggested quantitation schemes If a generic 1 milliliter (ml) plating technique is used for E. coli quantitation for cattle or swine carcass sponge sample analysis, the average plate count (if 2 plates are used) or the single plate count (if 1 plate is used) would be divided by 12 to equal the count of colony forming units per cm<sup>2</sup>. Record this value even if it is less than 1 cfu\cm. For cattle samples the undiluted sample extract (10\u00b0) and a 1:10 dilution should be plated, preferably in duplicate. For swine samples the undiluted sample extract (10\u00b0), a 1:10, a 1:100, and a 1:1, 000 dilution should be plated, preferably in duplicate. Higher or lower dilutions may need to be plated based on the specific product. If a hydrophobic grid membrane filtration method is used, the only difference would be filtration of 1 ml of the undiluted sample extract (10\u00b0) and 1:10 dilution for cattle samples and 1 ml of the 10\u00b0 - 103 dilutions for swine samples. Additional dilutions of the original extract may need to be used if a 3-tube MPN protocol is used. The 3 highest dilutions that were positive for E. coli are used to calculate the MPN. MPN values from the appropriate MPN Table represent the count per ml of original extract and therefore must be divided by 12 to obtain the count per cm<sup>2</sup> of carcass surface area. Record

this value even if it is less than 1 cfu/cm<sup>2</sup>. Recordkeeping Each test result must be recorded in terms of colony forming units per square centimeter (cfu/cm<sup>2</sup>). Record this value even if it is less than 1 cfu/cm<sup>2</sup>. A process control table or chart can be used to record the results and facilitate evaluation. Results should be recorded in the order of sample collection and include information useful for determining appropriate corrective actions when problems occur. The information needed for each sample includes date and time of sample collection, and, if more than one slaughter line exists, the slaughter line from which the sample was collected. These records are to be maintained at the establishment for 12 months and must be made available to Inspection Program employees on request. For E. coli testing to be most useful for verifying process control, timeliness is important and the record should be updated with the receipt of each new result. Records should also be kept of any corrective actions taken if process control deviations are detected through microbiological testing. Note: Occasionally, samples shipped to off-site laboratories may be lost during shipping or may arrive at the laboratory late or outside the acceptable temperature parameters for sample analysis (0-10@C). Any reasons for missing data should be documented.", "Figure 1. Example of sampling template (not drawn to scale) 15 10 cm 10 cm", "Figure 2. Sampling locations for E. coli testing of cattle carcasses Rump Locate the posterior aspect of the aitch bone. Draw an imaginary line toward the achilles tendon. At the point where the line intersects the cut surface of the round is the starting point for the rump sample. Measure 10 cm up the line leading to the achilles tendon, then 10 cm over (laterally), then 10 cm back to the cut surface of the round, then 10 cm along the cut surface to form the 10 cm by 10 cm square area. Note: The upper illustration has been purposely altered somewhat. A true lateral view of the carcass would not show the aitch bone. From a medial view, the whole 10 cm x 10 cm sampling area could not be seen. Therefore, a lateral view with a portion of the round removed so the location of the aitch bone is shown is illustrated. Flank Locate the cutaneous flank muscle (external abdominal oblique) and follow the medial border of the muscle anteriorly until it comes within approximately 3\'' of the midline. This will be the starting point. Measure up (posteriorly) 10 cm (approximately 4 inches) along a line approximately 3\'' from the midline (measure up or parallel to the midline), then over (laterally) 10 cm (approx. 4 inches) to form a 10 cm wide by 10 cm long square sample. Brisket Locate the elbow of the carcass. Draw an imaginary line straight across (medially) to the midline cut. This will be the starting point. Measure up along the midline 10 cm (approximately 4 inches), then over 10 cm (approximately 4 inches) to form a 10 cm wide by 10 cm long square sample.", "Figure 3. Sampling location for E. coli testing on swine, carcasses belly Locate the elbow of the carcass. Draw an imaginary line straight across (medially) to the midline cut. This will be the starting point. Measure up along the midline 10 cm (approximately 4 inches), then over 10 cm (approximately 4 inches) to complete the 10 cm long by 10 cm wide square sample. This square area will be the 100 cm<sup>2</sup> area to swab for the belly sample. Jowls Draw an imaginary line from the atlas/axis joint to the ventral midline; all skin below that point will be considered the jowl. Ham From the dorsal position, locate the lateral surface of the base of the tail and measure up caudal) 5 cm along the lateral edge of the exposed fat margin, then 10 cm laterally. Now measure 10 cm down cranial), then 10 cm medially, then 5 cm up (posteriorly) to complete a 10 cm long by 6 cm wide rectangular sampling area. 17", "ADDENDUM EXCISION SAMPLE COLLECTION AND ANALYSIS TECHNIQUES USED IN THE FSIS NATIONAL BASELINE STUDIES PREPARATION 1. Label 3 sample bags with the labels provided: for cattle brisket, flank,

and rump; for swine - jowls, belly, and ham). It is important that the labels be applied to the bags at normal room temperature; they will not stick if applied in the cooler. 2. Measure the length of the blade on the knife you will be using for sample collection. You can use this measurement to estimate the size of the 10 inch long by 5 inch wide ham and belly samples for swine, and the 8 inch long by 6 inch wide samples for cattle. 3. Assemble the following: labeled bags knife (cleaned and sanitized) hook (or hemostat-type forceps), cleaned several packages containing sterile surgical gloves clean container (volume of 1 gallon or greater) FSIS-approved household bleach product potable water Also, locate a wheeled ladder, sampling platform, or step ladder that can be used to help you safely reach the ham or rump of the carcass. You will need at least one assistant to hold the sample bag and help you in other ways. 4. Prepare the chemical sanitizing solution by adding 2 to 4 oz. bleach to 1 gallon (128 oz.) potable water in the container (this will give a strength of 1000-2000 ppm hypochlorite, which is strong enough to sanitize properly even in the presence of some organic matter). Note: prepare fresh bleach solution immediately before going into the cooler for sampling; its strength diminishes upon standing.

**SAMPLE COLLECTION**

1. Have your assistant immerse the entire sampling tool (including the handle) in the bleach solution for 1-2 minutes. Have your assistant put on a pair of sterile gloves (taking care not to touch the sterile outer surface of the glove with fingers) before carefully retrieving the sampling tools from the bleach solution. Shake excess solution from utensils, and then protect the sampling ends of the tools from contamination. Do not put the sanitized sampling implements into your scabbard (it has not been sanitized).
2. Put on one sterile glove at a time, taking care not to touch the sterile outer surface of the glove with your fingers. Having both hands gloved will remind you that you need to follow "aseptic" procedures. Remember: Touch nothing with your gloved hands except the sanitized instruments or the carcass if necessary.
3. Locate the 3 carcass sampling sites. (Note: Remember you can use the knife blade to estimate the length of samples.)
4. For cattle: Use the knife to mark out the sample borders of the brisket sample from one side of the carcass. You do not need to cut very deep since only the skin surface is needed; a 1/2 inch thick sample is sufficient. It is very important that the sample be 8 inches long by 6 inches wide (not 6 1/2 long and 8 1/2 wide) and that it be in one piece. Carefully excise the sample using the knife and the sanitized hook or forceps. Roll or fold the sample so that it fits easily into the sample bag (do not cut the sample into strips). Have your assistant hold open the labeled sample bag, and place the brisket sample inside the bag without touching the outside of the sample bag or the assistant. Have assistant close the sample bag.
- For swine: You will be collecting the surface (skin) of both jowls. A 1/2 inch thickness is sufficient; you do not need to cut very deep since only the skin is being sampled. It is very important that you collect all the skin from both jowls; the laboratory analysis requires that each of the two jowl samples provide a surface area equivalent to a 5 inch by 5 inch square. Surface area in excess of this is acceptable, as the laboratory will trim it down. The skin on each jowl should be carefully removed in one piece using the knife and the sanitized hook or forceps. Roll or fold the samples so that they fit easily into the sample bag (do not cut the samples into strips). Have your assistant hold open the labeled sample bag, and place the two jowl samples inside the bag without touching the outside of the sample bag or the assistant. Have assistant close the sample bag.
5. Do not put the sampling implements back into your scabbard. You may wish to "sheathe" your knife in the carcass where you will be able to reach it from the ladder or platform (insert it

perpendicular to the floor, perhaps into the teat line or the medial flank). 6. For cattle: Remove the knife from the carcass and mark out the sample borders for the flank sample. Collect the 8 inch long by 6 inch wide by 4 inch thick skin sample and place it in the appropriately labeled bag. For swine: Use the knife to mark out the sample borders of the belly sample from one side of the carcass. You will be excising only the skin from an 10 inch long by 5 inch wide sample. You do not need to cut very deep since only the skin surface is needed; a 1/8 inch thick sample is sufficient. 'It is very important that the sample be 10 inches long by 5 inches wide (not 5" long and 10" wide) and that it be in one piece. Carefully excise the sample using the knife and the sanitized hook or forceps. Roll or fold the sample so that it fits", "easily into the sample bag (do not cut the sample into strips), and place the sample in the bag. 7. Do not put the sampling implements back into your scabbard. You may wish to "sheathe" your knife in the carcass where you will be able to reach it from the ladder or platform (insert it perpendicular to the floor, perhaps into the teat line or the medial flank). 8. Remove your gloves and climb the ladder or platform, holding onto the hand-rail. Once at a convenient and safe height for sampling the ham or rump, carefully put on a new pair of sterile gloves. 9. For cattle: Remove the knife from the carcass and mark out the sample borders for the rump sample. Collect the 8 inch long by 6 inch wide by 4 inch thick skin sample and place it in the appropriately labeled bag. Knives and sampling implements may now be put into your scabbard as sampling has been completed. For swine: Remove the knife from the carcass and mark out the sample borders for the ham sample. Collect the 10 inch long by 5 inch wide by 1/2 inch thick skin sample and place it in the appropriately labeled bag. Knives and sampling implements may now be put into your scabbard as sampling has been completed. 10. In the event that a sample is dropped, discard that sample. Go to the companion carcass side and sample the area corresponding to the dropped sample. If gloves and\or instruments have touched-any surface other than the carcass or the sanitized instruments, gloves will need to be changed and\or instruments sanitized. SAMPLE SHIPMENT Shipping containers (temperature-controlled container or similar container), gel-ice packs (specifically designed for shipment of refrigerated samples), and cardboard spacers should be specified by the designated receiving laboratory. If samples are too large to fit into a single shipping container, use 2 shipping containers (make a duplicate of the data sheet and include a notation that you have used 2 shippers). Pre-chill shipping container properly. Address shipping container to the designated laboratory. Samples are to be shipped refrigerated. 1. Freeze gel-ice packs according to label instructions (0°F for 24 hours). Shipping box may be pre-chilled in the cooler if space permits. 2. Place samples into the shipping container as indicated in its instructions. If more space is needed, use another shipping container; do not force too much material into too small a space. 3. Check the sample data sheet for the designated receiving laboratory, and select the appropriate delivery service label. Be sure to enclose", "the sample data sheet in a separate plastic bag and put it into the shipper with the samples. 4. Close and seal shipping container according to printed instructions on the carton. Apply the preprinted address label to the shipping box and ship immediately via the designated overnight-express delivery service so that the samples arrive chilled at the laboratory. FSIS PROCEDURES FOR THE ENUMERATION OF GENERIC E. COLI 1. Sample Preparation A. In order for the samples to be valid and to maintain consistency, analyses must begin the day following sample collection. Samples must meet temperature criteria (0-10°C) in order to be considered for analysis. B. Three refrigerated subsamples,

representing one sampled carcass, will be received by the laboratory. Sample condition and temperature upon receipt should be documented on each sample, together with the date of receipt. Only those samples received at = 0.0°C and 10.0°C will be analyzed.

1. Using a sterile trier (e.g. a circular trier with a 3.6 cm diameter, yielding approximately 10 cm<sup>2</sup>/surface area), randomly cut 2 intact tissue discs from each subsample (flank, rump, and brisket for cattle; belly, ham, and jowls for swine). (Optional: Remaining subsample tissue may be retained under refrigeration in the event the analysis needs to be repeated.)

2. If the thickness of a disc greatly exceeds 1/8 inch, take a sterile scalpel and forceps and aseptically remove fat from the bottom of the plug so disc is approximately 1/8 inch thick. (Bacterial contamination should be limited to the outer, skin, surface of the disc, so excess tissue must be trimmed from the bottom surface.)

3. Label a sterile Stomacher 3500 bag so that it corresponds to the label on the original subsample bag. Aseptically place the 2 tissue discs from each single subsample into the sterile Stomacher 3500 bag.

C. Begin quantitative analyses for E. coli (biotype I) on the day of sample receipt. Using aseptic techniques, remove 2 tissue discs from each of the three subsample stomach bags and place these 6 discs into the labelled Stomacher 3500 bag.

"II. Analytical Methods

A. Preparation of sample homogenate for generic E. coli

1. Select the labelled Stomacher 3500 bag containing a composite of 6 discs that was prepared as described in Section IC (above).

2. Add 600 ml Butterfield's Phosphate Diluent (BPD) or buffered peptone water (BPW) to the core samples (this should approximate a 1:10 s.a./v. (surface area/volume) ratio).

3. Stomach for 2 minutes, prepare serial dilutions of 10-2 to 10-6, and then proceed according to Instructions IIB (below).

B. Quantitative Test for generic E. coli

1. Samples must be analyzed using one of the generic E. coli quantitation methods found in the Official Methods of AOAC International, 16<sup>th</sup> edition, 3rd revision, 1997, or by any method that is validated by a scientific body in collaborative trials against the 3-tube Most Probable Number (MPN) method and that agrees with the 95% upper and lower confidence limits of the appropriate MPN index.

2. The excised sample is considered negative for generic E. coli when no E. coli colonies are present on plates of the lowest dilution (10-1). If E. coli colonies are present, multiply the average plate count by the appropriate dilution factor and record E. coli results as cfu/cm<sup>2</sup>.

APPLYING PERFORMANCE CRITERIA TO EXCISED-SAMPLE TEST RESULTS

E. coli excised-sample results for cattle and swine tested in the FSIS baseline studies have been separated into three categories for the purpose of process control verification: acceptable, marginal, and unacceptable. In the Pathogen Reduction/HACCP Regulation, m and M, representing respectively the 80th and 98th percentile of sample results, leaving 18 percent of results in the marginal range denoted the upper limits for the acceptable and marginal ranges.

"Table 3. Values for Marginal and Unacceptable Results for E. coli performance criteria Slaughter Acceptable Range Marginal Range Unacceptable Range Class

Cattle \*negative positive above 100 but not above 100 cfu/cm<sup>2</sup> cfu/cm<sup>2</sup> Swine 10 cfu/cm<sup>2</sup> above 10 cfu/cm<sup>2</sup> above 10,000 but not above 10,000 cfu/cm<sup>2</sup> cfu/cm<sup>2</sup> \*

An excised sample is considered negative when no E. coli colonies are present on plate(s) Of the lowest dilution (10-1). If E. coli colonies are present, multiply the average plate count by the appropriate dilution factor and record the result as cfu/cm<sup>2</sup>. To illustrate the use of Table 3, consider a cattle slaughter establishment. E. coli test results for this establishment will be acceptable if negative, marginal if positive but not above 100 cfu/cm<sup>2</sup> (>m but =M), and unacceptable if above 100 cfu/cm<sup>2</sup> (>M). Verification Criteria The verification criteria should be applied to test

results in the order that samples are collected. The criteria consist of limits on occurrences of marginal and unacceptable results. As each new test result is obtained, the verification criteria are applied anew to evaluate the status of process control with respect to fecal contamination. This way of looking at the number of marginal and unacceptable results is described as a \"moving window\" approach in the regulation. With this approach, results are accumulated until 13 have been accrued. After this, only the most recent 13 results - those in the \"moving window\" are considered. 1. An unacceptable result should trigger action to review process controls, discover the cause if possible, and prevent recurrence. 2. A total of more than 3 marginal results in the last 13 consecutive results also signals a need to review process controls. Having 3 marginal results out of 13 samples approximates the 18 percent found as marginal in the baseline studies." "An example of a record of results for cattle testing is shown below for an establishment performing 2 tests a

day."],[{"file\_name":"FSIS\_GD\_1996\_0002","title":"Guidelines for Escherichia coli Testing for Process Control Verification in Poultry Slaughter Establishments","num":"FSIS-GD-1996-0002","id":"5461301f47df3624107b0587ed6273895b6d26e29b4d2c2ecbc05f75a670a801","corpus":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/import/Guideline\_for\_Ecoli\_Testing\_Slaughter\_Estab.pdf","type":"pdf","n\_pages":20,"word\_count":6043,"text\_by\_page":[{"text":-----}]}]

Guidelines for Escherichia coli Testing for Process Control Verification in Poultry Slaughter Establishments INTRODUCTION Under the Pathogen Reduction\HACCP Regulation, poultry slaughter establishments are required to test carcasses for generic E. coli as a means of verifying process control. This document outlines sampling and microbial testing procedures that would meet this requirement. These guidelines may be helpful to your company microbiologist or testing laboratory. This document is a supplement to the Regulation but not a substitute; indepth details of microbial sampling and testing may be found in the Regulation. In this protocol, carcass sampling for broiler and turkey carcasses employs the same nondestructive whole bird rinse used in the FSIS Nationwide Microbiological Baseline Data Collection Programs. Poultry carcasses should be sampled at the end of the chill process, after the drip line, and before packing\cut-up. (Hot-boned poultry, which is boned before chilling, should be sampled at the end of the slaughter line instead of at the end of the drip line.) Samples taken in this manner will have analytic results comparable to National Baseline figures. E. coli test levels from National Baseline studies, expressed as colony forming units per milliliter (cfu\ml) of rinsate, have been separated into 3 categories for the purpose of process control verification: acceptable, marginal, and unacceptable. In the Pathogen Reduction\HACCP Regulation, the upper limits for the acceptable and marginal ranges were denoted by m and M.

Table 1. Values for Marginal and Unacceptable Results for E. coli performance criteria Type of Acceptable Range Marginal Range Unacceptable Range poultry over 100 cfu\ml above 1,000 Chicken 100 cfu\ml or but not over 1,000 cfu\ml less cfu\ml Turkey NA \* NA \* NA \*\* The FSIS Baseline study has not been completed for this type of poultry. Levels will be set upon completion of this baseline.", "The E. coli test results for a chicken slaughter establishment will be acceptable if not above 100 cfu\ml, marginal if above 100 cfu\ml but not above 1,000

cfu/ml, and unacceptable if above 1,000 cfu/ml. To evaluate overall process performance, the establishment must apply verification criteria to a set of samples; see discussion on pp. 14-16. If no m/M criteria have been established for the type of birds you are required to sample and analyze, you should use a process control approach. The statistical process control approach required by the Agency is based on the principle that every product is produced by a process. All processes are subject to variation, which should be understood and controlled by statistical methods. A process that is in control is stable in terms of average level and degree of variation, i.e., it is predictable within limits and is thus 'doing its best.' Processes that have not been subjected to analysis are not likely to be in control. Control is attained, often by degrees, by detecting and eliminating special causes of variation, those not present all the time or not affecting all product output. This involves initially evaluating data to determine process capability (the typical process performance level), and then checking subsequent data to see if they are consistent with this baseline level, i.e., the process is in control and variations are within normal and acceptable limits. This is accomplished by checking for unreasonably high results, trends, etc., and looking for and correcting problems in the process when these signals occur. It is important to recognize that an in-control process may not necessarily result in product of the desired quality improvements may be needed or the entire process may require reconsideration. Problems in a process may stem from many sources, for example: inadequate knowledge of how a process should work or how a specific process is performing; errors or deficiencies in executing procedures; failure to recognize the need for preventive measures; unnecessary complexity in the process; and uncontrolled variation among inputs. Specific techniques of statistical process control include the time plot, which charts measurements over time; this is the first technique to use with data collected over time and analyzed for patterns. A further development is the control chart, which plots data over time but also displays an upper control limit for specific measurements, and a centerline, above and below which there is an equal number of sample results (the centerline is in effect a median average). A sample result above the upper control limit would indicate the likely presence of a special cause of variation that should be addressed. Results within control limits indicate simply that the process is in control. Control charts have two essential uses: after-the-fact analysis of process performance and gaining and maintaining control of a process. In most situations more than one type of control chart would be applicable; detailed information can be found in texts on statistical quality control, under the topic "control charts." In general, statistical process control techniques help to provide experience in "process thinking" (a central tenet of HACCP), develop an historical record of performance, evaluate the long-term stability of a process and determine process capability (i.e., how it is actually working), and evaluate the effectiveness of process improvement actions. With specific reference to E. coli test results, statistical process control techniques will not be directly useful for attaining and maintaining control of a process, as,"test results will come from the end of the process and in any case would not be timely enough; observations made earlier in the process would be more useful for attaining and maintaining process control. Rather, E. coli testing would serve to verify process control. Process control techniques, applied and verified in this manner, would accomplish the essential intent of the Regulation by integrating process control and microbial testing into slaughter operations. GUIDELINES FOR SAMPLE COLLECTORS/MICROBIOLOGISTS Pre-sampling Preparation Sample collection shall be conducted by the individuals) designated in the

establishment's written procedures for microbiological sampling, as required by 9 Code of Federal Regulations (CFR) Part 381. 94 (a) (2) (i). These procedures shall also specify the location of sampling, the random sample selection method chosen by the establishment, and sample handling procedures that will ensure sample integrity. Before beginning sample collection, assemble sampling supplies, such as sterile gloves, sterile sampling solutions, hand soap, sanitizing solution, etc. Sterile sampling solutions, such as Butterfield's phosphate diluent (BPD) or buffered peptone water (BPW), can be stored at room temperature; however, at least the day before sample collection, check such solutions for cloudiness and do not use solutions that are cloudy or turbid or that contain particulate matter. To obtain the most accurate results, samples should be analyzed as soon after collection as possible. If samples must be transported to an off-site laboratory, they should be refrigerated and then shipped refrigerated, on the same day they were collected, via an overnight delivery service to the laboratory. A sample should arrive at the laboratory and be analyzed no later than the day after it is collected. If sample collection, pick-up or shipment, and laboratory analysis cannot be carried out within this timeframe, the carcass selected for sampling should be held until the process can be accomplished in the appropriate span of time. The same principle applies for samples that are analyzed in-plant: If a carcass cannot be sampled and the sample analyzed by the day after it is taken, the carcass should be held until this is possible. Rinsate from a collected sample should not be held; it should be either analyzed in-plant by the next day or immediately shipped for overnight delivery to the laboratory that will conduct the analysis. The Sample Shipment section below gives information on shipping containers and transporting samples to off-site facilities.",-----  
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----- Sampling frequency Sampling frequency for E. coli testing is determined by production volume. The required minimum testing frequencies for all but very low volume establishments are shown in Table 2 by type of poultry. An establishment need sample only the predominant type when two or more types are slaughtered. Table 2. E. coli Testing Frequencies Chickens 1 test per 22,000 carcasses, or at least 1 test per week Turkeys 1 test per 3,000 carcasses, or at least 1 test per week NOTE: These testing frequencies do not apply to very low volume establishments. See Table 3. Very low volume establishments Some establishments may be classified as very low volume establishments based on their annual production volume. The maximum yearly slaughter volumes for very low volume establishments are described in Table 3. An establishment need sample only the predominant type when two or more types are slaughtered. Table 3. Maximum Yearly Poultry Slaughter Volumes for Very Low Volume Establishments Type of Poultxy Criteria (Yearly Slaughter Valme) Chickens not more than 440,000 birds Turkeys not more than 60,000 birds Mixed Birds not more than 440,000 total, with not more than 60,000 turkeys A very low volume establishment will sample the predominant type once per week beginning the first full week of operation after June 1, until at least 13 test results have been obtained or the following June 1, whichever comes first. The establishment will repeat the same sampling regime once per year, beginning the first full week of operation after June 1.", "If a very low volume establishment predominantly slaughters a type of poultry for which m\|M criteria have been determined, the establishment must sample once

per week until results show that it has met the m/M criteria outlined in the Pathogen Reduction\HACCP Regulation and following amendments; see Verification Criteria, pp. 14-16. Random selection of carcasses Samples are to be taken randomly at the required frequency. For example, given the frequency of testing for turkeys of one test per 3,000 turkeys slaughtered, if a plant slaughters 1,500 turkeys an hour, one sample will be taken every two hours. Note: If more than one shift is operating at the plant, the sample can be taken on any shift. Poultry carcass selection Different methods of selecting the specific carcass for sampling could be used, but all require the use of random numbers. Examples of methods include random number tables, calculator- or computer-generated random numbers, or drawing cards. The carcass for sampling must be selected at random from all eligible carcasses. If there are multiple lines or chillers, randomly select the line or chiller for sample collection for that interval. Each line should have an equal chance of being selected at each sampling interval. The poultry carcasses will be selected at random after chilling and after the drip line, before packing\cutup. A whole carcass is required, that is, one that has not been trimmed. Aseptic techniques\sampling Extraneous organisms from the environment, hands, clothing, sample containers, sampling devices, etc., may contaminate samples and lead to non-representative analytical results. It is necessary to use aseptic sampling techniques and clean, sanitized equipment and supplies. An area should be designated for preparing sampling supplies. A stainless steel, wheeled cart or table would be useful during sampling. A small tote or caddy could be moved to the location of sampling and used for carrying supplies; sample bags could be placed on the tote or caddy when sterile solutions are added to the bags.", "Sterile gloves should be used for collecting samples. Nothing should contact the external surface of the glove except the exposed sample being collected. Keep in mind that the outside surfaces of the sample container are not sterile. The following procedure for putting on sterile gloves can be followed when collecting samples: a) Peel open the package of sterile gloves from the top without contaminating (touching, breathing on, contacting) the exterior of the gloves. b) Remove a glove by holding it by the inner . surface of the wrist-side opening. Avoid any contact with the outer surface of the glove. Insert the washed and sanitized hand into the glove, taking care not to puncture the glove. c) Next, taking care not to contaminate the outer surface of the glove, repeat the step above for the hand you will use to physically handle the sample. d) If at any time you are concerned that a glove may be contaminated, discard it and begin again with Step a) above. Preparation for Sample Collection On the day of sampling, gather all sample collection bags, sterile gloves, sanitizer, hand soap, sterile solutions for sampling, and any other materials needed. Ensure that all sampling supplies are on hand and readily available before beginning sample collection. Label the sample bags before starting the sampling procedure. Use permanent ink. If you are using paper labels, it is important that the label be applied to the bag at normal room temperature; it will not stick to the sample bag if applied in the cooler. Outer clothing such as frocks, gloves, or head gear worn in other areas of the plant should be removed before entering the sampling area or preparing to collect samples. Replace outer clothing with clean garments, such as a laboratory coat, that have not been directly exposed to areas of the plant outside of the sampling area.", "Sanitize the sample work area surfaces by wiping with a clean disposable cloth or paper towel dipped in a freshly prepared 500 ppm sodium hypochlorite solution (0.05% sodium hypochlorite) or other approved sanitizer that provides an equivalent concentration of available chlorine. The sample work area surfaces must

be free of standing liquid before sample supplies or product containers are placed on them. Before sampling, thoroughly wash and scrub hands to the midforearm. Use antibacterial hand soap. This procedure should include a sanitizer with 50 ppm equivalence available chlorine. Dry the hands using disposable paper towels. Chicken Carcass Rinse Sampling Procedure Material : 1. 2 Sterile 3500 milliliter (ml) stomacher-type or ziplock-type bags or equivalent. The bag must be sterile and should be large enough to hold the carcass while rinsing. 2. 400 ml sterile Butterfield's phosphate diluent (BPD) or sterile buffered peptone water (BPW) 3. Plastic tie wraps or equivalent (to secure the bag) 4. Sterile gloves 5. Sterile leak-proof container (optional) Collection 1. Ensure all sampling supplies are present and have been properly labeled. An assistant may be helpful during sampling. 2. Open a large stomacher-type bag without touching the sterile interior of the bag. (Rubbing the top edges of the bag between the thumb and forefinger will cause the opening to gap for easy opening.) 3. Put on sterile gloves. 4. With one hand, push up through the bottom of the sampling bag to form a 'glove' over one hand with which to grab the bird, while using your other hand to pull the bag back over the hand that", "will grab the bird. This should be done aseptically without touching the exposed interior of the bag. 5. Using the hand with the bag reversed over it, pick up the bird by the legs (hocks) through the stomacher bag. (The bag functions as a 'glove' for grabbing the bird's legs.) Take care not to contaminate the exposed interior of the bag. Allow any excess fluid to drain before reversing the bag back over the bird. 6. Rest the bottom of the bag on a flat surface. While still holding the top of the bag slightly open, add the sterile BPD or BPW (400 ml) to the bag containing the carcass, pouring the solution into the carcass cavity and over the exterior of the carcass. 7. Expel most of the air from the bag, then close the top of the bag. While securely holding the bag, rinse the bird inside and out using a rocking motion for 30 shakes (approximately one minute). This is done by holding the bird through the bottom of the bag with one hand and the closed top of the bag with the other hand. Hold the bird securely and rock it in an arcing motion, alternating the weight of the bird from one hand to the other (motion like drawing an invisible rainbow or arch), ensuring that all surfaces (interior and exterior of the carcass) are rinsed. 8. Rest the bag with the bird on a flat surface and, while still supporting the bird, open the bag. 9. With a gloved hand, remove the carcass from the bag, first letting any excess fluid drain back into the bag. Since the carcass was rinsed with a sterile solution, the bird can be returned to the chill tank. Be sure not to touch the interior of the bag with your gloved hand. 10. Secure the top of the bag so that the rinse fluid will not spill out or become contaminated. 11. Place the sample bag (or leak-proof container) into another bag and secure the opening of the outer bag. 12. a) If samples are to be analyzed at an on-site laboratory, begin sample preparation for the selected method of analysis.", "b) If samples are to be analyzed at an off-site laboratory, follow the Sample Shipment procedures. Turkey Carcass Rinse Sampling Procedure Materials: 1. 2 Sterile 3500 ml stomacher-type or ziplock-type bags or equivalent. The bag must be sterile and should be large enough to hold the carcass while rinsing; the bags FSIS will be using for the Salmonella sampling program measure approximately 18\" x 24\". Large turkeys should be placed in a plain, clear polypropylene autoclave bag, about 2411 x 30" to 36". 2. 600 ml sterile Butterfield's phosphate diluent (BPD) or sterile buffered peptone water (BPW) 3. Plastic tie wraps or thick rubber bands or equivalent, if needed to secure sample bag 4. Sterile gloves 5. Optional - sterile, leak-proof container Collection 1. Ensure that all supplies are on hand and readily available. An assistant will be needed to hold

the bag for collecting the bird. 2. Have an assistant open the large sterile stomacher-type bag (designated for rinsing the carcass) and be ready to receive the turkey carcass. (Rubbing the top edges of the bag between the thumb and index finger will cause the opening to gap open.) 3. Put on sterile gloves. 1","4. Remove the selected turkey from the drip line by grasping it by the legs and allowing any fluid to drain from the cavity. 5. Place the turkey carcass, vent side up, into a sterile sampling bag. Only the carcass should come in contact with the inside of the bag. 6. Manipulate the loose neck skin on the carcass through the bag and position it over the neck bone area to act as a cushion and prevent puncturing of the bag. The assistant will need to support the carcass with one hand on the bottom of the bag. 7. While still supporting the bottom of the bag, have the assistant open the bag with the other hand. Alternatively, rest the bottom of the bag on a pre-sanitized surface (i.e. a table), and while still supporting the carcass in the bag, open the bag with the other hand. 8. Add the sterile BPD or BPW (600 ml) to the bag containing the carcass, pouring the diluent into the carcass cavity and over the exterior of the carcass. 9. Take the bag from the assistant and expel excess air from the bag and close the top. While securely holding the bag, rinse the bird inside and out using a rocking motion for 30 shakes (approximately one minute). This is done by holding the carcass through the bag with one hand and the closed top of the bag with the other hand. Holding the bird securely with both hands, rock in an arcing motion alternating the weight of the bird from one hand to the other (motion like drawing an invisible rainbow or arch), ensuring that all surfaces (interior and exterior of the carcass) are rinsed. 10. Hand the bag back to the assistant. 11. With a gloved hand, remove the carcass from the bag letting excess fluid drain back into the bag. Since the carcass was rinsed with a sterile solution, the bird can be returned to the chill tank. Be sure not to touch the interior of the bag with your gloved hand. 12. Expel excess air, taking care not to expel any rinse fluid. Secure the top of the bag so that the rinse fluid will not spill out or become contaminated.", "13. Place the sample bag (or container) into another bag and secure the opening of the outer bag. 14. a) If samples are to be analyzed at an on-site laboratory, begin sample preparation for the selected method of analysis. (See Analytical Methods section.) b) If samples are to be analyzed at an off-site laboratory, follow Sample Shipment procedures.

**Sample Shipment** Samples analyzed on-site must be analyzed as soon after collection as possible. If no on-site facilities are available, samples must be shipped to an off-site laboratory the same day they were collected. Samples must be analyzed no later than the day after collection. **Shipping containers and coolant packs** It is important that samples fit easily into the shipping containers so that the sample bags do not break. Correct use of the coolant gel-ice packs and proper packing of the shipping container are necessary so that samples arrive at the laboratory at an acceptable temperature (0-10°C). Maintaining samples at improper temperatures may cause inaccurate results. The sample should be kept refrigerated, not frozen, in the shipping container before pickup by the courier service. The shipping container itself should not be used as a refrigerator; however, multiple samples (if needed) for that day may be stored in the open shipping container in the cooler or refrigerator. **Recommended procedure**

1. Prechill shipping container by placing the open shipping container in the refrigerator at least the day before sampling.
2. Place the appropriately-labeled, double-bagged sample in the prechilled shipping container in an upright position to prevent spillage. Newspaper may be used for cushioning the sample and holding it in the upright position. Ensure that samples are maintained at refrigeration temperature. Refrigeration temperatures limit multiplication of any

microorganisms present.", "3. Place a corrugated cardboard pad on top of samples. The corrugated pad prevents direct contact of frozen gel packs with the samples. Next, place the frozen gel pack(s) on top of the corrugated pad. Use sufficient frozen coolant to keep the sample refrigerated (0-10°C) during shipment to the designated laboratory. Insert foam plug and press it down to minimize shipper head space. 4. Ship samples via overnight delivery or courier to the laboratory. Suggested Criteria for Microbiological Laboratories These suggestions are not meant to be exhaustive. Specific needs will vary from one processor to another.

Personnel Both laboratory analysts and supervisors must have education, training, and experience in food microbiology. Specific familiarity with poultry operations would be desirable. Personnel should be well versed in methods of analysis for poultry samples and the organisms associated with poultry products. Facilities Laboratory facilities should be suitable for conducting routine and specialized microbiological analyses and should provide adequate bio-safety precautions. It is crucial that the laboratory maintain separate, defined areas for sample receipt, preparation, and analytic work. Equipment The laboratory should have suitable equipment, appropriate preventive maintenance programs, readily available equipment manuals, and log books for documentation. Specialized equipment may be necessary for some applications. Operations The laboratory should have in place a written quality assurance (QA) program that is available to all employees. The QA program should include bio-safety equipment, media preparation, ","microbiological methods and procedures, control programs, equipment control, culture maintenance, sample receipt, handling, result reporting, and record keeping. Records Records should contain a complete sample description, including condition, source, lot code, date, quantity, etc. Results should be reported promptly and all data and summaries permanently recorded with the results. Analytical Methods All sample analyses must begin no later than the day after collection. Samples must be analyzed using one of the E. coli (Biotype I) quantitation methods found in the Official Methods of AOAC International, 16 th edition, 3 rd revision, 1997, or by any method that is validated by a scientific body in collaborative trials against the 3-tube Most Probable Number (MPN) method and that agrees with the 5% upper and lower confidence limits of the appropriate MPN index. The following methods for generic E. coli quantitation in foods have been AOAC-approved: 1) 3-tube MPN method - AOAC 17.2.01-17.2.02 2) Modified 3-tube MPN method - AOAC 17.3.07 - Substrate Supporting Disc Method (ColiComplete\u00ae). ColiComplete\u00ae Substrate Supporting Discs are available from BioControl Systems, Inc., 19805 North Creek Parkway, Bothell WA 98011. 3) Modified 3-tube MPN method - AOAC 17.4-01 - Fluorogenic Assay for Glucuronidase. Lauryl sulfate tryptose broth with added 4-methylumbelliferyl-O-D-glucuronide (MUG) is used in a 3-tube MPN method. 4) Plating Method - AOAC 17.3.04 - Dry Rehydratable Film (Petrifilm E. coli Count Plate) Method. Medical-Surgical Division\3M, 275-5W 3M Center, St. Paul MN 55144.", "5) Filtration\Plating Method - AOAC 17.3.09 - Hydrophobic Grid Membrane Filter\ MUG (ISO-GRID) Method. QA Life Sciences, Inc., 6645 Nancy Ridge Dr., San Diego CA 92121. Note: For most quantitative assays, week-end laboratory work can be kept to a minimum by refrigeration of incubated plates\tubes until Monday. A programmable refrigerated incubator is useful in such cases. For commercially available methods follow manufacturer's recommendations. Suggested quantitation schemes For poultry rinse fluid samples, if a generic 1 milliliter (ml) plating technique is used for E. coli quantitation, the plate count would not have to be divided to get the count per ml of rinse fluid. Record this value

even if it is less than 1 cfu/ml. To cover the marginal and unacceptable range for E. coli levels, the undiluted extract (optional), a 1:10 and a 1:100 dilution should be plated, preferably in duplicate. Higher or lower dilutions may need to be plated based on the specific product. If a hydrophobic grid membrane filtration method is used, the only difference would be filtration of 1 ml of the undiluted extract (optional), 1:10 and 1:100 dilutions. Additional dilutions of the original extract may need to be used if a 3-tube MPN protocol is used. The 3 highest dilutions positive for E. coli are used to calculate the MPN. Recordkeeping Results of each test must be recorded in terms of colony forming units per milliliter rinse fluid (cfu/ml) for chicken and turkeys. Record this value even if it is less than 1 cfu/ml. A process control table or chart can be used to record the results and facilitate evaluation. Results should be recorded in the order of sample collection and include information useful for determining appropriate corrective actions when problems occur. The information needed for each sample includes date and time of sample collection and, if there is more than one slaughter line, the slaughter line from which the sample was collected. These records are to be maintained at the establishment for twelve months and must be made available to Inspection Program employees on request. For E. coli testing to be most useful for verifying process control, timeliness is important and the record should be updated with the receipt of each new result. Records should also be kept of any corrective", "actions taken if process control deviations are detected through microbiological testing. Note: Occasionally, samples shipped to off-site laboratories may be lost during shipping or may arrive at the laboratory late or outside the acceptable temperature parameters for sample analysis (0-10\u00baC). Any reasons for missing data should be documented.

**APPLYING PERFORMANCE CRITERIA TO TEST RESULTS**

As was stated above on pp. 1-2, E. coli test levels for chickens have been separated into three categories for the purpose of process control verification: acceptable, marginal, and unacceptable. E. coli test results for a chicken slaughter establishment will be acceptable if not above 100 cfu/ml (#@m), marginal if above 100 cfu/ml but not above 1,000 cfu/ml (>m but <M), and unacceptable if above 1,000 cfu/ml (>M).

**Verification Criteria**

Verification criteria are applied to test results in the order that samples are collected. The criteria consist of limits on occurrences of marginal and unacceptable results. As each new test result is obtained, the verification criteria are applied anew to evaluate the status of process control with respect to fecal contamination. This way of looking at the number of marginal and unacceptable results is described in the regulation as a "moving window" approach. With this approach, results are accumulated until 13 have been accrued. After this, only the most recent 13 results - those in the "moving window" are considered.

1. An unacceptable result should trigger action to review process controls, discover the cause, and prevent recurrence.
2. A total of more than 3 marginal or unacceptable results in the last 13 consecutive results also signals a need to review process controls.

An example of a table of results for Chicken testing is shown below for an establishment performing 2 tests per day.", "---

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	1	2	3	4	5	6	7	8	9	10	11	12	13									
14	15	16	17	Test Time	Test Result	Date Collected (cfu/ml)	Number	Marginal	Result	Result or	Unacceptable	Pass\	Unacceptable?									
14:00	10	No	No	1	Pass	10-08	07:10	150	No	Yes	2	Pass	13:00	50	No	No	2	Pass	10 - 09	10:00		
negative	No	No	2	Pass-	12:20.	10	No	No	2	Pass	10-10	09:20	800	No	Yes	3	Pass	13:30	10	No	No	3
Pass	10-11	10:50	10	No	No	3	Pass	14:50	10	No	No	3	Pass	10-14	08:40	500	No	Yes	4	Fail	12:00	30

No No 4 Fail 10-15 09:30 10 No No 4 Fail 15:20 10 No No 3 Pass 10-16 07:30 10 No No 3 Pass 11:40 10 No No 2 Pass 10-17 10:20 1200 Yes No 3 Fail 118 1 14:40 10 No No 3 Pass", "The following observations can be made regarding this example: 1. As of 10-14 at 08:40 (sample 11), there are 4 marginal or unacceptable results in the last 11 results, which exceeds the limit of 3 in 13 consecutive tests. 2. The limit of 3 in 13 also is exceeded for the next 2 tests, but since no new marginal or unacceptable result has occurred, these failures should not be treated as evidence of a new problem. The log or documentation of corrective action taken for the first failure should be adequate to verify that the deviation or problem, if any, was addressed. 3. On 10-15 at 15:20 (sample 14) the number of marginal or unacceptable results in the last 13 tests goes down to 3 because the marginal result for 10-07 at 08:50 is dropped and replaced by the next, acceptable result as the 13-test window moves ahead 1 test. 4. The result for 10-17 at 10:20 (sample 17) exceeds 1,000 (>M) and is unacceptable. Such a result should trigger immediate establishment review of process controls to discover the cause of the failure, prevent recurrence, and if product has been affected, consider the status and proper disposition of the product. Note, however, that this specific result >M only counts as one result that exceeds m. With the next sample (18) - 10-17 at 14:40 - the establishment is again defined by having no more than 3 samples >m in the last 13. At this point, a negative result would mean that the current set of 13 samples was passing, a marginal result would mean that the set would fail for having 4 results >m in its 13 samples (samples 6-18), and a result >M would mean that sample would fail by exceeding M and the sample set would fail for having 4 results >m in its 13 samples. 5. The result for 10-17 at 14:40 is negative. The set is now passing by virtue of having had no more than 3 results >m in its 13 samples (samples 6-18). This information could also be displayed in chart form, with test numbers, times, dates, and results.", "Billing Code 3410-DM-P DEPARTMENT OF AGRICULTURE Food Safety and Inspection Service (Docket No. 97-041N] Notice of Request for Extension and Revision of a Currently Approved Information Collection AGENCY: Food Safety and Inspection Service, USDA. ACTION: Notice and request for comments. SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and the office of Management and Budget (OMB) regulations, this notice announces the Food Safety and Inspection Service's (FSIS) intention to request an extension for and revision of a currently approved information collection regarding processing procedures and quality control systems. DATES: Comments on this notice must be received on or before [insert date 60 days after publication of this notice]. ADDITIONAL INFORMATION OR COMMENTS: Contact Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, 300 12th Street SW, Washington, DC 20250-3700, (202) 720-0346. SUPPLEMENTARY INFORMATION: Title: Processing Procedures and Quality Control Systems OMB Number: 0583-0089 E2Miration Date of Approval: October 31, 1997. Type of Request: Extension and revision of a currently approved information collection. Abstract: FSIS has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, et seq.). These statutes mandate that FSIS protects the public by ensuring that meat and poultry products are safe, wholesome, unadulterated, and properly labeled and packaged.", "To carry out its responsibility, FSIS has promulgated specific regulations containing requirements for the processing of certain meat and poultry products. FSIS requires that establishments producing cooked beef, roast beef, and corned beef document the time, temperature, and humidity at which the product is cooked and

cooled. FSIS program employees review these records no less than three times a week to ensure regulatory compliance. Establishments canning meat and poultry products must document the date of production; type of product canned; canning process used; size and type of container used; and any time\temperature processing requirements. FSIS program employees review these records no less than three times a week to verify regulatory compliance. Additionally, FSIS permits establishments to develop total quality control (TQC) systems or partial quality control (PQC) programs which provide establishments with flexibility in meeting FSIS's regulations. TQC systems encompass all aspects of product processing; PQC programs cover only a specific processing operation. Quality control systems\programs incorporate inspection activities contained in FSIS's regulations. TQC systems and PQC programs must contain detailed information concerning the manner in which the system will function. Such information must include procedures for raw material control; the nature and frequency of tests to be made; the critical check or control points to be addressed; the nature of charts and other records that will be used; the length of time such charts and records will be maintained; the nature of deficiencies the system is designed to identify and control; the parameters or limits that will be used; and the points at which corrective action will occur and the nature of such corrective action -- ranging from the least to the most severe. FSIS program employees review TQC and PQC system charts and records. FSIS program employees review these records no less than three times a week to ensure regulatory compliance. Because of the continued need for these information collection activities, FSIS is requesting OMB extension for and revision of the Information Collection Request covering information collection activities related to these requirements.", "Estimate of Burden: The public reporting burden for this collection of information is estimated to average 120 hours per response. Respondents: Meat and poultry establishments Estimated Number of Respondents: 6,186 Estimated Number of Responses per Respondent: 2,292 Estimated Total Annual Burden on Respondents: 743,750 hours Copies of this information collection assessment and comments can be obtained from Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, 300 12th Street SW, Room 109, Washington, DC 20250-3700, (202) 720-0346. Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS' estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record. Thomas J. Billy Administrator"]}, {"file\_name": "FSIS\_GD\_2008\_0003", "title": "Food Safety and Inspection Service (FSIS) Compliance Guide on the Determination of Processing Aids", "num": "FSIS-GD-2008-0003", "id": "8fb0ccb1e3be736fcbb6171a1d4b195a326e15e0cccd3889694446883976d5c9", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Determination\_of\_Processing\_Aids.pdf", "type": "pdf", "n\_pages": 2, "word\_count": 484, "text\_by\_page": ["Letter to

Industry - July 13, 1998 Dear Sir or Madam: This is to acknowledge receipt of your request for USDA evaluation of your chemical compound(s). We must advise you, however, that it is unlikely that we will be able to consider your request. On August 25, 1997, in an effort to clarify and consolidate the sanitation requirements for meat and poultry establishments, FSIS proposed to eliminate the regulatory requirement for prior approval of certain nonfood compounds and proprietary substances (62 FG 45045). More recently, FSIS published a notice in the Federal Register ( 63 FR 7319; February 13, 1998) stating that the Agency is eliminating the prior approval program for nonfood compounds and proprietary substances. The staff engaged in the evaluation process is being assigned to other, high priority tasks. Consequently, it is unlikely that FSIS will complete the review of your request. Therefore, your compound(s) will not be listed in the final update to the List of Nonfood Compounds and Proprietary Substances. USDA-inspected establishments have a responsibility to ensure that they do not use chemical compounds in a way that will result in the adulteration of the food they produce. To assist official establishments in avoiding such a result, FSIS is developing a compliance guide for meat and poultry establishments concerning the appropriate use of nonfood compounds and proprietary substances. Once completed, the compliance guide will be available not only to the regulated industry, but also to chemical manufacturers and the general public. FSIS also is developing an instructional directive for inspection personnel on how to verify that meat and poultry establishments are using nonfood compounds and proprietary substances in a manner that will not adulterate product. This directive will be available to the public, the regulated industry, and to chemical manufacturers. The information that you submitted will be retained in our files pending a final decision on the proposed rule. Thank you for your interest in USDA's authorization program and for your patience during this transition. Sincerely, \s\ William J. Hudnall Assistant Deputy Administrator Standards and Methods Review Last Modified Sep 30, 2013"]}, {"file\_name": "FSIS\_GD\_2008\_0004", "title": "Guidance on Meaning of \"Prohibited Substances\" in FSIS Actions on the Use of Ingredients in Meat and Poultry Products", "num": "FSIS-GD-2008-0004", "id": "fd8a79ba35be9424b128aa42dc60323163c5e31fbadceb56c7d92cfb42801bf", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Prohibited\_Substances\_in\_FSIS\_Actions\_on%2B\_Use\_of\_Ingredients.pdf", "type": "pdf", "n\_pages": 2, "word\_count": 744, "text\_by\_page": ["Food Safety and Inspection Service United States Department of Agriculture Washington, D.C. 20250-3700 News and Information FSIS Constituent Update: December 17, 1999 FSIS Final Rule on Irradiation of Meat to Publish Next Week; Agency Will Hold Constituent Briefing on December 21 The final rule, \"Irradiation of Meat Food Products,\" is expected to publish in the Federal Register December 23. Constituents were faxed a December 14 USDA news release on the approval of the irradiation of meat to help improve food safety. A briefing for constituent groups on the final rule will be held on December 21 at 2:00 p.m. in Room 3109-South Building. For additional information on the constituent briefing, contact: Barbara O'Brien, Constituent Affairs Specialist, at (202) 720-8594. For technical information on the final rule, contact: Dr. Daniel Engeljohn, Director, Regulations Development and Analysis Division, at (202) 720-5627. Published Federal Register notices are available on the FSIS Web site: www.fsis.usda.gov, access \"Federal Register.\" FSIS Makes Responses to Questions from the First Technical Conference on HACCP Implementation Available Attached"}]

are the responses to various questions raised at the First Technical Conference on HACCP Implementation held on August 17-18, 1999, in Omaha, Nebraska. In a number of instances, a specific response will depend upon the circumstances in a particular case. For more information, contact: Phil Derfler, Deputy Administrator, Office of Policy, Program Development and Evaluation, at (202) 720-2710. FSIS Makes Draft Report--The Future of FSIS Veterinarians: Public Health Professionals for the 21st Century Available FSIS is making available the Draft Report--The Future of FSIS Veterinarians: Public Health Professionals for the 21st Century. [Also available in PDF - Ed.] This draft report represents the work-in-progress of a Task Force composed of a diverse group of individual including veterinarians from inside and outside of FSIS, a variety of FSIS management personnel, and individuals affiliated with academia, non-government organizations and foreign governments. The group convened in early 1999. A public meeting to discuss the draft report will be held in February 2000, in Washington, DC. A Federal Register notice with details about the meeting will provided at a later date. Copies of the draft report are available by faxing requests to: Barbara O'Brien, CPA Constituent Affair Specialist, at (202) 720-5704. Copies will also be available on the FSIS Web site: [www.fsis.usda.gov](http://www.fsis.usda.gov), access \"Publications--Technical Publications.\\" For more information, contact: Linda Russell, FSIS Planning Staff, at (202) 501-7138. E. coli Sampling Program Yields Fourth Positive for FY 2000 The FSIS sampling program for E. coli O157:H7 reported a confirmed positive in a ground beef sample taken on November 29, 1999, from a retail store in Missouri. All product was retained at the store. This is the fourth positive in FY 2000 out of over 700 samples and the 56th overall our of over 34,000 samples take since FSIS began the sampling program in 1994. For more information on the sampling program, contact the FSIS Office of Public Health and Science at (202) 501-7521.", "Federal Register Activity The following notices were published in the Federal Register this week: December 16, 1999--FSIS Reopening of comment period--Docket No. 98-027R--\"Meat Produced By Advanced Meat\Bone Separation Machinery and Recovery Systems\" Comments must by received on or before January 18, 2000. Constituent groups were faxed a December 16 USDA news release announcing the reopening of the comment period. For more information, contact: Dr. Daniel Engeljohn, Director, FSIS Regulations Development and Analysis Division, at (202) 720-5627. December 14, 1999--FSIS Notice of public meetings and request for comments--Docket No. 99-061N--\"Codex Alimentarius: Eight Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) Constituent groups were faxed a December 14 USDA news release with times and locations of the meetings. For more information, contact: Patrick Clerkin, Associate U.S. Manager for Codex, at (202) 205-7760. FSIS Notices FSIS issued the following two notices on December 15, 1999: FSIS Notice 45-99--\"Residue Testing Program\" FSIS Notice 46-99--\"Documentation of HACCP 02 Procedure\" Copies of the notices are available by faxing requests to: Barbara O'Brien, CPA Constituent Affair Specialist, at (202) 720-5704. Clarification--Packing Dates on Poultry Labeling Recently, an issue regarding the appropriate application of the Federal poultry products inspection regulations on \"date of packing\" (9 CFR 381.126) arose. The circumstances involved a processor who packages poultry food products in consumer-ready film-wrapped packages that are in refrigerated storage awaiting shipment to customers when orders are received. At the time an order is received, a price label and sell-by date is applied to the consumer packages that are then placed in master shippers to which box end labeling, including a \"pack date,\" is applied. The pack date that has

been applied, however, has been the date the consumer packages are placed in the shipper, not the original pack date on which the poultry was slaughtered and placed in the consumer packaging. The application of the date the consumer packages are placed in the shipper does not constitute the \"pack date\" that is required by Federal regulations. The regulations indicate that the pack date can be applied to the shipper or immediate containers of poultry food products using either a code or the actual calendar date of packing. The date of packing is the original date the poultry is slaughtered and placed in the consumer packaging; the use of any other calendar date will mislead consumers. After discussions with the company and the National Chicken Council, it was resolved that, perhaps, misinterpretation of the pack date provisions has occurred within industry. Understanding that the immediate containers or the shipping containers of poultry food products must be marked with the original pack date, there are actually three options available to poultry processors to comply with the packing date provisions, one of which must be used. These options are: a code is applied that represents the original pack date of the poultry food product in the consumer package, or the original pack date of the poultry food product is applied to the consumer package or the shipping container", "accompanied by an explanatory statement, e.g., \"packing date\" (per 9 CFR 381.129 (c) (2)), or the original pack date of the poultry food product is applied to the consumer package or the shipping container along with a date representing when the consumer packages are placed in shippers. In this case, each date must be accompanied by an explanatory statement in accordance with 9 CFR 381.129 (c) (2), e.g., \"packing date,\" and \"date put in shipping container.\" For more information, contact: Dr. Robert Post, Director, Labeling and Additives Policy Division, at (202) 205-0279. \*Editor's Note: Attachments are sent with faxed versions of this report only. Links will be provided to electronic copy, when available. For Further Information Contact: FSIS Constituent Affairs Program Phone: (202) 720-9113 Fax: (202) 720-5704 E-mail: LisaWallenda.Picard@fsis.usda.gov FSIS Update Menu | FSIS Home Page | USDA Home Page"]}, {"file\_name": "FSIS\_GD\_2008\_0005", "title": "Questions and Answers - FSIS Directive 6100.4 - Verification Instructions Related to Specific Risk Materials", "num": "FSIS-GD-2008-0005", "id": "e6c89251cad44a7c80e4c8e14d394b97563c4db4ed1bd3bee40e07a55e1876b9", "co\_rpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/QA\_6100.4.pdf", "type": "pdf", "n\_pages": 15, "word\_count": 5975, "text\_by\_page": ["1 FSIS has developed the following guidance for water, ice and solution reuse. ICE REUSE Ice from ice packed poultry may be reused to repack raw whole birds or parts. The following are recommended: \* Establish a procedure to assure that ice is collected and held in a container that drains freely and in a sanitary manner. The procedure should address collection and washing of ice before it is reused. \* Establish a procedure for identifying reused ice from fresh ice. \* The ice or the product should be packaged in an impervious, sealed container, such as a plastic bag, to prevent direct contact between the product and ice. \* Ice used on raw product should not be reused on any partially- or fully-cooked product. \* The ice should be free of any observable foreign material as well as large particles of poultry meat and fat. If the ice is washed, continuous drainage should be maintained during the washing procedure. \* Ice from damaged containers should not be used. \* Establish procedures to correct deficiencies that occur and to prevent reoccurrence.", "2 BRINE REUSE Brine may be reused to chill cooked product for various

lengths of time based on the type of casing, salinity, and temperature. Brine solution that is reused to chill raw or heat-treated, but not fully cooked product ( e.g., smoked bacon) should be reconditioned in a manner to prevent the brine solution from becoming contaminated and adulterating the product. Brine reuse to chill raw product should follow the same criteria as brine reused to chill heat-treated, not fully cooked product. The following are recommended: \*

\* Establish procedures for monitoring the temperature, salinity, and free chlorine concentration of the brine being reused to chill heat-treated product.

\* Establish an ongoing microbiological plan to ensure that the brine solution is maintained pathogen free. The monitoring plan should cover the type and frequency of any microbiological analysis, action limits (upper\lower control limits), and actions taken to ensure product safety when those limits are exceeded. It is recommended that the establishment perform the following ongoing monitoring of the reused brine solution:

Cooked Product Analysis Frequency Action Level Total Plate Count Daily >2500 cfu\ml Total Coliform Weekly Positive Fecal Coliform Weekly Positive Raw or Heat-Treated, Not Fully Cooked Product (i.e. Bacon Bellies) Analysis Frequency Action Level Total Plate Count Daily >5000 cfu\ml Total Coliform Weekly >10 cfu\ml Fecal Coliform Weekly Positive \*

Initially, frequency of microbial testing should be at the highest level until control is established. Reduced testing may be appropriate once control has been established.", "3 However, loss of control may necessitate a return to increased testing frequency until system controls are reestablished.

\* Visible contamination defects should be removed from the product before it is placed in the brine solution.

\* The solution should be kept free of visible meat and fat particles and other objectionable conditions by effective methods such as filtration, skimming, or overflow.

\* When the brine solution is used without reconditioning for one shift or longer, the solution should be discarded at the following specified intervals, and all equipment, tanks, lines should be thoroughly cleaned and sanitized:

Heat-Treated Product Duration of Use (Classes)

Additional Conditions One production All Classes: None shift No casing Perforated casing Edible casing Semipermeable casing Impermeable casing Up to 24 hours All classes: 1. Minimum salt 5% No casing (19\u00b0F salimeter) Perforated casing 2. Maintain 40\u00b0F. Edible casing or lower Semipermeable casing Impermeable casing Up to 1 week One class: 1. Minimum salt 9% Semipermeable casing (32\u00b0F salimeter) Impermeable casing 2. Maintain 28\u00b0F. or lower Up to 4 weeks One class: 1. Minimum salt 20% Semipermeable casing (76\u00b0F salimeter) Impermeable casing 2. Maintain 10\u00b0F. or lower", "4

\* Cooked product, for example frankfurters, cannot be chilled in a brine solution that has been used to chill raw or heat-treated, not fully cooked product, for example, bacon bellies. (Raw product may be chilled after cooked product).

\* Products with semipermeable or impermeable casing that are being chilled in brine that is being reused for longer than 24 hours should be trimmed if they have broken casings or have been similarly exposed. The trimmings should be discarded as inedible.

\* A free chlorine concentration of 1-5 ppm should be maintained in the reuse brine solution.

\* Establish procedures to correct deficiencies that occur and to prevent reoccurrence.", "5

**COOK AND CHILL WATER REUSE**

Water may be reused to cook product and to chill cooked product. The following are recommended:

\* Establish procedures for monitoring the temperature of the cook or chill water, and free chlorine concentration of the chill water being reused to chill cooked product.

\* Establish an ongoing microbiological plan to ensure that the reuse cook or chill water is maintained pathogen free. The monitoring plan should cover the type and frequency of any microbiological analysis, action limits (upper\lower control limits), and

actions taken to ensure product safety when those limits are exceeded. It is recommended that the establishment perform the following ongoing monitoring of the reused cook and\or chill water: Chill Water Analysis Frequency Action Level Total Plate Count Daily >500 cfu\ml Total Coliform Weekly Positive Fecal Coliform Weekly Positive Turbidity Weekly >5 NTU Cook Water Analysis Frequency Action Level Total Plate Count Daily >500 cfu\ml Gas Forming Anaerobes Weekly >10 cfu\ml Total Coliform Weekly Positive Turbidity Weekly >5 NTU \* Initially, frequency of microbial testing would be at the highest level until control is established. Reduced testing may be appropriate once control has been established. However, loss of control may necessitate a return to increased testing frequency until system controls are re-established. \* Visible contamination defects should be removed from the product before it is placed in the cook and\or chill water. \* The cook or chill water should be kept free of visible meat and fat particles and other objectionable conditions by effective methods such as filtration, skimming, or overflow.", "6 \* The chill water should be maintained at a temperature of 50\u00b0 F. or less. \* The cook water should be maintained at a temperature of 150\u00b0 F. or higher. \* A free chlorine concentration of 1-5 ppm should be maintained in the reuse chill water \* Establish procedures to correct deficiencies that occur and to prevent reoccurrence.", "7 PROPYLENE GLYCOL REUSE Propylene glycol solution may be reused to chill raw product such as hamburger chubs, sausage chubs, and bagged poultry for up to an indefinite length of time. The following are recommended: \* Establish procedures for monitoring the temperature, propylene glycol concentration, and free chlorine concentration of the propylene glycol solution being reused to chill raw product. \* Establish an ongoing microbiological plan to ensure the continuous safety of the propylene glycol solution. The monitoring plan should cover the type and frequency of any microbiological analysis, action limits (upper\lower control limits), and actions taken to ensure product safety when those limits are exceeded. It is recommended that the establishment perform the following ongoing monitoring of the reused propylene glycol solution: Analysis Frequency Action Level Total Plate Count Weekly >500 cfu\ml Total Coliform Weekly >10 cfu\ml Fecal Coliform Weekly Positive \* Initially, frequency of microbial testing should be at the highest level until control is established. Reduced testing may be appropriate once control has been established. However, loss of control may necessitate a return to increased testing frequency until system controls are re-established. \* Visible contamination defects should be removed from the product before it is placed in the propylene glycol solution. \* The propylene glycol solution should be kept free of visible meat and fat particles and other objectionable conditions by effective methods such as filtration, skimming, or overflow. \* The propylene glycol solution should be maintained at a temperature of 10\u00b0 F. or less during production hours and 40\u00b0 F. or less during nonproduction hours. \* The propylene glycol should be of a type that is authorized for use for immersion freezing of meat and poultry products. \* The product should be enclosed in a package that does not allow the propylene glycol solution directly or indirectly", "8 to contact it. It is recommended that product be enclosed within an impervious package. \* Products that are exposed to the propylene glycol solution should be appropriately handled as contaminated product. One appropriate way of handling the contaminated product would be to rewash the product by water spraying. All traces of refrigerant should be removed before product is passed for food. If water washing or trimming cannot remove all contamination, the affected portion should be condemned. \* The propylene glycol solution should be adequately removed from the

packaged products after freezing and before placing into shipping containers by effective methods such as water spray washing equipment. \* A free chlorine concentration of 1-5 ppm is recommended to be maintained in the propylene glycol. \* Establish procedures to correct deficiencies that occur and to prevent reoccurrence.", "9 CHILLER OVERFLOW WATER REUSE Overflow water from the poultry chilling units may be reused to move heavy solids in eviscerating troughs (not to flush sides of trough), scald tank, picker aprons, and washing picking room floors. The following are recommended: \* Establish a procedure to assure that chiller overflow water is collected and used in a sanitary manner. \* Chiller overflow water added to the scalding should be a minimum of 140\u00b0 F. \* The use of chiller overflow water to rinse picker aprons and wash picking room floors should be used in a manner that prevents cross-contamination to other areas of the plant such as that due to employee traffic. \* The chiller overflow water should be kept free of visible solids. \* The chiller overflow water is collected and handled in a sanitary manner. \* Establish an ongoing microbiological plan to ensure that the chiller overflow reuse water is maintained pathogen free. The monitoring plan should cover the type and frequency of any microbiological analysis, action limits (upper\lower control limits), and actions taken to ensure product safety when those limits are exceeded. It is recommended that the establishment perform the following ongoing monitoring of the reused chiller overflow water: Analysis Frequency Action Level Total Coliforms Weekly Positive Fecal Coliforms Weekly Positive Salmonella Weekly Positive Staphylococcus aureus Weekly Positive (coagulase positive staphylococci) \* Initially, frequency of microbial testing should be at the highest level until control is established. Reduced testing may be appropriate once control has been established. However, loss of control may necessitate a return to increased testing frequency until system controls are re-established. \* Establish procedures to correct deficiencies that occur and", "10 to prevent reoccurrence.", "11 CONDENSER OR COMPRESSOR WATER REUSE Water from condensers or compressors may be reused in edible and inedible product areas providing that it is maintained pathogen free. The following are recommended: \* The reuse condenser or compressor water should be collected and handled in a sanitary manner. \* The reuse condenser or compressor water should be maintained in a manner that prevents the solution from becoming contaminated with coliforms, oil and grease, refrigerant, or heavy metals that can adulterate product. \* A free chlorine concentration of 1-5 ppm should be maintained in the reuse condenser or compressor water. \* An ongoing monitoring plan should be established to ensure that the reuse condenser and compressor water is maintained pathogen free. The monitoring plan should cover the type and frequency of any physical, chemical, and microbiological analysis, action limits (upper\lower control limits), and actions taken to ensure product safety when those limits are exceeded. It is recommended that the establishment perform the following ongoing monitoring of the reuse chill water: Analysis Frequency Action Level Total Plate Count Weekly >500 cfu\ml Total Coliform Weekly Positive Fecal Coliform Weekly Positive Turbidity Weekly no samples > 5 NTU \* Initially, frequency of microbial testing should be at the highest level until control is established. Reduced testing may be appropriate once control has been established. However, loss of control may necessitate a return to increased testing frequency until system controls are re-established. \* Establish procedures to correct deficiencies that occur and to prevent reoccurrence.", "12 REUSE WATER TO FLUME CHICKEN FEET (PAWS) Poultry chiller overflow water and water used to flume chicken feet (paws) may be used to flume chicken feet including through an in-line paw chiller.

The following are recommended: \* Potable water should be added periodically to prevent organic matter buildup. \* The chiller overflow water and paw flume water should be kept free of visible solids. \* A free chlorine concentration of 1-5 ppm should be maintained in the reuse water used to convey chicken feet (paws). \* An ongoing microbiological monitoring plan should be established to ensure that the reuse chiller overflow water and paw flume water used to flume chicken paws is maintained pathogen free. The monitoring plan should cover the type and frequency of any microbiological analysis, action limits (upper\lower control limits), and actions taken to ensure product safety when those limits are exceeded. It is recommended that the establishment perform the following ongoing monitoring of the reuse chiller overflow water and paw flume water: Analysis Frequency Action Level Total Coliforms Weekly Positive Fecal Coliforms Weekly Positive Salmonella Weekly Positive Staphylococcus aureus Weekly Positive (coagulase positive staphylococci) \* Initially, frequency of microbial testing should be at the highest level until control is established. Reduced testing may be appropriate once control has been established. However, loss of control may necessitate a return to increased testing frequency until system controls are re-established. \* Establish procedures to correct deficiencies that occur and to prevent reoccurrence.", "13 REUSE WATER USED TO WASH LIVESTOCK PENS, TRUCKS, POULTRY CAGES, AND SIMILAR AREAS Water from establishment's secondary and tertiary wastewater treatment facility or other processing water may be reused to wash livestock pens, trucks, poultry cages, and other similar areas. The following are recommended: \* Water from the establishment's wastewater treatment facility or other processing water used for washing should be kept free of visible solids. \* A free chlorine concentration of 1-5 ppm should be maintained in the reuse water. \* The water from the establishment's wastewater treatment facility or other processing water should be collected and handled in a sanitary manner. \* The establishment\u2019s wastewater treatment system must not be treating human waste. Human waste must be kept separate from plant waste and not commingled at the wastewater treatment system. \* An ongoing microbiological monitoring plan should be established to ensure that the reuse water from the establishment's wastewater treatment facility or other processing water are maintained pathogen free. The monitoring plan should cover the type and frequency of any microbiological analysis, action limits (upper\lower control limits), and actions taken to ensure product safety when those limits are exceeded. It is recommended that the establishment perform the following ongoing monitoring of the reuse water from the establishment's wastewater treatment facility or other processing water: Analysis Frequency Action Level Total Coliforms Weekly Positive Fecal Coliforms Weekly Positive Salmonella Weekly Positive Staphylococcus aureus Weekly Positive (coagulase positive staphylococci) \* Initially, frequency of microbial testing should be at the", "14 highest level until control is established. Reduced testing may be appropriate once control has been established. However, loss of control may necessitate a return to increased testing until system controls are re-established. \* Establish procedures to correct deficiencies that occur and to prevent reoccurrence.", "15 REUSE WATER USED TO WASH INEDIBLE PRODUCT AREAS Water from throughout the plant may be reused in inedible product areas (i.e. washing offal sump screen, flushing feather flow-away troughs, flushing eviscerating troughs that are covered with metal plates, etc.). The following are recommended: \* The reuse water should be used in a manner that prevents cross-contamination to other areas of the plant such as that due to employee traffic. \* The reuse water used should not violate any OSHA requirements. \* The reuse water

used in inedible areas under FDA jurisdiction, such as pet food areas, must also meet FDA requirements. \* The reuse water should be kept free of visible solids. \* The reuse water is collected and handled in a sanitary manner. \* Establish procedures to correct deficiencies that occur and to prevent reoccurrence.", "16 REUSE WATER FROM AN ADVANCED WASTEWATER TREATMENT FACILITY Reuse water from an advanced wastewater treatment facility may be used on edible product (but not in product formulation) and throughout the plant in edible and inedible production areas. The following are recommended: \* An advanced wastewater treatment facility should meet EPA requirements. \* The establishment\u2019s advanced wastewater treatment must not be treating human waste. Human waste must be kept separate from plant waste and not commingled at the advanced wastewater treatment facility. \* The establishment should have qualified and trained personnel who monitor, regulate, and record the wastewater treatment system. \* The establishment should have a program in place that identifies, monitors, and records the treatment measures necessary for safe and effective operation of the wastewater treatment facility. \* The potable and reuse water lines should be identified and separated except at junctions where appropriate valves, etc. protect the potable water supply. \* Dual check valves, alarms, etc., should be in place in case the reuse water system malfunctions to prevent the reuse water from contaminating the potable water supply. \* A \"Fail-Safe\" system should be in place to prevent substandard reuse water from entering the \"end use\" part of the system and contaminating edible product. \* A final potable water rinse should be applied to any edible product and any equipment that contacts reuse water. \* The \"End Use\" reused water should be monitored and tested daily to ensure that the reuse water meets the criteria for the intended use. \* The reuse water should meet the following \"Safe for the Intended Use\" EPA Criteria: 1. Microbiological analysis a. Total Aerobic Plate Count \u2264 500 CFU/ML b. Total Coliforms - None", "17 c. E. coli - None 2. Chemical analysis Total Organic Carbon (TOC) \u2264 100 MG/L 3. Physical analysis Turbidity - \u22645% of samples analyzed \u2265 1 NTU by EPA nephelometry method or equivalent method; no samples > 5 NTU 4. The reuse water should be tested for heavy metals at least once a year and meet the appropriate EPA Maximum Contaminant Levels (MCL\u2019s). \* Establish procedures to correct deficiencies that occur and to prevent reoccurrence.", "18 REUSE WATER IN VAPOR LINES FROM DEODORIZERS Water in vapor lines from deodorizers (condensers) used in preparation of lard and similar edible product may be reused for the same identical use. The following are recommended: \* The complete drainage and disposal of the reused water, effective cleaning of the equipment, and renewal with fresh potable water should be accomplished often enough to assure an acceptable supply of reuse water for the preparation of lard and similar edible product. \* The reuse water in vapor lines from deodorizers should be maintained in a manner that prevents the solution from becoming contaminated such as with coliforms, oil, or grease that can adulterate the product. \* An ongoing monitoring plan should be established to ensure that the reuse water in vapor lines from deodorizers is maintained pathogen free. The monitoring plan should cover the type and frequency of any physical, chemical, and microbiological analysis, action limits (upper/lower control limits), and actions taken to ensure product safety when those limits are exceeded. It is recommended that the establishment perform the following ongoing monitoring of the reuse water: Analysis Frequency Action Level Total Plate Count Weekly >500 cfu/ml Total Coliform Weekly Positive Fecal Coliform Weekly Positive Turbidity Weekly No samples > 5 NTU \* Initially, frequency of

microbial testing should be at the highest level until control is established. Reduced testing may be appropriate once control has been established. However, loss of control may necessitate a return to increased testing frequency until system controls are re-established. \* Establish procedures to correct deficiencies that occur to prevent reoccurrence.", "19 Reuse Water From Single Or Multiple Point Sources Can Be Used For Single Or Multiple Point Sources In The Slaughter Process Reuse water from any slaughter process location(s) (e.g., scalding, inside\outside bird washer, chiller overflow water, etc) can be used at any location(s) in the slaughter process including the chiller make-up water and for general sanitation purposes. For example, chiller overflow water and water from the final bird washer that are reconditioned and meet the criteria listed below can be reused in the scalding, throughout the eviscerating line, inside\outside bird washer, final bird washer, chiller make-up water and for general sanitation purposes. Consequently, since the reuse water can replace potable water used during the slaughter process, it needs to meet a higher water reuse standard than pathogen free. The following are recommended: \* Establish procedures for monitoring turbidity and concentration of the water being reused during the slaughter process. \* A free chlorine concentration of 1-5 ppm should be maintained in the reuse water. \* The potable and reuse water lines should be identified and separated except at junctions where appropriate valves, etc, protect the potable water supply. \* A system should be in place to prevent substandard reuse water from entering the \u201cend use\u201d part of the system and contaminate edible product. \* Establish an ongoing microbiological plan to ensure the continuous safety of reuse water during the slaughter process. The monitoring plan should cover the type and frequency of any microbiological analysis, and action limits (upper\lower control limits) and actions taken to ensure product safety when those limits are exceeded. It is recommended that the establishment perform the following ongoing monitoring of the reconditioned water:

Analysis Frequency Action level Total Plate Count Weekly >500 cfu\ml Total Coliform Weekly Positive Fecal Coliform Weekly Positive Turbidity Daily >5 NTU", "20 \* Initially, frequency of microbial testing should be at the highest level until control is established. Reduced testing may be appropriate once control has been established. However, loss of control may necessitate a return to increased testing frequency until system controls are re-established. \* Establish procedures to correct deficiencies that occur and to prevent reoccurrence."], {"file\_name": "FSIS\_GD\_2010\_0001", "title": "Mobile Slaughter Unit Compliance Guide", "num": "FSIS-GD-2010-0001", "id": "12a87adef7f93489a2eb171c587cc0d205267255d2c2a6bd3248ce96aa2c99e", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-04/Compliance\_Guide\_Mobile\_Slaughter.pdf", "type": "pdf", "n\_pages": 10, "word\_count": 3507, "text\_by\_page": ["12/20/01 (Additional Questions May Lead to Updated Versions in the Future) IRRADIATION Q\u2019s & A\u2019s LABELING ISSUES 1. Is the Agency reviewing labels for irradiated products or products containing an irradiated meat or poultry component or can such labels be generically approved? Such labels must be evaluated by FSIS\u2019s Labeling Consumer Protection Staff (LCPS), Labeling Compliance Team (LCT), for an initial sketch approval. Subsequent changes permitted by the generic labeling regulations (9 CFR 317.5 and 381.133) do not require re-approval through FSIS. However, FSIS will be tracking the types and numbers of labels for irradiated products and products containing irradiated meat or poultry

ingredients for possible future rulemaking. 2. Does the radura (irradiation logo) have to be green as was previously required by the poultry regulations? No. There are no longer any specific color requirements. However, other countries may have different or additional requirements for importation of irradiated products. 3. Are the labeling requirements for irradiated poultry the same as those for beef? Yes. The labeling requirements are identical for meat and poultry products with respect to irradiation. 4. When \u201cirradiated\u201d is part of the product name, e.g., \u201cIrradiated Beef,\u201d what other irradiation labeling is required? The product labeling also must bear the radura. 5. If a label bears the radura and a \u201ctreated with radiation\u201d statement, but, the company chooses to put the term \u201cirradiated\u201d with the product name, e.g., \u201cirradiated beef patties,\u201d does the term \u201cirradiated\u201d become part of the product name and need to be one third the size of the largest letter in the product name? Yes. Even though, in this case, the term \u201cirradiated\u201d is not required as part of the product name, if a company chooses to include \u201cirradiated\u201d as,"part of the product name, the product name sizing rules (i.e., no letter in the product name can be less than one third the size of the largest letter in the product name.) will apply. 6. How can irradiated beef be identified in the ingredients statement of a multiingredient product? Irradiated beef can be listed in the ingredients statement either as \u201cIrradiated beef,\u201d or \u201cBeef, treated by irradiation.\u201d The acceptability of similar identifications of irradiated ingredients will be handled on a caseby-case basis. 7. If a beef carcass is irradiated and then broken down into primal and retail cuts, how would the primal and retail cuts be labeled? The labeling of all single-ingredients products made from an irradiated carcass must bear the radura and either the term \u201cirradiated\u201d as part of the product name or the inclusion of a statement, such as, \u201cTreated with Radiation\u201d or \u201cTreated by Irradiation.\u201d Such labeling would also be required at the grocery store for product that is packaged and placed in the display counter for consumers. 8. What are the requirements for labeling bulk irradiated product at retail, e.g., irradiated beef in a butcher shop? Point of purchase identification of an irradiated meat or poultry product can be by a label on the package or by the use of placards or brochures located next to the product. 9. If ground beef is manufactured from irradiated beef or irradiated beef trimmings, would it be labeled as \u201cGround Irradiated Beef?\u201d The product labeling would be required to include the radura and a statement, such as, \u201cTreated with Radiation\u201d or \u201cTreated by Irradiation.\u201d If \u201cirradiated\u201d is part of the product name, e.g., \u201cGround Irradiated Beef,\u201d or \u201cIrradiated Ground Beef,\u201d the statement is not required. Additionally, labeling a product as \u201cGround Irradiated Beef\u201d still requires the product must meet the standard for ground beef. 10. How would a ground beef product be labeled if it was a combination of irradiated beef and non-irradiated beef? All that would be required on the label would be to list \"beef\" and \"irradiated beef\" or \"beef, treated by irradiation\" in the ingredients statement. However, in addition to the ingredients statement declaration, the product label could include the radura and the required statement or the radura and a product name which indicated the combination, e.g., \"\u201cIrradiated Ground Beef and Ground Beef,\u201d or \u201cGround Beef and Irradiated Ground Beef,\u201d depending on the order of predominance. 11. What is the proper way to label a fabricated multi-ingredient product, e.g., fresh sausage, made with only non-fluid seasonings and irradiated beef, which is then packaged and irradiated? The fresh

sausage label would bear the radura and either be labeled as \u201cirradiated\u201d sausage or contain a required statement, such as, \u201cTreated with radiation\u201d or \u201cTreated by irradiation.\u201d Secondly, the sausage ingredients statement would identify the beef as either \u201cIrradiated beef\u201d or \u201cBeef, treated by irradiation.\u201d 12. Would an irradiated meat or poultry component used in a multi-ingredient product need to be labeled as \u201cirradiated\u201d in the ingredients statement of the multi-ingredient product, if the finished product is also irradiated? Yes. 13. Do point-of-purchase labeling requirements apply to restaurants? No. There are no labeling requirements for irradiated products at restaurants. However, FSIS is aware of several restaurants that voluntarily disclose irradiation information on menus and encourages this type of disclosure. 14. What labeling statements about the purpose of radiation processing have been authorized for use on labeling in conjunction with the radura in addition to or instead of \u201cTreated with radiation\u201d or \u201cTreated by irradiation?\u201d FSIS has reviewed and approved the following statements: \u201cTreated with irradiation for your food safety\u201d \u201cTreated with irradiation for food safety\u201d \u201cTreated with irradiation to improve food safety\u201d \u201cTreated with irradiation to reduce the potential for foodborne illness\u201d \u201cTreated with irradiation to reduce E. coli bacteria\u201d \u201cTreated with irradiation to reduce pathogens such as E. coli and Salmonella\u201d \u201cIrradiated for your food safety\u201d \u201cIrradiated for food safety\u201d 15. Would FSIS consider the term \u201cpasteurized\u201d as an acceptable term to describe the irradiation process? At this time, labeling statements or claims for irradiated products that include the term \u201cpasteurization\u201d are misleading. FSIS will continue to \u201cexamine this term in light of developments in irradiation technology and FDA policy. In the future, use of the term \u201cpasteurization\u201d will be considered on a case-by-case basis and would require significant documentation and validation as to process controls that demonstrate that vegetative cells of pathogens have been reduced to safe levels and produces a ready-to-eat product. 16. We are aware that steam-pasteurization is currently permitted, and that labeling can state that the product was steam-pasteurized. Why is the phrase permitted on such product if not permitted on irradiated product? The use of steam-pasteurization is only permitted for whole carcasses and parts of carcasses that are to be further processed. Moreover, the labeling of further processed products, such as retail cuts (e.g., ground beef, steaks) and offal (e.g., tripe, intestines, etc.) with statements about reductions in microorganisms or the use of the term \u201csteam-pasteurized\u201d is not permitted because it is misleading to consumers. 17. Can the terms \u201call,\u201d \u201cpure,\u201d and \u201c100%\u201d be used on irradiated beef? Yes. The regulations in 9 CFR 317.8(b)(34) and 381.129(b)(5) specify the terms \u201call,\u201d \u201cpure,\u201d \u201c100%,\u201d and terms of similar connotation shall not be used on labels for products to identify ingredient content unless the product is prepared solely from a single ingredient. Thus, irradiated, single ingredient meat or poultry can be labeled in this manner. 18. Is a \u201cNo MSG Added\u201d claim acceptable on irradiated ground beef? Since MSG is not classified as a non-fluid seasoning, it is not permitted to be in a product that is subsequently irradiated. Therefore, a \u201cno MSG added\u201d claim is a \u201cnegative claim\u201d and may only be used if accompanied by the statement \u201cUSDA regulations do not permit the addition of MSG to irradiated products.\u201d 19. Can an irradiated product be labeled as \u201cnatural\u201d or \u201ccertified Organic by (a

certifying entity)?\u201d The term \u201cnatural\u201d can not be used since FSIS considers irradiation to be more than minimal processing. Thus, such products would not meet the \"natural\" criteria established by Policy Memo 55. Regarding the use of \u201ccertified Organic by (a certifying entity),\u201d we are not aware of any organization providing organic certification that allows the use of irradiation. Further, on March 13, 2000, AMS issued a re-proposed regulation on organic agricultural products which does not permit the use of irradiation on products labeled \u201corganic.\u201d", "20. How can a company label a box containing a variety of meat or poultry products including some that are irradiated and some that are not irradiated? It must be perfectly clear to consumers which products are irradiated and which products are not irradiated. The best method of conveying this information is to include \u201cirradiated\u201d as part of the product name on the principal display panel of all irradiated products as well as the radura on the label. 21. Does the labeling of the shipping container of irradiated products require inclusion of the radura and other required information? Not for a true shipper that is only labeled with the inspection legend and a handling statement, if necessary, and that holds fully labeled products. 22. Can whole livestock blood (dried or fluid) be irradiated? Yes. Whole blood is considered a byproduct which can be irradiated provided it does not contain additives, e.g., sodium citrate as an anticoagulant. 23. If pork is irradiated to eliminate trichinae, can the pork be labeled as \u201ccertified pork?\u201d Yes, if irradiation, in compliance with requirements in 21 CFR 179.26 for treatment of *trichinella spirallis*, is used to treat pork and the company demonstrates that viable trichinae have been destroyed or rendered ineffective in causing infection, the resulting pork can be labeled as \u201ccertified pork.\u201d Additionally, all of the other labeling requirements for the irradiated product, i.e., use of the radura and the required statement or the radura and \u201cirradiated\u201d as part of the product name would be required. Furthermore, when such irradiated pork is used in a secondary product, the ingredients statement must identify the pork as \u201cirradiated Pork\u201d or \u201cPork, treated by irradiation.\u201d", "INGREDIENT ISSUES 1. Consider this situation: A company intends to use irradiated beef in its beef patty; however, it is concerned about the availability of the irradiated beef component. Can the company use \u201cand\u201d or \u201cmay contain\u201d labeling with respect to the irradiated beef component? No. Consumers wishing to purchase products containing an irradiated meat component consider the irradiated meat to be a \u201cvaluable\u201d constituent of the finished product. FSIS labeling regulations do not include provisions for \u201cand\u201d labeling and policies have not permitted the use of a \u201cmay contain\u201d statement in reference to a \u201cvaluable\u201d component, e.g., truffles, veal, etc. FSIS policies have only permitted the use of a \u201cmay contain\u201d statement with \u201cminor\u201d ingredients, generally under two percent of the total formulation, that do not affect the character of the product. FSIS has never considered the meat or poultry components to be classified to be \u201cminor\u201d in this situation. 2. What are non-fluid seasonings? Non-fluid seasonings are dried spices, e.g., thyme and basil, dried flavorings from botanical sources, e.g., garlic powder and lemon powder, salt and sugar. Ingredients such as MSG, autolyzed yeast extract, hydrolyzed (source) proteins, and garlic have not been considered to be non-fluid seasonings. For example, whole garlic is a vegetable, not a spice, while garlic powder is a spice\u201d/seasoning. 3. If non-meat\u201d/non-poultry ingredients, such as irradiated spices, wheat flour, potatoes, and fruits, are added to an irradiated or non-

irradiated meat\poultry product, must the fact that they have been irradiated be disclosed in the ingredients statement? No. However we would permit this ingredient statement identification for irradiated non-meat and non-poultry components. 4. For the purposes of irradiation, are ingredients such as BHA, BHT, TBHQ permitted in sausage products that will be irradiated? At this time, no.","PACKAGING MATERIAL ISSUES 1. Do poultry products that are packaged and irradiated still need to be packaged in air permeable packaging materials? Yes, until FDA issues a final rule that no longer mandates the use of air permeable packaging materials for irradiated poultry products. However, poultry that is irradiated and packaged after irradiation is not required to be packaged in air permeable packaging materials. 2. If meat and poultry are packaged together and irradiated, would they need to be packaged in air permeable packaging materials? Yes. While red meat alone is not required to be packaged in air permeable packaging materials if packaged prior to irradiation, because that requirement still exists for poultry, a combination, e.g., beef roast and chicken breast packaged together prior to irradiation would have to be packaged in air permeable packaging materials. 3. Can meat irradiated with electron beam be packaged in the same packaging materials as meat irradiated by gamma ray? Yes. Recently, FDA provided approval on a trial basis (until February 22, 2001) to permit any of the materials currently approved under 21 CFR 179.45 to be used when pre-packaged meat food and poultry food products are treated with X-ray, electron beam and gamma ray irradiation under the following conditions: a. \u201cThe irradiation processor will comply with all general provisions for food irradiation listed in sections CFR 179.25 and 21 CFR 179.26(b); b. The machine sources of X-radiation and electron beams are used at dose levels not to exceed that specified in section 21 CFR 179.45 for packaging materials used, and at dose levels not to exceed those specified in 21 CFR 179.26(b) for the foods packaged; c. With the exception of the radiation source, as noted above, the packaging materials must comply with all other provisions of 9 CFR 179.45; and d. FSIS will monitor the participating establishments and immediately inform FDA of any unexpected findings.\u201d","PROCEDURAL ISSUES 1. Can hot-boned meat or poultry be irradiated? As of today, no. The regulation covers only refrigerated or frozen product. However, FSIS has petitioned FDA to allow the irradiation of hot-boned meat and poultry. 2. Will USDA accept imported meat and poultry products that have been irradiated in other countries into the US for distribution? Yes, provided they were treated and labeled consistent with USDA regulations. 3. If a company has its product irradiated, at another facility, must the HACCP plan at the producing establishment incorporate the irradiation step and CCP, or can there be two separate plans, i.e., one at the producing establishment and one at the irradiation establishment? FSIS considers any firm that irradiates meat food or poultry products to be an official establishment. Official establishments are required to irradiate meat food and poultry products only in accordance with HACCP systems. If an establishment contracts for its products to be irradiated for the purpose of reducing pathogens, we expect that establishment to have a CCP in its HACCP plan for irradiation, even though it does not conduct the irradiation in its own facility. Through review of receipts, certificates, and other records provided by the irradiator, the establishment would monitor and verify that its product was irradiated in accordance with its HACCP plan, contractual specifications, and the regulations. We also expect an establishments that has contracted out irradiation to address hazards it has identified to complete and sign its pre-shipment review only after verifying that its products have received the appropriate irradiation treatment by the contractor. 4. Can meat be irradiated more than

one time? Yes, but the total permitted absorbed dosage can not be exceeded. In these situations, it is the responsibility of the manufacturer to maintain records to document permissible limits are not exceeded.

5. What can be done with products that inadvertently receive too high an irradiation dosage? The products must be condemned as inedible and denatured."

"6. Are there special concerns with a fabricated multi-ingredient product, e.g., fresh sausage, made with only seasonings and irradiated beef, which is then packaged and irradiated? Yes. Total dosage of irradiation permitted for beef and other components, e.g., spices, could not be exceeded. Additional recordkeeping would probably be necessary to ensure that the maximum absorbed dosage is not exceeded."]}

{ "file\_name": "FSIS\_GD\_2010\_0002", "title": "Updated Questions and Answers Food Safety and Inspection Service (FSIS) Labeling Compliance Policy Guide on Poultry Food Product Dating", "num": "FSIS-GD-2010-0002", "id": "0ffb02f0a32a3e9202d3ebe0d595fbe3eebfd82efbf94d7103a629153e0a29c2", "corp\_us": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Labeling\_Guide\_on\_Poultry\_Food\_Dating.pdf", "type": "pdf", "n\_pages": 8, "word\_count": 3557, "text\_by\_page": [ "I. General Q. What is the new final rule that eliminated the standards of identity for pizza with meat or sausage products? A. The final rule published on July 31, 2003, in the Federal Register and was effective October 22, 2003. It eliminated the standards for pizza products, i.e., the standards in 9 CFR 319.600, which required a minimum meat content and required components of a traditional pizza. The standards were eliminated to allow for more innovation in pizza manufacturing. To inform consumers of the changes in pizza products, 9 CFR 317.8 (b)(40)and 381.129 (f) require a percentage statement regarding the meat/poultry component to be placed contiguous to the ingredients statement for a time period of approximately 3 years. II. Requirements for Labeling the Percentage of a Meat/Poultry Component on Pizza Products 1. Q. When is the percentage labeling no longer required? A. The percentage labeling requirement expires October 30, 2006. The date of October 24, 2006, placed in the \"Date\" section of the final rule in the July 31, 2003, Federal Register is an error in printing. 2. Q. Is there a minimum type size requirement for the percentage labeling of the meat/poultry component? A. No, however, consistent with rules on all required labeling features, the information must be prominent and conspicuous, e.g., navy blue print on a black background is not considered to be prominent and conspicuous. 3. Q. Can a company declare the exact percentage of the meat/poultry component on the label if the formula lists the amount to the hundredth or thousandth decimal place? A. We suggest the required percentage listing be limited to one place past the decimal point, e.g., 5.2% would be acceptable. 4. Q. Can the required percentage declaration of the meat/poultry component be rounded up to the nearest whole number or tenths? A. No, the percentage cannot be over-declared. Consistent with the Agency's current labeling policies, rounded numbers have to be rounded down, e.g., 5.26% could be rounded to "5%" or "5.2%." 5. Q. Can the required percentage declaration of the meat/poultry component be rounded up to the nearest whole number or tenths? A. No, the percentage cannot be over-declared. Consistent with the

Agency's current labeling policies, rounded numbers have to be rounded down, e.g., 5.26% could be rounded to "5%" or "5.2%. 6. Q. If the ingredients statement and signature line fill the space of the side panel on the product packaging, can the percent declaration of meat/poultry component be moved to the next panel to the right? A. No. The percentage is required to appear on the same panel, and contiguous to, the ingredients statement. It may appear above, below, or to the right or left of the ingredients statement. 7. Q. Can the percent declaration be placed contiguous to the ingredients statement by a means other than reprinting the label or using a pressure-sensitive sticker? A. Yes, the percentage information can be ink jetted on the label, hand stamped with indelible ink, or imprinted on the label, provided it is in the required location and is prominent and conspicuous. For Child Nutrition (CN)-labeled products, see the section entitled "Child Nutrition (CN)-Labeled Products." 8. Q. For a pizza topped with meat components, e.g., sausage and pepperoni, can the two meat percentages be combined and declared as a total meat percentage contiguous to the ingredients statement? A. The regulation states that pizza products that "list a meat component as part of the product name must bear a parenthetical statement contiguous to the ingredients statement that conveys the percent of the cooked, cured, or dried meat component." Thus, if two meat components are declared, e.g., sausage and pepperoni, in the product name, companies should list the percentage of each contiguous to the ingredients statement. However, the Agency will also view other percentage listings as being in compliance with the intent of the regulation. There is no objection to listing a combination of the labeled meat/poultry components, and the total percentage of meat/poultry food products or a declaration of the percentage of meat/poultry in the components, provided that the percentage of meat/poultry present in the finished meat/poultry," food products is known. Examples below show acceptable declarations based on meat/poultry components:

Percentage Of Ingredients In Product Formula Examples Of Acceptable Labeling Of Percentages To Meet Requirement In Final Rule

5% Pepperoni (60% pork, 20% beef) "5% Pepperoni, " 5% Meat food product, " "40% Meat, " "3% pork and 1% beef, " "4% Meat ingredients" 3% Sausage and 2% Pepperoni "3% Sausage and 2% Pepperoni" "Sausage and Pepperoni 5%" 10% Beef Patty Mix (8% Beef Sausage&133) "10% Beef Patty Mix, " "8% Sausage, " "8% Beef Sausage" 3% Bacon and 3% Chicken Sausage "3% Bacon and 3% Chicken Sausage, " "6% Bacon and Chicken sausage, " "6% Meat and poultry food product" 8% Turkey Sausage (50% Turkey) "8% Turkey Sausage, " "4% turkey, " "8% poultry food product, " "4% poultry ingredients" 4% Ham and Water Product "4% meat food product, " "4% Ham and Water Product" 6% Turkey Ham and Water product "6% Turkey Ham and Water Product" 5% Uncooked Sausage "5% Uncooked Sausage" 5% FatReduced Pepperoni "5% Fat-Reduced Pepperoni"

9. Q. If a product is named "Sausage Pizza" but the product is topped with 20% "meat pizza topping" (e.g., 12% sausage/8% textured soy protein), is it acceptable to declare the required meat content simply as "20% meat food product?" A. No, that name would be misleading since the implication would be that the product contained 20% sausage when in reality it contained only 12%. Accurate, non-misleading percentage declarations would include "12% sausage, " "12% meat food product, " and "X % meat, " if the actual percentage of meat in the pizza topping is known. The declaration of "20% Pizza Topping" would be acceptable because it is a name that conveys the presence of additives", "beyond the sausage portion in the meat food product.

10. Q. Can the amount of meat or poultry topping in the pizza be determined based on precooked

weight if the percentage statement is qualified, e.g., "15% beef (pre-cooked)"? A. No. The amount of meat or poultry must be determined according to the cooked, cured, or dry weight of the topping as a percentage of total weight according to the new final rule. III. Exhausting the Inventory of Existing Labels of Pizza Products 1. Q. What are the allowances for exhausting inventories of existing labels before the declaration of meat\poultry is needed? A. In order to use existing label inventory, the product would need to remain the same, i.e., a traditional pizza. There are three situations that apply: (1) The first is where there is no change to the product formulation, label, order of predominance of ingredients, and nutrition facts (outside of the 80\120 parameters) so no modification to the label is necessary. In this case, we are extending the effective date of the final rule to July 31, 2004, for the provision of adding the percentage of meat content to the labeling of existing pizza products, provided that the percentage declaration remains on each individual label for at least three years from the date of first use. (2) The second situation involves changes to the formulation and, therefore, to the label. However, in this case, the manufacturer decides to make the changes to the existing label by use of pressure sensitive stickers, ink jetting, indelible ink hand-stamps, etc. The product labeling qualifies for generic label approval under 9 CFR 317.5(b)(1) and 9 CFR 381.133(b)(1) which means that some changes may be made to the existing labeling under the generic provisions in 9 CFR 317.5(b) (9) or 381.133(b) (9), e.g., the order of predominance of the ingredients statement can be corrected by use of a pressure sensitive sticker covering the inaccurate information. The label would bear the percent declaration when the formula is changed to lower the amount of meat\poultry or meat food product or poultry product from that which was required in the traditional standardized pizzas. In all cases, the labeling must prominently bear all mandatory features and cannot be false or misleading in any manner. (3) The third situation involves changes to the formulation and label where a temporary approval is sought by the company, and it meets the conditions specified in 9 CFR 317.4(f) and 381.132(f).

2. Q. If the pizza formula remains the same, is the percentage of meat\poultry component required to be added to the existing labels for them to be used up? A. No, the existing labels can be used up without", "adding the percentage, provided that the formulation does not change. However, the percentage may be voluntarily added by a sticker to existing stock under the generic labeling provisions. (For Child Nutrition (CN) labeled products, see the section entitled "Child Nutrition Labeled Products.") 3. Q. If the supplier of a company\u00b4s pepperoni or crust makes minor changes to the formula of the purchased component, can the old labels continue to be used? A. The company would need to submit such labels to the Labeling and Consumer Protection Staff (LCPS) with a request for a temporary approval. The conditions for granting temporary approvals are listed on the website. Minor changes can be granted temporary approval, or the company can change the existing label by use of pressure sensitive stickers, ink jetting, indelible ink hand-stamps, etc. Such labeling qualifies for generic label approval ( 9 CFR 317.5(b)(1) and 9 CFR 381.133(b)(1)) and generic label modifications ( 9 CFR 317.5(b) (9) and 381.133(b) (9)). (See the answer to " 2 Q." above, in this section.) 4. Q. If a company wants to reduce the percentage of the meat\poultry component, can the old labels be used by adding a sticker declaring the percent of meat\poultry component without an LCPS temporary approval? A. Yes, but only when there are no other changes needed to the label, i.e., the order of predominance in the ingredients statement does not change, the nutrition information remains in compliance, and all other information on the label remains accurate. If

there are changes, e.g., order of predominance, the company would need to request a temporary approval that provides data on the nutrient profile of the revised formula to ensure that the nutrition facts information remain in compliance with the regulations. Temporary approvals will be permitted on a case-by-case basis. (For CN labeled products, see the section entitled "Child Nutrition Labeled Products.") IV. Generic Label Record (Final Labeling) 1. Q. If a company only adds a sticker that declares the percentage of the meat\poultry component to previously approved labeling, can the label be approved generically? A. Yes, provided there are no other deficiencies on the label (See answer to III. Q. 4 above). (For CN labeled products, see the section entitled "Child Nutrition Labeled Products.") 2. Q. If a company changes their existing formula, can label modifications be approved generically? A. No, since there is no longer a standard of identity for pizza with meat\sausage products, "such products are now classified as nonstandardized products or products guided by a common or usual name, "pizza." The first time new or modified labels for such products need to be approved, they must be sent to LCPS for approval. Further modifications to the LCPSapproved label may be handled generically if they fall under the generic labeling modifications in 9 CFR 317.5(b)(9) or 381.133(b)(9) of the regulations. V. Naming of "Traditional" and NonTraditional, Descriptively Labeled Pizza-Like Products 1. Q. For the purposes of this regulation, what is a traditional versus non-traditional pizza? A. A traditional pizza is a product formulated with the components that were stipulated in the regulatory standard that existed in 9 CFR 319.600, i.e., tomato sauce, cheese, and meat topping on a bread-based crust. A non-traditional pizza is a product missing one or more of these components, e.g., instead of tomato sauce, it may include a white sauce, and instead of a breadbased crust it may use a corn tortilla. 2. Q. If a company renames their pizza-like product with a descriptive name that does not include the term "pizza," do they need to include a percent declaration of the meat\poultry component? A. No, if the product is descriptively named, e.g., "sausage, cheese, and sauce on a crust," and the term "pizza" does not appear anywhere on the label (including the nutrition facts panel, heating instructions, and romance copy), percent declaration of the meat\poultry component is not required. 3. Q. Does the order of ingredients\components in the product name of descriptively labeled pizza-like products have to follow the order of ingredients in the product formula? A. No, the Agency does not require a specific order of predominance in the product name of descriptively labeled products. 4. Q. In naming traditional pizzas or nontraditional pizza-like products, if a company uses 1% Italian sausage, 1% pepperoni, and 1% bacon, can the product name list all three meat components individually or collectively as "meat?" A. Even though the three meat components are at levels of 1 percent, they can each be identified in the product name since they could each characterize the product. The general term "meat" could also be used in the name, e.g., "Meat Pizza," for the traditional pizza, and "Meat, Cheese, and Pesto Sauce on a Crust," for a non-traditional product. 5. Q. If a company formulates their product with, "a pizza topping that contains textured vegetable (source) protein (TVP), does the TVP need to be included in the product name? A. The final rule that eliminated the pizza with meat or sausage standards did not affect the Agency\u00b4s longstanding labeling policy on meat\poultry-to-TVP ratios which was created to ensure that meat and poultry products are identified in an accurate and non-misleading way. The meat\poultry-to-TVP ratios are applicable to the naming of all pizza products unless the pizza is formulated with a meat food or poultry product the policy for which provides for the use of TVP without product name implications, e.g.,

\"(species or kind) Patty\" or \"(species or kind) Pizza Topping.\" In the case of these two examples, TVP is an expected ingredient in such products. 6. Q. Is the requirement in 9 CFR 317.8(b) (27) and 381.120 for qualifying the presence of calcium propionate or sodium propionate in pizza crust in the product name still in effect? A. Yes. The final rule only eliminated the standards of identity for pizza with meat or sausage products; other prevailing regulations, e.g., those dealing with ingredients labeling, are not implicated. 7. Q. Is it acceptable for the pizza product name to list some \"characterizing\" components that are at or below two percent and not mention other ingredients that are at a higher level but still below the two percent or less characterizing amount? A. Yes, some components, e.g. anchovies, garlic, and jalapeno peppers, are used at levels that are well below two percent and low levels can significantly characterize a product to the extent that they are included in the product name. However, it is not necessary to list all other components that are at a higher level, but still below the two percent level, e.g., imitation cheese. 8. Q. What guidance exists for naming substitute cheese and real cheese on pizza-like products? A. Consistent with the final rule, which stated that ingredients above two percent are characterizing, non-standardized products, such as pizza products, that highlight \"cheese\" in the product name or on the principal display panel (PDP) must contain above two percent real cheese to be characterizing. In addition, imitation\\substitute\\fat-reduced cheese, when used above two percent, also would be included as part of the product name. For descriptively named pizza products, cheese and imitation\\substitute\\fat-reduced cheese at characterizing levels, i.e., above two percent, would be included as part of the product name. 9. Q. The preamble to the final rule stated that once the final rule became effective, other \"pizza\", \"products with standards specified in the Food Standards and Labeling Policy Book will no longer be subject to the requirements of 9 CFR section 319.600, including minimum meat requirements.\" Which entries will be removed from the Policy Book? A. Because the pizza product entries in the Policy Book, viz., \"Pizza with Meat,\" \"Pizza with Sausage,\" \"Pizza with Poultry,\" \"Pizza with Bacon,\" \"Pizza with Chili and Beans,\" \"Pizza with Meat Pattie Crumble,\" and \"Pizza, Combination or Deluxe,\" were interpretations of the now-deleted 9 CFR section 319.600, it would not make sense to apply them. They will be removed shortly. 10. Q. What is the status of the entries in the Policy Book that include \"pizza\" in the product description that were not based on the previous pizza with meat\\sausage standard? Will they be retained? A. At the present time, the Agency will retain the entries for products that include \"pizza\" that were not established as interpretations of the previous standard in 9 CFR section 319.600. These entries include: Pizza Burger Pizza, Chicago Style Pizza Dogs Pizza, Pan Style Pizza Pups Pizza Roll Pizza Sauce with Sausage Pizza Sausage Pizza, Sicilian Style Pizza Topping Mix White Pizza I. Child Nutrition (CN) - Labeled Products 1. Q. Can CN-labeled products (i.e., products bearing CN labeling features that are required by the Food and Nutrition Service, FNS) get temporary approval for formulation changes? A. Temporary approvals for minor changes not affecting crediting will be granted by FNS. 2. Q. Can formulation changes to CN-labeled products be handled by generic approval? A. No. All formulation changes to CN-labeled products must be resubmitted to FNS for approval 3. Q. Can pressure-sensitive stickers be used to correct CN-labeled products? A. No. Stickers cannot be used on CN-labeled products for final or temporary approval. 4. Q. Can CN-labeled products that do not meet CN requirements be given a temporary approval\", \"by FSIS? A. No. 5. Q. Can a label keep the same CN identification number if the declaration of the percent of

meat\meat food product in the product is added voluntarily or as required by FSIS? A. Generally, FNS requires a new CN identification number and approval for any changes to the product name. However, if there are no other changes to the label application, FNS will not object to the generic approval of the addition of the declaration of percent meat\meat food product. FNS requires one copy of the generically approved label, along with a statement that indicates what was changed, to be sent to USDA, FNS, 3101 Park Center Drive, Rm. 632, Alexandria, VA 22302 ("Attention CN Label Reviewer"). 6. Q. Will CN product labels with changes need to be resubmitted to FSIS, LCPS, for reapproval? A. The answer depends on the circumstances: Yes - for labels resubmitted for temporary approval Yes - for labels submitted with new CN ID numbers No - for labels resubmitted as required by FNS that can be generically approved by FSIS. In this situation, the FNS re-approval will retain the previous FSIS approval number. (It is the company \u00b4s responsibility to convey to FNS that the label change can be done generically for FSIS so that the label is not forwarded to FSIS after the FNS review.) 7. Q. How do I contact the FNS, CN labeling staff, if I have other questions? A. The FNS, CN labeling staff can be reached at 703-305-2609. I. Miscellaneous Issues 1. Q. How low can the level of meat\poultry be before the product is no longer amenable to U.S. Department of Agriculture (USDA) jurisdiction (i.e., to the FMIA or PPIA)? A. In general, foods containing less than 3 percent raw or less than 2 percent cooked livestock or poultry ingredients are not defined as meat food or poultry products and, thus, are under the jurisdiction of FDA. 2. Q. If a pizza-like product contains 1% cooked meat sausage and 1% cooked poultry meat, is the", "product amenable? A. Yes. The product would bear the inspection legend of the meat or poultry component that is listed first in the product name."]}, {"file\_name": "FSIS\_GD\_2010\_0004", "title": "FSIS Guidance for Test Kit Manufacturers, Laboratories: Evaluating the Performance of Pathogen Test Kit Methods", "num": "FSIS-GD-2010-0004", "id": "2b46dc35a86dafc46d2f10aa6e9d2db235d8ae5b0f321d2664c57842fbff47eb", "corp\_us": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Validation\_Studies\_Pathogen\_Detection\_Methods.pdf", "type": "pdf", "n\_pages": 22, "word\_count": 6875, "text\_by\_page": ["Supplemental Pizza Q's & A's to Address the Names of Non-Traditional Pizza-Like Products and Pizzas with Modified Cheeses Supplemental Pizza Q's & A's to Address the Names of Non-Traditional Pizza-Like Products and Pizzas with Modified Cheeses New Questions\Answers: Naming Non-Traditional Pizza-Like Products In the absence of a pizza with meat standard, the prevailing regulations on naming meat and poultry products apply. According to the regulations (9 CFR 317.2(c)(1) and 381.117(a)), when a product's name is not guided by a standard of identity, products are named using a recognized common or usual name, if one exists, or a descriptive naming approach. After further consideration, the Agency has determined that a modification to the naming convention for certain nontraditional pizza-like products is needed. This modification relates to the continued use of the \"common or usual\" naming conventions of traditional pizza products. A question has also been added to clarify naming conventions with respect to the use of modified versions of standardized cheese products. 1. Q. What naming approach is acceptable for nontraditional pizza-like products that consist of the four traditional components (i.e., bread-base component used as a crust, shell, or other similar way; tomato sauce; cheese; and meat\poultry component) and only differ in their \"form\" from a traditional pizza, e.g., rolled, filled, or stuffed in a crust or breading, and fried

or baked? A. Such products could be named with the common or usual \"traditional\" pizza name; however, the basic nature or characteristics would also need to be identified, e.g., how the \"form\" of the product differs from the traditional pizza product. Examples would be \"pepperoni pizza in rolled dough and fried,\" \"sausage pizza enclosed in crust,\" \"Combination pepperoni and sausage pizza folded and sealed,\" and \"chicken pizza wrapped in a dough pocket.\" The term \"sandwich\" is not sufficiently descriptive for the form of the product because an enrobed or formed pizza is not defined as a traditional sandwich.

2. Q. Do imitation\\substitute cheese and modified versions of standardized cheese (per 21 CFR 130.10) need to be included in the product name on the labeling of traditional pizzas and non-traditional pizza-like products that consist of the four traditional components (i.e., bread-base component, tomato sauce, cheese, and meat\\poultry component) and only differ in their \"form\" from a traditional pizza? A. All of the traditional components of a traditional pizza that are present at 2 percent or more of the formulation do not need to appear in the common or usual product name. However, when \"cheese\" is included in the product name, or when a descriptive name is used that includes all the components that are present at 2 percent or more of the formulation, the amount of real cheese must be equal to or greater than\", \"that of the imitation, substitute, or modified versions of standardized cheese in the product or the imitation\\substitute\\modified cheese must be included in the product name. For example, a product identified as a \"Bacon, Cheddar Cheese, Hickory Flavored Sauce, and Sourdough Pizza,\" that contains 15 percent Cheddar and Reduced Fat Mozzarella Cheese would be expected to contain Cheddar at greater than 7.5 percent of the product formulation. Otherwise, the reduced fat cheese would need to be declared as part of the product name.

3. Q. Can a traditional pizza contain only a modified version of the standardized cheese for the required cheese component, or will this make the pizza a \"nontraditional\" pizza-like product requiring a descriptive name? A. Yes, a traditional pizza can contain only a modified cheese. Modified versions of standardized cheeses are actually covered by a \"general standard of identity\" in 21 CFR 130.10. In order for such products to contain novel ingredients, they must be identified with the standardized name in addition to a nutrient content claim. Thus, a pizza with a modified cheese would be regarded as a traditional pizza. However, the product name or other label features (e.g., starbursts) could not simply state the term \"cheese\" because of the nature of the modified standardized cheese and its required special labeling. Any statements regarding cheese would need to use the correct name of the component consistent with 21 CFR 130.10, e.g., \"fat free mozzarella cheese\" and \"reduced fat cheddar cheese.\" Revised Question\\Answer to Address Modified Versions of Standardized Cheese: Section V. Naming of \"Traditional\" and NonTraditional, Descriptively Labeled Pizza-Like Products

8. Q. When should real cheese and imitation\\substitute and modified versions of standardized cheese be declared on non-traditional, pizza-like products? A. The final rule stated that ingredients above two percent are characterizing ingredients. Consistent with the final rule, non-standardized products, including non-traditional pizza-like products, that highlight \"cheese\" or an imitation\\substitute\\modified cheese in the product name or on the principal display panel (PDP) must contain more than two percent real cheese for that cheese ingredient to be a characterizing ingredient. For descriptively named pizza products, cheese and imitation\\substitute\\modified versions of standardized cheese used at characterizing levels, i.e., above two percent, would be reflected as part of the product name. (Guidance on the

common or usual names of cheese products is found in FDA standards of identity regulations (21 CFR \u00a7 130.10 and Part 133).")],{"file\_name":"FSIS\_GD\_2009\_0001","title":"Import Permit Guide for Products with Small Amounts of Meat and Poultry","num":"FSIS-GD-2009-0001","id":"4d54f49dfb78074591e8bd65132b76d1dc59807f7ffaa320cdeb27ac71caa3af","corp\_us":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/import/Import\_Permit\_Guide.pdf","type":"pdf","n\_pages":40,"word\_count":5585,"text\_by\_page":["COMPLIANCE GUIDELINES FOR ESTABLISHMENTS ON THE FSIS MICROBIOLOGICAL TESTING PROGRAM AND OTHER VERIFICATION ACTIVITIES FOR ESCHERICHIA COLI O157:H7 April 13, 2004 TABLE OF CONTENTS I. Risk-Based Verification Sampling II. Sample Collection of Raw Ground Beef Products III. Sampled Lot IV. FSIS-Collected Sample That Tests Positive for E. coli O157:H7 V. Establishment Testing of Product for E. coli O157:H7 VI. Transfer of Products That Test Presumptive Positive or Positive for E. coli O157:H7 A. Producing or Shipping Establishments B. Receiving establishments VII. Use of Instructional or Disclaimer Statements Concerning E. coli O157:H7 A. Establishments that Place Instructional or Disclaimer Statements on Their Product Label B. Establishments that Receive Products with Instructional or Disclaimer Statements on Their Product Label VIII. Purchase Specifications IX. Validation of Critical Control Points (CCPs) A. Use of peer-reviewed studies for validation B. Use of indicator organisms C. CCP for finished product testing to determine product disposition","I. Risk-Based Verification Sampling The revised FSIS Directive 10,010.1, entitled \u2018Microbiological Testing Program and Other Verification Activities for Escherichia coli O157:H7 in Raw Ground Beef Products and Raw Ground Beef and Beef Patty Components\u2019 includes instructions to FSIS inspection personnel and other program investigators on sampling and other verification activities for Escherichia coli O157:H7 (E. coli O157:H7) in raw beef products. All official establishments producing raw ground beef products, raw ground beef components, or raw beef patty components may be sampled. In 1994, FSIS declared all raw ground beef contaminated with E. coli O157:H7 to be adulterated unless it is further processed to destroy the pathogen. In the January 19, 1999 Notice (64 FR 2803), FSIS stated that intact cuts of beef that are to be further processed into non-intact cuts prior to distribution for consumption must be treated in the same manner as non-intact cuts of beef, because pathogens may be introduced below the surface of these products when they are processed into non-intact products. Non-intact raw beef products are ground or chopped beef, or beef that has been injected with solutions, or mechanically tenderized by needling, cubing, Frenching, or pounding devices, or reconstructed into formed entrees. Examples of non-intact raw beef products include beef that has proteolytic enzymes applied to or injected for tenderizing, beef that has been scored to incorporate a marinade, or formed and shaped products such as gyros. The following products are adulterated if contaminated with E. coli O157:H7 unless further processed to destroy the pathogen: 1) non-intact raw beef products and 2) intact raw beef products that are intended to be processed into non-intact products such as manufacturing trimmings (e.g., pieces of meat remaining after steaks, roasts, and other intact cuts are removed). FSIS has been collecting samples of raw ground beef products from establishments for E. coli O157:H7 testing to verify establishment control of the pathogen. In the revised Directive 10,010.1, FSIS may also sample raw ground beef components and raw ground beef patty components, which are source materials for raw ground beef and other nonintact raw beef products. FSIS will collect raw

ground beef products from grinding establishments, and may collect raw ground beef components and raw beef patty components from establishments that supplied source materials implicated in FSIS collected raw ground samples that tested positive for E. coli O157:H7. Retail facilities and import establishments producing raw ground beef products will also be sampled by FSIS. Raw ground beef components include raw esophagus (weasand) meat, head meat, and cheek meat; beef manufacturing trimmings (e.g., 90\10, 85\15, 75\25, 65\35, 50\50); boneless beef; beef from AMR systems; and lean finely textured beef (LFTB). Raw beef patty components include all products listed above in raw ground beef components; as well as partially defatted chopped beef (PDCB); finely textured PDCB; heart; and partially defatted beef fatty tissue (PDBFT). 2", "FSIS intends to develop a risk-based verification sampling program for raw ground beef products. Sampling is expected to be based on factors that may influence prevalence of and exposure to E. coli O157:H7, such as the volume of production of raw ground beef products, season of the year, and the number of suppliers for an establishment. The FSIS risk assessment on E. coli O157:H7 has determined that volume of production is a better determinant of the risk of E. coli O157:H7 than size of the establishment. It also determined that the prevalence of E. coli O157:H7 in cattle, and the incidence of foodborne illness and of products positive for E. coli O157:H7 are higher during the warmer months. Therefore, an establishment producing a large volume of ground beef products will likely be sampled more frequently than an establishment producing a lower volume of raw ground beef products. Likewise, FSIS will sample more frequently and with a higher number of samples during the high prevalence season. An establishment that has designed and implemented sampling plan and verification testing with a high degree of confidence of finding the pathogen in both the trim and finished ground product presents a lower risk of producing an adulterated product, and therefore will be sampled less frequently than other establishments. FSIS may also sample establishments that form ground beef patties but do not grind product. Establishments should have already reassessed their HACCP plans to comply with the FSIS Notice (October 7, 2002) requiring establishments that had not already reassessed their HACCP plans for raw beef products to do so in order to determine whether E. coli O157:H7 contamination was reasonably likely to occur in their production process for raw beef products. The Notice also stated that establishments receiving product for grinding should address E. coli O157:H7. Establishments that slaughter, fabricate and grind could employ control methods in their food safety systems, i.e., HACCP plans Sanitation SOPs or prerequisite programs to address the pathogen. Some control methods that can be included are the following: \u2022 Use of intervention treatments validated to control E. coli O157:H7 \u2022 Use of purchase specifications restricting source materials to those that have undergone validated intervention treatment \u2022 Use of source materials that have been rigorously tested for E. coli O157:H7 to verify that process controls to produce source material were effective \u2022 Use of less risky source material, such as use of beef manufacturing trimmings only \u2022 Use of more rigorous sanitation program \u2022 Verification testing that control programs are effective These control methods are discussed in the \u201cGuidance for Minimizing the Risk of Escherichia coli O157:H7 and Salmonella in Beef Slaughter Operations\u201d and the \u201cGuidance for Beef Grinders and Suppliers of Boneless Beef and Trim Products- Guide for Minimizing Impact Associated with Food Safety Hazards in Raw Ground Meat and Other FSIS Regulated Products\u201d found on the FSIS website:

[www.fsis.usda.gov\OPPDE\rdad\FRPubs\docs\\_00-022N.htm](http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/docs_00-022N.htm) Another guidance document that would be useful for slaughter, fabrication and grinding establishments is the BIFSCO Best Practices. Best Practices offer guidelines for processing and handling 3", "of raw ground beef products as well as slaughter and fabrication safety measures. The document can be found at [http:\www.bifasco.org\BestPractices.htm](http://www.bifasco.org/BestPractices.htm)

II. Sample Collection of Raw Ground Beef Products

FSIS will routinely collect samples of the following raw ground beef products: \u2022 Raw ground beef products which include raw ground or chopped beef, hamburger, ground or chopped veal, veal or beef patties, beef patty mix, or raw ground beef product containing any amount of beef product derived from advanced meat recovery (AMR) systems. FSIS will collect samples of the following raw beef products generally as a result of a supplier producing or shipping raw ground beef components that, once ground and made into ground beef, tested positive for E. coli O157:H7: \u2022 Beef manufacturing trim, including raw product consisting only of beef from AMR systems \u2022 Beef carcasses FSIS will not be collecting samples of the following products: \u2022 Ground or chopped products made from both beef and other meat or poultry products, such as a ground beef and pork product \u2022 Beef sausage products FSIS will be notifying establishment management before collecting samples in order to provide enough time for the establishment to hold the lot to be sampled. The establishment will also be informed of the reason for collecting samples. Establishments may be sampled for any of the following reasons: 1) routine FSIS verification testing; 2) follow-up sampling in response to an E. coli O157:H7 positive; 3) traceback sampling; 4) follow-up sampling in response to an E. coli O157:H7 outbreak of foodborne illness. FSIS will typically be collecting one sample per lot. However, more than one sample could be collected if FSIS has a reason to believe that the product is at high risk of being contaminated with E. coli O157:H7 because of : \u2022 illness or outbreaks that may have been associated with the establishment, or \u2022 the establishment or its suppliers have previously produced product that tested positive in FSIS verification samples for E. coli O157:H7. Samples for the current day\u2019s production will be collected in their final packaged form and will be shipped after the establishment has completed its pre-shipment review.

4", "III. Sampled Lot

The establishment defines the sampled lot for raw ground beef products. The establishment should have a scientific or other supportable basis for defining the sampled lot. The establishment could consider factors, such as the following, in defining the sampled lot: \u2022 the establishment\u2019s definition of a lot included in its E. coli O157:H7 sampling plan (if applicable); \u2022 the establishment\u2019s history of setting lot size; \u2022 product coding ; \u2022 how products are intermingled or queued during processing and packaging; \u2022 if the same equipment was used for all the products; \u2022 process control performance including those for other pathogens; \u2022 establishment HACCP plan monitoring and verification activities; \u2022 sanitation SOP records; and \u2022 types of raw beef components used. Establishments that test for E. coli O157:H7 usually have a sampling plan. A sampling plan would include the definition of what the sample represents, i.e., the sampled lot, whether a single combo, 5 combos or an entire trailer load. It would also include the number of samples to be collected and whether testing is to be done in-plant or by an external laboratory. The sampling plan would include a written protocol for sample collection, procedures for microbial analysis and reporting results, and action to be taken in the event of a positive result. FSIS will recognize the establishment\u2019s definition of the sampled lot, provided the establishment has a supportable basis for defining the sampled lot.

However, FSIS cautions that the defined lot size does not relieve an establishment from its responsibility to consider whether there are connections between lots. Possible scenarios: \u2022 If multiple lots of beef trim were produced from source materials from the same production lot of a single supplier, and some of this product were found positive for E. coli O157:H7, FSIS would expect the establishment to have a supportable basis that justifies why any other trim produced from those source materials should not be considered to be adulterated. \u2022 A grinding establishment must have supporting documentation that a lot is not adulterated with E. coli O157:H7 if the lot comes from the same source material in which the other lots produced were found contaminated with E. coli O157:H7. \u2022 If the establishment mixes raw materials from different suppliers and one supplier\u2019s raw material was found positive for E. coli O157:H7, FSIS would expect the establishment to have a supportable basis that justifies why any product from these source materials should not be considered to be adulterated. It should be noted that if an establishment has a validated control system and verifies throughout each shift by sampling and testing, that specific lots of product are negative for E. coli O157:H7, this information could possibly be a basis for determining that one E. coli O157:H7-positive lot does not implicate other lots produced on the same day. 5", "In situations where recall, detention or seizure is necessary, more product than the product from clean-up to clean-up under the HACCP plan may be represented by the sample. More product than the establishment\u2019s definition of a sampled lot, or all products produced from the same source materials may be determined as representing the sample. An establishment\u2019s detailed production records will help the establishment in establishing the product that is represented by the sample. Records that are useful in tracebacks (i.e., tracing back the source of contamination) would include grinding logs showing the times of each grind, the formulation or blend of raw ingredients together with amounts used, and supplier lot identification numbers and results of any tests conducted on the raw materials or finished products. The \u201cProduct Recall Guidelines for Firms\u201d, which is an attachment for FSIS Directive 8080.1 includes some examples of how records will help in defining the lots that are affected by a sample testing positive for E. coli O157:H7. This document will be posted on the FSIS web site. It is recommended that the establishment consider staging the production of raw ground beef in a manner such that this product is handled prior to the production of raw beef product in which the equipment or source materials not specifically controlled to prevent, eliminate, or reduce the level or presence of E. coli O157:H7 are handled. This process would involve handling the least risky product prior to the more risky product. Below is a list of products believed to be ranked from the least risky product to the more risky product: 1) Source materials that have undergone intervention treatments during slaughter and fabrication that are validated to eliminate or reduce E. coli O157:H7 to nondetectable level, and statistically-based verification testing of the lot resulted in a negative test for the pathogen. 2) Source materials that have undergone validated intervention treatments, but not verified as testing negative for E. coli O157:H7. 3) Source materials that were verified as testing negative for E. coli O157:H7 but have not undergone validated intervention treatments. 4) Source materials that have not undergone validated intervention treatments, nor verification testing for E. coli O157:H7. For any of the four categories of source materials mentioned above, the different kinds of source materials could also be queued from lowest to the highest risk product in the following order: a) Source

materials that are intact products intended for non-intact product b) Source materials that are from only one supplier source c) Source materials that include AMR products, raw esophagus (weasand) meat, head meat, cheek meat, and diaphragm (skirt) meat, lean finely textured beef (LFTB), partially defatted chopped beef finely textured (PDCBFT) or partially defatted beef fatty tissue (PDBFT). d) Rework products 6", "IV. FSIS-Collected Sample That Tests Positive for E. coli O157:H7 FSIS laboratories will screen samples for the presence of E. coli O157:H7 and confirm any presumptive positive samples. The Agency notifies the establishment if a sample collected by FSIS is presumptive positive or confirmed positive for E. coli O157:H7. A test is considered presumptive positive when analytical steps of microbiological analysis indicate the strong possibility that E. coli O157:H7 is present, but additional steps are needed to confirm the presence or absence of the organism. Rapid screening methods can be used to detect the pathogen as presumptive positive, but additional steps are needed to confirm its presence or absence. The test is confirmed positive when biochemical, serological and \or genetic testing result in a finding of E. coli Serotype O157:H7, O157:H7:NM (non-motile), or O157:H7indeterminate. A sample is confirmed to contain the bacterial isolate of E. coli O157:H7 through testing conducted by either FSIS or non-FSIS laboratories. Establishments should have information on the suppliers of source materials because this information will be needed if a sample tests positive for E. coli O157:H7. The information provided by the establishment will help in tracing the source of contamination. FSIS will be asking for the following information: 1) Name and phone number of the supplying establishment and point of contact (name, title, e-mail address and fax number) 2) Supplier lot number 3) Production date If the source materials for the sampled raw ground beef products are from a foreign establishment, the following information will be needed: 1) Country of origin 2) Foreign establishment number 3) Shipping mark 4) Import house 5) Barcodes or any other information that identifies the origin of the product When a sample collected by FSIS is found positive for E. coli O157:H7 the sampled lot is adulterated. The establishment should have records on file to determine the lots implicated by the positive sample. FSIS will determine if the affected product lots will be retained, detained or recalled. Establishments should take the following actions if a sample collected by FSIS tests positive for E. coli O157:H7: 1) An establishment must ensure proper disposition of affected products. All affected product lots must be further processed to destroy the pathogen (e.g. 7", "cooking, irradiation), or the product could be destroyed. This could be done onsite or at another inspected establishment, renderer, or landfill. Disposition of the product must be documented (Procedures for documenting transfer and disposition of positive products are discussed in Section VII). 2) An establishment that has one or more validated CCPs for E. coli O157:H7 should take corrective actions in accordance with 9 CFR 417.3 (a). 3) An establishment that does not have one or more validated CCPs for E. coli O157:H7 should take corrective actions according to 9 CFR 417.3 (b). 4) An establishment that has purchase specifications addressing E. coli O157:H7 in their prerequisite programs and do not address E. coli O157:H7 in its HACCP plan should take corrective actions according to 9 CFR 417.3 (b) and, if the establishment addresses E. coli O157:H7 in its Sanitation SOP, 9 CFR 416.15. V. Establishment Testing of Product for E. coli O157:H7 Some establishments test their finished products for E. coli O157:H7 to verify that their control methods are effective and that their products are not adulterated. Establishments testing their finished products should use FSIS testing methods, or methods that are equal to or better in sensitivity. FSIS testing methods can

be found on the FSIS website: [www.fsis.usda.gov\OPHS\microlab\mlgbook.htm](http://www.fsis.usda.gov/OPHS/microlab/mlgbook.htm) Following are the criteria for a testing method to be considered or accepted as equivalent to the FSIS method: \u2022 The sample test portion (analytical unit) must equal at least 325 grams, analyzed as individual sub-samples having a maximum weight of 75 grams. \u2022 Evidence must be provided that demonstrates the method is equal to or greater in sensitivity than the current FSIS method. [Notes: (a) The current FSIS E. coli O157:H7 method employs an immunomagnetic separation (IMS)-based technique for cultural confirmation of screen-positive test results which has significantly increased the sensitivity of the method. (b) In lieu of cultural confirmation methods, reliance on positive results from screen tests approved by AOAC International or other internationally recognized scientific organizations could be deemed equivalent to the FSIS method.] When an establishment tests its own finished product for E. coli O157:H7 for verification purposes, pre-shipment review will not fulfill its purpose unless the results of the tests are known. However, while the establishment is awaiting test results, it may move product to different locations. In this case, FSIS is providing establishments the flexibility to move product prior to conducting pre-shipment review as long as the establishment maintains control of the product. The establishment has to maintain control of the product, so that in case the samples test positive for E. coli O157:H7, the establishment can conduct procedures for proper disposition of the product. This allows an establishment to conduct pre-shipment review even if the product is at a location or at locations other than the producing establishment, provided the producing establishment maintains control of the product. FSIS should have access to results of any testing and any monitoring activities performed by the establishment which may have an impact on the hazard analysis. If the establishment moves product before test results become available and the lot tests presumptive positive or positive, the establishment should complete pre-shipment review only after it has records showing that the product received proper disposition. When establishment testing finds the product to be positive for E. coli O157:H7, the sampled lot is considered adulterated. If the product is found presumptive positive and the establishment does not test to confirm the presence or absence of the pathogen, the sampled lot is not eligible to bear the mark of inspection. Thus, the establishment must take corrective actions and ensure appropriate disposition of the product. The establishment may further process the product from the sampled lot on-site or transport the product to another official establishment or to renderers or landfills for further processing to destroy the pathogen or for destruction. FSIS will review the records associated with the testing conducted by the establishment or FSIS and verify if the establishment implemented corrective actions and ensured proper disposition of the positive products.

**VI. Transfer of Products That Test Presumptive Positive or Positive for E. coli O157:H7**

**A. Producing or Shipping Establishments**

Establishments should provide for the disposition of products that tested presumptive positive or positive for E. coli O157:H7. As mentioned above, establishments may further process the product from the sampled lot on-site or transport the product to another official establishment for further processing to destroy the pathogen, or establishments may move such product to a renderer or landfill. Any movement of products that tested presumptive positive or positive for E. coli O157:H7 should be under documented company control (such as company seals) to safeguard the products. If such product is going to another official establishment, it may also move under FSIS control (e.g., under USDA seal or accompanied by FSIS form 7350-1). Establishments that produced products that are

presumptive positive or positive should obtain documentation evidencing proper disposition from the official establishment, renderer, or landfill where disposition will occur. A producing establishment that transports presumptive positive or positive product or product for which results are pending should maintain the following: 1) Records identifying the official establishment, renderer, or landfill operation that received presumptive positive or positive product; 2) Records identifying the official establishment that is to receive the product for which results are pending; 3) Control of product destined for a landfill operation or renderer while the product is in transit (e.g., through company seals); 9", "4) Control of product destined for an official establishment while the product is in transit (e.g., through company seals) or ensures the product moved under FSIS control (e.g., under USDA seal or accompanied by FSIS form 7350-1); 5) Records showing that the presumptive positive or positive product, including product that was moved pending test results, received proper disposition, including documentation from the official establishment, renderer or landfill operation where disposition occurred, showing that the product received proper disposition. The producing establishment should complete pre-shipment review (of corrective action records) for product from a lot that tested presumptive positive or positive only after it has the records described in paragraph #5 above for that particular product.

B. Receiving Establishments An establishment receiving E. coli O157:H7 presumptive positive or positive product for further processing should document the following: 1) Receipt of the presumptive positive or positive product; 2) That the receiving establishment maintains control of the product; 3) E. coli O157:H7 is addressed in the establishment\u2019s hazard analysis and HACCP plan. . Presumptive positive or positive products can be further processed to destroy the pathogen by lethality treatments, e.g. cooking, irradiating. FSIS will verify these processes and the resulting documentation. The documentation of the lethality treatment should be sent to the producing establishment. A receiving establishment that is producing ready-to-eat and irradiated products and also not ready-to eat products and not irradiated products should segregate product from a sampled lot that is presumptive positive or positive for E. coli O157:H7 from those that are not to be further processed to destroy the pathogen.

VII. Use of Instructional or Disclaimer Statements

Concerning E. coli O157:H7 An instructional statement concerning E. coli O157:H7 is a statement that addresses how the product should be prepared or handled to ensure that the pathogen is eliminated or reduced to an undetectable level. Examples of instructional statements concerning E. coli O157:H7 in raw ground beef components, raw beef patty components, and ground beef products may include, \u201cfor full lethality treatment\u201d or \u201cfor cooking only.\u201d A disclaimer statement concerning E. coli O157:H7 is a statement regarding the type of controls or verification activities addressing the pathogen that were NOT used in the production of the product. An example of a disclaimer statement concerning E. coli O157:H7 is, \u201cproduct has not been tested for E. coli O157:H7\u201d.

Establishments are not required to include instructional or disclaimer statements concerning E. coli O157:H7 on labels of raw ground beef products, raw ground beef components, or raw beef patty 10", "components; however, some establishments may choose to include such statements on the labels of these products.

A. Establishments that Place Instructional or Disclaimer Statements on Their Product Label To use labels on raw ground beef products, raw ground beef components, or raw beef patty components that include an instructional or disclaimer statement concerning E. coli O157:H7, establishments must obtain sketch approval from FSIS

Labeling and Consumer Protection Staff and maintain a sketch approval in the company's required labeling records (see 9 CFR 317.4(a)). The labeling of ground beef products, single-ingredient raw ground beef components, or single-ingredient raw beef patty components that include special instructions or disclaimer statements concerning E. coli O157:H7 cannot be generically approved because FSIS considers these special instructions or disclaimers to be special claims (see 9 CFR 317.5(b)(2)). Labeling products with instructional (e.g., "for cooking only") or disclaimer statements (e.g., "not tested for E. coli O157:H7") is not a means to control pathogens. These statements should not be used to justify a determination that E. coli O157:H7 is not a hazard reasonably likely to occur in their production of raw ground beef products, raw ground beef components, or raw beef patty components. Therefore, such statements cannot be used as a CCP or intervention for E. coli O157:H7. If an establishment has determined that E. coli O157:H7 is a hazard reasonably likely to occur in its production of ground beef products, raw ground beef components, or raw beef patty components, the establishment must have an intervention to address the hazard, and NOT use labels that include disclaimer or instructional statements on these products as a means of addressing the hazard presented by E. coli O157:H7. An establishment may use a disclaimer statement, such as, "not tested for E. coli O157:H7" on labels of ground beef products, raw ground beef components, or raw beef patty components only if it has a validated intervention for the pathogen in its HACCP plan for these products. A disclaimer that the product has not been tested for E. coli O157:H7 implies that E. coli O157:H7 may be a food safety hazard reasonably likely to occur in the product in the absence of controls. Therefore, the information contained in the disclaimer statement would be inconsistent with a determination in the hazard analysis that it is unnecessary to address this hazard in the HACCP plan and the HACCP plan may be determined inadequate. The placement of any instructional statement addressing E. coli O157:H7 on labels of raw ground beef products, raw ground beef components, or raw beef patty components must be reflected in an establishment's decision-making documents (9 CFR 417.5(a)(2)), and hazard analysis, (9 CFR 417.2(a)(1)). For example, if an establishment places the statement "for cooking only" or "for full lethality treatment" on raw ground beef products, raw ground beef components, or raw beef patty components, the establishment's hazard analysis should show how the establishment is ensuring that the product will go for cooking only, or for other full lethality treatment only. If the establishment places a "for cooking only" statement on the product and cooks the product in the establishment, the establishment's flow chart should show the cooking steps the product will undergo. If the establishment places a "for cooking only" statement on the product and ships it to outside establishments, the shipping establishment should have controls in place to ensure that the product goes only to establishments that cook it. If the shipping establishment also produces product that is not intended for cooking, it should have controls in place to segregate product intended for cooking from product not intended for cooking. If an establishment places the statement "for cooking only" on its finished product, but the establishment has not addressed the intended use of its finished product in its decision-making documents or hazard analysis, the establishment's hazard analysis and decision-making documents would not be consistent with the information contained in the instructional statement. Note: Product labeled "for cooking only" may go to an establishment that cooks product intended for additional

further processing. As long as the cooking establishment cooks the product at a sufficient temperature and for a sufficient period of time to eliminate or reduce E. coli O157:H7 to an undetectable level, the cooking establishment would be complying with the labeling instructions.

B. Establishments Receiving Products with Instructional or Disclaimer Statements on the Label

Establishments receiving raw ground beef products, raw ground beef components, or raw beef patty components with a label that includes an instructional statement meant to address E. coli O157:H7 (e.g., "for cooking only" or "full lethality treatment") or disclaimer statements should:

- 1) address the use of the incoming product with disclaimer statements in their HACCP plan as if the product may be contaminated with E. coli O157:H7; and
- 2) follow the instructional statements on incoming product. For example, if the establishment receives ground beef products, raw ground beef components, or raw beef patty components that bear the instructional statement, "for cooking only," the establishment should cook the product so that the product receives an adequate lethality treatment.

Note: An establishment that receives product labeled "for cooking only" may cook product that is intended for additional further processing. Even if the product will undergo further treatment before it is fully processed, as long as the establishment cooks the product at a sufficient temperature and for a sufficient period of time to eliminate or reduce E. coli O157:H7 to an undetectable level, the cooking establishment would be complying with the labeling instructions.

VIII. Purchase Specifications

One of the methods that establishments producing raw ground beef product can use to control E. coli O157:H7 in ground beef is the use of purchase specifications to ensure 12", "receipt of source materials that have undergone interventions that eliminate or reduce E. coli O157:H7 to an undetectable level. The Agency has determined that beef grinders can include purchase specifications addressing E. coli O157:H7 in their HACCP plan, or their Sanitation SOP, or other prerequisite programs. An establishment that decides that E. coli O157:H7 is not a hazard reasonably likely to occur due to the presence of purchase specifications included in its Sanitation SOPs or its prerequisite program should include information on its relevant prerequisite programs in its supporting documentation (417.5(a)(1)). The hazard analysis should include scientific support and the decision-making documents associated with the development and use of this program in order to support through recordkeeping requirements (Section 417.5(a)(2)) that this pathogen continues to be a hazard not reasonably likely to occur because of the established program. The establishment should be able to demonstrate that the design and execution of its purchase specification program ensures that the pathogen is not likely to occur in its production process as a direct result of this prerequisite program. The establishment with purchase specifications should require documentation from the suppliers accompanying the product showing that the purchase specifications are being met. The receiving establishment should verify that the purchase specifications are being met at some frequency. There should be a process whereby the supplier notifies the establishment when the supplier determines that its interventions have been ineffective or not appropriately applied, and for the receiving establishment to verify that the supplier is regularly meeting the receiving establishment's specifications. This documentation and other verification activities are necessary to ensure that the food safety hazard is not reasonably likely to occur, and for the establishment to determine that it will not have to develop a CCP in the HACCP plan. A grinding establishment that has a purchase specification program and is receiving source materials for grinding from an establishment that

is utilizing a validated pathogen reduction intervention on beef carcasses and routinely verifying the intervention through E. coli O157:H7 testing should receive documentation from the supplier stating that a validated intervention is being used, and that the intervention is operating effectively as shown by negative tests for the pathogen during verification testing. The document should also specify the interventions of the supplying establishment. The documentation should accompany each shipment. A single annual letter from a supplier stating that it has interventions in place or just sending photocopies of the same information with each shipment of product is not enough supporting documentation to provide for good decision-making to support that this food safety hazard is not likely to occur. Adequate documentation would provide information to the receiving establishment concerning the control of this pathogen at the establishment supplying the product on an ongoing basis. The documentation should show that the interventions were operating effectively. Establishments with purchase specifications that are receiving source materials for grinding should find out what the supplying establishments are doing to prevent, eliminate or reduce E. coli O157:H7 to undetectable levels. They should find out whether the supplying establishments have CCPs addressing E. coli O157:H7, and if they conduct 13", "verification testing for the pathogen. If an establishment has purchase specifications addressing E. coli O157:H7 in its prerequisite program and has determined that E. coli O157:H7 is not a hazard reasonably likely to occur in its production because of the purchase specifications, the establishment should have supporting documentation showing that its suppliers have CCPs addressing E. coli O157:H7. If a grinder has incorporated purchase specifications addressing E. coli O157:H7 as a CCP at receiving, and upon verification testing finds that product received under purchase specifications is positive for E. coli O157:H7, the grinder should conduct corrective actions specific to this CCP. Examples of corrective actions include among others, no longer buying from that supplier, or contacting the supplier so that the supplier could determine what controls may have failed. If the supplier makes any appropriate changes to its controls or interventions so that the supplier could certify that it had effectively eliminated any E. coli O157:H7, the grinder could continue purchasing from that supplier. FSIS recommends that establishments that have purchase specifications to prevent E. coli O157:H7 from entering the facility include testing for E. coli O157:H7 as part of their verification activities (67 FR 62331). In addition, given the nature of E. coli O157:H7, FSIS recommends that receiving establishments that have purchase specifications addressing E. coli O157:H7 determine whether CCPs preventing E. coli O157:H7 growth or contamination after product receipt are necessary (67 FR 62330). Whether letters of guarantee obtained when meat was received at a given establishment will be sufficient to satisfy the requirements of a second receiving establishment, should the first receiving establishment ship the product, depends on whether the first receiving establishment can guarantee that it prevented any E. coli O157:H7 growth or contamination of the product after its receipt and whether the second receiving establishment is willing to accept a letter of guarantee from the establishment that initially supplied product to the first receiving establishment. IX. Validation of Critical Control Points (CCPs) An establishment that determines that E. coli O157:H7 is a food safety hazard reasonably likely to occur must have one or more CCPs that are validated to eliminate or reduce E. coli O157:H7 below detectable levels. The receiving establishment does not have the responsibility for validating the CCPs used at the supplying establishment. The receiving establishment must:

\u2022 Ensure that the supplier meets purchase specifications; \u2022 Verify that the purchase specifications prevent the pathogen from entering the plant in product received; \u2022 Verify suppliers validated CCPs are effective on an ongoing basis \u2022 Maintain supporting documentation on their verification activities (417.5(a)(2);and \u2022 Validate and CCPs in their HACCP plan. 14", "If an establishment finds positive E. coli O157:H7 product and has not identified the pathogen as a hazard reasonably likely to occur, and therefore does not have a CCP for E. coli O157:H7 in its HACCP plan, the positive test would be considered an unforeseen hazard\"). In this case the plant must conduct corrective actions, including reassessing its HACCP plan under 9 CFR 417.3 (b). However, if an establishment has CCPs that address E. coli O157:H7, and the establishment or FSIS testing detects the pathogen, reassessment is not required but corrective actions under 9 CFR 417.3(a) should be taken. The establishment should examine its intervention methods. They should determine why they are not working. In slaughter establishments carcass mapping may be conducted to determine areas of carcass contamination. In addition, if FSIS testing finds E. coli O157:H7, the establishment may decide to intensify its verification program or ensure that the sensitivity of its testing method is equivalent to FSIS\"). A. Use of peer-reviewed studies for validation Peer-reviewed articles can be used as validation for a critical limit addressing E. coli O157:H7. Guidance materials that FSIS developed for slaughter establishments, grinders, and suppliers on minimizing the risk of E. coli O157:H7 contamination included the parameters of certain peer-reviewed studies. If using a peer-reviewed article, validation activities consist of repeatedly testing the adequacy of the CCPs, critical limits, monitoring, recordkeeping procedures, and corrective actions. Initial validation demonstrates that the establishment is able to repeatedly meet the parameters in the peer-reviewed article and verification that the pathogen is not detected. In order to determine that the intervention derived from the peer-reviewed article is controlling the pathogen, the validation process must be carried out in the establishment, subject to the establishment's facilities, processes, and unique conditions. All the parameters used in the study must be applied to the establishment's process. For example, a peer-reviewed scientific article has four parameters to be followed for the intervention to be effective. The establishment is only capable of meeting one of the parameters defined in the article. Then, the establishment cannot use the article to support the use of the intervention method. Additional validation would be needed using the new combination of parameters. This is important because if one parameter is changed, the interaction of the new combination of parameters will also change the results and the effectiveness of the intervention method. A challenge study (using pathogens) is one means to validate a process. Challenge studies should be conducted in a laboratory outside the establishment facility (i.e., do not conduct studies in an establishment if pathogens are intended to be introduced into the operation). B. Use of indicator organisms Intervention treatments to control E. coli O157:H7 should be validated by conducting challenge studies using E. coli O157:H7. However, these studies should not be conducted in the plant. Indicator organisms that are not pathogens can be used to demonstrate in-plant process control. Even though indicator organisms are not a true marker for the likely elimination or reduction of E. coli O157:H7, they are useful in studying the general effectiveness of plant interventions and making determinations about process control. FSIS recognizes that there is no true non-pathogenic surrogate organism that mimics pathogenic E. coli O157:H7. However, if at some

point in the future, establishments can demonstrate through valid studies that there is an organism that can be used as an indicator for E. coli O157:H7 this information should be submitted to the appropriate FSIS office. C. CCP for finished product testing to determine product disposition In most cases, a CCP based on finished product testing to determine product disposition would be inappropriate. However, for an establishment that conducts its own slaughter, fabrication, and grinding, and does not use product from other establishments, a CCP for disposition that relies on product testing may be acceptable. If the establishment includes CCPs at slaughter and fabrication, and a CCP for disposition based on finished product testing at a level sufficient to find the pathogen if present at very low frequency, then a CCP for disposition may be appropriate. In this case, the establishment would have identified E. coli O157:H7 as a hazard reasonably likely to occur and would have interventions for the pathogen. A positive test would therefore signify a deviation from the critical limit at the CCP. The critical limit for this CCP would have been that E. coli O157:H7 is non-detectable because of the intervention. Therefore the positive result would trigger corrective actions required under 9 CFR 417.3 (a), but not necessarily a reassessment of the HACCP system. The corrective actions may include examining the parameters used in the intervention method to ensure that they are used correctly, or determining whether the verification program needs to include more frequent testing, or conducting carcass mapping to determine areas of the carcass where contamination is more concentrated. If a grinder has internal controls for E. coli O157:H7, receives product from suppliers (both slaughter and fabrication establishments) that have controls for E. coli O157:H7, and the grinder and its suppliers conduct rigorous verification testing of the finished product at multiple points during the production process, a CCP for disposition based on finished product testing may be appropriate. A CCP for disposition based on finished product testing should employ testing at a level sufficient to find the pathogen if present at very low frequency. Corrective and preventive actions in response to a positive in finished product testing should accompany an examination of the whole system, not only the disposition of the product.

16"]},{"file\_name":"FSIS\_GD\_2009\_0002","title":"Peer Reviewed Articles of Antimicrobials Approved by the FDA and FSIS as Safe and Suitable Ingredients","num":"FSIS-GD-2009-0002","id":"9fd8c54deff59dfe44a466575a1013737476b59d7afc380bdbabff9784935e59","corpus":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/import/Chemical\_%2BAntimicrobials.pdf","type":"pdf","n\_pages":1,"word\_count":422,"text\_by\_page":["Compliance Guidelines for Retained Water The Retained Water In Raw Meat And Poultry Products (January 9, 2001) final rule requires that establishments produce those products with either no retained water or only the amount of water that is an unavoidable consequence of the process to meet food safety standards, such as the Salmonella performance standards. The amount of water retained must be specified on the product label. As noted in the preamble to the final rule, the Agency is not prescribing a method to determine added or retained water. The Agency is, however, requiring the establishment to prepare and have on file a written data collection protocol and the data for determining unavoidable moisture retention. If the establishment has data on file regarding retained water, such as antimicrobial spray testing for meat or air chilling for poultry, additional data collection may not be necessary. In addition to the final rule, FSIS is issuing these compliance guidelines with attached model data collection protocols. These

compliance guidelines are designed to assist establishments in developing their data collection protocols, maintaining operational control of their process, and properly labeling the finished product. Protocol Development Protocols for data collection must be placed on file and made available to FSIS. The Agency will review the protocols. The nine expected elements of a protocol are listed below. Examples of expected content are noted for each element. In the examples, the term chilling refers to poultry and cooling refers to meat.

1. Purpose Statement  
State the primary purpose of the protocol. The primary purpose should be to determine the amount or percentage of retained water that is unavoidable while achieving the regulatory performance standard for Salmonella and the time\temperature requirements for chilling. Additional purposes could be to evaluate product quality and to determine chilling system efficiency.

Example 1: The primary purpose of this protocol is to determine the amount of water absorption and retention by young chicken carcasses that is unavoidable while meeting the regulatory pathogen reduction standard for Salmonella set forth in the PR\HACCP regulations [9 CFR 381.94] and the time\temperature requirements set forth in 9 CFR 381.66.

Example 2: The primary purpose of this protocol is to determine the amount of water absorption and retention by beef carcasses that is unavoidable while meeting the regulatory pathogen reduction standard for Salmonella set forth in the PR\HACCP regulations [9 CFR 310.25(b)]. The protocol also will be used to evaluate product quality.

1","2. Type of washing and chilling\cooling system used by the establishment. Describe any post-evisceration washing or chilling\cooling processes that affect the water retention levels by, and microbial loads, on raw products. For poultry establishments, describe the main chiller types, e.g., the drag-through, the screw type, and the rocker-arm type, identified by the mechanism used to transport the birds through the chiller or to agitate the water in the chiller. For meat establishments, describe the type of coolers, e.g., blast freezers, refrigeration systems, or hot boxes.

3. Configuration and any modifications of the chiller\cooling system components. Describe the chiller\cooling-system configurations and modifications, including the number and type of chillers\coolers in a series and arrangements of chilling\cooling system components, and the number of evisceration\kill lines feeding into a chiller\cooling system. Accurately describe the purpose and type of equipment used if there is a pre-chilling\cooling step in the process. Describe any mechanical or design changes to the chilling\cooling equipment.

4. Special features in the chilling\cooling process. Describe any special features in the chilling\cooling process, including antimicrobial treatments, length and velocity of the dripping line, and total time allowed for dripping. Explain any special apparatus, such as a mechanism for removing excessive water from cooled meat or chilled birds.

5. Description of variable factors in the chilling\cooling system. Describe variable factors that affect water absorption and retention. In poultry processing, such factors include:

- \ufffd scalding temperature
- \ufffd pressure and amount of buffeting applied to the birds by feather removal machinery and its effect on loosening the skin
- \ufffd method used to open the bird for evisceration
- \ufffd temperature of the pre-chiller
- \ufffd water temperature of chiller
- \ufffd agitation including air agitation if used
- \ufffd time in the chiller water

In meat processing, such factors include:

- \ufffd scalding temperature (hog carcasses)
- 2"
- \ufffd amount and intervals of antimicrobial chill sprays
- \ufffd time in cooler rooms

6. Standards to be met by the chilling system. The Salmonella pathogen reduction standards, as set forth in the PR\HACCP final rule, have been suggested as the standard for pathogen minimization. Although there is not yet an

applicable Salmonella standard for turkeys, guidance standards are listed in Attachment 4 of FSIS Notice 22-01, "Procedures for FSIS personnel during pre-implementation period for retained water in raw meat and poultry products; poultry chilling requirements." (A permanent FSIS Directive will replace this Notice.) As stated in the Notice, establishments producing turkey products are free to adopt other microbiological targets or surrogate microorganisms, such as E. coli, Campylobacter, or reductions in numbers of other microorganisms. However, the acceptability of the surrogate microorganism in raw poultry or meat depends on an expert determination that there is a correlation between the surrogate and Salmonella. The chilling system for ready-to-cook poultry may be designed simply to achieve a reduction in the temperature to less than 40°F within the time limit specified by the regulations. On the other hand, the time for temperature reduction in meat may be based on that amount of time, or less, necessary to meet the performance standard for Salmonella and minimize the retention of water in the final product.

7. Testing methods to be employed. Describe testing methods used both for measuring water absorption and retention and for sampling and testing product for pathogen reductions at various chilling equipment settings and chilling time-and-temperature combinations. The method for calculating water absorption and retention should be reproducible and statistically verifiable. For pathogen reduction testing, FSIS recommends the methods used for E. coli and Salmonella testing under the PR/HACCP regulations. The pathogen reduction standards are based on a percentage of positive samples rather than the microbial load per carcass or carcass part. The number of samples, type of samples, sampling time period, type of testing or measurement, and the test results should be included. The trials should represent processing procedures that can be maintained in the establishment. It is understood that very small plants or those establishments producing a very small volume of the product may experience a greater variation in measurements than plants producing a large volume of the products. Initially, the establishment would perform several trials to determine the amount of unavoidable retained water, if any, in achieving the food safety standard. The establishment would have to determine the variables in the process that would affect the amount of retained water. For example, time in the chiller/cooler may be a variable to consider. In each trial the water retention data and Salmonella levels would be plotted. When the water retention data showed an increase in 3%, Salmonella, the time in the chiller/cooler before the increase could be the maximum amount of time allowable. However, if an antimicrobial rinse was used, the amount of time in the chiller/cooler may be further reduced. The primary purpose of the protocol is to determine the amount or percentage of retained water that is unavoidable while achieving the regulatory performance standard for Salmonella. However, the percentage of samples positive for Salmonella should not increase. It would not be regarded as acceptable to reduce the amount of retained water with a resultant increase in Salmonella, or surrogate microorganism, even if the increase in Salmonella met the performance standard.

8. Reporting of data and evaluation of results. Explain how data obtained are to be reported and summarized. Examples of reported information include, but are not limited to, the number of sample replicates, reporting of Salmonella, and the calculation or formula used to determine the level of water retention. In addition, the criteria for evaluating the results and the basis for conclusions to be drawn should be explained.

9. Conclusions Explain what the data demonstrate, the conclusions reached, and how the conclusions were reached.

Process Control Once a meat or poultry

establishment has determined the amount of water that is unavoidable in meeting applicable food safety requirements, the establishment must keep the water retention level in its products from exceeding that amount. The establishment must be able to ensure, on a continuing basis, that the amount of retained water in its raw products is unavoidable (9 CFR 441.10(a)), and that the product labels state the amount of retained water (9 CFR 441.10(b)). To be able to do this consistently, the establishment should have good process control. A process would be considered under control if there is a reasonable confidence (i.e., 95% statistical confidence) that a given package in a lot retains no more water than is unavoidable. That is, considering measurement and processing variables, there should be 95% confidence that the continuing measurements are within 20% of the moisture level determined at that establishment. If the establishment fails to meet the performance standards for E. coli and Salmonella, it should consider reevaluating its process with regard to retained water in addition to reassessing its HACCP plan. Labeling Retained Water Products Establishments will be required to include a retained water statement on labeling of raw, single-ingredient, whole, ground or cut-up meat or poultry products that retain water that 4", "is used in meeting food safety requirements during post-evisceration processing, e.g., chilling. Retained water is not regarded as intentionally added or as a product ingredient. However, the labeling of products with retained water must bear a prominent statement on the principal display panel disclosing the maximum amount of water, and how it got incorporated, e.g., \u201ccontains up to X% retained water,\u201d or \u201cwith X% absorbed water.\u201d The retained water statement must be prominently located on the principal display panel of the label and could be contiguous to the name of the product. Refer to Retained Water \u2013 Sample Labels. Prominence of the retained water statement is determined by several factors, including size of lettering in the statement compared with other lettering on the label, location of the statement, and color contrast between the lettering and the background. There is no specific letter size requirement for the percent-retained water statement. Establishments having data or information to demonstrate that their products do not contain retained water will not be required to label the products with such a statement and could include a \u201cno retained water\u201d claim on the label. Processors can modify existing labels by use of pressure sensitive stickers or indelible ink rubber stamps bearing the percent-retained water statement or a \u201cno retained water\u201d claim. This type of label change is possible under the generic label approval regulations. The generic labeling regulations 9 CFR 317.5 and 381.133 and the nutrition labeling regulations 9 CFR Part 317 Subpart B and Part 381 Subpart Y apply to retained water products as they do to other single-ingredient products. Multi-Ingredient Product Multi-ingredient product labeling is not affected by retained water in a meat or poultry component. Thus, retained water is not an ingredient, and the retained water statement on meat or poultry components is not an ingredient declaration. Refer to product examples. 1. Any retained water in raw meat or poultry items used as ingredients would not be declared on the labeling of multi-ingredient products, e.g., raw or cooked sausage, prebasted turkeys, or deli meats. 2. Retained water has no effect on the declared amount of flavor solution in basted, marinated, injected, tumbled, etc. products. 3. Standards of identity or composition are not affected by the retained water rule. 5", "Labeling Questions and Answers The Q&A\u2019s numbered from 1 through 18 first appeared in FSIS Directive 6700.1, Amendment 1. 1. If a plant determines through testing that the amount of retained moisture in a particular item is a fractional

percentage (e.g., 0.3, 0.4, 0.5, or 1.3 percent, etc.), how would the agency expect this to be labeled? Answer: As with nutritional labeling, rounding rules would apply (i.e., round to the nearest whole number). Therefore, labeling of fractional percentages of retained water would not be required. For example, 0.5 percent-retained water is rounded up to 1 percent and 1.3 percent is rounded down to 1 percent.

2. Are labeling statements permitted explaining the purpose of the retained water, e.g., \u201cfor safety purposes contains up to X percent retained water?\u201d Answer: Explanatory statements regarding the retained water will be reviewed by the Labeling and Consumer Protection Staff on a case-by-case basis since they are viewed as special claims. The statements will be evaluated to determine whether they misrepresent products or imply that products are safer than other similarly chilled products.

3. Is there a size requirement for the prominent lettering in the retained-water statement? Answer: There is no letter size requirement for the percent-retained-water statement, but if the lettering is inconspicuous or not visible to consumers with normal visual acuity, it is not prominent. Prominence is determined by several factors, including size of lettering in the statement compared with other lettering on the label, location of the statement, and color contrast between the lettering and the background.

4. Can the term \u201cmoisture\u201d be used instead of the term \u201cwater\u201d within the retained water statement? Answer: The term \u201cmoisture\u201d is not acceptable since it does not convey the specific substance used during the post-evisceration chilling of the product.

6", "5. Is the retained water statement required on a shipping container label when the product inside is packaged and labeled? Answer: The shipping container is not required to bear a retained water statement since the regulation addressing the labeling of retained water products applies to the principal display panel of immediate containers. Shipping containers holding packaged and labeled products do not have principal display panels.

6. Most meat carcasses, half carcasses, and primals are shipped from the establishment with only the mark of inspection identifying them. If the carcass gains water as a result of the chilling process, a water retention statement is required. How could an establishment meet this requirement if it is shipping full and half carcasses and primals to other establishments for further processing into retail cuts, ground beef, etc? Answer: Retained water in red meat carcasses, half carcasses, quarters, primals, or byproducts that are simply branded with a mark of inspection would also need to be declared with a prominent retained water statement. This could be accomplished by adding the retained water statement by branding or affixing with a secure tag.

7. Can pressure sensitive stickers be used to modify the percent-retained water statement and is handwriting permitted for the value of the retained water? Answer: Pressure sensitive stickers may be applied to labeling to modify the percent-retained water statement. This type of change is a generic approval. Handwriting is not permitted for the value of the retained water because a legibility factor involved with handwriting. The value should be uniform and produced by mechanical means as with other mandatory features.

8. The label contains a \u201cno retained water\u201d claim. Does the 20 percent variation apply? Answer: The 20 percent variation permitted for the retained water statement would not apply when a no retained water claim is made on labeling. Rounding rules apply. Thus, the product could not retain more than 0.49 percent water such that the rounded amount of water is 0 percent.

7", "9. How does retained water affect restricted ingredients, e.g., bacon? Answer: The levels for restricted ingredients remain the same as indicated in the substance chart, 9 CFR 424.21(c), e.g., sodium nitrite and sodium

erythorbate are based on the weight of the meat or poultry product regardless of the amount of water possibly retained in the meat or poultry as a result of post-evisceration processing. 10. Does the regulation cover products that may be treated with water which produces no gain in net weight of the finished product? Answer: The regulation, including its requirement of the submission of protocols, deals with products for which the manufacturer anticipates a particular water-based weight gain, is targeting its procedures to control that gain, and will label its products accordingly. As a result, establishments that anticipate zero weight gain are not required to develop and submit protocols. Such establishments should, however, maintain records that demonstrate through data or information that their product does not gain water as a result of the process. 11. Does the regulation apply to intermediate (in-process) processing steps? Answer: No. The regulation focuses on the labeling of single-ingredient finished products as they leave the establishment. Procedures, such as the application of antimicrobial solutions or of water that may temporarily contribute weight to the product, need not be declared. However, establishments are expected to maintain data clearly demonstrating that the finished products do not retain water. 12. Is it acceptable to export products with retained water without labeling bearing a percentage retained water statement? Answer: Deviations from domestic labeling rules are permitted in accordance with 9 CFR 317.7 or 381.128. However, the labeling record at the Federal establishment and in the label submission must assure that the labeling deviation is in accordance with the specifications of the foreign purchaser and with the laws of the foreign country. Additionally, the shipping container must be labeled to show that the product is intended for export. The documentation can be provided by the importer, the exporter, or an official with the foreign government of the country to which the product is destined. (NOTE: Labels for export product that deviate from the domestic requirements cannot be generically approved and must be submitted to the Labeling and Consumer Protection Staff for approval). 8", "13. Can one document, i.e., letter, be applied to multiple products for export? Answer: Yes, if the documentation is complete by indicating all exported products with labeling deviations and is only for the country to which the products are destined. 14. Does the retained water rule apply to ice-glazed poultry? Answer: Yes. A retained water statement is required because the product is single ingredient regardless of whether the product is ice-glazed or not. The ice-glaze is not an ingredient; its purpose is to prevent shrinkage during freezing. 15. How are single-ingredient products with retained water (e.g., bearing contains X percent retained water statements) handled when they are sent in bulk to retail stores for packaging? What effect would in-store cut-up or grinding operations have on the labeling of single-ingredient products with retained water at the retail store? Answer: The retained water statement that is applied to the cuts or ground products would be the same as the retained water statement that was applied to the bulk product. However, the retail store may choose to show through documentation that less or no water is retained in the cuts or ground product and to label the product accordingly. 16. What happens to a product when the retained water declaration exceeds the 20 percent label declaration? Answer: The company has two options. One is to accurately re-label the product. The other option would be to allow the product to drain so that the retained water statement is truthful. This may involve re-packaging the product unless the product is ice pack poultry in drainable containers. 17. How is the retained water statement handled with chitterlings since the product is allowed to be packaged with up to a 20 percent purge? Answer: Many years ago, before 1992, FSIS allowed, under

normal conditions and good manufacturing practices, purge in containers of chitterlings not to exceed 20 percent of the marked weight of the product. The policy is long-held and is practiced industry wide. Consumers who purchase 9", "this product are aware of the policy and practice and have come to expect moisture content in chitterlings. As a result of this long-standing policy, no retained water statement is required when chitterlings are packaged with a purge. If chitterlings retain water during post evisceration processing and are not packaged with a purge, the product\u2019s labeling is required to bear a retained water statement. 18. What is FSIS position regarding the use of water in thawing process? Answer: Frozen meat, meat byproducts, poultry, or poultry byproducts are often thawed using chilled water.

Establishments have to assess whether the product is absorbing water during the thawing process. If the final product is raw, single-ingredient, and absorbed water during the thawing process, a retained water statement is necessary. However, if the final product is subsequently processed into a multi-ingredient item or cooked, the retained water is not a labeling or standards concern. Labeling Questions and Answers Not Addressed in Directive 6700.1,

Amendment 1 General Labeling Issues 19. Is ice chilling of single-ingredient product subject to the retained water rule? Answer: Yes when ice is directly applied to single-ingredient raw carcasses or parts for food safety purposes and the product consequently gains water, they are subject to the retained water regulation. Similarly, raw single-ingredient carcasses or parts mixed with iced used for food safety purposes that are consequently processed into single-ingredient products are subject to the retained water rule, e.g., iced frames and\or shells processed through a mechanical deboner for mechanically separated poultry. Water in excess of naturally occurring moisture at a level at or above 0.5 percent would require a prominent retained water declaration on the label. The establishment must maintain a written data-collection protocol on file in accordance with the retained water regulation. Conversely, an establishment does not have to maintain a protocol on file if it has data or information that clearly demonstrate that its raw single-ingredient product does not retain water as a result of a food safety process, e.g. ice chilling of frames or shells for food safety purposes where the end product does not retain water from the ice treatment. 10", "20. Is it acceptable to indicate the percentage of retained water on a pricing label that is placed on the principal display panel of raw single-ingredient parts packaged in a tray-pack or a raw single-ingredient carcass in a bag?

Would the statement on a pricing label meet the requirement that the statement is on the principal display panel? Answer: Yes, the location requirement is met when the retained water statement is placed on the weight and price sticker (in an area that is not intended for the weight or price), which is subsequently placed on the principal display panel. Of course, the retained water statement must be prominent. 21. Can the retained water statement be placed on a hang-tag at the neck of a netted bag containing a vacuum packaged meat or poultry product with retained water? Answer: Yes, the retained water statement can be placed on a hang-tag as long as the statement is prominent and readily visible to the consumer. 22. Can meat or poultry with retained water be irradiated? Answer: Yes, in accordance with the current Federal meat and poultry inspection regulations. 23. Can meat or poultry with retained water bear the claims natural,\u201d \u201c100 %,\u201d or \u201cpure?\u201d Answer: Yes, in accordance with the regulations and policies on the use of these claims. 24. If the water retention statement is added to a bi-lingual label, does it need to be in both languages?

Answer: Yes, the water retention statement should be in both languages. 25. Are giblets that

are inserted into the cavity of a whole poultry carcass subject to the retained water regulations? Answer: Yes. A whole carcass with giblets is regarded as a single-ingredient product in the same manner that a package of poultry parts, e.g., drumsticks, thighs and breasts are a single ingredient product. 26. How is mixed percent meat or poultry with retained water labeled when packaged together, e.g., packaged cuts or whole birds packaged with necks and giblets? Answer: The labeling for meat or poultry with retained water from different sources bearing different retained water statements can be easily accomplished by labeling the product with a highest range statement from the multiple suppliers, e.g., "less than 11%," "6% retained water." A range statement with the highest value clearly indicates that a range is present, e.g., "may contain up to X% retained water" or "not more than X% absorbed water." As an option, the label could bear separate retained water statements for each item within the package, e.g., "whole bird with 5% retained water, necks with 3% retained water and giblets with up to 2% retained water." 27. Could check-off blocks be used on immediate container labeling for identifying different retained water statements? Answer: Yes, provided, establishment operators develop a control procedure which would ensure correct labeling of the packaging of end products that look alike but contain varying amounts of retained (absorbed) water. The procedure should demonstrate what steps the establishment operators will take so the appropriate retained water statement check-off block will be marked and how the company will monitor the product to ensure proper labeling. The procedure is part of the labeling record. This information is similar to FSIS Directive 7220.1, Policy Memo 083A Check-Off Blocks on Labeling. Can the labeling of product that has been fabricated into cuts or ground products from carcasses and parts bear retained water statements with lesser values or no value? 28. Can the labeling of product that has been fabricated into cuts or ground products from carcasses and parts bear retained water statements with lesser values or no value? Answer: Yes, however, the company should have data on file that shows the loss. The method used for determining the loss is the company's choice but results of the data should be reproducible and verifiable. 29. Can an average be used for the retained water statement when meat or poultry with different retained water levels is packaged together and labeled? Answer: No, the labeling would bear a statement reflecting the highest range, e.g., "less than 4% retained water" or "contains up to 3% retained water" unless the company can document a loss. The method used is up to the company but the results should be reproducible and verifiable. 30. Can an added solution statement like those on marinated product labeling be used in place of a retained water statement? Answer: No, an added solution statement may not be used on a raw, single-ingredient meat or poultry products in which retained water is merely the by-product of a process intended to meet applicable food safety requirements. Added solution statements are only permissible when water is used as an ingredient rather than absorbed during a process intended to achieve a food safety objective. 12%," 31. Are absorbent pads used to absorb moisture in packages of product part of the net weight of the product? Answer: It varies depending upon the jurisdiction, i.e., wet tare jurisdiction versus dry tare jurisdiction to determine net weight. Compliance with net weight regulations is determined by following the wet-tare and dry-tare procedures in National Institute of Standards and Technology Handbook 133, which are incorporated by reference in FSIS regulations 9 CFR 317.19 and 381.121(b). 32. Can retained water in the product be tared out of the net weight so that the retained water

statement does not have to be labeled? Answer: No. 33. Can the purge during shipping and distribution be subtracted from the amount of retained water absorbed during post-evisceration processing for the purpose of labeling with the retained water statement based on the loss of the purge? Answer: No. 34. Can a rubber stamp with indelible ink be used to mark labeling with the retained water statement? Answer: Yes, the marking of labeling with a rubber stamp coated with indelible ink is permissible as long as the statement is prominent and located on the principal display panel. 35. Is mechanically separated meat or poultry subject to the retained water rule? Answer: Yes, as long as the product is raw and single-ingredient. 36. Do insert labels have to bear a retained water statement? Answer: No. They are not required to bear the retained water statement. While the insert label is not required to bear the retained water statement, the retained water statement must prominently appear on the principal display panel. 37. Are raw single-ingredient meat and poultry products processed prior to January 9, 2003, and warehoused in cold storage subject to the retained water rule? Answer: Product processed prior to January 9, 2003, is not governed by the retained water rule. 38. Can export labels with labeling deviations be generically approved instead of sending the labeling applications to the Labeling and Consumer Protection Staff for sketch approval? 13", "Answer: The generically approved label regulations do not provide for generic approval of labeling with deviations, which is why generic label approval is not acceptable. Labeling with deviations have to receive sketch approved from the Labeling, Consumer and Protection Staff until the generic labeling regulations are changed. 39. Are giblets that are inserted into the cavity of a basted turkey carcass subject to the retained water regulations? Answer: No, the retained water statement for the giblets is not required on the labeling of the basted turkey because the giblets are packaged within a multiingredient product. Retained water statements are not mandatory on multi-ingredient product labeling since multi-ingredient product labeling is not affected by retained water. 40. The product is a single-ingredient whole duck with giblets but which may contain a packet of stuffing or sauce. Is a water retention statement required? Answer: Yes, when a sauce or stuffing packet is indicated as \u201cfree\u201d on the duck label, the duck with giblets would have to be labeled with a retained water statement if the carcass and\or giblets has absorbed any post evisceration water. In such a situation, the duck with giblets would still be regarded as a single-ingredient product since only the duck with giblets is sold. The labeling would have to include information regarding the packet, e.g., a product name qualifier \u201cfree sauce (stuffing) packet,\u201d and an ingredients statement. On the other hand, when a sauce or stuffing packet is packaged with the duck and giblets, and not labeled as free, the product is a multi-ingredient product, and the retained water statement for the whole duck with giblets is not mandatory. 41. Can salt be added to a chiller for poultry carcasses and parts? If that is possible, is a retained water statement necessary? Answer: Salt is a permitted additive in chill water for raw poultry products according to 9 CFR 424.21. When the amount of salt is 70 pounds or below in 10,000 gallons of water, the salt would not need to be labeled because it would be an incidental additive. A retained water statement would then be mandatory if the product absorbed the chiller solution. On the other hand, when salt is in amounts from above 70 pounds up to 700 pounds per 10,000 gallons of water, the water and salt would have to be declared since both substances are additives. A special labeling statement would be required, e.g., \u201cBrine Chilled in Water and Salt\u201d or \u201cChilled in Water and Salt.\u201d When the pickup of the solution in the carcasses or

parts is less than 0.5 percent, the product would not need a percentage declaration in the special labeling statement. In situations where the pickup of the solution is 0.5 percent or greater, the special labeling statement would include the percent of solution rounded to the nearest whole number, e.g., "Chilled in 1% Water and Salt." 42. Do the antimicrobial solutions need to be declared on the label? Answer: When approved antimicrobial agents are used in meat or poultry processing for the momentary reduction of microorganisms, and are determined by FSIS to be consistent with FDA's definition of an incidental additive (21 CFR 101.100(a)(3)), they do not require labeling. The treatment of meat or poultry with an approved antimicrobial agent in water should not result in the product retaining any water. Therefore, as long as an establishment can demonstrate that no water is absorbed during, prior, or subsequent to processing steps, such as chilling, a meat or poultry product's labeling would not need to bear a retained water statement. Exemptions or Religious Dietary Product Labeling 43. Is meat or poultry with retained water that will be shipped for further processing exempt from bearing a retained water statement? Answer: No, all raw, single-ingredient product with water retained as a result of post-evisceration processing used to meet a food safety standard must be properly labeled with a declaration showing the amount of retained water prior to shipment. 44. Are inspected kosher meat or poultry products exempt from the retained water rule? Answer: No, kosher carcasses and parts are soaked and salted during a process called kashering. Any water absorbed as a result of the kashering process does not need to be declared as part of a retained water statement. However, any water above naturally occurring water that is absorbed during other prior or subsequent process steps, such as chilling, does need to be declared. Such products would bear the retained water statement if they absorbed water prior to kashering or after kashering. Although, kosher carcasses and parts are labeled as "soaked and salted," they are not considered multi-ingredient products. 45. Is religious exempt poultry subject to the retained water rule? Answer: No, labeling of poultry slaughtered under religious exemption does not bear the mark of inspection. Labeling of poultry that bears an inspection legend is subject to the retained water rule. 46. Is the retained water statement required on labeling of uninspected raw single-ingredient product, e.g., non-certified pet food? Answer: No, the retained water statement is exempt from labeling of uninspected products. 47. When retail service cases display unpackaged raw single-ingredient meat or poultry products, should the retained water in the product be declared? Answer: Yes, the retained water statement is required adjacent to the product, e.g., case card, placard, or shelf tag, which would provide information about the product. The retained water statement is necessary because it is mandatory information that indicates an aspect of the product that is different from similarly processed products that absorb no water used for food safety purposes 48. Do packaged meat or poultry products with retained water sold from a retail service case displaying unpackaged product have to be marked with the retained water statement? Answer: Yes, the package of the product would bear an accurate label that includes the retained water declaration. 49. When a retail store buys from multiple suppliers of meat or poultry with retained water and displays unpackaged product in a retail service cases, can they simply label the product with the declaration of the supplier claiming the greatest amount of retained water rather than label product with multiple declarations? Answer: Yes, the labeling for meat or poultry with retained water from several sources bearing different retained water statements

would be achieved by using the highest range statement from the multiple suppliers, e.g., "less than 6% retained water." A range statement with the highest value does indicate an assortment of various retained water statements were present on suppliers' products packaged together, e.g., "chicken legs may contain up to 5% retained water" or "beef liver not more than 4% absorbed water."<sup>50</sup> When transportation to retail and display for retail (i.e. placement on draining racks) cause the product to release purge and thus decreases the total amount of retained water, how can the retail service counter relay this information to consumers? Would the service counter have to do their own analysis based on their practices and label accordingly? Answer: Labeling with the highest range retained water statement would be the easiest method available. However, if the service counter can document the amount of drainage, the product can be labeled with a reduced value in the retained water statement. Also, if the service counter can document that all the retained water has drained from the product, a retained water statement is unnecessary. The method used to determine the loss is the retailer's choice but the results should be reproducible and verifiable.<sup>16</sup>, "Retained Water Sample Labels 17", "Product Examples Product Examples from FSIS Directive 6700.1, Amendment 1, 1/7/2003. Example 1 Basted turkey injected with up to 3 percent flavor solution is made with turkey containing 3 percent absorbed water. The ingredient declaration would not identify any retained water in the turkey that would have possibly been absorbed during post evisceration processing in the slaughter establishment because the retained water is not an ingredient. The retained water in the turkey would not affect the 3 percent flavor solution injected into the product and declared as part of the product name. Example 2 Beef and Turkey Italian Sausage contains starting material that is labeled as turkey containing 3 percent retained water.<sup>17</sup> The ingredient declaration would not identify the retained water in the turkey because the retained water is not an ingredient. The post evisceration retained water in the turkey would not affect the 3 percent added water limit for the finished product that is established by the standard of identity or composition. Water added to facilitate mixing to dissolve ingredients is an ingredient and is permitted up to 3 percent in raw sausage. Example 3 When beef trimmings that have been sprayed with chilled water so that they contain 5 percent retained water are used to make a single ingredient raw ground product, like ground beef or hamburger, the resulting product must be labeled to declare any retained water above naturally occurring water. Also, single-ingredient ground poultry produced from poultry containing retained water would be required to be labeled to declare any retained water above naturally occurring water. The retained water would not affect compliance with the standard, i.e., no added water, because retained water is not an ingredient. If the products were subsequently cooked, the retained water would have no effect on the finished product or its labeling.

18"]}, {"file\_name": "FSIS\_GD\_2009\_0003", "title": "Less Than Daily Sanitation Procedures Compliance Guideline", "num": "FSIS-GD-2009-0003", "id": "c201a199fb10c8de4e76bb2bb78c4bac6b6c6a2a245797a33567d1bbe3e05563", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Less\_than\_Daily\_Sanitation\_Procedures.pdf", "type": "pdf", "n\_pages": 10, "word\_count": 3619, "text\_by\_page": ["USDA United States Department of Agriculture 2: USDA eAuthentication \*\*\* \*\*\*\*\*\n\*\*\*\*\*WARNING\*\*\*\*\* \u2022 You are accessing a U.S. Government

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\*\*\*\*\* \*\*\*\*\*WARNING\*\*\*\*\* eAuthentication Home I USDA. go., I Site Map Accessibilit Statement Pri,,ac Po lie Non-Discrimination Statement www. FirstGo,,, O-' Label Submission and Approval System (LSAS) FSIS Enrollment Process The information in this section will help guide you through the enrollment process to request a Submitter role in LSAS. Pre-requisite: Customer must have already established a Level 2 eAuth account To access LSAS, direct your browser to https://lsas.fsis.usda.gov. Your browser will be re-directed to eAuth and the eAuthentication Warning screen will appear: When the user clicks the I Agree button, the eAuthentication Login screen is presented", "USDA :E United Stales OeJilrtment ot Agrk:uttre USDA eAuthentication 1> What is an account? 1> Create an account User JO is a required field 1> Update your account Forgot your User ID? .. Password: 1> Local Registration Authority Login Forgot your Password? Change My Password USDA thlldSIIINo.i,.tmnofAg,Iculll.,. ---Food Safety and Inspection Service Welcome to the FSIS Enrollment Application! Jane Doe, Your FSIS account was not found. An account 1s required to access FSIS epphcatt101\\"1s. Submit an enrollment request to en FSIS edministretor. See the option below. Enroll by SubnilttinQ Enrollment Request Clock Submit Enrollment Request to run the Enrollment Request wizerd. You w,11 be nobfied when your request os e roved or denied. \u2022 Submit Enrollment Request \u2022\u2022\u2022 41) Need to contact us? Click <:ontact Us on the top na111gabon bar to request FSIS Applocabon Support or ITS Help Desk support. The user must provide an eAuth User ID and password, and then click the Login button. Next, the user will be presented with the FSIS Welcome Screen and Enrollment Application. Note: PHIS and LSAS share the Enrollment Wizard, so it is important that you follow the instructions specific for LSAS selections. FSIS Enrollment Welcome Screen: Select Submit Enrollment Request", "USDA u,;,1o<1 Stotot Oopa,tn, .... , J\\gtb>ltu\u202220 ::a;, Food Safety and Inspection Service J.Doe Enrolment Welcome Account Type Primary Role My Preferences My Comments Summary Home Help Contact Us Logout eAuth The FSIS Enrollment Request Wizard (Step 1) Welcome to the FSIS Enrollment Request Wizard The wizard helps you submit your enrollment request to an FSIS administrator. An administrator reviews each enrollment request and either approves or denies it. After the review proce-SS, you will receive. an email notification. Your progress through these steps will be displayed on the left side navigation menu. Click Next to continue. Click Cancel to exit the wi2ard. All modifications will be aincled.

431,iii FSIS Enrollment Request Wizard: Click Next", "USDA United States Department of Agriculture ;;;, Food Safety and Inspection Service J.Doe Enrollment Welcome Account Type Primary Role My Preferences My Comments Summary J.Doe -Enrollment Welcome | Account Type Primary Role My Preferences My Comments Summary | Home Help Contact Us Logout eAuth The FSIS Enrollment Request Wizard (Step 2) Select Your Account Type Select your account type. \u2022 Account Type: 1-L\_S\_A\_S\_S\_u\_b\_m\_i\_tt\_e\_r \_\_\_\_\_. Description: \u00b7\u00b7Select\u00b7\u00b7 e if you are an industry user (includ Domestic Non FSIS Federal Employee ;;;;;;+ \u2666 11\u00a5 8\u00a51:i\u00a7i he FSIS Enrollment Request Wizard (Step 2) This 'Wizard helps you prepare and submit your enrollment request. Select Your Account Type Select your account type, \u2022 account Type: ,\_!\_L\_S\_A\_S\_S\_u\_b\_m\_i\_tt\_e\_r \_\_\_\_\_. Description: Select LSAS Submitter for your Account Type if you are an industry user (includ ;;;;;;a Account Type: Select \u201cLSAS Submitter\u201d from the drop-down Click Next", "USDA United States Oej)a,1m.. ot Ilg\"\\\"\\\"\\\" 3? Food Safety and Inspection Service he FSIS Enrollment Request Wizard (Step 3 of 3) J.Doe This wizard helps you prepare and submit your enrollment request. Enrollment LSAS User Orientation Welcome Account Type Click Finish below to complete your LSAS enrollment. You will be re\u2022directed to LSAS to create your Profile information. LSAS Info \" ++;;;;1 USD\\ u1tu<.1 St~,.,os o,pat1-\\"\\\"!el'.111:Ulkn LSAS iiiii Food Safety and Inspection Se~,ice Label Submission and Approval System You do not 1\u2022t h\u2022v\u2022 \u2022ny profilo\u2022 >HO<iowd wth your \u2022\u00abount. To oontinuo. you m\u2022y oith1 <ro>IO \u2022 n)w profilo, or r~ouest aeee.5s to an \*x1snng pr01111t. LSAS User Orientation: Click Finish to Complete Your Enrollment Welcome to LSAS: Select Create to Set Up Your New Profile in LSAS Select: Submit and then Confirm You will be prompted to click on the created profile\u2019s dashboard link to continue to your homepage."], {"file\_name": "FSIS\_GD\_2001\_0001", "title": "Irradiation Qs and As", "num": "FSIS-GD-2001-0001", "id": "7e3a114fa03641fe719646f455ec3280758af36644b24313a600bee6df1225b9", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2020-08/IradQA.pdf", "type": "pdf", "n\_pages": 9, "word\_count": 2626, "text\_by\_page": ["Food Safety And Inspection Service Office of Policy, Program and Employee Development August 2005 Food Standards and Labeling Policy Book Revised for Web Publication August 2005 Replaces Publication Dated May 2003 and Removal of Publication Dated 1996", "PREFACE The Policy Book is intended to be guidance to help manufacturers and prepare product labels that are truthful and not misleading. Compliance with the requirements set forth in this publication does not, in itself, guarantee an authorization. On receipt of the label application, consideration will be given to suitability of ingredients statements, preparation, and packaging so as not to mislead the consumer. Adherence to the product and label requirements in this Policy Book does not necessarily guarantee against possible infringement of all related patents, trademarks or copyrights. Changes in this publication are to add new entries, correct errors, condense material, and reformat the entries for ease in reading and use. There will be updates of the publication to conform to changes in meat and poultry inspection standards and to reflect any current policy developments. Errors found in this issue should be reported through channels to your district office.", "INTRODUCTION This Policy Book is assembled in dictionary form and may"]}

be used in conjunction with the Meat and Poultry Inspection Regulations and the Meat and Poultry Inspection Manual, Directives and Notices. It is a composite of policy and day-to-day labeling decision, many of which do not appear in the above publications. They are subject to change and therefore a periodic updating of this book will take place. Note: Red Meat Required percentages of meat required for red meat products are shown on the basis of fresh uncooked weight unless otherwise indicated. For purposes of this Policy Book, whenever the terms beef, pork, lamb, mutton, or veal are used they indicate the use of skeletal muscle tissue from the named species (9 CFR 301.2). Note: Poultry Required percentages for poultry products are based on a cooked deboned basis unless otherwise stated. When the standards indicate \u201cpoultry\u201d, the skin and fat are not to exceed natural proportions per (9 CFR 381.117(d)). Applications for label approval should be addressed as follows: USDA, FSIS, OPPD Labeling and Consumer Protection Staff (LCPS) 1400 Independence Avenue, SW Room 614 \u2013 Annex Building Washington, DC 20250-3700 Product samples (only when requested by LCPS) should be packed with sufficient refrigerant to last until received. Shipping should be coordinated with requestor to assure delivery before 4:00 p.m. Friday. Labeling and Consumer Protection Staff 1400 Independence Avenue, SW Room 614 \u2013 Annex Building Washington, DC 20250-3700", "UPDATED ENTRIES SINCE LAST PUBLICATION AUGUST 2005 CORRECTIONS: Aged Aged Beef Artificially Colored Products Bratwurst Bratwurst, Cured Buffalo Style Cereal Chili Sauce with Meat Chorizo, Fresh Egg Roll with Meat Egg Roll with Poultry Enzymes \u2013 Proteolytic Fajitas Giblets and\|or Necks Sold with Carcasses Kiska, Kisba, Kishka, or Stuffed Derma Labeling of Boneless Beef, Ham or Poultry Products Labeling of Modified Breakfast Sausage, Cooked Sausage, and Fermented Sausage Products Identified by a Nutrient Content Claim Labeling of Modified Substitute Versions of Fresh (Species) Sausage, Hamburger or Ground Beef Products Pasty (Cornish Style) Pizza Burger Pizza Sauce with Sausage Pizza Topping Containing Sausage Pizza Topping Mix Poultry Meat, Raw Protective Coverings (Meat) Serving Suggestion, Serve as Suggested and Similar Phrases Solutions in Red Meat Products Textured Vegetable Protein (TVP) Products-Fresh Meat or Poultry Meat Ratios Yeast DELETIONS: Added Solutions (Poultry) (Boneless) Chicken Tocino Dipped Steaks Ham, Smithfield Jambalaya \u2013 6\|4\|19 Marinated Methyl Cellulose Pizza, Combination or Deluxe Poultry Roast Select or Higher", "REVISIONS: Amenability Approximate Artificial Marbling -Red Meat Products Barbecue Meat or Poultry \u201cEastern North Caroline Style\u201d \u2013 Renamed Barbecue Meat or Poultry \u201cEastern North Carolina Style\u201d Beef a La Mode Caddies Cheese Cheese Products Containing Meat Chicken Cordon Bleu Chinese Style Barbecue Meat Cooked Red Meat Products Containing Added Substances \u2013 Renamed Cooked Red Meat Products Containing Added Solutions Dry Salt Cured Fabricated Steak Fajitas For Further Processing Fresh, \u201cNot Frozen\u201d and Similar Terms When Labeling Meat and Poultry Products Glazes \u2013 Renamed Ice Glazes with Flavor Grade Marks Halal and Zabiah Halal Kosher Hearts\|Heart Meat Jerk or Jerk Style Labeling of Products Containing Meat with Added Solutions or Other Nonmeat Ingredients In Secondary Products Natural Claims Papain Pizza Pizza Chicago Style Pizza Containing Cheese Substitutes Potato Sausage, Swedish Style, or Potato Ring or Potato Pudding Poultry Grading (Labeling) Poultry, Raw Solution \u2013 Renamed Poultry, Raw with Added Solution Pressure Sensitive Stickers and Indelible Ink Product Name Qualifiers Rolls Teriyaki, Meat or Poultry \u2013 Renamed Teriyaki, Meat or Poultry (Cooked) Teriyaki Products Tocino (Filipino or Philippine Style Tocino, Poultry Water

Base Solutions in Red meat In Meat Products Weisswurst DEFINITIONS: Corrections: Previous entries that were inadvertently removed from last publication have been added back in, or typographical errors which have been corrected, and\or regulatory cites corrected Deletions: Entries which have been removed Revisions: Previous entries which have been revised to reflect current agency policy","ABBREVIATIONS AMS Agriculture Marketing Service BHA Butylated Hydroxyanisole (anti-oxidant) BHT Butylated Hydroxytolune (anti-oxidant) CRDSM Calcium Reduced Dry Skim Milk FDA Food and Drug Administration FR French FSIS Food Safety and Inspection Service FTC Federal Trade Commission GRAS Generally Recognized as Safe HVP Hydrolyzed Vegetable Protein IMPS Institutional Meat Purchase Specifications IT Italian LCPS Labeling and Consumer Protection Staff MPR Moisture Protein Ratio MSG Monosodium Glutamate NAMP National Association of Meat Purveyors NFDM Nonfat Dry Milk NOP National Organic Program OPPED Office of Policy Program and Employee Development PDBFT Partially Defatted Beef Fatty Tissue PDCB Partially Defatted Chopped Beef PDCP Partially Defatted Chopped Poultry PDPFT Partially Defatted Pork Fatty Tissue PER Protein Efficiency Ratio PFF Protein Fat Free pH Measure of Acidity PPM Parts Per Million SP Spanish TVP Textured Vegetable Protein URMIS Uniform Retail Meat Identity Standards USA United States of America USDA United States Department of Agriculture VPP Vegetable Protein Product","ADDED SOLUTIONS (WITH JUICES): Products with added solutions that are cooked in an impervious bag and as a result of the cooking contain free flowing juices that are not drained, should be labeled to reflect the solution and the juices, e.g., (\u201cRoast Beef Contains up to 12 percent solution with Juices\u201d). AGED: Aging is the process by which fresh beef (carcasses or cuts) are held in a controlled environment for a specified period of time of slaughter, to allow enzymatic activity to degrade complex proteins and promote the development of flavor and tenderness. The term \u201cAged\u201d on a label must be qualified, e.g., \u201cAged 65 days.\u201d See: Dry Aged AGED BEEF: The beef products (carcass or cuts) are maintained in a fresh unfrozen state for a minimum of 14 days from the day of slaughter. Aging claims made within the supply chain (e.g., prior to the point of sale at retail or food service) shall specify the minimum number of days aged and the type of aging used on the principal display panel on the label (e.g., \u201cWet aged for a minimum of days.\u201d). If an aging claim is made at the point of sale to the consumer, the minimum claimed for aging shall appear on the principal display panel of the label (e.g., \u201cAged for a minimum of a minimum of days.\u201d). For additional information refer to USDA, AMS, Standardization Branch \u201cALL\u201d, \u201cPURE\u201d, AND \u201c100 PERCENT\u201d POULTRY: A labeling claim, such as, \u201cmeat used is 100 percent white meat\u201d, may only be used when the poultry meat contains no added ingredients. A labeling claim, such as, \u201cwhite meat only,\u201d is acceptable when white meat is used to the exclusion of dark meat. In this situation, other ingredients may be present in the poultry portion of the product.", "\u201cALL or 100 PERCENT BEEF (Patty Mix)\u201d: Beef patty mix may be labeled \u201call,\u201d \u201cpure,\u201d or \u201c100 percent beef,\u201d when the only added ingredients are partially defatted chopped beef or finely textured beef. An ingredients statement would be required on bulk packed product but not retail packages. \u201cAll,\u201d \u201cPure,\u201d or \u201c100 percent,\u201d may not be used if partially defatted beef fatty tissue (PDBFT), is used or mechanically separated species (MSS), are used. ALPHA CELLULOSE: When used as a carrier of flavoring ingredients, it need not be shown in the ingredients statement, unless it functions as a

binder in the meat or poultry product. AMENABILITY: The Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA), and their implementing regulations, provide for certain exemptions from USDA jurisdiction (and, therefore, inspection), e.g., products prepared for human consumption that contain meat or poultry ingredients in relatively small proportions, or are not considered by consumers to be products of the meat or poultry industry. Generally, the USDA has determined by policy that the \u201crelatively small proportions\u201d of livestock ingredients are: 3 percent or less raw meat; less than 2 percent cooked meat or other portions of the carcass; or 30 percent or less fat, tallow or meat extract, alone or in combination. In the case of poultry, the \u201crelatively small proportions\u201d are: less than 2 percent cooked poultry meat; less than 10 percent cooked poultry skins, giblets or fat, separately; or less than 10 percent cooked poultry skins, giblets, fat and poultry meat (limited to less than 2 percent) in any combination (refer to 9 CFR Part 381.15(a)). For dried products containing poultry, these percentages are computed on the basis of the moist cooked chicken in the ready to serve product when prepared according to the directions on the consumer package. Regarding the second exemption criterion, the USDA has determined the application of the \u201chistorical perception\u201d criterion to food products containing meat or poultry on a case-by-case basis. Some products that are exempted from USDA jurisdiction based on the criteria above include stocks or broths prepared with \u201crelatively small amounts\u201d of meat or poultry, bouillon cubes, dehydrated meat soups, cheese balls with pepperoni, pork and beans, closed-face sandwiches, mince meat, bagel dogs, and pepperoni rolls. A condition for the application of these exemptions is that product exempt from USDA jurisdiction must still be prepared with USDA inspected meat or poultry product or meat or poultry from an inspection system equivalent to the USDA inspection system. In addition, generally, any product exempted from USDA jurisdiction cannot be represented as a meat food or poultry product, except as provided in the meat or poultry regulations. A product is deemed as representing a meat food or poultry product if a term representing meat or poultry is used on labeling, e.g., in the product name, without appropriate qualification.", "ANDOUILLE (FR): Made with pork and/or pork byproducts stuffed into large intestines. Product can be sold cooked or uncooked.

Andouille is a coined name and must be accompanied by a true product name, e.g., \u201csausage\u201d or \u201cpudding\u201d depending on formulation. If beef is used, it must be shown in the product name, e.g., \u201cBeef Andouille Sausage\u201d or \u201cBeef Andouille Pudding.\u201d ANTIOXIDANTS: BHA and BHT are permitted in spice mixtures at 0.02 percent of the essential oil content without declaration on meat or poultry food product labels. Antioxidants are permitted in cooked fresh sausages and fresh sausage-like products (e.g., a pork, water soy protein product). BHA and BHT are not permitted in non-specific meat or poultry products. APPROXIMATE: The word \u201capproximate\u201d may be used to describe the thickness of bacon and the number of pieces in an institutional package when the actual net weight is declared (for example, 18 21 pieces). \u201cApproximately\u201d is acceptable in a descriptive designation for meat and poultry products (for example, \u201cContaining approximately 6% of a solution of...\u201d or \u201cMarinated with approximately 3% solution of...\u201d). The word \u201capproximate\u201d cannot be used in conjunction with the serving size or the required declaration of net weight of contents. ARROZ CON POLLO (SP): The product must contain at least 15 percent cooked chicken meat. The label must show, the true product name, in English, i.e., \u201cRice with Chicken,\u201d except if the product is

distributed solely in Puerto Rico. ARTIFICIAL MARBLING -RED MEAT PRODUCTS: Fats and oils, for example, butter, margarine, vegetable oils. etc., may be added to red meat products, for example, roast beef and steaks. However, the presence of such substances must be indicated as part of the product name, as a product name qualifier, or in a solution statement, for example, \u201cRoast Beef and Margarine Product,\u201d \u201cVegetable Oil Added,\u201d \u201cContaining 10% of a solution of milk,...\u201d All applicable regulations and policies should be followed for these products. In addition, products that appear to be of a higher quality must include a statement to indicate this, for example, \u201cInjected with Beef Fat\u201d or \u201cProduct may appear to be of a higher quality than the actual grade.\u201d Samples may be necessary to determine if this requirement applies.", "ARTIFICIALLY COLORED PRODUCTS: Labels of products which are artificially colored either by artificial colors or natural colors must bear a statement to indicate the presence of the coloring, e.g., \u201cartificially colored\u201d or \u201ccolored with annatto.\u201d Products whose true color is disguised by packing media, e.g., colored pickling solutions, must also have labels that include a statement that indicates the presence of the color. The statement must appear in a prominent and conspicuous manner contiguous to the product name. When a component within a product is artificially colored, e.g., breading, sauce, and sausage, a qualifying statement is not necessary. However, in all cases, the presence of the coloring must appear in the ingredients statement. Whenever FD&C Yellow No. 5 is used, it must be declared in the ingredients statement by FD&C Yellow No. 5 or Yellow 5. Some products, e.g., chorizos and some of the sausages of the longaniza variety, are expected to be characterized by coloring. In these situations, the presence of the coloring need only be indicated in the ingredients statement. See: Policy Memo 112 on caramel coloring Policy Memo 095 on colored casings Policy Memo 113 dated June 24, 1988 AU GRATIN POTATOES AND BACON: At least 8 percent fully cooked bacon (based on 40 percent yield). BABY FOOD: High Meat Dinner -At least 26 percent meat. High Meat Poultry Dinner -At least 18.75 percent cooked poultry meat, skin, fat and giblets. Meat and Broth -At least 61 percent meat. Vegetable with Meat -At least 8 percent meat. Poultry with Broth -At least 43 percent cooked poultry meat, skin, and giblets. Poultry and Rice -At least 5 percent cooked deboned poultry meat. Note: Wine, Mechanically Separated Species, nitrites, and nitrates are not acceptable in baby and toddler foods. BABY FOOD WITH FRESH HAM OR BACON: Ham or bacon without nitrates or nitrites must be shown in the ingredients statement as ham or bacon (water, salt, sugar, etc., without nitrates or nitrites).", "BACON: The term \u201cbacon\u201d is used to describe the cured belly of a swine carcass. If meat from other portions of the carcass is used, the product name must be qualified to identify the portions, e.g., \u201cPork Shoulder Bacon.\u201d \u201cCertified\u201d refers to products that have been treated for trichinae. See: 9 CFR 318.10 BACON AND PORK SAUSAGE: Product is formulated with a high percentage of bacon (usually bacon ends and pieces) with at least 20 percent pork. BACON ARKANSAS AND ARKANSAS STYLE BACON: Product which is identified as Arkansas Bacon or Arkansas Style Bacon is produced from the pork shoulder blade Boston roast. The pork shoulder blade Boston roast includes the porcine muscle, fat and bone, cut interior of the second or third thoracic vertebrae, and posterior of the atlas joint (first cervical vertebrae), and dorsal of the center of the humerus bone. For Arkansas Bacon, the neck bones and rib bones are removed by cutting close to the underside of those bones. The blade bone (scapula) and the dorsal fat covering, including the skin (clear plate), are removed, leaving no

more than one-quarter inch of the fat covering the roast. The meat is then dry cured with salt, sugar, nitrites, and spices, and smoked with natural smoke. The meat may not be injected or soaked in curing brine, nor may any artificial or liquid smoke be applied to the meat. Product that is prepared outside the state of Arkansas but in the manner prescribed may be identified as "Arkansas Style Bacon." The true product name must be shown as  
"Boneless Cured Pork Shoulder Butt." BACON (Canned -Pasteurized): A shelf stable item, which must have at least 7 percent brine concentration. BACON (Canned, Prefried): In  
"Canned Prefried Bacon," e.g., "Bacon Crumbles," the following criteria should be applied: 1. M/SP Index of 0.4 or more. M/SP = Moisture/(Salt x Protein) 2. A Brine Ratio of 9.0 or less. Brine Ratio = Moisture/Salt", 3. A Brine concentration of 10 percent or more. Brine concentration = Salt/(Moisture + Salt) 4. Maximum 40 percent yield BACON (Cooked): Not to yield more than 40 percent bacon -60 percent shrink required. BHA and BHT may be used as antioxidants in precooked bacon at level of 0.01 percent individually or 0.02 percent collectively, based on fat content. TBHQ can be used in products as an antioxidant in combination with BHT and BHA; but it can not be used alone except in cooked bacon. BACON DRESSING FOR STUFFING: The product must contain at least 8 percent bacon. BACON-LIKE PRODUCTS: Bacon-like products, including poultry bacon, labeled with "bacon" in the name must follow the same requirements as those applied to pork bacon. These requirements include, but are not limited to, limits on restricted ingredients and the requirement that the bacon must return to green weight. Beef bacon is a cured and smoked beef product sliced to simulate regular bacon. It is prepared from various beef cuts and offered with a variety of coined names, including "Breakfast Beef," "Beef Bacon," etc. A common or usual name is required, e.g., "Cured and Smoked Beef Plate," and should be shown contiguous to the coined name. Poultry bacon products are acceptable and may be designated as (Kind) Bacon. However, a true descriptive name must appear contiguous to (Kind) Bacon without intervening type or design, in letters at least one-half the size of the letters used in the (Kind) Bacon, and in the same style and color and on the same background. An example of an acceptable designation is "Turkey Bacon-Cured Turkey Breast Meat-Chopped and Formed." The descriptive name can serve alone as the product name. See: Policy Memo 106A dated December 17, 1991 BACON PRODUCTS: The bacon products intended for further cooking before consumption, i.e., slab bacon for deli slicing, can be labeled "certified," "croasted" or "partially cooked" provided the product is cooked to 148°F and the labeling clearly indicated the product is intended to be further cooked before consumption.", "BANGERS: A sausage-like product prepared with meat and varying amounts of rusk or other cereals. The label must show percentage of rusk (or other cereal) adjacent to product name in prominent lettering. May be labeled British, Scottish or Irish Style. BARBECUE (BBQ), PRODUCTS: Barbecue (BBQ), products that are composed of uncured red meat products that are injected, massaged, tumbled, etc., and which are cooked back to or below the weight of the raw meat product (green weight), must use the term "seasoned" or "flavored" in conjunction with the meat product in the product name, e.g., "BBQ Seasoned Pork," or "Sliced Seasoned Beef with Barbecue Sauce." The labeling for uncured red meat products containing some solutions that are used to make BBQ products (9 CFR 319.312 or 319.80) which are not cooked back to green weight or are not in compliance with the cooking yield must have

a containing statement on the label. A containing statement is required in the product name when the cooking yield is not met, e.g., \u201cBBQ Pork Containing up to 15 percent of a solution.\u201d Similarly, a containing statement is required in the product name when the product does not have sufficient quantities of meat minus the solution to meet the minimum meat requirement. However, in limited situations when the minimum meat requirement (minus the solution) is met and when cook yield is compensated for by adding additional meat, the containing statement can either be placed in the product name or attached to the meat component in the ingredients statement, e.g., \u201cIngredients: Beef Containing up to 25 percent \u2026sugar, spices.\u201d Also, see Policy Memo 84A and Policy Memo 102. Red meat components that contain binders and extenders and do not meet one of the barbecue standards (9 CFR 319.80, 319.312) shall be descriptively labeled to include the extender, nomenclature in the product name, e.g., \u201cBBQ Seasoned Beef, Modified Food Starch and Gelatinized Wheat Starch\u201d, \u201cPork and Binder Product with Barbecue Sauce\u201d, or \u201cBBQ Cooked Beef and Binder Product\u201d followed by a parenthetical list of all of its ingredients. Bone-in red meat products do not have to comply with Federal meat regulation, 9 CFR 319.312 or 319.80 with regard to cooking yield and must indicate the presence of bones in product name, e.g., \u201cSeasoned Cooked Pork Ribs with Barbecue Sauce\u201d or \u201cBarbecue Beef Ribs.\u201d When bone-in red meat products are injected, massaged, tumbled, etc., and do not return to green weight after cooking, the containing statement shall appear once on the label in (1) the ingredients statement as part of the red meat component (only if there is enough Beef Ribs without solution to meet the requirement for \u201cBeef Ribs and BBQ Sauce\u201d), or (2) in the product name, e.g., \u201cBeef Ribs, containing 10 percent of a solution and BBQ Sauce.\u201d", "BARBECUE (Infrared Cooked): The label must indicate heat source, e.g., \u201cinfrared cooked,\u201d with lettering no less than one-half the size of the largest letter in the word \u201cbarbecue.\u201d BARBECUE MEAT OR POULTRY \u201cEASTERN NORTH CAROLINA STYLE\u201d: Acceptable identification for barbecued meat (9 CFR 319.80) or barbecued poultry (9 CFR 381.164 or 381.165) product that is flavored with a vinegar based solution using apple cider vinegar or white vinegar. The solution is seasoned with pepper, that is, black pepper, red pepper, or cayenne pepper. Other ingredients may include salt, sugar and hot pepper sauce. BARBECUE SAUCE WITH CHICKEN: The product must contain at least 15 percent cooked chicken meat. Changing the size of the term \u201cChicken\u201d does not change the 15 percent cooked chicken meat requirement. BARBECUE SAUCE WITH MEAT: The product must contain at least 35 percent cooked meat. When the name of the product shows meat in smaller letters, not more than one-half the size of the largest letter in the product name, 25 percent cooked meat is required. BEEF A LA KING: The product must contain at least 20 percent cooked beef. BEEF A LA MODE: A product consisting of sliced cooked beef (that is marinated in wine, cognac, vegetable stock) with carrots, onions, and other ingredients covered with wine sauce. The product must contain at least 50 percent cooked beef. BEEF ALMONDINE WITH VEGETABLES: The product must contain at least 18 percent cooked meat on the ready-to-serve basis. The product must contain almonds. BEEF AND DUMPLINGS WITH GRAVY: The product must contain at least 25 percent meat and not more than 25 percent water blanched dry dumplings. BEEF AND GRAVY: The product contains at least 50 percent cooked beef.", "BEEF BLOOD: This is an acceptable ingredient for beef patties provided the product name is qualified, such as \u201cBeef and Blood Patties\u201d or

\u201cBeef Patties with Blood.\u201d BEEF BLOOD GLAZE: A coating of beef blood is permitted on cured products (e.g., ham, hamette, etc.) if the product name is prominently qualified to reflect the coating. Nitrite is not permitted in the glaze. BEEF BRISKET (Canned): The minimum brine concentration required is 5.5 percent. BEEF BURGUNDY OR BOURGUIGNONNE: The product must contain at least 50 percent beef. Product contains beef cubes, mushrooms, onions, and red wine or burgundy gravy. May include other vegetables, e.g., carrots, shallots, tomato paste, or potatoes. Other acceptable names include \u201cBeouf A La Bourguignonne,\u201d \u201cBeef Burgundy Style,\u201d \u201cBeef Burgundy,\u201d and \u201cBurgundy Beef.\u201d BEEF BURGUNDY WITH NOODLES: The product must contain at least 50 percent beef in the beef burgundy portion. Total product should not contain more than 50 percent cooked noodles. BEEF CHEEK MEAT AND BEEF HEAD MEAT AND PORK CHEEK MEAT AND PORK HEAD MEAT (USE AND LABELING AS AN INGREDIENT IN MEAT FOOD PRODUCTS): Beef cheek meat and pork cheek meat refers to beef and pork cheeks from which the glandular material has been removed. Beef head meat and pork head meat refer to muscle tissue remaining on the beef and hog skull after removal of the skin, cheeks, tongue, and lips. The meat normally attached to and considered as part of the tongue trimmings when detached from the tongue trimmings may also be included as beef head meat or pork head meat although it can be labeled as \u201cbeef\u201d or \u201cpork.\u201d When beef cheek meat and/or beef head meat are included in boneless beef, its presence must be specifically declared. Examples include: \u201cBoneless Beef -Contains Beef Cheek Meat and Beef Head Meat,\u201d \u201cBoneless Beef Head Meat,\u201d \u201cBoneless Beef - Ingredients:\u201d, "Beef, Beef Head Meat, Beef Cheek Meat,\u201d or \u201cBoneless Beef -20 percent Beef Head Meat, 15 percent Beef Cheek Meat.\u201d Beef cheek meat and/or beef head meat may be used in unlimited quantities and identified as \u201cbeef\u201d in meat food products unless restricted by regulatory standards for specific products as indicated in 9 CFR 319.15(a) (Chopped beef, ground beef), 319.15(b) (Hamburger), 319.15(d) (Fabricated steak), 319.81 (Roast Beef parboiled and steam roasted), 319.100 (Corned beef), 319.300 (Chili con carne), 319.301 (Chili con carne with beans), and 319.303 (Corned beef hash). The presence of pork head meat is not required to be identified on the labeling of boneless pork. However, pork cheek meat and/or pork head meat may be used in unlimited quantities and identified as \u201cpork\u201d in meat food products, unless restricted by regulatory standards as indicated in 9 CFR 319.300 (Chili con carne) and 319.301 (Chili con carne with beans). See: Policy Memo 098B dated August 1, 1990 -Cheek Meat BEEF CONCENTRATE AND SALT: Broth derived from cooking fresh beef containing 3 percent to 4 percent solids is centrifuged and evaporated to approximately 60 percent solids under vacuum. The water fraction is salted to a level of 25.5 percent of the water weight (100 lbs. concentrated stock at 60 percent will have 10.2 lbs. of salt added, making a total weight of 110.2 lbs.). There is no need for refrigeration. BEEF CONSOMME: The standard requires beef as an ingredient and a minimum protein content of at least 3 percent in the finished product. \u201cBeef stock\u201d or \u201cbeef broth\u201d (or mixture of both) may be used to comprise the beef ingredient. Additional optional ingredients are gelatin, beef extract, tomato puree, hydrolyzed plant protein, and seasoning. BEEF (Dried or Air Dried): Product name is \u201cAir Dried Beef\u201d or \u201cDried Beef.\u201d MPR 2.04:1. It is usually cured by rub and/or stitch pump followed by cover pickle for 4 to 8 weeks with several overhauls (turned over for the application of

additional cure), then placed in smokehouse or drying chambers for 3 to 10 days. BEEF FIBRIN: This is a component mixture of beef fibrinogen and beef thrombin plasma protein used to bind pieces of meat or poultry together. It is limited to 10 percent." "1. If used from seven percent of ten percent, it must appear in the product name, e.g., \u201cBacon Wrapped Beef Tenderloin Steak Formed with Beef Fibrinogen and Thrombin.\u201d Therefore, the smallest letter in the product name must be at least 1\3 size of the smallest letter in the product name. 2. If used at less than seven percent, it must be a product name qualifier, e.g., \u201cFormed with Beef Fibrinogen and Thrombin.\u201d As a product name qualifier, there is no size requirement, however, it must contiguous to the product name and be prominent and conspicuous.

Additionally, the terms \u201cBeef Fibrin\u201d or \u201cFibrin\u201d may be used in the product name as a qualifier and its components identified elsewhere on the principal display panel. In this situation, the terms \u201cBeef Fibrin\u201d or \u201cFibrin\u201d and its components are linked to each other by means of asterisks. Acceptable terminology\u2019s for the components are \u201cBeef Fibrinogen and Thrombin Plasma Protein,\u201d or

\u201cBeef Fibrinogen and Thrombin.\u201d BEEF GRAVY MIX: The product must contain at least 15 percent dried beef. BEEF MARSALA: The product must contain at least 50 percent beef.

Product contains beef cubes, Marsala wine sauce, and usually mushrooms and onions. White wine may be used, but it may not replace Marsala wine. BEEF ORIENTAL OR ORIENTAL BEEF:

The product must contain at least 12 percent meat and oriental style vegetables and sauce. The label must show true product name, e.g., \u201cBeef Oriental with Vegetables.\u201d BEEF

ROULADE: The product must contain at least 50 percent cooked meat. Usually a thin strip of flank meat wrapped around vegetables and cooked. BEEF SLICES A-LA-PIZZAIOLA: The product must contain at least 50 percent cooked beef. BEEF STROGANOFF: A dish with a creamy sauce prepared with beef cut into narrow strips or cubes and saut\u00e9ed. Product labeled

\u201cBeef Stroganoff\u201d should be prepared with a formula, which includes at least 45 percent beef, or 30 percent cooked beef." "1. The product must contain at least 10 percent

sour cream, or 2. 7.5 percent sour cream, and 5 percent wine, or 3. 9.5 percent whole milk, 2 percent sour cream, and 2 1\2 percent wine. BEEF STROGANOFF WITH NOODLES: Meat and

sauce portion must meet the standard for Beef Stroganoff. Total product shall contain no more than 50 percent cooked noodles. BEEF SUKIYAKI: The product must contain at least 30 percent meat based on total product. Consists of thinly sliced beef and various vegetables cooked in a

flavored beef stock. This is not a stew as the vegetables and components are mixed during the cooking process. Vegetables used with this food are celery, bean sprouts, leeks, onions,

mushrooms, Chinese cabbage, carrots, spinach, water chestnuts, bamboo shoots, and bean curds. BEEF TRIPE STEW: There are two versions of this product. One is of Mexican origin and

merchandised in association with the term \u201cMenudo.\u201d Corn is a prominent ingredient in its formula. The standard for an item of this nature requires that it contain not less than 33 percent beef tripe computed on the basis of the uncooked tripe in relation to total ingredients. The second product is popular in Puerto Rico. It is referred to as

\u201cMondungo.\u201d The product is made with 25 percent raw beef tripe. The remainder consists principally of potatoes, a squash with pumpkin-like appearance and flavor, and a native vegetable called \u201cTanier.\u201d When the vegetables are not distinguishable, this

product can be labeled as \u201cDominican Style Mondungo.\u201d BEEF WELLINGTON: It is made with beef tenderloin that is roasted very rare. It is then spread with a liver pate, covered

with pastry, and baked in a hot oven until pastry is brown. The product must contain at least 50 percent cooked meat and no more than 30 percent pastry. Alternatively, mushroom duxelle is an acceptable substitute for liver pate, but a true descriptive product name is required, e.g., \u201cbeef tenderloin covered with mushroom duxelle and wrapped with pastry.\u201d

BEERWURST, BIERWURST: A cooked smoked sausage. Same requirements as beef salami, with the exception that pork may be used.", "BERLINER: A cooked smoked sausage usually made from coarsely cut cured pork in large casings. When beef is used, it shall not exceed 50 percent of the meat block. Pork stomachs or beef tripe not permitted. See: Policy Memo 048 dated May 18, 1982

BERLINER BLOOD SAUSAGE: A cooked blood sausage containing diced bacon. After cooking it is dried and smoked. Ham fat, snouts, and lips are not permitted. See: Blood Sausage

BIER SCHINKEN (GR): The literal translation is \u201cBeer Ham.\u201d If product is made of all pork, it may be labeled \u201cBier Schinken.\u201d

BINDERS IN POULTRY, BONELESS, RAW OR COOKED: Binding agents may be added individually or collectively in amounts not to exceed 3 percent for cooked poultry products and 2 percent for raw poultry products based on total finished product. When binders are added in excess of these levels, the common or usual name of the binder or the generic term \u201cBinders Added\u201d shall be included in a product name qualifier, e.g., \u201cTurkey Breast-Gelatin Added.\u201d In all cases, the presence of these ingredients must be shown in the ingredients statement. This policy is intended to apply to binders which are used in chopped or chunked poultry products that are formed into rolls, loaves, etc., but not to binders added directly into whole muscle by injection, massaging, tumbling, etc., which then act as extenders. See: Policy Memo 103 dated February 13, 1987

BLOCKWURST: A semi-dry type sausage. The maximum MPR is 3.7:1.

BLOOD AND TONGUE SAUSAGE: Same as blood sausage, except cured and cooked pork or beef tongues are used.", "BLOOD SAUSAGE: A cooked sausage formulated with blood and some meat. Usually contains pork skins and\;/or pork jowls. May also contain sweet pickled ham fat, snouts, and lips. If the product does not contain meat, it must be labeled as \u201cBlood Pudding.\u201d

BOINGGHETTI: This label must show a true product name, \u201cSpaghetti with Chicken Sauce.\u201d The product must contain at least 6 percent cooked chicken meat.

BONE-IN MEAT WITH SAUCE: Must have at least 50 percent meat (cooked basis). Product with barbecue sauce must comply with 9 CFR 319.312.

BONELESS BREAST TRIMMINGS: Boneless breast trimmings (turkey or chicken) are defined as trimmings that are removed from the breast portion only. When a product is formulated with boneless breast trimmings, the amount of skin should be indicated in order to determine that the meat requirement is met for a standardized product and that the product is properly labeled. Trimmings from the ribs may be identified as white turkey or white chicken trimmings, or white turkey or white chicken rib meat (excluding skin).

BRATWURST: This is a fresh sausage product that may contain byproducts when properly declared in the ingredients statement. Vegetables, cheese and fruit are also acceptable when properly declared as part of the product name e.g., \u201ccheddar bratwurst.\u201d See: 9 CFR 319.140 Sausage Classification Sausage Type Products with Fruits and Vegetables Sausage Containing Cheese

BRATWURST, CURED: Product that meet the requirement for bratwurst but also contain cures must be labeled as \u201cCured Bratwurst.\u201d Bratwurst can be a cooked product.

BREAKFAST LINKS OR PATTIES: The names \u201cBreakfast Links\u201d and \u201cBreakfast Patties\u201d can be considered fanciful names, which must be followed by a descriptive product name. Such products are acceptable without compliance with the fresh

pork sausage or breakfast sausage standard. If the "," names \u201cBreakfast Links\u201d or \u201cBreakfast Patties\u201d are used without further qualification, the products must meet either the fresh pork sausage standard or the breakfast sausage standard.

**BREAKFASTS**

(Containing Meat): The product must contain at least 15 percent cooked meat or poultry or meat or poultry food product based on the total net weight of breakfast.

**BROTH, BEEF OR PORK:** No distinction has been made between \u201cbroth\u201d and \u201cstock.\u201d They may be used interchangeably as the resulting liquid from simmering meat and\or bones in water with seasonings. Both products have an MPR of 135.1 or a 67.1 MPR for concentrate.

**BROTWURST:** A cured and cooked sausage that may be smoked.

**BROWN AND SERVE SAUSAGE:** The standard is based on one of the four options as listed below:

1. Moisture Protein Ratio (MPR) is no more than 3.7:1, fat limited to 35 percent, and 10 percent water at formulation.
2. No more than 10 percent added water at formulation and a yield of no greater than 80 percent.
3. No more than 8.8 percent added water at formulation and a yield no greater than 85 percent.
4. Product must meet fresh sausage standard before cooking. The label must show true product name, e.g., \u201cBrown and Serve Pork Sausage.\u201d

**BROWN AND SERVE SAUSAGE (Canned):** A cooked sausage, usually without cure, and not more than 8 percent water. The weight of the sausage at canning shall not exceed weight of fresh uncured meat ingredients plus weight of curing and seasoning ingredients.

**BRUNSWICK STEW:** The product must contain at least 25 percent (fresh basis) of at least two kinds of meat, one of which may be poultry. Product must contain corn as one of the vegetables.", "See: Poultry Brunswick Stew

**BUFFALO STYLE:** Meat or poultry products that are cooked and usually coated with a mild or spicy sauce containing, Cayenne red pepper, vinegar, salt and garlic, can be labeled, \u201cBuffalo Style.\u201d It would also be acceptable on any product labeled, \u201cmade in Buffalo, NY.\u201d Buffalo wings is a fanciful term that requires a descriptive name.

**BURGUNDY SAUCE WITH BEEF AND NOODLES:** The product must contain at least 25 percent cooked beef in the product, with up to 20 percent cooked noodles. Product must contain enough wine to characterize the sauce.

**BURRITOS:** A Mexican style sandwich-like product consisting of a flour tortilla, various fillings, and at least 15 percent meat or 10 percent cooked poultry meat. The flour tortilla is rolled and may or may not have tucked ends. Fillings may contain, in addition to meat or poultry meat, such major ingredients as beans, potatoes, cheese, rice, tomatoes, and chilies. Examples of product names are \u201cBEEF BURRITO,\u201d \u201cTURKEY BURRITO,\u201d \u201cCHICKEN FAJITA BURRITO,\u201d AND \u201cCHILI VERDI WITH BEANS BURRITO.\u201d If ingredients, e.g., rice or beans, are declared in the product name, they must appear in the proper order of predominance. Ingredients cannot be mentioned in the product name unless all other ingredients present in amounts equal to or above the declared ingredient are included in the name, e.g., \u201cBEANS, BEEF, TOMATO, ONION, AND RICE BURRITO.\u201d The use of \u201cRed Chili\u201d or \u201cGreen Chili\u201d or a similar designation of the chili content in a starburst, flag, or similar display, separated from the product name, is acceptable. If such designations are used as part of the descriptive name, the presence of the chilies must appear in the correct order of predominance, and all other ingredients present in amounts equal to or greater than the chilies must appear in the product name. A claim or name that identifies the use of shredded meat or shredded poultry meat is permitted. However, if ground meat or ground poultry meat is also used, its presence must also be identified in the claim or name, e.g., \u201cShredded Beef and

Ground Beef Burrito.\u201d \u201cBURRITO\u201d alone, may be used to name the product without a descriptive name. However, the ingredients statement must appear directly beneath \u201cburrito.\u201d BURRITOS WITH SAUCE OR GRAVY: Product must contain at least 50 percent burritos.", "BUTIFARRA-SAUSAGE: An uncured sausage. Labeling that features the term \u201cButifarra\u201d would require an additional product name: Pork Sausage -for those products that meet the fresh pork sausage standard. Fresh Sausage -for those products that include byproduct but do not meet the standard for pork sausage. Sausage -for those products that are incubated or fermented. The term Puerto Rican Style would be applicable if manufactured in Puerto Rico. See: Policy Memo 002 dated May 30, 1980 CADDIES, DISPLAY CADDIES-LABELING WITH RESPECT TO THE MARK OF INSPECTION: All meat and poultry product placed inside a display caddy must be fully labeled with all mandatory labeling features of an immediate container per 9 CFR 317.2 or 381 Subpart N. Display caddies when used as a shipping container are required to bear the mark of inspection and may continue to bear the mark of inspection when used as a caddie at retail for one-time use display. Display caddies may bear other labeling features as duplicated from the approved product labeling for the product or products within the display caddy. CAJUN: Refers to product made in Louisiana. CAJUN STYLE\CAJUN RECIPE: Acceptable identification for products containing onion\onion powder\dehydrated onion, garlic\garlic powder\dehydrated garlic, white pepper, red pepper, and black pepper. CALABRESE (IT): A salami originating in Southern Italy. Usually made entirely of pork seasoned with hot peppers. CALZONE, CALZONI (IT): Turnover-like product made with dough stuffed with meat or poultry, cheese, and seasonings and baked. It must contain 25 percent meat or 14 percent poultry meat. The label must show a true product name, e.g., \u201cSausage and Cheese Calzone.\u201d CANADIAN AND CANADIAN STYLE BACON: \u201cCanadian Bacon\u201d and \u201cCanadian Style Bacon\u201d are synonymous and should not be considered geographical terms.", "The term \u201cCanadian Style Bacon,\u201d when featured on the label as a product name or part of a product name (i.e., as a description, etc.), may stand alone without an additional qualifier indicating the true geographical origin of the product. \u201cChunked and Formed\u201d and \u201cWater Added\u201d products are permitted, provided proper labeling is applied. Uncooked and\or unsmoked \u201cCanadian Style Bacon\u201d is also permitted, provided labeling describes the product as uncooked and\or unsmoked. Product which is identified as \u201cCanadian Style Bacon\u201d is made from a trimmed boneless pork loin. On the shoulder end, the cross section of the longissimus dorsi muscle shall be equal to or larger than the combined cross sectional areas of the splenius and semispinalis capitis muscles. The ham end shall be removed anterior to the ilium. The exposed faces shall be approximately perpendicular with the skin surface. The dorsal and ventral side on each end of the \u201cCanadian Style Bacon\u201d shall not be more than 1.0 inch different in length. The belly is removed adjacent to the longissimus dorsi muscle. All bones and cartilage shall be removed. The tenderloin and the flesh overlying the blade bone are excluded. The surface fat (and false lean when necessary) shall be trimmed to 0.3 inches thick at any point. The fat on the ventral and dorsal sides is neatly beveled to meet the lean. See: Policy Memo 050B dated December 19, 1985 CANADIAN STYLE BACON MADE WITH\FROM PORK SIRLOIN HIPS: The sirloin is obtained by removing a 5-to 7-inch section of the pork loin immediately in front of the hip or pelvic bone. The sirloin hip is obtained by removing the half of the sirloin which comprises the posterior end of the pork loin. The tenderloin is not included

and surface fat shall be trimmed to 0.3 inches in thickness. The labeling for these Canadian Style Bacon products must bear a qualifying statement, adjacent to the product name, clarifying that pork sirloin hips are included or that the product is made entirely from pork sirloin hips, e.g., \u201cCanadian Style Bacon--Includes Pork Sirloin Hips\u201d or \u201cCanadian Style Bacon--Made from Pork Sirloin Hips.\u201d The smallest letter in the qualifier should not be less than one-third the size of the largest letter in the product name. The qualifier must be of equal prominence to the product name. Chunked (or chopped) and formed varieties and substances controlled by the protein fat free (PFF) regulation for cured pork products 9 CFR 319.104 shall be labeled in accordance with applicable guidelines. Use of this type of product in a secondary product, e.g., a pizza, requires complete identification only in the ingredients statement; the product name of the secondary", "product need only refer to Canadian Style Bacon, e.g., Canadian Style Bacon Pizza. See: Policy Memo 116 dated July 11, 1988 CANNED CHOPPED BEEF OR PORK: Cured product with no more than 3 percent water in formula.

CANNED MEAT: \u201cCanned meat with Natural Juices;\u201d is acceptable for product that has been pumped or contains up to 10 percent of a solution before canning and processing. Processed canned uncured meat products, when water or broth is added to the can may not be called \u201cwith natural juices,\u201d but the acceptable name would be \u201cwith juices.\u201d

CANNELLONI (IT): Product must contain at least 10 percent meat or 7 percent cooked poultry meat. Cannelloni is an Italian term referring to a product with the same characteristics as \u201cRavioli\u201d except Cannelloni has a tubular form. The product name should show the type of species, e.g., \u201cBeef Cannelloni.\u201d

CANTONESE STYLE SPECIES: Marinated in a solution of soy sauce, cooked and returned weight. In addition, product is mildly seasoned with sugar, salt, wine, and spices.

CAPACOLLO, COOKED (Capicola, Capocolla, Capacola, Capicollo, Cappicola, Capacolo) (IT): Boneless pork shoulder butts which are cured and then cooked. The curing process may be dry curing, immersion curing, or pump curing. The cured product is coated with spices and paprika before cooking. This product shall always be labeled with \u201cCooked\u201d as part of the product name. Water added is permitted.

CARAMEL COLORING: Caramel is considered a natural color. However, when caramel coloring is added to a product, the product name must be qualified to indicate the presence of artificial coloring, e.g., \u201cCooked Roast Beef-Caramel Coloring Added\u201d or \u201cArtificially Colored.\u201d This requirement does not apply to gravies, sauces, and similar products where the use of such coloring is customary. Seasoning mixes containing small quantities of caramel coloring may be used if the caramel coloring does not impart color to the finished product. Caramel coloring may be used on the surface of raw products, e.g., beef patties, if the name is appropriately qualified. However, caramel coloring may not be added directly to", "the formulation of a raw product where the caramel coloring becomes an integral part of the total product. See: Policy Memo 112 dated June 6, 1988 CARBONADE (FR): Product must contain at least 50 percent meat. It may contain beef, pork, or mutton, and beer or wine. Product is slowly cooked, either by braising or stewing. Label must show a true product name, e.g., \u201cBeef Carbonade.\u201d

CARRIERS: Substances, as defined by the Food and Drug Administration, that carry flavoring compounds, e.g., essential oils, on their surface, and are not expected to provide a functional effect, e.g., binding and emulsifying, in the finished food product and are considered incidental. Some substances, e.g., maltodextrin and modified food starch, are not carriers but actually diluents or bulking agents, and must be declared in the ingredients

statement. Dextrose and\or sugar are commonly used as carriers for spice extracts and resins of spices. The carrier must be declared in the ingredients statement, except in those cases where a sweetening agent is used separately in formulating the meat or poultry product and the use of the spice mixture will not result in the quantity of the carrier being more than 0.75 percent of the seasoning mix. When a determination cannot be made from the information on the label application, declaration is required. Salt, when used as a carrier, will always be declared regardless of amount used. CASING, ARTIFICIAL: Frankfurters packaged in retail containers with the artificial casing left on must bear a prominent statement, e.g., \u201cRemove casing before eating,\u201d contiguous to the product name on the label.

CASSEROLE: Product must contain at least 25 percent meat or 18 percent cooked meat.

CASSOULET (FR): Product must contain at least 25 percent meat. A complex stew consisting of dried white beans and a combination of pork, lamb, game, and sausages. The ingredients are cooked, then put into a casserole, usually covered with crumbs, and baked. Label must show true product name, e.g., \u201cBeans and Bacon in Sauce.\u201d","CENTER SLICE: When the term \u201cCenter Slice\u201d is used on labels for slices of ham from smoked and cooked, smoked, or water cooked hams, product must be sliced from an area of the original ham positioned about 1 inch on each side of a center cut. CEREAL: Cereal is a generic term for grains from grass, e.g., wheat, rice, rye, oats, barley, and corn. All ingredients must be listed by common or usual name on labeling. However, cereal is not a common or usual name and requires a sublisting in the ingredients statement. CERTIFIED: With the exception of the term \u201cCertified Pork\u201d the term \u201ccertified\u201d implies that the United States Department of Agriculture (USDA) and the Agriculture Marketing Service (AMS) have officially evaluated a meat product for class, grade, or other quality characteristics. When used under other circumstances, the term should be closely associated with the name of the organization responsible for the \u201cCertification\u201d process (e.g., \u201cXYZ Company's Certified Meat,\u201d or \u201cOur Certified Meat\u201d). CERVELAT: A cured and cooked sausage, often a semi-dry or dry summer sausage. Hog stomachs, beef tripe and extenders are permitted. There is no MPR (moisture protein ratio) requirement. CHA SHU BOW (CH): A steamed bun with a dry roasted pork filling requiring 15 percent cooked pork. Label must show true product name, e.g., \u201cSteamed Bun with a Pork and Cabbage Filling.\u201d CHEEK MEAT, BEEF: Natural proportions are considered to be 2 percent. See: Policy Memo 098B dated August 1, 1990 See: 9 CFR 319.15 The use of cheek meat is limited to 25 percent in ground beef, chopped beef and similar type products. If cheek meat exceeds 2 percent (natural proportions), its presence must be declared.","CHEESE: 1. When cheese is declared in the ingredients statement of a fabricated product, cheddar cheese must be used in the product's formulation. 2. Swiss, Gruyere: The term \u201cGruyere\u201d pertains to a cheese that closely resembles \u201cSwiss Cheese\u201d both in its appearance and on analysis, although it has smaller holes than Swiss Cheese. FDA advises that Gruyere Cheese is a suitable substitute for Swiss Cheese and gives the same character to a finished food product, e.g., \u201cChicken Cordon Bleu.\u201d 3. The term Cheese may appear in the product name, e.g., \u201cHam and Cheese Loaf,\u201d provided the common name is declared in the ingredients statement. 4. When a cheese product and meat or poultry food product are packaged together, the product name shown on the label must show the name of each component product. For example, if slices of ham and slices of a cheese product are packaged together, the product name should include

CHA SHU BOW (CH): A steamed bun with a dry roasted pork filling requiring 15 percent cooked pork. Label must show true product name, e.g., \u201cSteamed Bun with a Pork and Cabbage Filling.\u201d CHEEK MEAT, BEEF: Natural proportions are considered to be 2 percent. See: Policy Memo 098B dated August 1, 1990 See: 9 CFR 319.15 The use of cheek meat is limited to 25 percent in ground beef, chopped beef and similar type products. If cheek meat exceeds 2 percent (natural proportions), its presence must be declared.","CHEESE: 1. When cheese is declared in the ingredients statement of a fabricated product, cheddar cheese must be used in the product's formulation. 2. Swiss, Gruyere: The term \u201cGruyere\u201d pertains to a cheese that closely resembles \u201cSwiss Cheese\u201d both in its appearance and on analysis, although it has smaller holes than Swiss Cheese. FDA advises that Gruyere Cheese is a suitable substitute for Swiss Cheese and gives the same character to a finished food product, e.g., \u201cChicken Cordon Bleu.\u201d 3. The term Cheese may appear in the product name, e.g., \u201cHam and Cheese Loaf,\u201d provided the common name is declared in the ingredients statement. 4. When a cheese product and meat or poultry food product are packaged together, the product name shown on the label must show the name of each component product. For example, if slices of ham and slices of a cheese product are packaged together, the product name should include

\u201cHam\u201d and the name of the cheese product (e.g., Ham and Pasteurized Processed American Cheese). Alternatively, the Pasteurized Processed American Cheese could be parenthetically qualified contiguous to the product name (e.g., \u201cHam and Cheese (Pasteurized Processed American Cheese)\u201d). The name \u201cHam and Cheese\u201d alone would be acceptable if the cheese used was \u201cCheddar Cheese.\u201d 5. Use of substitute or imitation cheese in products where real cheese is expected (e.g., Cordon Bleu) requires the product name be changed or qualified to indicate the presence of the ersatz cheese. Substitute and imitation cheeses cannot be described as \u201ccheese\u201d in the product name. There is no limitation on the amount of ersatz cheese used. 6. Expressed Nutrient Content Claim Standardized Cheese \u2013 FDA regulation 21 CFR 130.10 is a general definition and standard of identity rule for manufacturing and labeling of substitute cheese products where its normal counterpart is governed under 21 CFR Part 133. Such products use the name of a standardized cheese in their statement of identity but do not comply with the standard of identity because of a deviation that is described by an expressed nutrient content claim that has been defined by FDA regulation. These products must be identified on the labeling of meat and poultry products by their common or usual name which contains an expressed nutrient content claim along with the standardized name of cheese, e.g., \u201cLow Fat Cheddar Cheese.\u201d In addition, the expressed nutrient content cheese must be properly identified in the ingredients declaration by its common or usual name and a sublisting of its ingredients that display an asterisk(s) identifying an ingredient(s) in the cheese sublisting and linked to another asterisk with a statement indicating \u201cingredients not in regular\u2026\u201d and/or \u201cingredients in excess of amount permitted by\u2026\u201d The asterisk(s) and the statement in the ingredients declaration are necessary as they are part of the identity of the expressed nutrient content cheese.", "7. Cheese is a standardized product. See: 21 CFR 130.10 and 133 for a listing of standardized cheeses CHEESE (PASTEURIZED PROCESSED CHEESE FOOD OR SPREAD): A cheese food product with a standard of identity, but is not considered a cheese. Therefore, it cannot be used in meat food products where cheese is an expected ingredient, e.g., \u201cCheesefurters\u201d or \u201cVeal Cordon Bleu.\u201d It is acceptable in non-specific loaves, etc. CHEESE PRODUCTS CONTAINING MEAT: Homogeneous cheese and meat products, e.g., cheese balls with pepperoni, must contain more than 50 percent meat to be amenable to USDA inspection. Cheese products that contain 50 percent or less meat are considered products of the dairy food industry and, thus, are exempt from federal inspection. When cheese and meat are separate components in a package, the packaged product is amenable, provided, it contains 2 percent cooked meat. CHEESE STANDARDIZED PRODUCTS: Cheese standardized products that require real cheese, e.g., chicken cordon bleu, must use FDA standardized cheese or those FDA standardized cheeses specified. Use of a substitute, imitation cheese or other non FDA standard cheeses, if permitted, must be declared in the product name, or a suitable qualifier, e.g., chicken cordon bleu made with reduced fat cheese. The 90/10-cheese rule is only applicable to pizza. CHICHARRONES (PR): The Spanish name for fried pork skins. Product must have an English product name, \u201cFried Pork Skins\u201d except in Puerto Rico. CHICHARRONES de POLLO (PR): An acceptable product name for \u201cMarinated Cut-up Fried Chicken\u201d sold in Puerto Rico. When product is destined for sale only in Puerto Rico, \u201cChicharrones de Pollo\u201d can be the product name. When destined for sale in other places,

\u201cChicharrones de Pollo\u201d must be explained with true product name. CHICKEN, ALOHA: \u201cAloha Chicken\u201d is acceptable as a coined name which must be followed by a true product name, e.g., \u201cChicken and Sauce with Rice.\u201d The standard for the product is 22 percent cooked poultry meat.", "CHICKEN AND NOODLES AU GRATIN (FR): Product must contain at least 18 percent cooked chicken meat. CHICKEN CORDON BLEU (FR): Product should contain: 1. Chicken breast meat (sliced) with or without chicken skin. Marinade or solution may be included in the meat content of the product. If another part of the chicken is used, product would need to be descriptively labeled, for more information see #5 in this entry. 2. Cured pork, e.g.: ham, Canadian Style Bacon 3. Cheese or pasteurized processed cheese 4. Product can be breaded or unbreaded. If breading is used, breading is limited to 30%. 5. If any of the conditions for chicken cordon bleu are not met, the product should be descriptively labeled. Not meeting the conditions can include using uncured bacon, uncured turkey ham, cured turkey ham, imitation cheese, or some other part of the chicken than the breast. CHICKEN ENCHILADA SUIZA: The product consists of chicken enchiladas with a cream sauce. The sauce used must be made with sour cream, heavy cream, or whipping cream in an amount sufficient to characterize the sauce. The label must show a true product name, e.g., \u201cChicken Enchilada with Cream Sauce.\u201d CHICKEN OVA: These can not be used for human consumption without first going to an egg products plant for pasteurization (because of problem with potential Salmonella contamination). Chicken Ova can not use the poultry inspection legend. CHICKEN PAPRIKA: Product must contain at least 35 percent chicken. A Hungarian dish. Sauce must contain either sour or sweet cream and enough paprika to give a pink color.", "CHICKEN WELLINGTON: It is made with roasted chicken that is spread with liver pate, covered with pastry, and baked in a hot oven until pastry is brown. The product must contain at least 59 percent cooked meat and no more than 30 percent pastry. CHILI: 1. \u201cBrick Chili\u201d or \u201cCondensed Chili\u201d requires 80 percent meat. Cereal is limited to 16 percent. 2. Chili with reconstitution directions should meet the chili standard when reconstituted. 3. When beef heart meat, cheek meat, or head meat is used in excess of 25 percent of the meat block, it must be reflected in the product name, e.g., \u201cChili with Beef and Beef Heart Meat.\u201d 4. When beef appears in the product name, BEEF MAY BE THE ONLY MEAT SOURCE USED. Beef Chili may not contain beef fat or other beef byproducts. 5. \u201cChili Gravy with Meat\u201d requires at least 40 percent fresh meat and no more than 8 percent cereals. 6. Cured meats are not an expected ingredient in chili; when used, they must be shown as part of the product name. 7. The terms \u201cChili\u201d or \u201cChili con Carne\u201d may be used interchangeably. 8. Since \u201ccon carne\u201d means \u201cwith meat,\u201d products labeled as chili con carne should include only red meat and not poultry. Products which meet the chili standard and include poultry may be labeled \u201cbeef and chicken chili,\u201d \u201cbeef chili, chicken added,\u201d etc., as appropriate. The binder and extender limitation of 8 percent is based on total formulation. See: 9 CFR 319.300 CHILI COLORADO: Product must meet 9 CFR 319.300 requirements. Chili peppers must be exclusively of the red variety. If a prepared chili powder is used, it must be prepared exclusively from red chili peppers. The term \u201cColorado\u201d is used for red more than \u201cRojo\u201d in Mexico. The term \u201cRojo\u201d is used more in Spain, Puerto Rico, and Cuba. See: Policy Memo 013 dated September 12, 1980", "CHILI-MAC: Product must contain at least 16 percent meat. The label requires a true product name, e.g., \u201cBean, Macaroni and Beef in

Sauce\ud83c\udc1d. CHILI PIE: Chili component of the total product must have at least 40 percent fresh meat. CHILI PUPS: An emulsion stuffed in casing and smoked. Label requires a true product name, e.g., \ud83c\udc1dChili con Carne and Ground Beans Product.\ud83c\udc1d Product must contain at least 60 percent fresh meat in total formulation. CHILI RELLENO: Product must contain at least 12 percent fresh meat and be coated with a batter and then fried. Sometimes product is called \ud83c\udc1dChili Pepper Relleno.\ud83c\udc1d Relleno means stuffed. CHILI SPAGHETTI: Product must contain at least 16 percent meat. CHILI SAUCE WITH MEAT: Product must contain at least 6 percent meat. CHILI VERDE (SP): Product must meet 9 CFR 319.300 requirements. Chili peppers must be exclusively of the green chili or Verde chili pepper varieties. If a prepared chili powder is used, it must have been prepared exclusively from green chili or Verde chili peppers. Products, e.g., \ud83c\udc1dChili Verde with Beans\ud83c\udc1d shall comply with 9 CFR 319.301 and the above requirements for \ud83c\udc1dChili Verde.\ud83c\udc1d See: Policy Memo 013 dated September 12, 1980 CHILI WITH BEANS: 1. \ud83c\udc1dBrick Chili with Beans\ud83c\udc1d or \ud83c\udc1dCondensed Chili with Beans\ud83c\udc1d requires 50 percent meat and cereal is limited to 16 percent. 2. Chili with Beans with reconstitution directions should meet the Chili with Beans standard when reconstituted.", "3. When beef heart meat, cheek meat, or head meat is used in excess of 25 percent of the meat block, it must be reflected in the product name, e.g., \ud83c\udc1dChili with Beef and Beef Heart Meat with Beans.\ud83c\udc1d 4. When beef appears in the product name, beef may be the only meat source used. Beef Chili with Beans may not contain beef fat or other beef byproducts. 5. Cured meats are not an expected ingredient in Chili with Beans; when used, they must be shown as part of product name. 6. \ud83c\udc1dChili with Beans\ud83c\udc1d formulae usually contain up to 25 percent of beans in a product. About one-fourth of these beans may be incorporated in the product as ground beans and should be listed in the ingredients statement as ground beans. 7. The terms \ud83c\udc1dChili with Beans\ud83c\udc1d or \ud83c\udc1dChili con Carne with Beans\ud83c\udc1d may be used interchangeably. 8. The binder and extender limitation of 8 percent is based on total formulation. See: 9 CFR 319.301

CHIMICHANGA: Product must contain at least 15 percent meat or 10 percent poultry meat. A Mexican specialty from the State of Sonora. Like burritos, product is made by wrapping a flour tortilla around a filling; but unlike the burrito, chimichanga is fried until brown and crisp. \ud83c\udc1dFried Burritos\ud83c\udc1d is acceptable.

CHINESE BRAND LINKS: Raw nonspecific sausage-like products. These products are permitted to contain artificial red coloring; however, if pork is used it must be certified. Unlike the term \ud83c\udc1dlinks,\ud83c\udc1d \ud83c\udc1dChinese Brand Links\ud83c\udc1d is considered a coined or fanciful name, and [as a] nonspecific product, it must be accompanied by an ingredients statement. Furthermore, \ud83c\udc1dmade in USA\ud83c\udc1d must be contiguous to the word \ud83c\udc1dbrand\ud83c\udc1d but cannot intervene between \ud83c\udc1dlinks\ud83c\udc1d and the ingredients statement.

CHINESE PEPPER STEAK: A Chinese main dish, usually served with rice, must contain at least 30 percent cooked beef. Beef steak is cut into thin strips, browned in fat or oil, and added to a soy flavored sauce. Vegetables are also added to the sauce. Green pepper strips are always used and other vegetables may be included.", "CHINESE STYLE BARBECUE MEAT: Acceptable identification for barbecued meat (9 CFR 319.80) product that is flavored with a solution with soy sauce, grain alcohol or dry sherry wine, and a sweetener, that is, sugar or honey. Other ingredients may include garlic or scallions, ginger or ginger juice, sesame or peanut oil. The product may be artificially colored. If artificially colored, a qualifier is needed.

CHINESE STYLE BEEF: Product must contain grain alcohol and soy sauce. CHINESE STYLE

**SAUSAGE:** Product must contain grain alcohol and soy sauce. **CHIPPED BEEF:** Beef that is dried, chipped, or sliced and may be cured or smoked. An MPR 2.04:1 is required. It may be chunked, ground, chopped, and formed. If so, the product name must be qualified, e.g., \u201cChipped Beef, Chunked and Formed.\u201d Acceptable fill: 1. 2 oz. in a 4 fluid oz. glass, or 2. 2 1\2 oz. in a 5 fluid oz. glass, or 3. 5 oz. in a 9-5\8 fluid oz. glass. **CHITTERLINGS:** Approved label must identify the species of food animal from which the product is derived. Hog bungs may be labeled \u201cPork Chitterlings.\u201d The purge under normal conditions should not exceed 20 percent of the net weight of frozen chitterlings. See: 9 CFR 317.8(b)(30) **CHOICE GRADE, FANCY GRADE POULTRY:** \u201cChoice\u201d or \u201cFancy\u201d may not be used in conjunction with \u201cGrade\u201d on poultry labels. These terms and others like \u201cPrime\u201d and \u201cTop Quality\u201d on poultry labels indicate only that product is equal to U.S. Grade A. **CHOPPED CHICKEN LIVERS:** Total product must contain at least 50 percent cooked chicken livers. Wheat flour and similar ingredients are acceptable.," **CHOPPED CHICKEN LIVERS COMBINED WITH OTHER CHARACTERIZING COMPONENTS:** Product must contain at least 30 percent cooked livers, e.g., \u201cChopped Chicken Livers with Eggs and Onions\u201d. **CHOPPED HAM:** A total of 15 percent shank meat is permitted. This is 3 percent above the normal proportion of 12 percent shank meat found in a whole ham. See: 9 CFR 319.105 **CHOP SUEY, AMERICAN:** Product must contain at least 25 percent fresh meat in total formulation. A stew-like dish prepared with beef, pork, or veal. Vegetables include onion and celery. Macaroni, noodles, or rice are usually incorporated in the product, although recipes suggest serving chop suey over one of these. **CHOP SUEY (VEGETABLES WITH MEAT):** Product must contain at least 12 percent fresh meat. **CHORIZO (SP):** The product name \u201cChorizo\u201d can be used for any type of chorizo sausage that is cooked, dry, semi-dry, cured and fresh without further product name qualification. Other requirements for various types of chorizo apply, including the sausage standard. It is seasoned with Spanish pimento and red pepper. Partially defatted pork fatty tissue is acceptable in Chorizo. Wine is considered a flavoring and need only appear in the ingredients statement. However, the liquid is credited as added water. **CHORIZO, FRESH:** These products may contain vinegar. The vinegar used must have a strength of no less than 4 grams of acetic acid per 100 cubic centimeters (20o C.). Policy Memo 034 dated October 1, 1981 **CHORIZO IN LARD:** Product must contain at least 55 percent chorizo.," **CHORIZO IN LARD, CANNED:** Canned chorizos that are packed hot, usually in lard, and are not thermally processed must have a moisture protein ratio of 1.8:1 and a pH of not more than 5.5. An alternative standard is a water activity (Aw) of 0.92. **CHOW MEIN WITH MEAT:** Product must contain at least 12 percent fresh meat. **CHULENT (CHOLENT):** Product must contain at least 25 percent fresh meat. A meal-in-one dish of Jewish cuisine made in various ways. The product name can stand without qualification. **COARSE GROUND MEAT TRIMMINGS:** Coarse ground trimmings may be shipped from an establishment without meeting the 30 percent fat limitation if a specific fat content is declared, e.g., \u201cCoarse Ground Beef Trimmings-40 percent fat beef.\u201d If the labeling terminology is \u201cCoarse Ground Beef\u201d or \u201cGround Beef\u201d, the 30 percent fat limitation shall apply. **COLORED CASING:** Colored casings on meat and poultry products which do not transfer color to the product, but which change and give a false impression of the true color of the products, must be labeled to indicate the presence of the casings. Acceptable terminology includes \u201cCasing Colored\u201d or \u201cArtificially Colored.\u201d These phrases must appear

contiguous to the product name. Casings which are the same color as the product and not misleading or deceptive, e.g., a white opaque casing on a summer sausage, do not have to be so labeled. Also, products consisting of whole muscle bundles, e.g., hams, pork butts, etc., packaged in colored wrappings where a cut surface is not visible through the casing are exempt. The color agent must be specifically identified on the label either in the product name qualifier or ingredient statement. See: Policy Memo 095 dated February 27, 1986 See: 9 CFR 319.15(d)

**COMPOSITE INGREDIENTS STATEMENT:** Processors who use a multi-ingredient product, e.g., pepperoni from various sources, as an ingredient, may identify all the ingredients that may be present from all the various formulations (i.e., a composite ingredients statement). However, the ingredients", "identified as those that may be present can only be those ingredients that are minor in nature and cannot include ingredients, e.g., the meat component that have a bearing on the overall characteristics or value of the product. The minor ingredients must be identified using one of the following examples of acceptable formats: 1. pepperoni (pork, beef, water, salt, spices, sodium nitrite. May also contain lactic acid starter culture, sugar, and sodium ascorbate). 2. bacon bits (cured with water, salt, dextrose and\or sugar, sodium nitrite). 3. pepperoni, pork, beef, water, sweeteners (contains one or more of the following: sugar, dextrose, fructose, corn syrup), salt, spices, sodium nitrite). Labeling records must identify all the ingredients of each type of component that is used so the accuracy of the composite ingredients statement can be determined. All labeling for meat and poultry products must either comply with this type of format or, alternatively, accurately list all ingredients used in the product. See: Policy Memo 072 dated May 18, 1984

**COOKED BEEF, EQUIVALENCY:** In lieu of fresh beef, a 70 percent yield figure is used if no yield information is provided. See: FSIS Directive 7124.1 Table 2

**COOKED BREAKFAST SAUSAGE:** Antioxidants are permitted when product is formulated on a raw basis (no more than 3 percent water).

**COOKED RED MEAT PRODUCTS CONTAINING ADDED SOLUTIONS:** Cooked corned beef products and cooked cured pork products not addressed by the cured pork products regulation (9 CFR 319.104, 319.105), that weigh more than the weight of the fresh uncured article, may be prepared if they are descriptively labeled to indicate the presence and amount of the additional substances.

Acceptable product names include: \u201cCooked Corned Beef and X % Water\u201d or \u201cCooked Cured Pork and Water Product, X % of Weight is Added Ingredients,\u201d and \u201cCooked Pastrami and Up to 20 % of a Solution.\u201d The ingredients of the solution may accompany the product name or appear in locations prescribed for ingredient statements. Product name prominence guidelines are found in Policy Memo 087A (on Word Size in Labeling of Product Names and Fanciful Names) and Policy Memo 109 (on Labeling Prominence Guidelines for Cured, Cooked Products with Added Substances That Do Not Return to Green Weight). If product name qualifiers, such as \u201cX % of Weight is Added Ingredients,\u201d are used, the labeling prominence guidelines used for cured pork products as found in 9 CFR 319.104(b) apply." , "Uncured red meat products that weigh more than the weight of the fresh article after cooking should be labeled with a qualifying statement indicating the amount of solution remaining after cooking, for example, \u201cAfter cooking, contains X % of a seasoning solution of . . .\u201d The ingredients of the solution may accompany the qualifying statement or appear in locations prescribed for ingredient statements. The qualifying statement must be one-fourth the size of the largest letter in the product name. If the ingredients of the solution accompany the qualifier, they must appear in print one-eighth the size of the most prominent

letter in the product name. Other labeling prominence guidelines are found in Policy Memo 087A (Word Size in Labeling of Product Names and Fanciful Names). If cooked, uncured red meat products that contain added solutions prior to cooking are cooked back to or below the weight of the fresh (green weight) article, words, such as \u201cseasoned\u201d and \u201cflavored,\u201d are to be used to reflect the addition of the added substances, for example, \u201cSeasoned Cooked Beef.\u201d For cooked products, the % added solution for the label statement is determined by subtracting the fresh (green) weight of the article from the weight of the finished cooked product, (that is, after injecting, marinating, etc., and cooking), dividing by the weight of the finished product, and multiplying by 100. This policy is intended to apply to solutions that impart favorable flavor and other sensory characteristics, but not to solutions containing ingredients used to extend a product, such as isolated soy protein and carrageenan. Nonstandardized, raw red meat products containing added solutions must comply with 9 CFR 317.2(e)(2). See: Policy Memo 084A dated November 30, 1994 (Cooked Red Meat Products Containing Added Substances) CORN DOG OR KORN DOG: A coined name which must be accompanied by a true product name, e.g., \u201cBatter Wrapped Franks on a Stick.\u201d Product is limited to 65 percent batter and a minimum of 35 percent frankfurter. CORN DOG OR KORN DOG (POULTRY): \u201cCorn Dogs\u201d made from poultry cooked sausage, e.g., poultry franks or poultry frankfurters, must show the \u201ckind\u201d of poultry used in conjunction with the coined name \u201cCorn Dogs,\u201d e.g., \u201cChicken (or Turkey) Corn Dogs.\u201d The \u201ckind\u201d name should be shown in type size at least one-third the size of the largest letter of the coined name. A descriptive name, e.g., \u201cBatter Wrapped Chicken Frank on a Stick,\u201d must accompany the coined name. If the descriptive name is at least one-third the size of the coined name, the \u201ckind\u201d name need not precede the coined name. See: Policy Memo 061A dated September 16, 1985", "CORN MEAL MUSH WITH BACON: Product must contain at least 15 percent cooked bacon. CORNED BEEF AND CABBAGE: Product must contain at least 25 percent cooked corned beef. CORNED BEEF (Canned, Cooked with Natural Juices): Canned product labeled \u201cCooked Corned Beef with Natural Juices,\u201d is limited to 10 percent added solution before cooking. If the added solution is greater than 10 percent, the label must indicate the total added solution, e.g., \u201cCooked Corned Beef and Water product-X percent of weight is added ingredients.\u201d See: Cooked Corned Beef Products With Added Substances CORNED BEEF, GRAY: Gray corned beef is not a cured product but one that contains water, salt, sugar, flavorings, etc. It should be labeled as \u201cGray Corned Beef,\u201d \u201cGray Corned Beef Rounds,\u201d etc. The label must show an ingredients statement rather than a curing statement as shown on other corned beef labels. CORNED BEEF WITH JUICES: Uncooked corned beef with juices (or without juices and spices) is unacceptable terminology for corned beef products meeting standards in 9 CFR 319.101 and 319.102 for corned beef brisket and corned beef round (and other cuts). The presence of free flowing juices in a package does not change this policy. The net weight includes free flowing juices. COTECHINO (IT): Pork skin sausage. Meat and meat by-products other than pork skin can be used in this product. It could also be given the name of pork skin sausage in parentheses as a common name. Italian sausage. A variety of cooked sausage. See: 9 CFR 319.140 COUNTRY: A geographical term that refers to an unincorporated area. To use country, the product must be made in the country.", "COUNTRY FRIED: Refers to a fried product that is usually breaded. It is not considered a geographical

term. COUNTRY OF ORIGIN: Statement, \u201cProduct of \u2026\u2026\u2026.\u201d need only appear beneath the product name on the Principal Display Panel on imported product.

COUNTRY STYLE CHICKEN: Cut up chicken in which the wishbone is left whole.

COUNTRY STYLE (FARM STYLE) SAUSAGE: When sausage products are labeled \u201cfarm style\u201d or \u201ccountry style,\u201d they must be prepared with natural spices with the exclusion of oleoresins, essential oils, or other spice extractives. Sugar is the sweetening agent for \u201cfarm style\u201d or \u201ccountry style.\u201d HVP, MSG, and antioxidants are permitted ingredients. Products so labeled are not necessarily prepared in the country (on the farm) but are expected to have these characteristics. See: 9 CFR 317.8(b)(2) Manual 19.3(a)

CREAMED BEEF (Chipped or Dried): Product must contain at least 18 percent dried beef. It may be produced using a cured beef, or beef product which has been chopped, pressed, or cooked.

CREAMED CHEESE WITH CHIPPED BEEF: Product consists of cream cheese, chipped beef, cream and chopped onions. The meat component must be at least 12 percent of the total formulation.

CREAMED SAUCE WITH MEAT OR CREAMED MEAT PRODUCTS (Chipped Beef, Cooked Beef, Sausage, Ham, Franks, Meatballs, Etc.): Product must contain at least 18 percent meat or meat products (on a cooked basis). The kind of meat product used should be reflected in the product name (e.g., \u201cCreamed Cured Beef, Chopped, Pressed, Cooked\u201d).

CREOLE STYLE: Term applies to many dishes made with tomatoes, spices, and green peppers. Spices include onion, garlic, bell pepper, white pepper, red pepper, black pepper, parsley, and other Louisiana seasonings, e.g., bay leaf, fil\u00e9, paprika, or pepper sauce." ,

"CREPE FILLING: Must contain at least 40 percent cooked meat or 20 percent cooked meat if filling has one other characterizing ingredient, e.g., cheese, and at least 14 percent cooked meat when the filling has two other characterizing ingredients, e.g., cheese and mushrooms. This is based on the total weight of the filling.

CREPES: Product must contain:

- At least 20 percent cooked meat when the filling contains no other major characterizing component.
- At least 10 percent cooked meat when the filling contains one other major characterizing component (e.g., cheese).
- At least 7 percent cooked meat when the filling contains two or more other major characterizing components (e.g., cheese and mushrooms).

These percentages are based on the total weight of the product.

CROISSANT: A crescent shaped roll requiring 18 percent cooked meat. Label must show a true product name, e.g., \u201cCroissant with a ham and cheese sauce filling.\u201d

CROQUETTE: Product must contain at least 35 percent cooked meat, based on total formulation. Beef, ham, etc., must appear as part of the product name.

CURDLAN: A substance identified by the common or usual name \u201ccurdlan\u201d has been approved for use in foods (see 12/16/1996 Federal Register), and for non-standardized meat products, poultry products, and in Policy Memo 123 and 121B products as a binder/stabilizer/thickener/texturizer.

CURED MEAT PRODUCTS -Labeling of Mechanically Reduced: The traditional names of cured meat products, e.g., bacon, may be used even though mechanical reduction-like chopping or chunking has taken place before the product has acquired the characteristics expected of the product, provided the finished product acquires the characteristics expected. Furthermore, the mechanical reduction must be", "noted in the product name or in a qualifier to the product name (e.g., chopped bacon or bacon-chopped and formed). See: Policy Memo 033 dated September 4, 1981

CURED MEAT PRODUCTS -Packed in Brine: Cured meat products, e.g., pork tails, pork snouts, and cured boneless beef brisket, that contain 120-200 PPM nitrite and are packed and sold in brine solution, do not require a

handling statement, e.g., \u201cKeep Refrigerated,\u201d provided the finished product has at least 10 percent brine concentration, and the packing medium contains a sufficient quantity of salt to maintain the 10 percent brine concentration in the product. CURED PORK BELLIES: Such products are assumed to be further processed into bacon. Therefore, cured pork bellies must meet the restricted ingredients requirement for bacon. CURED PORK: Cured pork products, that contain modified food starch, X percent solution ISP, carrageenan or sodium caseinate, that fall into the PFF value of \u201cHam, Water Added\u201d and the \u201cHam and Water product X percent solution\u201d category, must be labeled with the appropriate PFF Nomenclature, Descriptive Labeling, e.g., \u201cham, water and binder product,\u201d will be used if: 1. binders are at levels above those permitted by the regulations 2. binders other than those permitted are used 3. two or more binders are used in combination or 4. if the PFF value of the finished product falls in the \u201cham\u201d or \u201cham with natural juice\u201d category which do not permit binders. CURED TURKEY THIGH MEAT: A product labeled \u201ccured turkey thigh meat\u201d (without turkey ham in the name) must follow the turkey ham standard. The product \u201ccured turkey thighs\u201d (which includes skin and bone), is not required to meet the standards for turkey ham and cannot be labeled \u201cturkey ham.\u201d CURRIED SAUCE WITH MEAT (POULTRY) AND RICE CASSEROLE: Product must contain at least 35 percent cooked meat or poultry meat based on the sauce and meat portion only.", "CURRY PRODUCT: 1. Meat Curry-Must contain at least 50 percent meat (lamb, beef, etc.) 2. Poultry Curry-Must contain at least 35 percent cooked poultry meat. CUTLET, BEEF: Beef cutlet may be chopped and formed. CUTLET, PORK: \u201cPork Cutlet\u201d may consist of pork temple meat, inside masseter muscles, and small pieces of lean from the tip of pork jaws. These are flattened and knitted together in \u201ccutlet\u201d size products by means of \u201ccubing\u201d or \u201cFrenching\u201d machines, or by hand pounding with \u201ccubing hammers.\u201d The term \u201ccutlet\u201d relates to thin slices of meat. They can be identified as sliced pork meat product when the designation clearly states the specific part of the carcass from which the meat in the product is derived (e.g., \u201cPork Loin Cutlets\u201d). All of the terms should be conspicuously displayed on labels. CUTLET, POULTRY: Poultry cutlets may be fabricated as opposed to using whole pieces of poultry meat. However, the term \u201ccutlet\u201d must be properly and distinctly qualified to describe the product, e.g.: \u201cTurkey Cutlet From a Turkey Loaf\u201d \u201cChicken Cutlet From Chicken Roll\u201d \u201cTurkey Cutlet, Chopped and Formed\u201d Cooked poultry cutlets, which are solid pieces and contain added water, should not be labeled as patties. A solution statement is not needed. CUTLET VEAL: Must be a solid piece of meat from the round; slice thickness may vary. However, combining several thin slices to represent a single cutlet is not permitted. DEHYDRATED MEAT CALCULATION FACTOR: The fresh meat equivalent based on a given amount of dehydrated meat can be found by multiplying the weight of the dehydrated beef by the factor 2.8. This factor was derived as follows: Assuming cannery and cutters grade beef was used, the composition of meat would be approximately 12 percent fat, 18 percent protein, 69 percent water, and 1 percent ash. Then 100 pounds of beef, when dehydrated to 5 percent moisture, would be 100 less 64 or 36 pounds dehydrated meat. Thus, 100 divided by 36 equals 2.8.", "Assuming that the amount of dehydrated beef equivalent of 100 pounds of fresh beef is that quantity containing 18 pounds of protein, then 18 divided by the percentage of protein found by analysis of dehydrated beef would be the amount of dehydrated beef

equivalent to 100 pounds of fresh meat.

**DEHYDRATED POULTRY CALCULATION FACTOR:** The moist deboned cooked poultry or poultry meat equivalent based on a given amount of dehydrated poultry or poultry meat which can be found by multiplying the weight of the dehydrated poultry or poultry meat by the factor of 4.0.

**DEHYDRATED PRODUCTS WHEN WATER IS ADDED:** Three methods are acceptable for listing dehydrated products. Listing of the ingredients (1) As \u201cwater, dehydrated potatoes\u201d or \u201cdehydrated potatoes, water,\u201d whichever is the proper order, (2) As \u201creconstituted potatoes,\u201d or (3) As \u201crehydrated potatoes.\u201d If the reference was to meat instead of potatoes, the word beef, pork, or whatever was appropriate would be substituted for the word \u201cpotatoes.\u201d

**DEVILED POULTRY:** Is a semi plastic cured poultry food product made from finely comminuted poultry in natural proportions and containing condiments. Deviled poultry may contain poultry fat, provided that the total fat content shall not exceed 35 percent of the finished product and the moisture content shall not exceed that of the fresh unprocessed poultry. When skin is in excess of natural proportions, skin must be included in the product name (e.g. \u201cDeviled (Kind) with (Kind) Skin Added\u201d).

**DINNER DOG:** A coined name - must show true product name, e.g., \u201cA Meat and Soy Protein Concentrate Product.\u201d

**DINNERS AND SUPPERS, FROZEN:** Frozen products labeled as \u201cdinner\u201d or \u201csupper\u201d must weigh at least 10 ounces and shall contain at least 3 components consisting of the following: meat, poultry, cheese, eggs, vegetables, fruit, potatoes, rice or other cereal-based products (other than bread or rolls). This is not intended to include products like casseroles and stews that have all of the components combined. Sauces and gravies are not considered one of the components. They may also contain other servings of food, e.g., soup, bread or rolls, appetizer, beverage, and dessert, and these components may be included in the minimum 10-ounce net weight requirement. If meat is featured in the product name, e.g., Beef Dinner, the requirement is 25 percent or 2.5 ounces cooked meat. If a meat food product is featured in the product name, e.g., Beef Burgundy Dinner, then 25 percent or 2.5 ounces of meat", "food product is needed. If poultry is featured in the name, e.g., Chicken Dinner, the standard is 18 percent or 2 ounces cooked deboned poultry meat, whichever is greater. However, if a poultry food product is featured in the product name, e.g., Chicken a La King Dinner, the 25 percent or 2.5 ounces of poultry food product, whichever is greater, is needed. The meat requirement for products with net weights greater than 10 ounces may be established exclusive of the appetizer, bread, and dessert, provided the remaining components weigh not less than 10 ounces. The name for dinner and supper products shall consist of or include a listing of each of the dish components in descending order of predominance by weight, for example, Fried Chicken Dinner -Fried Chicken, Mashed Potatoes, Peas and Carrots. Dinner or supper identification may appear on side panels without the complete product name shown, for example, \u201cFried Chicken Dinner\u201d or \u201cBeef Dinner.\u201d When a dessert is one of the components of a frozen dinner or supper, i.e., a multicomponent item, it may appear out of the order of predominance in the product name and appear as the last component in the product name.

**DIXIE BACON:** True product name, e.g., \u201cPork Jowl Dixie Bacon, Cured and Smoked\u201d shall appear on the label.

**DIXIE SQUARE:** Same as for Dixie Bacon.

**DOG FOOD:** See: 9 CFR 355.29

**DOUGH CONDITIONER:** A generic or class name that cannot stand alone in the ingredients statement. The term \u201cDough Conditioner\u201d must be followed immediately by the common or usual name of all ingredients present."

**DRIED EGG**

**WHITE ADDED:** See: Wheat Gluten DRIED SOUP MIXES (MEAT): Dried meat soups are not amenable. Poultry -See: 9 CFR 381.15 **DRY AGED:** Fresh Meat is held (without vacuum packing) for various periods of time (usually 10 days to 6 weeks) under controlled temperatures (34o F to 38o F), humidity, and airflow to avoid spoilage and ensure flavor enhancement, tenderness, and palatability. There is a difference of opinion regarding the best cooler humidity. Some prefer low humidity of from 70 to 75 percent so that exposed surfaces of meat remain dry. Others use humidity\u2019s up to 85 to 90 percent in order to purposely develop a mold growth on the outside of the meat and reduce evaporation losses. Ultraviolet light may be used to reduce microbial load in the aging room. The number of days aged does not have to appear on the label when the product is identified as \"Dry Aged\" (e.g., \"Dry Aged Beef.\") **DRY CURED:** Product labeled as \"dry cured\" shall not be injected with a curing solution or processed by immersion in a curing solution. **DRY MILK PRODUCTS:** Approved dry milk items include whole dry milk, nonfat dry milk, calcium-reduced dried skim milk, dried whey and lactose-reduced dried whey. If nonfat dry milk is reconstituted prior to addition to product, it would be declared on the label as \"Reconstituted Skim Milk.\" **DRY SALT CURED:** Dry salt cured product may contain a curing solution injected directly into the tissue but not through the circulatory system before it is covered with a dry curing mixture. It may be momentarily moistened to facilitate initial salt penetration but cannot be immersed in a curing solution.", "DUAL WEIGHT REQUIREMENT FOR STUFFED POULTRY LABELS: Poultry products that consist solely of bone-in poultry and stuffing, e.g., a \"Stuffed Turkey,\" shall bear weight statements on the label indicating the total net weight of the product and a statement indicating the minimum weight of the poultry in the product. When a stuffed poultry product is a component of a dinner or an entree, only the total net weight needs to be shown on the label. See: Policy Memo 018A dated December 26, 1985 **DUCK, SALTED:** This product should reach an internal temperature of 155o F. **DUMPLINGS WITH BEEF:** The product must contain at least 18 percent meat in total formulation. **DUTCH BRAND LOAF:** A nonspecific loaf that must be qualified as \"Made in USA.\" **EASTER NOLA:** Salami that is made with pork that is coarsely chopped and mildly seasoned with black pepper and garlic. **EGG FOO YOUNG WITH MEAT:** The product must contain at least 12 percent meat. **EGG FOO YOUNG WITH POULTRY:** The product must contain at least 3 percent poultry meat. **EGG ROLL, VIETNAMESE STYLE:** The product must contain soy bean noodles or cellophane noodles, and fish sauce or anchovy extract. They are usually rolled in a thin spring roll skin or a dry rice paper skin. **EGG ROLL WITH MEAT:** The product must contain at least 10 percent meat.", "EGG ROLL WITH POULTRY: The product must contain at least 2 percent poultry. **EGGS BENEDICT:** The product must contain at least 18 percent cured smoked ham. A poached egg on a toasted English Muffin, topped with a slice of ham, and covered with hollandaise sauce. **EGGS, FRESH:** For breakfast-type foods the egg portions may be referred to in the product name and the ingredients statement as \u201cFresh U.S. Grade A Large.\u201d The eggs must be received in shells or broken and blended and not in dry or frozen form. **EMPANADILLAS (SP):** A turnover containing 25 percent fresh meat or poultry (raw basis). The species or kind is part of the product name, e.g., \u201cBeef Empanadillas.\u201d The product may vary in size from large to hors d'oeuvre size. **EMPANADILLAS CHORIZO:** An empanadilla that contains at least 25 percent fresh chorizo or 17 percent dry chorizo. **ENCAPSULATION:** An encapsulated additive, e.g., salt is an acceptable name. It does not require a sublisting if encapsulated in vegetable oil. If encapsulated in an

animal fat, the specific animal fat must be identified in the ingredient statement. Encapsulated lactic acid starter culture does not need to be sublisted.

**ENCHILADA (SP):** The product must contain at least 15 percent meat or 10.5 percent poultry meat. A Mexican type food consisting of a tortilla which has been filled with a variety of fillings and then rolled. The species must appear in the product name, e.g., Beef Enchilada.

**ENCHILADA WITH BEEF CHILI GRAY OR ENCHILADA PREPARED WITH MEAT AND SAUCE:** The product must contain at least 50 percent Enchilada.

**,"ENCHILADA -Sonora Style:** The product consists of two or more tortillas stacked pancake style with filling spread between each tortilla. Cheese may be mixed into the tortilla dough prior to frying.

**ENTREE (Principal Dish or Main Course):** Product labeled entree should fall into one of the following categories:

1. All meat or meat food product -100 percent meat or meat food product.
2. Meat or meat food product and one vegetable; or meat or meat food product and gravy -50 percent cooked meat or meat food product.
3. Meat and Vegetable with Gravy -30 percent cooked meat portion; meat and gravy portion at least 50 percent, (e.g., Salisbury Steak with Potatoes and Gravy).
4. Meat or Entree portion of a meal type products -25 percent cooked meat or meat food product, (e.g., Meat Loaf Dinner would require 25 percent meat loaf).

**ENZYME TREATED PRODUCT:** Product from carcasses of animals injected with papain; liver, heart, tongue, cheek and head meat, trimmings, boneless beef, tenderloin, tails, tripe and cuts of meat not showing an imprint of the roller brand reading, tenderized with papain, shall be properly identified and kept separate from other product. Kidneys must be segregated and properly labeled. When such product leaves an official establishment, the immediate container shall bear a label showing, in addition to the other required labeling, a statement like tenderized with papain prominently displayed contiguous to the product name. The establishment will furnish retail dealers handling such product with labels bearing the statement, tenderized with papain prominently displayed contiguous to the product name for use by such dealers on consumer packages or on product prepared from carcasses of animals injected with papain. Inspection personnel visiting retail markets should observe the effectiveness of this requirement. When retail outlets do not follow this identification, these facts should be immediately reported to the Food Labeling Division.

**ENZYME TRIMMINGS FROM ANTE-MORTEM INJECTED BEEF:** Beef trimming from this operation may be used in fresh meat products without label declaration.

**,"ENZYMES -PROTEOLYTIC:** A 3 percent limit permitted pickup on dipped items, e.g., steak and solid pieces of meat. The label must declare the presence of the enzyme, e.g., Tenderized with Papain.

**,"u201d Trimmings from this method may be used in fresh meat products up to 25 percent of the formula, provided the finished product is immediately frozen and that distribution is limited to institutional use only.**

**The labeling record should state the conditions and means of inspection control.** Meat from this method may be used in cooked ground beef products up to 25 percent of the formula without showing the ingredients of the solution. See: 9 CFR 317.8(b)(25) 9 CFR 424.21 9 CFR 381.120

**EXOTIC\NON-AMENABLE PRODUCTS-USE OF CURE AGENTS:** Only amenable meat\poultry products can contain curing agents (i.e., nitrites etc.), with the exception of ratites (ostrich, rhea, emu) and squab. The prior function of nitrite and nitrate, according to FDA regulations, applies only to those species that were considered meat\ or \cpoultry\ prior to September 1958. Therefore, amenable species that can contain cure agents are identified as the following:

1. Poultry \u2013 (domesticated birds) chicken, turkey, duck, geese,

and guineas. 2. Meat \u2013 cattle, sheep, swine, and goat. Non-amenable products, such as buffalo, reindeer and pheasant, can not contain curing agents; such products are considered to be regulated under FDA regulations. However, if non-amenable products are included in an amenable product, curing agents would be permitted. The curing agents would be calculated based on both the amenable meat\poultry product and non-amenable meat\poultry product. For example, the formula includes 3 lbs. Cooked chicken and 97 lbs. buffalo. The calculation for the curing agents would be based on 100 lbs. of meat. In addition, in those situations where the meat block consists of an amenable product and a nonamenable product (refer to the example), the appropriate inspection legend should represent the amenable product. Therefore, using the example above, the label would have a poultry legend. Product derived from exotic\non-amenable species that contain over 3 percent raw meat (cattle, sheep, swine, goat, horses or other equine) are subject to inspection. The game meat used in these products must be derived from carcasses slaughtered under the Food Safety and Inspection Service. Products made with meat from exotic and non-amenable exotic species with 3 percent or less of meat or edible portion from cattle, sheep, swine, goat, horses or other equine, or up to 30 percent fat from these species are non-amenable provided the only reference to meat or meat byproducts on the labeling is in the statement of ingredients and the product name includes the term \u201cflavored with (amenable species).\u201d",---- Custom prepared products composed of meat from exotic\Nonamenable species and up to 30 percent animal fat are not amenable. Labeling such products with the term applies (see: 303.1 (a) (2)). Products made with meat from game animals with 3 percent or less of meat or edible portion from cattle, sheep, swine, goat, or up to 30 percent meat fats provided the only reference to meat or meat byproducts on the labeling is in the statement of ingredients or referred to as \u201cflavored with.\u201d Custom prepared products composed of meat from game animals and up to 30 percent animal fat. Labeling \u201cNot For Sale\u201d applies. See: 303.1 (a)(2) Buffalo and venison must be federally or state inspected; however, venison may also be produced under the supervision of inspection officials of a country approved to export meat products into the United States. All other meat from exotic\Nonamenable species that is used in formulating amenable products must be derived from carcasses slaughtered under the Food Safety and Inspection Service. EXTRA AND MORE THAN: The terms \u201cextra\u201d or \u201cmore (component) than\u201d may be used provided the following guidelines are followed: (1) There is at least a 10 percent increase in the particular component of interest over the amount that is found in the usual or \u201cregular\u201d formulation. (2) Information must be provided with the label application that compares the product formulation containing the \u201cextra\u201d amount of the component to the regular formulation of the same product to establish that at least a 10 percent increase in the component has occurred. Therefore, the usual or \u201cregular\u201d component claims at the time of label review must be presented so that the necessary comparison of formulations can be made. (3) In the situation where production of the \u201cregular\u201d product formulation ceases, the \u201cextra\u201d or \u201cmore (component) than\u201d product labels would be given a 6-months temporary approval. (4) A comparison to a similar product on the market may be made to support the \u201cextra\u201d or \u201cmore\than\u201d type claim, provided suitable market basket data are submitted with the label application that establish the similarity of formulations and show the increased amount of the component over the \u201cusual\u201d amount. See: Policy

Memo 118 dated October 31, 1988", "FABRICATED STEAK: 1. Steaks that include large sections or pieces of meat that are molded or shaped to form one large piece and then sliced. A qualifier such as \u201cformed\u201d must be included in the product name. 2. Raw fabricated steaks with added solutions must be labeled in accordance with 9 CFR 317.2(e)(2). 3. Antioxidants are permitted. 4. When made from simulated fat covering and or marbling, the product name must contain a truthful descriptive designation, for example, \u201cartificially marbled-simulated fat covered beef steak.\u201d FAJITAS: The Spanish translation is \u201clittle belts\u201d or strips of meat. Fajitas are strips of seasoned or marinated red meat or poultry meat, which have been cooked. Red Meat Fajitas require labeling in accordance with the current policy memo for cooked red meat with added solutions (Policy Memo 084A). Fajitas may also be sandwich-like product, requiring 15 percent strips of cooked meat or poultry meat (excluding the solution above green weight), topped with onions, peppers, and sauce, and rolled in a flour tortilla. Fajita, including the name of the meat or poultry, may stand alone, for example, \u201cBeef Fajita,\u201d \u201cChicken Fajita.\u201d Raw meat or poultry strips with added solutions must be labeled in accordance with 9 CFR 317.2(e)(2) or 9 CFR 381.117(h), and identified as \u201c...for fajitas\u201d, for example, \u201cbeef strips containing 10% of a solution of water, salt, spices, and spice extractives for fajitas.\u201d FARM STYLE SAUSAGE: See: Country Style (Farm Style) Sausage FARMER SAUSAGE CERVELAT: Is usually a semi-dry sausage; but may be made in dry form. Usually made of equal parts of pork and beef delicately seasoned without garlic. FARMER SUMMER SAUSAGE: This is a special type of sausage made of beef and pork, salt, spices, nitrite or nitrate, and heavily smoked. It is classed as \u201cCervelat,\u201d and no extenders are permitted. It is dry with an MPR of 1.9:1. The word \u201cFarmer\u201d is considered a generic term, and labels can be approved without any qualifying words like \u201cStyle\u201d or \u201cBrand.\u201d Such labels are not required to bear a statement identifying the place of manufacture. The Product must be trichina-treated. FIBER PRODUCTS: Fiber products such as bran are acceptable only in non specific products.", "Fiber type foods are permitted in meat and poultry products and must be identified by their common or usual name, such as oat bran. However, fiber is not permitted in meat or poultry products, e.g., soy fiber, oat fiber, and wheat fiber. Presently, there is no recognized definition for fiber. FILLET STYLE: \u201cFillet style\u201d must be qualified, e.g., \u201cchunked and formed,\u201d if the meat or poultry product is not made from a solid piece of meat or poultry. The term \u201cfillet\u201d is defined as a solid piece of meat or poultry. FLANKEN IN THE POT: The product must contain at least 25 percent beef. Product is made from beef plates and may contain such components as Matzo Balls, Noodles, and Vegetables. True product name, e.g., \u201cFlanken in the Pot with Matzo Balls, Noodles and Vegetables\u201d must be used. FLAVORED WITH --: Any product with a standard in Section 9 CFR 319 and 9 CFR 381 of the regulations must meet that standard and may not be designated \u201cflavored with.\u201d If a product does not meet the standard as it appears in the Policy Book it can be labeled \u201cFlavored with.\u201d \u201cFlavored with\u201d can be anything from over 3 percent fresh meat or 2 percent cooked meat to below the standard for the product. FLAVORING: Ingredients, e.g., thiamine hydrochloride, monosodium glutamate, disodium inosinate, disodium guanylate, hydrogenated vegetable oil, and other commonly used materials must be listed separately. Such ingredients as diacetyl, hexanal, ethyl alcohol, dimethyl sulfide, diallyl sulfide, and furfuryl mercaptan may be declared as artificial flavors or artificial flavorings

without naming each. When spices and\or flavorings are presented on labels coming from foreign countries, the identity of the spices and\or flavorings must be made known.

**FOIE GRAS PRODUCTS, DUCK LIVER AND\OR GOOSE LIVER:** Goose liver and duck liver foie gras (fat liver) are obtained exclusively from specially fed and fattened geese and ducks. Products in which foie gras is used are classified into the following three groups based on the minimum duck liver or goose liver foie gras content:","

**(A) FRENCH PRODUCT NAME ACCEPTABLE ENGLISH PRODUCT NAME** Foie Gras d'Oie Entier Whole Goose Foie Gras Foie Gras de Canard Entier Whole Duck Foie Gras These are products in which goose liver or duck liver foie gras are the only animal tissues present. They may contain added substances, e.g., seasonings and cures and when truffles are featured in the product name, they are required at a minimum 3 percent level.

**(B) FRENCH PRODUCT NAME ACCEPTABLE ENGLISH PRODUCT NAME** Foie Gras D'Oie Goose Foie Gras Foie Gras de Canard Duck Foie Gras Bloc de Foie Gras D'Oie Block of Goose Foie Gras Bloc de Foie Gras de Canard Block of Duck Foie Gras Parfait de Foie Gras D'Oie Parfait of Goose Foie Gras Parfait de Foie Gras de Canard Parfait of Duck Foie Gras These products are composed of a minimum 85 percent goose liver or duck liver foie gras, although \u201cparfaits\u201d may contain mixtures of goose liver and\or duck liver foie gras. These products may also contain a wrapping or stuffing consisting of the lean or fat of pork, veal, or poultry, pork liver, and\or aspic jelly. When these ingredients are used, their presence must be indicated in a product name qualifier. Truffles, when featured in the product name, are required at a minimum 3 percent level.

**(C) FRENCH PRODUCT NAME ACCEPTABLE ENGLISH PRODUCT NAME** Pate de Foie D'Oie Pate of Goose Liver Pate de Foie de Canard Pate of Duck Liver Galantine de Foie D'Oie Galantine of Goose Liver Galantine de Foie de Canard Galantine of Duck Liver Puree de Foie D'Oie Puree of Goose Liver Puree de Foie de Canard Puree of Duck Liver These products must contain a minimum of 50 percent duck liver and\or goose liver foie gras and may also contain a wrapping or stuffing of the lean or fat of pork, veal, or poultry, pork liver, aspic jelly, extenders, and\or binders. When these ingredients are used, their presence must be indicated in a product name qualifier. Truffles, when featured in the product name, are required at a minimum 1 percent level.","

-- In all groups, an English translation of the term \u201cfoie gras\u201d is not required, although all other product name terms must be translated into English. The kinds of poultry liver(s) used must be indicated in the product name. Also, other species and\or binders used must be indicated in a product name qualifier immediately following the product name, while the ingredients statement must follow the product name or qualifier as the case may be. See: Policy Memo 076 dated September 21, 1984

**FOR FURTHER PROCESSING:** Products that require further processing at another federally inspected plant may leave a federally inspected plant under one of the following conditions: 1. With the name of the finished product qualified by a \u201cFor Further Processing\u201d statement (for example, \u201cTurkey Ham For Further Processing\u201d); or 2. With a fully descriptive name. (for example, uncooked ham contains up to 30% of a solution of water, salt, sodium erythorbate, and sodium nitrite) \u201cFor Further Processing\u201d is not acceptable on a label when a product is formulated or processed in a manner contrary to the regulations.

**FRESH,\u201d \u201cNOT FROZEN\u201d AND SIMILAR TERMS WHEN LABELING MEAT AND POULTRY PRODUCTS:** The word \u201cfresh\u201d may not be used to describe: 1. Any cured product, e.g., corned beef, smoked cured turkey, or prosciutto. 2. Any canned, hermetically sealed shelf stable, dried, or chemically preserved product. 3. Any raw poultry, poultry part, or

any edible portion thereof whose internal temperature has ever been below 26 degrees Fahrenheit. 4. Any injected, basted, marinated poultry, poultry part or any edible portion thereof whose internal temperature has ever been below 26 degrees Fahrenheit. 5. Any other finished processed poultry product (including cooked poultry products) where its temperature has ever been below 26 degrees Fahrenheit, e.g., turkey sausage, chicken meatballs, cooked breaded chicken nuggets, etc. 6. Any uncured red meat product permitted to be treated with a substance that delays discoloration, such as, ascorbic acid, erythorbic acid, or citric acid. 7. Any product treated with an antimicrobial substance or irradiated.", "8. The phrase \u201cnever frozen\u201d or similar verbiage is not permitted on an unprocessed or processed poultry product where the internal temperature of the product has ever been below 0 degrees Fahrenheit or on any red meat product that has ever been frozen. Further, the phrase \u201cnever frozen\u201d or similar verbiage is not permitted on refrigerated secondary products where the meat or poultry component has ever been frozen, e.g., multi-component meals, dinners, etc. Generally, trademarks, company names, fanciful names, etc., containing the word \u201cfresh\u201d are acceptable, even on products produced in a manner described in one through seven above, provided the term is used in such a manner that it remains clear to the purchaser that the product is not fresh. Secondary products, e.g., pizza, multi-component meals, dinners, etc., sold in the refrigerated state, i.e., not frozen or previously frozen, may be labeled as \u201cfresh\u201d when the term is used to describe the product as a whole even when made from components processed in a manner described in one through seven above. This entry cancels Policy Memo 022C dated January 11, 1989, since 022C is out of date.

**FRESH THURINGER:** Not an acceptable name.

**FRIED NOODLES WITH PORK:** The product must contain at least 12 percent fresh pork in total formulation.

**FRIED PRODUCTS:**

1. Frying medium need not be shown on the label.
2. Breading is not limited to 30 percent unless breaded is in the product name.
3. Fried chicken labels do not need to state \u201cfully cooked\u201d or refer to breading because fried denotes fully cooked and breading is expected. Fried poultry products in dinners are limited to 30 percent breading.

**FRIED RICE WITH MEAT:** The product must contain at least 10 percent meat; may contain eggs and vegetables.

**FRIES:**

1. Beef testicles may be labeled as \u201cBeef Fries.\u201d They are not permitted to be used as an ingredient in meat food products.
2. \u201cFries\u201d is not a required part of the product name, \u201cspecies mountain oyster.\u201d

**FRITTERS:** The product must contain at least 35 percent raw red meat\poultry or red meat\poultry food product in the total formulation depending on the name, i.e., \u201cBeef Fritter\u201d must contain 35 percent beef and a \u201cChicken Patty Fritter\u201d must contain 35 percent chicken patty. Fritters can contain up to 65 percent batter\breading (coating). If \u201cbreaded\u201d is included in the product name, the batter\breading is limited to 30 percent. See: Policy Memo 089 dated May 29, 1985

**FRIZZES:** An acceptable name. Similar to pepperoni but not smoked. MPR of 1.6:1.

**GALICIAN SAUSAGE:** Cured beef and pork is seasoned and stuffed into beef rounds. It is then smoked at a high temperature. Cooling is done in a blast of air which produces a wrinkled appearance which is characteristic of Galician sausage.

**GELATIN:** Gelatin is a binder\extender and is only permitted in a few meat and poultry products. Examples where gelatin is permitted include:

1. non-specific products
2. jellied products, e.g., souse, jellied beef loaf and head cheese
3. as a covering for products such as pat\u00e9, to bind two pieces of meat together and in products where \u201cgelatin\u201d would be part of the product name

Gelatin is permitted as a

thickening agent in menudo (i.e., beef tripe stew). If it is used in red meat pat\u00e9 products, its presence must be indicated by product name qualification. It is not permitted in products like sausage, luncheon meat, and meat loves. Gelatin is an acceptable ingredient in souse, jellied beef loaf, headcheese, canned whole hams requires qualifier if gelatin is added. See: MPI Manual 18.19 (b)(2) See: Policy Memo 121B GELATIN IN POULTRY ROLLS: If gelatin or some other binder comprises more than 3 percent of the formula, the name of the product must be qualified by wording, e.g., \u201cGelatin Added.\u201d See: MPI Manual 18.19 (b)(2)"GENERAL OFFICES: The company\u2019s grant of inspection permits the general office address to be used in the signature line for any firm \u201cdoing business as.\u201d GENOA OR GENOA SALAMI: Is a dry sausage product with an MPR not in excess of 2.3:1. It is prepared with all pork or with a mixture of pork and a small amount of beef. The meat is given a coarse grind and enclosed in a natural casing. No smoke is used in its preparation. GEOGRAPHIC AND RELATED TERMS (REQUIREMENTS FOR THE USE ON PRODUCT LABELS): Any label representation that expresses or implies a particular geographical origin of the product, or any ingredient of the product, shall not be used except when such representation is: 1. A truthful representation of geographical origin, e.g., \u201cVirginia Ham\u201d for a ham produced in the State of Virginia; or 2. A trademark or trade name which: a. has been so long and exclusively used by a manufacturer or distributor that it is generally understood by consumers to mean the product of the particular manufacturer or distributor, e.g., \u201cSwiss Chalet;\u201d or b. is so arbitrary or fanciful that it is generally understood by the consumer not to suggest geographical origin, e.g., \u201cMoon Sausage;\u201d or 3. A part of the name required or allowed by an applicable Federal law, regulation or standard, e.g., \u201cFrankfurter,\u201d \u201cVienna;\u201d or 4. A name whose market significance is generally understood by consumers to connote a particular class, kind, type or style of product, or preparation rather than to indicate geographical origin of the product, e.g., \u201cMexican Style Dinner,\u201d \u201cItalian Style Pizza.\u201d Such terms must be qualified with the word \u201cstyle\u201d or \u201ctype,\u201d unless specifically approved by the Administrator as a generic term, e.g., \u201cLebanon Bologna,\u201d \u201cGenoa Salami,\u201d \u201cMilan Salami.\u201d Any geographical representation that does not meet the aforementioned guidelines should be qualified by the word \u201cbrand,\u201d provided that the word \u201cbrand\u201d is not used in such a way as to be false or misleading. A qualifying statement identifying the place where the product was actually made is required in proximity to the brand name, e.g., \u201cMilwaukee Brand Bacon, Made in Chicago, Illinois.\u201d The word \u201cBrand\u201d must be in the same size", "and style of type as the geographical term. If the product has a foreign brand name, it may be identified as having been made in this country, e.g., \u201cScandinavian Brand Bacon, Made in U.S.A.\u201d. See: Policy Memo 068 dated February 9, 1984 GEOGRAPHIC TERMS: 1. Country, Ranch, and Farm in Trade, Branch and Fanciful Names: Trade names, brand names, or fanciful names that include the words country, ranch, or farm, e.g., \u201cCountry Kitchen,\u201d \u201cRanch House,\u201d \u201cHickory Farms,\u201d or \u201cCarabeef Ranch Brand\u201d do not invoke section 9 CFR 317.8 of the regulations regarding the use of the term \u201cCountry\u201d or \u201cFarm\u201d. However, if the terms are used alone in conjunction with the product name, e.g., \u201cCountry Stew,\u201d then such products must be prepared in the country or on the ranch or farm and meet any other requirements prescribed. 2. Southern: The term

\u201cSouthern\u201d is restricted to use only in areas south of the Mason-Dixon Line and east of the Mississippi River as well as Arkansas, Louisiana, and Missouri, which are also considered southern states. GERMAN POTATO SALAD WITH BACON: The product must contain at least 14 percent cooked bacon in total formulation. See: Salad-German Potato Salad

GERMAN SAUSAGES WITH MILK: Whole milk is a permitted ingredient in the following meat food products when the ingredients statement is shown immediately under the name of the product or the milk is shown in a qualifying statement contiguous to the product name: Speckblutwurst, Kalbsbratwurst, Langblutwurst, Blutwurst, Gelbwurst, Zengenwurst, Brand Tongue and Blood Pudding Kalbslebenwurst. (Swiss Liver Sausage, Kalbslebenwurst should be considered on the same basis as Bockwurst (e.g., no limit on water or milk)). Milk is a characterizing ingredient in German sausages and not an extender. Products which contain milk should be called by their proper names.

GIBLET GRAVY (Kind): Requires 7.25 percent giblets. The product must contain an equal number of livers, hearts, and gizzards." "GIBLETS AND\OR NECKS SOLD WITH CARCASSES: Poultry giblets consist of approximately equal numbers of hearts, gizzards, and livers, as determined on a count basis. Rabbit giblets consist of the liver and heart. Although often packaged with them, the neck is not a gibblet. Gibblet packs are expected within the cavities of eviscerated whole birds or eviscerated whole rabbits or when packaged with cut-up whole birds or cut-up whole rabbits, therefore, qualifying the presence of giblets is not required on labeling. However, when giblets are not expected, a product name qualifier is required, e.g., \u201cPacked with Giblets.\u201d In situations where parts of giblets are missing, a product name qualifier is required, e.g., \u201cParts of Giblets Missing\u201d or \u201cParts of Giblets May Be Missing.\u201d In situations where the giblets are missing entirely from an eviscerated carcass or a cut-up whole carcass, a product name qualifier is required, e.g., \u201cPacked Without Giblets.\u201d In addition, an excess of one of the gibblet components can not be added to make up for another missing gibblet component. In this case, a proper qualifying statement is required, e.g., \u201cPacked with 2 Gizzards, 1 Liver.\u201d A neck, when not attached to the carcass of a whole bird, is also expected to be present within the carcass or packed with the cut-up whole carcass. Accordingly, a product name qualifier is not required to flag the presence of the neck. Rather, when the neck is missing, a product name qualifier is required, e.g., \u201cWithout Neck.\u201d See: 9 CFR 381.170 (b) (21) and 9 CFR 354.

(m) GLYCERIN: May not be added to any product as such; may be used in proprietary mixes.

GOETTA: An oatmeal product similar to scrapple. Goetta is prepared with a formula containing not less than 50 percent meat and meat byproducts. The cereal component should consist of oats or oat products and just enough water to prevent product from sticking and burning", "during the preparation process. The term \u201cOld Fashioned\u201d when noted on a label for \u201cGoetta\u201d refers to the round shape.

GOETTINGER CERVELAT: A dry cervelat with no byproducts or binders.

GOOSE LIVER OR GOOSE LIVER SAUSAGE: At least 30 percent cooked goose liver. When pistachio nuts are added, product name must be qualified, i.e., \u201cpistachio nuts added.\u201d

GORDITAS, MEAT\POULTRY: The product must contain at least 15 percent cooked meat\poultry based on the weight of the total product. The \u201cspecies\u201d or \u201ckind\u201d gorditas name (Beef Gordita, Chicken Gordita) may stand alone. If other characterizing ingredients such as potatoes, rice, beans, etc, are included in the name, they must be reflected in their order of predominance, e.g., Beef and Potato Gorditas, Rice and Chicken Gorditas, as determined by the formula.

GOTEBORG: A Swedish dry

sausage made of coarsely chopped beef and sometimes pork. Mildly seasoned with thyme. It has a somewhat salty flavor and is heavily smoked, usually in long casings and air dried.

GOTHAER CERVELAT: Originated in Gotha, Germany. Usually made of very lean pork finely chopped and cured. GOULASH: A stew-like product with at least 25 percent meat or 12 percent poultry meat. Unless designated "Hungarian," generally means stew, whether veal, pork, beef, turkey, etc., are used. Product may be just meat and gravy or meat and gravy with vegetables served with or without rice, potatoes, or noodles. GOULASH, HUNGARIAN STYLE: The product must contain paprika and at least 25 percent meat or 12 percent poultry meat. May not contain noodles, potatoes or dumplings.", "GRADE MARKS: Labeling of grades on species that are not officially graded, that reference US, USDA, or enclosed within an official shield, are not permitted (e.g., "USDA Choice pork," or "US Prime pork") statements are not allowed because pork product is not graded). However, official grade names may be used for non-graded species products, provided they do not reference US, USDA, or are enclosed in or near an official grade shield. For example, Prime Ham or Choice Pork Shoulder. Grade marks for products imported from foreign countries can only use that country's grading system. Foreign countries cannot use USDA, AMS grading terminology, i.e., prime, choice, select on foreign product entering or processed in the U.S. The grading term "good" on poultry is considered puffery and is acceptable. Meat (beef, veal, and lamb) grading terms, "prime," "choice," "select," may not be used immediately preceding "kind" poultry, unless the poultry is equivalent to USDA Grade A. For example, "Choice Turkey" or "Select Chicken" must come from Grade A birds. Graded product labeled as "Select or Higher" "Choice or Higher" are only allowed on wholesale labeled product, not on retail. Product intended for retail can only be labeled with one specific grade e.g., "Choice" product in a Choice retail package." GRAVIES: The product must contain at least 25 percent meat stock or broth, or 6 percent meat. Mono and diglycerides allowed in amount of 1 percent in gravies. GRAVY AND BEEF: The product must contain at least 35 percent cooked beef (beef same size lettering as gravy). For 25 percent cooked beef (beef lettering no larger than one-half size gravy). GRAVY AND DRESSING WITH PORK OR GRAVY AND PORK WITH DRESSING: The product must contain at least 14 percent cooked pork. GRAVY AND POULTRY SALISBURY STEAK: Not more than 65 percent gravy and at least 35 percent poultry salisbury steak. GRAVY AND SWISS STEAK: The product must contain at least 35 percent cooked meat. GRAVY AND YANKEE POT ROAST: The product must contain at least 35 percent cooked beef. Beef is cooked with or without vegetables.", "GREEK SAUSAGE: The product must contain orange peel. GROUND BEEF: May not contain added fat. Maximum total fat 30 percent. Cheek meat is permitted up to 25 percent and must be declared in the ingredients statement. For more than 25 percent, show as "Ground Beef and Cheek Meat," all the same size. Beef of skeletal origin, or from the diaphragm or esophagus (weasand) may be used in the preparation of chopped beef, ground beef, or hamburger. Heart meat and tongue meat as organ meats are not acceptable ingredients in chopped beef, ground beef, or hamburger. See: Policy Memo 027 dated June 15, 1981 GROUND BEEF CHUCK AND ROUND: Product to be labeled "Ground Beef Chuck" or "Ground Beef Round" must comply with the following guidelines:

1. "Ground Beef Chuck" must be derived from all or part of the primal part of the beef carcass commonly referred to as the "Beef Chuck" except as provided for in 3.

The product must comply with the fat requirements of 9 CFR 319.15(a). 2. \u201cGround Beef Round\u201d must be derived from all or part of the primal part of the beef carcass commonly referred to as the \u201cBeef Round,\u201d except as provided for in 3. The product must comply with the fat requirements of 9 CFR 319.15(a). 3. Generally, shank meat may be added but may not exceed the natural proportion of the beef carcass, which is considered to average 6 percent. Higher quantities of shank meat may be used if the shank meat remains attached during the cutting and boning of the boneless chuck or round, or if the processor can demonstrate that a higher percentage is applicable. See: Policy Memo 091 dated September 16, 1985 GROUND BEEF -Hamburger and Soy Products: Combinations of ground beef or hamburger and soy products may be descriptively labeled, e.g., \u201cHamburger and Textured Vegetable Protein Product\u201d or \u201cGround Beef and Isolated Soy Protein Product\u201d if the combination product is not nutritionally inferior to hamburger or ground beef. If the combination products are nutritionally inferior, they are to be labeled as Imitation Ground Beef (or Imitation Hamburger) or Beef Patty or Beef Patty Mix in accordance with Section 9 CFR 317.2(j)(1) and Section 9 CFR 319.15(c) respectively. See: Policy Memo 016B dated August 18, 1994", "GUM ARABIC: May be used up to 2 percent in breading and batter mixes. GUM TRAGACANTH: A carrier and stabilizer in liquid spice extractives not to exceed 0.1 percent in finished product. Not permitted in sausage products. GUM-Vegetable: Spice extractive products which employ vegetable gums as emulsifiers have been approved. The addition of vegetable gum is limited to no more than 15 percent in the seasoning blend emulsion. GUMBO: A Creole word for okra. It is now recognized as meaning a dish or a soup thickened with okra. To qualify, the dish must have okra as an ingredient. Either the soup or the stew standard would apply, depending on product name (\u201cChicken Gumbo\u201d). Product identified as \u201cCreole Style Gumbo\u201d does not contain okra, however, it must contain a roux (flour, milk, or water, etc.) or gumbo file (dried powder young leaves and leaf buds of sassafras). GYROS: Products identified with this term must contain at least 65 percent meat and no more than 12 percent extenders and binders. Examples include gyro loaf, gyro cone, gyro portions, and gyro slices. HALAL AND ZABIAH HALAL: Use of the terms, \u201cHalal and Zabiah Halal\u201d on labeling requires certification by an appropriate third party authority. HAM A LA KING: Must contain at least 20 percent ham (cooked basis). HAM AND BACON LOAF: There is a limit of 3 percent water in this product.", "HAM AND CHEESE LOAF: Nonspecific loaf. Cheese is chopped into small cubes and combined with finely ground ham. HAM AND CHEESE SALAD: Product must contain at least 25 percent ham (cooked basis). See: Salads HAM AND CHEESE SPREAD: Product must contain at least 25 percent ham (cooked basis). HAM AND DUMPLINGS AND SAUCE OR GRAVY: Product must contain at least 18 percent cooked ham. HAM, BOILED: A fully cooked, boneless product which must be cooked in water and may be processed in a casing or can. The product may be of various shapes and may be partially cooked in boiling water. HAMCOLA: Not an acceptable product name; should be accompanied by true product name, i.e., \u201cBoneless Cooked Ham Coated with Spices.\u201d HAM CAPACOLLA, COOKED: Ham that has been cured and then cooked. HAM CHOWDER -CONDENSED: Product must contain at least 10 percent cooked ham. HAM-COOKED-SECTIONED AND FORMED: The qualifying phrase \u201csectioned and formed\u201d is no longer required on boneless ham products, e.g., \u201cham\u201d and \u201cham-water added.\u201d The addition of small amounts of ground ham added as a binder to such products may be used without declaration.

The amount of ground ham that may be used can represent no more than 15 percent of the weight of the ham ingredients at the time of formulation. Products containing more than 15 percent ground ham trimmings must be labeled to indicate the presence of the ground ham, e.g., "\u201ca portion of ground ham added.\u201d Policies regarding the required use of terminology such as \u201ccunked and formed\u201d and \u201cground and formed\u201d will continue. See: Policy Memo 023 dated February 10, 1981 Policy Memo 041B dated February 15, 1991 Whole hams require a cooking temperature to differentiate the ready to eat products from trichinae treated products. The reason that the temperature is required is to determine the label requirements (e.g., safe handling) and proper serving size. HAM

CROQUETTES: Product must contain at least 35 percent cooked ham. If chopped ham is used, the product name must be \u201cChopped Ham Croquettes.\u201d HAM, FRESH (or uncured): Ham that does not contain a cure must be labeled either \u201cFresh\u201d or, if the ham meets the requirements of 9 CFR 319.2, \u201cUncured.\u201d This also applies to cooked product, and must be labeled cooked product \u201cCooked Uncured Ham.\u201d HAM HALF: \u201cHalf Ham\u201d is permitted on labels for semi-boneless ham products which during their processing have had the shank muscles removed. The two halves of the finished product have approximately an equal amount of bone. The term \u201cNo Slices Removed\u201d has also been deemed suitable for use with a ham item referred to as \u201cHalf Ham.\u201d HAM OMELET: Product must contain at least 18 percent cooked ham. HAM\PARMA

HAM\PROSCIUTTO DI PARMA: Ham, when labeled \u201cParma Ham\u201d and\or \u201cProsciutto di Parma,\u201d would have to be produced in the region of Parma, Italy, in accordance with Italian Law, which defines the denomination of origin, the territorial limits of production, characteristics of the product, and the method of manufacture. HAM, QUARTER, SEMI-BONELESS (No Slices Removed): The product consists of a ham prepared as a

\u201cRegular Semi-Boneless, Half Ham\u201d which is sectioned again to result in four pieces just about equal not only in weight but also in content of bone.", "HAM ROLL SAUSAGE: Ham trimmings and ham shank meat are permitted. HAM SALAD: Product must contain at least 35 percent cooked ham. Chopped ham may be used without it appearing in the product name.

See: Salads HAM, SCOTCH STYLE: A cured, uncooked, boned, and rolled whole ham either tied or in a casing. HAM, SHANKLESS: When the term, \u201cshankless\u201d is used in reference to a ham, it indicates that the shank has been removed by a cut through the joint at a right angle to the femur bone. The distal tip of the semitendinous muscle may be severed above its tendinous attachment, leaving an extension approximately 2 inches long. The extension is considered an integral part of the ham's body and is usually folded over the femur's end. HAM SHORTCAKE: Product must contain at least 25 percent cooked ham. HAM TRIMMINGS: Ham trimmings, to be labeled as ham, cannot contain excess shank meat. The fat content will not exceed 35 percent. It will consist of at least 65 percent lean meat as determined by chemical analysis. HAM, WESTPHALIAN OR WESTPHALIAN STYLE HAM: Ham is cut with bone in, the hip bone cut out, cured in a combination of dry and pickle cure but not a pickle alone. It is smoked in a medium warm (no greater than 100o F.) smokehouse until a shining red brown or chestnut color is acquired. Beechwood may be used and will impart the characteristic Westphalian flavor. Other hard woods are also acceptable. Juniper berries are permitted.", "HANDLING STATEMENTS: Acceptable handling statements, in addition to those required in sections 9 CFR 317.2(k) and 9 CFR 381.125, include \u201cKeep Refrigerated -May be Frozen\u201d or

\u201cKeep Refrigerated-Can be Frozen.\u201d See: Policy Memo 014 dated September 12, 1980. HANDLING STATEMENTS ON RETORTED PRODUCTS: Handling statements may appear on labels for shelf stable product, even though such product does not have to be refrigerated or frozen, and provided the statement will accurately reflect conditions of distribution and sale. These products are to be handled in the plant as shelf stable items including incubation and condition-of-container examinations. Once the product is refrigerated or frozen for shipment, distribution, and display for sale it is to be handled as a refrigerated or frozen item. See: Policy Memo 104 dated February 13, 1987 The statement \u201cpreviously handled frozen for your protection, refreeze or keep refrigerated\u201d is now acceptable on poultry products under the usual restriction of use for such statements. HEAD MEAT: After removal of the cheeks, lips, snout, skin, and tongue from the head there remains small pockets and areas on the skull to which muscle tissue is attached. This muscle may be removed and used in product and declared on labeling as beef or pork as the case may be. However, there are a few standardized products in which the regulations limit the amount of this meat that may be used and require that it be specifically declared on the label (e.g., chili, chili with beans, and corned beef hash). See: Beef Cheek Meat and Beef Head Meat (use and labeling as an ingredient in meat Food Products) HEADCHEESE: A jellied product consisting predominantly of pork byproducts and seasoning ingredients. It must contain some product from the head. Extenders like cereal, soy derivatives, nonfat dry milk, etc., are not permitted ingredients of headcheese.", "HEARTS: Beef and Pork Hearts that include the heart cap are considered meat by-products defined in 9 CFR 301.2. They may not be labeled as \u201cbef,\u201d \u201cpork,\u201d etc. in an ingredients statement. When used in a product, they must be identified by species, for example, \u201cBeef Hearts.\u201d Hearts that include the heart cap may be considered meat only for the purpose of calculating the meat to textured vegetable protein ratios. HEAT AND EAT SAUSAGE: Not the same as Brown and Serve Sausage. When the \u201cheat and eat\u201d term is used, product must comply with cooked sausage regulations, e.g., limitation of 10 percent added water and not more than 3 1\2 percent binder. HICKORY SMOKED: \u201chickory flavored\u201d ad \u201chickory taste\u201d are acceptable terms on products that have been smoked with some hickory in the sawdust. They do not need to be smoked with 100 percent hickory smoke. HIGH FRUCTOSE CORN SYRUP (HFCS): HFCS may be used to flavor meat or poultry products in amounts sufficient for its intended purpose, provided the following conditions are met: 1. HFCS must contain not less than 40 percent fructose on a solids basis. 2. HFCS must have a dextrose equivalence (D.E.) of not less than 93. 3. HFCS must have a sweetening power greater than or equal to sugar (sucrose). 4. HFCS must be identified on the label as High Fructose Corn Syrup in the ingredients statement, curing statement, etc. See: Policy Memo 035 dated October 27, 1981 HOLSTEIN OR HOLSTEINER: Product is the same as FARM STYLE SAUSAGE, except that it is stuffed into wide casings and heavily smoked, usually in long casings, and air dried. No extenders are permitted.", "HONEY CLAIM IN PRODUCT: A honey claim may be made or implied on a product label if: 1. The product contains at least 3 percent honey. 2. Honey contains at least 80 percent solids, U.S. grade C or above. 3. When other sweeteners, (sugar, dextrose, maltose, invert sugar, corn syrup solids, and similar ingredients) are used, the quantity may not exceed one-half that of the honey, e.g.. If 3 percent honey is used, then no more than 1 1\2 percent of all other sweeteners may be used. 4. Product to be identified as \u201choney Glaze\u201d must contain honey to other sweeteners at a ratio no less than 2:1. If dried honey

is used, the ratio is to be no less than 1.6:1. 5. When honey is included in a breading, a honey claim may be made regardless of the quantity of honey used. HONEY CURED OR SUGAR CURED: \u201cHoney Cured\u201d may be shown on the labeling of a cured product if: (1) the honey used contains at least 80 percent solids or is U.S. grade C or above; (2) honey is the only sweetening ingredient or when other sweetening ingredients are used in combination with honey, they do not exceed one-half the amount of honey used; and honey barbecue touch of honey (3) honey is used in an amount sufficient to flavor and\or affect the appearance of the finished product. Traditionally, cured products which are labeled to indicate the presence of honey, e.g. Honey ham, must meet the parameters prescribed herein. \u201cSugar Cured\u201d may be used on the labeling of a cured product if: (1) the sugar used is cane sugar or beet sugar; (2) sugar is the only sweetening ingredient or when other sweetening ingredients are used in combination with sugar, they do not exceed one-half the amount of sugar used; and (3) sugar is used in an amount sufficient to flavor and\or affect the appearance of the finished product.", "\u201cHoney and Sugar Cured\u201d or \u201cSugar and Honey Cured\u201d may also be used on labeling if: (1) the honey and sugar are of the nature described above; (2) the honey and sugar are the only sweetening agents or when other sweetening ingredients are used in combination with the honey and sugar, they do not individually exceed either the amount of honey or sugar used and collectively do not exceed one-half the total amount of honey and sugar; and (3) the honey and sugar are used in amounts sufficient to flavor and\or affect the appearance of the finished product. See: Policy Memo 038 dated December 16, 1981

HORS D'OEUVRE (Snack): Product must contain at least 15 percent cooked meat or 10 percent bacon (cooked basis). True product name must be shown, e.g., \u201cPuffed Pastry Wrapped Frank.\u201d HOT DOG CHILI SAUCE WITH MEAT: Product must contain at least 6 percent meat. HOT DOG CHILI WITH MEAT: Product must contain at least 40 percent meat. Sausages and bologna rework not permitted. HUNAN STYLE SEASONED PORK: Acceptable for pork shoulder sliced into one inch pieces and marinated in a solution of soy sauce, garlic, and ginger, cooked and returns to green weight. The product may be flavored with other seasoning ingredients, e.g., star anise and coriander.

HYDROLYZED BEEF STOCK: A beef stock which has been treated with acid, alkali, or enzymes to digest the protein. The protein molecules are broken down into amino acids, peptides, polypeptides, and peptones. As the digestion is carried out for longer periods of time, more and more of the larger molecules are broken down into amino acids, with free alpha-amino groups. By analyzing these alpha-amino nitrogens one can determine the degree of hydrolysis. 100 percent hydrolysis would mean that all the nitrogen (protein) is in the form of amino acids. 10 percent of hydrolysis would mean that only 10 percent of the nitrogen is in the form of free amino acids, while the rest is still present in polymeric form.", "The label should indicate the degree of hydrolysis. This is determined from the ratio of amino nitrogen to total nitrogen. amino nitrogen = percent hydrolysis total nitrogen

A product labeled 50 percent Hydrolyzed Beef Stock must, therefore, have 50 percent of the total nitrogen present as amino nitrogen. Adding percent solids is optional. The percent solids would not necessarily be the same percent as hydrolysis depending on the thickness (consistency) of product.

HYDROLYZED GELATIN: Hydrolyzed gelatin is permitted in frankfurters and similar products (9 CFR 319.180) at levels typically used for flavorings (less than 2 percent). Hydrolyzed gelatin may currently be used a 2 percent in 9 CFR 319.180 and like products as a flavoring. If gelatin is used in a product, make sure it is permitted for use in the product.

Hydrolyzed gelatin is acceptable in poultry franks 9 CFR 319.180 and like products at levels not to exceed 2 percent of total formula until otherwise notified. Hydrolyzed gelatin is recognized as a binder rather than flavoring and may be used at levels of 2 percent or less in 9 CFR 319.180 type products. HYDROLYZED OAT FLOUR: Hydrolyzed oat flour is safe and may be used in non-standardized meat\poultry products as a binder at below typical binder use levels, i.e., 3 percent. It may be used in low fat hamburger, water, and hydrolyzed oat flour product as per Policy Memo 121. HYDROLYZED PROTEIN: \u201cHydrolyzed Protein (milk, egg, soy)\u201d is an acceptable common or usual name provided all components are hydrolyzed.

\u201cHydrolyzed Protein (potato, gelatin)\u201d is an unacceptable ingredient declaration and must be declared as \u201chydrolyzed potato protein and hydrolyzed gelatin.\u201d Salt is present in hydrolyzed protein and must appear in the sublisting of the hydrolyzed protein if it does not appear elsewhere in the ingredients statement. HYDROXYPROPYL METHYLCELLULOSE (HPMC): Emulsifying agent, binder, thickener, and a stabilizer. This is accepted for its emulsifying qualities when prepared as a solution and applied as a dip. 1. Not more than 2 percent in solution.", "2. Not more than 4 percent weight gained in product. 3. Not more than .08 percent hydroxypropyl methylcellulose in finished product. 4. Must be identified in the ingredients statement for purpose. 5. Approved on individual basis only. ICE GLAZES WITH

FLAVOR: If an ice glaze component contributes to the flavor profile of the product, the ice glaze coating must be counted toward the total net weight of the finished product. In addition, the product name must contain a descriptive designation for the coating and coating percentage in accordance with 9 CFR 317.2(e)(2) or 381.117(h), for example, \u201craw chicken breast filets with rib meat containing up to 16% of a solution of water seasonings and salt and coated with 6.5% butter garlic seasoning.\u201d Or, if the same solution is used for injection (or by any other method of incorporation) and for the ice glaze coating the percentages may be combined, for example, \u201cchicken breast filets with rib meat, containing and glazed with up to 22.5% of a solution of water, salt, seasonings, and garlic.\u201d ICE-GLAZED BREADED CHICKEN

NUGGETS: If an ice glaze is applied for the purpose of setting the breading, the term \u201cice glazed\u201d needs to appear in close contiguous to the product name. The water cannot be included as part of the net weight statement and the transmittal form should indicated this.

IMITATION FLAVORS: Imitation beef flavor, imitation mushroom flavor, flavor base for gravies and similar substances which enhance, fortify, or help to simulate a flavor are usually composed of food additives and, as such, are not \u201cartificial flavors\u201d for labeling purposes. This class of imitation flavors can be composed of such ingredients as flour, fats, oils, salt, hydrolyzed vegetable protein, vegetable gums, thiamine hydrochloride, beta alanine, disodium inosinate, glutamic acid, and a host of other ingredients. These flavorings must be identified on labels by showing each individual ingredient by its common name. Class names, e.g., amino acids are not acceptable. Each specific amino acid must be listed. INCIDENTAL ADDITIVES: As defined in the Food and Drug Administration regulations (21 CFR 101.100(a)(3)), incidental additives are substances present in foods at insignificant levels and that do not serve a technical or functional effect in that food. In determining whether a substance is an incidental additive, the following criteria may be applied: 1. Substances that are present in a food as a result of having been present in an ingredient added to the food and have a technical or functional effect on the", "ingredient but not on the finished food, or 2. Substances that are processing aids, defined as: a. substances added during processing but removed before the

food is packaged in its finished form, or b. substances added during processing but that are converted to constituents normally present in the food, and do not significantly increase the amount of those constituents naturally found in the food, or", "c. substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.

**INGREDIENT LABELING:** 1. All ingredients in FDA standardized products, e.g., Cheddar Cheese (Water, salt, cheddar, etc.), and on standardized products, e.g., Soy sauce, Worcestershire sauce, require complete disclosure of all ingredients on the labels of meat and poultry products. 2. Protein hydrolysates must identify the common and usual names and identify the source from which the protein is derived, e.g., \u201chydrolyzed vegetable protein\u201d would be declared as \u201chydrolyzed corn protein.\u201d 3. FDA certified color additives require the listing of the common or usual names, e.g., FD&C Blue No. 1, Blue 1, or Blue 1 Lake. Color additives not subject to certification may be declared as \u201cartificial color,\u201d \u201cartificial color added,\u201d or \u201ccolor added.\u201d Alternatively, color additives not subject to certification may be declared as \u201ccolored with ,\u201d or \u201c color,\u201d with blank space filled in with the name of the color additive listed in 21 CFR 73, e.g., \u201ccolored with annatto\u201d or \u201ccaramel color.\u201d 4. Cured meat products used as ingredients, regardless of their level of use, require complete disclosure of all ingredients in the formulation of meat and poultry products. See: FSIS Directive 7237.1, Rev. 1, \u201cLabeling of Ingredients\u201d FSIS Directive 7140.1, Rev. 1, \u201cQuestions and Answers Relating to Ingredients\u201d

**INSERT LABELS FOR USE AT RETAIL STORES:** No inspection legend is permitted on insert labels. **INSPECTION LEGENDS (DUAL):** Products consisting of mixed meat and poultry ingredients shall bear either the official meat inspection legend or poultry legend, depending on which ingredients are present in the greater amounts. If meat or poultry ingredients exist in equal proportions, either official legend may be used. If meat and poultry ingredients exist in exact proportions and both appear in the product name, the official legend must reflect the ingredient appearing first in the product name. Containers of products intended for sale to household consumers can bear only the official mark of inspection of the product enclosed. Containers of products intended for distribution to other than the retail trade may bear both the official meat inspection legend and the official poultry products inspection legend.", "See: Policy Memo 075 dated August 14, 1984

**INSPECTION MARK ON WING TAG:** When the inspection mark is shown on a wing tag, either the plant number or the firm's name and address must also appear.

**INTESTINES:** Intestines can be prepared as edible product and bear the mark of inspection.

**IRISH STEW:** Product does not require a geographical qualifying statement nor the words, \u201cStyle,\u201d \u201cType,\u201d or \u201cBrand.\u201d Usually it contains lamb or mutton but beef may be used. It must meet the stew standard. Vegetables include onions, carrots, potatoes, and turnips. Dumplings are often used. Beans are not acceptable in \u201cIrish Stew.\u201d

**ISOLATED SOY PROTEIN:** This food ingredient is similar to soy protein concentrate except that additional extraction has removed more of the non-protein fraction, thereby increasing its protein content. It is prepared by alkaline solubilization of the soy protein and then precipitation of same in an acid bath. It may be powdered, extruded, or spun into fibrils and has a protein content of 90 to 95 percent. Products of spun fibrils may be referred to as \u201cTextured Soy Protein Isolate,\u201d \u201cIsolated Soy Protein Fibers,\u201d or \u201cSpun Isolated Soy Protein.\u201d

The PER

of isolated soy protein is about 1.9 and indicates a poorer quality protein than that of soy flour or soy protein concentrate (PER 2.2). When hydrated textured (structured) protein isolate is added to meat food products, the ingredients statement should read \u201cHydrated Textured (Structured) Isolated Soy Protein.\u201d ITALIAN SAUSAGE: Beef and pork Italian sausage is acceptable. Tomato products and other unexpected ingredients can be added if the product name indicates their presence. Red pepper permitted under 9 CFR 319.145(b)(1). See: 9 CFR 319.145 ITALIAN STYLE: Acceptable term for products containing anise or fennel or Italian type cheese (e.g., Mozzarella, Parmesan, Provolone, Ricotta, Romano) or at least three of the following: basil, garlic, marjoram, olive oil, or oregano. Sausage products must meet the Italian Sausage requirements as per Regulation 9 CFR 319.145. "ITALIAN STYLE SMOKED SAUSAGE: This is a smoked sausage (10 percent added water) and is not a 9 CFR 319.145 (Italian sausage) product. However, the product must contain Italian style ingredients found in the policy book under Italian style. JAGWURST: The product is the same as yachtwurst (The Americanized name for the item). It is a cooked sausage made from a fine emulsion with cubes of lean meat rather than fat (as in mortadella). JAMAICAN STYLE: Term may be used to identify meat and poultry food products made with allspice, garlic, onion, red pepper, and thyme. The name of the product must be further qualified with a statement, like \u201cwith Jamaican Style Seasoning,\u201d e.g., \u201cJamaican Style Chicken Wings-with Jamaican Style Seasonings.\u201d If the product formula contains textured soy product, then the ration rules apply. JAMAICAN STYLE PATTIES: Product has at least 25 percent meat enclosed in a crust. The label must show true product name, e.g., \u201cBeef Turnover.\u201d If the formula contains textured soy product, then the ratio rules apply. JAMON: Spanish word for \u201cham.\u201d In the usage of Spanish-speaking people outside Spain, it has come to mean cured pork. \u201cJamon di Cocinar\u201d is cured pork for cooking as opposed to slicing. When the term \u201cJamon\u201d appears before the name of a limb, it means the product is cured. With the exception of products available for sale in Puerto Rico, all Spanish product names followed with the English translation. Examples of acceptable product names are: Jamon de Paleta - Cured Pork Shoulder Jamon de Pierna -Cured Pork Leg JARDINIERE (FR): Must contain at least 50 percent cooked meat based on total product. It means \u201cin the manner of the gardener.\u201d The term applies to dishes made with diced garden vegetables which have been cooked with meat. Jardiniere should be followed by a true product name, e.g., \u201cBeef with Vegetables.\u201d "JERK OR JERK STYLE: The terms \u201cJERK\u201d or \u201cJERK STYLE\u201d can be used to describe red meat or poultry whole muscle, fabricated products, and other meat poultry food products that are mixed or placed in a \u201cspicy seasoning.\u201d The seasoning usually contains scallion, onion, thyme, allspice (pimento), hot peppers, and usually contains at least one or more of the following: nutmeg, cinnamon, sugar, brown sugar, garlic, and rice or wine vinegar. The seasoning may be in the form of paste, marinade, sauce, or dry seasoning mixture. The product is mixed or placed in the spicy hot seasoning raw or the product may be grilled, cooked, or smoked. Examples of acceptable product names are, for example, \u201cOven Roasted Jerk Chicken\u201d, \u201cJerk Pork Sausage\u201d or \u201cJerk Style Smoked Beef Sausage.\u201d Raw \u201cjerk\u201d or \u201cjerk style\u201d meat or poultry products with added solutions must be labeled in accordance with 9 CFR 317.2(e)(2) or 9 CFR 381.117(h), for example, \u201cJerk Style Beef containing 10% marinade of water and spicy seasoning.\u201d JERKY: All Jerky products must

have a MPR of 0.75:1 or less; \u201cspecies\u201d or \u201ckind\u201d must be in the name. Products may be cured or uncured, dried, and may be smoked or unsmoked, air or oven dried. A reference to the particular type of drying method is not a labeling requirement.

1. \u201cBeef Jerky\u201d -Produced from a single piece of beef. May also be classified as \u201cNatural Style Beef Jerky\u201d provided this product name is accompanied by the explanatory statement \u201cmade from solid pieces of beef\u201d or comparable terminology. When a \u201cNatural\u201d claim (not natural style) is made, the policies as outlined in Policy Memo 055 are to be applied.

2. \u201cBeef Jerky Chunked and Formed\u201d -Produced from chunks which are molded and formed and cut into strips.

3. \u201cBeef Jerky Ground and Formed or Chopped and Formed\u201d -Produced as described, molded and formed and cut into strips.

4. Jerky products that contain over 3\u00bd percent binders (2 percent ISP) must reflect the binder in the product name, i.e., \u201cBeef Soy Protein Concentrate jerky, ground and formed. Jerky products that contain binders at levels below 3\u00bd percent should express the binder in a qualifying statement, e.g., beef jerky -soy protein added." ,

"5. \u201cSpecies (or Kind) Jerky Sausage.\u201d The word \u201cJerky\u201d can appear on labels for product in which the \u201cspecies\u201d or \u201ckind\u201d has been processed by chopping or grinding and stuffed into casings under the following conditions only:

a. The word \u201cSausage\u201d must appear immediately contiguous to \u201cJerky\u201d whenever it is shown. \u201cSausage\u201d must be in type at least one-third as high as \u201cJerky\u201d in the same color ink and on the same background. The words \u201cstick,\u201d \u201cpiece\u201d etc. cannot be used as substitutes for \u201csausage\u201d in the product name. \u201cSausage\u201d means that the product has been chopped.

b. The product may be dried at any stage of the process.

JUNIOR MEAT SNACKS: Product must conform to the sausage standards going into the jar before processing. Limited to 3 1/2 percent extenders.

JUNIPER BERRIES: Juniper berries and twigs are normally thrown on the fire from which dry cured hams are smoked. Juniper berries have been approved in the curing ingredients of Westphalian Ham.

KABOBS: Product consists of chunks of red meat or poultry and vegetables placed on a metal or wooden skewer.

\u201cKabob\u201d may be included in the descriptive name, e.g., \u201cBeef, Mushrooms, and Onion Kabob.\u201d A kabob may be cooked or uncooked, but the label must clearly indicate this. This product may contain but does not require vegetables.

KALBELWURST: Product is similar to Bockwurst with no limit on water or milk.

KATRIFITAS: A coined word used to describe a type of empanadillas. The product consists of dough containing yucca made to resemble a meat turnover and has a special meat filling. The product must contain at least 25 percent raw meat (beef) in total formulation. Label must include a true product name in conjunction with \u201cKatrifitas,\u201d e.g., \u201cKatrifitas, Beef Turnover made with Yucca Shell,\u201d or similar wording.

KELCO-GEL: A thickening agent used in sauces. It contains sodium alginate, calcium carbonate, and disodium phosphate. The amount of disodium phosphate in the finished product is approximately 0.099 percent. Its use should be judged on an individual basis.",

"KIDNEYS FROM ENZYME INJECTED BEEF: Product may be exported to other countries. They must be labeled \u201cBeef Kidneys, Tendered with Papain -For Export Only.\u201d

KIELBASA: A sausage that is cured, cooked, and usually smoked. Kolbassy is Czechoslovakian spelling; other variations include Kielbassy, Kolbasa and Kolbase. Kielbasa is made from coarsely ground pork or coarsely ground pork with added beef or mutton. \u201cHungarian Style

Kolbase\ufe0f is finely ground product, seasoned and stuffed into casings. The 70\30 rule can be used, however, pork must always be the predominant meat ingredient. \ufe0fcBeef Kielbasa\ufe0f is prepared with only beef as the meat ingredient. Byproducts are not permitted ingredients in these sausages. An uncured (fresh), uncooked variety, with no more than 3 percent water exists. \ufe0fcFresh\ufe0f shall be used in the name when the product is uncured. When fresh Kielbasa is cooked or smoked, then cooked or smoked is required in the product name. The requirements of Policy Memo 110 apply when these perishable, cooked, uncured products are packaged in hermetically sealed containers. KIPPERED BEEF: A cured dry product similar to beef jerky but not as dry. MPR of 2.03:1 is applied to product. KISKA; Kisba, Kishka, or Stuffed Derma. Ingredients statement is part of the product name. A meat food product prepared two ways: 1. Prepared with meat byproducts, including beef blood, pork snouts, pork livers, pork cheeks, etc. Packaged in fully labeled retail size packages or individually banded. When beef blood is used, it must be shown as part of product name. 2. Prepared with more than 30 percent animal fat, mixed with farinaceous (consisting of or made of flour or meal) materials containing no other meat byproducts and ordinarily stuffed into beef casings and cooked. Product containing 30 percent or less fat is not considered amenable to the Federal Meat Inspection Act.","KNISHES: Product must contain at least 15 percent cooked meat or poultry or 10 percent bacon (cooked basis). Same as snack standard. The type of meat or poultry should be identified in a true product name, e.g., \ufe0fcChicken Knishes.\ufe0f KONJAC FLOUR: Food ingredient that provides the effects of thickening, gelling, texturizing, and waterbinding, e.g.,\ufe0dbinder,\ufe0f similar to that of starch vegetable flours, such as potato flour. Konjac flour can be used in meat and poultry products in which starch vegetable flours are permitted, e.g., 3.5 percent in cooked sausage products such as frankfurters and bologna. KOSHER: Use of the term, \ufe0fcKosher\ufe0f on labeling requires certifications by an appropriate third party authority. KOSHER (Product Containers): Containers must be labeled \ufe0fcKosher tags attached\ufe0f when used for hearts, livers, and other products or tissues with attached metal tags indicating kosher inspection. KRAKOW: Acceptable name for a cooked sausage similar to \ufe0fcBerliner.\ufe0f KREPLACH: Product must contain at least 20 percent meat. The type of kreplach should be identified in a true product name, e.g., \ufe0fcBeef Kreplach.\ufe0f KUBBEE: Other acceptable names are: Kubbe, Kibbe, Kabeda, Kilin, Kibbes, Kibby, Kabbo, or Kabe.\ufe0f A product popular in Syria and Lebanon. It must contain at least 25 percent meat based on total formulation; it must contain soaked cracked wheat and show the true product name, e.g., \ufe0fcFried Cracked Wheat and Beef Balls,\ufe0f \ufe0fcBaked Stuffed Wheat and Beef Patty.\ufe0f Products may be shaped like a hamburger and fried or shaped into balls and fried.","KUEMMELWURST: An acceptable name. The product is the same as Carawaywurst and is a cooked sausage of the ring variety, with whole caraway seeds. Usual ingredients are beef, pork, salt, caraway, flavorings, and cure. KURMA: Product must contain at least 50 percent meat or at least 35 percent poultry meat. LABELING, CHECK-OFF BLOCKS: The use of check-off blocks on immediate containers for identifying products that look alike but are different in composition is not permitted. Examples of product that may look alike but are different in composition are as follows: \uf0a7 Ground Beef and Beef Patty Mix \uf0a7 Partially Defatted Chopped Beef and Partially Defatted Beef Fatty Tissue \uf0a7 Frankfurters and Frankfurters with Variety Meats \uf0a7 Finely Ground Chicken and Finely Ground Chicken Meat \uf0a7 Comminuted Chicken and Comminuted Chicken With Kidney and Sex Glands Removed

However, exceptions to this policy may be granted. Exceptions would require that the establishment operators develop a procedure which the assigned inspector can readily monitor to ensure correct labeling. Such procedures, accompanied by written comments from the assigned inspector and where possible, the circuit supervisor, must be forwarded to the area supervisor for review and approval. Approved procedures must be attached to the label records accompanying new or modified labels submitted for approval. See: Policy Memo 083A dated May 12, 1988

**LABELING FOR SUBSTITUTE PRODUCTS:** If a product fails to comply with a standard only because the meat or poultry content is lower than required and the product has generic identity as a nonmeat product (e.g., pizza, stew, pies), then the product may be designated by the nonmeat terminology in the standardized name (e.g., \u201cPIZZA,\u201d \u201cSTEW,\u201d \u201cPIE\u201d), provided the meat\poultry content of the product is conspicuously disclosed contiguous to the product name along with a", "statement of the amount of meat\poultry in the standardized product. (For example, PIZZA (contains 5 percent sausage; SAUSAGE PIZZA contains 12 percent sausage.) Such product may not be nutritionally inferior to the standardized product it resembles. For this purpose, nutritional inferiority is defined, consistent with the requirement of 21 CFR 101.3(e)(4), as any reduction in the content of an essential nutrient that is present at 2 percent or more of the U.S. RDA per serving of protein or any of the vitamins or minerals for which U.S. RDAs are established. A quality control procedure must be approved for such products by the Processed Products Inspection Division before the label can be used. If a product is nutritionally inferior to the standardized product it resembles, it must be labeled \u201cimitation\u201d in accordance with 9 CFR 317.2(j) and 9 CFR 381.1(b). See: Policy Memo 069 dated March 23, 1984

**LABELING OF PRODUCTS WITH GROUND OR EMULSIFIED TRIMMINGS:** The addition of small amounts of ground or emulsified ham trimmings, beef trimmings, or poultry trimmings to these products may be used without declaration. However, if poultry skin is being used to produce poultry trimmings, it may not exceed natural proportions as prescribed in 9 CFR 381.117 and 381.118 of the Poultry Products Inspection Regulations. The amount of ground or emulsified trimmings that may be used can represent no more than 15 percent of the fresh or green weight of the ham, beef, or poultry block at the time of formulation (e.g., 85 lbs. intact muscle and 15 lbs. of trimmings). These trimmings may be from a different process, however, they must be derived from like cuts or parts, e.g., emulsified round trimmings injected into product called \u201cBoneless Roast Beef Round,\u201d emulsified breast meat trimmings injected into product called \u201cBoneless Roasted Turkey Breast,\u201d or emulsified chuck trimmings injected into product called \u201cCooked Roast Beef\u201d derived from the beef chuck. The information pertaining to the source of trimmings and cut of product being used must be indicated in the product formulation on label submittals. Emulsified trimmings consist of suspending ground trimmings in a curing solution or other solutions (i.e., that impart flavor) through the use of a mechanical emulsifier, then injecting the liquid suspension directly into the whole muscle portion of the hams, beef roasts, or poultry products. The emulsified suspension must be used during the same day of production. Furthermore, a written proposal outlining processing procedures for injecting the suspensions of ham, beef, or poultry trimmings into the boneless product must be submitted by establishments, through appropriate inspection channels, to the Processed Products Inspection Division, Science and Technology, for review and approval. Such approval is a prerequisite for label use. Products containing more than 15 percent ground trimmings or emulsified trimmings

must be labeled to indicate the presence of the ground ham, beef or poultry trimmings added or emulsified ham, beef or poultry trimmings being injected, e.g., "A Portion of Ground Ham Added," "Emulsified Beef Added," "Ground Poultry Trimmings," "Added," or "Emulsified Beef Trimmings Added." Policies regarding the required use of terminology such as "chunked and formed" and "ground and formed" will continue. See: Policy Memo 041B dated February 15, 1991 LABELING OF MODIFIED BREAKFAST SAUSAGE, COOKED SAUSAGE, AND FERMENTED SAUSAGE PRODUCTS IDENTIFIED BY A NUTRIENT CONTENT CLAIM: Modified breakfast sausage, cooked sausage, and fermented sausage products are substitute versions of the standardized or traditional products that have been formulated and processed to reduce the fat contents to qualify for use of nutrient content claims, but do not comply with the standard of identity or composition as described in the meat and poultry regulations or the Standards and Labeling Policy Book (Policy Book) because of the use of ingredients used for fat replacement which are precluded or restricted by these standards. The deviation from the standard or the traditional, i.e., regular product, is conveyed by associating an expressed nutrient content claim for the appropriate reduction in fat content and the standardized or traditional product name, e.g., "Reduced Fat Frankfurter" or "Low Fat Pepperoni." The nutrient content claims that may be used are those related to a reduction in fat contents that are identified in the regulations for meat products in 9 CFR Part 317 and for poultry products in 9 CFR Part 381. Maintaining Product Integrity: The following guidelines must be applied to assure that the modified versions of the subject meat and poultry sausage products do not violate the integrity of the standardized or traditional product for which they purport to be substitutes: (1) the product must be similar in shape, flavor, consistency, and general appearance to the product as prepared according to the regulatory or traditional standard, (2) the meat or poultry used to formulate the modified product must come from the same anatomical location when the standardized term is related to an anatomical region on an animal, e.g., "ham" is expected to be from the hind leg of the hog and cured; thus, "smoked ham sausage" would be comprised of meat from the hind leg of a hog that has been smoked and cured, (3) the modified sausage product must result from the same processing procedures as those specified for the subject sausage products described by regulatory or Policy Book standards, (4) there must not be deviations from product safety criteria (e.g., salt content, curing agents, pH, water activity and/or moisture/protein ratio) that are provided in the regulatory or Policy Book standards for sausages, and (5) the modified product must achieve the appropriate reduction in fat content to be eligible to use a nutrient content claim in conjunction with the standardized or traditional product name. Performance Characteristics: In producing modified, substitute versions of sausages, the deviations from ingredient provisions of the regulatory and Policy Book standards should be the minimum necessary to qualify for the nutrient content claim while maintaining the performance characteristics similar to the standardized or traditional product, i.e., similar preparation, cooking, and handling characteristics. If a modified version of the standardized or traditional sausage does not perform in substantially the same way as the standardized or traditional item, the label must include a prominent statement informing "the consumer of such differences. For example, a "low fat frankfurter" that essentially has all of the characteristics of a frankfurter, but cannot be grilled, would indicate "not recommended for grilling." A "reduced fat pepperoni" that displays essentially all the characteristics of

pepperoni, but cannot be cooked, would, for example, indicate \u201cnot recommended for cooking\u201d or \u201cdon\u2019t cook.\u201d Safe and Suitable Ingredients: A modified, substitute sausage product must be formulated with approved safe and suitable ingredients, e.g., those identified in 9 CFR 424.21, and those determined to be safe and suitable by the Food Standards and Ingredients Branch, Product Assessment Division. Such ingredients are to be used at the lowest level necessary to achieve the intended effect of reducing fat as compared to the standardized or traditional product. Safe and suitable ingredients are those used to replace fat, improve texture, and prevent syneresis. An ingredient or component of an ingredient that is specifically required by the regulatory or Policy Book standard for characterizing purposes, e.g., cheese in a cheesefurter, fresh livers in liver sausage, cured ham in a ham sausage, and fennel or anise in an Italian sausage, shall be present in the required amount, if applicable, or otherwise in a significant amount to provide a characterizing identity to the product. Moreover, an ingredient or component of an ingredient that is not permitted by regulations for use in any meat or poultry sausage product, e.g., sodium benzoate, shall not be added to a modified, substitute product. Product Identity: The name of the modified version of the standardized or traditional product that complies with all parts of the policy prescribed herein is the appropriate expressed nutrient content claim for the meat and\or poultry product with a reduction in fat content and the applicable standardized or traditional term, e.g., \u201cLean Sausage,\u201d \u201c97 percent Fat-Free (or \u201cLow Fat\u201d Kielbasa,\u201d \u201cLow-Fat Frankfurter Made with Beef, Pork and Turkey,\u201d \u201cReduced Fat Pepperoni,\u201d \u201cExtra Lean Turkey Italian Sausage,\u201d and \u201cLite Genoa Salami.\u201d The size and style of type must conform to the nutrition labeling regulations. Ingredients Statement: To assist the consumer in differentiating between the standardized or traditional sausage product and the modified, substitute version, ingredients that are not provided for by regulatory or Policy Book standards, or used in excess of the allowable levels specified, must be appropriately identified with an asterisk in the ingredients statement. The statement(s) defining the asterisk(s), e.g., \u201c\*Ingredient(s) not in regular \u201c(fill in name of the standardized or traditional product), or \u201c\*Ingredients(s) in excess of amount permitted in regular \u201c(fill in name of the standardized or traditional product), or both as appropriate, must be legible and conspicuous, and shall immediately follow the ingredients statement in the same size and style of type. See: Policy Memo 123 dated January 20, 1995", "LABELING OF MEAT AND POULTRY STICK ITEMS: Stick items such as beef jerky, pepperoni sticks, and beef sticks must be labeled (i.e., contain the required label features as outlined in 9 CFR 317 and 9 CFR 381, Subpart N) according to the following guidelines: 1. If sold in fully labeled bulk containers, i.e., canisters, caddies, or similar containers, stick items do not have to be fully labeled unless they are individually wrapped. This type of container cannot be reused. 2. If sold in bulk containers, i.e., canisters, caddies, or similar containers that are not fully labeled, stick items must be fully labeled. Bulk containers such as these may only be refilled with fully labeled product. 3. If sold in small, fully labeled cartons, boxes, or similar containers (e.g., 3 oz., net weight) that are only intended for retail sale intact, stick items may be individually wrapped and unlabeled. See: Policy Memo 111 dated June 6, 1988 LABELING OF MODIFIED SUBSTITUTE VERSIONS OF FRESH (SPECIES) SAUSAGE, HAMBURGER OR GROUND BEEF PRODUCTS: This policy allows modified versions of fresh (species) sausages, ground beef, or hamburger to contain non-meat or poultry, \u201cfat-

replacing ingredients (e.g., binders such as carrageenan, modified food starch) and to be identified by certain nutrient content claims in accordance with nutrition labeling regulations effective on August 8, 1994, in conjunction with descriptive labeling, e.g., "Lean Pork Sausage with a X percent Solution of ..., " or "Low Fat Ground Beef, Water, and Carrageenan Product." This policy allows for the use of terms defined in regulations, e.g., "Lean," "Reduced Fat," "Low Fat," etc., to be used to describe fresh (species) sausage, ground beef, or hamburger products with a reduction in fat content resulting from the use of added ingredients (i.e., fat replacers) such as carrageenan and isolated soy protein). These products must meet the criteria for use of the nutrient content claim associated with the fat reduction. The nutrient content claim may be used in conjunction with the standardized name provided the consumer is informed of the actual components of the product through labeling, i.e., descriptive product name, ingredients statement, and Nutrition Facts. Meat products, including those that meet the criteria established for claims, such as "Lean," "Low Fat," "Lower Fat," "Reduced Fat," etc., that combine fresh (species) sausage, ground beef, or hamburger, and other safe and suitable ingredients, for the principal purpose of replacing fat, may be descriptively labeled. Examples of such products are "Lean Ground Beef, Water, and Carrageenan Product," "Low Fat Ground Beef With a X percent Solution of ..., " "Lean Beef Sausage, Water, and Carrageenan," "Product," or "Reduced Fat Pork Sausage, Water, and Binders Product," provided conditions prescribed in the regulations, viz., 9 CFR 317, for use of the nutrient content claim are satisfied. In contrast, modified versions of fresh (species) sausage, ground beef or hamburger product containing added ingredients that do not qualify for use of a nutrient content claim prescribed in the nutrition labeling regulations must be labeled as Imitation Pork Sausage, Imitation Beef Sausage, Imitation Ground Beef, Imitation Hamburger, Beef Patty or Beef Patty Mix in accordance with 9 CFR Section 317.2(j)(1) and Sections 9 CFR 319.141 (Fresh pork sausage), 319.142 (Fresh beef sausage), and 319.15 (Miscellaneous beef products), respectively. Descriptively labeled, modified, substitute versions of fresh (species) sausage, ground beef, or hamburger product with a reduction in fat content must comply with the following guidelines:

1. The descriptive name of a modified, substitute product with a reduction in fat content is the applicable nutrient content claim used in conjunction with the appropriate standardized name and fat-replacing ingredients, e.g., "Low Fat Ground Beef, Water and Carrageenan Product," or "Lean Pork Sausage with an X percent Solution of Water, Modified Food Starch, Spices, and Salt." Words in the descriptive name may be of a different size, style, color, or type but, in all cases, the words must be prominent, conspicuous, and legible. Moreover, no word in the descriptive name should be printed in letters that are less than one-third the size of the largest letter used in any other word in the descriptive name. The solution statement, when used, is considered to be part of the descriptive product name and must comply with descriptive name sizing requirements.
2. Fat-replacing ingredients (e.g., binders and water) and fat in the finished product may not exceed 30 percent of the product as formulated for the modified, substitute ground beef, hamburger, or fresh beef sausage product, and no more than 40 percent of the product formulation for the substitute fresh pork sausage. The fat content must be in accordance with requirements for use of the applicable nutrient content claim.
3. The product includes mandatory nutrition labeling prescribed in the

meat inspection regulations, viz., 9 CFR 317. 4. The product is formulated with approved safe and suitable ingredients, e.g., those identified in 9 CFR 424.21(c)(4), and which are determined to be safe and suitable by the Labeling and Consumer Protection Staff, that are used at the lowest level necessary to achieve the intended effect as a fat-replacing ingredient (i.e., binder). See: Policy Memo 121B dated January 20, 1995 LABELING OF PRODUCT NAMES, FANCIFUL NAMES, WORD SIZE: Words in product names or fanciful names may be a different size, style, color, or type, but in all cases, the words must be prominent, conspicuous, and legible. Moreover, no", "word in a product name, i.e., a common or usual name, a standardized name, or a descriptive name should be printed in letters that are less than one-third the size of the largest letter used in any other words of the product name. The same guidelines apply to letters of words in fanciful names that may accompany the product name. For example, for a product labeled Chili Mac--Beans, Macaroni and Beef in Sauce, \u201cChili Mac\u201d is the fanciful name and \u201cBeans, Macaroni and Beef in Sauce\u201d is the product name. No letter in \u201cChili Mac\u201d may be smaller than one-third the size of the largest letter in \u201cChili Mac.\u201d Similarly, no letter in the descriptive name may be smaller than one-third the size of the largest letter in the descriptive name. This policy is not intended to address the relative size of words in fanciful names versus product names. The size of words in qualifying statements, e.g., \u201cWater Added,\u201d \u201cContains up to ...,\u201d \u201cSmoke Flavoring Added,\u201d etc., are not affected by this policy memo. See: Policy Memo 087A dated September 16, 1985 LABELING OF PRODUCTS CONTAINING MEAT WITH ADDED SOLUTIONS OR OTHER NONMEAT INGREDIENTS IN SECONDARY PRODUCTS: In those situations where meat containing an added solution or other nonmeat ingredients, for example, Ham-Water Added, Cooked Corned Beef and Water Products, Uncooked Beef-Containing up to 10% of a solution of water, salt, and sodium phosphate, are used in secondary products in sufficient quantities to meet the minimum meat requirement without including the added solution, or nonmeat ingredients, the product name need not include any reference to the added solution or nonmeat ingredients; for example, Corned Beef and Cabbage would be an acceptable name for a product if the corned beef portion of the corned beef and water product was present in a sufficient quantity to satisfy the 25 percent cooked corned beef requirement. The ingredients statement, however, must include nomenclature as required by the regulations or policy (see also 9 CFR 317.2(e)(2) and 084A (Cooked Red Meat Products Containing Added Substances)). In this example, the ingredients statement would list \u201cCooked Corned Beef and Water Product-X percent of added ingredients are . . .\u201d For products in which the added solution ingredient as a whole is used to meet the minimum meat requirement, the product name must contain The appropriate nomenclature (i.e., descriptive designation for raw red meat products or containing statement for cooked red meat products above green weight) for the added solution component, for example, a product made with cooked beef with solution above green weight named \u201cBeef (containing up to 10% of a flavoring solution) Burgundy\u201d. The ingredients statement must also include the same nomenclature for the added solution meat ingredient. See: Policy Memo 102 dated January 6, 1987 (The Labeling of Products Containing Meat with Added Solutions or Other Nonmeat Ingredients in Secondary Products) LABELING OF PRODUCTS WHICH INCLUDE PACKETS OF OTHER COMPONENTS: Wording indicating that the product contains, in addition to the meat or poultry product, another component, e.g., a gravy, sauce, or seasoning packet must

appear in conjunction with the name of the product in such a manner that it is obvious to the purchaser that he","or she is also purchasing that packet along with the meat and\or poultry product. The wording must be shown in print no smaller than one-third the size of the largest letter in the rest of the product name, of such color that will insure it not being overlooked at point of purchase, and positioned contiguous to the rest of the product name, so as not to appear in whole or part on any panel except the main display panel. The net weight individual components may be shown but are not required. See: Policy Memo 099 dated September 2, 1986 LABELING OF SAFE THAWING INSTRUCTIONS ON CONSUMER PACKAGES: Thawing instructions which appear on the label of a frozen meat or poultry product must be given in accordance with FSIS' recommendations for safe thawing procedures. These procedures are as follows: 1. Thawing product in the refrigerator. 2. Thawing product in cold water, changing water every 30 minutes until product is thawed. 3. Thawing product in a microwave oven for less than 2 hours. Cook immediately. Upon request, alternative thawing procedures may be considered. However, scientific evidence which thoroughly establishes the safety of an alternative thawing procedure must be presented with the procedure when it is submitted for review. See: Policy Memo 119 dated September 28, 1989 LABELING PROMINENCE GUIDELINES FOR CURED, COOKED PRODUCTS WITH ADDED SUBSTANCES THAT DO NOT RETURN TO GREEN WEIGHT: The cured, cooked products covered by sections 9 CFR 319.100 (\u201ccorned beef\u201d), 319.101 (\u201ccorned beef brisket\u201d), 319.102 (\u201ccorned beef round and other corned beef cuts\u201d), and 319.104(a) (\u201ccured pork products\u201d under PFF) of the Federal meat inspection regulations; and by Policy Memos 057A (\u201cLabeling Turkey Ham Products Containing Added Water\u201d) and 084A (\u201cCooked Corned Beef Products and Cured Pork Products with Added Substances\u201d), whose weights after cooking exceed the weight of the fresh uncured article, shall bear the product name and qualifying statements on the principal display panel using the following guidelines: (1) The product name and the qualifying statements must be prominent and conspicuous. (2) The label will bear the product name on the principal display panel in lettering not less than one-third the size of the largest letter in terms commonly associated with","the product name, e.g., cooked, boneless, chopped, pressed, smoked, or words which could be a part of the product name, e.g., steak, butt portion, shank portion. (3) The product name will be judged prominent if the lettering is of the same style and color, and on the same color background as that which is used for the terms commonly associated with the product name or words which could be a part of the product name (see guidelines (2)). If other styles, colors, and\or backgrounds are used, the prominence must be judged equal to those terms and words which could be associated with or part of the product name. (4) The product name must be distinct and separate from other label information. Thus, the product name should not be part of or embedded in qualifying phrases or descriptions that include a list of added solution ingredients. Examples of acceptable terminology are \u201cCorned Beef and Water Product\u201d and \u201cCured Pork and X percent of a Solution.\u201d (5) The label for the products covered by this policy memo must also bear qualifying statements that conform to established policies on the size of the lettering in these statements in relation to product name (as outlined in Policy Memo 087A, FSIS Directive 7110.2, and Policy Memo 057A). See: Policy Memo 109 dated October 8, 1987 LABELING REQUIREMENTS FOR PUMP-CURED BACON PRODUCTS TREATED WITH D-OR D1-ALPHA-TOCOPHEROL IN SURFACE APPLICATIONS: Pump-cured bacon treated on the surface

with d-or d1-alpha-tocopherol must be labeled with a product name qualifier which identifies the substances involved and the method of application. The qualifier must identify both the carrier and active substance in their order of predominance. The specific names, d-or d1-alpha-tocopherol, or the term, Vitamin E, may be used in the name qualifier. Examples of acceptable name qualifiers are \u201cSprayed with a solution of vegetable oil and Vitamin E\u201d or \u201cDipped in a solution of corn oil and d-alpha-tocopherol.\u201d The name qualifier must be contiguous to the product name and printed in a style as prominent as the product name. The type used for the statement must be at least one-fourth the size of the most prominent letter in the product name, except that the ingredients of the mixture may be in print not less than one-eighth the size of the most prominent letter in the product name. The specific name of the ingredients, d-alpha-tocopherol or dl-alpha-tocopherol, and of the carrier must be listed as such in the ingredients statement or curing statement, as required by 9 CFR 317.2(f)(1). See: Policy Memo 105 dated April 13, 1987 LAMB CURRY: Product must contain at least 50 percent fresh meat.", "LANDJAEGER CERVELAT: A semi-dry sausage that originated in Switzerland. It is about the size of a large frankfurter but pressed flat, smoked and dried giving it a black appearance. LARD CONTINUOUS PROCESS: This nomenclature identifies the commodity produced from clean and sound edible tissues of swine by a low-temperature separation process in which the oil is separated from the fatty tissue by means of a combination of heat and centrifugal force. Labeling records containing the above designation should identify in detail the process and equipment used in producing the commodity. LARD -CURED PORK TISSUE USE: Cured pork trimmings may be rendered to produce lard manufactured in compliance with the lard and leaf lard standard. Rendered bacon is not acceptable in lard. See: Policy Memo 052 dated September 15, 1982 LARD REFINED: This term is applied to open-kettle rendered, prime steam, or dry-rendered lard put through a filter press, with or without bleaching agent. LASAGNA: Sauce is an expected ingredient of lasagna products and its declaration in the product name is optional. Cheese Lasagna with meat: 12 percent meat Lasagna with Meat and Sauce: 12 percent meat Lasagna with Meat Sauce: 6 percent meat in total product Lasagna with Poultry: 8 percent poultry meat Lasagna with Tomato Sauce, Cheese, and Pepperoni: 8 percent pepperoni Meat Lasagna: 12 percent meat Poultry Lasagna: 8 percent poultry meat", "LAU -LAU: Product must contain at least 25 percent meat. A Hawaiian dish made with pork and fish, wrapped in taro leaves. Label must have a true product name, e.g., \u201cPork and Fish Stuffed Taro Leaves.\u201d LEBANON BOLOGNA: A coarse ground, fermented, semi-dry sausage. If the product has a MPR of 3.1:1 or less and a pH of 5.0 or less, no refrigeration is required. It is made with beef. No extenders or hearts are permitted in the product. This is not a 9 CFR 319.180 product. LEGENDS: Products consisting of mixed meat and poultry ingredients shall bear either the official meat inspection legend or poultry legend, depending on which ingredients are present in the greater amounts. If meat or poultry ingredients exist in equal proportions, either official legend may be used. If meat and poultry ingredients exist in exact proportions and both appear in the product name, the official legend must reflect the ingredient appearing first in the product name. LENTIL SOUP WITH BACON - German Style: Acceptable name for a lentil soup containing only bacon. The bacon requirement is 4.0 percent for condensed and 2.0 percent for ready to eat. LEONA: An acceptable name. A coarse ground cooked sausage. LIMA BEANS WITH HAM OR BACON IN SAUCE: Product must contain at least 12 percent ham or bacon. See: 9 CFR 319.310 LINGUICA: A Portuguese type

sausage containing pork and excluding other meat and meat byproducts. Usually contains nonfat dry milk and condiments, e.g., vinegar, cinnamon, cumin seed, garlic, red pepper, salt, and sugar. Paprika and cures are acceptable in this product. See: Policy Memo 015A dated June 22, 1981","LINKS: This designation falls into four categories: 1. \u201cLinks\u201d without further qualification refers to an all pork fresh sausage in links. 2. \u201cLinks Sausage\u201d can be used to designate any sausage type formulation usually cured and smoked in links, except for those formulations containing poultry. (See Policy Memo 030A.) 3. \u201cLinks cereal and nonfat dry milk added\u201d usually formulated with meat and meat byproducts cured and smoked, and approved with the understanding each link is banded with an approved band label. 4. \u201cLinks, A pork and textured vegetable protein product\u201d followed immediately by the ingredients statement is acceptable. \u201cLinks,\u201d \u201cTop's Links,\u201d \u201cJoe's Links\u201d are coined names and must be followed immediately by true product name. LITTLE SMOKIES: A smoked small variety sausage link made with beef and pork. LIVER AND ONIONS: Product must contain at least 45 percent liver. LIVER, CHOPPED: Product must contain at least 50 percent liver. LIVER, ONIONS AND EGGS: Product must contain at least 40 percent liver. LIVER PRODUCTS: The product name does not have to include the species for multi-ingredient liver products, such as chopped liver, liver pate, and pureed liver. However, the species must be identified in the ingredients statement. For single ingredient liver products, such as sliced beef liver, the species must be identified in the product name. \u201cKind\u201d liver must always be identified. Products with liver in the name (except for products listed) must contain a minimum of 30 percent liver.", "LIVER SPREAD (STREICH LEBERWURST): The product name \u201cLiver Spread (Stretch Leberwurst)\u201d is acceptable. Product name must contain at least 30 percent liver in total formulation. LIVERWURST OR \u201cPATE DE FOIE -STYLE LIVERWURST\u201d: Product must meet liver sausage requirements. (See Regulation 9 CFR 319.182) LOAF: A \u201cLoaf\u201d (other than meat loaf) consists of meat in combination with any of a wide range of nonmeat ingredients. These products are not identified with the term \u201cMeat Loaf,\u201d \u201cBeef Loaf,\u201d or the like but with designations, e.g., \u201cOlive Loaf,\u201d \u201cPickle and Pimiento Loaf,\u201d \u201cHoney Loaf,\u201d \u201cLuxury Loaf,\u201d and others that are descriptive. LOAF, CANNED, PERISHABLE: Canned perishable products in the loaf category must: 1. Meet the perishable requirements. (See 9 CFR 317.2(k).) 2. Show a brine concentration of not less than 3.5 percent in finished product. Show a brine concentration of not less than 6.0 percent when the products contain cereal, starch, or other extenders. 3. Be cooked to a minimum internal temperature of at least than 150o F. 4. When extenders are added the product name must be qualified, e.g., \u201c(Name of extender) added.\u201d LOLA AND LOLITA (IT): Dry sausage products of Italian origin. Consists of mildly seasoned pork and contains garlic. Lolita comes in 14 oz. links, while Lola comes in 2 1\2 lb. links. LONDON BROIL: Name can only be applied to a cooked product. Products including the expression \u201cLondon Broil\u201d on labels must be prepared with beef flank steak. Uncooked product must be labeled to indicate this, e.g., \u201cBeef Flank Steak for London Broil.\u201d If prepared from another cut, the identity of that cut must accompany the term \u201cLondon Broil,\u201d e.g., \u201cSirloin Tip London Broil.\u201d", "LONG ISLAND STYLE OR TYPE: Not acceptable for poultry products. LONGANIZA: Longaniza is a fresh sausage product. If it is prepared otherwise, the product name must indicate its nature, e.g., \u201cCured

Longaniza.\u201d Paprika is an acceptable ingredient because it is expected. LONGANIZA AND PUERTO RICAN STYLE LONGANIZA: Longaniza is an acceptable name for Puerto Rican sausage made from pork which may contain beef but does not contain annatto. Added fat is not permitted. Puerto Rican Style Longaniza is acceptable labeling for sausage made from pork which may contain beef and does contain annatto. Added fat is not permitted, although up to 3 percent lard may be used as a carrier for annatto. When annatto is used, it should be included in the ingredients statement as \u201cannatto\u201d in accordance with Section 9 CFR

317.2(j)(5) of the meat inspection regulations. See: Policy Memo 021 dated February 9, 1981

LOUKANIKA: An acceptable name for cooked fresh Greek sausage. It is usually made with lamb and pork, oranges, allspice, whole pepper, and salt. LUMPIA or LOOMPYA: A Philippine style or Filipino style egg roll. There are no special ingredient requirements; it refers to a shape of the egg roll. Lumpia or Loompya are generally longer and thinner than traditional egg rolls.

LUNCHEON MEAT: 1. \u201cLuncheon Meat\u201d cannot contain livers, kidneys, blood, detached skin, partially defatted pork or beef tissue, or stomachs. 2. On the label the meat components of \u201cLuncheon Meat\u201d are identified in the ingredients statement as \u201cbeef,\u201d \u201cpork,\u201d \u201cbEEF tongue meat,\u201d \u201cpork tongue meat,\u201d \u201cbEEF heart meat,\u201d and \u201cpork heart meat.\u201d 3. In the ingredients statement \u201cBeef\u201d and \u201cPork\u201d means lean meat with overlying fat and the portions of sinew, nerve, and the blood vessels which normally accompany muscle tissue and which are not separated in the process of dressing","but not including bone and skin. Up to 10 percent of the meat portion of the formula can consist of cured and smoked meat trimmings which does not require special declaration in the ingredients statement except included under \u201cpork\u201d and \u201cbeef.\u201d 4.

Heart or heart muscle, tongues, or tongue meat and cheek meat can be included in \u201cLuncheon Meat\u201d under the following restrictions: a. Hearts or heart meat or tongues or tongue meat must be declared individually by species in the ingredients statement on the label. b. No restriction on the percentage limits of hearts, heart meats, tongues, and tongue meats in the formulation. c. The terms \u201cheart meat\u201d and \u201ctongue meat\u201d refer to the muscle tissue remaining after heart caps, glands, nodes, connective tissue, etc. are trimmed away. 5. Water added to \u201cLuncheon Meat\u201d during manufacture cannot exceed 3 percent by weight of the total ingredients, this is controlled by weighing ingredients and not by analysis. Care must be used to see that water is not added indirectly through the use of undrained hearts and tongues. 6. The only ingredients permitted in \u201cLuncheon Meat\u201d are curing ingredients, sweetening agents, spices, and flavoring. All of these substances must be declared in the ingredients statement by name, except the various \u201cflavorings\u201d and \u201cspices\u201d which need not be named individually. \u201cSpices\u201d refer to natural spices and not to extracts. LYONER WURST: A

cooked, smoked, and finely ground sausage originating in Germany. It is usually made with

beef, pork, (no chicken) flavoring, cure, and contains green peppercorns. LYONS SAUSAGE (FR):

A dry sausage made exclusively of pork (four parts finely chopped lean and one or two parts small diced fat) with spices and garlic which is stuffed into large casings, cured and air-dried. MACARONI AND BEEF IN SAUCE: Product must contain at least 12 percent beef.", "MACARONI AND CHEESE WITH HAM: Product must contain at least 12 percent cooked ham. MACARONI SALAD WITH (Meat or Poultry): Product must contain at least 12 percent cooked meat or

poultry meat. MADE WITH \u2026 QUALIFIERS: Need only mention the species or kind in the statement even when only a byproduct of the specific species or kind is used, e.g., pork, chicken and beef hearts in a sausage would carry a qualifier \u201cmade with pork, chicken and beef.\u201d MADE WITH 100 percent REAL CHEESE: This statement is acceptable on products as long as the cheese components are all 100 percent real cheese. It is not acceptable if a cheese food product or imitation cheese is included in the formula. MALIC ACID: Malic acid has been used extensively for many years as part of flavoring\//seasoning mixtures which are added to components of meat or poultry products. It may be approved as a flavoring agent, and is acceptable as a component in a seasoning mix, e.g., in marinades and sauces, but may not be added alone to a product. MANICOTTI (IT): Product must contain at least 10 percent fresh meat. An Italian main dish consisting of rectangular-shaped pasta spread with a filling of meat (e.g., sausage, ground beef, or chopped prosciutto) and\//or cheeses (e.g., ricotta and mozzarella). The pasta is rolled, edges pressed to seal, and covered with grated parmesan cheese and tomato sauce. A true product name must be shown, e.g., \u201cBeef Manicotti in Sauce.\u201d MARGARINE SUBSTITUTES: Meat food products that are substitutes for margarine because they contain less than 80 percent fat and\//or oil need not be labeled \u201cimitation\u201d if the product has a fully descriptive name and the finished product contains 15,000 international units of Vitamin A per pound. The descriptive name of the product may include the term \u201cSpread\u201d (or \u201cSpred\u201d), which has been widely adopted as a generic fanciful name for this class of product.", "The following guidelines shall be used in selecting the appropriate descriptive product name: 1. \u201cAnimal Fat Spread (or Spred)\u201d is an acceptable product name for a product prepared from animal fat as the sole source of fat. 2. \u201cAnimal Fat and Vegetable Oil Spread (or Spred)\u201d is an acceptable product name for a product prepared with a combination of animal fat(s) and vegetable oil(s) in which the vegetable oil(s) content is greater than 20 percent of the total of the fat(s) and oil(s) used but less than 50 percent of the total. 3. \u201cAnimal Fat Spread (or Spred) -Vegetable Oil Added\u201d is an acceptable product name for a product prepared with a combination of animal fat(s) and vegetable oil(s) in which the vegetable oil(s) content is 20 percent or less of the total of the fat(s) and oil(s) used but greater than 2 percent of the total. 4. The fanciful name \u201cSpread\u201d (or \u201cSpred\u201d) accompanied by a list of all ingredients individually identified by their common or usual name in order of decreasing predominance is acceptable regardless of the nature and amount of fat(s) and\//or oil(s) used. In 1., 2., and 3. above, the descriptive product name may include the percent of each fat and\//or oil and may include the common or usual name of each fat and\//or oil used. See: Policy Memo 045 dated April 7, 1982 MARENGO: Product must contain at least 35 percent cooked meat or poultry meat. It has chicken or veal in a sauce containing tomatoes, mushrooms, onions, and wine, and label must show true product name, e.g., \u201cChicken Marengo.\u201d MARINE OIL: Herring oil and other marine species oils found by FDA to be satisfactory may be combined with animal and mixture of animal and vegetable oils processed as meat food products. Labels will bear statements identifying the presence of such substances, e.g., a shortening consisting of 50 percent herring oil and the remainder equal amounts of animal and vegetable oils would be \u201cShortening, Prepared with Herring Oil, Animal and Vegetable Oils.\u201d MARKING: Labeling may consist of a combination of printing, stenciling, box dyes, etc. for large true containers and for shipping containers. Crayons are unacceptable for applying required labeling

features except for figures indicating content quantity. Approval of official marks appearing in newspaper advertisements, billboards, etc. is not necessary; however, such marks may be reviewed locally before publication. Such markings should conform to the illustrations in the regulations and not be misleading.", "\u201cMAY CONTAIN\u201d STATEMENTS: The use of \u201cmay contain\u201d or \u201cand\u201d labeling may be used in the ingredients statement\u2019s sublisting of sliced and\u201d or diced products from various sources. See: \u201cComposite Ingredients Statement.\u201d MEAT AND DRESSING: Product must contain at least 50 percent cooked meat. MEAT AND DRESSING WITH GRAVY: Product must contain at least 30 percent cooked meat. MEAT BASE: A granular, paste-like product which is shelf-stable primarily because of its high salt content (30-40 percent). 1. Beef Base -15 percent beef or 10.5 percent cooked beef 2. Pork Base -15 percent pork or 10.5 percent cooked pork 3. Ham Base - 18 percent ham MEAT BROTH OR MEAT STOCK: MPR 135:1. Condensed 67:1 MEAT BYPRODUCTS: Byproducts must be individually declared by species and specific name in the ingredients statement, e.g., Pork Liver, Beef Tripe, and Beef fat.", "MEAT CASSEROLES: Product must contain at least 25 percent meat or 18 percent cooked meat. MEAT CURRY: Product must contain at least 50 percent meat. MEAT FLAVORING: Meat flavoring \u2013 when characteristic meat flavorings such as bacon are added in amounts less than 2 percent in addition to the required meat component of a product, such meat flavorings need not appear in the product label. MEAT FOLDOVER MIT DRESSING: Product must contain at least 50 percent meat (chopped and formed). MEAT FOOD PRODUCTS CONTAINING POULTRY INGREDIENTS - LABELING: Meat food products containing poultry ingredients in amounts that exceed 20 percent of the total livestock and poultry product portion of the meat food product must have product names that indicate the presence of the poultry ingredients, e.g., \u201cBeef and Chicken Chili\u201d or \u201cChili made with Beef and Chicken.\u201d Meat food products containing poultry ingredients in amounts at 20 percent or less of the total livestock and poultry product portion of the meat food product must have product names that are qualified to indicate the presence of the poultry ingredients, e.g., \u201cBeef Stew -Turkey Added.\u201d However, meat food products that do not meet specified minimum livestock ingredient requirements because poultry ingredients are replacing any part of the required livestock ingredients must have product names that indicate the presence of the poultry ingredients, e.g., \u201cBeef and Turkey Stew\u201d or \u201cStew Made with Beef and Turkey.\u201d This policy does not apply to: (1) red meat products that are expected to contain poultry ingredients, e.g., \u201cBrunswick Stew and Potted Meat Food Product\u201d (Section 9 CFR 319.761); (2) cooked sausages identified in Section 9 CFR 319.180 of the meat regulations (Policy Memo 005A); or (3) nonspecific loaves, rolls, logs, etc., e.g., Pickle and Pimento Loaf. See: Policy Memo 030A dated September 13, 1982", "MEAT LOAF: Uncooked or cooked pork, beef, veal or lamb, and other ingredients in loaf form, but not canned. 1. Ingredients, e.g., cracker meal, oatmeal, bread crumbs, nonfat dry milk, soy ingredients (untextured), milk, and whole eggs are not required in the product name. 2. Product may contain: a. Head meat, cheek meat, heart meat, and tongue meat under label declaration in the ingredients statement only. b. Not more than 12 percent extenders and binders. c. Partially defatted chopped beef or pork up to 25 percent and declared as meat in the ingredients statement. 3. Product must contain at least 65 percent meat. 4. Onion, tomato juice, water, and other liquid extenders are not directly controlled. MEAT LOAF, CANNED (Perishable): Canned perishable products in the loaf category

must: 1. Meet the perishable labeling requirements. See: 9 CFR 317.2(k), 2. Be cured with at least 1 ounce nitrate per 100 pounds of product and 1½ percent dextrose or 1 percent sugar. 3. Have a brine concentration of at least 3.5 percent in the finished product. Products that contain cereal, starch, or other extenders must have a brine concentration of at least 6.1 percent. MEAT LOAF, CANNED (Sterile Packed): No head, cheek, heart, or tongue meat permitted. Other requirements are the same as uncanned cured meat loaf. Binders and extenders must be shown in the product name, e.g., Meat Loaf, cereal added.

MEAT PASTY OR PASTIES: Product must contain at least 25 percent meat. The label must show the true product name, e.g., Beef Pasty.

MEAT PIE FILLING: Product must contain at least 37 percent meat.

MEAT PIES (OR VEGETABLE MEAT PIES): Product must contain 25 percent meat; meat in gravy may be counted towards meat content.

MEAT/POULTRY EXTENDED PRODUCTS: These should always be listed in the ingredients statement of the secondary product by their correct name, e.g., Beef, water and binder product, unless it is included in the name of the product, e.g., Chili made with beef and binder product.

MEAT RAVIOLI: Product must contain at least 10 percent meat in ravioli.

MEAT RAVIOLI IN MEAT SAUCE: Product must contain at least 10 percent meat in ravioli and at least 50 percent ravioli in total product, and at least 6 percent meat in sauce.

MEAT RAVIOLI IN SAUCE: Product must contain at least 10 percent meat in the ravioli and at least 50 percent ravioli in the total product.

MEAT SAUCE: Product must contain at least 6 percent ground meat.

MEAT SPREADS: Product must contain at least 50 percent meat or 35 percent cooked meat. When another major component is considered a significant source of protein such as cheese is added the requirement is reduced to 25 percent cooked meat. Product must show a true product name, e.g., Sausage and Cheese Spread.

MEAT STICK AND CHEESE COMBINATION PRODUCTS: The following criteria are used for dry meat stick and cheese combination products that need not bear a "keep refrigerated" handling statement.

(1) The dry meat stick portion must have a water activity of less than 0.90, the cheese portion must have a water activity of less than 0.94, and the equilibrium of the water activity of the two components must be no greater than 0.92;

(2) the dry meat portion, if fermented, must be fermented by an active fermentation culture (typically to a pH 5.0 or below) and;

(3) for products where the meat portion and the cheese portion are packaged together, there must be a heat seal between the dry meat stick and cheese components which separates the meat stick from the cheese stick by at least 4 mm.

(4) Dry meat stick and cheese combination products not meeting these criteria must be labeled with a "keep refrigerated" statement in lieu of compelling data that establish safety. Products not meeting the criteria stated above can be labeled without a "keep refrigerated" statement if a control program ensuring safety and shelf stability is established by the established.

MEATBALL STEW: Meatball stew contains at least 25 percent meatballs and usually contains vegetables such as potatoes, peas, carrots, etc., and gravy or thick broth resulting from cooking all ingredients together. The meatballs must meet the Meatball Standard.

MEATBALLS: Uncooked or cooked pork, beef, veal, and lamb, and other ingredients in a ball form.

1. Product must contain at least 65 percent meat.

2. Binders and extenders are limited to 12 percent of the total product. 6.8 percent of isolated soy protein is considered the equivalent to 12 percent of the other binders or extenders. The permitted binders and extenders include, but are not limited to, cereal, bread crumbs, cracker meal, soy flour, soy protein concentrate, isolated soy

protein, and textured vegetable protein. 3. Cheeks, hearts, and tongues are not allowed, but product may contain head meat, cheek meat, heart meat, and tongue meat when declared in the ingredients statement. 4. Partially defatted chopped (PDC) (species) may be used up to 25 percent of the meat block. PDC (species) can be identified as (species) in the ingredients statements. (See entry for Partially Defatted Chopped (species).)"**MEATBALLS IN SAUCE:** Requires a 50 percent minimum of meat-balls, by weight in finished product. **MEATBALLS, SWEDISH STYLE:** Product must contain at least 65 percent fresh meat. \u201cSwedish Meatballs\u201d or \u201cSwedish Style Meatballs\u201d are small in size and usually contain two or three different varieties of meat, nutmeg and\or allspice, potatoes, and milk. \u201cSwedish Brand Meatballs Made in USA\u201d means any meatball. **MEATBALLS, TURKEY:** Product must contain at least 65 percent raw turkey meat. Skin is permitted in natural proportions of meat used, if skin is in excess of natural proportions, it shall be reflected in the product name. **MEDITERRANEAN STYLE:** Acceptable identification for product containing onion or garlic, olive oil and four of any of the following groups: 1. Vegetable or fruit: dried apricot, artichoke, dried date, dried fig, eggplant, tomato, pepper (green or red), squash, lemon or lemon juice, raisin and olives. 2. Legume or nut: fava bean, chick pea, white cannelloni bean, green bean, lentil, almond, pine nut, pistachio. 3. Seasoning: dill, coriander, cinnamon, cumin, fennel, basil, oregano, thyme, saffron, rosemary, parsley, mint, sumac, turmeric. 4. A regional dish as component, e.g., pita bread, yogurt, Italian or Greek type cheese, pasta, couscous or bulgur. **MERGUEZ, MERGUES OR MERGHEZ SAUSAGE:** A hot and spicy fresh sausage originating in North Africa and common in France which contains hot pepper and\or paprika. The meat component must contain beef and may contain lamb or mutton when labeled as \u201cMerguez Sausage.\u201d When pork is used as part of meat component, the product is labeled as \u201cMerguez Sausage with Pork.\u201d When pork is the only meat ingredient, the product is labeled \u201cPork Merguez Sausage.\u201d", "**METTWURST:** An uncooked cured smoked sausage in which byproducts and extenders are not permitted. Beef heart meat is acceptable. Water is limited to 3 percent and the fat content shall not exceed 50 percent. See: Policy Memo 020A dated March 26, 1981 **METTWURST, COOKED:** Mettwurst which is cooked must be labeled \u201cCooked Mettwurst,\u201d and may contain up to 10 percent water based on the finished product. See: Policy Memo 020A dated March 26, 1981 **METZ SAUSAGE:** Cured lean beef and pork and bacon are finely chopped, seasoned, and stuffed into beef middles. It is air-dried for 5 days, then given a cool smoke. It is classed as a semi-dry sausage. **MEXICAN STYLE:** Acceptable for products that contain at least four of the following: jalapeno peppers, chili peppers, green chilies, cumin, cayenne peppers, red or green peppers, chili powder, jalapeno powder, Monterey Jack cheese, or cheddar cheese. This policy applies to a single food and does not supersede Policy Memo 068. **MEXICAN STYLE DINNERS:** Products like tamales, enchiladas, and tacos must make up 25 percent of the dinner or entree to qualify as \u201cMexican Style.\u201d The individual product standard must also be met. **MEXICAN STYLE SAUCES:** A garnish (decoration) of cheese in or on the sauce of Mexican style foods does not require the presence of the cheese to be declared in the product name or qualifying statement. **MILAN OR MILANO SALAMI:** A dry sausage with a maximum MPR of 1.9:1. It is an Italian-type salami, except the meat is finely cut. It is made with beef, pork fat, spiced with garlic, and has a distinctive cording.", "**MINCE MEAT:** Product must contain at least 12 percent fresh meat or 9 percent cooked meat. Heart meat may be substituted. In addition to

\u201cMince Meat,\u201d the product name should include kinds of meat, e.g., \u201cMince Meat with Beef\u201d or \u201cMince Meat with (species) Heart Meat.\u201d When 2 percent or more cooked meat but less than 9 percent cooked meat is present in the formula, the product is amenable and the name must state that the product is \u201cMince Meat Flavored With .\u201d A product marketed as \u201cMince Meat\u201d which contains less than 2 percent cooked meat or contains only beef suet as the ingredient of animal origin, is not considered as a meat food product and is not amenable. MIXTURES: Mixtures of nonfat dry milk (NFDM), calcium reduced dry skim milk (CRDSM), or dried whey, reduced lactose whey, reduced minerals whey, and whey protein concentrate with other substances are not allowed, except in batter and gravy mixes and batters. Mixtures of cereal, soy preparations and/or sodium caseinate with other substances are permitted to come into the plant for use in batter and gravy mixes, but they must be labeled to show their intended use, e.g., \u201cPatty Mix\u201d or \u201cGravy Mix.\u201d The labels of the mixtures must show the ingredients in order of their predominance. MOCK DRUMSTICKS: An imitation product; nonspecific. MOCK TURTLE SOUP: Product must contain at least 10 percent beef and may be made with beef and beef byproducts. MOFONGO: Pork skins and plantain type product with at least 20 percent pork skins in the total formulation. It must show true product name, e.g., \u201cPork Skin Filling Wrapped in Plantain.\u201d", "MOISTURE PROTEIN RATIO (MPR)": Frizzes 1.6:1 Ukrainian Sausage 2.0:1 Jerky 0.75:1 Kippered Beef 2.03:1 Pepperoni 1.6:1 Dry Salami 1.9:1 Dry Sausage 1.9:1 Genoa Salami 2.3:1 Tropic Cure Pork 3.25:1 Sicilian Salami 2.3:1 Thuringer 3.7:1 Italian Salami 1.9:1 Dried Meat 2.04:1 Roast Beef, Canned 2.25:1 Chipped Beef 2.04:1 Farmer Summer Sausage 1.9:1 MOISTURE PROTEIN RATIO (MPR) -PH: Nonrefrigerated or shelf-stable sausages must have an MPR of 3.1:1 or less and a pH of 5.0 or less, unless commercially sterilized. This does not apply to products containing more than 3.5 percent binders or 2 percent isolated soy protein. MONDONGO: A mixture of one or more of the following: (a) beef tripe, (b) cattle feet with or without hide on, (c) chitterlings, and (d) beef intestines. See: Beef Tripe Stew MORCELLA BLOOD PUDDING: Nonspecific. The product is made from pork fat, beef blood and/or pork blood, and may contain meat. MORTADELLA: Normally a cooked sausage but can be dry or semi-dry. It is similar to salami and cervelat except that it has large chunks of pork fat. Red sweet peppers up to 4 percent and pistachio nuts up to 1 percent are acceptable as long as they are shown in the true product name. MORTADELLA (CANNED): Canned items designated \u201cMortadella\u201d must be labeled with the phrase \u201cPerishable, Keep Under Refrigeration\u201d and must have an MPR of 3.85:1 or less. See: Manual 18.46", "MORTADELLA -POULTRY: Poultry Mortadella is a dry, semi-dry, or cooked sausage formulated with poultry. The sausage must contain large chunks of pork fat and may contain extenders and/or binders. Red sweet peppers are permitted up to 4 percent and pistachio nuts up to 1 percent and shown as added in the true product name. See: Policy Memo 029 If product is canned, the MPR must not exceed 3.85:1, the internal temperature must have reached 160o F and the product labeled \u201cPerishable, Keep Under Refrigeration\u201d or similar wording. MORTADELLA WITHOUT FAT CUBES OR CHUNKS: Product must meet the standard for Mortadella and the label be qualified to indicate the absence of Fat Cubes or Chunks, e.g., \u201cMortadella without Fat Cubes\u201d or \u201cMortadella without Fat Chunks.\u201d MOUSAKA, MOUSSAKA, MUSAKA (GK): Must contain at least 25 percent meat. Mousaka is a casserole containing layers of meat and eggplant made in various ways throughout the Middle

East. A true product name is required, e.g., \u201cEggplant and Meat Casserole.\u201d MULLICATAWNY SOUP: Product must contain at least 2 percent cooked poultry meat and enough curry powder and pepper to characterize the product. The label must show a true product name, e.g., \u201cChicken Mullicatawny Soup.\u201d MULLIGAN STEW: Product must contain at least 25 percent fresh meat or meat and poultry. Mulligan stew is a mixture of vegetables and meat combined in a gravy or sauce. The label must have a true product name, e.g., \u201cChicken and Meat Mulligan Stew.\u201d MUSTARD BRAN: This is not considered a spice and must be declared as \u201cMustard Bran.\u201d It is not acceptable in sausage.

MUSTARD FLOUR: It is a spice that is commonly used in sausage products." , "MYVACET: (Distilled Acetylated Monoglycerides). Acceptable for use as a coating on sausage casings. Sausages coated with Myvacet shall show, adjacent to the product name, a qualifying statement disclosing the presence of the compound, e.g., \u201cSummer Sausage Coated with a Solution of Distilled Acetylated Monoglycerides.\u201d NACHO STYLE, NACHO FLAVOR, AND SIMILAR TERMS: Acceptable terminology for products possessing the commonly expected flavor characteristics associated with \u201cNachos,\u201d a Mexican hors d'oeuvre. The characterizing flavor components generally include, but are not limited to, cheese (Cheddar or Monterey Jack), tomato (tomato solids, tomato powder), spices, or other natural seasonings and flavorings (usually garlic and onion), and chili peppers (mild or hot). Romano and Parmesan cheese are also often present. However, these cheeses may not be used to satisfy the above cheese requirement.

NATURAL CLAIMS: The term \u201cnatural\u201d may be used on labeling for meat products and poultry products, provided the applicant for such labeling demonstrates that: (1) the product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 CFR 101.22), or any other artificial or synthetic ingredient; and (2) the product and its ingredients are not more than minimally processed. Minimal processing may include: (a) those traditional processes used to make food edible or to preserve it or to make it safe for human consumption, e.g., smoking, roasting, freezing, drying, and fermenting, or (b) those physical processes which do not fundamentally alter the raw product and\or which only separate a whole, intact food into component parts, e.g., grinding meat, separating eggs into albumen and yolk, and pressing fruits to produce juices. Relatively severe processes, e.g., solvent extraction, acid hydrolysis, and chemical bleaching would clearly be considered more than minimal processing. Thus, the use of a natural flavor or flavoring in compliance with 21 CFR 101.22 which has undergone more than minimal processing would place a product in which it is used outside the scope of these guidelines. However, the presence of an ingredient which has been more than minimally processed would not necessarily preclude the product from being promoted as natural. Exceptions of this type may be granted on a case-by-case basis if it can be demonstrated that the use of such an ingredient would not significantly change the character of the product to the point that it could no longer be considered a natural product. In such cases, the natural claim must be qualified to clearly and conspicuously identify the ingredient, e.g., .all natural or all natural ingredients except dextrose, modified food starch, etc.\u201d , "All products claiming to be natural or a natural food should be accompanied by a brief statement which explains what is meant by the term natural, i.e., that the product is a natural food because it contains no artificial ingredients and is only minimally processed. This statement should appear directly beneath or beside all natural claims or, if elsewhere on the principal display panel; an asterisk should be used to tie

the explanation to the claim. The decision to approve or deny the use of a natural claim may be affected by the specific context in which the claim is made. For example, claims indicating that a product is natural food, e.g., \u201cNatural chili\u201d or \u201cchili - a natural product\u201d would be unacceptable for a product containing beet powder which artificially colors the finished product. However, \u201call natural ingredients\u201d might be an acceptable claim for such a product. Correction: In the August 2005 edition of the Policy Book, a \u201cNote\u201d was added to the entry on \u201cnatural claims\u201d indicating that \u201cSugar, sodium lactate (from a corn source), and natural flavorings from oleoresins or extractives are acceptable for \u201call natural\u201d claims. The Note was followed by other new text that stated \u201cThis entry cancels Policy Memo 055 dated November 22, 1982. See: 7 CFR NOP Final Report, Part 205.601 through 205.606 for acceptable ingredients allowed for all natural claims.\u201d This \u201cNote\u201d is now revised to read as follows: Note: Sugar and natural flavorings from oleoresins or extractives are acceptable for \u201call natural\u201d claims. The other text, including the reference to \u201csodium lactate (from a corn source)\u201d has been removed from the guidance on \u201cnatural claims\u201d for the reasons explained below. The note regarding sodium lactate (from a corn source) was added to the \u201cnatural\u201d entry in recognition that manufacturers could show that the ingredient was from a natural source (i.e., from corn), was no more than minimally processed, and provided a flavoring effect, not an antimicrobial effect, at levels consistent with those regulated for the purpose of flavoring (i.e., less than 2 percent of a formulation). Thus, the Agency considered such uses to be consistent with the meaning of \u201cnatural.\u201d However, recent information provided to FSIS raises questions about this judgment. This information indicates that sodium lactate, potassium lactate, and calcium lactate provide an antimicrobial effect at levels that have been regulated as providing a flavoring effect. Therefore, regardless of whether it can be shown that any form of lactate is from a natural source and is not more than minimally processed, the use of lactate (sodium, potassium, and calcium) may conflict with the meaning of \u201cnatural\u201d because it may be having a preservative effect at levels of use associated with flavoring. Thus, listing \u201csodium lactate (from a corn source)\u201d in the previous entry may have been in error, at least without qualifying the listing by stating that the use of this ingredient or any ingredient known to have multiple technical effects needs to be judged on a case-by-case basis at the time of label approval to assess that the intended use, level of use, and technical function are consistent with the 1982 policy. Whether there should ever be a blanket acceptance of any ingredient that has multiple functions, including an antimicrobial or preservative function, in products labeled \u201cnatural\u201d is a complicated issue that is best addressed through notice and", "comment rulemaking. Therefore, FSIS has removed the reference to sodium lactate from this guidance but will judge claims that foods to which a lactate has been added can be characterized as \u201cnatural\u201d on a case-by-case basis, pending the outcome of a rulemaking on the use of \u201cnatural\u201d that the Agency intends to initiate in the near future. This correction also removes the statement in the entry on \u201cNatural Claims,\u201d \u201cSee: 7 CFR NOP Final Report, Part 205.601 through 205.606 for acceptable ingredients allowed for all natural claims.\u201d This statement was intended to help manufacturers locate a source to support the claims that ingredients they use in \u201cnatural\u201d products are not more than minimally processed, are not artificial or

synthetic, and do not act to preserve products. The Agency has removed this text because it was confusing users of the policy guidance who thought that any ingredient that is \u201corganic\u201d could be used in a \u201cnatural\u201d product, which is not the case.

**NATURAL SMOKED COLOR:** Approval can be properly granted to labels with this statement when the products involved are \u201cSmoked\u201d and not artificially colored. The results of the use of artificial smoke materials can, by means of a number of processing operations, result in a color characteristic being acquired by the frankfurters, bologna, and the like. The term \u201cNatural Smoked Color\u201d can be used to properly identify this point.

**NAVARIN:** Navarin is a stew containing lamb or mutton and vegetables and considered a national dish of France. It must meet the meat stew standard of 25 percent meat. Show true product name, e.g., \u201cNavarin-Lamb Stew.\u201d

**NEGATIVE LABELING:**

- (1) Negative labeling is allowed if it is unclear from the product name that the ingredient is not present. For example, the use of the term \u201cno beef\u201d on the label of \u201cturkey pastrami\u201d would further clarify that the product does not contain beef.
- (2) Negative labeling is allowed if the statement is beneficial for health, religious preference, or other similar reasons. For example, highlighting the absence of salt in a product would be helpful to those persons on sodium-restricted diets.
- (3) Negative labeling is allowed if the claims are directly linked to the product packaging, as opposed to the product itself. For example, flexible retortable pouches could bear the statement \u201cno preservatives, refrigeration or freezing needed with this new packaging method.\u201d
- (4) Negative labeling is allowed if such claims call attention to the absence of ingredients because they are prohibited in a product by regulation or policy. The statement must clearly and prominently indicate this fact, so as not to mislead or, "create false impressions. For example, \u201cUSDA regulations prohibit the use of preservatives in this product\u201d would be an acceptable statement for ground beef.
- (5) Negative labeling is allowed to indicate that absence of an ingredient when that ingredient is expected or permitted by regulation or policy. This could also apply to ingredients which are not expected or permitted by regulation or policy if the ingredients could find their way into the product through a component. For example, the use of \u201cno preservatives\u201d on the label of \u201cspaghetti with meat and sauce\u201d (where regulations do not permit the direct addition of preservatives) would be acceptable if the product contained an ingredient, such as cooking oil, which could contain antioxidants but do not. These guidelines do not preempt the requirements of the nutrition labeling regulation. Therefore, negative claims such as \u201cunsalted\u201d would have to comply with the provisions stated in the nutrition labeling regulations. See Policy Memo 019B dated August 18, 1994.

**NET QUANTITY OF CONTENTS ON COMBINATION PACKAGES:** The guidelines for stating the net quantity of contents on combination packages containing both liquid and solid products are as follows:

1. The declaration of net quantity of contents for a combination package shall be expressed in terms of fluid measure for individual products that are liquid and in terms of avoirdupois weight for individual products that are solid, semisolid, or viscous, provided the quantity statements for identical packages or units are combined. For example, the fruit drink would be expressed in fluid measure and the meat, cheese, crackers, and cookies would be expressed in the combined avoirdupois weight.
2. The declaration of quantity shall be preceded by one of the following terms, as appropriate: \u201cNet Weight,\u201d \u201cNet Wt.,\u201d or \u201cNet Contents.\u201d The net quantity of contents declaration may appear in more than one line.

Therefore, both stacked and side-by-side declarations would be considered appropriate. - Descriptive terms may be used to identify the liquid and solid components of the package, e.g., entree, meal, or drink; however, such terms shall not include brand names. -Connecting words such as \u201cand\u201d or \u201cplus\u201d are permitted to be used as part of the declaration of contents. Examples of acceptable net content declarations are as follows: (1) Entree Net Wt. 8 oz., Drink 4 fl. oz. (120ml)", "(2) Net Contents: lunch 8 oz. plus fruit drink 4 fl. oz. (3) Net Wt. 8 oz. Drink 4 fl. oz. (120ml) (4) Net Weight 8 oz. and 4 fl. oz. Federally inspected meat and poultry products are exempt from the requirements of the Fair Packaging and Labeling Act (FPLA), including the mandatory metric labeling provisions that went into effect February 14, 1994. However, if metric labeling is included voluntarily, such labeling should comply with the FPLA. The guidelines contained in this policy memo will be subject to the provisions prescribed in 9 CFR 317.2(h) and 9 CFR 381.121 of the Federal regulations. See: Policy Memo 124 dated January 17, 1995 NET WEIGHT STATEMENT: Divider Pak: On a product where two cans are taped together, one of which contains the meat or poultry item and the other a vegetable, e.g., \u201cChicken Chow Mein,\u201d the meat or poultry label may include the net weight on the 20 percent panel. The vegetable can bears the true name of the product with the total net weight of the other can and the drained weight of the vegetable can. Double Packing: When a poultry product and a non-poultry product are separately wrapped and placed in a single immediate container bearing the name of both products, the net weight shown on the immediate container may be the total net weight of the two products or the net weight of the poultry product and the non-poultry product separately. Additional Net Weight Information: Nonregulatory information of a net weight nature, e.g., 4-3 oz. packages, accompanying a net weight statement is acceptable and need not adhere to the size and spacing restrictions. Open Net Weights: Open net weights may be presented in pounds and ounces, decimals, decimal fractions, or fractions, e.g., 1 1\2 lbs., 1.6 lbs. Net Weight Requirements: The statement of net quantity of contents is required on all products intended for sale at retail intact. In addition, shipping containers must bear a net quantity of contents statement if product inside is not uniform in weight (i.e., random weight). Piece counts may not be used in lieu of a required net quantity of contents statement on a shipping container but may be used as additional information. Multi-Unit Retail Packages: Fully labeled packages of more than one of the same meat or poultry product packages in an open (i.e., clear) overwrap do not have to include a net weight statement.", "See: 9 CFR 317.2(h), and 9 CFR 381.121(b) MPI Bulletin 211 NET WEIGHT STATEMENTS ON PACKAGES WITH HEADER LABELS: The guidelines for determining the size and location of net weight statements on meat food product packages with header labels are as follows: 1. The entire front of the package is considered the principal display panel of the package and its area is used to determine the size of the net weight statement. Print size specifications for the net weight statement specified by the regulations must be followed. 2. The net weight statement should be placed within the lower 30 percent area of the header label if no other mandatory labeling features are printed on the rest of the principal display panel of the package. If mandatory features do appear below the header label, the net weight statement must be placed within the lower 30 percent of the total area containing any mandatory information. A \u201cHeader Label\u201d is a small label applied across the top of a package usually bearing all of the mandatory labeling information. The rest of the package is most often a clear film containing a meat or poultry product, e.g., luncheon

meat. This type of packaging is designed to be used on pegboard type displays. See: Policy Memo 047 dated May 3, 1982 \u201cNEW\u201d AND SIMILAR TERMS: Terms like \u201cnew,\u201d \u201cnow,\u201d \u201cimproved,\u201d and similar terms may be used within the following guidelines: 1. The terms may only be used for a period of 6 months from the date of the initial approval, except as noted in 2., 3., and 4. below. 2. Extensions to the 6-month period may be granted if: a. Processors can demonstrate that production or distribution delays precluded the use of the approved labeling as scheduled. In such situations, the lost time can be restored. b. Processors can demonstrate that labeling inventory needs for the 6-month period were over estimated due to poor sales. The processors must maintain records which indicate the amount and the date the labeling was originally purchased. In this situation, up to an additional 6 months can be granted. No further extension will be considered.", "3. In those situations where it is customary to distribute \u201cnew\u201d products to various geographical regions, each geographic area may receive a sketch approval for 6 months if the processor can assure adequate controls over the segregation and distribution of the products. 4. In situations where it is customary to test market product in no more than approximately 15 percent of the intended total marketing area before total distribution begins, labeling for the test market area can receive a sketch approval and also be included in the 6-month sketch approval given to the labeling of the product distributed to the total marketing area. Processors must be able to assure that only 15 percent of the total market is involved in test marketing. See: Policy Memo 107 dated August 18, 1987 NEW ENGLAND BOILED DINNER: Product must contain at least 25 percent cooked \u201cCorned Beef.\u201d NEW ORLEANS STYLE: Acceptable for products that contain any five of the following ingredients: Roux base, rice, onion, green onions garlic, celery, bell peppers, cayenne pepper, white pepper, parsley, or tomato. The product may contain various protein sources including seafood and game. NITRITE: Calculations should be based on the total meat block including the muscle tissue, fat and blood (e.g., \u201cBlood Pudding\u201d). If the product is cured, the blood would be included and considered part of the meat. NON-AMENABLE PRODUCT\VOLUNTARY INSPECTION: [Examples of non-amenable products are sandwiches containing meat or poultry, clam chowder which has less than 1 percent bacon for export to Japan, and natural casings for export]. Any non-amenable product can be produced under voluntary inspection when requested (9 CFR 318.13 and Subchapter B, Part 350.3(c)). However, most FSIS requirements have to be met concerning labeling, i.e., mandatory labeling features, an accurate ingredients statement, handling statement, etc. Safe Handling Instructions are not required even for raw non-amenable products. FDA nutrition labeling rules apply to such products.", "NON-DAIRY WHITE SAUCE OR NON-DAIRY SAUCE: A sauce made with a non-dairy creamer. If this type of a sauce is proposed for use with \u201cChipped Beef,\u201d a suitable name would be \u201cNon-Dairy White Sauce with Chipped Beef\u201d or \u201cNon-Dairy Sauce with Chipped Beef.\u201d The reference to \u201cCream\u201d or any of its derivations should not appear in the product name. NONSPECIFIC MEAT FOOD PRODUCTS: Red meat items of this type do not have specific requirements, i.e., they do not possess a standard of identity or composition. Consequently, these products shall be identified by one of two ways: (1) A descriptive name that identifies characterizing components and\or ingredients, or (2) a fanciful or coined name that is accompanied by an ingredients statement. The latter approach should be used when the use of a descriptive name is not practical, e.g., when the descriptive name would read like an

ingredients statement. When a fanciful name or coined name is used, the ingredients statement should appear contiguous to the product name on the principal display panel of an immediate container. NONSTANDARDIZED COOKED SAUSAGE PRODUCTS CONTAINING BOTH LIVESTOCK AND POULTRY INGREDIENTS: The labeling of nonstandardized cooked sausage products must comply with 9 CFR 319.180. Meat food products are those in which more than 50 percent of the livestock and poultry product portion consists of livestock ingredients. Such cooked sausage products which contain poultry ingredients at more than 15 percent of the total ingredients (excluding water) must have product names that indicate the species of livestock and kind(s) of poultry ingredients, e.g., \u201cBeef and Turkey Frankfurter\u201d or \u201cFrankfurter Made From Beef and Turkey.\u201d Poultry food products are those in which more than 50 percent of the livestock and poultry products portion consists of poultry. Livestock ingredients at more than 20 percent of the total poultry and livestock ingredients must have product names that indicate the kind(s) of poultry and species of livestock ingredients, e.g., \u201cTurkey and Beef Frankfurter\u201d or \u201cFrankfurter Made From Turkey and Beef.\u201d Such cooked sausage products which contain livestock ingredients at 20 percent or less of the total poultry and livestock ingredients must have product names that are appropriately qualified to indicate the inclusion of livestock ingredients, e.g., \u201cTurkey Frankfurter -Pork Added or Turkey Frankfurter -With Pork. \u201d (The product names of cooked sausage products which contain no livestock ingredients designate the kind(s) of poultry ingredients, e.g., \u201cTurkey Frankfurter.\u201d) Cooked sausage products containing over 50 percent meat ingredients would carry the red meat legend while those containing over 50 percent poultry ingredients would carry the poultry legend.", "See: Policy Memo 087A regarding word size in the labeling of product names. See: Policy Memo 005A dated November 25, 1987

NOODLE CHICKEN VEGETABLE DINNER OR NOODLE CHICKEN DINNER WITH VEGETABLES: (Canned or in glass jars). Product must contain at least 6 percent cooked chicken. NUGGET LABELING: Nuggets are irregularly shaped, usually bite-sized meat and\or poultry products which are usually breaded and deep fat fried and intended to be used as finger foods. There are a number of different types of nuggets, the labeling for which is: (1) Products made from a solid piece of meat or poultry may use the term \u201cNugget\u201d as part of the product name without further qualification (e.g., \u201cChicken Nugget,\u201d \u201cBeef Nugget\u201d). (2) Products made from chopped and formed meat or poultry may use the term \u201cNugget\u201d as part of the product name, provided a qualifying statement describing such process is shown contiguous to the product name (e.g., \u201cChicken Nugget, Chopped and Formed\u201d or \u201cBeef Nugget, Chopped and Formed\u201d). (3) Products made from chopped meat or poultry and containing binders, extenders and\or water may use the term \u201cNugget\u201d as a fanciful name, provided a descriptive name immediately follows \u201cSpecies\u201d or \u201cKind\u201d nugget (e.g., \u201cBreaded Nugget-Shaped Chicken Patties\u201d). (4) Products described in (1), (2), and (3) above which are breaded shall be labeled as \u201cbreaded\u201d and shall be limited to 30 percent breading. See: Policy Memo 088 dated May 23, 1985 OAT FIBER: \u201cOat fiber,\u201d should be identified in the ingredients statement as \u201cisolated oat product.\u201d It may be used in non-standardized products and in products, such as, \u201ctaco fillings.\u201d OLEOMARGARINE: The Establishment Number may be omitted from the outer container, provided that articles are completely labeled including Establishment Number inside. See: 9 CFR

317.2(i)", "OMELET, DENVER OR WESTERN STYLE: Product must contain at least 18 percent ham with onions and green and\or red peppers. OMELET, FLORENTINE: Product must contain at least 9 percent cooked meat and must contain spinach. OMELETS WITH: Bacon -must contain at least 9 percent cooked bacon Chicken Livers -must contain at least 12 percent cooked liver Corned Beef Hash -must contain at least 25 percent corned beef hash Creamed Beef -must contain at least 25 percent creamed beef Ham -must contain at least 18 percent cooked ham Sausage -must contain at least 12 percent dry sausage Sausage and Cheese, (omelet with pepperoni, cheese and sauce) -must contain at least 9 percent sausage in the total product. OPEN DATING: Labels showing further qualifying phrases in addition to the explanatory phrase must submit with the application sufficient documentation to support these additional claims. See (9 CFR 317.8(b)(32) and 9 CFR 381.129(c).) Some local authorities require that packaged foods heated and sold hot from industrial catering vehicles be dated with the day the foods were placed in the warming units (e.g., Tuesday, Friday, etc.). When assured by the local authorities that the foods are under a rigid local inspection program, the designations may be approved without an explanatory statement as required by the regulations. To date, only the county of Los Angeles, California, has provided this assurance. The packing date should be shown on immediate or shipping containers of poultry food products as required by regulations (9 CFR 381.126 and 381.129(c)). When meat or poultry products are packed and held in freezer storage for later repacking, the explanatory phrase on repacked product should be in terms of \u201csell by\u201d or \u201cuze before.\u201d However, if a \u201cpacked on\u201d phrase is desired, the date shown shall be that of the original packing of the product.", "OSTRICH AND OTHER RATITES (EMU): Products that do not contain 3 percent of beef, pork, chicken or turkey, can not contain cure ingredients, i.e., Nitrite, nitrate. PAELLA CON BACALAO (SP): Product must contain at least 35 percent cooked meat or poultry meat and include seafood and no more than 25 percent cooked rice. The label must show true product name, e.g., \u201cBeef and Fish with Rice.\u201d PAPAIN: Meat and poultry products that are dipped in a solution containing papain are required to show in conjunction with the product name a statement, for example, \u201cTenderized with a solution of (list ingredients of solution).\u201d Carcasses of animals treated with papain by antemortem injection are required to be roller branded \u201cTenderized with Papain.\u201d Parts not so marked are required to be labeled as \u201cTenderized with Papain.\u201d See: 9 CFR 317.8(b) (25) 9 CFR 381.120 9 CFR 424.21 Enzymes-Proteolytic PAPRIKA: Generally, paprika and\or oleoresin of paprika are not permitted in or on fresh red meat products, fresh ground poultry, or fresh poultry sausage. They are permitted under the following conditions: 1. In both red meat and poultry products where such ingredients are acceptable and expected, including Italian Sausage, Salisica, Chorizo, Longaniza, and Hungarian Style products. All requests for additional products should be referred to the Labeling and Consumer Protection Staff to determine their acceptability. 2. On red meat products where their use does not misrepresent the leanness or freshness, e.g., application to a surface layer of fat and not to the muscle tissue. However, the name must be appropriately qualified, e.g., \u201ccoated with paprika\u201d or \u201cartificially colored.\u201d 3. In or on products where they are expected and the product name discloses this fact, or the product name refers to a component expected to contain the ingredients. Examples include: \u201cBeef with Barbecue Sauce,\u201d \u201cBeef -Barbecue Flavor,\u201d \u201cChicken Paprikash,\u201d \u201cChicken with Orange Sauce,\u201d or

similar type products.", "4. In fresh whole muscle poultry products, provided their presence is properly described, e.g., \u201ccoated with paprika,\u201d or \u201cartificially colored,\u201d as appropriate. PARTIALLY COOKED: 1. Partially cooked bacon \u2013 acceptable nomenclature if shrink requirement for fully cooked bacon is not met must meet requirements for trichinae treatment. Cooking instructions are required. 2. Partially cooked poultry \u2013 unacceptable for cooked poultry products. PARTIALLY DEFATTED (BEEF OR PORK) FATTY TISSUE: These are byproducts produced from fatty trimmings containing less than 12 percent lean meat. These ingredients may be used in meat products in which byproducts are acceptable. Products include nonspecific loaves, beef patties, frankfurters with byproducts, bologna with variety meats, imitation sausage, potted meat food product, sauces, or gravies. May be used in excess of the amounts of meat necessary to satisfy the standard for only the products listed in the Policy Book. However, in this situation, the PDCB or PDCP must always be declared in the ingredients statement. See: 9 CFR 319.15(e) 9 CFR 319.29(a) PARTIALLY DEFATTED CHOPPED (Beef or Pork) (PDCB, PDCP): 1. Partially Defatted Chopped Beef is not permitted in hamburger, ground or chopped beef. The School Lunch Program requires that when PDCB is used in products like taco mix, which later may be used in preparing other products (e.g., tacos or patties), the PDCB or PDCP must always be declared in the ingredients statement on the labeling of the taco mix. All Beef or 100 percent Beef is acceptable as product name. 2. Partially Defatted Chopped may be used in excess of meat necessary to satisfy the standards on only the products listed in the Policy Book. However, in this situation, the PDCP must always be declared in the ingredients statement. See: MPI Manual 18.55 PARTIALLY DEFATTED COOKED (Beef or Pork) FATTY TISSUE: This product may be used as an ingredient in: Beef patties (cooked and uncooked), Potted meat food product, Sauces, Gravies, Imitation sausage, and Nonspecific loaves. No limit on quantity is made. It is believed to be self-limiting.", "THE AMOUNT AND LABELING OF PDCB AND PDCP IN FOOD PRODUCTS CLASS FOOD CATEGORY AMOUNT LABELING Beef or Pork, or both I Beef Patties No Limit Beef or Pork, or both Imitation Sausage No Limit Beef or Pork, or both Non Specific Loaf No Limit Beef or Pork, or both Potted Meat Food Product No Limit Beef or Pork, or both Patty Mix No Limit Always must be declared Beef for Roasting 12 percent of Meat Block II Chinese Egg roll and other Chinese Specialties Up to 12 percent of the Meat Block Beef or Pork Chopped Beef Steak Up to 12 percent of the Meat Block Beef or Pork Corned Beef Hash Up to 12 percent of the Meat Block Beef or Pork Fabricated Steaks Up to 12 percent of the Meat Block Beef or Pork Pepper Steak Up to 12 percent of the Meat Block Beef or Pork Salisbury Steak Up to 12 percent of the Meat Block Beef or Pork Luncheon Meat (nonspecific) Up to 25 percent of Meat Block Pizza Meat Topping Up to 25 percent of Meat Block Beef or Pork Pizza With Meat Up to 25 percent of Meat Block Beef or Pork Cooked Sausage (9 CFR 319.180 (b)) Up to 15 percent of Meat Block Always must be declared Pepperoni Up to 15 percent of Meat Block Must be declared III Chili Up to 25 percent of Meat Block or larger As beef; or pork, if larger must be declared Meat Loaf Up to 25 percent of Meat Block or larger As beef; or pork, if larger must be declared Meat Balls Up to 25 percent of Meat Block or larger As beef; or pork, if larger must be declared Meat Fillings for Tacos, Burritos, Enchiladas, Tamales and other Mexican Foods Up to 25 percent of Meat Block or larger As beef; or pork, if larger must be declared IV Corned Beef Hash Up to 12 percent of Total Product Formulation Beef", "Note: All percentages as calculated on the basis of the fresh weight of meat content. PARTIALLY HYDROLYZED WHEY PROTEIN: An acceptable ingredient name for a binder. PASTELLES (SP): Product must contain at

least 10 percent fresh meat. Product is always made with pork in Puerto Rico. The label must show the true product name, e.g., \u201cPork Pastelles.\u201d PASTELLILLOS (SP): Puerto Rican Style product containing at least 8 percent cooked meat. Species is part of the product name. The label must show the true product name, e.g., \u201cPork Pastellilos.\u201d PASTITSIO: (Greek for casserole). Product must contain at least 25 percent fresh meat or 18 percent cooked meat. A product containing macaroni, ground beef, tomato paste, wine, white sauce, and Parmesan cheese that may be labeled \u201cGreek Style Pastitsio.\u201d PASTRAMI: Cooked cured beef with spices, generally made from the plate but other cuts can be used. The product must be smoked or treated with smoke flavoring. \u201cPastrami, Water Added\u201d is not permitted, although similar products labeled according to Policy Memo 084A are permitted. The term \u201cUnsmoked Cooked Pastrami\u201d must be used when the product is not smoked or does not contain smoke flavoring. Pastrami may or may not be coated with spices. When product is coated, a qualifier is not required. PASTRAMI JERKY: Acceptable name for product processed as pastrami prior to meeting the requirements for jerk. PASTRAMI, TURKEY: A cured turkey product that is cooked. The product must be smoked or treated with smoke flavoring. The term \u201cUnsmoked Cooked Turkey Pastrami\u201d must be used when the product is not smoked or does not contain smoke flavoring. Cured turkey thigh meat is an acceptable name.", "PASTY (CORNISH STYLE): Product must contain at least 25 percent beef. Product consists of a round or square of piecrust with a filling of chopped beef, potatoes, and onions. PATE DE FOIE: Product must contain at least 30 percent liver. Pate means paste; foie means liver. See: Foile Gras Products PATTIE FOLDOVER MIT DRESSING: Product must contain at least 50 percent pattie. PATTIES: Chopped and shaped and similar terms not required on products labeled patties. 1. Paprika not permitted in fresh meat patties. 2. PDCB or PDCP may be listed as beef or pork, except in patties with mechanically separated (species) product and school lunch labeled products. 3. PDBFT and PDPFT permitted. Must show as such in the ingredients statement. 4. Meat patties, with added fat up to 20 percent of the meat block, from a source other than that shown in the name, show as added (ex., Veal Patties, Beef Fat Added): over 20 percent to be part of the product name, e.g., \u201cVeal and Beef Fat Patties.\u201d 5. Ground beef patties -no extenders or water added. Hamburger patties -no extenders or water added. Same requirement as hamburger. 6. Pre-broiled beef patties with simulated stripes (patties are deposited on conveyor and pre-broiled). Parallel stripes are applied with a solution of caramel coloring and water through parallel spigots. Product name will identify artificial color marks on the label. 7. Antioxidants are permitted in pork or beef patties both raw and cooked. 8. Beef Patties: If beef byproducts are added which are not permitted by the standard, the list of ingredients must immediately follow the product name. See: 9 CFR 319.15(c) 9. Pork Patties: The standard for beef patties 9 CFR 319.15(c) shall be applied with the exception that the species is pork.", "PAUPIETTE (FR): Thinly sliced pieces of meat stuffed and rolled. Same standard as \u201cBeef Roulade,\u201d which is at least 50 percent cooked meat. PEANUT FLOUR: Can only be used in nonspecific products that are not subject to moisture controls. PECTIN: Can be used at a maximum use level of 3 percent in nonstandardized meat and poultry food products. The common and usual name of the ingredient, regardless of its source, is \u201cpectin\u201d (21 CFR 184.1588). PEPPER: The term \u201cpepper\u201d: as used in the Italian sausage regulation refers to the pungent spices, such as: black, white, cayenne, or red pepper. \u201cPaprika\u201d as an optional

ingredient is less pungent and is used primarily for its coloring qualities. Bell peppers, chilies, paprika and cayenne or red pepper, are from the capsicum pepper family. These products have specific uses and are recognized by specific names. \u201cPaprika\u201d should not be substituted for \u201cpepper\u201d in a meat or poultry food product.

**PEPPERONI:** A dry sausage prepared from pork or pork and beef. Combinations containing more than 55 percent beef are called beef and pork pepperoni. Pepperoni made with beef must be called beef pepperoni. Pepperoni must be treated for destruction of possible live trichinae and must have an MPR of 1.6:1 or less. Antioxidants are permitted in pepperoni. The casing, before stuffing, or the finished product, may be dipped in a potassium sorbate solution to retard mold growth. Extenders and binders are not permitted in pepperoni. Hearts, tongues, and other byproducts are not acceptable ingredients.

**PEPPERONI, COOKED:** Cooked pepperoni is not an acceptable product name.

**PEPPERONI WITH POULTRY:** Poultry may be added to pepperoni if properly labeled. If the meat block contains 20 percent or less poultry, the product is labeled \u201cPepperoni with Turkey (kind) Added.\u201d When poultry over 20 percent of the meat and poultry block product is labeled \u201cPork and Turkey (kind) Pepperoni,\u201d an MPR of 1.6:1 is applied. If the amount of poultry exceeds that of the meat, the product label reads \u201cTurkey and Pork Pepperoni.\u201d This would carry a poultry legend."

**"PEPPERS AND COOKED SAUSAGE IN SAUCE:** Product must contain at least 20 percent cooked sausage in total formulation.

**PERISHABLE UNCURED MEAT AND POULTRY PRODUCTS IN HERMETICALLY SEALED CONTAINERS:** Establishments seeking approval of label applications for perishable, uncured products which have received a less rigorous heat treatment than traditionally canned product (9 CFR 318 and 381, SUBPARTS G and X, respectively) must submit a sufficiently detailed processing procedure either incorporated on or attached to the FSIS Form 7234-1, APPLICATION FOR APPROVALS OF LABELS, MARKING OR DEVICE. The procedure must include a description of product formulation, method(s) of preparation, cooking and cooling temperatures, type of container, and cooking and handling instructions. Hermetically sealed containers include glass jars, metal cans, flexible retortable pouches, plastic semi-rigid containers, etc., that are airtight and\or impervious after filling and sealing. The policy does not apply to raw meat or poultry, cooked or roast beef, cooked poultry rolls and similar products, whole or uncut cured products, or products that are distributed and marketed frozen. However, products containing cured meat or poultry as components in combination with raw vegetables, e.g., pasta salads and other chilled meat\poultry meals or entrees containing raw or partially cooked vegetables, are covered under this policy, provided the above-mentioned procedural attributes are indicative of the manufacturing process. In addition, an approved partial quality control program (PQCP) is required which must address the critical points in the manufacturing process. As such, the PQCP must contain a detailed description of: ingredient storage controls, product formulation and preparation, container filling and sealing, any heat treatment (times\temperatures) applied, including a description of the equipment used, any other treatments applied, cooling procedures (times\temperatures), lot identification procedures; finished product storage conditions, in plant quality control procedures, and records maintenance procedures. The PQCP must be forwarded to the Processed Products Inspection Division (PPID) for appropriate review and approval before the product label may be used. Guidelines for development of PQCP's for these products may be obtained from PPID upon request. See: Policy Memo 110 dated December 8, 1987

**PET FOOD:** 1. Certified pet food

is manufactured under fee-for-service inspection in a facility approved for the manufacture of animal food. Labeling regulations for certified animal food specify that approval is granted by the labeling staff. However, final approvals are not granted since LCPS no longer grants final approvals. Rather, the company should keep a copy of the final label attached to the sketch approval." "2. Most food for animal consumption produced in a Federal facility is non-certified. It is not an inspected product; therefore, it is inedible product and does not bear any mark of inspection. The product has to be conspicuously labeled to distinguish it from human food. Additionally, the labeling must be in conformance with 21 CFR Part 501, Animal Food Labeling since animal food labeling is also under the jurisdiction of the Food and Drug Administration.

PFEFFERWURST (GR): Product should conform to sausage standard and contain whole peppercorn. Pork livers, pork stock, and beef blood are not acceptable ingredients.

PHOSPHATED TRIMMINGS IN LOAVES: Trimmings from preparation of pork cuts, cured with approved phosphates besides other curing ingredients, may be used without limitation in loaves other than meat loaves. When such trimmings are used, phosphates may be listed in the ingredients statement using the term \u201csodium phosphates\u201d or other applicable generic terms. PHOSPHATES IN DIPPING SOLUTIONS CONTAINING PROTEOLYTIC ENZYMES:

Phosphates have been approved for use as buffering agents in dry mixtures intended for solutions containing proteolytic enzymes. The phosphates should not exceed 0.1 percent of the \u201ctenderizing\u201d solution if they are to be considered incidental additives.

PICADILLO (SP): Product must contain at least 35 percent cooked meat. A Mexican style hash usually made with beef, garlic, onions, vinegar, and raisins. The species should be in the product name, e.g., \u201cBeef Picadillo.\u201d PICKLED PRODUCTS, DRY PACKED: Products that are pickled and dry packed should be qualified with the name of the pickle as part of the product name, e.g., \u201cKnockwurst Pickled with Vinegar,\u201d or \u201cKnockwurst Pickled.\u201d The weight of the package shall be the weight of the product less the weight of the pickle that will weep out of the product.

PIE FILLING: Product must contain at least 37 percent meat. Poultry pie filling must contain at least 18.75 percent cooked poultry meat. PIES: Product must contain at least 25 percent meat. Meat in the gravy may be counted. Poultry pies require at least 14 percent cooked poultry meat." "PIES, ENGLISH STYLE-AUSTRALIAN STYLE: Product must contain at least 25 percent meat or meat byproduct. Contains gravy and no vegetables with a puff pastry top.

PIMENTO (SP): Refers to allspice, but must be specifically named. It is also known as Jamaica pepper. PIMENTO SAUSAGE: Pimientos permitted when declared in product name as \u201cPimiento Sausage.\u201d See: Policy Memo 120 dated August 1, 1990

PINKELWURST (GR): A cooked product that is stuffed in a casing with a diameter of from 1 1/2 to 2 inches and a length of about 10 to 12 inches. It is formulated with beef fat, pork fat, onions, oat groats, water, and sufficient spice to satisfy seasoning requirements.

PIROSHKI OR PIROGI: Product must contain at least 10 percent cooked meat. A Russian or Jewish dish made of thin rolled dough or pastry that is filled and either steamed, baked, or fried. They resemble small turnovers, pockets, or raviolis.

PIZZA: Products identified as \u201cpizzas\u201d that contain a meat or poultry component as part of the product name are no longer required to contain a minimum amount of meat or poultry provided that the meat component is sufficient to make the product subject to USDA jurisdiction. An antioxidant used in pepperoni or sausage need only be reflected in the ingredients statement. See: 9 CFR 317.8(b)(40) and 9 CFR 381.129(f)

PIZZA BURGER: Product meets the burger standard, e.g., hamburger or ground beef patty. It

can be two patties with cheese (usually Romano) and\or tomato or pizza sauce between the patties. PIZZA, CHICAGO STYLE: Acceptable labeling for a product which has been manufactured by first placing the cheese on the crust, then following with the meat and then the sauce. Condimental quantities of a grated cheese may then be placed on the top. The product usually has the deep dish characteristics.", "PIZZA CONTAINING CHEESE SUBSTITUTES: The labels for products containing cheese in a ratio less than one part cheese to nine parts cheese substitute, need to include additional qualifying information. Example: Pizza Sausage, cheese substitute and cheese; Combination Pizza -Sausage -Pepperoni Imitation Cheese and Cheese. See: Policy Memo 01 dated May 6, 1980 PIZZA DOGS: A nonspecific product. PIZZA, PAN STYLE: Pizza that is marketed in a pan and contains a thick crust. PIZZA PUPS: Product has two crusts, filled with a mixture of pork, tomato puree, and condimental substances. The finished article is approximately 8 inches in length, 2 1\2 inches wide with a thickness of 3\4 inches. It is a type of pizza. The label must show a true product name, e.g., \u201cPork and Sauce Filling in A Crust.\u201d PIZZA ROLL: This is a nonspecific meat food product. When the name appears on a label, there must be a contiguous statement identifying the major components of the product or a complete ingredient listing. There are two major types of pizza rolls. One is a cooked sausage-like meat food product that contains cheese, usually contains peppers and has no water limitation. The second type consists of a roll-shaped dough enclosure with various fillings. A manufacturer of the latter type of product has asserted trademark protection of the term \u201cpizza roll.\u201d PIZZA SAUCE WITH SAUSAGE: Product contains at least 6 percent sausage. PIZZA SAUSAGE: Not an acceptable name. Product must be labeled \u201cSausage for Pizza.\u201d PIZZA, SICILIAN STYLE: A thick crust pizza. The crust is usually 50 percent or greater of the total pizza product.", "PIZZA TOPPING CONTAINING SAUSAGE: The sausage portion of cooked pizza topping contains up to 10 percent water and 3.5 percent binders (9 CFR 319.140). The formulation must indicate the sausage portion of the pizza topping. However, the ingredients statement of the cooked pizza topping does not have to list \u201csausage\u201d in its sublisting. There are no restrictions on the amount of seasonings in the sausage portion. 1. Pizza topping must be cooked. 2. In the sausage portion: a. Water \u2264 (less than or equal to) 10 percent of the sausage portion b. Binders including TVP \u2264 (less than or equal to) 3.5 percent of the sausage portion c. Seasonings are unlimited 3. The ingredients statement of the pizza topping can be arranged in different ways: a. Composite e.g., cooked pizza topping [pork, water, TVP (\u2026), Seasonings (\u2026)] b. Component, e.g., cooked pizza topping [sausage (pork, water, seasonings (\u2026), TVP (\u2026), water (\u2026)] These parameters do not apply when specific sausage products are subject to other regulations, e.g., Italian Sausage. In these situations, the specific regulation (i.e., Italian Sausage) provides the requirements, such as, the amount of water and binders are permitted. PIZZA TOPPING MIX: A nonspecific product, which includes products with names that indicate the type of meat or poultry in the product (e.g., Chicken and Pork Pizza Topping or Beef Pizza Topping). Antioxidants are permitted, see 9 CFR 424.21. Water, extenders, and binders are acceptable. PIZZA, WORD SIZE: When a pizza has a true product name, e.g., \u201cCombination Sausage and Pepperoni Pizza,\u201d the true product name must be prominent, conspicuous, and legible, with all words at least one-third the size of the largest letter in any word of the product name. If on the label the manufacturer also elects to display elsewhere the word \u201cPizza\u201d in exaggerated fashion, the word \u201cPizza\u201d is not considered in the determination of the size of the letters within the

true product name. See: Policy Memo 087A dated September 16, 1985", "PFF (PROTEIN FAT FREE) ADJUSTING FOR USE: Protein Fat Free (PFF) controlled cured pork products with qualifying statements, e.g., \u201cHam-Water Added,\u201d may be used in place of PFF controlled cured pork products without qualifying statements, e.g., Ham, to meet the minimum meat requirements of various products. However, the amounts of the PFF controlled cured pork products with qualifying statements used will need to be increased. For example, if a standard requires a certain amount of Ham and a processor wishes to use \u201cHam-Water Added,\u201d a greater amount of the \u201cHam-Water Added\u201d will be needed to meet the standard. The magnitude of the additional amount is directly related to the relationship between the respective PFF values. See: Policy Memo 093 dated December 16, 1985 Example: Ham Salad requires 35 percent Cooked Ham. \u201cHam Water Added\u201d will be used in the product formula. Calculation: Multiply the PFF value for Ham (20.5) by the amount of required Ham (35 percent). Divide this answer by the PFF value of the product being used to formulate the product. (In this example, PFF value for \u201cHam-Water Added\u201d is 17.0.) Answer: [(0.35 x 20.5) \u2225 17.0] x 100 = 42.21 percent \u201cHam-Water Added\u201d needed in the formula. Example: Ham Pie requires 25 percent Ham based on green weight. \u201cHam with Natural Juices\u201d will be used in the product formula. Calculation: Multiply the PFF value for Ham (20.5) by the amount of required ham (25 percent). Divide this answer by the PFF value of the product being used to formulate the product. (In this example, PFF value for \u201cHam with Natural Juices\u201d is 18.5.) Answer: [(0.25 x 20.5) \u2225 18.5] x 100 = 27.70 percent \u201cHam with Natural Juices\u201d needed in the formula.

ADJUSTING FOR \u201cHAM AND WATER PRODUCT X percent OF THE WEIGHT IS ADDED INGREDIENTS.\u201d Consider a formulated product which is required to contain at least 50 percent Cooked Ham. If the processor chooses to use a \u201cHam and Water Product (HWP)\u201d in which 20 percent of the weight is added ingredients as the source of the Ham in the formulation, this product contains 80 percent Ham and 20 percent added ingredients. Clearly, the processor must use more than 50 percent HWP in the process. Using 50 percent HWP would result in only 40 percent Ham in the finished product, i.e., the added ingredients in the HWP represents 25 percent of the ham content. (If it were a 10 lb. HWP, there would be 8 lbs. of Ham and 2 lbs. of added ingredients.  $(2 \u2225 8 \times 100 = 25$  percent). Consequently, an additional 25 percent of HWP is required in the formulation. The following example may be used to determine the percentage HWP needed to equal", "Ham: Ham and Gravy requires 50 percent Cooked Ham. \u201cHam and Water Product 20 percent of Weight is Added Ingredients\u201d will be used in the formulation. Step 1: Subtract the percent added ingredients from 100 percent. In this example:  $1.00 - 0.20 = 0.80$  Step 2: Determine the amount of Ham needed in the formula. (In this example: 50 percent) Step 3: Divide the amount of Ham required. Determined in Step 2) by the answer in Step 1 (In this example:  $(0.50 \u2225 0.80 = 0.625$ ) Step 4: Multiply the answer in Step 3 by 100. Answer for this example is 62.50 percent \u201cHam and 20 percent Water Product\u201d is needed as the equivalent of 50 percent Ham.

PLANTATION: The regulations and policies applicable to \u201cFarm\u201d also apply to plantation.

POINT OF PURCHASE MATERIALS: Point of purchase materials which refer to specific meat or poultry products are considered labeling under certain circumstances. When printed and\u2014or graphic informational materials (e.g., pamphlets, brochures, posters, etc.) accompany or are applied to products or any of their containers or wrappers at the point of purchase, such materials and the claims that

they bear are deemed labeling and they are subject to the provisions of the Federal Meat Inspection Act and the Poultry Products Inspection Act. Although the Food Labeling Division (FLD) does not exercise its authority to subject point of purchase materials to specific prior approval (materials shipped with the products from the federally inspected establishment are an exception), we do expect point of purchase materials to be in accordance with the Federal regulations and all current labeling policies. Upon request, FLD will review and comment on the point of purchase materials submitted to our office. During the review process, promotional materials will be scrutinized for special claims, particularly those related to nutrition, diet, and animal husbandry practices. Claims related to nutrition and diet must be made in accordance with all current nutrition labeling regulations. Continuing compliance with stated claims will be assured through periodic sampling, as necessary. Claims are expected to be within the compliance parameters identified in the nutrition labeling regulations. Animal husbandry claims (e.g., the nonuse of antibiotics or growth stimulants) may be made only for products shipped in containers or wrappers labeled with the same animal production claims. See: Policy Memo 114A dated August 18, 1994", "POLISH SAUSAGE: A sausage that is cured, cooked, and usually smoked. Pork and pork byproducts shall comprise at least 50 percent of the meat and meat byproducts ingredients. To have beef as a predominant ingredient, the product name would be \u201cBeef and Pork Polish Sausage.\u201d Green peppers are permitted up to 4 percent in total formulation. An uncured (fresh), uncooked variety with no more than 3 percent water also exists. \u201cFresh\u201d shall be used in the name when the product is uncured. When Fresh Polish Sausage is cooked or smoked, then the product name is either \u201cCooked Fresh Polish Sausage\u201d or \u201cSmoked Fresh Polish Sausage.\u201d The requirements of Policy Memo 110 apply when these perishable, cooked, uncured products are packaged in hermetically sealed containers. POLYNESIAN STYLE SAUSAGE: Product must contain fruit juices, a sweetening agent, and soy sauce. POLYSORBATE: Permitted in pickling solutions without declaration. PORK AND BACON SAUSAGE: Up to 50 percent bacon permitted provided: 1. bacon is brought back to green weight before use. 2. product is trichinae treated. 3. product name is \u201cPork and Bacon Sausage.\u201d The standard for \u201cPork Sausage and\u201d with Bacon\u201d is 10 to 20 percent bacon, and for \u201cPork and Bacon Sausage\u201d is more than 20 percent but not more than 50 percent bacon. PORK AND DRESSING: Product must contain at least 50 percent cooked pork. PORK AND DRESSING WITH GRAVY: Product must contain at least 30 percent pork. PORK CRACKLINGS: Product eligible to be labeled as \u201cPork Cracklings\u201d must be prepared from fatty tissues from which the skin has been detached. If the skin is not removed from the product before rendering, a descriptive name, e.g., \u201cPork Cracklings, Fried-Out Pork Fat with Attached Skin,\u201d must be used.", "PORK FAT: Pork fat shall be declared as such in the ingredients statement. Clear fatbacks and clear shoulder plates must be declared as \u201cPork Fat.\u201d Pork fat may be declared as pork in the ingredients statement if it contains visible lean and it is used in a standardized product which has a fat limitation. PORK JOWLS: Product may be declared as pork if skinned. See: Pork Skins PORK SAUSAGE: Product identified as pork sausage does not include the use of pork cheeks. When such an item is offered as \u201cWhole Hog,\u201d tongues, hearts, and cheeks may be used in the natural proportion as found in the hog carcass. \u201cFresh\u201d shall be used in the name when the product is not cured, cooked and\u201d or smoked. PORK SKIN RESIDUE AFTER GELATIN EXTRACTION: This material consists of back fat

skins from which the gelatin has been extracted by means of soaking the skin in acid and subsequent low temperature cooking for the extraction of gelatin. It is not permitted in sausage but may be used in imitation sausage, potted meat food product, loaves (other than meat loaves), and other nonspecific products. PORK SKINS: Not permitted in salami, bologna, frankfurters, Vienna sausage, and braunschweiger. When packed in vinegar pickle, they are not permitted to be artificially colored. When pork skin, either attached to fat and\or muscle tissue or detached from fat and\or muscle tissue, is used to manufacture meat or poultry products, it must be specifically listed in the formulation on the label approval application form and in the ingredients statement on the label, e.g., \u201cPork Skins,\u201d Unskinned Pork Jowls,\u201d \u201cUnskinned Pork Shoulder Trimming,\u201d \u201cUnskinned Pork Fat,\u201d and \u201cUnskinned Pork Bellies.\u201d \u201cDetached skin\u201d refers to the portion of skin from which most of the underlying fat is removed, e.g., skin from bacon intended for slicing, skin from closely skinned hams, shoulder cuts, fat backs, etc. If removal of skin portions is incidental to removal of a considerable proportion of underlying fat from ham, shoulder, back, etc., preparatory to rendering such fat, portions of skin so removed should not be regarded as detached skin and may be included with fats and rendered into lard. Ham facings are not regarded as detached skin.", "PORK SKINS, FRIED: When prepared from the skin of smoked pork bellies, it may be labeled as \u201cFried Bacon Skins,\u201d \u201cFried Bacon Rinds,\u201d or \u201cFried Pork Skins.\u201d The kind of skin used must be stated on the labeling records when submitted for label approvals. PORK SPARE RIBS, CENTER CUT: Center cut pork spare ribs refers to pork spare ribs with the loin portion, the brisket (brisket must be removed at a point which is dorsal to the curvature of the costal cartilages), the tail and two ribs from the shoulder removed, this remaining center section may be further portioned or left in one piece. PORK SPARERIBS, ST. LOUIS STYLE: St. Louis Style Spare Ribs are the same as \u201cPork Spareribs\u201d except that the sternum and the ventral portion of the costal cartilages are removed with the flank portion. This cut is made at a point in which the sternum and costal cartilages are removed dorsal to the curvature of the costal cartilages. If specified by the purchaser, the diaphragm shall be removed. This anatomical description of the cut must be provided with the information for label approval. POTATO SAUSAGE, SWEDISH STYLE, OR POTATO RING OR POTATO PUDDING: Labels for sausages and pudding identified as \u201cPotato Sausage,\u201d \u201cPotato Brand Sausage,\u201d \u201cPotato Ring,\u201d and \u201cSwedish Style Potato Sausage\u201d may be approved under the following guidelines: 1. The product must contain a minimum of 45 percent meat and no byproducts. 2. Water must be limited to 3 percent at formulation. 3. When extenders or binders are used, they must be limited to 3.5 percent or 2 percent in accordance with 9 CFR 424.21 of the finished product. 4. The product must include a minimum of 18 percent potatoes. Sausage identified as \u201cSwedish Style Potato Sausage\u201d is provided for under the following guidelines: 1. The product must contain a minimum of 65 percent meat and no byproducts 2. Water must be limited to 3 percent at formulation. 3. No extenders or binders are permitted. 4. The product must include a minimum of 18 percent potatoes. Meat food product identified as \u201cPotato Pudding\u201d is provided for under the following guidelines: ", "1. The product must contain a minimum of 18 percent potatoes. 2. The product does not meet the other requirements for products identified as \u201cPotato Sausage,\u201d \u201cPotato Ring,\u201d or \u201cSwedish Style Potato Sausage.\u201d See: Policy Memo 011 dated September 8, 1980 POULTRY: Cuts of poultry that are not identified in 9 CFR 381.168, Table V, may use the maximum amount of

poultry skin permitted for that \u201ckind.\u201d For example, \u201cturkey\u201d is listed in the table and may contain up to 15 percent skin. Therefore, a product identified as \u201cwhite turkey\u201d can be placed in this category for a maximum of 15 percent skin.

**POULTRY, ASSORTED PIECES:** The product name \u201cPoultry (Kind) Assorted Pieces\u201d is acceptable and does not require the product to be in natural proportions. In addition, the term \u201cpiece\u201d is not the same as the term \u201cpart,\u201d i.e., a piece does not have to be a whole part, e.g., a breast, thigh, or drumstick.

**POULTRY BACON:** See: Bacon-Like Products

**POULTRY BREASTS:** When poultry breasts with ribs are boned and the resulting product contains portions of the scapula (shoulder) muscles and/or muscle overlying the vertebral ribs, they must be labeled to indicate that fact. Proper names for such products are \u201cBoneless Breast with Rib Meat,\u201d White Chicken Meat or White Turkey Meat,\u201d or if the skin is left intact, \u201cWhite Boneless Chicken or White Boneless Turkey.\u201d Product labeled \u201cBoneless Breast\u201d without further qualification may not contain scapula or rib meat.

**POULTRY FRANKFURTERS (SIMILAR COOKED SAUSAGES):** Products which contain pork fat must be labeled with pork fat added in the product name.

**POULTRY GRADING: (LABELING)** Indicates the quality grades of poultry (U.S. grade A, B, or C). The shield design contains the letters \u201cUSDA,\u201d the U.S. grade of the product, and if not shown elsewhere, the class of poultry. Any letter grade on a consumer package or individual carcass indicates the product was graded by a licensed grader of the Federal or Federal-State grading service, and may not be applied otherwise. Letter grades on bulk packaging or shipping containers only indicate that the product is equal to that particular U.S. Grade." , "A. **APPLYING GRADEMARKS TO SHIPPING CONTAINERS** All poultry classes and kinds listed in 9 CFR 381.170, except necks, giblets, detached tails, wing tips, skin and stripped backs (below Grade C) are eligible for grading. In addition, the following poultry parts may be officially graded: Boneless, Skinless Breast and Thigh Tenderloin or Boneless Breast without Tenderloin Boneless Breast Quarters Breast Quarters with Bone in Boneless Thigh Halves Wing Portion or Section Breast Halves Broiler Turkey or Duck Halves Split Breast Split Fryers Skinless, bone-in Thighs, Drums and Breasts Boneless Breast, Thigh Bone-in products marinated in a colorless solution Poultry cuts other than those identified above may not be eligible for grading; therefore, particular attention should be given to the product name when approving labels for various poultry products which include grade marks (for example, \u201cThin Breast Fillets, Thigh Strips\u201d). Grade marks on raw poultry parts processed with solutions that may impart color (for example, injected with a 5% solution of water, salt, butter) or cooked poultry products are required to include a statement, for example, \u201cPrepared from Grade A Poultry.\u201d The USDA grader in the plant makes the final determination concerning the necessity of the \u201cPrepared from\u201d statement in situations where it is not apparent at the time of label approval that the added solutions have the ability to impart color to the finished poultry product.

Products which may not be grade marked: Detached Necks Giblets Packed Separately Detached Tails Wings Tips Stripped Backs Below C Quality Diced or Shredded Meat B.

**WING DESCRIPTION** The wing is made up of three sections. The section attached to the carcass is the first section. The wing tip is the third section.

**C. GRADING BACKS WITH NECKS** In applying grade standards, when necks are packed with backs following these steps:" , "1. When backs are graded as provided for in the standards, the name of the product is required to read as follows: a. Grade A Backs \u201cwith necks,\u201d or \u201cand necks.\u201d b. Grade B

Backs \u201cwith necks,\u201d or \u201cand necks.\u201d c. Grade C Backs \u201cwith necks,\u201d \u201cGraded backs and necks,\u201d or \u201cbacks and necks.\u201d 2. Necks are to be packed with backs in natural proportions. 3. Necks may or may not be attached to backs. Necks for all officially graded backs are to be free from serious discolorations, feathers, pin feathers, and accumulations of blood and\or excess water. 4. A neck, front, or hind portion of back, when removed from birds which meet the stated quality, may be used to achieve exact weights. Only one of these portions may be used per package. Scraps of backs or necks may not be used. 5. Labels for packages with portions are required to indicate which portions, for example, first (1st) portion, 2nd portion, 1st and 2nd portions, 2nd and 3rd portions, etc. D. PRESSURE SENSITIVE STICKERS AND TAPE: 1. Inserts or pressure sensitive stickers with the trademark are required to have plant number. 2. Trademarks on pressure sensitive tape should not be used on consumer packages. 3. Insert with the trademarks are not to be used inside opaque bags.

**POULTRY HINDQUARTERS:** The term \u201chindquarters\u201d on labels for single cut poultry items is an acceptable alternative to the recognized terminology \u201cLeg Quarter\u201d specified in the regulations. The use of the term \u201cHindquarters\u201d requires only a specified class of poultry to be considered a true product name, e.g., \u201cChicken Hindquarters.\u201d Either term refers to a poultry thigh and drumstick, with a portion of the back attached.",

**"POULTRY HINDSADDLES:** Poultry hindsaddles are connected poultry leg quarters (the rear of the bird). The product name \u201cPoultry Hindsaddles\u201d may be used alone on the product's label if the product is not intended for retail sale. In contrast, the name \u201cpoultry hindsaddles\u201d on the label of a product intended for retail sale must be accompanied by a fully descriptive name (e.g., \u201cPoultry Hindsaddles, Connected Leg Quarters\u201d).

**POULTRY MEAT, RAW:** The labeling of raw poultry meat obtained from other than young poultry includes the class designation, e.g., \u201cYearling Turkey Meat\u201d or \u201cMature Chicken Meat.\u201d

See: Policy Memo 032 dated September 4, 1981 See: 9 CFR 381.117(b)

**POULTRY PARTS:** Specific net weight packages for poultry parts, usually those containing legs or wings, include a single part, e.g., a drumstick or thigh, to make the stated weight. The name on the label must reflect this practice, e.g. \u201cChicken Legs -Chicken Thigh added to make weight.\u201d The single part must be cut at the joint. Wing tips are not permitted as added parts.

**POULTRY PRODUCTS:** In poultry products where \u201cmeat\u201d appears in the product name, e.g., \u201cWhite Meat Chicken Roll,\u201d and \u201cDark Meat Turkey Loaf,\u201d skin and attached fat are permitted in greater than natural proportions. However, the ingredients statement must have the poultry skin or poultry fat listed. When skin and attached fat appear in the ingredients statement, their placement should be in the correct order of predominance and determined by the amount present over the permitted natural proportions.

**POULTRY PRODUCTS CONTAINING MEAT INGREDIENTS-LABELING:** Poultry products containing meat in amounts that exceed 20 percent of the total meat and poultry product portion of the poultry product must be descriptively labeled to indicate the presence of the meat ingredients, e.g., \u201cChicken and Beef Stew or Stew made with Chicken and Beef\u201d. Poultry products containing meat ingredients in amounts at 20 percent or less of the total meat and poultry product portion of the poultry product must have names that are qualified to indicate the presence of the livestock ingredients, e.g., \u201cChicken Stew-Beef Added\u201d. However, poultry products that do not meet specified minimum poultry ingredient requirements because meat ingredients

are replacing any part of the required poultry", "ingredients must be descriptively labeled to indicate the presence of meat ingredients, e.g., \u201cTurkey and Pork Chop Suey\u201d. See: Policy Memo 029 dated September 4, 1981 POULTRY PRODUCTS WITH OTHER THAN NATURAL PROPORTIONS OF WHITE AND DARK POULTRY: Poultry products containing white and dark chicken or turkey of a distinguishable nature and in quantities other than natural proportions of white to dark meat must bear a qualifying statement identifying the types of poultry meat used in conjunction with the kind of poultry in the product name. The poultry block of white and \dark meat (excluding products labeled as \u201cMechanically Separated (Kind of Poultry)\u201d) solely determines the usage of the terms \u201cwhite and dark,\u201d \u201cdark and light,\u201d \u201cwhite,\u201d \u201cdark,\u201d etc. in the product name. Ground poultry (excluding the skin) that bears the terms \u201cwhite\light,\u201d \u201cdark,\u201d \u201cbreast,\u201d \u201cthigh,\u201d etc. in the product names is also considered as part of the poultry block for determining the usage of terms \u201cwhite and dark,\u201d \u201cdark and light,\u201d \u201cwhite,\u201d \u201cdark,\u201d etc.

However, products labeled as \u201cMechanically Separated (Kind)\u201d do not have any bearing on the use of terms \u201cwhite,\u201d \u201clight\u201d or \u201cdark\u201d in the product name since, \u201cMechanically Separated (Kind)\u201d is as indistinguishable paste-like product that is considered a separated standardized poultry food product ingredient. Additionally, products with mixture of distinguishable poultry (white or dark) and \u201cMechanically Separated (Kind)\u201d can not bear claims of \u201call white,\u201d \u201cpure breast,\u201d \u201c100 percent dark,\u201d or similar terms. In this situation, the poultry portion of the product contains at least two separated poultry ingredients, or one of which is \u201cMechanically Separated (Kind).\u201d See 9 CFR 381.117(c), Table 1 POULTRY PUFFS: Product must contain at least 15 percent cooked poultry meat. Chicken or Turkey Puffs are classified as hors d'oeuvres and must show a true product name, e.g., \u201cBreaded Chicken and Rice Balls.\u201d POULTRY, RAW WITH ADDED SOLUTION: Unless addressed by other regulations and policies, water and\or oil based solutions may be added to raw poultry and poultry parts at various levels. The product name must contain a descriptive designative in accordance with 9 CFR 381.117(h). POULTRY SALAMI PRODUCTS: Poultry sausages prepared to resemble salami and offered to consumers as a salami shall bear product names as follows: 1. \u201c(Kind) Salami\u201d shall be the product name when the moisture-to-protein ratio in the finished product does not exceed 1.9:1. This product resembles a dry salami made from red meats." 2. \u201cCooked (Kind) Salami\u201d shall be the product name when the product is cooked and the moisture-to-protein ratio is above 1.9:1. This product resembles \u201ccooked salami\u201d made from red meats. See: Policy Memo 006 dated July 30, 1980 POULTRY SAUSAGE: Sausage products made from poultry must be labeled to indicate kind, e.g., \u201c(Chicken) Sausage,\u201d \u201c(Turkey) Bologna,\u201d etc. Products containing more than one kind of poultry or red meat must declare the added ingredient in the product name, e.g., \u201cChicken Bologna, Beef Added\u201d and \u201cTurkey Franks, Chicken Hearts Added\u201d per Policy Memo 029 dated September 4, 1981. The basic sausage standards, per meat 9 CFR 319.140, also apply to poultry, except for added water and fat." POULTRY SKIN: When determining the amount of poultry skin allowed, refer to 9 CFR 381.168. If the specific part is not identified in this part, use the figure for boneless kind. POULTRY STANDARDS: Name Minimum or Maximum percentage Poultry a la King At least 20

percent poultry meat Poultry Barbecue At least 40 percent poultry meat Poultry, Breaded No more than 30 percent breading Poultry, Brunswick Stew At least 12 percent poultry meat Brunswick Stew with At least 8 percent poultry meat Poultry Poultry Burgers 100 percent meat with skin and fat in natural proportions Poultry Cacciatore At least 20 percent poultry meat or 40 percent with bone. Poultry Cannelloni At least 7 percent poultry meat Poultry Chili At least 28 percent poultry meat Poultry Chili with At least 17 percent poultry meat Beans Poultry Chop Suey At least 4 percent poultry meat Chop Suey with Poultry At least 2 percent poultry meat Poultry Creole with Rice At least 35 percent cooked poultry meat and sauce portion. Not more than 50 percent cooked rice in total product. Poultry Chow Mein At least 4 percent poultry meat (w/o noodles)", "Poultry Croquettes At least 25 percent poultry meat Poultry, Creamed At least 20 percent poultry meat Poultry Dinners At least 18 percent poultry meat Poultry Fricassee At least 20 percent poultry meat Poultry Fricassee At least 40 percent poultry wings with Wings (cooked basis with bone) Poultry Gizzards and At least 35 percent cooked Gravy gizzards Poultry Hash At least 30 percent poultry meat Poultry Liver Omelet At least 12 percent cooked poultry liver Poultry Meatloaf At least 65 percent raw poultry or 50 percent poultry meat and a Poultry Noodle Dinner At least 15 percent poultry meat. Poultry Noodle Dinner At least 6 percent poultry meat. with Gravy Poultry with Noodles At least 15 percent poultry meat or Dumplings or 30 percent poultry meat with bone. Noodles or Dumplings At least 6 percent poultry meat. with Poultry Poultry Paella At least 35 percent poultry meat or 35 percent poultry meat and other meat, no more than 35 percent cooked rice, must contain seafood. Poultry Parmigiana At least 40 percent breaded poultry See: Veal Parmigiana Poultry Pies At least 14 percent poultry meat Poultry Ravioli At least 2 percent poultry meat", "Poultry Salad Mix At least 45 percent poultry Poultry Salad At least 25 percent poultry See: Salad, Poultry Poultry Soup At least 2 percent poultry meat Poultry Flavored Soup No minimum requirement (less than 2 percent poultry meat) Poultry Spread At least 30 percent poultry Poultry Stew At least 12 percent poultry meat Poultry Stew with At least 8.4 percent poultry meat Dumplings (Based on 70 percent of Stew requirement). Poultry Subgum At least 12 percent poultry Poultry Tamales At least 6 percent poultry meat Poultry Tetrazzini At least 15 percent poultry meat Poultry Turnover At least 14 percent poultry meat Poultry with Gravy\ At least 35 percent poultry meat Sauce Gravy with Poultry At least 15 percent poultry meat Poultry with Gravy and At least 25 percent poultry meat Dressing Poultry with Rice At least 15 percent poultry meat Poultry Scrapple At least 30 percent poultry and/or poultry byproducts. Poultry with At least 15 percent poultry meat. Vegetables POULTRY TENDERS AND POULTRY TENDERLOINS: A \u201c(Kind) Tender\u201d is any strip of breast meat from the kind of poultry designated.", "A \u201c(Kind) Tenderloin\u201d is the inner pectoral muscle which lies alongside the sternum (breast bone) of the kind indicated. See: Policy Memo 100 dated September 3, 1986 POULTRY WING SECTIONS -(KIND): Wing Sections is an acceptable designation for a product consisting of equal proportions of the parts of a wing. It may be and is usually used for equal proportions of wing portions and drummettes. PREMIER JUS OR (OLEO STOCK): The product obtained by rendering at low heat the fresh fat of heart, caul, kidney, and mesentery collected at the time of slaughter of bovine animals. The raw material does not include cutting fats. Premier Jus is not an acceptable name unless accompanied by the term \u201cOleo Stock.\u201d PRESSURE SENSITIVE LABELS: Labels applied to packages shall be of the self-destructive type and must adhere to the packages under all conditions of use. PRESSURE SENSITIVE STICKERS AND

**INDELIBLE INK:** Pressure sensitive stickers are as a means for manufacturers to use existing labeling material by covering inaccurate and\or misleading labeling information with corrected text or used as a promotional tool, e.g., a starburst encircling sweepstakes terminology. A pressure sensitive sticker must be the type that destroys the underlying label or package if removed, or be self-destructive. Similarly, indelible ink is used as a means for manufacturers to use existing labeling material by covering inaccurate and\or misleading labeling information with opaque ink or adding required information with a rubber stamp. Temporary label approval is not required when the entire label including the pressure sensitive sticker or marking\covering from indelible ink is truthful, not misleading, and the product is not misbranded. Corrected text on pressure sensitive sticker can cover mandatory or non-mandatory information. Indelible ink may be used to cover inaccurate information or apply markings to existing labeling material in order to make the labeling accurate and truthful. Labeling bearing pressure sensitive stickers or marking\covering from indelible ink falls under the provisions of the generic label approval regulations in 9 CFR 317.5 and 9 CFR 381.133, which provides the conditions for use of final labeling without first submitting sketch labeling for evaluation and approval at headquarters. Companies need to create and maintain records of all final labeling, otherwise known as generic approvals.","Consistent with the rules on generic labeling approval, sketch labeling approval is required for the entire label when pressure sensitive stickers or marking from indelible ink contain special claims (e.g., quality, nutrient content, health, negative, geographical origin, animal production (e.g., \u201cno antibiotics administered,\u201d breed claims, and \u201cno hormones added\u201d), and other claims (e.g., \u201cnatural\u201d), guarantees, foreign language or a change of the nutrition facts serving size. For non-standardized amenable product labeling (e.g., descriptive name products, meat flavors or poultry reaction flavors, etc.) that received sketch approval and the existing labeling is modified by use of pressure sensitive stickers or indelible ink, a sketch approval is required when a change is made to the product label not covered by generic approval regulations 9 CFR 317.5(b) (9) and 381.133(b) (9), e.g., a product name change. Certain products are not compliant with the generic approval regulations, e.g., exotic animal product labeling, rabbit product labeling, certified pet food labeling, etc. In situations where existing labeling is modified by use of pressure sensitive stickers or indelible ink, the labels must be submitted to the Labeling Consumer Protection Staff in Washington, D.C for sketch approval. Transferred labels bearing a pressure sensitive sticker covering the existing legend or indelible ink covering the existing legend, are operating under the original establishment\u2019s final label approval record, even though the establishment number is for that of the producing establishment. When pressure sensitive stickers are used to cover and correct other existing information or indelible ink is used to cover or add information, the rules for sketch approval and generic labeling apply to the entire label. This entry cancels Policy Memo 115 dated July 11, 1988, since 115 is out of date.

**PRIMAL PARTS AND SUBPRIMAL MEAT CUTS:** Red meat carcasses, primals, subprimals or cuts can be labeled: 1) as the species of origin, e.g., beef tenderloin bearing the simple product name of \u201cbeef,\u201d 2) as species without identifying the primal or subprimal when certain terms associated with various sizes are part of the product name, i.e., chop, cutlet, steak, fillet, filet, roast, strips, etc., e.g., \u201cBeef Steak,\u201d 3) as species and primal or subprimal cut, e.g., "Veal Shoulder Blade Steak," and 4) as species, coin name (butt, cala, daisy, picnic, etc.) and primal or subprimal cut. The species

and coin name are not appropriate as a complete product name since it is missing the primal or subprimal cut, e.g., the phrase \u201cpork picnic\u201d is incomplete without \u201cshoulder.\u201d Recent editions of the \u201cUniform Retail Meat Identity Standards (URMIS),\u201d published and distributed by the National Livestock and Meat Board, and \u201cThe Meat Buyers Guide,\u201d published by the National Association of Meat Purveyors, may be used to identify recommended names. These guides have been prepared through extensive review and analysis of the most recent edition of \u201cInstitutional Meat Purchase Specifications (IMPS)\u201d,"and in cooperation with the U.S. Department of Agriculture, Agriculture Marketing Service (AMS) and public and industry associations. PRIME RIB OF BEEF OR STANDING BEEF RIB ROAST FOR PRIME RIB: These products do not have to be derived from USDA prime grade beef. PRINCIPAL DISPLAY PANEL, ALTERNATE: The determination as to whether or not a panel is an alternate principal display panel shall be based on whether or not the panel is likely to be displayed, presented, shown, or examined under customary conditions of sale. If the intent of the panel cannot be determined and demonstrated, and if it has the appearance of a principal display panel, the presence of three or more mandatory labeling features shall serve to characterize the panel as an alternate principal panel. As such, any remaining mandatory features required to be placed on a principal display panel must be also included. See: Policy Memo 037 dated November 4, 1981 PRODUCT NAMES: 1. A product standard should only be applied if the product name is the same as that described by the standard in the regulations or in the Policy Book. For example, the product, \u201cBeef, Cheese and Vegetables in a Crust,\u201d would not be required to meet the standard for a \u201cturnover\u201d in the policy book. 2. Products such as \u201cPizza Pouches\u201d must meet the standard for pizza since they are named \u201cPizza\u201d even though they are not traditional type pizza. Furthermore, cheese may not be substituted for meat in products named \u201cPizza.\u201d PRODUCT NAME QUALIFIERS: Product name qualifiers have no sizing requirements other than appearing contiguous to the product name and being prominent and conspicuous. Examples of product name qualifiers are \u201cSmoked Flavor Added\u201d and \u201cColored with Paprika.\u201d PRODUCT NAME QUALIFIERS IN SECONDARY PRODUCTS: Product name qualifiers, e.g., \u201cbinders added,\u201d are not required on secondary products with labeling, with the exception of the statement \u201cCalcium Propionate Added to Retard Spoilage of Crust\u201d on pizza labeling. Secondary products are those meal like products that contain a multi-ingredient meat or poultry component, e.g., \u201cLemon Pepper Seasoned Chicken Breast with Rib Meat, Binders Added in \u2018Lemon Pepper Chicken Breast with Vegetable Medley.\u2019\u201d The characteristics of the meat or poultry added ingredients, are disclose in the ingredients statement. See: Policy Memos 112 and 117" "PRODUCT OF USA: Labeling may bear the phrase \u201cProduct of U.S.A.\u201d under one of the following conditions: 1. If the country to which the product is exported requires this phrase, and the product is processed in the U.S., or 2. The product is processed in the U.S. (i.e., is of domestic origin). This entry cancels Policy Memo 080 dated April 16, 1985 PROSCIUTTO: Italian for ham, dry cured. The product name \u201cProsciutto\u201d is acceptable on labeling to identify a dry-cured ham. PROSCIUTTO, COOKED: The product name \u201cCooked Prosciutto\u201d is acceptable on labeling to identify a dry-cured Prosciutto ham that is cooked. PROSCIUTTO COTTO, COOKED HAM: The product name \u201cProsciutto Cotto, Cooked Ham\u201d is acceptable on labeling to identify a regular pickle-cured cooked

ham. Prosciutto Cotto is the Italian name for cooked ham. PROTECTIVE COVERINGS (MEAT): Processed or Prepared Product -Immediate containers, e.g., bags, cardboard cartons, tray packs, and film bags enclosing processed or prepared product can be considered protective coverings and exempt from the marking and labeling requirements if placed in a shipping container which meets all mandatory labeling requirements of an immediate container. This does not exempt the mandatory identification and marking which is specifically required on the immediate container of cooked beef (9 CFR 318.17). In addition, the shipping container must be clearly marked \u201cPacked for Institutional Use\u201d or an equally descriptive statement of intended limited distribution. Unlabeled product may not be removed from shipping containers for further distribution nor displayed or offered for sale.", "Unprocessed Meat Cuts -Transparent film bags enclosing individual meat cuts in an unprocessed state can be considered protective coverings and exempt from the marking and labeling requirements if placed in a shipping container which meets all mandatory labeling of an immediate container. These unlabeled meat cuts may only be removed from the shipping container for resale and further distribution to retailers, hotels, restaurants, and similar institutions if the product itself or the film bag bears a clearly legible official mark of inspection and the establishment number. See: Policy Memo 090B dated December 18, 1990 PROTECTIVE COVERINGS (POULTRY): Under provision of the Poultry Products Inspection Act, protective coverings may be exempt from labeling requirements for immediate containers. Under certain circumstances, some protective coverings are considered immediate containers; under different circumstances, they are regarded only as protective product coverings. When plastic film bags, cardboard cartons, etc., are used for protecting poultry sold for export or to institutions, e.g., hotels, restaurants, and hospitals (where the contents are consumed on the premises), they are exempt from the mandatory labeling of immediate containers, provided the shipping container meets all the labeling requirements for an immediate container. Such product may not be diverted to retail channels and displayed for sale or be sold to household consumers unless they bear all labeling features required for immediate containers. See: 9 CFR 381.65(p) PUDDING: Nonspecific product. PULLED PORK: Refers to pork removed from bones by hand or by mechanical means. The meat must retain its natural striated muscle fiber structure, i.e., it can be shredded, chunked, etc., but may not be ground, chopped, or comminuted. QUALITY GRADE TERMS AND SUBJECTIVE TERMS ON LABELS: Terms designated as grades of meat, i.e., prime, choice, select, good, etc., may only be used on red meat which has been officially graded. However, the Food Labeling Division (FLD) will take no action to rescind currently approved labels which contain the word \u201cselect.\u201d Labels for new or reformulated products or new product lines will be approved in accordance with the policy for grading terms described above.", "Letter grades A,B,C, which are designated grades for poultry, may only be used on poultry (whole birds and parts) that are officially graded and may not be used on red meat. Although poultry grade terms (U.S. grade A, etc.) are not allowed to be used on red meats, the terms prime, choice, and select may be used on poultry (whole birds or parts) that are equivalent to U.S. grade A. The use of a possessive, e.g., XYZ's Prime, does not relieve a company of this requirement. The use of quality grade terms on further processed meat and poultry products will be evaluated on a case-by-case basis to determine if they wrongly imply that the meat or poultry used in these products has been graded. Terms which are subjective in nature, e.g., but not limited to, fancy, finest, super, supreme, ultimate, premium, greatest, best, old fashioned,

homestyle, hotelstyle, deluxe, special, famous, and old time may be used unqualified on labels for meat and\or poultry products. The term \u201cselected\u201d as well as other terms, will be considered individually by the Labeling and Consumer Protection Staff, again to determine if these terms wrongly imply that the meat or poultry has been graded. See: Policy Memo 101A dated August 30, 1988 QUICHE PRODUCTS: The term \u201cQuiche\u201d does not have to be qualified to indicate it is a custard cheese pie. However, when characterizing ingredients, e.g., bacon, ham, chicken, onion, etc. are used either alone or in combination, the ingredients shall be either clearly identified as part of the product name or prominently displayed elsewhere on the principal display panel (PDP) of the label (e.g., Bacon Quiche, Ham and Onion Quiche, etc.). Similarly, the characterizing ingredients in Quiches bearing fanciful names shall be identified as part of the product name or highlighted elsewhere on the PDP (e.g., Quiche Bercy -made with ham and wine). Since \u201cQuiche Lorraine\u201d is widely recognized, the characterizing ingredients do not have to be identified as a part of the product name or elsewhere on the PDP. Meat and poultry quiches must contain at least 8 percent cooked meat or poultry and sufficient cheese so that the combined total at least comprises 18 percent of the finished product. Quiche Lorraine must contain cooked bacon and\or ham and the only cheeses are Swiss and\or Gruyere. If other characterizing ingredients (excluding cheese), e.g., onions, peppers, olives, etc., are used in addition to the meat or poultry ingredient in Quiche Lorraine or in any other quiche, the combination of these other characterizing ingredients and the meat or poultry ingredients must comprise at least 8 percent of the total product, and the cooked meat or poultry portion must be at least 5 percent of the total product. See: Policy Memo 077 dated October 11, 1985","RANCH: The regulations and policies applicable to \u201cFarm\u201d also apply to ranch. RAVIOLI (MEAT): This product must contain at least 10 percent meat.

REHYDRATED DEHYDRATED VEGETABLES: Rehydrated dehydrated vegetables acceptable as name. The specific vegetable must be identified in the ingredient statement. RELLENO DE PAPA (PR): This product must contain 8 percent cooked meat. A Puerto Rican product that must show a true product name, e.g., \u201cPotato Balls with Beef,\u201d or \u201cPotato Dough with a Beef Filling.\u201d RENDERED BEEF FAT TISSUE SOLIDS: The solid remains of a fat extraction process from beef that was ground and rendered by a high temperature (180o F) continuous wet rendering system. See: Beef Greaves REWORK: Rework \u2013 is allowed in unlimited quantities when added to like product. However, if breaded\battered rework is added to similar products, the rework is limited to 2 percent. RICE AND MEAT: The product must contain at least 12 percent meat. ROASTED: The term \u201croasted\u201d may be used to describe products that have been subjected to cooking methods that result in a roasted appearance. ROLLS: Six uses exist for the term \u201cRoll\u201d in conjunction with names for meat food products: 1.Items consisting of a solid piece of meat, for example, \u201cBoned Veal Rib,\u201d formed and tied as a roll and usually offered with seasonings. 2.Chopped meat in combination with condiments, also formed and processed. It can be and often is offered in the fresh meat state." "Water (or any other liquid) is not an ordinary or usual ingredient in the above \u201cMeat Roll\u201d items. If water (liquid) is an ingredient in these products and they are raw, then the product name must contain a descriptive designation in accordance with 9 CFR 317.2(e)(2). If water (liquid) is an ingredient in these products and they are cooked, then the product name must include a containing statement in accordance with Policy Memo 084A. 3. \u201cSausage Rolls\u201d have similar formulas and water limitations to cooked sausage.

The finished product may contain up to 10 percent added water, is in roll shape, and is Cooked, or Smoked and Cured (species) Roll Sausages. 4. Non-descriptive rolls, for example, \u201cPizza Roll,\u201d \u201cPickle Roll,\u201d \u201cRelish Roll,\u201d etc., contain meat with cheese, peppers, pimentos, relishes, and other similar materials. An ingredients statement is required as a part of the product name on the basis of instructions in 9 CFR 317.2(c)(1) and (2), and 317.2(e). 5. Product made from meat and water that has been chunked, ground, chipped, wafer-sliced, etc., and formed into a roll containing a plant protein product or other binder could be labeled as a \u201cMeat, Water, and Textured Vegetable Protein Roll.\u201d The same size lettering is required to be used for the product name. 6. Product made from meat that has been chunked, ground, chipped, wafer-sliced, hydroflaked, etc., and formed in a roll containing a plant protein product or other binder is required to be labeled as \u201cBeef and Textured Vegetable Protein Roll\u201d or \u201cBeef and Soy Protein Concentrate Roll.\u201d ROLLS, POULTRY: Only natural proportions of skin to the whole carcass or designated part may be used. If skin is in greater than natural proportions, the name must be qualified with the term \u201cSkin Added.\u201d See: 9 CFR 381.159 ROMANO CHEESE: Label must show \u201ckind\u201d of milk, e.g., (Caprino), \u201cRomano Cheese made with Goat's Milk;\u201d (Pecornia), \u201cRomano Cheese made from Sheep's Milk;\u201d or (Vaccino), \u201cRomano Cheese made from Cow's Milk.\u201d The words in parenthesis are not required to be shown. RUMAKI: This product must contain at least 50 percent chicken livers. An hors d'oeuvre or appetizer. Rumaki is a combination of chicken livers, water chestnuts, and bacon.", "SALAD -FREEZE DRIED HAM: Antioxidants have been permitted in Freeze Dried Ham at a level of 0.01 percent, based on total weight of the ham. SALAD -GERMAN STYLE POTATO SALAD WITH BACON: Requires at least 14 percent cooked bacon. SALAD MIX, POULTRY: Product must contain at least 45 percent cooked poultry. SALADS: Standards for salads: Meat salads must include at least 35 percent cooked meat or meat food product (e.g., corned beef, ham). Ingredients, e.g., \u201cHam water added\u201d or \u201cCorned Beef and water product\u201d may be used if the formula is adjusted to account for the amount of added substances. Example: if 85 percent of a meat food product is meat, then 35 percent required meat divided by 0.85 equals 41 percent required meat food product in the salad. Cobb Salad - Contains lettuce and chicken or turkey. The other ingredients that may be found include bacon, hard cooked eggs, tomatoes, Roquefort or other blue cheese or dressing. The product name must include the poultry component(s) and also identify any meat ingredient when present about 2 percent, e.g., \u201cBacon and Chicken Breast Cobb Salad.\u201d Caesar Salad - is an acceptable product name and normally contains cheese, meat, or poultry pieces and may contain other vegetables. Ham and Cheese Salad -Must contain at least 25 percent cooked ham. Macaroni with ham or beef -Must contain at least 12 percent cooked meat. Poultry Salad -Must contain at least 25 percent cooked poultry (natural proportions of skin and fat). Chopped egg and ham salad -Must contain at least 12 percent ham. Chopped egg and bacon salad -Must contain at least 12 percent bacon (9 percent fully cooked bacon). Vegetable and/or fruit with poultry -Must contain at least 25 percent cooked poultry. Cracker meal, bread crumbs, and similar ingredients may be included in meat or poultry salads up to 2 percent of the total formula. If more than 2 percent is used, a product name qualifier is required. Modified food starch and textured vegetable protein cannot be substituted for cracker meal and bread crumbs in salad products.", "SALAMI: A dry sausage that requires an MPR of 1.9:1 or less. Extenders and

binders are permitted. It may be cooked to shorten drying period.

**SALAMI, BEEF:** A cooked, smoked sausage, usually mildly flavored, in a large casing, containing coarsely ground beef. Cereals and extenders are permitted. May contain fat. Product does not have to be labeled cooked.

**SALAMI, COOKED:** The product \u201cSalami\u201d must be labeled to include the word \u201cCooked,\u201d regardless of the type and size of its packaging, unless it is one of the following: 1. A salami with a moisture protein ratio of no more than 1:9 to 1; 2. \u201cGenoa salami\u201d with a moisture protein ratio of no more than 2.3:1; 3. \u201cSicilian salami\u201d with a moisture protein ratio of no more than 2.3:1; 4. Labeled, as . . . , a. Kosher Salami, b. Kosher Beef Salami, c. Beef Salami, d. Beer Salami, and e. Salami for Beer. Pork skins are not a permitted ingredient in cooked salami. See: Policy Memo 031A dated July 23, 1986

**SALAMI, COTTO:** A mildly flavored cooked, cured sausage, in a large casing, usually containing coarsely ground beef and pork. The product contains whole or visible pieces of peppercorns. It is cooked in dry heat.

**SALAMI, HARD:** A dry sausage with an MPR of 1.9:1. It is made with beef and pork and seasoned with garlic. Less highly flavored but usually more heavily smoked than Italian Salami. It is tied with loops or twine that gives a scalloped appearance.

**SALAMI, ITALIAN:** This kind of dry salami is usually prepared in the San Francisco area and is easily", "distinguished by its covering of a white mold. This salami consists of about 80 percent finely chopped pork, to which a small amount of pork fat may be added. Nonfat dry milk can comprise 3 1\2 percent of the finished product. The remainder consists of chopped beef, seasoning, salt, and curing agent. The product should have an MPR not in excess of 1.9:1 to insure the fat content and dryness properties associated with a \u201cdry salami.\u201d

**SALCHICHON (SP):** This term, meaning \u201cLarge Sausage,\u201d This term may only be used for large casing sausage products that are 3 inches in diameter or more. Label must show a true product name.

**SALISBURY STEAK:** Finished product must contain at least 65 percent meat. Fat is limited to 30 percent. Other requirements are: 1. It is an unbreaded cooked product. 2. The meat block may contain 25 percent pork, with the remainder beef. Or, the meat block may contain up to 12 percent partially defatted chopped beef and pork. 3. Extenders are permitted up to 12 percent. When isolated soy protein is used, 6.8 percent is the equivalent of 12 percent of the other extenders. Those extenders include, but are not limited to: cereal, bread crumbs, cracker meal, soy flour, soy protein concentrate, isolated soy protein, and textured vegetable protein. 4. Meat byproducts are not permitted. Beef heart meat is permitted. 5. Permitted liquids include, but are not limited to: water, broth, milk, cream, skim milk and reconstituted skim milk (9 parts water to 1 part NFDM). 6. Product not cooked which conforms to the above may be labeled \u201cPatties for Salisbury.\u201d

**SALISBURY STEAK, TURKEY:** Product must contain at least 55 percent turkey meat in natural proportions (light and dark) or 65 percent turkey with skin and fat in natural proportions (skin 10 percent, turkey met 55 percent). Maximum amount of binders and extenders is 12 percent.

**SALPICAO:** A smoked sausage. The label must show a true product name, e.g., \u201cSmoked Sausage.\u201d No more than 3 percent water can be added at formulation.

**SALSICCIA (IT):** A fresh pork sausage, highly spiced, in which paprika is permitted. It is a rope style sausage made of finely cut pork trimming."

**"SALT AS A CURE:** Dry processed hams, pork shoulders, and bacon are ordinarily cured with mixtures that contain mostly salt along with sugar and nitrates plus nitrites. However, some processors use salt alone in preparing their products. The salt in contact with the meat provides the desired cured color, taste, and necessary product protection. Salt is an

acceptable cure when used singly in the curing and salt equalization of dry processed hams, pork shoulders, and bacon. The cured products must have a 10 percent brine concentration.

SAMOSA: This product originated in India, although it is also associated with Pakistan. It resembles a Meat Turnover and consists of a spiced vegetable and meat mixture in a dough crust. At least 25 percent meat is required. Label must show a true product name, e.g., Beef Turnover.

SAMPLES: Free samples included along with the meat and poultry food products are not to be included in the net weight statement, and the ingredients do not need to be identified in the ingredients statement as long as the ingredients appear on sample package.

SANDALWOOD: SANDWICH -CLOSED: Product must contain at least 35 percent cooked meat and no more than 50 percent bread. Sandwiches are not amenable to inspection. If inspection is requested for this product, it may be granted under reimbursable Food Inspection Service. Typical closed-faced sandwiches consisting of two slices of bread or the top and bottom sections of a sliced bun that enclose meat or poultry, are not amenable to the Federal meat and poultry inspection laws. Therefore, they are not required to be inspected nor bear the marks of inspection when distributed in interstate commerce.

SANDWICH -OPEN: Must contain at least 50 percent cooked meat. Sandwiches are amenable only if they are open faced sandwiches. Product must show a true product name, e.g., Sliced Roast Beef on Bread.

This regulatory policy in no way alters the Department's present policy with respect to caterers who include meat sandwiches in their dinners.

SANDWICHES (MEAT OR POULTRY AS COMPONENTS OF DINNER PRODUCTS): Dinners containing a sandwich type product, e.g., a frankfurter, hamburger, or sliced poultry meat with a bun, are amenable and subject to inspection.", "SANTA FE STYLE: Acceptable for products that contain chilies with corn or beans and one of the following ingredients: Cheese (jack, cheddar, Mexican Style or fresh goat), bell pepper, onion, garlic, tomatoes, tomatillos, cumin, oregano or cilantro. The beans should be either black, kidney, navy, pink, pinto, red, or white beans or an indigenous variety.

SARNO: A dry smoked sausage that is air dried. The label must show a true product name, e.g., Smoked Sausage.

Coarsely chopped beef, pork, and garlic are not permitted.

SATAY: This term refers more to a preparation method than to the nature of a finished product. Satay can be made from chicken, beef, lamb, pork, and other food items, and prepared in two ways: 1. Meat is cut into one inch cubes, then dipped into a spicy sauce, skewered, and roasted over an open fire (similar to Kebobs except no vegetables or fruit). Label must show a true product name, e.g., Beef Cubes on Stick.

2. Meat is cut into one inch cubes, then dipped into a spicy sauce and canned. Label must show a true product name, e.g., Beef Cubes in Spicy Sauce.

SAUCE WITH MEAT OR MEAT SAUCE: Product must contain at least 6 percent ground meat.

SAUERBRAUTEN (GR): Sauerbrauten must contain at least 50 percent cooked beef.

Gravy with Sauerbraten must contain at least 35 percent cooked meat. Sauerbrauten is cooked beef in a vinegar flavored sauce. The beef is marinated in vinegar sauce, then separated from the sauce and partially cooked, and put back in the sauce and cooked completely.

SAUERKRAUT BALLS WITH MEAT: Product must contain at least 30 percent meat or meat food product.

SAUERKRAUT WITH FRANKS AND JUICE: Product must contain at least 20 percent franks.

SAUSAGE CLASSIFICATION: Fresh Sausage: Made of fresh, uncured meat, generally cuts of fresh pork, and sometimes beef. Its taste, texture, tenderness, and color are related to the ratio of fat to lean. Trimmings from primal cuts, e.g., pork, loin,

ham, and shoulders are often used. When ice or water is used to facilitate chopping and mixing, it is limited to a maximum of 3 percent of the total formula. It must be kept under refrigeration and thoroughly", "cooked before serving. Bratwurst is in this class. Binders and extenders are permitted in fresh sausages except where regulations do not permit the use of such ingredients, i.e., 9 CFR 9 CFR 319.140 (Pork Sausage), 9 CFR 319.142 (Beef Sausage), 9 CFR

319.144 (Whole Hog Sausage), and 9 CFR 319.145 (Italian Sausage). See: 9 CFR 319 Subpart E  
Uncooked smoked sausage: Has all the characteristics of fresh sausage except it is smoked, producing a different flavor and color. It must be thoroughly cooked before serving.

\u201cSmoked Pork Sausage\u201d is included in this class. If it is a mixture of pork and other meats, regardless of size, it must be treated for trichinae. See: 9 CFR 319 Subpart F Cooked sausages and\|or Smoked sausages: These products are chopped or ground, seasoned, cooked and\|or smoked. Added water is limited to 10 percent of the finished product. Meat byproducts may be used when permitted by standard. Cure is required for particular sausages, e.g., wieners or Polish sausage. These sausages come in various shapes and sizes, e.g., short, thin, long and chub. Cotto salami, liver sausage, and cooked weisswurst are included in this category.

Wieners, bologna, knockwurst, etc., are also in this class but are further distinguished by a fat and moisture limitation. See: 9 CFR 319.180 Dry and Semi-dry sausages: Dry sausages may or may not be characterized by a bacterial fermentation. When fermented, the intentional encouragement of a lactic acid bacteria growth is useful as a meat preservative as well as producing the typical tangy flavor. The meat ingredients, after being mixed with spices and curing materials, are generally held for several days in a curing cooler. Afterward, the meat is stuffed into casings and is started on a carefully controlled air-drying process. Some dry sausage is given a light preliminary smoke, but the key production step is a relatively long, continuous air-drying process. Principal dry sausage products are salamis and cervelats. Salamis are coarsely cut, cervelats finely cut with few exceptions. They may be smoked, unsmoked, or cooked. Italian and French dry sausage are rarely smoked; other varieties usually are smoked.

Dry sausage requires more production time than other types of sausage and results in a concentrated form of meat. Medium-dry sausage is about 70 percent of its \u201cgreen\u201d weight when sold. Less dry and fully dried sausage range from 80 percent to 60 percent of original weight at completion. Semi-dry sausages are usually heated in the smokehouse to fully cook the product and partially dry it. Semi-dry sausages are semi-soft sausages with good keeping qualities due to their lactic acid fermentation. Although dry and semi-dry sausages originally were produced in the winter for use in the summer and were considered summer sausage, the term \u201csummer sausage\u201d now refers to", "semi-dry sausages, especially Thuringer Cervelat.

SAUSAGE CONTAINING CHEESE: Sausages may contain cheese under the following conditions: 1. If there is a standard for that particular sausage, it must be met as though it contained no cheese. 7. The cheese must characterize the product and appear as part of the product name. Example \u201cItalian Sausage with Cheese.\u201d See: Policy Memo 010 dated September 8, 1980

SAUSAGE -LIQUIDS ADDED: Sausages containing fluid ingredients that are expected such as fruit and juice and vinegar, are permitted at any level as long as the product is descriptively labeled. The sausage portion of the product, however, must meet any applicable standard. Vinegar is an expected ingredient in chorizos and the name does not have to indicate its presence. SAUSAGE -SHELF STABLE: Dry sausage must have a Moisture Protein Ratio (MPR) of 1.9:1 or less, unless an MPR is cited under MOISTURE PROTEIN RATIO. Non-

refrigerated, semi-dry, shelf-stable sausage must have an MPR of 3.1:1 or less and a pH of 5.0 or less, unless commercially sterilized or unless an MPR is cited under MOISTURE PROTEIN RATIO. Alternately, non-refrigerated, semi-dry, shelf-stable sausages are those that: 1. are fermented to a pH of 4.5 or lower (or pH may be as high as 4.6 if combined with product water activity no higher than 0.91), 2. are in an intact form or, if sliced, are vacuum packed, 3. have internal brine concentration no less than 5 percent, 4. are cured with nitrite or nitrate, and 5. are smoked with wood.

**SAUSAGE, REWORK:** This term applies to a fully or partially processed product (excluding uncooked trimmings) re-routed for reasons other than unwholesomeness or adulteration (i.e., emulsion residue, product breakage, slicing operations, smoked meats, returns, etc.) and intended for inclusion in cooked sausage, loaves, and similar products. Rework may be used provided it does not adulterate the product, violate its standard of composition, change the order of predominance of ingredients, or perceptibly affect the "normal", "characteristics of the product. Rework is subject to the following restrictions: 1. Cooked sausage, meat loaves may be used in similar products without limitation. 2. Except in products covered by section 9 CFR 319.180, pieces of cooked and\or smoked meat may be used without limitation if properly identified in the ingredients statement. 3. Pieces of uncooked, cured pork from primal parts may be used without limitation if properly identified in the ingredients statement. 4. Sausage products in edible collagen casings may be used in similar finely comminuted products without limitation and need not be peeled. 5. Finished cooked sausage in natural casings may be used in similar finely comminuted products without limitation, except sausages in bungs, middles, beef rounds, bladders, or stomachs, which must be stripped of the casings before use. Also, natural casings of any type that break during the stuffing operations should not be included in emulsions.

**SAUSAGE TYPE PRODUCTS WITH FRUITS AND VEGETABLES:** Sausage type products that contain unexpected ingredients that significantly alter the character of the product may be descriptively labeled as (characterizing ingredient) Sausage, e.g., \u201cCherry Pecan Sausage,\u201d \u201cWild Rice Sausage,\u201d or other equally descriptive names, e.g., \u201cSausage with Wild Rice.\u201d The sausage portion of fresh sausage products must meet any applicable standards, including fat and added water limitations, moisture\protein ratios, and use of binders and extenders prior to the addition of any characterizing ingredient(s). For cooked, smoked, or dry sausages, the finished sausage type product must meet the sausage standard prior to the addition of any characterizing ingredients. The unexpected ingredient must be present in sufficient quantity or form to characterize the sausage type product in flavor, texture, or other sensory attributes. However, there are no minimum use levels. This policy applies to products containing unexpected food ingredients, e.g., fruits and vegetables, e.g., cherries, pecans, tomatoes, etc., that change the character of the product by the addition of unique flavor and other sensory characteristics. The policy does not apply to imitation products, i.e., products formulated to resemble in taste, texture, color, etc., the traditional sausage products, but which are nutritionally inferior. Sausages containing cheese are addressed Policy Memo 010, and Potato Sausages are addressed in Policy Memo 011.

**SAUSAGE WITH SAUERKRAUT IN SAUCE:** Product must contain at least 40 percent sausage.", "SAUSAGE (Species): (Species) sausages identified in 9 CFR 319.141, 319.142, 319.144, and 319.160 of the meat inspection regulations may be cooked, cured or smoked (or any combination), but must comply with the standards before being processed if the product name is to include \u201c(species) sausage.\u201d For example,

fresh beef sausage identified in 9 CFR 319.142 which is cured and cooked may be labeled \u201ccured, cooked beef sausage.\u201d Prior to this processing, these products could not contain more than the 3 percent water permitted by the standard. Cooked cured sausages or smoked cured sausages containing up to 10 percent added water in the finished product and prepared from one species may be labeled as \u201ccooked cured sausage,\u201d \u201csmoked sausage,\u201d \u201ccooked cured sausage made with (species),\u201d or \u201csmoked sausage made with (species).\u201d Semi-dry and dry sausages made from a single species may be labeled \u201c(species) sausage,\u201d e.g., \u201cbeef sausage.\u201d This policy does not apply to cooked sausages identified in section 9 CFR 319.180 of the meat regulations. See: Policy Memo 051 dated September 13, 1982 SCALLOPED POTATOES AND HAM: Product must contain at least 20 percent cooked ham. SCALLOPED POTATOES AND SAUSAGE: Product must contain at least 20 percent cooked sausage. SCALLOPED POTATOES FLAVORED WITH SAUSAGE: Product must contain at least 3 percent sausage. SCALLOPPINI: Product must contain at least 35 percent cooked meat or poultry meat. Thin slices of cooked veal, sometimes beef or poultry, seared or fried. Label must show a true product name, e.g., \u201cVeal Scaloppini\u201d or \u201cChicken Scaloppini.\u201d SCHICKENWURST (GR): The product is made of two parts, one of which is an emulsion prepared from pork and beef cuts. The second component consists of chunks of ham measuring from 2 to 3 inches in size. The two parts are mixed, stuffed into large casings, and smoked while being cooked. The final product appears as a luncheon sausage with large pieces of red ham meat held together by a light pink binder. The ham sections comprise at least 50 percent of the product and the item has a distinct smoked flavor. This product is very similar in appearance to the product sold as \u201cHam Bologna.\u201d "SCRAMBLED EGGS WITH BACON": Product must contain at least 10 percent cooked bacon. SEAWEED: The term is not an acceptable ingredient declaration. There are many types of seaweed, some are not as safe. \u201cSERVING SUGGESTION,\u201d \u201cSERVE AS SUGGESTED,\u201d AND SIMILAR PHRASES: Vignettes should reasonably illustrate ingredients that could be in the packaged products as sold, and not be misleading to the consumer. See: 9 CFR 317.8 9 CFR 381.129 SHEPHERDS PIE (With or Without Vegetables): Product must contain at least 25 percent meat in total formulation. Shepherds Pie is a meat food product consisting of chopped, minced, or cubed beef or lamb, seasoned with gravy or sauce, with or without vegetables, and baked with a covering layer or surrounding border of seasoned mashed potatoes. The label must show a true product name, e.g., \u201cBeef Shepherds Pie.\u201d SHIPPING CONTAINERS: A mark of inspection and a handling statement is required on all shipping containers. Safe Handling Instructions are required with all other required features only when they shipping container is also the immediate or primary container. See: 9 CFR 316.13 SHU-MAI: Product must contain at least 10 percent meat. A Chinese product that resembles a dumpling. It is similar to a meat ravioli. The label must show a true product name, e.g., \u201cPork Dumpling\u201d. SIGNATURE LINE: It is not necessary to include the term \u201cGeneral Office\u201d in signature lines on labels used by companies with multiple plant operations. A zip code shall appear following the address. See: 9 CFR 317.2(g)(1) 9 CFR 381.122", "SLOPPY JOE: A coined name that must be qualified by a true product name, e.g., \u201cBarbecue Sauce with Beef.\u201d The meat content depends on the name of the product. Heart meat and tongue meat can be used but not to satisfy the minimum meat requirement. SMOKE: For imported Canadian products, e.g., bacon, which are physically

smoked during processing, the word \u201cSmoke\u201d is acceptable in the ingredients statement. Although not required or customary, smoke can also appear in the ingredients statement of domestically produced products which are physically smoked. If included in the ingredients statement, smoke should appear as the last item. SMOKE FLAVORING: The use of smoke flavoring (natural or artificial) in a component of a meat or poultry food product, e.g., ham in a ham salad, does not require that the product name be qualified to indicate the presence of the smoke flavoring. However, the smoke flavoring must be declared in the ingredients statement on the meat or poultry product labels. Secondary product \u2013 when meat and extender product is produced using a meat product in which smoke flavoring is added, the secondary product name does not have to be qualified with a phrase as \u201csmoke flavoring added.\u201d When smoke flavor (natural or artificial) has been directly added to a product as part of a seasoning mix, the presence of the smoke flavor must be identified in a qualifying statement to the product name, e.g. 1. \u201cChicken soup smoked flavor added,\u201d and in the ingredients statement. 2. \u201cBeef soup smoke flavor.\u201d 3. If a product is simply sprayed with liquid smoke, it must be labeled \u201csmoke flavoring added.\u201d See: Policy Memo 117 dated August 30, 1988 SMOKED PRODUCTS: The guidelines for approving labels for products prepared with natural smoke and\or smoke flavor (natural or artificial) are as follows: 1. Meat or poultry products which have been exposed to smoke generated from burning hardwoods, hardwood sawdust, corn cobs, mesquite, etc., may be labeled as \u201cSmoked\u201d or with terms, e.g., \u201cNaturally Smoked\u201d to indicate that the traditional smoking process is used. 2. Meat or poultry products which have been exposed to natural liquid smoke flavor which has been transformed into a true gaseous state by the application of heat or transformed into vapor by mechanical means, e.g., atomization, may be labeled \u201cSmoked.\u201d", 3. Meat or poultry products may be labeled \u201cSmoked\u201d if natural liquid smoke flavor is applied by spraying, dipping, liquid flooding, or similar processes prior to or during heat processing. In such cases, the natural liquid smoke flavoring must be transformed into a true gaseous state by the heat of processing. If a product is simply sprayed with liquid smoke it must be labeled \u201csmoke flavoring added.\u201d 4. Meat or poultry products to which smoke flavor (natural or artificial) has been directly applied to the exposed product surface, e.g., massaging or margination, or incorporated into the product by such means as injection, must be labeled to identify the smoke flavor as part of the product name, e.g., \u201cHam-Natural Smoke Flavor Added,\u201d and in the ingredients statement. 5. Meat or poultry products that are smoked, as provided for in (1), (2) and (3) above and also treated with smoke flavor as described in (4), may only be labeled \u201cSmoked\u201d or with terms, e.g., \u201cNaturally Smoked,\u201d if it is clearly disclosed that the product is also treated with smoke flavor. The presence of the smoke flavor must be identified as part of the product name, e.g., \u201cSmoked Ham-Smoke Flavoring Added\u201d and in the ingredients statement. 6. Product may be labeled as \u201chickory smoked\u201d only if the plant provides the inspector with appropriate certification that such sawdust or wood for smoking is 100 percent hickory. See: Policy Memo 040 dated January 18, 1982 Policy Memo 058A dated August 5, 1983 SMOKED THURINGER LINKS: A cooked smoked sausage made with pork only. SNACKS (HORS D'OEUVRES): Product must contain at least 15 percent cooked meat or 10 percent cooked bacon. The label must show a true product name, e.g., \u201cLiver Pate on Toast.\u201d SODIUM ALGINATE: This is

added as a binder in \u201cTaquitos.\u201d Approval may be given for use at a level of less than 1 percent with .25 percent of calcium citrate to stabilize a pizza sauce or pizzas heated in household toasters. Sodium alginate when used as glue to seal burrito and burrito like products is acceptable, if declared in the ingredients statement, or if a statement such as \u201csealed with sodium alginate\u201d appears at the end of the ingredients statement.

**SODIUM BENZOATE:** Sodium Benzoate is not an acceptable ingredient for meat and poultry products, except in oleomargarine. It is accepted as an incidental additive when it is a part of a product", "prepared under FDA rules, e.g., sauces, gravies, and similar substances.

**SOFRITO WITH PORK:** This is a sauce containing 6 percent smoked pork.

**SOPPRESATE (IT):** This is an acceptable name for a dry salami with an MPR of 1.9:1. This is an Italian salami that is lightly flavored with garlic and, generally, hotly seasoned with paprika and black or red peppers. It is smoked to varying degrees depending on regional tastes.

**SORBITOL:** This is only permitted in 9 CFR 319.180 products, cured pork products, dried beef, kielbasa and products similar to kielbasa. Do not approve when used in other products.

**SOUFFLE (SPECIES) OR (KIND):** Product must contain at least 18 percent cooked meat or poultry meat.

**SOUJOUK (TK):** This is a Turkish sausage made from beef which is very dry and highly spiced with an MPR of 2.04:1. The product is usually flattened or resembles a dry salami or ring bologna. The label must show a true product name, e.g., \u201cDried Beef Sausage.\u201d

**SOUP:** 1. Soups that declare meat stock in the product name are meat food products and shall contain at least 25 percent meat stock with an MPR of not less than: a. Condensed soup -67:1 b. Ready-to-eat -135:1 c. Beef Bouillon - 67:1 and at least 50 percent beef stock 2. Soups made with meat shall contain not less than: a. Condensed soup -4 percent cooked meat b. Ready-to-eat -2 percent cooked meat 3. Soups containing smoked meats shall contain not less than: a. Condensed soup -4.0 percent smoked meat b. Ready-to-eat -2.0 percent smoked meat 4. Soups made with cooked sausages shall contain at least 4 percent cooked sausage. See: Policy Memo 122 dated August 11, 1992","**SOUP PRODUCTS:** Bean & Ham Shank: When soup is made from ham shanks, they must be shown in the true product name, e.g., \u201cBean and Ham Shank Soup.\u201d Blood: Product must contain at least 1 percent blood and be made under inspection.

**Chowders:** Follow standard for soups.

**Consomme:** A broth cooked with vegetables and then strained. Must have an MPR of 135:1.

**Consomme Instant:** Dehydrated -not amenable.

**Cream:** Condensed cream soups may be made from various creams, whole milk, or dry milk powder. The amount of cream, whole milk, or dry milk powder should provide a minimum of .45 percent butterfat to the final product. Examples: A cream containing 18 percent butterfat should make up the product formulation; this provides .45 percent butterfat to the product formulation.

**1. Dry milk powder containing 27 percent butterfat should make up 1.67 percent of the product formulation.**

**Dried Meat Soup Mixes:** Not amenable.

**Italian Style Minestrone:** Soup must contain zucchini. Identify meat in the true product name.

**Pepper Pot:** Soup must contain at least 20 percent scalded tripe.

**Petite Marmite (FR):** A soup made with meat, chicken, and vegetables.

**Scotch Broth:** Soup must contain at least 3 percent mutton in a thick mutton broth.

**Vegetable:** Vegetable soups made with soup stock are not considered amenable.

**SOUSE:** This is a nonspecific product that can be made with all pork byproducts. The ingredients statement directly follows the product name.

**SOUTHERN FRIED:** Southern fried poultry cuts or patties are breaded and fried. This is not geographical.

**SOUTHWESTERN STYLE:** An acceptable identification for products containing any five (5) of the following types of food

ingredients:,"Beans (kidney beans, black beans, pinto beans, red or pink beans), corn, chili peppers, bell peppers, cheddar cheese, cilantro, onions or onion powder, cumin, oregano, garlic or garlic powder, paprika, chili powder, either mesquite smoked, or mesquite smoke flavor added. SOY PROTEIN PRODUCTS: Whenever soy flour, defatted soy grits, soy protein concentrate, isolated soy protein, and similar products are used as ingredients of meat and poultry products, they must be called by their common or usual name (e.g., soy flour, soy protein isolate, etc.). Two percent isolated soy protein is equivalent to 3.5 percent binders. If these products are textured, then \u201ctextured\u201d should also be included in the name. We allow the use of the term \u201ctextured vegetable protein\u201d when the textured soy products are mixed with spices, colorings, enrichments, etc., and the ingredients of the textured vegetable protein are listed parenthetically. \u201cVegetable Protein Product\u201d is an acceptable declaration for a soy product fortified in accordance with Food and Nutrition Service regulations. The ingredients of the VPP must be listed parenthetically. SPAGHETTI: Sauce with meatballs Must contain at least 35 percent cooked meatballs Sauce with meat Must contain at least 6 percent meat with meatballs Must contain at least 12 percent meat with meatballs & sauce Must contain at least 12 percent meat with meat and sauce Must contain at least 12 percent meat with franks and sauce Must contain at least 12 percent franks SPAGHETTI SAUCE WITH MEAT STOCK: This spaghetti sauce consists mainly of tomatoes with seasoning. Product must contain 5 percent fresh beef and 12.5 percent concentrated meat stock. SPAGHETTOS IN CHEESE SAUCE WITH GROUND BEEF: Product must contain at least 12 percent meat. SPANISH RICE WITH BEEF: Product must contain at least 20 percent cooked beef. SPECKWURST: Product should conform to sausage standard (9 CFR 319.140) without the use of","byproducts. Chunks of fat are usually present. STARCH: Starch, wheat starch, and cornstarch are synonymous in meaning. When \u201cVegetable Starch\u201d is used as a designation, it refers to the starchy materials derived from any vegetable source, e.g., potatoes, peas, etc. Tapioca starch cannot be declared as \u201cstarch.\u201d See: Tapioca Starch STEAK, CHINESE PEPPER: Product must contain at least 30 percent cooked steak. A Chinese dish usually served with rice. Beef steak is cut in thin strips, browned, and added to a sauce. Vegetables are also added to the sauce; green pepper strips are always used, and other vegetables may include celery, onions, scallions, red pepper, bean sprouts, tomatoes, or water chestnuts. STEAK, COUNTRY STYLE: This term is popular in the Southern region of the country. It resembles a \u201cGravy and Swiss Steak\u201d product. Characteristics of this product are: 1. It is prepared from the steaking portions of beef (usually from the round) and braised. 2. The meat is mechanically \u201ctenderized\u201d and floured prior to browning. 3. The meat is browned by saut\u00e9ing or oven browning, but not flame browned nor cooked in water. 4. When a true product name is shown as \u201cGravy and Beef Steak,\u201d at least 35 percent cooked steak must be used. 5. When a true product name is shown as \u201cBeef Steak with Gravy,\u201d at least 50 percent cooked steak must be used. STEAK, PEPPER: Product must meet the standard for \u201cFabricated Steak\u201d in 9 CFR 319.15(d) and contain green and\or red peppers. STICKS: There are three types of meat or poultry sticks. 1. Meat Sticks, which are an extended \u201cpattie-like\u201d product and are usually breaded. No more than 10 percent extenders and 30 percent breading are permitted. When whole egg, tomato, and nonfat dry milk are used, they must appear as added ingredients in the true product name, e.g., \u201cBREADED MEAT STICK -NONFAT DRY MILK ADDED. 2. The infant finger food type of sticks

is usually packed in jars. It conforms to the sausage standard and must show a true product name, e.g., "Meat Stick.", "3. Nonspecific dry or semi-dry sticks that do not meet the sausage standard must be followed by the ingredients statement. If products meet the sausage standard, they may be identified as Smoked Sausage." STROGANOFF, MEATBALL: Product must contain at least 45 percent cooked meatballs. Sauce portion shall comply with the Stroganoff Sauce standard. STROGANOFF SAUCE: The sauce must contain at least 10 percent sour cream or a combination of at least 7.5 percent sour cream and 5 percent wine, or 2 percent sour cream, 2 1/2 percent wine, and 9 1/2 percent whole milk.

STROGANOFF SAUCE WITH AND BEEF: Product must contain at least 31 percent beef or 21 percent cooked beef based on the total weight of the product, with sauce portion complying with the stroganoff sauce standard. STROGANOFF SAUCE WITH AND MEATBALLS: Product must contain at least 31 percent cooked meatballs. Sauce portion shall comply with the stroganoff sauce standard. STROMBOLI (IT): Product is not considered a traditional sandwich. Minimum meat requirement is 25 percent fresh or 18 percent cooked meat. The label must show a true product name, e.g., "Pepperoni and Cheese Wrapped in Dough."

STUFFED CABBAGE WITH MEAT IN SAUCE: Product must contain at least 12 percent meat or at least 8 percent cooked poultry. STUFFED PEPPERS WITH MEAT IN SAUCE: Product must contain at least 12 percent meat or at least 8 percent cooked poultry. SUKIYAKI: Product must contain at least 30 percent beef. Sukiyaki consists of cut up vegetables, e.g., mushrooms, leeks and celery, which are cooked briefly with thin slices of beef and soy sauce. SULFITING AGENTS: The presence of sulfiting agents (sulfur dioxide, sodium sulfite, sodium bisulfite, potassium bisulfite, sodium metabisulfite, and potassium metabisulfite) must be declared on the label if their concentration in the finished meat or poultry food product is 10 PPM, or higher. However, some finished meat and poultry food products may be comprised of multiple separable components, e.g., potatoes or apple cobbler in frozen dinner. For these products, if a separable component contains 10 PPM or more sulfiting agents, the sulfiting agents must be declared even though the total product contains less than 10 PPM of sulfiting agents. When sulfiting agents are required to be declared under conditions described above, their declaration shall be according to the following: 1. Sulfiting agents shall be declared by their specific name or as "sulfiting agents." 2. Declaration shall be in the ingredients statement in order of predominance or at the end of the ingredients statement with the statement "This Product Contains Sulfiting Agents" (or specific name(s)). 3. When the total product contains less than 10 PPM, but a separable component contains 10 PPM or more, the sulfiting agent must be declared as part of the component according to (1) and (2) above. See: Policy Memo 094B dated December 17, 1986 SUMMER SAUSAGE: Product may be a semi-dry or cooked sausage. Meat byproducts and extenders are permitted. SWISS STEAK: Swiss Steak and Gravy: Contains not less than 50 percent cooked beef. Gravy and Swiss Steak: Contains not less than 35 percent cooked beef. Product labeled "Swiss Steak" must be floured or dusted before searing, or may have flour added to gravy. SWEET AND SOUR PORK, BEEF OR POULTRY: Product requires at least 25 percent meat or poultry meat, or 18 percent cooked meat or poultry meat. Product also requires sufficient traditional sweet and sour ingredients (fruit, fruit juices, vinegar, etc.) to impart sweet and sour characteristics. SZECHWAN STYLE: Acceptable identification for any product containing one item from three or the four groups below. 1. Soy sauce. 2. Spring onions, scallions or leeks.", "3. Garlic, ginger, ginger root. 4. Chili,

Szechwan peppercorn, Chili oil. TACO: Product must contain at least 15 percent meat. TACO FILLING: Product must contain at least 40 percent fresh meat. The label must show true product name, e.g., \u201cTaco Filling with Meat,\u201d \u201cBeef Taco Filling,\u201d or \u201cTaco Meat Filling.\u201d TACO FILLING, KIND: Product must contain at least 40 percent raw poultry meat. TAGS, TISSUE STRIPS, BRANDS: When tags, tissue strips, brands, etc. are used to apply ingredients statements on sausages and other products in casings or link form, the only additional marking required is the official inspection legend. However, if other features are added, e.g., the product name, all applicable required labeling features are required. See: 9 CFR 316.10 TALLOW: Acceptable product name for the meat food product consisting of rendered beef fat or mutton fat or both. TAMALES: Product must contain at least 25 percent meat. Tamales prepared with meats other than beef and\or pork must include them in the product name, e.g., \u201cChicken Tamale\u201d or \u201cChicken and Beef Tamale\u201d. See: 9 CFR 319.305 When inedible wrappings are used, they must be indicated: a. In the product name, e.g., \u201cBeef Tamale Wrapped in Corn Husk.\u201d b. As a qualifier to the product name, e.g., \u201cremove parchment paper prior to eating,\u201d or", "c. As information in the preparation instructions, e.g., \u201cremove the inedible covering prior to serving.\u201d The wrapper cannot be included as part of the net weight. Filling -must contain at least 40 percent beef. Pie -must contain at least 20 percent fresh meat. Filling must be at least 40 percent of the total product. (kind) -must contain at least 6 percent poultry meat. (kind) With sauce or gravy - must contain at least 5 percent poultry meat. (species) -must contain at least 25 percent meat. (species) With sauce or gravy -must contain at least 20 percent fresh meat. If byproducts are used, their presence must be included in the product name. TAPIOCA PRODUCT: Tapioca flour \u2013 can be used as a binder in some products in which \u201cstarchy vegetable flour\u201d is permitted, as long as it is declared as tapioca flour. Tapioca starch \u2013 can be used as a binder in some meat and poultry products n which \u201cvegetable starch\u201d is permitted as long as it is declared as \u201ctapioca starch or food starch.\u201d Tapioca starch cannot be declared as \u201cstarch.\u201d TAQUITOS: A Mexican dish requiring at least 15 percent meat. Cooked meat product is cut into strips or shredded and placed in center of tortilla. The tortilla is then rolled around the filling. TASAJO SALTED BEEF (SP): MPR not to exceed 2:1. Product is stitch pumped and cured in salt brine for 72 hours or more after which it is dried with circulated warm air for a period of at least 20 days. If the item is dipped in a tallow mixture, a statement must be shown contiguous to the product name identifying the constituents of the dipping mixture. TEAWURST OR TEEWURST: A cooked or uncooked product processed with or without curing and cold smoked 2 to 5 days. It is ground or coarsely chopped and is characterized by a soft spreadable texture.", "Typical meat ingredients include: pork, beef, pork bellies, and bacon. Fresh pork bellies may be used in place of pork fat and bacon. TEMPURA: A Japanese dish consisting of shrimp, fish, vegetable, meat, poultry etc., each dipped in an egg batter and deep fried. The label must show true product name, e.g., \u201cChicken Tempura,\u201d \u201cPork Tempura,\u201d etc. TERIYAKI, MEAT OR POULTRY (COOKED): Cubes or slices of cooked meat or poultry which have been marinated in a sauce containing soy sauce, some kind of sweetener, and usually ginger, garlic, or wine. When the cooked marinated product is combined with additional sauce the product name is required to reflect the sauce; for example, \u201cBeef Teriyaki with Sauce.\u201d See: Teriyaki Products when product has not been cooked TERIYAKI PRODUCTS: Meat and poultry teriyaki products are not required to be cooked,

provided a prominent statement is on the principal display panel informing the consumer that the product is not cooked. Example: \u201cCook and Serve,\u201d \u201cRaw,\u201d and \u201cReady to Bake.\u201d In addition, raw \u201cteriyaki\u201d meat or poultry products with added solutions must be labeled in accordance with 9 CFR 317.2(e)(2) or 9 CFR 381.117(h). See: Policy Memo 012 dated September 8, 1980 (Uncooked Meat and Poultry Teriyaki)

TETRAZZINI, POULTRY OR BEEF: Product must contain at least 15 percent cooked poultry or cooked beef. Made with diced cooked poultry or meat in a rich cream sauce containing sherry. This is added to cooked spaghetti or noodles in a casserole. Usually topped with bread crumbs or grated cheese. TEXTURED VEGETABLE PROTEIN (Textured Vegetable Protein Product) FOR COOKED MEAT and\or POULTRY MEAT: If the cooked meat and\or poultry meat to TVP ratio exceeds 9:1, then the TVP is declared by its common or usual name in the ingredients statement only. If the cooked meat and\or poultry meat to TVP ratio is less than 9:1 but at least 7:1, the label must contain a qualifying phrase contiguous to the product name, e.g., \u201cChicken Salad, Textured Vegetable Protein Added.\u201d If the cooked meat and\or poultry meat to TVP ratio is less than 7:1, the TVP must be shown in the product name, e.g., \u201cChicken and Textured Vegetable Protein Salad.\u201d", "TEXTURED VEGETABLE PROTEIN (TVP) PRODUCTS-FRESH MEAT OR POULTRY MEAT RATIOS: The following guidelines and labeling requirements have been established regarding use of TVP in products other than patties and pizza toppings. If the ratio of fresh meat or poultry meat to TVP is greater than or equal to 13:1, the TVP product is not considered to be characterizing or deceptive, e.g., 40 percent fresh meat: 3 percent textured soy flour = 13.3:1, and the TVP need only to appear in the ingredients statement. If the ratio of fresh meat or poultry meat to TVP product is less than 13:1 but greater than or equal to 10:1, the TVP is characterizing and must be shown as a product name qualifier contiguous to the product name, e.g., \u201cHot Dog Chili Sauce made with Beef Textured Vegetable Protein added.\u201d If the ratio of fresh meat or poultry meat to TVP is less than 10:1, the TVP must be part of the product name, e.g., as \u201cBeef and Textured Vegetable Protein Hotdog Chili Sauce\u201d or \u201cHotdog Chili Sauce Made with Beef and Textured Soy Flour.\u201d THAI STYLE: Acceptable identification for products containing at least five of the following: Basil, chilies or chili products, cilantro, coconut or coconut products, coriander, cumin, fish sauce, galangal, garlic, ginger, green onions, jasmine rice, lemon grass, peanuts or peanut products, rice noodles, shallots, or soy sauce. THURINGER: Usually classed as a \u201cSemi-Dry\u201d sausage with an MPR of 3.7:1. It is usually smoked and complies with the following factors: 1. Pork fat as such may comprise up to 10 percent of the total ingredients. 2. Heart meat (Beef or Pork) may comprise up to 50 percent of meat ingredients. 3. Tongue meat (Beef or Pork) may comprise up to 10 percent of meat ingredients. 4. Cheek meat (Beef or Pork) may comprise up to 50 percent of meat ingredients. 5. No binders or extenders are allowed. 6. \u201cCooked Thuringer\u201d can contain up to 10 percent added water.", "7. Acceptable product names for uncooked Thuringer include: \u201cBeef Summer Sausage -Thuringer Cervelat\u201d and \u201cSummer Sausage -Thuringer Cervelat.\u201d TIPS: Is the sub-primal of the beef round and is often referred to as the \u201cSirloin Tip.\u201d If the term \u201cTips\u201d is used for other than from the \u201cSirloin Tip,\u201d it must be qualified as to the specific part of the primal such as \u201cBeef Ribs Tips.\u201d TITANIUM DIOXIDE: When Titanium Dioxide is used in poultry salads, a qualifying phrase should appear under the product name stating that the product has been

\u201cArtificially Whitened\u201d or \u201cArtificially Lightened.\u201d TOCINO: Spanish word for salt Pork or Bacon. Except in Puerto Rico, must show and use true product name in English, e.g., bacon, salt pork. TOCINO (Filipino or Philippine Style): The thinly sliced piece of meat taken from either the hind leg or shoulder portion of the pork carcass. The product is treated with salt, sugar, and nitrite and\or nitrates, with optional ingredients of ascorbic acid, spices, monosodium glutamate, and phosphates. Acceptable color agents are annatto, beet powder, and paprika that are required to be shown as \u201cartificially colored.\u201d A true product name is required to be shown on the label, for example, \u201cSliced Marinated Cured Pork Shoulder Butt.\u201d In addition, raw \u201ctocino\u201d meat products with added solutions must be labeled in accordance with 9 CFR 317.2(e) (2). TOCINO, POULTRY: Acceptable with a true descriptive product name, e.g., \u201cChicken Tocino, Sliced, Marinated, Cooked, Cured Chicken Thigh Meat.\u201d Raw \u201ctocino\u201d poultry products with added solutions are required to be labeled in accordance with 9 CFR 381.117(h), e.g., \u201cSliced Tocino Cured Marinated Chicken Thigh Meat with 8% solution of water, sugar, salt, and spices.\u201d TOCOPHEROL: May be listed as \u201cTopcopherol (Vitamin E)\u201d on the label but not \u201cVitamin E (Tocopherol).\u201d Tocopherol and Vitamin E are not synonyms. Also, acceptable in rendered or unrendered fat. TOMATO AND BACON SPREAD: Product must contain at least 25 percent cooked bacon.", "TONGUE TRIMMINGS: Labeling terminology for the various kinds of tongue and cheek trimmings shall be as follows: 1. \u201c(Species) tongue trimmings\u201d shall be used to identify all tissues except cartilage and bone that are obtained by converting long-cut to short-cut tongues. This conversion is done by making a transverse cut anterior to the epiglottis, removing the soft palate and epiglottis, and cutting through the hyoid bone. Approximately 1 1/2 inches of the bone is left with the tongue. \u201c(Species) tongue trimmings\u201d may also be used to identify salivary glands, lymph nodes, and fat from which the muscle tissue has not been removed. 2. \u201c(Species) salivary glands, lymph nodes, and fat (tongue)\u201d must be preceded by the name of the species from which derived. Tongue meat should not include any tissues described in paragraph 2. 3. Trimmings from the tongue itself should be identified as \u201ctongue meat\u201d preceded by the name of the species from which derived. Tongue meat should not include any tissues described in paragraphs 2 and 3 above. 4. Trimmings with fat from tongue is acceptable ingredient in cooked sausage products covered under section 9 CFR 319.180 of the regulations. Lymph nodes and salivary glands are not acceptable ingredients. TOPPING -(Species) or (Kind): Topping is an acceptable product name for a nonspecific product containing the species or kind indicated as well as various other ingredients. The ingredients statement must follow the product name. See: Pizza Topping Mix TORTELLINI WITH MEAT: Product must contain at least 10 percent meat. TORTILLA WITH MEAT: Product must contain at least 10 percent meat. Tortilla is a thin, flat unleavened masa cake which is baked on both sides. TOSTADA WITH MEAT: Product must contain at least 15 percent meat. A tortilla is usually topped with refried beans, meat, cheese, and fresh vegetables.", "TOURISTEN WURST: A semi-dry type of sausage. The MPR must not exceed is 3.7:1. \u201cTROPIC CURE\u201d PORK PRODUCTS: Pork products when ready for shipment from the official establishment must have a moisture protein ratio not in excess of 3.25:1, and a salt content not less than 6 percent. TRUFFLES: Meat food product, e.g., \u201cLiver Pate with Truffles\u201d or \u201cSandwich Spread with Truffles\u201d would be expected to be prepared with at the least 3 percent truffles. Labels of product

containing less than 3 percent truffles should indicate the amount of truffle content in the name, e.g., \u201cLiver Pate with 2 percent truffles.\u201d If the name does not feature truffles and they are mentioned only in the list of ingredients, we have no minimum requirement, provided the illustration does not show truffles. TURKEY BRAUNSCHWEIGER: The product name must be shown on the label as \u201cTurkey Liver Sausage.\u201d No byproducts other than liver are permitted in the product. TURKEY CHOPS: Turkey chops are prepared by cutting the frozen breast into slabs with each cut being made perpendicular to the long axis of the keel bone (sternum). The larger slabs are split in half through the center of the sternum, resulting in two individual servings of meat with a piece of bone on one side and a thin layer of skin on the other. The smaller pieces at each end of the breast are left intact as individual servings. The word steak is unsuitable because a turkey steak is boneless by definition. TURKEY HAM PRODUCTS CONTAINING ADDED WATER: Product otherwise conforming to the standard for turkey ham under section 9 CFR 381.171 of the poultry products inspection regulations but weighing more than the original weight of the turkey thigh meat used prior to curing shall be descriptively labeled as follows: 1. The product name must include in addition to \u201cTurkey Ham\u201d, words that specify the amount of the additional substances, e.g., \u201cand percent Water,\u201d \u201cWith percent Water Added,\u201d or \u201cTurkey Ham and Water Product percent of Weight is Added Ingredients.\u201d (The ingredients of the added solution may be incorporated into the product name, e.g., \u201cTurkey Ham and Water Product percent of Weight is Added Water, Salt, Dextrose, Sodium Phosphate, and Sodium Nitrite.\u201d) The blank is filled", "in with the percent determined by subtracting the original weight of the turkey thigh meat from the weight of the cooked finished product. \u201cTurkey Ham and 12 percent Water\u201d is an example. 2. In retail and non-retail size packaging, the qualifying statements described in 1 above must be shown in lettering that is either not less than three-eighths inch in height or is at least one-third the size of the letters used in the product name and in the same color and style and on the same background as the product name. Full length of the product labeling is not required. 3. The \u201cTurkey Ham\u201d portion of the product name must be qualified with the statement \u201cCured Turkey Thigh Meat\u201d in the manner described in 9 CFR 381.171(e). This may be effected by using an asterisk as long as there is no type or other designs between the total product name and the qualifying statement. Other means of qualifying \u201cTurkey Ham\u201d will be evaluated based on clarity. Alternatively, the total name as described in 1 and 2 above may be qualified with a statement that includes \u201cCured Turkey Thigh Meat\u201d and the amount of added water, e.g., \u201cCured Turkey Thigh Meat and 12 percent Water.\u201d The statement should be presented in the manner described in 9 CFR 381.171(e). 4. The product name shall be further qualified with the statement(s) required by section 9 CFR 381.171(f) and any other statements required in Part 381. A product complying with the standard for Turkey Ham, containing added water, and descriptively labeled as stated above, must be produced under a Partial Quality Control (PQC) program approved by the Processed Products Inspection Division (PPID) prior to the use of the approved label. See: Policy Memo 057A dated September 16, 1985 TURKEY HAM AND WATER PRODUCTS CONTAINING BINDERS: Turkey ham products containing added water and binders must be labeled as \u201cTurkey Ham and Water Products\u201d X percent of weight is added ingredients as described in Policy Memo 057a to provide freeze\thaw stability and reduce

purge in packages. The binders that are acceptable for use in cured pork product can be used in these turkey ham products. The binders must be used in accordance with 9 CFR, Sections 9 CFR 319.104 (d) and 424.21 (c). Where several limits are listed, depending upon the cured pork product, the maximum amount permitted in the regulation is acceptable.

**TURKEY HAM**

**PRODUCTS CONTAINING GROUND TURKEY THIGH MEAT (LABELING):** Small amounts of ground turkey thigh meat may be added as a binder in turkey ham products as defined in 9 CFR 381.171 without declaration, provided the ground turkey thigh meat is made from trimmings that are removed from the turkey thighs during the boning and trimming process. The amount of ground turkey thigh meat that may be used", "can represent no more than the amount that was trimmed and in no case more than 15 percent of the weight of the turkey thigh meat ingredients when formulated. Products containing any ground turkey thigh meat not removed during the boning and trimming processes or products containing more than 15 percent ground turkey thigh meat must be labeled to indicate the presence of the ground turkey thigh meat, e.g., \u201ca portion of ground turkey thigh meat added.\u201d The provision in the regulations (9 CFR 381.171(f)) regarding the required use of terminology, e.g., \u201cChunked and Formed,\u201d \u201cChopped and Formed,\u201d and \u201cGround and Formed\u201d will continue to be followed. See: Policy Memo 059 dated March 29, 1983

**TURKEY LOAF: CURED, CHOPPED, (CANNED):** May contain seasonings, cures, and no more than 3 percent water at formulation. Binders and extenders are not permitted.

**TURNOVERS:** Product must contain 25 percent meat or 14 percent poultry meat. Similar to pies except the dough is folded. Cheese may be substituted for meat or poultry meat in an amount not to exceed 50 percent under the conditions outlined below: 1. Cheese must be part of the product name, e.g., \u201cBeef and Cheese Turnover\u201d or \u201cChicken and Cheese Turnover.\u201d 2. Imitation Cheese, substitute cheese, cheese food, and cheese spreads are not acceptable replacements for cheese.

**TZIMMES:** The true product name is \u201cBeef and Vegetables\u201d (or similar wording) when at least 50 percent beef is present in the product. \u201cVegetables with Beef\u201d (or similar wording) is acceptable when at least 35 percent raw beef is used.

**UKRAINIAN SAUSAGE:** A dry sausage made from lean pork and\veal chunks, containing large amounts of garlic which dominates the flavor. It is cooked and smoked at high temperatures and then air dried. The water activity (Aw) of the finished product shall not exceed 0.92 or a moisture\protein ratio 2.0:1 or less.", "VARIETY MEATS IN FRANKS: Cooked sausages with variety meats (byproducts) identified in 9 CFR 319.180(b) must contain not less than 15 percent red skeletal meat based on total meat block weight. The meat block includes meat, meat by-products, and if applicable, poultry.

**VARIETY PACKS -HORS D'OEUVRES:** Whenever FDA regulated products are included as a part of a variety pack bearing the legend (e.g., seafood hors d'oeuvres included with meat and poultry hors d'oeuvres), the labeling information must still be reviewed to assure accuracy. FDA regulated products that are found mislabeled should be corrected according to the policies of the FDA before the label can be approved.

**VEAL AND PEPPERS IN SAUCE:** Product must contain at least 30 percent cooked veal.

**VEAL BIRDS:** Product is similar to a turnover made with meat and no more than 40 percent stuffing. Categories of products are as follows: 1. Veal Birds -At least 60 percent veal 2. Veal Birds Beef Added -At least 60 percent veal and beef of which 20 percent may be beef 3. Veal and Beef Birds -At least 60 percent veal and beef of which up to 50 percent may be beef 4. Veal Birds (made from patties) -Birds made from patties shall bear a true product name descriptive

of patty used, e.g., "Veal Birds made with Veal Patties -Beef Added." The patty portion shall contain 70 percent meat. VEAL CORDON BLEU (FR): The standard requires at least: 1. 60 percent veal; 2. 5 percent ham, Canadian bacon, or cooked cured pork loin; and 3. Cheese (either Swiss, Gruyere, Mozzarella, or Pasteurized Processed Swiss)". "If the product is breaded, it must be shown in the product name. When the product is made with other than solid pieces of meat, "Chopped and Formed" must be shown contiguous to the product name. Beef is not permitted in this product. Veal that has been injected with water and phosphates and used for Veal Cordon Bleu should be labeled "Veal Roll Cordon Bleu" or other descriptive names as appropriate. VEAL DRUMSTICK, BREADED: May not contain more than 15 percent water or more than 10 percent extenders. VEAL FRICASSEE: Must contain at least 40 percent meat. VEAL PARMIGIANA: The following categories of products exist: 1. "Breaded Veal Parmigiana" is the product name for a solid piece of veal that is breaded and topped with cheese and tomato sauce. Breaded cooked veal must represent 40 percent of the finished product. 2. "Breaded Veal Parmigiana, Chopped and Formed Beef (or Beef Fat) Added" is the product name for chopped veal with up to 20 percent beef and/or beef fat added that is formed, breaded, and topped with cheese and tomato sauce. The chopped and formed beef added statement is shown one-third the size of "Veal" contiguous to the product name. Breaded cooked patty must represent 40 percent of the finished product. 3. "Breaded Veal Parmigiana made with Veal Patties, Beef (or Beef Fat) Added" is the product name for a veal patty containing at least 70 percent fresh meat (in unbreaded patty) of which 20 percent may be beef or beef fat. The patty is breaded, topped with cheese and tomato sauce. The entire qualifying statement in the product name is to be shown 1/3 size of "Veal" contiguous to product name. The breaded cooked patty represents 40 percent of the finished product. 4. Breaded Veal and Beef Patty Parmigiana. The patty may be prepared in proportions as governed by 9 CFR 317.2(f)(1)(v) of the regulations; the minimum meat patty requirement is 50 percent. If the product is breaded, the name must reflect this fact. The cheese component of the product does not have to be shown in the name of the product. A specific kind of cheese is not required, although Romano, Mozzarella, and Parmesan are the usual types used. No specific spelling of the word "Parmigiana" is required. Name applies to a "Cooked Product Assembled, Ready to Heat and Eat." The labeling of Veal Parmigiana made from a veal patty shall include veal patty in the product name, e.g., "Breaded Veal Parmigiana made with Veal Patties" or "Breaded Veal", "Patty Parmigiana." The ingredients of the veal patty do not have to be part of the product name. See: Policy Memo 092 dated December 16, 1985 VEAL PATTIES: Up to 20 percent beef and/or beef fat of the meat block permitted. Beef and/or beef fat must show in the true product name, e.g., "Veal Patties, beef added" or "Veal Patties, beef fat added." Beef and/or beef fat in excess of 20 percent of the meat block must show as "Veal and Beef Fat Patties." VEAL SCALOPPINI: Veal and sauce type product that must contain at least 35 percent cooked sliced veal. VEGETABLE DECLARATION ON LABELS: 1. The use of the terms onion, garlic, celery, and parsley shall mean fresh, frozen, or canned. 2. Processed onion or garlic must be qualified in a manner, e.g., "dried" or "dehydrated onion" or may be shown as "onion flakes" or "powdered." 3. It is usually not necessary to show vegetables as whole, diced, sliced, granulated, powdered, or pureed; however, whenever the name of the vegetable is

necessary to describe a food, then the name of the vegetable should be modified to show the form of its degree of processing. 4. Onion or garlic juice to which water has been added shall be noted, e.g., onion juice with water added. 5. Celery seed may be listed as a spice. 6. Celery salt shall be shown as celery salt. 7. Oil of celery may be listed as a flavoring. VEGETABLE EXTRACT: The source must be identified i.e. \u201csoy,\u201d \u201ccorn\u201d and \u201cbeet.\u201d

VEGETABLE GUM: Declare common or usual name of each vegetable gum, e.g., Guar Gum.", "VEGETABLE PIE WITH: \u201cSpecies\u201d meat must contain 12 percent meat on a raw basis. \u201cKind\u201d poultry must contain 7 percent cooked poultry.

VEGETABLE STEW WITH: MINIMUM MEAT CONTENT Meatballs 12 percent meat Meat 12 percent meat Meat Sauce or Gravy 6 percent meat Sauce and Meat 12 percent meat Poultry 6 percent cooked poultry meat VIENNA SAUSAGE -PACKED IN BEEF BROTH: Product must contain 80 percent sausage to be in compliance prior to inclusion in can. Broth component to have a MPR of not more than 135:1. A manufacturer holds trademark rights to the terms \u201cVienna\u201d and \u201cVienna Beef.\u201d

VINEGAR: Product must contain at least 4 grams of acetic acid per 100 cubic centimeters (approximately 4 percent acetic acid). This strength is referred to as 40 grain vinegar. Cider vinegar, which during the course of manufacture has developed an excess of acetic acid over 4 percent, may be reduced to a strength not less 4 percent. Cider vinegar so reduced is not regarded as adulterated but must be labeled as to its nature as \u201cdiluted\u201d or \u201cwater added\u201d cider vinegar. However, when vinegar of any concentration (not less than 4 percent acetic acid) is used in a food product, the only labeling requirement is \u201cvinegar.\u201d Statements like \u201cdiluted\u201d or \u201cwater added\u201d are not required.

VINEGAR PICKLE: Sausage in vinegar pickle is approved with the understanding that sausage is completely covered with pickle and that the pickle has a pH level not higher than 4.5.

WATER BASE SOLUTIONS IN RED MEAT IN MEAT PRODUCTS: Many raw red meat products with added solutions are required to be labeled in accordance with 9 CFR 317.2(e)(2) to indicate the addition of a solution has taken place, for example, \u201cBeef Containing 6% of a Solution of water, teriyaki sauce, and spices.\u201d As explained below, these requirements do not apply to except for cured red meat products that meet a standard of identity in 9 CFR 319.100-105. See the Final Rule Descriptive Designation for Raw Meat and Poultry Products Containing Added Solutions (79 FR 79044; Dec. 31, 2014). In situations where a raw product\u2019s surface is coated by rubbing, spraying, or dipping water mixed with seasonings, flavorings, etc., onto the surface of the meat, the qualifying statement describing this treatment does not have to include the percentage of solution. If, "however, these components are incorporated into the raw product by excessive rubbing, massaging, or tumbling, a descriptive designation indicating the composition and the amount of any solution absorbed is needed in accordance with 9 CFR 317.2(e)(2). Since the regulations (9 CFR 319.101 and 102) allow uncooked corned beef brisket to contain 20 percent of a curing solution, and uncooked corned beef round and other cuts to contain 10 percent of a curing solution above the weight of the fresh, uncured (green weight) product without disclosure, 9 CFR 317.2(e)(2) would not apply unless the product does not meet the standard of identity in accordance with 9 CFR 317.2(e)(2). 9 CFR 317.2(e)(2) does not apply to uncooked cured pork products that are labeled and manufactured in accordance with the standards of identity for cured pork products in (9 CFR 319.104 and 105) If the product does not meet these standards then it is required to be labeled in accordance with 9 CFR 317.2(e)(2). However, 9 CFR 317.2(e)(2) would apply to

uncooked cured pork trimmings or uncooked cured pork products that contain added solutions that are not labeled and manufactured in accordance with or are not subject to a standard of identity for cured pork products, such as hams, loins, shoulders, butts, picnic, hocks, jowls, etc. The addition of an enzyme solution to meat products is limited to 3 percent of the raw meat product (green weight) by the meat inspection regulations (9 CFR 424.21). If a product is treated with an enzyme solution and a flavoring solution, separately or in one step, both treatments are required to be identified on the label. The label must contain a descriptive designation indicating the percent flavoring solution, and a product name qualifier, such as \u201cTenderized with Papain\u201d in accordance with 9 CFR 317.8(b)(25). In this case, product qualifying statements should not intervene between the product name and the descriptive designation for the solution. Alternately, the descriptive designation and the product qualifying statement may be combined into one statement. For example, an acceptable name for raw beef pumped with 10% solution that contains papain could be \u201cbeef contains up to 7% tenderizing and seasoning solution of water, teriyaki sauce, spices, and papain.\u201d For uncooked products, the percent added solution for the label statement is determined by subtracting the fresh (green) weight of the article from the weight of the finished (total) product that is, after injecting, marinating, etc., dividing by the weight of the fresh article, and multiplying by 100. Cooked red meat products containing added solutions are addressed in Policy Memo 084A WATER-DECLARATION: The use of water must be declared in the ingredients statement of all products with the exception of the following: 1. The water added to lactic acid starter culture (.05 percent or less) for the purpose of rehydration. 2. The water added to products which are freeze-dried or sprayed-dried. WATER IN CANNED SAUSAGE:,"Water, not to exceed 8 percent of the total product weight, may be used in the preparation of precooked pork sausage links intended for canning. The amount of water used is for the purpose of replacing that which is lost during the processing operation that takes place prior to canning. The weight of the sausage at the time of canning shall not exceed the weight of the fresh uncured meat ingredients plus the weight of the curing ingredients and the seasoning ingredients. WATER-MISTED AND ICE-GLAZED MEAT AND POULTRY PRODUCTS: When meat or poultry products are water-misted or ice-glazed, the net weight of the product may not include the weight of the water or ice. An acknowledgment to this effect must be indicated on the label application form. A prominent and conspicuous statement must appear on the principal display panel adjacent to the product name, describing that the product is protected with a water-mist or ice glaze (e.g., \u201cProduct Protected with Ice Glaze\u201d).","If the manufacturer can show that a water or ice glaze is sublimed from the unpackaged product during freezing so as not to compromise the integrity of the product's formulation or the standard with which it must comply, the labeling of the product need not bear the statements identified above. Because the regulatory standard 9 CFR 319.15 precludes the addition of water -hamburger, ground beef and chopped beef patties cannot be ice-glazed and, if there is evidence of an ice-glaze on such patties subsequent to freezing, they must be labeled appropriately to be sold in commerce, e.g., as \u201cbeef patties.\u201d However, water-misting of formed hamburger, ground beef, or chopped beef patties just prior to freezing individual patties is permitted if (1) the water applied in misting acts as a processing aid to prevent shrinkage of the patties, and (2) the misted water sublimes from the surface of the patties during the freezing process such that the weight of the patty exiting the freezer does

not exceed the green weight of the patty just prior to water-misting and freezing. See: Policy Memo 108B dated June 24, 1993 WEISSWURST: A name for uncured sausage usually made of pork or veal. It is of German origin and means white sausage. The color of the sausage after cooking is white because of the lack of cure and the type of meat used. Weisswurst is similar to Bratwurst. When milk or milk and eggs are added to a Weisswurst batch, it should be labeled as \u201cKalbsbratwurst\u201d or \u201cBockwurst\u201d respectively. WELSH RAREBIT SAUCE WITH COOKED HAM: Product must contain at least 20 percent cooked ham in the total formulation. WHEAT GLUTEN: Acceptable for use to bind fresh meat cuts, e.g., boneless loins, boneless legs, and livers together, so that they may be cooked and sliced without falling apart. The amount used should not exceed 2 percent of the weight of the total product. The product name shall be qualified by the phrase \u201cWheat Gluten Added.\u201d Wheat gluten is not acceptable for use with chunked and\or chopped specific products as roasts, rolls, and reformed meat cuts. Acceptable in nonspecific products and home-style meat loaves within the prescribed limits of other extenders and binders.", "WHOLE HOG SAUSAGE: Must contain all primal parts of a hog. Hearts and tongues, in natural proportions, are permitted ingredients in whole hog sausage when declared in the ingredients statement. Other meat byproducts are not permitted in whole hog sausage. See: 9 CFR 319.144 WIENER SCHNITZEL (GR): A veal cutlet prepared by dipping in egg, flour, and bread crumbs and frying to a golden brown. WILD BOAR: Products prepared from wild boar from feral swine are amenable and subject to the meat inspection regulations. \u201cWild Boar\u201d is an acceptable label term for a product, provided the words \u201cWild Boar\u201d are directly followed by the statement \u201cMeat from Feral Swine.\u201d The statement \u201cMeat from Feral Swine\u201d must appear prominently on the principle display panel as described in 9 CFR 317.2(d)(1)(2) and (3). If the statement \u201cMeat from Feral Swine\u201d does not directly follow the term \u201cWild Boar,\u201d then an asterisk may be included with the term \u201cWild Boar\u201d and the statement \u201cMeat from Feral Swine\u201d should appear prominently elsewhere on the principal display panel. \u201cWild Boar from Feral Swine,\u201d \u201cWild Boar Meat from Feral Swine,\u201d \u201cWild Boar (byproduct) from Feral Swine,\u201d are also acceptable product names. In order to obtain approval for a product label bearing the name \u201cWild Boar from Feral Swine,\u201d or similar acceptable names, a statement describing and verifying the following physical and environmental characteristics typical of wild boar is required: color patterns, e.g., white stripes or spots, longer bristly haircoat, elongated snout with visible tusks, a \u201crazorback\u201d body shape, and wild boar males which are uncastrated. (We acknowledge both males and females under the term \u201cWild Boar.\u201d) The purchased hogs should be obtained from a nonrestrictive environment which permits foraging for uncultivated feed, natural selection, and breeding and farrowing without confinement. A letter should be submitted with \u201cWild Boar from Feral Swine\u201d labels describing the environment where such swine live and their method of capture or entrapment. These same criteria would also apply to imported \u201cWild Boar Meat from Feral Swine\u201d and arrangements should be made through Foreign Programs for slaughter and export from approved establishments. In multi-ingredient products, e.g., \u201cBeans in Sauce with Wild Boar,\u201d the \u201cWild Boar\u201d part of the product name must be followed by an asterisk and a statement \u201c(Meat or meat byproduct) from Feral Swine\u201d must appear somewhere on the principal display panel. The ingredient wild

boar, wild boar meat, or wild boar byproduct, must be listed as "\u201cWild","Boar ((Meat or meat byproduct) From Feral Swine)\u201d in the ingredients statement in its proper order of predominance. See: Policy Memo 097 dated June 4, 1986 WING SECTIONS: First wing section is described as the wing drummette Second wing section is described as the wing portion Wings Sections is an acceptable wing term for both wing drummette and wing portion when in natural proportions. WITH NATURAL JUICES (POULTRY): The term "\u201cWith Natural Juices\u201d may be used with poultry products to indicate the presence of cooked out juices derived solely from the liquid normally associated with the poultry prior to cooking. If liquids have been added to the poultry prior to cooking, natural can not be used. WRAPS: A ready-to-eat meat\poultry food product that may contain vegetables and seasoning ingredients and is wrapped in a dough based component, e.g., tortilla. The product name must bear the kind or species, e.g., "\u201cHam Wraps.\u201d The minimum meat or poultry requirement is 2 percent cooked meat or 2 percent cooked poultry meat. YEARLING: The term "\u201cyearling\u201d (e.g. yearling beef) may be used to describe an animal of either sex that is too old to be classified as a calf or lamb but less than 2 years of age. The company is required to segregate carcasses and provide product identification to insure that no commingling occurs between qualifying and nonqualifying products. The terms "\u201cYearling Ovine\u201d, "\u201cYearling Mutton\u201d and "\u201cYearling Sheep Meat\u201d are acceptable product names for meat derived from sheep between 1 and 2 years of age. Yearling Lamb is not an acceptable name for this product. YEAST: 1. Dried Brewers Yeast: Acceptable ingredient of meat food products. 2. Autolyzed Yeast Extract: (Dehydrate of Paste form) Autolyzed yeast extract is not considered an artificial flavoring. Its presence should be reflected in the statement of ingredients as "\u201cautolyzed yeast extract.\u201d", "See: 9 CFR 317.2(f)(l)(i) 9 CFR 317.8(b)(7) 9 CFR 424.21 9 CFR 381.118(c) 9 CFR 381.147(f)(4) YIELD GRADES: When using specific grades for beef and pork cuts, the yield grade numbers must be identified based on the boxed product. Therefore, yield grades such as 2 or higher, are not acceptable."],{"file\_name":"FSIS\_GD\_2003\_0001","title":"Guidance on the Elimination of the Pizza with Meat or Sausage Standard Q & A's","num":"FSIS-GD-2003-0001","id":"01e1002888c5f3a50c7cc77c34762942baa1eb9a0853f2f67b1607ef52ffe964","corp\_us":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/media\_file/2021-07/FSIS-GD-2003-0001.pdf","type":"pdf","n\_pages":10,"word\_count":3346,"text\_by\_page":["Water Reuse Questions and Answers (Q&As) INTRODUCTION Water use in many federally inspected meat and poultry establishments is extensive. In an attempt to conserve this valuable natural resource, it can be appropriate in certain circumstances to reuse water. In all instances where reused water is employed, it is important to emphasize the primacy of ensuring that the water that is being reused is safe for its intended purpose. FSIS encourages the development of water reuse technologies in federally inspected establishments. However, food safety cannot be compromised by the use of such technologies. The source of the water, the measures taken to recondition the water, and the intended reuse application must be taken into consideration by an establishment when determining whether food safety hazards exist. Establishments are responsible to ensure that water is reused in a way that will not result in the adulteration of product or the creation of insanitary conditions. If an establishment reuses water, FSIS expects that the establishment will consider the effects of water reuse in its hazard analysis, and

support and document all decisions that it makes associated with the reuse. Establishments are expected to consider whether reusing water will create physical, chemical, or biological hazards, and whether additional measures are necessary to ensure that product is neither contaminated nor adulterated. Inspection personnel verify that the regulatory requirements are met, including that sanitary conditions are maintained. The regulatory requirements for water reuse are listed in 9 CFR 416.2(g). FSIS has issued the Sanitation Performance Standards Compliance Guide (found at <http://www.fsis.usda.gov/oppde/rdad/frpubs/sanitationcover.htm>) which provides indepth guidance on how an establishment may meet the sanitation regulatory requirements with respect to specific water reuse applications. Compliance Guidelines are not regulatory requirements but are intended to suggest means by which compliance with the above regulatory requirements can be achieved. This Q&A document addresses the reuse of water, ice, and solutions that come into contact with product, equipment, or other surfaces and that are used again for the same or other purpose within the limits of 9 CFR 416.2(g). FSIS developed this Q&A document in response to numerous inquiries sent to the Technical Service Center regarding water reuse and the interpretation of the underlying regulations. The questions presented are representative of those that FSIS has received. A list of applicable regulations is included as Attachment 1 at the end of the Q&A\u2019s."

1. Question: Does an establishment that intends to reuse water in accordance with 9 CFR 416.2(g) need to have its program reviewed by the Agency prior to implementation? Answer: No. FSIS does not prior-approve the food safety control system used by an establishment. However, FSIS expects the establishment to fully consider the physical, chemical, and microbiological consequences of the reuse of water in its hazard analysis and to support all decisions it makes with respect to water reuse. As appropriate, the establishment will need to address the effects of water reuse in its HACCP plan or Sanitation SOP or other prerequisite program.

2. Question: All city water has to comply with the Environmental Protection Agency (EPA) National Primary Drinking Water regulations. If an establishment uses a municipal water supply, is a city water bill acceptable documentation that the water meets the EPA requirements? Answer: No. A water report attesting to or certifying the potability of the municipal water supply, issued by the responsible State or local agency, is required because such documentation directly addresses the regulatory requirement. Water supply requirements are covered in the sanitation regulations in 9 CFR 416.2 (g)(1). These requirements are also addressed in FSIS Directive 5000.1, Revision 1, Amendment 1. It is the responsibility of the establishment to ensure that plumbing systems provide an adequate supply of potable water for processing and other purposes without adulterating product or creating insanitary conditions.

3. Question: If an establishment purchases ice from a local store, can this ice be used to cool product? Answer: Yes, provided that the ice meets the same standards as potable water in that documentation is made available to attest to or certify that the ice is made from potable water. If the plant uses ice purchased from a local store, a water report indicating potability must be on file from the manufacturer of the ice to show that the water used to make the ice is potable. If the ice was made from a private well, documentation indicating the potability of the water supply used to make it must also be on file and renewed at least semi-annually. If water potability documentation from the manufacturer of the ice is not on file, then there is noncompliance with 9 CFR 416.2(g)(6) which states: \u201cWater that does not meet the use conditions of paragraph (g)(1) through (g)(5) of this section may not be

used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.\u201d 4. Question: Is a facility operating under 9 CFR Part 350 (Identification Service, Food Inspection Service or Certification Service) required to maintain water potability documentation on file?", "Answer: Yes. Facilities operating under 9 CFR Part 350 are required to meet all parts of 9 CFR 416.1 through 416.6. A supply of running water that complies with the EPA National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If a facility uses a municipal water supply, it must make available to FSIS, a water report certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS documentation certifying the potability of the water supply that has been renewed at least semi-annually. 5. Question: Can a brine solution used to cool fully cooked comminuted sausage products be reused for the same purpose (i.e., to cool subsequent production of fully cooked comminuted sausage)? Answer: Yes, in accordance with 9 CFR section 416.2(g)(2), it may be reused provided that it is maintained free of pathogenic organisms and fecal coliform organisms, and that other physical, chemical, and microbiological contamination has been reduced to prevent adulteration of product. 6. Question: In 9 CFR 416.2(g) (2) and (3), the regulations state that water may be reused for the same purpose. What does \u201cfor the same purpose\u201d mean? Answer: \u201cFor the same purpose\u201d as used in 9 CFR 416.2(g)(2) and(3) means that water used to cook or chill ready-to-eat products could be reused to cook or chill subsequent production of ready-to-eat products, and that water used to chill or wash raw product could be reused to chill or wash raw subsequent production of raw products. It would not be acceptable to reuse water that has contacted raw product for RTE product because of the increased likelihood that such water would contain pathogens and other contaminants that would be transfer from raw to cooked product. Under 9 CFR 417.2(a) an establishment should consider the effects of the reuse in its hazard analysis and support all decisions made in the hazard analysis associated with the reuse. The establishment must ensure that the reuse water is safe for its intended purpose by taking measures, as appropriate, to reduce contamination when deemed necessary by its hazard analysis. 7. Question: The Sanitation Performance Standards Compliance Guide lists requirements for turbidity. Does the reuse water need to meet the turbidity requirements of less than 5 NTU for cook and chill water reuse as indicated in the Compliance Guide? Answer: No, turbidity is not a required criterion for water reuse. However, turbidity is a measure of the water\u2019s relative clarity with regard to contaminants that may have been incorporated into the water as a consequence of reuse or inadequate water treatment. The Sanitation Performance Standards Compliance Guide contains guidelines that could be used by an establishment to meet water reuse regulations, but these are not in", "themselves regulatory requirements. An establishment needs to consider the impact that increased turbidity would have on water quality and address it in its hazard analysis. 8. Question: Must poultry chiller water that is intended for reuse whereby it is chilled via heat exchangers and returned to the poultry chiller comply with the water reuse requirements in 9 CFR 416.2(g)(3)? Answer: Yes. When poultry chiller water is chilled via heat exchangers and returned to the chiller, it is being reused for the same purpose and must comply with the requirements of 9 CFR 416.2(g)(3). This

section of the regulation requires that establishments take measures to reduce contamination in the water, as necessary, to prevent contamination or adulteration of product. To comply, an establishment must consider the effects of reusing the water in the hazard analysis and support all decisions made regarding this reuse. Depending on the results of the hazard analysis, establishments are expected to take the measures necessary to ensure that their products are not contaminated or adulterated. Failure to consider the effects of reusing water within the chill system would raise concerns about the adequacy of an establishment's hazard analysis.

9. Question: Are there specific test requirements or quantitative reductions that must be met to demonstrate compliance with 9 CFR 416.2(g)(3)? Answer: No. Section 416.2(g)(3) does not dictate what measures need to be taken, only that measures be taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. The extent of reconditioning is dependent on the source of the water and the specific reuse application. Each situation should be considered in the hazard analysis for the particular process, and the necessary measures to prevent contamination or adulteration of product should be identified.

10. Question: What are examples of measures to reduce physical, chemical, and microbiological contamination?

Answer: These measures could include methods used by the establishment to lower the level of contaminants in the reuse water that is to be reused when the establishment's hazard analysis determines that a reduction in physical, chemical, and microbiological contamination is necessary. Listed below are some examples of specific methods that an establishment may consider when needing to lower contamination levels:

- Filtration -- There are many different types of filters available to industry to address physical contamination, from simple cloth and sand filters to elaborate, patented technologies designed to remove extremely small sized contaminants. Specially designed filtration systems may also effectively reduce the build-up of chemical contamination.
- Antimicrobials -- Examples of measures to reduce microbiological contamination are the addition of antimicrobials, the use of ultraviolet light, or ozonation.

"11. Question: Can reuse water be used to rinse equipment on a poultry evisceration line? Answer: Yes, provided that the provisions of 9 CFR 416.2(g)(3) and (4), where applicable, are properly addressed. Regulation 9 CFR 416.2(g)(3) requires that the establishment take steps to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Regulation 9 CFR 416.2(g)(4) addresses water derived from an advanced wastewater treatment facility and also requires that after use of such water, a final rinse with non-reconditioned potable water must be performed.

12. Question: Can water that has been reconditioned by an onsite advanced wastewater treatment facility be used on or in ready-to-eat (RTE) product? Answer: No. Water reconditioned by an onsite advanced wastewater treatment facility may not be used in product formulation or in/on RTE product. Reconditioned water that has never contained human waste may be used on raw product provided it is followed by a separate final rinse with non-reconditioned potable water.

13. Question: Does reuse water that is to be used to wash antemortem pens or poultry cages need to be pathogen free as stated in 9 CFR 416.2(g)(5)? Answer: Yes, the Agency is concerned that there is the potential for the transfer of pathogenic organisms, such as *Salmonella* from contaminated poultry cages or antemortem pens to poultry or livestock that were previously free of them. The Agency is also concerned about the potential to create insanitary conditions and to expose plant employees and inspection personnel to pathogens.

when reuse water that has not been shown to be pathogen free is used for the initial cleaning of antemortem pens, poultry cages, and livestock vehicles. 14. Question: If a poultry establishment wishes to reuse water to float feathers in the picking area under the pickers, must that reuse water be free of pathogenic organisms? Answer: No. The Agency has determined that the reuse of water that may contain pathogens is acceptable for certain uses and under certain conditions. For example, the reuse of poultry chill water overflow to move feathers out of the picking area or to move solid wastes down the evisceration troughs for disposal are situations where it is acceptable under 416.2(g)(6) to reuse water that may contain pathogens. Evisceration troughs and floor drains are inedible areas separated from edible areas by space. The establishment is responsible to ensure that this is done in a sanitary manner and that it will not contaminate product or product contact surfaces or result in the adulteration of product. Establishments are required to consider the effects of the water reuse in the hazard analysis and support all decisions made regarding this reuse." "Attachment 1: 9 CFR 416.2(g)

416.2(g)(1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually. 416.2(g)(2) Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.

416.2(g)(3) Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse that which has come into contact with raw product may not be used on ready-to-eat product. 416.2(g)(4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a", "separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section. 416.2(g)(5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment. 416.2(g)(6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate

edible product or create insanitary conditions."],{"file\_name":"FSIS\_GD\_2003\_0002","title":"Supplemental Pizza Q & A's","num":"FSIS-GD-2003-0002","id":"90f24ad05eede88e92adaebd93cf0078ed06956dce3fc2f4f7b60ccc1463b15","corp\_us":"fsis\_guidelines","source\_page\_url":"https:\/\/www.fsis.usda.gov\/policy\/fsis-guidelines","url":"https:\/\/www.fsis.usda.gov\/sites\/default\/files\/media\_file\/2021-07\/FSIS-GD-2003-0001-supplemental.pdf","type":"pdf","n\_pages":2,"word\_count":849,"text\_by\_page":["Guidance for Determining Whether a Poultry Slaughter or Processing Operation is Exempt from Inspection Requirements of the Poultry Products Inspection Act United States Department of Agriculture Food Safety and Inspection Service Inspection & Enforcement Initiatives Staff Revision 1, April - 2006","Table of Contents Introduction

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State Officials Cooperative Meat and Poultry Inspection Programs Contact Information  
29","Guidance for Determining Whether a Poultry Slaughter or Processing Operation is Exempt from Inspection Requirements of the Poultry Products Inspection Act Introduction An increasing number of small poultry producers, also called \u201cgrowers,\u201d are raising, slaughtering, and processing their poultry on their farms and selling the poultry directly to

customers at the farms or at farmers\u2019 markets. Some of these small producers are going further by building processing facilities with the intent of supplying local customers, including household consumers, retail stores, restaurants, boarding houses, and institutions. Other producers and businesses are building processing plants to supply poultry that meets special religious dietary requirements such as Kosher and Halaal or (Halal), and niche markets, such as organically grown poultry and live poultry markets. At some point, a grower or business that plans to or has made the decision to sell poultry that he or she slaughters or processes will face the question \u201cCan I sell the poultry that I slaughter or process, without inspection by the Federal or State government?\u201d The Food Safety and Inspection Service (FSIS) of the Department of Agriculture (USDA) created this guide to help small businesses and poultry producers who slaughter or process poultry for human food to determine whether the slaughter or processing operations at their businesses are eligible for exemption from Federal or State inspection. In other words, this guide is helpful to producers or businesses in determining whether their slaughter or processing operations require USDA or State inspection, as mandated in the Poultry Products Inspection Act (PPIA). In addition, this guidance material can serve as a quick reference for Federal and State inspection personnel who have questions about whether a poultry operation qualifies for a exemption in the PPIA. This guidance does not address exemptions related to livestock product (e.g., meat from cattle, swine, sheep, goat, and equine) because the Federal Meat Inspection Act does not provide exemptions similar to those provided in the Poultry Products Inspection Act. In addition, this guidance material does not address exemptions requirements where State Laws may be different from those in the PPIA and FSIS\USDA regulations. The 1957 Wholesome Poultry Products Act (Public Law 90 \u2013 492), which is commonly referred to as the Poultry Products Inspection Act (PPIA)<sup>1</sup> was passed by Congress to ensure that only wholesome poultry that is not 1 A copy of the Poultry Product Inspection Act can be accessed by browsing the FSIS home page at ([http://www.fsis.usda.gov/regulations\\_&\\_policies/Poultry\\_Products\\_Inspection\\_Act/index.asp](http://www.fsis.usda.gov/regulations_&_policies/Poultry_Products_Inspection_Act/index.asp)). This is the Act found in the United States Codes Sections 451-470. There are published copies of the PPIA with the sections numbered from 1to 29 that correspond to U.S. Code sections 451 to 470. 1", "adulterated and not misbranded enters interstate or foreign commerce. The 1957 Act mandated Federal inspection at businesses that slaughter poultry or process poultry products that enter interstate or foreign commerce. Congress amended the Act in 1968, extending the mandate for Federal inspection to all businesses that slaughter or process poultry for shipment within a State, when the State does not enforce requirements at least equal to the Federal inspection requirements in the PPIA. Because of this amendment, any business in any State that slaughters or processes poultry for use as human food is required to do so under Federal or State inspection, unless the slaughter or processing operations at the business meets certain exemption criteria in the Act. What does exempt mean? The term \u201cexempt\u201d means that certain types of poultry slaughter and processing operations qualify to operate without the benefit of Federal inspection on a daily basis, and a grant of Federal inspection is not required. Such operations are exempt from continuous bird-by-bird inspection and the presence of inspectors during the slaughter of poultry and processing of poultry products. However, a facility operating under such an exemption is not exempt from all requirements of the Act. It was not the intent of Congress to mandate Federal or State inspection of an owner\u2019s private holdings of poultry or to mandate inspection at

businesses that slaughter or process a small amount of poultry. Therefore, the PPIA exempts some poultry slaughter and some processing operations from certain requirements of the Act. The Act does not exempt any person slaughtering or processing poultry from the provisions requiring the manufacturing of poultry products that are not adulterated and not misbranded. Thus, all businesses slaughtering or processing poultry for use as human food, including exempt operations, must produce poultry product that is not adulterated or misbranded. How is Adulteration Defined? Both the PPIA and the supporting Federal regulations define the circumstances and conditions that would render poultry products adulterated. Simply put, a product is adulterated if it bears or contains a substance that makes it injurious to health, or if it has been held, packed or produced under insanitary conditions. The specific definitions of circumstances that define adulteration are detailed in Section 453 of the PPIA, and in Title 9 Code of Federal Regulations ( 9 CFR). In addition, the definitions have been reproduced as Attachment 5 of this document. To qualify for any one of the poultry exemptions, a business must slaughter poultry or process poultry products under sanitary conditions using procedures that produce sound, clean poultry products fit for human food. Attachment 2 of this guidance is a list of sanitary standards and procedures. These sanitation procedures and practices are required for poultry businesses receiving full USDA inspection and are applicable to exempt poultry operations [Title 9 CFR part 416]. 2", "Specific sanitary practices are described in FSIS\u2019s Sanitation Performance Standards Compliance Guide, dated October 13, 1999. The specific sanitary practices in the document are not requirements. In the Guide, FSIS presents or references methods already proven effective in maintaining sanitary conditions in meat and poultry establishments. Establishments that follow the guidance can be fairly certain that they comply with the requirements in the Act and regulations to conduct operations under sanitary standards, practices, and procedures that result in poultry products that are not adulterated. How is Misbranded Defined? The regulations require that poultry products transported or distributed in commerce bear specific information. Poultry products inspected and passed under USDA inspection at official USDA establishments must bear the official inspection legend and meet specific labeling requirements prescribed in the regulation. However, exempt poultry products cannot bear the official mark of inspection. In addition, there is specific labeling or identification requirements for exempt product to meet in lieu of bearing all required elements of a label. The information that shipping containers or packages of exempt poultry products must bear varies depending on the exemption. The specific information required on the shipping containers or packages of exempt products is presented later in discussions for each type of exemption. What is Commerce? Commerce is the exchange or transportation of poultry products between States, U.S. territories (Guam, Virgin Island of the United States, and American Samoa), and the District of Columbia [Title 9 CFR \u00a7381.1(b)]. In this document, we qualify \u201ccommerce\u201d with \u201cinterstate\u201d when referencing the exchange or transportation of poultry products between States, United States territories, and the District of Columbia. We also qualify \u201ccommerce\u201d with \u201cintrastate\u201d when referring to the exchange or transportation of poultry products solely within a State, territory, or the District of Columbia. FSIS will not view the product as having been introduced into commerce if it has not left the control of the processing entity. What is Slaughter? The term slaughter refers to the act of killing poultry for use as human food. What is Processed or Processing? The terms \u201cprocessed\u201d and \u201cprocessing\u201d refer to

operations in which the carcasses of slaughtered poultry are defeathered, eviscerated, cut-up, skinned, boned, canned, salted, stuffed, rendered, or otherwise manufactured or processed.

3", "How can I determine whether an operation qualifies for an exemption under the Poultry Products Inspection Act? Use the decision chart on the following page to determine whether a slaughter or processing operation qualifies for one of the exemptions in the PPIA and supporting regulations. Read the question in bold type in the squares and then follow the \u201cyes\u201d or \u201cno\u201d response arrows to determine the exemption, if any, under which the poultry products may be produced. When the arrows lead to an oval read the exemption criteria for the exemption on the page indicated in the oval to determine the exemption, if any, for which the slaughter or processing operation would qualify. You should contact the FSIS District Office responsible for Federal inspection or the State Agency responsible for administering a State Poultry Inspection Program in the State where your slaughter and processing is located. This contact will facilitate reviews of the operation by FSIS or the State Agency with oversight of businesses operating under an exemption in your State. Some States may have requirements in their exemption laws for a business to qualify for an exemption that differ from Federal requirements. The FSIS District Office or the State Agency will determine whether your operation qualifies for the exemption. Attachments 3 and 4 are lists of FSIS district offices for the Office of Field Operations (OFO), and FSIS regional offices of the Office of Program Evaluation Enforcement and Review (OPEER), and State contacts. The information in these lists is subject to change as is the web\url cite for, OFO and OPEER. If you slaughter or process poultry that is donated or sold for use as human food, and the operation does not qualify for an exemption from inspection, you must contact the FSIS District Office or State Office responsible for inspection in the State where your operation is located. The FSIS District Office or State Office will provide instructions and guidance on obtaining FSIS or State inspection for your poultry products. Because the poultry exemption categories are complicated, please contact a FSIS, District Office if you have any questions.

4", "5 Do you slaughter or process poultry Is the poultry you slaughter or process for your private use? Is the poultry you slaughter or process delivered Do you raise, slaughter, and process Are you a business that raises, No Yes Yes No Yes Yes No qualify for an exemption. . May Have Different Limitations\Criteria for Exemptions than the PPIA.) No Yes No No Yes Do you slaughter and process in a calendar year no ? Inspection requirements of the PPIA are not applicable Personal Use Exemption \u2013 See page 6 Exemption \u2013 See page 7 Limit \u2013 See page 13 PGOP Exemption \u2013 See page 11 process poultry for sale in a retail store? No Retail Exemption \u2013 See page 15 Your slaughter or processing operation is not FSIS District Office. See pag , page 25 Yes No Figure 1 \u2013 See page 10 for sale as human food? to you by the owner of the poultry and you are not engaged in the buying and selling of poultry? for sale as human food no more than 1,000 poultry in a calendar year? Are you a producer\grower who in a calendar year slaughters, processes, and distributes between no more than 20,000 poultry that you raised? slaughters, and dresses poultry or purchases dressed poultry that you distributed as carcasses or parts? Ask yourself the question in the bold type and then follow the appropriate Yes or No response arrows to determine whether your poultry slaughter or processing operation may You must read the criteria on the cited page before you can determine whether your operation qualifies for the exemption (\* Some States Laws more than 20,000 poultry that you raised or you purchased for distribution directly to only household

consumers, restaurants, hotels and boarding houses, for use as meals in such businesses Custom Slaughter Producer\Grower \u2013 1,000 Exemption \u2013 See page 9 Small Enterprise Exemption Do you slaughter and\or exempt. Contact the e 4 and Attachment 3 Decision Flow Chart for Poultry Exemptions Under the PPIA\* Producer\ Grower \u2013 20,000 Limit Exemption","Exemptions Personal Use Exemption Mandatory inspection of the slaughter and processing of privately owned poultry is not required, provided that the following six criteria are met [PPIA Section 464(c)(1)(A), (d), & (e) \u201cSection 15 (2)(1)(A),(d) & (e)\u201d; Title 9 Code of Federal Regulations (CFR) \u00a7381.10(a)(3)]. Criteria: 1. The slaughtered and processed poultry is for the private use of the: a. grower\producer\owner, b. members of his or her household, and c. his or her nonpaying guests and employees; 2. The slaughter and processing of the poultry is performed by the grower\producer\owner; 3. The poultry is healthy when slaughtered; 4. The poultry is slaughtered and processed under sanitary conditions and practices that result in poultry products that are sound and fit for human food; 5. The exempt poultry is not sold or donated for use as human food; and 6. The shipping containers bear: a. the producer\u2019s name, b. the producer\u2019s address, and c. the statement, Exempt P.L. 90-492. \u201cExempt P.L. 90-492\" identifies the product as product produced under an exemption from the Act, Public Law 90-492. Instead of the Federal law 90-492, a State law may be cited when the inspection of the slaughter and processing of poultry is exempted under the authority of a State law and the operations are reviewed by a State Agency. Personal Use Exemption Notes: \u2022 There is no limit to the total amount of poultry that owners of poultry may slaughter and process for their private use. \u2022 If any of the six criteria are not met, the poultry is not eligible to be processed under the Personal Use Exemption. 2 Some published copies of the PPIA number the sections from 1 to 29 not 451 to 470 as numbered in the United States Codes. 6","Custom Slaughter\Processing Exemption A custom poultry slaughterer is a business or person who slaughters and processes poultry belonging to someone else. A custom slaughterer provides a service to a customer and does not engage in the business of buying or selling poultry products capable of use as human food. A custom slaughter business may slaughter or process an unlimited number of poultry when the poultry is delivered by the owner and the following five criteria are met [PPIA Section 464(c)(1)(B) \u201cSection 15 (c)(1)(B)\u201d; Title 9 CFR \u00a7381.10(a)(4) & (d)]. Criteria: 1. The custom slaughterer does not engage in the business of buying or selling poultry products capable for use as human food; 2. The poultry is healthy when slaughtered; 3. The slaughter and processing at the custom slaughter facility is conducted in accordance with sanitary standards, practices, and procedures that produce poultry products that are sound, clean, and fit for human food (not adulterated); 4. The custom slaughtered or processed poultry is for the personal use of the grower\owner of the poultry \u2013 the grower\owner of the custom slaughtered or processed poultry may not sell or donate the custom slaughtered poultry to another person or institution; and 5. The shipping containers bear: a. the owner\u2019s name, b. the owner\u2019s address, and c. the statement, \u201cExempt P.L. 90-492\u201d These three items are in lieu of all the required features of a label for inspected and passed poultry products. Also, instead of the Federal law 90-492, a State law may be cited when the inspection of the slaughter and processing of poultry is exempted under the authority of a State law, and the operations are reviewed by a State Agency. Custom Slaughter Exemption Notes: \u2022 If any of the five criteria are not met, the owner of the poultry is not eligible for this exemption. 3

Some published copies of the PPIA number the sections 1 to 29 not 451 to 470 as numbered in the United States Codes. 7", "\u2022 Selling live poultry to a customer does not disqualify a business from the Custom Slaughter Exemption. For example, a custom slaughterer may sell live poultry to a person and then custom slaughter the bird. However, a person who custom slaughters poultry may not buy or sell poultry products used for human food. \u2022 A person operating under a Custom Slaughter Exemption may slaughter and process poultry of his or her own raising provided such slaughtered poultry is for his or her exclusive consumption, or consumption by members of his or her household, nonpaying guests, and employees. \u2022 A person who is a custom slaughterer and who is also a poultry grower may raise and sell his or her live poultry to poultry businesses not associated with his or her custom slaughter business. \u2022 A custom slaughter business may use a mobile slaughter\processing unit to custom slaughter and process poultry. There is compliance with the requirements of the Act and regulations when the owner of poultry delivers poultry to a mobile slaughter\processing unit operated by a custom slaughterer provided the slaughtered or processed poultry is for the personal use of the owner of the poultry. The owner of the poultry may deliver the poultry to the mobile slaughter\processing unit located at his or her own premises or any other person\u2019s premises. \u2022 Ostrich and other poultry can be custom slaughtered and processed in an official red meat establishment that is subject to the regulatory requirements of the Federal Meat Inspection Act, provided the establishment does not engage in the business of buying and selling poultry products. Also, carcasses or parts of ostrich or poultry not slaughtered at the red meat establishment may be delivered by the owner for custom processing provided the poultry has been previously inspected, passed, and identified as such in accordance with the requirements of the Poultry Products Inspection Act or has been inspected and passed by an equivalent State inspection. 8", "Producer\Grower \u2013 1,000 Limit Exemption Limited provisions of the Act apply to poultry growers who slaughter no more than 1,000 poultry in a calendar year for use as human food. A person may slaughter and process on his or her premises poultry that he or she raised and they may distribute such poultry without mandatory inspection when the following five criteria are met [PPIA Section 464(c)(4) \u201cSection 15 (c)(4)\u201d; Title 9 CFR \u00a7381.10(c)]. Criteria: 1. The poultry grower slaughters no more than 1,000 healthy birds of his or her own raising in a calendar year for distribution as human food; 2. The poultry grower does not engage in buying or selling poultry products other than those produced from poultry raised on his or her own farm; 3. The slaughter and processing are conducted under sanitary standards, practices, and procedures that produce poultry products that are sound, clean, and fit for human food (not adulterated); 4. The producer keeps records necessary for the effective enforcement of the Act [Title 9 CFR 381.175]; and 5. The poultry products do not move in commerce. Note: Commerce means the exchange or transportation of poultry products between States, U.S. territories (Guam, Virgin Island of the United States, and American Samoa), and the District of Columbia [PPIA Section 453; Title 9 CFR \u00a7381.1(b)]. Producer\Grower \u2013 1,000 Limit Exemption Notes: \u2022 If any of the five criteria are not met, the owner of the poultry is not eligible for this exemption. \u2022 Records necessary for the effective enforcement of the Act include slaughter records and records covering the sales of poultry products to customers. USDA\FSIS or State employees review such records to determine compliance with the requirement of the sale of no more than 1,000 poultry in a calendar year. 4 Some published copies of the PPIA

number the sections 1to 29 not 451 to 470 as numbered in the United States Codes.

9","Producer\Grower \u2013 20,000 Limit Exemption A poultry grower may slaughter and process more than 1,000 birds as exempt product for distribution as human food when the following eight criteria are met [PPIA Section 464(c)(1)(C) &(c)(3) \u201cSection 15 (c)(4)\u201d; Title 9 CFR \u00a7381.10(a)(5) and (b)(1) and (2)]. Criteria: 1. The producer\grower slaughters and processes, on his or her own premises, no more than 20,000 poultry, raised by him or her, in a calendar year; 2. The producer\grower sells, in a calendar year, only poultry or poultry products he or she prepares according to the criteria for the Producer\Grower \u2013 20,000 Limit Exemption; he or she may not buy or sell poultry products prepared under another exemption in the same calendar year in which he or she claims the Producer\Grower \u2013 20,000 Limit Exemption [PPIA Section (464)(c)(1) last sentence before (c)(2)]; 3. The poultry products are distributed solely by the producer\grower and only within the District of Columbia or the State or Territory in which the poultry product is produced. 4. The poultry are healthy when slaughtered; 5. The slaughter and processing at the producer\grower\u2019s premises are conducted using sanitary standards, practices, and procedures that produce poultry products that are sound, clean, and fit for use as human food (not adulterated); 6. The producer only distributes poultry products he or she produced under the Producer\Grower Exemption; 7. The facility used to slaughter or process the poultry is not used to slaughter or process another person\u2019s poultry unless the Administrator of FSIS grants an exemption [PPIA Section 464(c)(3); Title 9 CFR 381.10b](2)] 8. The shipping containers, when distributed in intrastate commerce (instead of the required features of a label of inspected product) bear: a. producer\u2019s name, b. producer's address, and 5 Some published copies of the PPIA number the sections 1to 29 not 451 to 470 as numbered in the United States Codes. 10","c. the statement, \u201cExempt P.L. 90-492.\u201d Instead of the Federal law, a State law may be cited when operations are exempted under the authority of a State law and the operations are reviewed by a State Agency. Producer\Grower 20,000 Limit Exemption Notes: \u2022 The producer\grower may sell, intrastate, the poultry products he or she prepares to other businesses for resale as meat or meals, including a distributor, hotel, restaurant, retail store, institution, or small enterprise when the product is produced under a Federal or a State exemption. \u2022 FSIS has determined that when a grower producing poultry under the Producer\Grower Exemption rents slaughtering or processing equipment and operates such equipment on his or her premises, he or she is not disqualified for the Producer\Grower Exemption. In this situation, the grower is not required to request an exemption from the Administrator of FSIS. However, the slaughter or processing unit may not be used to slaughter or process another person\u2019s poultry while it is on the renter\u2019s premises. Producer\Grower or Other Person (PGOP) Exemption The term \u201cProducer\Grower or Other Person\u201d (PGOP) refers to a single entity, which may be: (1) A poultry grower who slaughters and processes poultry that he or she raised for sale directly to household consumers, restaurants, hotels, and boarding houses to be used in those homes and dining rooms for the preparation of meals served or sold directly to customers. (2) A person who purchases live poultry from a grower and then slaughters these poultry and processes such poultry for sale directly to household consumers, restaurants, hotels, and boarding houses to be served in those homes or dining rooms for the preparation of meals sold directly to customers. A business may slaughter and process poultry under this exemption

when the following nine criteria are met [PPIA Section 464(c)(1)(D) &(c)(3) \u201cSection 15 (c)(4)\u201d; Title 9 CFR \u00a7381.10(a)(6) and (b)]. Criteria: 6 Some published copies of the PPIA number the sections 1- 29 not 451-470 as numbered in the United States Codes. 11","1. The producer\grower or other person slaughters for processing and sale directly to household consumers, restaurants, hotels, and boarding houses for use in dining rooms or in the preparation of meals sold directly to customers; 2. The PGOP slaughters no more 20,000 poultry in a calendar year that the producer\grower or other person raised or purchased are slaughtered and processed under this exemption; 3. The poultry processed by a PGOP is poultry that the PGOP slaughtered;. 4. The poultry products produced under the PGOP Exemption are distributed solely by the manufacturer and only within the State or Territory or the District of Columbia in which the poultry product is produced; 5. The producer\grower or other person dose not engage in the business of buying or selling poultry or poultry products prepared under other exemptions in the same calendar year he or she claims the Producer\Grower Exemption [PPIA Section 464(c)(1) last paragraph before (c)(2)]; 6. The processing is limited to preparation of poultry products from poultry slaughtered by the PGOP for distribution directly to: 1) household consumers, 2) restaurants, 3) hotels, and 4) boarding houses for use in their dining rooms or in the preparation of meals sold directly to consumers within the jurisdiction were it is prepared; 7. The slaughter and processing at the producer\grower or other person\u2019s facility is conducted in a manner that results in the preparation of poultry products that are wholesome, sound, clean, and fit for human food (not adulterated), [PPIA Section 4 (g)]; 8. The facility used to slaughter and process poultry is not used to slaughter or process another person\u2019s poultry unless the Administrator of FSIS grants an exemption [PPIA Section 464(c)(3); Title 9 CFR 381.10b(2)]; and 9. The shipping containers, when distributed in intrastate commerce, (instead of all the required features of a label for inspected product) bear: a. the processor\u2019s name, b. the address, and c. the statement, Exempt P.L. 90-492. State law, rather than Federal law, may be cited when product is produced in accordance with requirements of a State exemption. Producer\Grower or Other Person Exemption Notes: 12","\u2022 A business preparing poultry product under the PGOP exemption may not slaughter or process poultry owned by another person. \u2022 A business preparing poultry products under the PGOP exemption may not sell products to a retail store or other producer\grower. Small Enterprise Exemption A business that qualifies for the Small Enterprise Exemption may be: (1) A producer\grower who raises, slaughters, and dresses poultry for use as human food whose processing of dressed exempt poultry is limited to cutting up; (2) A business that purchases live poultry that it slaughters and dresses whose processing of the slaughtered poultry is limited to the cutting up; or (3) A business that purchases dressed poultry, which it distributes as carcasses and whose processing is limited to the cutting up of inspected or exempted poultry products, for distribution for use as human food. Under this exemption, a business may slaughter, dress, and cut up poultry for distribution as human food when the following criteria are met [PPIA Section 464(c)(2) & (c)(3) \u201cSection 15 (c)(2) & (c)(3)\u201d; Title 9 CFR \u00a7381.10(a)(7) & (b)].] Criteria: 1. Processing of Federal or State inspected or exempt poultry product is limited to the cutting up of carcasses; 2. The business slaughters and dresses or cuts up no more than 20,000 birds in a calendar year under the exemption; 3. The facility operates and is maintained in a manner that prevents the creation of insanitary conditions and ensures that the product is not adulterated [PPIA Section 464(c)(2);

and Title 9 CFR 381.10(a)(7) and 416.2-416.5); See Attachment 2 for sanitation requirements for official establishments and businesses operating under the Small Enterprise and Retail Store Exemptions; 4. The facility used to slaughter or process poultry is not used to slaughter or process another person's poultry unless the Administrator of FSIS grants an exemption [PPIA Section 464(c)(3); Title 9 CFR 381.10b](2)]; 5. The exempted product is not distributed in interstate commerce; instead, its distribution is limited to premises within the District of Columbia or the State or Territory in which the poultry product is produced; and Note: Poultry products produced under a Small Enterprise Exemption are not misbranded when they bear all of the features of a label for inspected product with the exception that the labeling does not indicate that the product was inspected and passes. Label requirements for this exempt uninspected product include the following: weight or measures; the requirements of , statement indicating why the inspection legend is not permitted; for example, the phrase 'Small Enterprise Exemption from Inspection' is suggested by FSIS but is not a mandatory requirement. Title 9 CFR 381.500(f) is optional for poultry products produced by a small enterprise. The product is not misbranded. 1. Name of the product; 2. Ingredients statement; 3. Statement of the quantity of contents in terms of weight or measures; 4. Name and address of manufacturer; 5. Handling statement; 6. Safe handling instruction that complies with Title 9 CFR 381.125(b)(2)(ii); 7. Date of packing; and 8. Explanatory statement indicating why the inspection legend is not permitted. In addition, if the labeling does not bear nutrition or health claims, the nutrition facts feature, as explained in, Exemption from nutritional labeling is not required for the small enterprise exemption. Small Enterprise Exemption Notes: A small enterprise is not required to have slaughtered the poultry it cuts up under a Small Enterprise Exemption. The small enterprise may purchase Federal or State inspected and passed poultry for its cut up operation and from exempt businesses that are allowed to sell to a small enterprise. A small enterprise may handle exempt product and may cut exempt product produced under the Producer/Grower Exemption. A small enterprise may handle as exempt product through a poultry product that was produced under Federal or State inspection.

14", "A business may slaughter or cut up poultry under the Small Enterprise Exemption for sale to: a. household consumers, b. hotels, c. retail stores, d. restaurants, and e. similar institutions. A small enterprise may sell live poultry to a customer and then slaughter, dress, and cut up the poultry for the customer. Selling live poultry is not the same as buying or selling poultry products. One of the criteria that prevents a business from claiming as 'Custom Slaughter/Processing Exemption'. A small enterprise may not cut up and distribute poultry products produced under the Small Enterprise Exemption to a business operating under the following exemptions: a. Producer/Grower or PGOP Exemption, b. Retail Dealer Exemption, or c. Retail Store Exemptions. Retail Exemption (Store/Dealer/Restaurant): A retail business is a facility where poultry products are sold to a customer (household consumers and hotels, restaurants, and similar institutions) at the retail business and the amount purchased by the customer is considered to be a normal amount for a retail purchase. The Act provides for several types of retail exemptions: (1) the Retail Dealer Exemption, (2) the Retail Store Exemption, and (3) the Restaurant Exemption. The type of poultry slaughter and processing operations a business conducts determines which retail exemption under which the business may produce poultry. A business is qualified to operate

under a retail exemption when the following criteria are met [PPIA Section 454.(c)(2) \u201cSection 5 (c)(2)\u201d; PPIA Section 464.(a)(1) \u201cSection 15 (c)(2)\u201d; Title 9 CFR 381.10(a)(1) and (d)(2)(vi), and 381.10(d)(1) and (d)(2)(i), (ii) and (iii)].  
8 Some published copies of the PPIA number the sections from 1 to 29 not 451-470 as numbered in the United States Codes. 15","Criteria: 1. Only poultry carcasses and parts derived from federally inspected and passed poultry are transported in interstate commerce [Title 9 CFR \u00a7381.10(a)(1)]; 2. Poultry products used in the preparation of meals at a restaurant are derived from federally inspected and passed poultry products or federally exempt poultry products from exempt operations that may sell to restaurants [\u00a7381.10(d)(2)(iv)(2)]; 3. State inspected and passed or exempt State or exempt federal poultry products used in the preparation of poultry products, sold at the retail store, are not transported in interstate commerce, the exempt poultry product must be from an acceptable exempt source a Producer\Grower or Small Enterprise [\u00a7381.10(d)(2)(iii)(c)] (Note: A PGOP cannot sell their products to retailers \u2013 only to household consumers, boarding houses, hotels and restaurants]; 4. The business does not custom slaughter poultry delivered by the owner; 5. The retail business does not prepare exempt products that the business sells to another retail store or a distributor of poultry products; 6. The only poultry slaughtered at a retail store is poultry that is purchased live by the customer, at the retail store, and then the poultry product is prepared according to the customer\u2019s instructions and delivered back to the customer; 7. The business may custom process poultry delivered by the owner provided that the poultry is from an acceptable source, Federal or State inspected and passed, or exempt poultry); 8. The facility operates and is maintained in a manner that prevents the creation of insanitary conditions and ensures that the product is not adulterated [PPIA Section 464(c)(2); and Title 9 CFR 381.10(a)(7) and 416.2-416.5]; See Attachment 2 for sanitation requirements for official establishments and businesses operating under the Small Enterprise and Retail Store Exemptions; 9. Operations of types traditionally and usually conducted at retail stores are conducted in the store and include: a. boning, b. cut up, c. stuffing, d. smoking, e. rendering, or f. salting; 16","10. No canning operation is conducted in the retail store; Note: Poultry products produced under a Retail Store Exemption are not misbranded when they bear all of the features of an official label with the exception that the labeling does not indicate that the product was inspected and passes. Official label requirements include the following: 1. Name of the product, 2. Ingredients statement, 3. Statement of the quantity of contents in terms of weight or measures, 4. Name and address of manufacturer, 5. Handling statement, 6. Safe handling instruction that comply with the requirements of 9 CFR 381.125(b)(2)(ii), 7. Date of packing, and 8. Explanatory statement indicating why the inspection legend is not permitted; for example, the phrase \u201cRetail Exemption from Inspection\u201d is suggested by FSIS but is not a mandatory requirement. In addition, if the labeling does not bear nutrition or health claims, the nutrition facts feature, as explained in, Title 9 CFR 381.500 , is optional for poultry products produced by a business eligible for the small enterprise exemption. 11. Product sold in commerce is not misbranded; Title Exemption from nutritional labeling 12. Sales of poultry and poultry products are in normal retail quantities or served to consumers at the retail store (normal retail quantities are 75 pounds or less to household consumers and 150 pounds or less to hotels, restaurants, and similar institutions); and 13. Sales to hotels, restaurants, and similar institutions do not exceed either one of two limits: 1. 25 percent of the

dollar value of total poultry product sales, or 2. the calendar year dollar limit for retail stores set by the Administrator of FSIS; 17", "Note: retail store dollar limitation is the limit, measured in dollars, on sales of poultry products by retail stores each calendar year to non-household consumers such as hotels, restaurants, and similar institutions. stores may not exceed a specific dollar limit on the sale of poultry products to hotels, restaurants, and similar institutions. dollar limitation is adjusted during the first quarter of the year if the Consumer Price Index, published by the Bureau of Labor Statistics, indicates an increase or decrease of more than \$500 in the price of the same volume of product from the previous year. FSIS publishes a notice of the adjusted dollar limitation in the through products that are derived from USDA inspected and passed poultry that are not further processed at the retail store. To maintain their exemption from inspection under the PPIA, retail The Federal Register. The dollar limitation amount on retail sales does not include pass- Retail Store Exemption Notes: When a retail store that slaughters poultry takes orders for dressed poultry before the arrival of the customer, and also slaughters several birds at one time for various customers that have requested them, the birds must be identified throughout the process so that processed bird that the customer receives is the same live birds selected for or by the customer. How many exemptions may a person or business claim when slaughtering or processing poultry? A person or business may slaughter or process poultry under an exemption if the operation qualifies for the exemption. However, a slaughterer or processor of poultry may not simultaneously operate under more than one exemption. When FSIS or a State reviews a business to determine compliance with the Act and regulations, FSIS or the State inspectors must be informed of which exemption the business is claiming. FSIS or State inspectors will determine compliance based on only one exemption. A business may not simultaneously claim or operate under more than one exemption. 18", "The selection of either the Producer\Grower Exemption or the Producer\Grower or Other Person Exemption is for the calendar year. In the same calendar year, a poultry producer or other person producing product under either the Producer\Grower Exemption or the Producer\Grower or Other Person Exemption may not produce product under another exemption. In addition, a poultry business that slaughters or processes poultry operating under a Custom Slaughter or Small Enterprise Exemption may not operate under the Producer\Grower or Producer\Grower or Other Person exemption in the same calendar year. A facility or business may house more than one exempt operation if there is complete financial and structural autonomy of each operation. A true and complete separation must exist between the business records and the physical structures (rooms and equipment) of the two operations. A facility or business producing product under a Custom Slaughter, Small Enterprise, or Retail Store Exemption may operate under another one of these three exemptions in the same calendar when there is financial and temporal autonomy of each operation. For example, a person using a facility for a custom slaughter business may close the custom slaughter business and open a retail store or small enterprise business at the facility in the same calendar year. Who determines whether an operation qualifies for an exemption? Inspectors of the USDA\FSIS are authorized to make inspections in accordance with the law to ascertain whether any of the provisions of the Act or the regulations applying to producers, retailers, or other persons purporting to be exempt form and requirements (criteria) of the Act have been violated. [Code of Federal Regulations Title 9 Section 381.14 ] A State that does not operate a poultry inspection program at least equal to the Federal poultry inspection program

is a \u201cDesignated State\u201d [Title 9 Code of Federal Regulations Subpart V \u00a7381.220-225]. In a designated State, FSIS is responsible for conducting reviews of establishments operating under exemptions provided for in Section 15 of the PPIA i.e. personnel use, retail dealer, custom slaughter, poultry producers, or small enterprise exemptions and of retail stores operating under the PPIA, Section 5(c)(2) retail exemption. Such reviews may be conducted by a State Agency under a cooperative agreement with FSIS\USDA. When either a State Agency that has a cooperative agreement with FSIS or FSIS determines that an exempt operation does not comply with requirements of the Act, USDA is responsible for enforcement of compliance with the requirements of the Act. In States that operate a poultry inspection program equivalent to the Federal inspection program, a State Agency conducts inspections and reviews of exempted operations. Suspension or termination of exemptions 19", "The Administrator of FSIS may, by order, in accordance with the applicable rules of practice [Code of Federal Regulations Title 9 Part 500] suspend or terminate any exemption with respect to any person whenever FSIS finds that such action will aid in effectuating the purposes of the Act. Failure to comply with the conditions (criteria) of the exemption including but not limited to failure to process poultry and poultry products under clean and sanitary condition may result in termination of an exemption, in addition to other penalties [Code of Federal Regulations Title (Section 318.13)]. Religious dietary exemption To avoid conflicts with certain religious dietary requirements, the PPIA allows for exemption from certain requirements of the PPIA and the regulations when a religious dietary requirement conflicts with the Act or regulations. However, this exemption from certain requirements of the PPIA and the regulations is granted only if the purposes of the Act or regulations are met. Unlike the exemption previously discussed in this guidance, only official establishments may receive an exemption from a specific regulation that conflicts with a religious dietary requirement. An official establishment may request a religious dietary exemption on FSIS Form 5200-1 at the time that the establishment applies for inspection. Poultry prepared in accordance with a religious dietary law under a religious exemption does not bear the official inspection legend but must meet all inspection and regulatory requirements not specifically listed on the submitted application (FSIS Form 5200-1) and exempted on the exemption certificate issued by FSIS. 20", "Attachment 1. A Summary Table of Exemptions and Limitations Summary Table of Exemptions and Limitations Criteria Personal Use Custom Produce Grower \u2013 1,000 Bird Limit Producer Grower \u2013 20,000 Bird Limit Producer Grower or Other Person Small Enterprise 20,000 Bird Limit Slaughter Limit NONE NONE YES 1,000 YES 20,000 YES 20,000 YES 20,000 Processing YES YES YES YES YES CUT UP ONLY 75 lb. Sale Limit to Consumer NO SELLING NO SELLING NO LIMIT NO LIMIT NO LIMIT NO LIMIT 150-lb. Limit to HRI NO SELLING NO SELLING NO LIMIT NO LIMIT NO LIMIT NO LIMIT 25% of Total product\75% HRI Sale NO SELLING NO SELLING NO LIMIT NO LIMIT NO LIMIT N\A Can Sell to any customer NO NO YES YES NO YES Can Sell to HRI NO NO YES YES NOT TO ALL HRIs1 YES Sell to Distributor NO NO YES YES YES YES Sell to Retail Store NO NO YES YES NO YES Intra-State Distribution NO NO YES YES YES YES Inter-State Distribution NO NO NO NO NO NO Retail Dealer Retail Store Yes ZERO NONE CUT UP ONLY YES NO LIMIT YES NO LIMIT YES YES YES NO NO YES YES NO NO NO YES YES YES2 NO2 1. Product produced under the Producer\Grower or Other Person Exemption may not be sold to institutions. 2. Only poultry products derived from federally inspected and passed poultry may be transported in interstate commerce. 21", "Attachment 1 B Table of

Exemptions and Limitation EXEMPTION Personal Use Customer(s) that the exempted poultry may be sold to. Personal Use exempt poultry products may not be sold or donated for use as human food to any customer or consumer. The poultry is for the Limitations: 1. on amount poultry product produced under the exemption 2. 25% or less exempt sales to HRIs 3. calendar year total sales dollar limitation 4. Identification\labeling requirements 1 \u2013 No limit 2 & 3 \u2013 No sales of poultry permitted 4 \u2013 The statement \"Exempt P.L. 90-492\" and Type of operations exempt: 1. Slaughter, 2. Processing, 3. Cut-up only. 1. Slaughter 2. Processing. Custom Slaughter\ Processing Producer Custom Slaughtered exempt poultry products may not be sold or donated for use as human food. A custom slaughter may not engage in the business of buying or selling poultry used for human food exclusive private use of the owner. 1 \u2013 No limit 2 & 3 \u2013 No sales permitted 4 \u2013 The statement \"Exempt P.L. 90-492\" and the producer\u2019s name and address on shipping containers. producer\u2019s name and address on shipping contains 1. Slaughter, 2. Processing other person\u2019s poultry. 1. Slaughter Producer Grower Grower 1,000 bird limit Slaughters & processes on his\her premises poultry for distribution by him\her to any person Limited Provision of the Act apply May sell to any person, must keep records -of sales (Title 9 CFR 381.175) 1 \u2013 Yes, may slaughter and process no more than 20,000 poultry in calendar year of their raising on 1 \u2013 Yes, no more than 1,000 poultry in calendar year. Of their own raising on their own farm 1. Slaughter & 2. Processing of poultry 2. Processing of poultry grower\u2019s raised poultry for sale to customers. 20,000 bird limit The product may only be distributed in the State, territory, or DC where it was prepared their own premises. 2 \u2013 25% HRI limitation does not apply 3 \u2013 Dollar limitation not applicable. grower\u2019s raised poultry. Producer Grower or Other Person (PGOP) Slaughters & processes poultry for distribution to only household consumers, restaurants, hotels, or boarding houses. The exempt product may only be distributed in the State, territory, or District of Columbia producer\u2019s name and address on product when it is distributed. 4 \u2013 The statement \"Exempt P.L. 90-492\" and 1 \u2013 Yes, no more than 20,000 poultry in calendar year. 2 &3 not applicable. 4 \u2013 The statement \"Exempt P.L. 90-492\" and producer\u2019s name and address are required on product when it is distributed. 1. Slaughter 2. Processing of raised or purchased (live) poultry Small Enterprise No restrictions on type of customer A small enterprise may not use or distribute products from, PGOP, Retail Dealer, or Retail Store exemptions where it is prepared. 1 \u2013 Yes no more than 20,000 poultry in a calendar year. 2 &3 --not applicable. 4 \u2013 All the features of an official label when distributed, with the exceptions that the official 5 \u2013 May not slaughter or process poultry at a facility used for slaughtering or processing by another person. 1. Slaughter 3. Cut-up only The exempt product may only be distributed in the State, territory, or DC where it is prepared. safe handling instructions and the nutrition facts are optional, provided, the labeling does not bear nutrition inspection legend cannot be used, modification of the Retail Dealer Sales limited to household consumers, hotels, or restaurants, or similar institutions. Sales to household consumers in store must be 75% of total sales. Sales to retail markets or distributors disqualify an establishment form a Retail Exemption. Product prepared from poultry previously 5 \u2013 May not slaughter or process poultry at a facility used for slaughtering or processing by another person. or health claims. 1 \u2013 No limit on pounds sold to consumers. 2 \u2013 25% HRI limitation applies 3 \u2013 Dollar limitation not applicable. 4 \u2013 All the features of an official label, with the ex- 1. No Slaughter. 3.

Processing limited to cutting up of previously USDA Inspected and Passed Poultry Retail Store Sales limited to household consumers, hotels, or restaurants, or similar institutions. Sales to household consumers in store must be inspected and passed by USDA permitted to cross Stateline, move in \u201cCommerce.\u201d 1 \u2013 Yes, there is a limit of 75 lbs. for household sales and a 150 lbs. limit for HRI sales. ceptions that the official inspection legend cannot be used, modification of the safe handling instructions and the nutrition facts are optional, provided, the labeling does not bear nutrition or health claims. 1. Slaughter of live poultry purchased by consumer at the retail 75% of sales. Sales to retail markets or distributors disqualify an operation from a Retail Store exemption. Product prepared from product previously inspected and passed by USDA permitted to cross Stateline, move in \u201cCommerce \u201c Other, 2 \u2013 25% HRI limitation does apply 3 \u2013 Dollar limitation applicable. store and processed by the retail store operator in accordance with the consumer\u2019s instructions. 2. Processing exempt product may only be distributed in the State, territory, or DC where it is prepared. 22", "Attachment 2 Basic Sanitary Standards Following are general basic sanitary standards, practices, and procedures [9 CFR 416.2-416.5]. The list is a summary of the regulatory requirements for sanitation procedures and practices that are required for a poultry business receiving full U.S. Department of Agriculture inspection and are applicable to poultry exempt operations {Title 9 CFR Part 416}. In addition, specific sanitary practices are described in FSIS\u2019s Sanitation Performance Standards Compliance Guide, dated October 13, 1999. This 92-page document is also available from [http://www.fsis.usda.gov/FSIS\\_Employees/Compliance\\_Guides\\_Index/index.asp](http://www.fsis.usda.gov/FSIS_Employees/Compliance_Guides_Index/index.asp). A. Sanitary operating conditions. All food-contact surfaces and non-food-contact surfaces of an exempt facility are cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product. Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an exempt facility are safe and effective under the conditions of use. Such chemicals are used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment are available to inspection program employees for review. Product is protected from adulteration during processing, handling, storage, loading, and unloading and during transportation from official establishments. B. Grounds and pest control. The grounds of exempt operation are maintained to prevent conditions that could lead to insanitary conditions or adulteration of product. Plant operators have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within the facilities. The operator's pest control operation is capable of preventing product adulteration. Management makes every effort to prevent entry of rodents, insects, or animals into areas where products are handled, processed, or stored. Openings (doors and windows) leading to the outside or to areas holding inedible product have effective closures and completely fill the openings. Areas inside and outside the facility are maintained to prevent harborage of rodents and insects. The pest control substances used are safe and effective under the conditions of use and are not applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions. C. Sewage and waste disposal. Sewage and waste disposal systems properly remove sewage and waste materials\feces, feathers, trash, garbage, and paper\from the facility. Sewage is disposed of into a sewage system separate from all other drainage lines or disposed of through

other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, upon request, the management must furnish to the inspector a letter of approval from that authority. 23", "D. Water supply and water, ice, and solution reuse. A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141) at a suitable temperature and under pressure as needed, is provided in all areas where required (for processing product; for cleaning rooms and equipment, utensils, and packaging materials; for employee sanitary facilities, etc.). If a facility uses a municipal water supply, it must make available to the inspector, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If a facility uses a private well for its water supply, it must make available to the inspector, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually. E. Facilities. Maintenance of facilities during slaughtering and processing is accomplished in a manner to ensure the production of wholesome, unadulterated product. F. Dressing rooms, lavatories, and toilets. Dressing rooms, toilet rooms, and urinals are sufficient in number ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. Dressing rooms, lavatories, and toilets are separate from the rooms and compartments in which products are processed, stored, or handled. G. Inedible Material Control. The operator handles and maintains inedible material in a manner that prevents the diversion of inedible animal products into human food channels and prevents the adulteration of human food. 24", "Attachment 3 FSIS District Office Contact Information

[http://www.fsis.usda.gov>Contact\\_Us\Office\\_Locations\\_&\\_Phone\\_Numbers\index.asp](http://www.fsis.usda.gov>Contact_Us\Office_Locations_&_Phone_Numbers\index.asp)  
District Office Location Office Address & Telephone Number States and Territories Covered by  
District Alameda, CA 620 Central Avenue Building 2C Alameda, CA 94501 Phone: (510) 337-5000  
FAX: (510) 337-5081 California Albany, NY 230 Washington Ave. Extension Albany, NY 12203-  
5369 Phone: (518) 452-6870 Connecticut, Maine, Massachusetts, New Hampshire, New York,  
Rhode Island, and Vermont Atlanta, GA 100 Alabama St., SW; Bldg 1924 Suite 3R90 Atlanta, GA  
30303 Phone: (404) 562-5900 Florida, Georgia, Puerto Rico, and the Virgin Islands. Beltsville,  
MD 5601 Sunnyside Ave. Suite 1-2288 B Beltsville, MD 20705-5200 Phone: (301) 504-2136  
Delaware, District of Columbia, Maryland, Virginia, and West Virginia. Chicago, IL 1919 South  
Highland Avenue Suite 115C Lombard, IL 60148 Phone: (630) 620-7474 Illinois, Ohio, and  
Indiana Dallas, TX 1100 Commerce Street Room 516 Dallas, TX 75242-0598 Phone: (214) 767-  
9116 Texas Denver, CO Denver Federal Center PO Box 25387, Building 45 Denver, CO 80225  
Phone: (303) 236-9800 Alaska, American Samoa, Arizona, Colorado, Guam, Hawaii, Idaho, New  
Mexico, Nevada, Northern Mariana Islands, Oregon, Utah, Washington Des Moines, IA Room  
985, Federal Building 210 Walnut Street Des Moines, IA 50309 Phone: (515) 727-8960 or 1-800-  
990-9834 Iowa and Nebraska Jackson, MS 715 S. Pear Orchard Road Suite 101 Ridgeland, MS  
39157 Phone: (601) 965-4312 Alabama, Mississippi, and Tennessee 25", "Attachment 3 FSIS  
District Office Contact Information Continued District Office Address & States and  
Location Telephone Number Territories Covered by District Lawrence, KS 4920 Bob Billings  
Parkway Kansas and Missouri Lawrence, KS 66049-3855 Phone: (785) 841-5600 Madison, WI  
2810 Crossroads Dr. Michigan and Wisconsin Suite 3500 Madison, WI 53718-7969 Phone: (608)  
240-4080 Minneapolis, MN Butler Square West, Suite 989-C Minnesota, Montana, North

Dakota, 100 N. 6th Street Minneapolis, MN 55403 Phone: (612) 370-2400 South Dakota, and Wyoming Philadelphia, PA Mellon Independence Center Pennsylvania and New Jersey 701 Market Street \u2013 Suite 4100-A Philadelphia, PA 191061576 Phone: (215) 597-4219, Ext. 101 or 1-800-637-6681 Raleigh, NC 6020 Six Forks Road Raleigh, NC 27609 North Carolina, South Carolina, and Kentucky. Phone: (919) 844-8400 or 1-800-662-7608 Springdale, AR Country Club Center Bldg. B, Suite 201 Arkansas, Louisiana, and Oklahoma 4700 South Thompson Springdale, AR 72764 Phone: (479) 751-8412 26". Attachment 4 OPEER Regional Offices Contact Information

[http://www.fsis.usda.gov>Contact\\_Us\Office\\_Locations\\_&\\_Phone\\_Numbers\index.asp#op](http://www.fsis.usda.gov>Contact_Us\Office_Locations_&_Phone_Numbers\index.asp#op)eer OPEER, FSIS. Regional Offices, Location Office Address & Telephone Number States and Territories Covered by District Alameda, CA Regional Manager 620 Central Avenue, Building 2B Alameda, CA 94501 Phone: (510) 337-5000, Ext. 249 FAX: (510) 337-5080 Emergency: (202) 276-1610 Western Region States: Alaska, American Samoa, Arizona, California, Colorado, Guam, Hawaii, Idaho, Mariana Islands, Nevada, New Mexico, Oregon, Utah, Washington Dallas, TX Regional Manager 1100 Commerce Street, Room 516 Dallas, TX 75242 Phone: (214) 767-9116, Ext. 400 FAX: (214) 767-8230 Emergency: (214) 763-1853 Southwest Region States: Arkansas, Louisiana, Oklahoma, Texas Lawrence, KS Regional Manager 4920 West 15th Street, Suite B Lawrence, KS 66049 Phone: (785) 840-9026 FAX: (785) 843-0548 Emergency: (785) 423-5402 Great Plains Region States: Iowa, Kansas, Minnesota, Missouri, Montana, Nebraska, North Dakota, South Dakota, Wyoming Lombard, IL Regional Manager 1919 South Highland Avenue, Suite 120C Lombard, IL 60148 Phone: (630) 916-6226, Ext. 264 FAX: (630) 620-7876 Emergency: (630) 768-8418 (Alert 1) Midwest Region States: Illinois, Indiana, Ohio, Michigan, Wisconsin Atlanta, GA Regional Manager 100 Alabama Street SW 1924 Building, Suite 3R90 Atlanta, GA 30303 Phone: (404) 562-5962 FAX: (404) 562-5935 Emergency: (404) 569-3060 Southeast Region States: Alabama, Delaware, District of Columbia, Florida, Georgia, Kentucky, Maryland, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, Virginia, Virgin Islands, West Virginia 27", "Attachment 5 Adulterated The term ordinarily render it injurious to health; Federal Food, Drug, and Cosmetic Act; Federal Food, Drug, and Cosmetic Act; is prohibited by the regulations; slaughter; conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, greater value than it is. adulterated applies to any poultry product under one or more of the following circumstances: (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not (2) If it bears or contains (by reason of administration of any substance to the live poultry or otherwise) any added poisonous or added deleterious substance (other than one which is a pesticide chemical in or on a raw agricultural commodity; a food additive; or a color additive) which may, in the judgment of the Administrator, make such article unfit for human food; (3) If it is, in whole or part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 408 of the Federal Food, Drug, and Cosmetic Act; (4) If it bears or contains any food additive which is unsafe within the meaning of section 409 of the (5) If it bears or contains any color additive which is unsafe within the meaning of section 706 of the (6) if use of a pesticide chemical, food additive, or color additive in or on poultry or poultry products (7) If it consists in whole or in part of any filthy, putrid, or decomposed

substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food; (8) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; (9) If it is, in whole or in part, the product of any poultry which has died otherwise than by (10) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; (11) If it has been intentionally subjected to radiation, unless the use of the radiation was in Drug, and Cosmetic Act; or (13) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefrom; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of 28", "Attachment 6 STATE OFFICIALS COOPERATIVE MEAT AND POULTRY INSPECTION PROGRAMS ALABAMA Honorable Ron Sparks Commissioner AL Department of Agriculture & Industries P. O. Box 3336 Montgomery, AL 36109-0336 (334) 240-7100 FAX (334) 240-7190 Dr. Robert L. Barlow, Director Meat & Poultry Inspection Section Richard Beard Building P.O. Box 3336 Montgomery, AL 36109-0336 (334) 240-7210 FAX (334) 223-7352 Email: mipbismgr@agi.state.al.us ARIZONA Mr. Donald Butler, Director AZ Department of Agriculture 1688 West Adams Phoenix, AZ 85007 (602) 542-0998 FAX (602) 542-5420 Mr. Stewart Jacobson Program Manager AZ Department of Agriculture AZ Meat & Poultry Inspection 1688 West Adams Phoenix, AZ 85007 (602) 542-6398 FAX (602) 542-4194 Email: sjacobson@azda.gov DELAWARE Honorable Michael T. Scuse Secretary of Agriculture DE Department of Agriculture 2320 S. Dupont Highway Dover, DE 19901-5515 (302) 698-4502 FAX (302) 697-4463 Dr. Edwin Odor, Veterinarian\ Food Inspection Administrator DE Department of Agriculture 2320 S. Dupont Highway Dover, DE 19901-5515 (302) 698-4539 FAX (302) 697-4464 Email: edwin.odor@state.de.us GEORGIA Honorable Thomas T. Irvin Commissioner GA Department of Agriculture 19 Martin Luther King Jr. Drive Suite 204 Atlanta, GA 30334-2001 (404) 656-3600 FAX (404) 657-8206 Dr. Rex Holt, Director Meat Inspection Division GA Department of Agriculture 19 Martin Luther King Jr. Drive Room 108 Atlanta, GA 30334-2001 (404) 656-3673 FAX (404) 463-1998 Email: rholt@agr.state.ga.us ILLINOIS Mr. Charles A. Hartke, Director IL Department of Agriculture 801 Sangamon Avenue P.O. Box 19281 Springfield, IL 62794-9281 (217) 785-4789 FAX (217) 785-4505 Dr. Kris Mazurczak, Bureau Chief Meat & Poultry Inspection IL Department of Agriculture 801 Sangamon Avenue P.O. Box 19281 Springfield, IL 62794-9281 (217) 782-6684 (312) 814-6903 (Chicago Office) FAX (217) 524-7801 Email: kmazurczak@agr.state.il.us INDIANA Bret D. Marsh, D.V.M., State Veterinarian IN State Board of Animal Health 805 Beachway Drive Suite 50 Indianapolis, IN 46224-7785 (317) 227-0335 FAX (317) 227-0330 Paul L. Dieterlen, D.V.M. Director Division of Meat & Poultry IN State Board of Animal Health 805 Beachway Drive Suite 50 Indianapolis, IN 46224-7785 (317) 227-0359 FAX (317) 227-0330 Email: pdieterlen@boah.in.gov January 25, 2006 29", "Attachment 6 STATE OFFICIALS COOPERATIVE MEAT AND POULTRY INSPECTION PROGRAMS IOWA Honorable Patty Judge, Secretary IA Department of Agriculture & Land Stewardship Wallace Building Des Moines, IA 50319 (515) 281-5322 FAX (515) 281-6236 Mr. Michael M. Mamminga, Bureau Chief Division of Consumer Protection & Animal Health Wallace Building Des Moines, IA 50319 (515) 281-5597 FAX (515) 281-4819 Email: mike.mamminga@idals.state.ia.us KANSAS Mr. Adrian Polansky Secretary KS Department of Agriculture 109 SW 9th Street Topeka, KS 66612 (785)

296-3558 FAX (785) 296-8389 3 Dr. Evan Sumner Program Director Meat & Poultry Inspection  
KS Department of Agriculture Division of Inspection 109 SW 9th Street rd Floor Topeka, KS  
66612 (785) 296-3511 FAX (785) 296-0673 Email: Esumner@kda.state.ks.us LOUISIANA  
Honorable Robert F. Odom, Jr. Commissioner LA Department of Agriculture & Forestry P.O. Box  
631 Baton Rouge, LA 70821-0631 (504) 922-1234 FAX (504) 922-1253 Mr. Mike Windham  
Program Manager LA Department of Agriculture & Forestry P.O. Box1951 Baton Rouge, LA  
70821-1951 (225) 922-1358 FAX (225) 925-4103 Email: Mike\_w@ldaf.state.la.us MAINE Mr.  
Robert W. Spear, Commissioner ME Dept of Agriculture Food & Rural Resources Div. of Animal  
Health & Industry 28 State House Station Augusta, ME 04333-0028 (207) 287-3871 Mr. David  
Gagnon Acting Program Manager ME Department of Agriculture Food & Rural Resources Div. of  
Animal Health & Industry 28 State House Station Augusta, ME 04333-0028 (207) 287-4516  
FAX(207) 287-5576 Email: Henrietta.Beaufait@maine.gov MINNESOTA Mr. Gene Hugoson,  
Commissioner MN Department of Agriculture 625 Robert Street St. Paul, MN 55155-2538 (651)  
201-6219 FAX (651) 201-6118 Mr. Kevin Elfering Division Director Dairy, Food Feed & Meat  
Inspection Division Department of Agriculture 625 Robert Street St. Paul, MN 55155-2538 (651)  
201-6453 FAX (651) 201-6116 Email: kevin.elfering@state.mn.us Nicole Neeser, DVM Program  
Manager Dairy, Meat & Poultry Insp. MN Department of Agriculture 625 Robert Street St. Paul,  
MN 55155 (651) 201-6225 FAX (651) 201-6116 Email: Nicole.neeser@state.mn.us January 25,  
2006 30", "Attachment 6 STATE OFFICIALS COOPERATIVE MEAT AND POULTRY INSPECTION  
PROGRAMS MISSISSIPPI Honorable Lester Spell, Jr., D.V.M. Commissioner MS Department of  
Agriculture & Commerce P.O. Box1609 Jackson, MS 39215-1609 (601) 359-1100 FAX (601) 354-  
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perform Custom Exempt reviews for the Agency, under cooperative agreement. 34 January 25,  
2006"]}, {"file\_name": "FSIS\_GD\_2004\_0001", "title": "Compliance Guidelines for Establishments  
on the FSIS Microbiological Testing Program and Other Verification Activities for Escherichia Coli  
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Compliance Guidelines May 2006 COMPLIANCE GUIDELINES TO CONTROL LISTERIA  
MONOCYTOGENES IN POST-LETHALITY EXPOSED READY-TO-EAT MEAT AND POULTRY  
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and food contact and environmental testing (pp. 25-45). The guidelines also include a section on how to determine whether the product should be considered deli meat or hot dog. They also provide an example of a test and hold scenario that would occur when an establishment test of a food contact surface is positive, and the product is held while corrective actions and retesting are conducted (pp. 44, 68-71). The Agency has also included tables to show: 1) the recommended minimum log reduction of *L. monocytogenes* that is necessary for the post-lethality treatment to achieve to be considered under Alternative 1 and 2 (p.21); 2) the expected log suppression by the antimicrobial agent or process throughout the shelf life of the product (p. 21); and 3) the recommended frequency of testing food contact surfaces for the three alternatives (p. 42). The guidelines discuss how the establishment can receive reduced sampling from FSIS, labeling issues, information on new technologies and methods for testing food contact and environmental surfaces for *Listeria* spp., *Listeria*-like organisms and *L. monocytogenes*.," "Updated Compliance Guidelines May 2006 A. Introduction Food Safety and Inspection Service (FSIS) developed Compliance Guidelines to help the establishments producing Ready-to-Eat (RTE) meat and poultry products, especially small and very small establishments, in their use of control methods for *L. monocytogenes* to comply with the requirements of 9 CFR 430. Their purpose is to show establishments how the control methods can, if used singly or in combination, prevent or eliminate *L. monocytogenes* contamination in the product during post-lethality exposure. Establishments can use the guidelines to choose control methods that are best suited to their processing. Some establishments may have already instituted their control methods, which they have verified to be effective in controlling the pathogen and may not need to change their methods to follow these guidelines. However, FSIS will make a determination on the effectiveness of the controls and establishment verification testing when deciding how FSIS will conduct its verification procedures in the establishment. The interim final rule applies only to post-lethality exposed RTE meat and poultry products. Products containing both raw and cooked ingredients (e.g., a frozen entr\u00e9e containing blanched vegetables and fully cooked meat) will not be considered RTE if: (1) the product label prominently indicates the need to cook the products for safety, and (2) there are validated cooking instructions. A frozen product to be cooked may be either RTE or not ready-to-eat (NRTE) unless a food standard of identity requires that the product be RTE. FSIS distinguishes between RTE and NRTE foods in Attachment 2. This is the second update for these guidelines from the original document posted on the FSIS website on October 6, 2003. The first update in October 2004 responded to comments and questions that FSIS received about the rule and addressed questions that were asked during the workshops that the Agency held in preparation for the implementation of the interim final rule. This second update responds to additional questions and comments received. It also includes documents resulting from the Phase 1 activities for the risk-based verification for the rule. Added or revised sections are in color and in a different font. The updated version includes: \u2022 Summary of Guidance Material (p. 3) \u2022 Discussion of reduced frequency of sampling by the Agency for some products (pp. 13 and 20) \u2022 Adding the site for list of new technologies reviewed with \u201cno objection\u201d for use in establishments (p. 25) \u2022 Modified the section (VII. 3.) on the testing of food contact and environmental services (p. 42) and modified the title (p. 1 and 42) \u2022 Announcement of \u201cIndustry Best Practices for Holding Tested Products\u201d (p. 46) \u2022 Revision of section H. Risk-Based Verification Testing Program to

describe current and projected risk-based verification program (p. 48) 4", "Updated Compliance Guidelines May 2006 \u2022 Attachment 3. Deleted the draft production volume form and replaced with the website link to the form (p.58) \u2022 Attachment 6. Clarification on testing food contact surfaces (p. 71) \u2022 Attachment 7. Procedures for the Evaluation of Establishment Control Programs for Listeria monocytogenes (p.76) \u2022 Attachment 8. Guidance Derived from a Review of Comprehensive Food Safety Assessments Associated with Compliance (p. 99) \u2022 Attachment 9. Links to guidelines for Validation(p. 102): \u201cGuidelines for Conducting Listeria monocytogenes Challenge Testing of Foods\u201d and \u201cConsiderations for Establishing Safety-Based Consume-by-Date Labels for Refrigerated Ready-to-Eat Foods\u201d These guidelines will be updated periodically to include validated and other effective procedures as they become available.

B. Control of Listeria monocytogenes Using Three Alternatives

Listeria monocytogenes is a pathogen that is widely distributed in the environment such as plants, soil, animal, water, dirt, dust, and silage. Because L. monocytogenes may be present in slaughter animals and subsequently in raw meat and poultry as well as other ingredients, it can be continuously introduced into the processing environment. The pathogen can cross-contaminate food contact surfaces, equipment, floors, drains, standing water and employees. In addition, the pathogen can grow in damp environments and can establish a niche and form biofilms in the processing environment that are difficult to eliminate during cleaning and sanitizing.

Other characteristics of L. monocytogenes that makes it a formidable pathogen to control are its heat and salt tolerance and its ability to grow at refrigeration temperatures and survive at freezing temperatures. The lethality treatment received by processed ready-to-eat (RTE) meat and poultry products generally eliminates L. monocytogenes; however products can be recontaminated by exposure after the lethality treatment during peeling, slicing, repackaging, and other procedures. Several outbreaks of foodborne illness resulting in hospitalization, miscarriage, stillbirth, and death have been linked to the consumption of deli meats and hotdogs containing L. monocytogenes. One of the most likely causes of L. monocytogenes contamination in these outbreaks was traced to post-lethality exposure and contamination by the pathogen. Deli and hotdog products are examples of RTE meat and poultry products that receive a lethality treatment to eliminate pathogens, but are subsequently exposed to the environment during peeling, slicing, and repackaging operations. If L. monocytogenes is present on the equipment used for peeling, slicing or repackaging, the pathogen can be transferred to the product upon contact. These products are examples of RTE meat and poultry products that can support the growth of L. monocytogenes during refrigerated storage. Since RTE products are consumed without further cooking, if they are contaminated, there is a possibility of the occurrence of foodborne illness. The \u201cFDA/FSIS Draft Assessment of the Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods\u201d ([www.foodsafety.gov/~dms/lmr2-su.html](http://www.foodsafety.gov/~dms/lmr2-su.html)) indicated that deli meats and hotdogs posed the greatest per serving risk of illness/death from L. monocytogenes. RTE meat and poultry processing plants must include control programs for Listeria monocytogenes in their HACCP plans, Sanitation SOP or prerequisite programs to prevent its growth and proliferation in the plant environment and equipment, and prevent the cross-contamination of RTE products. The FSIS Listeria risk assessment (<http://www.fsis.usda.gov/OPHS/Lmrisk/DraftLm22603.pdf>) indicated that the use of a

combination of intervention methods to control *L. monocytogenes* in deli meats exposed to the environment after the lethality treatment has the greatest impact on lowering the risk of illness or death from *L. monocytogenes*. The Agency used these risk assessments as resources in developing the regulations to control *L. monocytogenes* in RTE meat and poultry processing. The interim final rule for the control of *Listeria monocytogenes* (9 CFR 430) includes three alternative approaches that establishments can take in the processing of RTE meat and poultry products during post-lethality exposure. Under Alternative 1, an establishment applies a post-lethality treatment and an antimicrobial agent or process to control *L. monocytogenes*. Under Alternative 2, an establishment applies either a postlethality treatment or an antimicrobial agent or process. In Alternative 3, the establishment does not apply any post-lethality treatment or antimicrobial agent or process. Instead, it relies on its sanitation program. Products produced under Alternative 1 and 2 are formulated and processed to eliminate *L. monocytogenes* and/or limit its growth if it is present. That means the number of organisms shall not increase during the product's shelf life to detectable levels, or levels which may result in a public health hazard. These alternatives provide greater control compared to Alternative 3 which involves only sanitation to control *L. monocytogenes*. Consequently, the rigor or stringency of the control methods decreases from Alternative 1 to 3. An establishment must identify which alternative their RTE product falls into based on its control program for *L. monocytogenes*. An establishment can choose to apply new control methods and subsequently move from one alternative to another; however, it must apply the control methods required for the specific alternative that it moved into. Each alternative has specific requirements with which the establishment must comply. A systematic table of the requirements for each alternative can be found in Attachment 1. FSIS recognizes that establishments may be producing products that fall under different alternative control programs. These various products may best be covered in individual HACCP plans, though an establishment is free to adopt whatever program can best enable compliance. Conversely, products processed according to different alternatives, may by covered by a single HACCP plan. Products are grouped in a single HACCP plan when the hazards, CCPs, and critical limits are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and observed in practice. Thus, a single HACCP plan could cover hotdogs 6", "Updated Compliance Guidelines May 2006 formulated with and without antimicrobial agents (Alternative 2 and Alternative 3), provided that the HACCP plan clearly distinguishes any critical differences. In addition, if an establishment uses the same food contact surfaces (FCS) on the same production day (clean-up to clean-up) for products falling within two alternatives, the products should be treated as if they were in the higher risk category with respect to on-going verification by the establishment, including testing of product, food contact surfaces and the environment. Products Covered by the *Listeria* rule: Establishments should determine the alternatives to which it will adhere in its processes. The following steps can guide establishments in making this decision: \u2022 Determine whether product is RTE or not RTE (NRTE) Resource 1 of the Directive and Attachment 2 of these Compliance Guidelines can guide the establishment in determining whether its product is RTE or NRTE. NRTE products are not covered by the rule. \u2022 If the product is RTE, the establishment should determine whether the product is exposed to the environment after the lethality treatment (e.g., cooking) and before packaging. Examples of exposure to the

environment after the lethality treatment are the following: 1) when product is removed from its cooking bag and re-packaged; 2) when product is removed from the cooking bag and sliced or cut-up and re-packaged; or 3) when product is peeled and repackaged; or when it is fermented or salt-cured or dried and smoked and packaged. (e.g., roast beef, cooked ham for slicing, hotdogs, fermented sausage, cured ham, and jerky). \u2022 If the product is not exposed to the environment after the lethality treatment and before packaging, then the product is not covered by the Listeria rule. Examples of these products are fully cooked product in cook-in-bag that leaves the official establishment in the intact cooking bag; thermally processed, commercially sterile products; and products receiving a lethality treatment and hot-filled as long as the lethality temperature and sanitary handling are maintained during the period of time in which the product moves from the point of lethality to the point of packaging. \u2022 If the product is post-lethality exposed, the establishment should determine the control methods it is using to control *L. monocytogenes* during the post-lethality exposure. The control methods used by the establishment will determine to what alternative the product can be categorized. 1. Alternative 1 Alternative 1 requires the use of post-lethality treatment (which maybe an antimicrobial agent or process) to reduce or eliminate *L. monocytogenes* and an antimicrobial agent or process to suppress or limit the growth of the pathogen. For RTE products that are cooked and then removed from their cooking bag and sliced, diced or repackaged, there is a risk of cross contamination from the equipment, conveyor belts and the processing environment. These products need to be aseptically processed and then repackaged under strict sanitary conditions to prevent contamination from *L. monocytogenes*. 7", "Updated Compliance Guidelines May 2006 a. Post-Lethality Treatment Post lethality treatments such as steam pasteurization, hot water pasteurization, radiant heating and high pressure processing have been developed to prevent or eliminate postprocessing contamination by *L. monocytogenes*. RTE products where post-lethality treatments were shown by studies to be effective in reducing the level of *L. monocytogenes* are whole or formed ham, whole and split roast beef, turkey ham, chicken breast fillets and strips, and sliced ham, sliced turkey, and sliced roast beef. Post-lethality treatments can be applied as a pre-packaging treatment, e.g. radiant heating, or as post-packaging treatments, e.g., hot water pasteurization, steam pasteurization, and high pressure processing. Ultra violet treatment can be used either as a post-lethality treatment or antimicrobial agent or process depending on whether it eliminates, reduces or suppresses growth of *L. monocytogenes*. Some of the published studies on postlethality treatments are reviewed in Attachment 4. Studies on post-lethality treatments showed reductions of inoculated *L. monocytogenes* from 1 to 7 log<sub>10</sub> CFU/g depending on the product type, and duration, temperature and pressure of treatment. Higher log reductions were obtained when both pre-packaging and post-packaging surface pasteurizations were applied, and when post-lethality pasteurization was combined with the use of antimicrobial agents. Establishments should refer to the details of these studies if they want to use the intervention method in their processing. The guidelines will be updated to include studies or other methods as they become available. Validation of Post-lethality Treatment The post-lethality treatment that reduces or eliminates the pathogen must be included in the establishment\u2019s HACCP plan. The post-lethality treatment must be validated according to 9 CFR 417.4 as being effective in eliminating or reducing *L. monocytogenes* to an undetectable level, and the validation should specify the log reduction or suppression achieved by the post-lethality treatment and

antimicrobial agents. Scott et al. (2005) developed guidelines for conducting challenge testing of foods for *L. monocytogenes* (Attachment 9). The effectiveness of the post-lethality treatments and antimicrobial agents must be verified, and establishments should make the verification results available to FSIS personnel upon request. FSIS expects the establishment's HACCP documentation to demonstrate that the post-lethality treatment is adequate to eliminate or reduce *L. monocytogenes* to an undetectable level. In cases of pre-packaging treatment, the establishment must be able to demonstrate how the level of contamination that may occur before packaging is eliminated. An establishment can use available published research studies as reference for their validation provided these studies use the product type or size, the type of equipment, time, temperature, pressure and other variables used in the study in order to result in equivalent level of reduction of *L. monocytogenes*. An establishment that uses products, treatments or variables other than those used in the referenced studies must perform its own validation studies to determine the effective reduction of *L. monocytogenes* as a result of the post-lethality treatment or antimicrobial agent applied to the products. Some of the published studies use different products and report a range of levels of reduction of 8<sup>o</sup>, "Updated Compliance Guidelines May 2006 L. monocytogenes. In this case, the establishment must validate the use of the postlethality treatment or antimicrobial agent for its specific products. The establishment must specify the level of reduction achieved by the post-lethality treatment or antimicrobial agent applied in its validation to show that the product is safe. In the absence of published peer-reviewed paper that would contain information needed for validation, unpublished studies may be used provided there is supporting documentation that the data and analysis of results demonstrate that the specific level of application on specified products or range of products is effective to produce a safe product. In addition to the validation of the post-lethality treatment and antimicrobial agent, the establishment must verify its effectiveness by testing for *L. monocytogenes*.

**Antimicrobial Process that Acts also as a Post-lethality Treatment**

An example of an antimicrobial process that controls the growth of *L. monocytogenes* in the post-lethality environment is a lethality process that renders a RTE product shelf stable. Shelf stable products are formulated with salt, nitrites and other additives, and processed to achieve a water activity, pH and moisture-protein ratio that will reduce the level of *L. monocytogenes* and other pathogens during processing. In addition, the lethality treatment exerts a continuing bactericidal and bacteriostatic effect in the product, enabling the product to not support the growth of *L. monocytogenes* and other pathogens during the shelf life of the product at ambient temperatures. Since products with water activity less than 0.85 will not support the growth of *L. monocytogenes* and can sometimes even cause *L. monocytogenes* death, FSIS will consider water activity of <0.85 at the time the product is packed to be a post-lethality treatment if there is a bactericidal effect (death of bacterial cells leading to a reduction in number) in the specific product, and the establishment has provided support documentation to document that the intended effect occurs prior to distribution of the product into commerce. In this case, the antimicrobial process could serve as both a postlethality treatment and growth inhibitor. The establishment should have documentation on file (e.g., copy of a published report, challenge study) to demonstrate the effectiveness of the lethality treatment through the shelf life of the product. These shelf stable products can be classified in Alternative 1 if the requirements for this alternative are satisfied. The requirement that an antimicrobial process or

product formulated with an antimicrobial agent suppress or limit growth throughout the commercial shelf life means that an establishment must have validated that the process or formulation does what is claimed. These validation records must be available to FSIS. Establishments must include in their HACCP plans the antimicrobial process used (e.g. drying, cooking\frying, or rendering) and the water activity achieved that renders the product shelf stable. Examples are shelf stable RTE jerky, country cured ham, pepperoni, dried soups, and pork rinds. Pre-packaging Treatment as a Post-lethality Treatment A pre-packaging treatment such as radiant heating can be used as a post-lethality treatment as long as it is validated to eliminate or reduce the level of *L. monocytogenes*. Since this is a post-lethality pre-packaging treatment, there is possible exposure to the environment after the treatment and before packaging. If there is separation between the treatment and packaging, then conditions have to be met to ensure a hygienic 9", "Updated Compliance Guidelines May 2006 environment to preclude contamination, or the post-lethality treatment would not likely be considered effective by FSIS. Some establishments may place the packaging machine right after the radiant heat treatment to reduce or eliminate this exposure. Support documentation must be made a part of the hazard analysis decision-making documents and validation data must be included in the HACCP plan. Studies have also shown that the use of pre-packaging treatment combined with a post-lethality treatment resulted in a higher log reduction of the pathogen. Post-lethality Treatment Not a Critical Control Point (CCP) in the HACCP Plan The rule states that *L. monocytogenes* is a hazard reasonably likely to occur for postlethality exposed product unless there is a control measure incorporated in the HACCP plan, prerequisite program or Sanitation SOP. For Alternative 1 or Alternative 2 (postlethality treatment) control measures, if a post-lethality treatment is used, it must be included in the establishment's HACCP plan as a CCP. FSIS encourages the use of any effective intervention for controlling *L. monocytogenes* contamination. However, if an establishment uses a post-lethality treatment for its product but does not incorporate the post-lethality treatment as a CCP, the post-lethality treatment cannot be used to justify Alternative 1 or 2 (post-lethality treatment). It could place the control measures for the operation in the Sanitation SOP or prerequisite program and the product can be categorized in Alternative 2 (antimicrobial agent) or Alternative 3. Why an Antimicrobial Agent can be included in the HACCP Plan, Sanitation SOP or prerequisite program. If an establishment chooses Alternative 2 and chooses to use an antimicrobial agent or process, the establishment can include the antimicrobial agent or process as a CCP in the HACCP plan, in the Sanitation SOP, or in a prerequisite program. The Agency gave establishments this flexibility because the Agency believes that how establishments choose to address control of *L. monocytogenes* will determine how they fit in the hierarchy. Antimicrobial agents or processes do not necessarily eliminate or reduce a food safety hazard from occurring but rather control for the hazard, by preventing or suppressing the growth of *L. monocytogenes*. A post-lethality process is applied at a specific step in the process that eliminates, reduces to an acceptable level, or prevents a food safety hazard, i.e., a critical control point. However, when the antimicrobial agent does eliminate or significantly reduce *L. monocytogenes*, it could be designated a CCP in the HACCP plan. On the other hand, if it only suppresses growth of *L. monocytogenes*, it could be addressed in the Sanitation SOP or other prerequisite programs. Hot-packed products: edible oils and fats, lard, soups Edible oils and fats resulting from a rendering process that processes them to 180\u00ba F and maintains at 160\u00ba F, with a

water activity of less than 0.2 making them shelf stable are considered RTE. Rendering is intended to make this meat food product a ready-to-use ingredient in the preparation of other foods, e.g., edible tallow and lard are used as shortening. They do not require additional lethality treatment before being consumed. If these products are hot filled (as defined above) and packaged, they are not considered post-lethality exposed and therefore are not covered by the rule. However, these products would be considered NRTE and not covered by the rule if the process calls for partially 10", "Updated Compliance Guidelines May 2006 rendering animal fat for tallow or lard and then further processing or finished rendering in another plant. Soups and other products that are cooked to eliminate pathogens and hot-packed in the final packaging material are RTE, but are not considered post-lethality exposed. Therefore the Listeria rule does not apply.

b. Antimicrobial Agents or Processes

Antimicrobial agents and processes must suppress or limit the growth of *L. monocytogenes* throughout the product shelf life i.e., the amount of time the product can be stored under specified conditions and still remain safe with acceptable quality. Antimicrobial agents were shown in research studies to reduce the levels of *L. monocytogenes*. These include lactates and diacetates added in the formulation and growth inhibitors in the immediate packaging material. These were shown to be effective in the control *L. monocytogenes* in RTE products such as hotdogs, bologna, cotto salami, and bratwurst. Antimicrobial agents can be added to the product during formulation, to the finished product or to the packaging material to inhibit growth of *L. monocytogenes* in the postlethality exposed product during its refrigerated shelf life. Lactates and diacetates are some antimicrobials added to the formulation of RTE meat and poultry products. Establishments should use antimicrobial agents that have been approved by FDA and FSIS for processed RTE meat and poultry products. FSIS recently increased the permissible levels of sodium diacetate as a flavor enhancer and as an inhibitor of pathogen growth to 0.25 % (65 FR 3121-3123\2000). The rule also permitted the use of sodium lactate and potassium lactate in fully cooked meat, meat food products, poultry, and poultry food products, except for infant foods and formulas at levels of up to 4.8 % of total product formulation for the purpose of inhibiting the growth of certain pathogens. Approved antimicrobials for processed meat and poultry products can be found in 9 CFR 424.21 and in Directive 7120.1. The addition of antimicrobials in the formulation must be included in the ingredient statement of the label. Studies on antimicrobials added to the packaging material or active packaging showed about 1-2 log<sub>10</sub> CFU\g reduction of *L. monocytogenes* during the refrigerated shelf life of the products. Based on published studies, growth reduction or inhibition achieved by adding these antimicrobials to product formulation depends on a variety of factors, such as the level of antimicrobial agent added, product formulation and whether the agent was added during formulation or to the finished product. Depending on the amount of antimicrobials and other growth inhibitors added to the product formulation and other ingredients in the product, growth inhibition of *L. monocytogenes* was shown to range from 30 days to 120 days at refrigerated temperatures. Some published studies on antimicrobials are reviewed in Attachment 4. Establishments should refer to the details of the studies if they want to use the intervention method in their processing. A report of the National Advisory Committee for Microbiological Criteria for Foods gives guidance on 11", "Updated Compliance Guidelines May 2006 how to establish safety-based consume-by date labels for RTE foods, and can be found in Attachment 9. An establishment that uses agents that inhibit *L. monocytogenes* on equipment and food contact surfaces in addition to using growth inhibitors

in the product formulation can qualify the product for Alternative 2 using antimicrobial agents. Using these inhibiting agents on equipment and food contact surfaces can be considered as part of the sanitation program. These inhibiting agents applied to equipment and food contact surfaces must be GRAS and approved by FDA. Antimicrobial Processes Some RTE products with added salt, nitrites and other additives achieve a water activity, pH, or moisture-protein-ratio that will reduce the level of *L. monocytogenes* and other pathogens during processing and continue to inhibit the growth of the pathogens during the refrigerated shelf life. These products are not shelf stable because they need to be refrigerated during their shelf life, but because of the water activity and pH attained during the initial lethality treatment, these products may not support the growth of *L. monocytogenes* during its refrigerated shelf life. These products can be classified as using an antimicrobial agent or process. Examples of these products are RTE, not shelf stable fermented sausages and country cured hams. Another antimicrobial process that controls the growth of *L. monocytogenes* in the postlethality environment is freezing of RTE products. Freezing prevents the growth of any microorganisms in the product because their metabolic activities are arrested, but depending on the method and length of freezing and other factors, some microbial kill can also result. Like other microorganisms, *L. monocytogenes* is resistant to freezing. Once the product is thawed, metabolic activities of microorganisms may resume, depending on whether the microorganisms are killed, injured, or not affected at all. Therefore this antimicrobial process is only effective while the product is frozen. The requirement that a product remain frozen throughout its shelf life therefore excludes situations where a product is distributed frozen and then thawed and sold as a refrigerated product. If the product is thawed as part of the preparation process by the consumer, the product will be deemed to have been frozen throughout its shelf life. Labels of RTE frozen products contain cooking instructions for the frozen product and for thawed and refrigerated product, and instructions for thawing at refrigerated temperatures. Examples of frozen RTE products are fully cooked frozen chicken nuggets, fully cooked frozen chicken breast patties or fully cooked frozen dinners. The chart below shows the growth limits for *L. monocytogenes*. These limits represent scientific consensus as to the temperature, pH, and water activity levels for *L. monocytogenes* (ICMSF, 1996). The pathogen can grow between the minimum and maximum levels. The pathogen cannot grow below the minimum growth limits and above the maximum growth limits. Establishments with processes that achieve levels below the minimum limits can use these as their control for the pathogen. Establishments that comply with the levels below the minimum growth parameters need not conduct further validation for their products to prove that growth of *L. monocytogenes* is not 12", "Updated Compliance Guidelines May 2006 13 supported throughout the shelf-life of the product. The Agency will conduct the least amount of verification, including sampling, within the Alternative on processes or products that have been demonstrated to not support any growth of *L. monocytogenes*. The establishment can place the attached reference on file in their control program documentation. However, the establishment should conduct on-going monitoring and verification activities to demonstrate that they are maintaining the conditions for pH, water activity, or temperature. Growth limits for *Listeria monocytogenes* (ICMSF, 1996) Minimum Optimum Maximum Temperature -0.4 °C (31.3 °F) 37 °C (98.6°F) 45 °C (113 °F) pH 4.39 7.0 9.4 Water activity 0.92 --- The antimicrobial agent or process that limits or suppresses *L. monocytogenes* must be included in the

establishment's HACCP plan, or sanitation SOP, or other prerequisite program. The establishment must have documentation in its HACCP plan, Sanitation SOP or other prerequisite program to demonstrate that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*. The establishment must validate and verify the effectiveness of its antimicrobial agent or process included in its HACCP plan in accordance with 9 CFR 417.4. If the antimicrobial agent or process is in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 9 CFR 416.14. If the control measures for *L. monocytogenes* are contained in a prerequisite program other than a Sanitation SOP, the program must ensure that the program is effective and does not cause the hazard analysis or the HACCP plan to be inadequate. The establishment must include the program and the results produced by the program in the documentation that the establishment maintains as required in 9 CFR 417.5. The establishment must include supporting documentation to show the effectiveness of the antimicrobials in suppressing or limiting *L. monocytogenes* in the HACCP plan, Sanitation SOP or prerequisite programs. An establishment can use published studies as reference for its validation and supporting documentation as long as it uses the same treatment variables as those used in the study. These variables include among others, specific antimicrobial agents and products, concentration, time and temperature of effectiveness. Use of antimicrobial singly or in combination, with different concentration and other variables, and for products not used in the studies must be validated or tested for their effectiveness. This must be validated for the HACCP plan, or documented in the Sanitation SOP or other prerequisite programs. The establishment must verify that the antimicrobial program is effective by testing product for *L. monocytogenes* and must verify that it does not cause the hazard analysis or the HACCP plan to be inadequate. That is, an effective prerequisite program will reduce the likelihood of occurrence of a hazard so that the product is safe. Based on such a program, an establishment could deem a hazard not reasonably likely to occur in its hazard analysis and therefore a CCP", "Updated Compliance Guidelines May 2006 for the hazard may not be needed. However, if the prerequisite program is not effective (or is not being followed), it means the hazard may become reasonably likely to occur. In such a case, the HACCP plan would be inadequate, since it does not include a CCP for the hazard. Accordingly, FSIS expects that establishments will routinely assess the effectiveness of the prerequisite programs and make any necessary adjustments to ensure that *L. monocytogenes* does not become a hazard reasonably likely to occur. An establishment with products in Alternative 1 must maintain sanitation in the postlethality processing environment in accordance with Part 416. The establishment must make available upon request to FSIS inspection personnel, the verification results that demonstrate the effectiveness of its controls, whether from carrying out its HACCP plan, or its Sanitation SOP, or other prerequisite program. The post-lethality processing environment encompasses all areas an exposed product goes through from the end of the lethality step to the time it is packaged. Should a post-lethality processing environment contact surface test positive, the establishment should investigate the potential source of the positive finding, take corrective actions to eliminate the source, and verify the effectiveness of the corrective actions. In certain situations, the source of Listeria may be the specific equipment that tested positive, such as a slicer. In other situations, such as a positive on a conveyor belt, the source may be a different location than the area tested. FSIS considers a product to be adulterated if a food contact surface, such as a surface of equipment used in the production of

the product, tests positive for *L. monocytogenes*. However, if a RTE post-lethality exposed product receives a post-lethality treatment (Alternative 1 or Alternative 2), that product which came in direct contact with a food contact surface that tested positive for *L. monocytogenes* would not summarily be considered adulterated. This is because the post-lethality treatment should have been validated and documented in the establishment's HACCP plan to be effective in eliminating or reducing *L. monocytogenes*. Without such validation and documentation, the establishment would have to present compelling argument for why the post-lethality treatment was effective for the Agency to conclude that the product is not adulterated. The product disposition would be made as part of the establishment's corrective actions under 9 CFR 417.3 or 416.15. Establishments have been using prerequisite programs before in their processing operations, and the Agency has recently included the use of prerequisite programs as an option in another policy document. However, giving the establishment the option to include the antimicrobial agent or process in a prerequisite program in this rule is the first time prerequisite programs are recognized in codified regulations. An establishment with products in Alternative 1 must have a post-lethality treatment that effectively reduces or eliminates *L. monocytogenes*, and an antimicrobial agent or process that suppresses any growth of the pathogen and extends the effect of the post-lethality treatment during the shelf life of the product. The Agency considers these treatments to be effective in controlling the pathogen resulting in a safe RTE product. If an establishment has an effective Sanitation SOP, any post-lethality contamination by *L. monocytogenes* would be very low, so the post-lethality treatment and the antimicrobial 14", "Updated Compliance Guidelines May 2006 will be able to reduce or eliminate this contamination. If there is gross contamination, the effectiveness of the treatments may be reduced or negated. Therefore the Agency is relying on the establishment's Sanitation SOP to prevent contamination with *L. monocytogenes*, and the post-lethality treatment and antimicrobials to further reduce or eliminate or suppress the pathogen. Because of this combination of controls, the Agency is not requiring establishments to have a testing program for food contact surfaces. However, testing is recommended. Testing food contact surfaces in Alternative 1 could be minimal and primarily serve as a means to verify that the sanitary conditions in the establishment will not overwhelm the post-lethality treatment. A positive test on a food contact surface should trigger the establishment to review its sanitation program and post-lethality treatment to ensure that the treatment was properly applied for the product that came into contact with the positive. Furthermore, the establishment may determine that it is appropriate to conduct a product test after the post-lethality treatment to provide additional assurance that the treatment was effective. The establishments may test food contact surfaces for *L. monocytogenes*, or its indicator organisms, *Listeria* spp. or *Listeria*-like organisms periodically, to verify that their Sanitation SOP is effective. *L. monocytogenes* belongs to the *Listeria* genus or group and species (sp.) *monocytogenes*. The genus *Listeria* includes other species (spp.) in addition to *monocytogenes*. Therefore a positive test for *Listeria* spp. or *Listeria*-like organisms would indicate the potential presence of the pathogen. If these specific indicator organisms test negative, this is indicative that *L. monocytogenes* is not present. Aerobic plate counts (APC), total plate counts (TPC), and coliforms are not appropriate indicator organisms for *L. monocytogenes*. Results from these tests do not indicate the presence or absence of the pathogen, although they could provide a measure of general sanitation. Guidelines on

sanitation procedures and food contact surface testing for *L. monocytogenes* or its indicator organisms, *Listeria* spp. or *Listeria*-like organisms, are found in section G-VII-3. 2. Alternative 2 An establishment that identifies its products in Alternative 2 must apply either a post lethality treatment or an antimicrobial agent or process that controls the growth of *L. monocytogenes*. Post-lethality treatments and antimicrobial agents and processes discussed above in the section on Alternative 1 can be used for Alternative 2. If an establishment uses a post-lethality treatment, it must have the post-lethality treatment in its HACCP plan and the treatment must be validated according to 9 CFR 417.4 as being effective in reducing or eliminating *L. monocytogenes* specifying the log reduction achieved by the post-lethality treatment. The effectiveness of the post-lethality treatment should be verified by testing the finished product for *L. monocytogenes*, and the verification results should be made available to FSIS personnel upon request. FSIS expects the establishment to conduct on-going verification of the CCP as detailed in its HACCP plan. The sanitary conditions likely will have a direct bearing on whether or not the post-lethality treatment is effective. If an establishment has a product identified in Alternative 2 and uses a post lethality treatment to control *L. monocytogenes* in its product, it is not required to test food contact surfaces in the post-lethality environment, 15", "Updated Compliance Guidelines May 2006 although it is recommended. However, FSIS most likely will conduct verification testing less frequently if the establishment tests food contact surfaces for *L. monocytogenes*, or its indicator organisms (*Listeria* spp. or *Listeria*-like organisms). Under Alternative 2, an establishment that only uses an antimicrobial agent or process to control *L. monocytogenes* in its product must have the agent or process included in the establishment\u2019s HACCP plan, or sanitation SOP, or other prerequisite program. The establishment should have documentation in its HACCP plan, Sanitation SOP or other prerequisite program to demonstrate that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*. The establishment should document the log levels of the pathogen that the antimicrobial agent or process can suppress and the length of time under specific temperatures in days that the antimicrobial is effective. The establishment must validate and verify the effectiveness of its antimicrobial agent or process included in its HACCP plan in accordance with 9 CFR 417.4. The Agency expects that the use of post-lethality treatments or antimicrobial agents and processes, will prevent a significant increase in numbers of organisms during the product\u2019s shelf life to levels resulting in a public health hazard. If the antimicrobial agent or process is in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 9 CFR 416.14. If the control measures for *L. monocytogenes* are contained in a prerequisite program other than a Sanitation SOP, the establishment must ensure that the program is effective and does not cause the hazard analysis or the HACCP plan to be inadequate. The establishment should document its antimicrobial agent or process, its implementation and its verification results sufficiently in order to show that the HACCP plan is adequate in controlling the pathogen. The establishment must verify that the antimicrobials are effective by testing for *L. monocytogenes* and have the verification results whether from carrying out its HACCP plan, or Sanitation SOP, or other prerequisite program, available upon request to FSIS. If an establishment produces a product under Alternative 2 by using an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes* in its product, it should maintain sanitation in the post-lethality environment in accordance with part 9 CFR 416. The sanitation program must include testing

for food contact surfaces in the post-lethality environment to ensure that the surfaces are sanitary and free of L. monocytogenes or its indicator organisms (Listeria spp. or Listeria-like organisms). Studies on antimicrobials showed growth inhibition of L. monocytogenes if present at low levels of contamination during the shelf life of the RTE product. Antimicrobials were not shown to be effective at higher levels of contamination, so an effective sanitation program, which includes verification testing for food contact surfaces, should be implemented at the same time that antimicrobials are used. The sanitation program must provide for testing food contact surfaces in the post-lethality processing area to ensure that surfaces are sanitary and free of L. monocytogenes or its indicator organisms. It must include the frequency of testing and identify the size and location of the sample sites to be sampled. It must include an explanation of why the testing frequency is sufficient to ensure that effective control of L. monocytogenes or its indicator organisms is maintained. In addition, the establishment must identify the conditions under which the establishment will implement hold-and-test procedures following a positive test for L. monocytogenes or its indicator organisms. The product produced with an antimicrobial agent or process will be subject to more frequent FSIS verification testing compared to a product using a post-lethality treatment to eliminate L. monocytogenes.

3. Alternative 3 Under Alternative 3, the establishment does not apply a post-lethality treatment or an antimicrobial agent or process to control the growth of L. monocytogenes in the postlethality exposed product. An establishment producing this type of product must control the pathogen in its post-lethality processing environment through the use of sanitation control measures, which may be incorporated in the establishment\u2019s HACCP plan, Sanitation SOP or prerequisite program. Because the establishment is not relying upon a post-lethality treatment or an antimicrobial agent or process to control L. monocytogenes, the product will be subject to frequent FSIS verification testing compared to the other alternatives. Examples of products in this alternative are fully cooked meat and poultry that are packaged and refrigerated such as hotdogs, deli meats, chicken nuggets, or chicken patties that did not receive any post-lethality treatment or antimicrobial agent or process. For this alternative, the establishment must maintain sanitation in the post-lethality processing environment in accordance with 9 CFR 416. The sanitation program must provide for testing food contact surfaces in the post-lethality processing area to ensure that surfaces are sanitary and free of L. monocytogenes or its indicator organisms. The testing program should include the frequency of testing, identify the size and location of the sample sites and include an explanation of why the testing frequency is sufficient to ensure that effective control of L. monocytogenes or its indicator organisms is maintained. In addition, the establishment should identify the conditions under which the establishment will implement hold-and-test procedures following a positive test for L. monocytogenes or its indicator organisms on a food contact surface. Recommended testing frequencies are discussed in the Sanitation section G VII-1. Moreover, an establishment that produces a deli product or a hotdog product must verify that the corrective actions that it takes with respect to sanitation after an initial positive test for L. monocytogenes or its indicator organisms on a food contact surface in the postlethality processing environment are effective. The corrective action must indicate steps that the establishment will take to clean and sanitize the suspected food contact surfaces to eliminate the contamination. The effectiveness of the corrective action can be verified by follow-up testing that includes a targeted test of the specific site on the food contact surface

area that is the most likely source of contamination by the organism and other additional tests in the surrounding food contact surface area as necessary. During this follow-up testing, if the establishment obtains a second positive test for L. monocytogenes or an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the establishment 17", "Updated Compliance Guidelines May 2006 corrects the sanitation problem indicated by the test result. If the food contact surface is positive for L. monocytogenes, the affected product lot (product that had direct contact with the food contact surface) would be considered adulterated. Affected product (product or food contact surface tested positive for L. monocytogenes) must be recalled, if in commerce, and destroyed or reworked with a process that is destructive of L. monocytogenes. If the food contact surface is positive for Listeria spp. or Listeria-like organisms (indicator organisms), the affected products are not considered adulterated. Establishments may move production from an affected line provided the new production line does not include the food contact surfaces that tested positive for L. monocytogenes and the new food and non-food contact surface areas are tested. In order to be able to release into commerce the lots of product that may have become contaminated with L. monocytogenes from the positive food contact surface, the establishment must sample and test the lots for L. monocytogenes or its indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with L. monocytogenes. The ICMSF (International Commission on Microbiological Specifications for Foods) statistical sampling plan is an example of a plan that some establishments have used (Attachment 5). If the held product tests positive for L. monocytogenes, the sampled product lot is considered adulterated and must be withheld from commerce. The establishment must destroy the held product, or rework the held product using a process that is destructive of L. monocytogenes. The establishment must document the results of the testing and the disposition of the product. An example of a hold-and test scenario can be found in section G-VII-4 or in Attachment 6. Products and the processing environment under Alternative 3 are likely to be subject to more frequent verification testing by FSIS than products and the processing environment in Alternative 1 or 2. This is because the products in Alternatives 1 and 2 are formulated and\or processed to reduce or eliminate L. monocytogenes or limit its growth in the RTE product and present a lower risk than products in Alternative 3 that do not have these interventions. Likewise, an establishment in Alternative 3 that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products because deli and hotdog products were ranked as higher risks for L. monocytogenes contamination in the FDA\FSIS risk assessment. In determining the frequency of verification sampling, the Agency expects to take into consideration the level of pathogen reduction achieved by the post-lethality treatment, the growth inhibition achieved by the antimicrobial agent or process during the shelf life of the product, and the rigor of the sanitation and testing program, i.e., whether the sanitation and testing program exceeds the compliance guidelines. Products considered as deli and hotdog Like all RTE products exposed to the processing environment, deli and hotdog products that are exposed to the post-processing environment are subject to this rule. If the RTE 18", "Updated Compliance Guidelines May 2006 product is not exposed to the post-processing environment, it is not subject to this rule. Depending on the method that an establishment chooses to control L. monocytogenes contamination in its processing, deli and hotdog products may be in Alternative

1, 2, or 3. Deli and hotdog products that receive a post-lethality treatment and antimicrobial agent or process fall under Alternative 1. An example is a hotdog that includes lactates or diacetates in the formulation and is steam pasteurized after repackaging. Deli and hotdog products with antimicrobial agents such as lactates or diacetates added in the formulation, but with no post-process lethality treatment would fall under Alternative 2. Another example of an Alternative 2 product is a hotdog product that received only a post-lethality treatment such as being packaged in casings with an antimicrobial agent that reduces the level of *L. monocytogenes*. If an establishment does not use a postlethality treatment or an antimicrobial agent or process in the processing of deli and hotdog products, these products would fall under Alternative 3. Deli salads are also RTE post-lethality exposed, so they are covered by the rule. Deli meats that are used in salads receive additional handling after they are removed from their packages, and are mixed with other ingredients, thus exposing them to crosscontamination. An establishment producing deli salads with the meat and poultry components that receive a post-lethality treatment or antimicrobial agent needs to have supporting documentation showing that the antimicrobial action is sufficient to control *L. monocytogenes* in all the salad ingredients if they choose to have their product in Alternative 1 or 2. A deli salad with a final pH below 4.39 in all ingredients of the salad, (e.g. due to the salad dressing or other ingredients added) would fall under Alternative 2, using an antimicrobial agent. A cook-in-bag product such as cooked ham or poultry roll that is shipped intact in its cooking bag is not covered by the rule. If the cook-in-bag product sold to a deli is not removed from the bag in the deli but sold to the consumer in the original cooking bag, then it is not considered post-lethality exposed, and therefore is not covered by the Listeria rule. It is also not considered a deli product because simply selling a product in a deli does not result in a product that is defined in 9 CFR 430 as a deli product. However, if it is sold to an establishment where it will be sliced and served in a sandwich or sold to the consumer, it is considered as a deli product. Cooked chicken filets that are sliced or cut in strips, and frozen are covered under the rule since they are post-lethality exposed when sliced or cut. If these frozen products are shipped frozen, they fall under Alternative 2, using an antimicrobial process. If these products were refrigerated and shipped refrigerated, these will fall in Alternative 3. C. Enhanced Level of Effectiveness of the Post-Lethality Treatment and the Antimicrobial Agent or Process Products that receive a post lethality treatment achieving at least 2.0 log reduction of *L. monocytogenes* may likely be sampled less frequently by FSIS than products that receive a post-lethality treatment achieving <2.0 log reduction. Post lethality treatment achieving <1.0 log reduction will likely not be considered a post-lethality treatment for Alternatives 19", "Updated Compliance Guidelines May 2006 20 1 and 2 for purposes of the rule nor likely be eligible to apply for the labeling claim regarding enhanced protection from *L. monocytogenes* without supporting documentation that demonstrates this level of reduction provides a sufficient safety margin. In this case, the product will be viewed by the Agency as produced under Alternative 2 or 3, depending on whether the establishment uses an antimicrobial agent or process in addition to the post-lethality treatment Likewise products receiving an antimicrobial agent or process that suppresses growth of *L. monocytogenes* such that there is 1.0 log or less increase during its shelf life may be expected to be sampled less frequently than products receiving an antimicrobial agent or process that allows the growth of *L. monocytogenes* by greater than 1.0 log increase during its shelf life. Use of an antimicrobial agent or process that allows more than

2.0 log growth increase during shelf life may not be considered an antimicrobial agent or process for Alternatives 1 and 2 for purposes of this rule unless there is supporting documentation that demonstrates that this level of growth provides a sufficient safety margin. In such cases, the product may be moved to a higher risk Alternative. In addition, products that allow greater than 1.0 log growth of the pathogen during its shelf life will not likely be eligible to apply for the labeling claim regarding enhanced protection from *L. monocytogenes*. In this case, the product may also be moved to a higher risk Alternative. The Agency will do the least amount of verification, including sampling, within the Alternative, of 1) products that include processes using extrinsic and intrinsic characteristics of freezing below -0.4°C (31.3°F), pH below 4.39 or water activity below 0.92 and have been demonstrated to not support the growth of *L. monocytogenes*; and 2) products that are formulated to prevent the growth of *L. monocytogenes* in the event of a post-lethality contamination. This means that the effect of the antimicrobial agent/process is effective in limiting growth not only at the time of packaging and during the shelf life of the intact product but also in the event that the package integrity is compromised or the product is sliced at retail. The document should show validation and documentation of the effectiveness of the antimicrobial agent or process for these scenarios. The chart below shows examples of levels of control that establishments could achieve with regards to post-lethality treatment and antimicrobial agent or process for Alternatives 1 and 2. Establishments should use these levels to base their minimum verification measures in determining the effectiveness of their controls.", "Updated Compliance Guidelines May 2006 Expected Levels of Control for Post-lethality Treatments and Antimicrobial Agents or Processes Levels of reduction or inhibition achieved to control *L. monocytogenes* Higher Level1 Lower level2 Not Eligible3 Post-lethality => 2 < 2 < 1 Treatment ( $\log_{10}$  (equal to or (less than 2) (less than 1) reduction of *L. greater than 2) moncytogenes) Antimicrobial Agent  $\leq 1 > 1 > 2$  or Processes ( $\log_{10}$  (less than or (greater than 1) (greater than 2) allowed increase of equal to 1) *L. moncytogenes*) 1Relatively less sampling by FSIS 2Relatively more sampling by FSIS 3Unless there is supporting documentation D. Labeling Antimicrobial agents that are added to RTE products, either to the formulation or to the finished RTE product, and those that are included in the primary packaging material of RTE products must to be listed in the ingredients statement of the product label. In addition, establishments that use a post-lethality treatment or an antimicrobial validated to effectively eliminate or reduce *L. moncytogenes*, or suppress or limit its growth in the product, can make claims or special statements on the labels of their products regarding the presence and purpose of use of the substances. The purpose of such claims is to inform consumers about measures taken by the processor to ensure the safety of the product and enable consumers to make informed purchase decisions. Such claims are voluntary and may be of value to consumers especially those in groups most vulnerable to foodborne illness. Processors need to document their validation of these claims. An example of a statement that can be made is: \u201cPotassium lactate added to prevent the growth of *L. moncytogenes*. \u201d All labeling claims and label changes to add such claims must be submitted for evaluation and approval to the FSIS Labeling and Consumer Protection Staff. Labeling Issues Generic label approval and the new use of approved or listed safe and suitable antimicrobial agents. An establishment does not need to submit a label to the Agency for evaluation and approval when it adds an antimicrobial agent (e.g., sodium diacetate) that is approved or listed by FDA and FSIS as safe and suitable to a product formulation, provided the*

label can be approved in accordance with the generic labeling regulations in 9 CFR 317.5 and 381.133, (i.e., the product must have a standard of identity in Title 9 of the Code of Federal Regulations (CFR) or the Food standards and Labeling Policy Book and the labeling must not bear special claims, guarantees, or foreign language). All 21", "Updated Compliance Guidelines May 2006 22 ingredients including antimicrobial agents require declaration on the label. Establishments may submit for temporary approval to use existing stocks of labels with revised formulations (up to six months) in order to update and produce new labels. Approval of labels bearing claims. As with all claims on labels, if there is a labeling claim about the use of antimicrobial agents or lethality treatments, the labels must be submitted to the Agency for evaluation and approval before use. Documents for validation of the effectiveness of the post-lethality treatment or antimicrobial agent must be included with the label application. An establishment cannot put labeling claims of enhanced protection on RTE products that are not post-lethality exposed, such as cookin-bag that are opened only by the consumer, because these are not covered by the Listeria rule. Antimicrobial agents in comminuted beef products. The standard of identity for ground beef, chopped beef, and their cooked versions, does not provide for the addition of ingredients with the exception of non-fluid condimental seasonings, e.g., salt, pepper. Therefore, these products cannot be formulated with or treated with antimicrobial agents that are classified as having a lasting technical effect, e.g., sodium lactate and sodium diacetate, unless these products are descriptively labeled to reflect the use of the antimicrobial agents. For example, if sodium lactate was added, the product name on the label should be \u201cGround Beef with Sodium Lactate\u201d. However, for beef patties, which are standardized products, the regulations permit the addition of ingredients such as, antimicrobial agents. Therefore, comminuted beef products formulated with antimicrobial agents and other approved or listed safe and suitable food ingredients can be labeled as \u201cbeef patties\u201d and can be generically approved if the labeling does not bear any special claims, guarantees or foreign language. The labeling for other products with standards of identity that permit the addition of antimicrobial agents, e.g., luncheon meats, hotdogs, cooked whole muscle cuts (such as roast beef), may be approved in accordance with the regulations on generic label approval to reflect the addition of new, approved safe and suitable antimicrobial agents on labeling. The addition applies provided that no special claims or guarantees, foreign language, appear on such labels, per the generic labeling regulations. Reclassification of products that are RTE as NRTE Some products are expected to be lethality treated and RTE as shipped, as a matter of their common or usual identity, e.g., pates. Other products are defined by a standard of identity as RTE, that is, cooked, e.g., hotdogs. Some products are RTE based on labeling features, including Nutrition Facts, which declare nutrients in a product on a ready to serve or ready to eat basis. When these factors do not prevail, manufacturers may decide to reclassify products that have long been marketed as RTE products to NRTE products by doing the following: (1) decide on the HACCP category that best fits their product based on the processing operations that are involved. In the situation where a product has been produced as a", "Updated Compliance Guidelines May 2006 RTE product and it is not a product that is defined by common or usual identity (e.g., pepperoni) or standard of identity (e.g., hotdog) as a lethality-treated (e.g., cooked\fermented\dried) product, the manufacturer can re-characterize their product in terms of HACCP category. The manufacturer would need to ensure that documentation exists to support the HACCP category selected by the establishment for the

product and that the appropriate category is reflected in the HACCP plan and labeling records; (2) generate data that validate the cooking instructions that must appear on the labeling of NRTE products (and include in all the alternative methods of cooking temperature that the product must reach, i.e., 160°F) to ensure that consumers provide the lethality step. When the product has historically been viewed by the consumers as a "heat and eat" type of product, it is especially important for the establishment to make the distinction between the RTE product and the NRTE product. In addition, the "cooking instructions" should not be the same "heating" instructions that were previously used on labeling for the RTE products. Cooking instructions would need to include the internal temperature to which the product is expected to reach for the consumer to eat the product safely. (3) assess the label to ensure that it adequately reflects the features that are necessary on the principal display panel to convey that the product is a ready to cook product, e.g., "cook and serve," "cook and eat," "cook thoroughly," as well as safe handling instructions. The basis for the Nutrition Facts declarations, e.g., serving size, must be on a ready-to-cook basis, not on a ready-to-serve basis (the company has to establish a ready- to-cook basis for serving size if the regulations do not provide one). (4) consider whether the label for the product can be approved consistent with the regulations on generic label approval (i.e., it is a label for a standardized product and that bears no claims, special statements, guarantees, or foreign language) -- such labels would not need to be sent to the Agency to be evaluated and approved prior to use. If a meat or poultry product that is processed to a time\temperature that traditionally is considered to attain a full cook but the intended use of the product is such that the product is intended to receive a lethality treatment by the consumer, the product does not have to be labeled as RTE unless the product is defined by a standard of identify as a RTE product (e.g., hotdogs, franks, pork with barbecue sauce, etc.). Such product may be identified as a NRTE product provided that the labeling and validated cooking instructions are adequate to discern that the product must be cooked for safety by the purchaser. An example of such product is a cooked thick-sliced, center-cut ham slice on which the labeling indicates that the product is ready to cook and for safety the product must be cooked to attain a minimum temperature. On the other hand, a thin sliced ham product in case-ready packaging states that the product is ready-to-eat without additional cooking and which would not be required to bear preparation\cooking instructions. Both products may have been processed in the same manner in the Federal establishment but handled differently regarding controls for L. monocytogenes. 23", "Updated Compliance Guidelines May 2006 Furthermore, some establishments also add a "cooking" statement on the label on a fully cooked, RTE product for consumers to cook to a specific temperature. In this case, the establishment is adding heating rather than cooking instructions on the label in order to specify the temperature to which the product must be heated for palatability. In this case, the establishment does not need to have cooking instructions that have been validated to eliminate or reduce pathogens, nor does it need safe handling instructions on the label and the other requirements mentioned above.

E. Production Information Collection An establishment that produces post-lethality exposed RTE products shall provide FSIS with estimates of annual production volume and related information for the types of meat and poultry products processed under Alternatives 1, 2, or 3 (9 CFR 430.4(d)). The establishment needs to provide the information at least annually, or more often, as determined by the Administrator. The Agency regards production volume as a

more important risk factor than establishment size and therefore needs these data so that it can target its resources on higher volume operations in its verification program. FSIS will develop sampling frequencies for the establishments and the products based on these data. When sufficient data have been gathered (at least a year from implementation of the rule), the Agency expects to have the sampling frequency available to the establishments so that they will have an indication of how the risk of *L. monocytogenes* is tied to verification sampling. The form by which to collect the data will be available to establishments in paper and electronic formats. An electronic form for this purpose will be available to the establishments at all times after the rule becomes effective. A sample form for the Production Information on Post-Lethality Exposed Ready-to-Eat Products collection can be found in Attachment 3. F. New Technology Review FSIS believes that the facilitation of the use of new technology represents an important means of improving the safety of meat, poultry and egg products. The Agency defines \u201cnew technology\u201d as new, or new applications of equipment, substances, methods, processes, or procedures affecting the slaughter of livestock and poultry, and processing of meat, poultry and egg products. The Agency has an interest in new technology if new technology could affect product safety, inspection procedures, or inspection program personnel safety, or if it would require a waiver of a regulation. Substances used as new technology must also meet the requirements for safety and suitability under the Agency\u2019s food ingredient approval process. While FDA has the responsibility for determining the safety of food ingredients and additives, as well as prescribing safe use, FSIS has the authority to determine that new ingredients and new uses of ingredients are suitable for use in meat and poultry products. The FSIS New Technology Staff reviews new technology that can be applied in meat, poultry, and egg processing and inspection to facilitate the introduction of the new technology in establishment or plant operations. New technology for use on post-lethality 24", "Updated Compliance Guidelines May 2006 RTE meat and poultry products to control the growth of *L. monocytogenes* should be sent to this office for review. FSIS issued the document on \u201cGuidance Procedures for Notification and Protocol Submission of New Technology\u201d

([www.fsis.usda.gov/Regulations\\_&\\_Policies/New\\_Technologies/index.asp](http://www.fsis.usda.gov/Regulations_&_Policies/New_Technologies/index.asp)) to aid in the submission of application for review of new technology. New technologies received and reviewed by FSIS, which FSIS has \u201cno objection\u201d to their use in FSIS establishments are posted on the web site:

[http://www.fsis.usda.gov/regulations\\_&\\_policies/New\\_Technology\\_Table/index.asp](http://www.fsis.usda.gov/regulations_&_policies/New_Technology_Table/index.asp). G. Sanitation Guidelines for Listeria monocytogenes Control of *L. monocytogenes* is a challenge to a processing plant\u2019s sanitation program. The pathogen can grow in a damp environment, attach to surfaces that come into contact with raw or finished product, establish a niche and form biofilms. The sanitation program should include cleaning and sanitizing procedures that have been proven effective for the particular operation, separation of raw and RTE processing areas, traffic control, employee hygiene, and equipment flow and design among others. Proper and effective sanitation involves both cleaning and sanitizing, and verifying that the cleaning and sanitizing were effective. This involves developing and implementing written sanitation standard operating procedures (Sanitation SOPs). Sanitation SOPs could be viewed as the first step to designing a total system, including the HACCP plan that will prevent, eliminate, or reduce the likelihood of pathogenic bacteria from entering and harboring in the plant

environment. The Sanitation SOPs as described in 9 CFR 416.12 through 416.16, give detailed requirements for developing and implementing the sanitation program, while 9 CFR 416.17 describes how FSIS will verify that each establishment is meeting the Sanitation SOP regulations. In brief, the regulations require the following:

- \u2022 Development of Sanitation SOPs (416.12) \u2013 Each establishment must develop a written Sanitation SOP that describes all sanitation procedures that will be performed each day, before and during operations, with specific frequencies of each procedure and the responsible person for each task. It must also describe the cleaning process for all food contact surfaces, utensils, and equipment used to process your product(s). This document must be signed and dated by either the person responsible for the overall sanitation operations or a higher level employee in the establishment once it is implemented, and when any changes are made to the Sanitation SOPs.
- \u2022 Implementation of SOPs (416.13) \u2013 All preoperational procedures identified in the Sanitation SOP must be done daily, before processing operations start. Each procedure must be performed at the specified frequency and they must be monitored daily.
- \u2022 Maintenance of Sanitation SOPs (416.14) \u2013 Each establishment must routinely determine if the written Sanitation SOP is still effective in preventing direct product contamination and adulteration. If the Sanitation SOP is determined not 25", "Updated Compliance Guidelines May 2006 to be effective because of changes in equipment, utensils, facility, operations, or personnel, changes in the procedures must be made to reflect changes
- \u2022 Corrective Action (416.15) \u2013 The appropriate corrective action(s) must be taken when it has been determined by FSIS or by an establishment employee that the written Sanitation SOP has failed to prevent direct product contamination or adulteration of product(s).
- \u2022 Recordkeeping Requirements (416.16) \u2013 Daily records must be maintained that describe how the sanitation activities were implemented and monitored, and all corrective actions taken; these records must be initialed and dated. Both computer records and paper records are appropriate; however, additional controls may be needed to ensure the integrity of the electronic data.
- \u2022 Agency Verification (416.17) \u2013 FSIS will verify the effectiveness and adequacy of the written Sanitation SOPs to ensure that they meet all of the regulatory requirements. This will be done by reviewing all records, direct observations, and microbial testing as deemed necessary.

In addition to the Sanitation SOP required by FSIS, the Listeria rule requires an additional sanitation program targeting Listeria monocytogenes.

#### I. General Cleaning and Sanitation Procedures

An example of equipment and processing room cleaning using eight steps is outlined below. Cleaning should be increased and intensified during periods of construction.

1. Remove waste material. Dry clean equipment, conveyor belts, tables, floors to remove meat particles and other solid debris. Some equipment such as slicers and dicers need to be disassembled so that parts can be cleaned thoroughly. Equipment may need to be cleaned and sanitized again after re-assembly.
2. Wash and rinse floor.
3. Pre-rinse equipment (rinse in same direction as product flow). Pre-rinse with warm or cold water \u2013 less than 140\u00b0F (hot water may coagulate proteins or \u201cset soils\u201d).
4. Clean and scrub equipment. Always use at least the minimum contact time for the detergent/foam. Written instructions should be provided on the location of possible niches and the cleaning method to use.
- CAUTION: Live steam for cleaning is not acceptable at this step since it may bake organic matter on the equipment.
5. Rinse equipment (rinse in same direction as product flow).
6. Visually inspect equipment to identify minute pieces of meat and biological residues (repeat steps 3 and 4 if not

clean visually or by testing such as with ATP bioluminescence). 7. Sanitize floor and then equipment to avoid contaminating equipment with aerosols from floor cleaning. Care should be taken in using high pressure hoses in cleaning the floor so that water won't splash on the already cleaned equipment. Use hot water, at least 180°F, for about 10 seconds to sanitize equipment. Sanitizers (e.g., chlorine, quaternary ammonia, etc.) may be more effective than 26", "Updated Compliance Guidelines May 2006 steam for L. monocytogenes control. If steam heating equipment in an oven or tarp, the target internal temperature is 160°F and hold for 20-30 min. Portable high-pressure, low volume cleaning equipment (131°F (55°C) with 20-85 kg/cm<sup>2</sup> pressure and 6- 16 liters/minute) can also be used. 8. Remove excess moisture. This can be done most safely and efficiently by air drying. Reduced relative humidity can speed the process. Avoid any possible cross-contamination from aerosol or splash if a method other than air drying (e.g., using a squeegee or towel) is used. If cross-contamination is suspected, repeat steps 4-7.

II. Determining the Effectiveness of Sanitation Standard Operating Procedures (Sanitation SOPs)

The establishment should determine if the cleaning and sanitizing procedures it uses are effective by visual examination or testing or both. Three examples of visual examination or visual examination and testing are described below.

1. Visual inspection of the equipment and environment. Visual inspection is the minimum means of determining the effectiveness of the sanitation SOPs. It can only detect observable contamination.
  - a. Before the start of operation, visually verify that no meat or product residue is on the equipment, especially those food contact surfaces and areas that may serve as niches for bacteria.
  - b. Record the results of the visual inspection.
  - c. If any residue is noted, corrective action should be taken and recorded.
  - d. The monitoring record should be designed to show any trends of insanitary conditions. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).
  - e. Visually verify that no meat or product residue is on the equipment, especially those food contact surfaces and areas that may serve as niches for bacteria, after post-processing cleanup.
2. Visual inspection and use of ATP bioluminescence testing. Visual verification combined with ATP testing can determine both observable contamination and contamination from bacteria and meat/poultry residues that may not be visually detectable. The combined methods are more effective in determining the effectiveness of the sanitation SOP.
  - a. The ATP test indicates the presence of both bacteria and meat or poultry residues and can be used to verify that no meat or poultry residue is on the equipment, esp. those food contact surfaces and areas that may serve as niches for bacteria, before the start of operation. The ATP test is a rapid test and results are available immediately.
  - b. Record the results of the ATP test and visual inspection.
- 27", "Updated Compliance Guidelines May 2006
- c. If any residue is noted or observed visually or the ATP test indicates an insanitary condition, corrective action should be taken and recorded.
- d. The monitoring record should be designed to show any trends of insanitary conditions. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).
3. Visual inspection and total plate counts (TPC). Visual verification combined with TPC can determine both observable contamination and the level of bacterial

contamination. Since TPC results are available in about 24 hours, and cannot be obtained at the time of inspection, its value lies in the measurement of the level of contamination. The level of contamination may assist the establishment in determining the source of contamination and the effectiveness of the sanitation SOP.

- a. Visually verify that no meat or product residue is on the equipment, esp. those food contact surfaces and areas that may serve as niches for bacteria, before the start of operation.
- b. Use swabs or RODAC plates for sampling food contact surfaces, non-food contact surfaces (e.g., push-button on\off switches for the conveyor belt), and the processing environment.
- c. Record the results of the visual inspection.
- d. If any residue is noted, corrective action should be taken and recorded.
- e. Record the TPC when analysis is complete.
- f. The monitoring record should be designed to show any trends of insanitary conditions as determined by visual inspection or TPC. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).
- g. Visually verify that no meat or product residue is on the equipment, especially those food contact surfaces and areas that may serve as niches for bacteria, again after post-processing cleanup.

III. Traffic Control Controlling the movement of personnel and raw and finished products will help prevent cross-contamination of finished products by raw materials and personnel. The following are steps that can be taken for traffic control:

- 1. Establish traffic patterns to eliminate movement of personnel, meat containers, meat, ingredients, pallets and refuse containers between raw and finished product areas.
- 2. Control traffic into and within the RTE areas

  - a. If possible, use air locks between raw and RTE areas.
  - 28", "Updated Compliance Guidelines May 2006
  - b. Clean, dry floors are preferable to foot baths at the point of entry because effective concentrations of disinfectant are difficult to maintain and may become a source of contamination.
  - c. If foot baths are used:
    - i) Wear rubber or other non-porous boots.
    - ii) Maintain them properly,
    - iii) Solutions should contain stronger concentrations of sanitizer than normally used on equipment (1) For example, 200 ppm iodophor, 400-800 ppm quaternary ammonia compound).
    - (2) CAUTION: Chlorine is not recommended as it is too quickly inactivated esp. if cleated boots are used. The accumulation of biological material adhering to the cleats inactivate (or reduce) the bioavailability of chlorine and make it less effective. Monitor and maintain its strength if used.
    - iv) Use a minimum depth of 2 inches.
  - d. Use foam disinfectant spray on floor for people or rolling stock entering the room.

- 3. Employees should not work in both raw and RTE areas, if possible. If they must work in both areas, they must change outer and other soiled clothing, wash and sanitize hands, and clean and sanitize footwear.

  - a. Use different color smocks or helmets for raw and RTE areas so the workers and garments in the raw and RTE areas are readily distinguishable.
  - b. Remove outer garments (e.g., smocks) when leaving RTE areas.

- 4. Do not allow employees who clean utensils and equipment for raw materials to clean RTE utensils and equipment, if possible. If not possible, there should be a time separation when utensils for raw processing\handling are cleaned after RTE. The tools to clean utensils and equipment for raw materials must be different than those used to clean RTE utensils and equipment. In either case, the intent is to prevent cross contamination of finished product.
- 5. Do not permit maintenance employees in RTE areas during operations if possible, primarily because they may cause direct product contamination or adulteration if they touch or lay their \u201cdirty\u201d equipment hands onto food contact surfaces.

If not possible:

- a.

Consider the need to cease operations until a full cleaning and sanitizing is done, or, b. Maintenance personnel must change outer clothing and any other soiled clothing, use separate tools for raw and RTE areas (or wash and sanitize tools and hands prior to entering RTE areas) and wear only freshly cleaned\sanitized footwear in such areas. 6. Use separate equipment, maintenance tools and utensils for the RTE and raw areas. If not possible, there should be a time separation between raw processing\handling and RTE processing in order prevent cross contamination of finished product. 29", "Updated Compliance Guidelines May 2006 7. Pallets can serve as a source of cross-contamination \u2013 pallets for raw materials should not be used in RTE areas or used for finished product. 8. Drains from the \u201cdirty\u201d or \u201craw\u201d side should not be connected to those on the \u201cclean\u201d or \u201ccooked\u201d side. 9. There are instances when small establishments cannot separate the raw and cooked areas, or separate employees handling raw and cooked products by operating time. In this case, the establishment should plan to process cooked products first, then do a complete clean-up (thorough cleaning and sanitizing) of the processing area, processing and maintenance equipment, and personnel, and then do the raw products. The establishment\u2019s Sanitation SOP and their GMP or prerequisite program should address employee hygiene and traffic control during operation to prevent cross contamination and insanitary conditions. 10. Eliminate standing water which can facilitate the spread of L. monocytogenes into other areas of the plant. Sanitizer boluses can be used to sanitize standing water on a continuing basis.

IV. Employee Hygiene Employee hygiene should be the responsibility of both the individual and management. The employee should be responsible for preventing contamination of food products and the management should be responsible for ensuring the employee is properly trained and maintains good practices.

1. Employee responsibilities and actions should include:

- a. Use a 20 second hand wash, allowing the soap suds to be in contact with the hands for this period of time, after using restroom facilities.
- b. Wash hands before entering the work area, when leaving work area, and before handling product.
- c. If gloves are worn:
  - i. Gloves that handle RTE product must be disposable.
  - ii. Dispose immediately and replace if anything other than product and food contact surface is touched.
  - iii. Dispose of gloves when leaving the processing line.
- d. Remove outer clothing when leaving RTE areas.
- e. Do not wear RTE clothing inside restrooms or cafeterias.
- f. Do not store soiled garments in lockers.
- g. Do not eat in the locker room or store food in lockers because food may attract insects and vermin.
- h. Do not store operator hand tools in personal lockers. This equipment must remain in the RTE area at all times.

2. Management responsibilities should include:

- a. Providing hand washing facilities at proper locations.
- b. Ensuring the employee receives proper hygiene instruction before starting \u2013 use of hand soaps and sanitizers, no-touch dispensing systems, and boot and doorway sanitizing systems.
- c. Developing a system for monitoring employee hygiene practices.
- d. Developing a system for tracking the training, testing, and certification.
- e. Retraining employees before placing back into production if they are absent from the job or have failed to follow acceptable hygiene practices. This will help ensure that the employees are following current, acceptable hygiene habits.

V. Sanitizers Cleaning and sanitizing are vital to any effective sanitation program. Thorough cleaning should be followed by sanitizing. Generally, the cleaning step is to remove all waste materials and soils, and the sanitizing step is to destroy all microorganisms. Careful consideration should be given to selecting both cleaning and sanitizing

solutions. It is important to use solutions that are compatible with the equipment materials, such as stainless steel or heavy plastics, and solutions that are effective in destroying the type of bacteria commonly associated with the type of products produced in the establishment. Rather than relying on a single sanitizer, rotating sanitizers will help prevent the development of microorganisms resistant to a particular sanitizer. The concentration and application processes for all sanitizers approved for use in meat and poultry establishments are referenced in Title 21 Code of Federal Regulations (21 CFR), Part 178.1010. All cleaners and sanitizers commercially available should have at the minimum, the following information either on the label or available on a specification sheet that must accompany the product: 9 Product Description 9 To Use \u2013 Instructions on how to use the product 9 Properties 9 Safety Information Additional information that is sometimes available includes: 9 Benefits 9 Quality Assurance Statements 9 Effectiveness against Listeria. Some manufacturers provide labeling in both English and Spanish, which makes the products more user friendly in various environments. At least one manufacturer also has commercially available color coded products that are easy to associate with a particular cleaning or sanitizing task. Krysinski, L.J., (1992) evaluated the ability of chemical cleaning and sanitizing compounds to remove and\or inactivate surface adherent Listeria monocytogenes from stainless steel and plastic conveyor belts. With respect to the sanitizers, the study showed 31", "Updated Compliance Guidelines May 2006 that resistance of attached cells followed in descending order: polyester\polyurethane, and stainless steel. For the stainless steel, all of the sanitizers were effective in inactivating the adherent Listeria monocytogenes except chlorine and iodophor. None of the biocides were effective in sanitizing the surface of the polyester\polyurethane. The most effective sanitizers in these evaluations were acidic quaternary ammonia, peracetic acid, and chlorine dioxide. The cleaning agents used were effective in removing the attached Listeria monocytogenes for the stainless steel but not effective when used on the polyester\polyurethane chips. When the cleaning agents were followed by a sanitizer, reductions in the microbial load were observed. The study concluded that generally, acidic quaternary ammonia, chlorine dioxide, and peracetic acid were the most effective biocides on attached Listeria monocytogenes, less effective were the mixed halogens and acid anionics, and the least effective were chlorine, iodophors, and neutral quaternary ammonium compounds.

VI. Sources and Control of Listeria monocytogenes Contamination

Listeria monocytogenes may be introduced into the processing environment by construction (perhaps the single most important factor associated with outbreaks), the failure to control sanitation procedures, employee hygiene, movement of supplies and products, or other entry vectors (Mead, 1999; Perl, 2000). The bacterium may be brought in by incoming raw product, processing environment or by employees. It can be transferred from coolers, walls, floors, equipment and construction by direct or indirect contact with the product. Dust generated by construction activities can move throughout the plant on air currents or be transferred by people or equipment traveling through the construction area into other areas of the establishment. A study by De Roin et al., (2003) showed that dust contaminated with L. monocytogenes, once in contact with meat surfaces can survive and grow. Construction or maintenance activities that can result in contamination with L. monocytogenes include removal of drains, removal of floor coatings, removal of a wall or ceiling that has absorbed moisture, movement of potentially contaminated materials through RTE areas or areas that directly connect with RTE processing

areas, and exposure of areas typically not accessible for cleaning. Tompkin (2002) considers the potential of introduction of a new, more virulent strain of *L. monocytogenes* into the environment from an outside source or through disturbance of a harborage site (e.g., the process of replacing floor drains, walls or cooling units) as a greater concern. The following are steps that should be taken to prevent contamination of product with *L. monocytogenes* after cooking:

1. Verify that cooking or other control measures will eliminate *L. monocytogenes*. Most meat products implicated in human listeriosis are contaminated with *L. monocytogenes* after these measures are applied. Undercooking product or other inadequately or improperly verified lethality treatments may introduce *L. monocytogenes* to food contact surfaces or the environment after cooking and before packaging.
- 32", "Updated Compliance Guidelines May 2006
2. Prevent contamination of food contact surfaces and prevent the formation and growth of *L. monocytogenes* in a niche, especially in areas after the lethality step. A niche is a harborage site within the plant that provides an ideal place for *L. monocytogenes* to establish and multiply. Factors involved in the formation of niches include equipment design, construction activities, operational conditions that move product debris into difficult to clean locations, mid-shift cleanup, high pressure during cleaning, and product characteristics that require excessive rinsing. Certain strains can become established in a processing environment for months or years. *L. monocytogenes* can be spread from these sites and re-contaminate food or food contact surfaces between the lethality step and packaging. Examples of reservoirs and harborages of *L. monocytogenes* in RTE processing environment

  - Drains
  - Hollow rollers on conveyors
  - On-off valves and switches
  - Worn or cracked rubber seals around doors
  - Vacuum\air pressure pumps, lines, hoses
  - Cracked tubular rods on equipment
  - Air filters
  - Condensate from refrigeration unit
  - Floors
  - Standing water
  - Open or gully drains
  - Ceilings and over head pipes
  - Overhead rails and trolleys
  - Chiller and passageway walls and doors
  - Chiller shelving
  - Roller guards
  - Door handles
  - Boots
  - Ice makers
  - Saturated insulation (wet or moldy)
  - Trolley and forklifts
  - Compressed air in-line air filters
  - Trash cans
  - Cracked hoses
  - Wet, rusting or hollow framework

- Walls that are cracked, pitted, or covered with inadequately sealed surface panels
- Maintenance and cleaning tools
- Space between close fitting metal-to-plastic parts
- Space between close fitting metal-to-metal parts

- 3. Examine routes taken by products from heat treatment, or other control steps to eliminate *L. monocytogenes*, to final packaging.
- 33", "Updated Compliance Guidelines May 2006
- Typical sites that result in *L. monocytogenes* contamination
- Filling or packaging equipment
- Solutions used in chilling food
- Peelers, slicers, shredders, blenders, brine chill, casing removal system, scales, or other equipment used after heating and before packaging
- Spiral or blast freezers
- Conveyors
- Bins, tubs, or other containers used to hold food for further processing
- 4. Frequently clean sites known to support *L. monocytogenes* using effective cleaning procedures. The following is a recommended frequency for cleaning and sanitizing processing equipment and the plant environment:

- a. Daily
- i. All processing equipment
- ii. Floors and drains
- iii. Waste containers
- iv. Storage areas

- b. Weekly
- i. Walls
- c. Weekly\monthly
- i. Condensate drip
- ii. Coolers
- d. Semiannually
- i. Freezers

- 5. Validate that the cleaning and sanitizing procedures are effective.
- 6. Maintain equipment and repair parts or machinery in a manner to prevent food deposits that are not easily removed with normal cleaning.
- 7. Implement a microbial sampling program to monitor and detect sources of *L. monocytogenes* in the environment. Environmental testing is more effective than product testing alone to monitor and detect Listeria in the environment. For positive test results,

conduct intensified cleaning and other necessary corrective actions. Follow up with intensified and targeted testing of implicated sites.

8. Design a sampling scheme to locate a niche before L. monocytogenes becomes established.

a. Determine the physical area to sample. Use prior experience with processing conditions and observation of cleaning and sanitizing procedures and equipment to determine the most likely source of contamination. For example, the use of high water pressure during cleaning may embed L. monocytogenes into parts of the equipment that are 34", "Updated Compliance Guidelines May 2006 hard to clean effectively. The cleaning and sanitizing procedures also should be monitored to assure that the established procedures are being followed. All surfaces of processing equipment should be sampled but with a bias toward those areas identified as possibly problematic.

b. Take 10 samples per line, with a maximum of 50 samples. The samples should include both food contact and non-food contact surfaces.

c. Review at least the last month of results to determine trends or to revise sampling scheme.

d. When a problem area is detected, take corrective action on the affected processing line as opposed to adjacent lines in the area. Target the area corresponding to the line associated with the findings for intensified cleaning. Contamination is usually line specific unless a vector in the system is present (e.g., an employee contaminates multiple sites; a common surface prior to splitting the lines is contaminated).

Equipment Design Selecting the appropriate equipment (e.g., designs that facilitate cleaning and sanitizing, equipment that easily dismantled for cleaning, durability) enhances cleaning operations and helps to control L. monocytogenes in the plant environment. The following are recommended steps to take when selecting equipment:

1. If possible, develop a team (persons from Quality Assurance, Sanitation, Maintenance, and Production) to evaluate equipment before it is purchased or set specific requirements for plant equipment. The equipment should be easy to clean and sanitize and not have potential L. monocytogenes harborage sites, such as hollow rollers.
2. Have the equipment reviewed by a third-party expert if possible.
3. Select equipment designed to minimize sites on the exterior or interior where L. monocytogenes can grow.
4. Select equipment designed to enhance cleaning.
  - a. All areas and parts should be accessible for manual cleaning and inspection or be readily disassembled.
    - i. Closed conveyor designs are more difficult to clean. Equipment on the processing line should be as easy to clean as possible.
    - ii. Avoid hollow conveyor rollers and hollow framing. If hollow material is used, have a continuous weld seal instead of caulk.
  - 35", "Updated Compliance Guidelines May 2006
  - iii. Select food contact surfaces that are inert, smooth and non-porous.
5. Equipment evaluation
  - a. Thoroughly clean and sanitize equipment prior to using in production. Pathogens can live on surfaces that appear visually clean.
  - b. Operate the equipment for 90 days, then,
  - c. Disassemble to normal daily level, then
  - d. Evaluate visually and microbiologically as the equipment is completely disassembled.
6. Maintain equipment and machinery by adopting regular maintenance schedules.
  - a. Damaged, pitted, corroded, and cracked equipment should be repaired or replaced.
    - i. Repair parts or machinery in a manner to prevent food deposits that are not easily removed with normal cleaning.
    - ii. Use separate tools for RTE equipment only. Sanitize them before and after each use.
  - b. If compressed air is used, maintain and replace in-line filters regularly.
  - c. Use lubricants that contain listericidal additives such as sodium benzoate. L. monocytogenes can grow in lubricants that are contaminated with food particles.
7. Control the Environment During Construction If possible, suspend operations during

construction. Otherwise:

- a. Dust from construction can be difficult to detect and control. Therefore, increased monitoring of product, food-contact surfaces, and the environment is recommended during and after these disruptive events.
- b. Establish negative air pressure in the construction area in order to ensure that air does not flow from the construction area into the plant.
- c. Temporary partitions can be established to protect the undisturbed areas of the plant from construction dust and debris.
- d. Cover any construction debris when moving out of the construction area.
- e. Do not move debris through RTE processing areas or areas that directly connect to RTE processing areas, if possible.
- f. Schedule construction during non-processing hours.

36", "Updated Compliance Guidelines May 2006

- g. Conduct intensified cleaning and monitoring of food contact and environmental surfaces.

8. Control the Environment After Construction

- a. Schedule removal of all construction equipment, barriers, and final debris after production hours.
- b. Perform a thorough clean-up and increased sanitation sampling at pre-operation inspection.
- c. Continue intensified cleaning and monitoring of food contact and environmental surfaces until 3 consecutive negative tests on the food contact surfaces for 3 consecutive days.

VII. Verifying the Effectiveness of the Sanitation Program

Establishments can verify the effectiveness of their sanitation program by testing food contact surfaces (FCS) and other relevant environmental surfaces. This section includes

- a) recommended testing of food contact surfaces to verify the effectiveness of the sanitation program for each alternative from 9 CFR 430,
- b) a guide to testing for Listeria spp. or Listeria-like organisms,
- c) an example of a hold-and-test scenario, and
- d) an example of a Sentinel Site Program.

1. Food Contact Surface and Environmental Testing

The sampling frequencies for food contact surface (FCS) testing suggested below are recommended minimum frequencies. Sampling is required for Alternatives 2 (using antimicrobial agents or processes only) and 3, and recommended for Alternative 1. The sampling frequencies increase from Alternative 1 to Alternative 3 because the control program for *L. monocytogenes* decreases in intensity and effectiveness from Alternative 1 to 3. These frequencies should be increased if there is construction, change in the HACCP plan, roof leaks, or other events that could change or increase the probability of product contamination.

Samples should be taken at least 3 hours after the start of operation or an appropriate time period after all parts of the food handling system are operational because the equipment has to be operational for seeding to occur. Establishments can also develop their own sampling plan based on their operations, or have a processing authority develop a sampling plan. Generally, no more than 5 samples may be composited because when samples are composited, it becomes more difficult to trace the source of contamination. In addition, it is recommended that like or similar surfaces should be composited (e.g., food contact surfaces with other food contact surfaces, etc.). The individual locations for the composite sample should be noted to assist in determining the site of contamination to facilitate follow-up testing in case a positive is obtained. Environmental samples other than food contact surface samples should be sampled by the establishment. This will also assist the establishment in locating potential sources of contamination.

37", "Updated Compliance Guidelines May 2006

The establishment is encouraged to hold all products being tested until the test results are received. This will prevent exposure of the consumer to a potential food hazard. Retaining the product being tested also will eliminate the cost of a recall to the establishment.

- a. Alternative 1 \u2013 Use of a post-lethality treatment and an antimicrobial agent or process that limits growth of *L. monocytogenes*.
- i. Conduct tests of food contact surfaces for *L. monocytogenes*, *Listeria* spp., or

Listeria-like organisms at least twice a year. This low frequency of testing is recommended because the post-lethality treatment and the antimicrobial agent and process are expected to reduce and inhibit the growth of L. monocytogenes in the product.

ii. Sample at least 1 square foot area for each surface, if possible.

iii. Record the test results.

iv. If test results are positive for L. monocytogenes, Listeria spp. or Listeria-like organisms:

- (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
- (2) If the FCS test is positive for L. monocytogenes, the product in the sampled lot that came in direct contact with a food contact surface would not summarily be considered adulterated, because the post-lethality treatment should have been validated and thus shown to be effective in eliminating or reducing L. monocytogenes, and documented in the establishment\u2019s HACCP plan.
- (3) Record the corrective actions taken.
- (4) Retest the food contact surface.
- (5) Repeat corrective action and testing until samples are negative for L. monocytogenes, Listeria spp. or Listeria-like organisms.
- (6) Initiate intensified environmental sampling after 2 consecutive positives, because this shows that the contamination was not eliminated by the corrective actions, and that there might be some other serious problems. FSIS will likely be looking at the support documentation following the first positive to see what the establishment did to justify that the product was not adulterated, particularly if there is evidence of harborage. Establishments should be on the preventive and reactive mode.

b. Alternative 2 - Use of a post-lethality treatment or an antimicrobial agent or process that limits growth of L. monocytogenes.

i. If a post-lethality treatment is used, conduct tests of food contact surfaces for L. monocytogenes, Listeria spp., or Listeria-like organisms at least quarterly. This recommended frequency is 2 times that for Alternative 1 because in this case, the product only receives one of the interventions.

- (1) Sample at least 1 square foot area for each surface, if possible.
- (2) Record the test results.

38", "Updated Compliance Guidelines May 2006

(3) If test results are positive for L. monocytogenes, Listeria spp. or Listerialike organisms:

- (a) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
- (b) If the FCS test is positive for L. monocytogenes, the product that came in direct contact with a food contact surface would not summarily be considered adulterated, because the post-lethality treatment should have been validated and thus shown to be effective in eliminating or reducing L. monocytogenes, and documented in the establishment\u2019s HACCP plan.
- (c) Record the corrective actions taken.
- (d) Retest the food contact surface.
- (e) Repeat corrective action and testing until samples are negative for L. monocytogenes, Listeria spp., or Listeria-like organisms.
- (f) Initiate intensified environmental sampling after 2 consecutive positives, because this shows that the contamination was not eliminated by the corrective actions, and that there might be some other serious problems. FSIS will likely be looking at the support documentation following the first positive to see what the establishment did to justify that the product was not adulterated, particularly if there is evidence of harborage. Establishments should be on the preventive and reactive mode.

ii. If an antimicrobial agent is used, conduct tests of food contact surfaces for L. monocytogenes, Listeria spp., or Listeria-like organisms at least quarterly. (Sampling is required in this case).

- (1) Sample at least 1 square foot area for each surface, if possible
- (2) Record the test results.
- (3) Each time a FCS test positive for L. monocytogenes, Listeria spp. or Listeria-like organisms, take corrective action, including intensified cleaning and sanitizing, and retest FCS area.
- (4) If the FCS test is positive for L. monocytogenes, the product

in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product. (5) If 3 consecutive tests of food contact surfaces are positive for Listeria spp. or Listeria-like organisms: (a) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing. (b) Record the corrective actions taken. (c) Hold the product. (d) Test product for L. monocytogenes. (e) Retest the food contact surface. (f) Repeat corrective action and testing until food contact surface test results are negative for L. monocytogenes, Listeria spp., or Listerialike organisms. (g) If the test results for the product are positive for L. monocytogenes, 39", "Updated Compliance Guidelines May 2006 (i) Recall the product, if already shipped, and (ii) Destroy the product, or (iii)Re-work the product with a process that is destructive of L. monocytogenes. c. Alternative 3 \u2013 Use of sanitation control measures and testing to prevent contamination of product with L. monocytogenes. (Sampling is required in this case) i. For establishments that produce non-deli or non-hotdog products, tests for L. monocytogenes, Listeria spp., or Listeria-like organisms should be conducted once a month for large, small or very small volume establishments. ii. For establishments producing deli and hotdog products, tests for L. monocytogenes, Listeria spp., or Listeria-like organisms should be conducted at least four times per month per line for large volume establishments, two times per month per line for small volume establishments, and once per month per line for very small (or low) volume establishments. FSIS regards production volume as a more important risk factor than establishment\u2019s size and intends to use volume as one of the primary triggers for when considering its verification activity. For now, regarding deli meat and hotdog operations, FSIS is considering the break point between high volume and low volume to be approximately 1.3 million pounds yearly, as derived from the RTE survey. iii. Sample at least 1 square foot area for each surface, if possible. iv. Record the test results. v. If the first test result of a food contact surface is positive for L. monocytogenes, Listeria spp., or Listeria-like organisms, take corrective actions (as specified in the HACCP plan, Sanitation SOP or prerequisite program) and record. vi. If the FCS test is positive for L. monocytogenes, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product. vii. Each time a FCS tests positive, take corrective action, including intensified cleaning and sanitizing, and retest FCS area. viii. For establishments producing hotdog or deli meat products, if the second test result of a food contact surface is positive for L. monocytogenes, Listeria spp., Listeria-like organisms: (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing. (2) If the FCS test is positive for L. monocytogenes, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product. (3) Record the corrective actions taken. (4) Hold the product (see hold-and-test scenario below and in Attachment 6). (5) Test product for L. monocytogenes at a rate that provides a level of statistical confidence that the product is not adulterated. 40", "Updated Compliance Guidelines May 2006 (6) Conduct follow-up test of the food contact surface each day until the test result is negative for Listeria spp., Listeria-like organisms. (7) At the same time, continue to hold each day\u2019s production lot until the test results for the food contact surfaces are negative. (8) If the test results for the product are positive for L. monocytogenes, (a) Destroy the product, or (b) Re-work the product with a process that is destructive to L. monocytogenes. ix. For establishments producing products other than hotdogs

or deli meats, if the third consecutive test of food contact surfaces is positive for Listeria spp., or Listeria-like organism (sampling is required in this case): (a) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include an intensified cleaning and sanitizing. (b) In addition, if the FCS test is positive for L. monocytogenes, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product. (c) Record the corrective actions taken. (d) Hold the product. (e) Test product for L. monocytogenes. (f) Retest the food contact surface. (g) Repeat corrective action and testing until food contact surface test results are negative for L. monocytogenes, Listeria spp., or Listerialike organisms. (h) If the test results for the product are positive for L. monocytogenes, (i) Destroy the product, or (ii) Re-work the product with a process that is destructive of L. monocytogenes. For repeated FCS positives, the establishment should also conduct a comprehensive investigation to determine the cause and source of the contamination. This establishment should: a. Review the cleaning and sanitizing procedures, including the types of cleaning agents. b. Review traffic control patterns, equipment layout and adherence to employee hygiene procedures. c. Locate niches i. Repeated, non-consecutive positives usually indicate the presence of a niche or harborage site for L. monocytogenes ii. Increase testing of the positive site including individual pieces of equipment to locate the source of the contamination d. Thoroughly clean and sanitize the individual parts. i. Intense scrubbing is necessary to breakup or dislodge a biofilm. ii. A change of cleaning or sanitizing solutions may be indicated. 41", "Updated Compliance Guidelines May 2006 iii. Fogging of the equipment or room with a sanitizer such as quaternary ammonium compounds could be used if problems persist. e. Reassemble and test again during operation until the FCS test negative on consecutive tests. At the same time as the comprehensive investigation, the establishment should examine and review its HACCP plan, Sanitation SOP or its prerequisite program where the sanitation and testing programs are included, evaluate and determine if there is any design or execution flaw, and modify as necessary. The establishment should evaluate the cleaning or sanitizing procedure, the method of verifying that the procedures are performed as prescribed, employee hygiene practices, monitoring traffic patterns, equipment design, or change in processing conditions.

2. Expected Frequencies of Establishment Verification Testing of Food Contact Surfaces for Alternatives 1, 2 and 3

The chart below shows the frequencies of testing food contact surfaces that establishments in Alternatives 1, 2 and 3 should conduct for verification of the effectiveness of their sanitation program. Establishments should consider these frequencies when determining the level of Listeria control they believe is prudent in their establishments based on their operation and historical data. Those establishments assuming these levels of verification testing likely would be subject to more intense verification activity by FSIS, and their vulnerability regarding the scope of a recall likely is increased in situations where product in commerce is linked to their establishment. The scope of a recall is dependent, in part, upon the level and type of documentation that establishment maintains on the on-going effectiveness of their operation.

Expected Frequencies of Establishment Verification Testing of Food Contact Surfaces for Alternatives 1, 2 and 3. Food Contact Surface Testing Higher Frequency Lower Frequency

Alternative	Frequency
Alternative 1	> 2/year/line
Alternative 2	> 4/year/line
Alternative 3	> 1/month/line

Deli, hotdogs: Very Small volume plant > 1/month/line

Small volume plant > 2/month/line

2\month\line Large volume plant > 4\month\line 4\month\line 3. Testing Food Contact Surfaces and Other Environmental Surfaces for Listeria spp. and Listeria-like Organisms RTE meat and poultry establishments perform many different microbiological testing programs, including: 42", "Updated Compliance Guidelines May 2006 43 \u2022 Testing for the presence of Listeria spp. or Listeria-like organisms. These organisms are appropriate for use as indicators of *L. monocytogenes* because their presence indicates the possible presence of the pathogen. If tests for these organisms are negative, it is unlikely that *L. monocytogenes* is present. Tests for Listeria spp. or Listeria-like indicator bacteria are typically abbreviated versions of *L. monocytogenes* methods, terminated after enrichment and screening steps, but before *Listeria monocytogenes* is confirmed, specifically:

- o Tests for Listeria spp. organisms are rapid screening procedures involving genus Listeria-specific immunoassays, genetically-based or other rapid assays, in which a positive result is obtained but not confirmed as *Listeria monocytogenes*
- o Tests for Listeria-like organisms are typical cultural procedures in which potential positives are indicated by biochemical reactions in differential broth or plating media, but are not confirmed as *Listeria monocytogenes* \u2022 Testing methods to enumerate Listeria spp. or Listeria-like organisms. Such methods are appropriate for enumerating the number, but are not sensitive enough for determining the presence or absence of these microorganisms, if present at low levels. Enumeration methods do not include an enrichment period, and therefore are not sufficiently sensitive for the requirements of a testing program designed to detect low numbers of organisms present. In addition, the surface area tested must be factored into the results in order to make a best estimate of the number of organisms present in that specified area. FSIS realizes that there may be circumstances when the establishment chooses to use such enumeration methods for their own purposes. Such techniques are important when trying to ascertain the likely level of contamination that comes into contact with RTE product. However, the establishment must provide scientific justification for any testing methods used for environmental testing, and a rationale for the conclusions derived from such testing. \u2022 Testing for aerobic plate counts (APC), total plate counts (TPC), coliforms, ATP etc. Such tests are not appropriate indicators for *L. monocytogenes* as they cannot establish the presence or absence of this organism. Testing for these organisms is appropriate for monitoring the effectiveness of the sanitation procedures or the level of contamination during processing. To ensure that any potential Listeria spp. or Listeria-like organisms are detected, it is necessary for the method used to provide the lowest possible limit of detection (i.e., maximum sensitivity for detection) for these organisms. Testing methods meeting the following criteria are most likely to be suitable for this purpose: \u2022 The method is used by a regulatory body or has been validated by a recognized independent body (e.g., AOAC, AFNOR, ISO), using the FSIS *Listeria monocytogenes* qualitative method as a reference method. A validated method from a scientifically robust study using the FSIS *Listeria monocytogenes* qualitative method as a reference method is also acceptable but may be subject to FSIS review. The", "Updated Compliance Guidelines May 2006 44 validation procedure should be consistent with the goal of providing sensitive qualitative detection of environmental Listeria, AND \u2022 The method includes an enrichment period that allows for the recovery and resuscitation of any sub-lethally injured cells also allows for the outgrowth (multiplication) of very low numbers of Listeria to levels that can be detected by the test method. In general, direct-plating enumeration methods, which do not include a period for outgrowth of cells and cannot detect

microorganisms at very low levels, are inappropriate for ensuring that Listeria contamination is not present on food contact or other environmental surfaces, AND \u2022 The method must accommodate analysis of the entire sample sponge (or other sampling device), and all associated diluent, to maximize the possibility of detecting any cells that are present. By only analyzing a portion of the diluent or by not testing the sponge or swab, any Listeria remaining in the untested sample portion would not be represented, thereby decreasing the potential for detecting Listeria contamination. Quantitative methods, including direct-plating and most-probable-number methods, typically test only a portion of the diluent and so are inappropriate for ensuring Listeria are not present on food contact or other environmental surfaces. The establishment is responsible for the choice of methods. It is the establishment\u2019s responsibility to share this guidance document with microbiological consultants and testing laboratories so that all parties understand what methods and sample test portions are appropriate for the intended purpose. Also, any methods used should be validated to ensure that they can reliably detect the presence of Listeria spp. or Listeria-like organisms on food contact and other environmental surfaces. In addition, the establishment should maintain documentation related to the selected testing procedure. If an establishment chooses not to use a proven methodology for food-contact and other environmental-surface testing, it may be assuming a greater risk of allowing adulterated product into the marketplace, and therefore being confronted with recall requests and regulatory actions. Should FSIS question the suitability of the method employed by an establishment, it may choose to review the scientific basis for the sampling and testing procedures used. In such a circumstance, the establishment could be subject to focused verification checks, including review of recordkeeping, observation of production, and collection of product and environmental sampling for testing. FSIS method for analysis and confirmation of *L. monocytogenes* and other FSIS microbiology laboratory methods are available and can be downloaded at

[http://www.fsis.usda.gov/Science/Microbiological\\_Lab\\_Guidebook](http://www.fsis.usda.gov/Science/Microbiological_Lab_Guidebook)

4. Hold-and-Test Scenario for Deli and Hotdog Products in Alternative 3 Assuming it takes to 3 days to obtain a test result for Listeria spp., or Listeria-like organisms:","Updated Compliance Guidelines May 2006 Day 1 \u2013 Take food contact surface (FCS) samples Day 4 \u2013 FCS sample (from Day 1) negative for Listeria spp. or Listeria-like organisms. 9 Continue production as the corrective action appears to resolve problem and test FCS as scheduled. If FCS sample positive (from Day 1) for Listeria spp. or Listeria-like organisms. 9 Take Corrective Action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include an intensified cleaning and sanitizing. 9 Test FCS-- target most likely source of contamination, and additional tests in surrounding FCS area 9 Continue production. Day 7 \u2013 Follow-up FCS sample (from Day 4) is negative for Listeria spp. or Listeria-like organisms. 9 Continue production as the corrective action appears to resolve problem and test FCS as scheduled. If follow-up FCS sample (from Day 4) is positive for Listeria spp., or Listeria- like organisms. 9 Take Corrective Action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include an intensified cleaning and sanitizing. 9 Test FCS-- target most likely source of contamination, and take additional tests in surrounding FCS area 9 Hold and test Day 7 product lot (for *L. monocytogenes* or Listeria spp. or Listeria-like organisms). 9 Continue production, hold product from the day\u2019s production Day 8 \u2013 9 Test FCS-- target most likely source of contamination, and take additional tests in surrounding FCS area 9 Hold product from this

day\u2019s production Day 9 \u2013 Test FCS-- target most likely source of contamination, and take additional tests in surrounding FCS area 9 Hold product from this day\u2019s production Day 10 \u2013 If FCS sample (day 7 sample) is negative for Listeria spp., or Listeria-like organisms. 9 Continue production and hold product from days 7, 8, 9 and 10 until the results from Day 7 product testing and Days 8, 9, 10 FCS testing are available and found negative, unless there is compelling justification that affected products are not adulterated. 9 Resume FCS testing according to frequency stated in sanitation program 45", "Updated Compliance Guidelines May 2006 46 If FCS sample (day 7 sample) is positive for Listeria spp., or Listeria-like organisms: \ufffd Hold and test product from day 10 production. \ufffd Test product from days 7, 8, 9, and 10 for L. monocytogenes, Listeria spp. or Listeria-like organisms \ufffd Take corrective action \ufffd Intensive cleaning and sanitizing \ufffd Take FCS sample-- target most likely source of contamination, and additional tests in surrounding FCS area Day 14 \u2013 If Day 7 product is positive for L. monocytogenes, destroy product, or rework product with a process that is destructive of L. monocytogenes. Recall product if already in commerce. If product is positive for Listeria spp., verify that products (Days 7, 8, 9, 10), which may have been exposed to insanitary conditions are not adulterated by testing to provide compelling justification. If the establishment tests FCS samples for L. monocytogenes, and the FCS test positive for the pathogen, the sampled lot is considered adulterated. Every time there is a second or more (consecutive) follow-up FCS positive, product is held and tested for L. monocytogenes. Only product lots implicated with a second or more (consecutive) follow-up FCS positive are held and tested. Every time there is a product positive for L. monocytogenes, product is held, and destroyed or reworked with a listericidal process. Once the FCS testing is negative, implying that the corrective action is working, production is continued. Repeated FCS positives would imply a critical sanitation problem and the establishment needs to conduct intensive testing and intensive cleaning and sanitizing. At the same time the establishment should investigate the cause and source of the contamination and review the documents where the sanitation and testing programs are included to determine if there are design or execution flaws. The establishment should have provisions in their sanitation and testing program for these kinds of situations. A joint industry group has completed guidelines titled \u201cIndustry Best Practices for Holding Tested Products.\u201d This document was designed to encourage all establishments to hold products that are tested for adulterants until the results are received and to assist companies in developing best practices to ensure that they in fact do so. To obtain a copy of this document, visit the International HACCP Alliance website at the following address: <http://haccpalliance.org/alliance/bestpractices.html> 5. Sentinel Site Program Example Some establishments have adopted a sentinel site program for the control of L. monocytogenes in RTE meat and poultry products. A sentinel site program is similar to traditional Listeria control programs \u2013 separate testing programs for the environment and food contact surfaces and increasingly aggressive corrective actions to eliminate Listeria", "Updated Compliance Guidelines May 2006 when it is detected. The distinctive characteristic of this control program is that in the case of a positive Listeria test result for a food contact surface area, the sanitation of that particular area will be included in the HACCP plan as a CCP. The CCP is removed when the establishment determines that the food safety hazard has been eliminated and is not reasonably likely to occur. The CCP is the sanitation program for the particular site and food contact surface sampling as verification of the CCP. If a

food contact surface or non-food contact surface tests positive for Listeria spp. or Listeria-like organisms, testing is intensified in the identified area. 1 If a non-food contact surface sampling site is found to be positive for Listeria spp. or Listeria-like organisms during routine monitoring, intensified sampling is initiated as soon as possible. Under intensified sampling, three samples per day (one each at pre-op, st shift, 2nd shift) are analyzed until a total of nine consecutive samples have been taken and are negative for Listeria spp. or Listeria-like organisms at that particular site. Swabs are analyzed for each day of production. If a sample finding is positive, testing of that site continues until nine consecutive samples are negative for Listeria spp. or Listeria-like organisms. Once nine consecutive samples are found negative, that site will be returned to routine sampling. Similarly, the food contact surface site that initially tests positive for Listeria spp. or Listeria-like organisms will be placed under intensified testing. If nine consecutive samples under the intensified testing are negative for Listeria, that site is returned to routine monitoring. However, if the food contact surface tests positive under the initial intensified sampling, sanitation for that area is designated as a CCP, since Listeria would, at that point be considered a hazard not reasonably likely to occur. The site testing positive for Listeria would be considered a suspect harborage for L. monocytogenes and corrective actions taken. Testing becomes the verification step. 1 Intensified sampling under the CCP requires that 3 samples per day (one each at pre-op, st shift, 2nd shift) be taken until nine consecutive samples are negative for both Listeria spp. and L. monocytogenes. If a sample is positive for Listeria spp. but negative for L. monocytogenes, additional sampling days are added (3 samples per day) until nine consecutive samples are negative for both Listeria spp. and L. monocytogenes. All products that have contact with that particular site must be placed on hold pending test results. If nine consecutive samples are negative for Listeria spp. and L. monocytogenes, the site can be returned to routine sampling. Product can be released when the line and production date receive negative test results for L. monocytogenes. Any sites testing positive for L. monocytogenes would require testing of the product. Sentinel Site Program Example Flowchart 47", "Updated Compliance Guidelines May 2006 1. Routine Environmental Sampling a. 5 samples\line\week i. 3 \u2013 food contact surface samples ii. 2 \u2013 non-food contact surface samples iii. Listeria spp. 2. Non-food Contact Surface Testing a. If negative for Listeria spp., continue Routine Environmental Testing b. If positive for Listeria spp., intensify sampling i. Collect 3 samples\site\day for 3 consecutive days for Listeria spp. (9 consecutive samples) ii. If 9 consecutive samples are negative for Listeria spp., return to Routine Environmental Sampling iii. If any sample is positive, continue sampling 3 samples\site\day until 9 consecutive samples are negative 3. Food Contact Surface (FCS) Testing a. If negative for Listeria spp., continue Routine Environmental Testing b. If positive for Listeria spp., intensify sampling i. Collect 3 samples\site\day for 3 consecutive days for Listeria spp. (9 consecutive samples) ii. If 9 consecutive samples are negative for Listeria spp., return to Routine Environmental Sampling iii. If any sample is positive, make sanitation for that site a CCP 4. CCP Testing a. Collect 3 samples samples\site\day for 3 consecutive days for Listeria spp. and L. monocytogenes (9 consecutive samples) b. If 9 consecutive samples are negative for Listeria spp. and L. monocytogenes, return to Routine Environmental Sampling and eliminate the CCP c. If a sample is positive for Listeria spp. but negative for L. monocytogenes i. Place product on hold ii. Release product if site and production date have negative results for L. monocytogenes iii. Continue testing until 9 consecutive samples are negative for Listeria spp. and L. monocytogenes, then return to

Routine Environmental Sampling and eliminate the CCP d. If any sample is positive for L. monocytogenes, test the product for L. monocytogenes i. Reprocess or destroy product testing positive for L. monocytogenes H. RISK-BASED VERIFICATION TESTING PROGRAM Risk-Based Sampling. Before the implementation of risk-based verification sampling, samples were collected under sampling project codes ALLRTE (all RTE products \u2013 both post-lethality exposed and non-post-lethality exposed), RTERISK1 (product priority list based on FSIS Directive 10,240.4), and RTE001 (establishments are identified for sampling based on risk ranking). For ALLRTE, all establishments, regardless of plant size, production volume, or process design had an equal chance of being sampled each fiscal year. Results from this project were unbiased to the extent that production practices were not addressed as they are in the other RTE verification sampling projects. Overall prevalence of the pathogens, for which FSIS tests, in all types of operations can be ascertained. FSIS randomly collected one sample of product at a time from an individual establishment and tested for pathogens of public health concern, namely, Listeria monocytogenes, Salmonella and E. coli O157:H7. Inspection program personnel carried out HACCP, Sanitation SOPs, and prerequisite program verification activities, including the review of records and laboratory results, to verify that establishment\u2019s are properly addressing the control of pathogens. The implementation of the risk-based verification program consists of two phases. Phase 1 of the risk-based verification testing program was implemented in January 2005 with the issuance of FSIS Notice 61-04 announcing the RTE001 project for testing of postlethality exposed ready-to-eat (RTE) meat and poultry products for L monocytogenes. Project RTE001 was designed to consider the Alternative (i.e., 1, 2. or 3 of 9 CFR 430.4) that the establishment selected for the production of post-lethality exposed products. That is, sampling was based on the risk of Listeria contamination of products produced under the three Alternatives. In Phase 2, this concept was expanded to include testing of food contact surfaces, environmental (non-food contact surfaces), and finished product. As more samples are taken for the RTE001 sampling project, sample project RTERISK1 will be discontinued. The ALLRTE project will still be continued in Phase 2. In Phase 1, a checklist (Procedures for the Evaluation of Establishment Control Programs for Listeria monocytogenes, Attachment 7) was developed to evaluate the effectiveness of the post-lethality treatment, antimicrobial agent or process and the sanitation program used by the establishment to control L. monocytogenes in their post-lethality exposed RTE meat and poultry products. The checklist will be completed by Enforcement, Analysis and Investigative Officers (EAIO) whenever a Food Safety Assessment (FSA) is conducted. Follow-up Sampling. When a sample taken under the sampling projects outlined above is found to be positive for a pathogen, FSIS will conduct follow-up verification testing after the establishment has taken its corrective and preventive actions. The follow-up sampling will be conducted under the Intensified Verification projects, as described below. Intensified Verification Testing. These projects are designed for testing in any operation involving any RTE meat or poultry product, regardless of the establishment\u2019s control procedures, the production volume, etc., due to the production of adulterated product (i.e., the pre-shipment review has been completed), investigative purposes (e.g., as a result of an outbreak of foodborne disease), or concern that the establishment may not be properly controlling for pathogens. The projects may include instructions to Inspection program personnel to collect multiple samples. Intensified verification testing will include: 49", "Updated Compliance Guidelines May 2006 1. Increased

frequency and number of samples taken for product testing (as compared to targeted verification testing), and the collection of environmental samples. 2. Increased FSIS record verification checks regarding the design and implementation of the food safety system. These sampling projects will be scheduled by OFO through OPHS on a case-by-case basis.

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1 ALTERNATIVE 2 ALTERNATIVE 3 Post-lethality Treatment (PLT) OR Antimicrobial Agent or Process Choice 1 Choice 2 Sanitation and Testing Program REQUIREMENTS Post-lethality Treatment (PLT) AND Antimicrobial Agent or Process PostLethality Treatment Antimicrobial Agent or Process Non-deli or Hotdog Product Deli or Hotdog Product Validate effectiveness of post-lethality treatment (PLT). Must be included as a CCP in the establishment\u2019s HACCP Plan and should show at least a 1 log reduction in Lm prior to distribution of the product into commerce. X X Document effectiveness of antimicrobial agent or process. Must be included as part of the establishment\u2019s HACCP, Sanitation SOP, or Pre-requisite program and should demonstrate no more than 2-logs growth of Lm over estimated shelf life. X X Sanitation Program Requirements1 X X X Testing food contact surfaces (FCS) in the post-lethality processing environment for Lm or an indicator organism. X X X Indicate testing frequency. X X X Identify size and location of sites to be tested. X X X Explain why testing frequency is sufficient to control Lm or an indicator organism. X X X Identify conditions for Hold-and-Test, when FCS (+) for Lm or an indicator organism. X X X Additional Sanitation Program Requirements2 X Follow-up testing to verify corrective actions are effective after 1st FCS (+) for Lm or an indicator organism. Includes testing of targeted FCS as most likely source and additional testing of the surrounding area. X If follow-up testing yields a 2nd FCS (+), hold products that may be contaminated until problem is corrected as shown by FCS (-) in follow-up testing. X Hold and test product lots using a sampling plan that will ensure that the lots are not adulterated with Lm and document the results of this testing. Alternately, rework the product with a process destructive of Lm or an indicator organism. X For further information see the following links: 9 CFR 430.4 FSIS Directive 10,240.4, Rev.2 FSIS Directive 10,240.4, Rev 2 Related Documents Listeria Fact Sheets 1 Sanitation program requirements as found in 9 CFR 430.4(b)(2)(iii) or (b)(3)(i) 2 Additional sanitation program requirements as found in 9 CFR 430.4(b)(3)(ii)", "Updated Compliance Guidelines May 2006 ATTACHMENT 2 CHART OF RTE VS NRTE PRODUCTS PROCESSING REG REQUIRED WHAT THE HAZARD ANALYSIS\HACCP TYPE CLASS CATEGORY ISP CODE SAFETY LABELING PLAN MAY ADDRESS A product containing a meat\poultry product (in whole or in part) which has not received an adequate lethality treatment for pathogens (i.e. raw or partially cooked product). Not ready-to-eat \u2022 Raw Product Ground \u2013 ISP 03B \u2022 Raw Product Not Ground \u2013 ISP 03C \u2022 Not Heat Treated Shelf Stable \u2013 ISP 03E \u2022 Heat Treated \u2013 shelf stable \u2013 ISP 03F \u2022 Heat Treated but not Fully Cooked Not Shelf Stable ISP 03H Product must be labeled with statements such as keep refrigerated, keep frozen, or refrigerate leftovers. Use of Safe Handling Instruction (SHI) labeling required. \u2022 Use of SHI labeling (Some establishments may have a CCP for SHI labeling application). If it is not obvious that the product is raw and needs to be cooked: \u2022 Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., \u201cCook and Serve\u201d) but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as \u201cneeds to be fully cooked,\u201d \u201csee cooking instructions,\u201d or \u201ccook before eating.\u201d \u2022 Validation that: \u2022 Products with secondary inhibitors Not Shelf Stable \u2013 ISP 03I a. Cooking and preparation instructions on the product are sufficient to destroy pathogens. b. Instructions are realistic for the intended consumer. \u2022 A product containing a meat\poultry component that has

received a lethality treatment for pathogens in combination with non-meat\poultry components that need to receive a lethality treatment by the intended user. This includes meals, dinners, and frozen entrees. Not ready-to-eat \u2022 Heat Treated but not Fully Cooked Not Shelf Stable ISP 03H Product must be labeled with statements such as keep refrigerated or frozen. Use of SHI labeling is recommended. \u2022 Validation that: a. The meat\poultry component received an adequate lethality treatment for pathogens. b. Cooking and preparation instructions on the product are sufficient to destroy pathogens. c. Instructions are realistic for the intended consumer. \u2022 Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., \u201cCook and Serve\u201d) but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as \u201cneeds to be fully cooked,\u201d \u201csee cooking instructions,\u201d or \u201ccook before eating.\u201d \u2022 If necessary, hazard analysis should address whether instructions on the label are needed related to cross-contamination (e.g., avoid contact of contents) and prevention of pathogenic growth (e.g., promptly refrigerate leftovers). NOTE: Inspection program personnel are to collect samples as RTE if the establishment does not follow the guidance above.

56", "Updated Compliance Guidelines May 2006 A product containing a meat\poultry component that has received a lethality treatment for pathogens that may or may not be in combination with a nonmeat\poultry component that does not need to receive a lethality treatment by the intended user. Ready-to-eat \u2022 Not Heat Treated Shelf Stable \u2013 ISP 03E \u2022 Heat Treated Shelf Stable \u2013 ISP 03F \u2022 Fully Cooked Not Shelf Stable \u2013 ISP 03G \u2022 Products with secondary inhibitors Not Shelf Stable \u2013 ISP 03I If the product is not shelf stable labeling such as keep refrigerated or frozen is required. \u2022 See part 417 of the meat and poultry regulations.

57", "Updated Compliance Guidelines May 2006 ATTACHMENT 3 PRODUCTION INFORMATION ON POST-LETHALITY EXPOSED READY-TO-EAT PRODUCTS The form can be accessed at: [http://www.fsis.usda.gov/Forms/PDF/Form\\_10240-1.pdf](http://www.fsis.usda.gov/Forms/PDF/Form_10240-1.pdf)

58", "Updated Compliance Guidelines May 2006 ATTACHMENT 4 STUDIES ON POST-LETHALITY TREATMENTS and ANTIMICROBIAL AGENTS A. Studies on Post-lethality Treatments (Mention of trade marks or commercial names does not constitute endorsement by USDA)

- I. Steam Pasteurization and Hot Water Pasteurization Post processing contamination of RTE meat and poultry is mostly confined to the surface. Pasteurization by steam and hot water acts on the surface microbial contaminants by the action of heat. Studies on surface pasteurization using steam or hot water were shown to be effective in reducing this contamination. Studies by Murphy et al. (2003a) showed that post-cook hot water pasteurization and steam pasteurization resulted in a 7 log<sub>10</sub> reduction of *L. monocytogenes* in inoculated vacuum packaged fully cooked sliced chicken. The reduction was effective when single \u2013 packaged breast fillets, 227 g- package strips and 454 g-packaged strips were heat treated at 90 C in a continuous steam cooker or hot water cooker for 5, 25 and 35 minutes respectively. These investigators developed a model called ThermoPro that could predict the thermal lethality of pathogens in fully cooked meat and poultry products during postcook in-package pasteurization (Murphy et al., 2001, 2003b, 2003c). The model was developed using *L. innocua* and verified for *L. monocytogenes*.
- II. Pre-Package Pasteurization and Post-Package Surface Pasteurization Pre-package surface pasteurization treatment of fully cooked meat removed from their packaging

wrap and inoculated with *L. monocytogenes* resulted in a 1.25 to 3.5 log reduction with a treatment time of 60-120 sec at 475 to 750°F air temperature (Gande and Muriana, 2003). Surface pasteurization was applied on cooked whole and split roast beef, whole corned beef, and whole and formed ham using a radiant oven. Pre-package pasteurization (60 sec) combined with post-package submerged water pasteurization using formed ham (60 or 90 sec), turkey bologna (45 or 60 sec), and roast beef (60 or 90 sec), resulted in a 3.2 to 3.9 log reduction for ham, 2.7-4.3 log reduction for bologna, or a 2.0-3.75 log reduction for roast beef. The level of reduction varied depending on the method of inoculation, type of product used, treatment temperature, and residence time. Muriana et al., (2002) used a stainless steel water bath to submerge cooked RTE delistyle whole or formed turkey, ham and roast beef, removed from their package, inoculated with *L. monocytogenes* and vacuum packaged. Results show a 2-4 log decrease in the levels of *L. monocytogenes* in inoculated products post-cooked at 195205°F for 2-10 min. 59", "Updated Compliance Guidelines May 2006 Treatment of processed foods with acidified sodium chloride (ASC) is another example of pre-packaging treatment. ASC is an antimicrobial agent that is approved for use on processed meat food products (unless precluded by standards of identity in 9 CFR 319) prior to packaging of the food for commercial purposes (21 CFR173.325 (f)). It is applied as a dip or spray at levels that result in sodium chlorite concentration of 500 to 1,200 ppm in combination with any GRAS acid at levels sufficient to achieve a pH of 2.5 to 2.9. It is approved as a secondary direct food additive, and considered as a processing aid, with very temporary or short term technical effect (bactericidal antimicrobial activity) after which it rapidly degrades to leave no long term residues or actives remaining (Kemp, Alcide Corp., personal communication, 2003). Because of this, it does not have to be included in the ingredient listing of the label. Marsden et al. (2000, unpublished), evaluated sodium chlorite (1,200 ppm) with 0.9% citric acid for its effectiveness in reducing *L. monocytogenes* on retail Little Smokies sausages. Results show that a water wash gave a 1.2 log cycle reduction of *L. monocytogenes*. An ASC dip for 15 sec provided a 1.0 log cycle reduction better compared to water wash. ASC exposure time of 30 sec gave 1.1 and 1.6 log cycle reductions over the water wash control, for spraying and dipping, respectively. Spray wash or dipping was found to be comparable in antibacterial effectiveness against *L. monocytogenes*.

III. High Hydrostatic Pressure Processing High pressure processing (HPP) is one of the new technologies used for food processing. This technology provides a means of ensuring food safety for those products that are difficult to be heat treated due to organoleptic effects. HPP was shown to inactivate pathogens without any thermal or chemical effects and at the same time preserve the quality of the product. Raghubeer and Ting (2003) evaluated the efficacy of high hydrostatic pressure processing in inactivating *L. monocytogenes* in retail-packaged samples of sliced ham, turkey and roast beef obtained from a manufacturer and repackaged in 25-g portions. Results show that an inoculum of about 10<sup>4</sup> *L. monocytogenes* cocktail in these 3 products and HPP treatment at 87,000 psi for 3 minutes showed no recovery of *L. monocytogenes* after 61 days of storage at 34°F. There were no pressure-injured cells detected. There were no adverse organoleptic effects detected on the 3 HPP treated products during the 61-day shelf life study. No signs of spoilage were seen on all 3 products after 61 days of storage, and for 100 days for ham and turkey. According to the investigators, the normal shelf life of these products is 30 days, so the HPP treatment extended the shelf life of the products.

B. Studies on the Use of Antimicrobial Agents I. Addition of Lactates, Acetates,

Diacetates to Meat Formulations Studies have shown that lactic acid and acetic acid have significant antimicrobial activity in broth and food systems. Sodium and potassium salts of these acids, when added to processed meat formulations are also known to potentially inhibit pathogenic bacteria especially *L. monocytogenes*. These antimicrobials inhibit growth of pathogens by 60%,"Updated Compliance Guidelines May 2006 inhibiting their metabolic activities. Interest in these antimicrobials is in the growth inhibition of *L. monocytogenes* in post lethality exposed RTE meat and poultry products. Several studies used these antimicrobials to show their ability to inhibit growth of *L. monocytogenes* in different meat formulations. Seman et al., (2002) developed a mathematical model capable of predicting the growth or stasis of *L. monocytogenes* in commercial cured meat products using a response surface method. The model can be used by manufacturers in the determination of the appropriate amounts of potassium lactate and sodium diacetate to be added to cured meat products that are organoleptically sensible and will not support the growth of *L. monocytogenes*. Thirty products were formulated by using a variety of raw material sources such as pork trimmings, trimmed turkey breast halves and four-muscle ham. Varying amounts of potassium lactate and sodium diacetate were added to the meat formulation and the meats were processed into different products. After chilling, the products were stripped of their casings, sliced into 25-g slices, placed into pouches, and inoculated with *L. monocytogenes* by applying to the surface of 100g of cured meat (four slices). The results show that increasing amounts of potassium lactate syrup and sodium diacetate decreased the growth rate of *L. monocytogenes*, while increasing finished product moisture increased the growth rate. Sodium chloride content was not significant but was found to have a negative correlation to growth rate. The investigators provided a final regression equation predicting the growth of *L. monocytogenes* in cured RTE meat products stored at 4\u00b0C. The investigators used predictive model performance factors and a simple linear regression analysis to evaluate the model generated in this study. They verified the accuracy of the model by comparing with actual *L. monocytogenes* growth data from an independent challenge study conducted with four different commercial RTE meat products using similar storage conditions. Performance factors calculated and evaluated for control products (those not containing potassium lactate and sodium diacetate) indicated that on the average, the predicted growth of *L. monocytogenes* exceeded those of the observed values by about 24 %. This study provided a useful model in determining the target amounts of potassium lactate and sodium acetate for cured meat product formulations to inhibit the growth of *L. monocytogenes*. The calculations would also require knowledge of the finished product sodium chloride and moisture contents. The investigators advised that this validated model is specific to the products designed for the study and the *L. monocytogenes* strains used. Testing of this model in other environments and with other *Listeria* spp., and to formulations that are outside the model's limits may result in different maximum growth rates. This study was used as the basis for the Opti.Form Listeria Control Model. The Opti.Form Listeria Control Model is a unique tool to calculate the levels of lactate and diacetate required to retard the growth of *Listeria monocytogenes* in cured meat and poultry products. The model is based on the study detailed in the paper by Seman et al, 2002, above. The model, which is available on CD-Rom includes: \u2022 instructions on how to use the model \u2022 explanation on the development of the model 61","Updated Compliance Guidelines May 2006 \u2022 information on the anti-microbial effect of lactate and diacetate \u2022 lactates and diacetates and use of

these products \u2022 regulations and labeling \u2022 literature references To receive a free copy of the model on CD-Rom, call: 888-899 8229, E-mail pam@purac.com Bedie et al., (2001) evaluated the use of antimicrobials, included in frankfurter formulations, on L. monocytogenes populations during refrigerated storage. Fully cooked and cooled frankfurters were inoculated with 103 to 104 CFU /cm<sup>2</sup> of L. monocytogenes after peeling and before vacuum packaging. Samples were stored at 4\u00b0 C for up to 120 days and sampled for testing on assigned days. Results are as follows: ANTIMICROBIAL LEVEL (%) L. MONOCYTOGENES GROWTH INHIBITION Sodium lactate 3 70 days no pathogen growth Sodium diacetate 0.25 50 days no pathogen growth Sodium acetate 0.25, 0.50 20 days no pathogen growth Sodium lactate 6 120 days no growth and reduced pathogen growth Sodium diacetate 0.5 120 days no growth and reduced pathogen growth Inoc. Control 0.0 Increased to 6 logs in 20 days Note: Sodium acetate is approved as a flavor enhancer, not as an antimicrobial agent. No pathogen growth refers to zero increase in the number of inoculated L. monocytogenes cells (bacteriostatic); while reduced pathogen growth refers to a decrease in the number of inoculated L. monocytogenes cells (bactericidal) in the product. In this study, tables showed the reduction varied with storage days, but was up to 1.0 log on some days. Antimicrobials were found to have no effect on pH except for sodium diacetate at 0.5 % which reduced the initial pH. Using the formulations and conditions in the study, establishments can add 3 % sodium lactate in the frankfurter formulation and obtain no growth of L. monocytogenes up to 70 days at refrigerated storage of 4\u00b0 C. If the lethality treatment is adequate to eliminate L. monocytogenes, then the only probable source of L. monocytogenes would be from exposure of the product during peeling and repackaging. However, the establishment\u2019s sanitation program may keep the numbers to a very low level, and 3 % sodium lactate included in the formulation would inhibit the growth of L. monocytogenes during the product\u2019s refrigerated shelf life. Levels of sodium lactate at 6.0 % and sodium diacetate at 0.5 % showed a reduction of the pathogens, however these levels are above the permitted levels. This study by Samelis et al., (2002) used similar treatments, processing and inoculation procedures and frankfurter formulations as the previous study described above. However, in this study combinations of antimicrobials were used, and in combination with hotwater treatment. Hot water treatment involved immersion of frankfurters, with two product links in a package to 75 or 80\u00b0 C for 60 s. Storage at 4\u00b0 C shows: 62", "Updated Compliance Guidelines May 2006 TREATMENT LEVELS (%) L. MONOCYTOGENES GROWTH INHIBITION Sodium lactate 1.8 35-50 days no growth Sodium lactate + 1.8 120 days no growth; 35-50 days growth sodium acetate 0.25 reduction Sodium lactate + 1.8 120 days no growth; 35-50 days growth Sodium diacetate 0.25 reduction Sodium lactate + 1.8 120 days no growth, 35-50 days growth Glucuno-delta0.25 reduction lactone Hot water treatment (80\u00b0 C, 60 s) + Inoc. population reduced by 0.4-0.9 log CFU/cm<sup>2</sup>, and Sodium lactate 1.8 50-70 days growth reduction by 1.1-1.4 CFU/cm<sup>2</sup> Hot water treatment Increase in growth to about 6-8 logs in 50 days (80\u00b0 C, 60 s) Inoculated Control, Increase in growth to about 6 logs in 20 days no treatment and 8 logs thereafter up to 120 days Note: Sodium lactate was used as a 3 % of a 60 % (wt/wt) commercial solution. Glucunodelta lactone is approved as an acidifier, and a curing accelerator, but not as antimicrobial. Sodium acetate is approved as a flavor enhancer, not as an antimicrobial agent. Glass et al., (2002) evaluated sodium lactate and sodium diacetate on wieners and cooked bratwurst containing both beef and pork supplied by a commercial manufacturer. Antimicrobial solutions used were sodium

lactate and sodium diacetate singly or in combination at varying concentration. Wieners were repackaged in gas-impermeable pouches, then surface-inoculated with *L. monocytogenes* mixture on multiple areas of the surface of each link. Packages were vacuum-sealed and stored at 4.5°C for up to 60 days. Two types of cooked bratwurst from a commercial manufacturer were evaluated: bratwurst that was cured and naturally smoked and bratwurst that was uncured and unsmoked. Bratwurst was stored at 3 or 7°C for up to 84 days. The surface treatment consisting of dipping wieners into solutions containing up to 6 % lactate and up to 3 % diacetate for 5 s did not delay pathogen growth, indicating that dipping wieners in the lactate/diacetate solutions is not an efficient way to apply the antimicrobials. However, the inclusion of lactates and diacetates in the formulation was found effective in inhibiting growth of *L. monocytogenes*. Results are as follows: PRODUCT Sodium Lactate (%) Sodium diacetate (%) *L. monocytogenes* levels (CFU/pkg) Bratwurst 3.4 0.1 Growth delayed for 4-12 weeks at 7 and uncured, unsmoked 3°C storage, respectively. 2.0 0.0 Growth delayed for 1-2 weeks at 7 and 3°C 63", "Updated Compliance Guidelines May 2006 Bratwurst 3.4 0.1 Growth inhibited for 12 weeks at 7 and cured, 3°C smoked 0.0 0.0 Growth up to 1 log after 4 weeks at 7 and 3°C Wieners 3.0 1.0 0.0 0.1 Growth inhibited for 60 days at 4.5°C Growth inhibited for 60 days at 4.5°C Study by (Porto et al., 2002) used freshly processed peeled frankfurters in vacuum sealed packages obtained from a commercial manufacturer. Two formulations of links were used in the study: one with added 2 or 3 % potassium lactate and the other without added potassium lactate. Frankfurters were aseptically removed from their original package, repackaged, and inoculated with a mixture of *L. monocytogenes*. The packages were vacuum-sealed to 95 kPa and incubated at 4 and 10°C. Results show that addition of 2 % or 3 % potassium lactate in frankfurters can appreciably enhance safety by inhibiting or delaying the growth of *L. monocytogenes* during storage at refrigeration or abused temperatures. The viability of the pathogen was influenced by pH, and the levels of lactate added, but not by the presence of indigenous lactic acid bacteria. Potassium lactate (%) Inoculum CFU/pkg Storage temp °C Days Storage *L. monocytogenes* levels (CFU/package) 2.0 20 4 90 Remained at about 1.6 log 3.0 20 4 90 Remained at about 1.4 log 3.0 500 4 90 Remained at about 2.4 log 0.0 20 4 90 Increased to about 4.6 log 0.0 500 4 90 Increased to about 5.0 log 2.0 20 10 60 Remained at about 1.4 log 3.0 20 10 60 Remained at about 1.1 log 0.0 20 10 60 Increased to about 6.5 after 28 days, declined to about 5.0 after 60 days 3.0 500 10 60 Remained at about 2.4 0.0 500 20 60 Increased to about 6.6 log after 40 days and declined to about 5.5 log after 60 days II. Growth Inhibitor Packaging Growth inhibitor packaging is an intervention, which delivers an active antibacterial agent to the surface of an encased sausage product. By incorporating this special coating onto the internal surface of cellulose casings, the antilisterial treatment is transferred to the surface of the processed meat/sausage during thermal processing. Upon removal of the casing, the treatment remains active on the meat surface, providing effective protection against inadvertent *Listeria* contamination during subsequent peeling and packaging processes. Growth inhibitor packaging used in conjunction with functional 64", "Updated Compliance Guidelines May 2006 HACCP and Good Manufacturing Practices provides the industry with one more tool in their intervention strategy to control the risk of pathogen contamination in ready-to-eat meat and poultry products. Studies on meat formulations for hotdogs using NOJAX® AL® showed that use of the casings provide a lethality hurdle to the growth of *Listeria monocytogenes*, not just

an inhibitory effect. The lethality impact is delivered within the first hours\days of the sausage\hotdog package life. This impact is dependent on many variables but is generally in the range of 1 \u2013 2 log kill of *L. monocytogenes* at high levels of inoculation. This performance has been observed in challenge studies conducted on hotdogs drawn from commercial full-scale trials at a number of commercial processing plants. In high inoculation trials, NOJAX AL has been combined with conventional growth inhibiting additives, and as expected, the lethality impact is obtained and then maintained throughout the product life cycle. In these same trials, without growth inhibiting additives, this casing produces lethality but in several weeks the remaining *L. monocytogenes* begin to grow. NOJAX AL is available in the U.S. having approval by both FDA and USDA for its key component, nisin. This GRAS component must be included in the ingredient statement via a label change request to the FSIS Labeling and Consumer Protection Staff. Because this is a naturally derived polypeptide, there are storage and use-by criteria that will have to be adhered to by the user for maximum benefit. Casing shelf-life is about 60-90days with a not to exceed 85\u00ba F. This technology can be applied to most hotdogs and sausages that are encased in cellulose casing. This casing intervention can be used in any instance where casing is used as a mold for processed meat and poultry during thermal processing. This would include cellulose, plastic, and possibly natural casing. As part of a manufacturer\u2019s decision to use this technology, benefits are: 1) no capital costs or new equipment; 2) no change in processing steps, plant reconfigurations or introduction of process bottlenecks\u2014essentially processor transparent in all aspects of use except casing storage requirements; 3) no impact on flavor, texture, or package appearance, and 4) minor labeling change to ingredient statement Since this is a surface treatment, cost will be proportional to the surface to volume ratio of the product: the larger the sausage diameter, the lower the cost per pound. In general, economic analyses put the cost of this lethality intervention at about 2-3 cents per pound of finished product, with a mid-range target price of 2.5 cents per pound for a traditional 10-to-the-pound retail pack of hotdogs.

Janes et al., (2002) investigated the effect of nisin added to zein film coatings (Z) coated onto cooked ready-to-eat chicken against *L. monocytogenes*. Cooked chicken samples inoculated with *L. monocytogenes* were dipped into Z dissolved in propylene glycol or ethanol, with or without added nisin (1,000 IU/g) and/or 1 % calcium propionate and stored at 4 C or 8 C for 24 days. After 16 d at 4 C, *L. monocytogenes* was suppressed by 4.5 to 5 log CFU/g with zein film coatings with nisin. The most effective treatment in the 65", "Updated Compliance Guidelines May 2006 study for controlling *L. monocytogenes* on the surface of ready-to-eat chicken was using edible zein film coatings containing nisin at a storage temperature of 4\u00b0C. The use of film coatings in a processing plant would be to fully process the meat products then coat them with the films. Coating can be done by spraying or dipping the processed meat products and then allowing them to dry. Zein coatings on the meat products can be dried by circulating air around the meat product using a fan. Finally, the dried coated meat products can be packaged with the usual plastic film material and refrigerated. This study has not been tested in commercial poultry processing conditions. Some general observations from the published studies on antimicrobials: \u2022 Lactates, acetates and diacetates were found more effective in inhibiting growth of *L. monocytogenes* when used in combination than when used singly. \u2022 These antimicrobials were found more effective when used to the maximum allowable concentration. However, higher concentrations of antimicrobials used in

the formulation may affect the sensory qualities of the product, such as flavor and texture, which would necessitate sensory evaluation of treated products. When used in combination, the amount needed to inhibit growth may be reduced. These antimicrobials were found to have listerostatic activity more than listericidal activity, i.e. they prevent growth of the pathogen more than reduce the number of cells of the pathogen, and therefore may not be effective against gross contamination of a product. The establishment's sanitation program should control gross contamination of the processing environment and equipment. Addition of antimicrobials would be effective only as part of the overall HACCP strategy. Including these antimicrobials in the formulation was found to be more effective in inhibiting listerial growth than dipping products in solutions of antimicrobials. The antimicrobial activity of lactates and diacetates when used singly or in combination is affected by the level of contamination of the meat product surface, and processing factors such as pH, moisture, water activity, fat, nitrite, salt content, time and temperature of storage, and packaging atmosphere. Application of the treatments used in these studies is limited to the formulations, products and treatments used in the studies. Applying these studies to other products and formulations may result in different rates of growth inhibition. Therefore the effectiveness of the antimicrobials used in these studies must be verified by the establishment for other processed meat products and other storage temperatures. Antimicrobials used in the formulation must have an effective antilisterial activity throughout the commercial shelf life of the product. Currently the targeted commercial shelf life of refrigerated cooked meat products in the U.S.A. is 75 to 90 days.

Using post-packaging thermal treatments in addition to antimicrobials was found to increase the total antilisterial effects of the antimicrobials. These antimicrobials were found to be more effective in smoked products formulated with sodium nitrite, or in products stored at strict refrigeration temperatures. 66", "Updated Compliance Guidelines May 2006

Use of these antimicrobials may be a cost effective antilisterial method that very small establishments can use. References are found on pp. 48-49. 67", "Updated Compliance Guidelines May 2006 ATTACHMENT 5 Hold-and-Test Sampling for the FSIS LM Rule Background On June 6, 2003, FSIS published an interim final rule on the control of Listeria monocytogenes in ready-to-eat (RTE) meat and poultry products. Most processors of RTE products will have to conduct microbiological testing of product contact surfaces. The rule states that establishments using antimicrobial agents or processes under Alternative 2 and establishments producing non-hotdog or non-deli products under Alternative 3 must identify the conditions under which they will implement hold-and-test procedures. The rule describes the hold-and-test procedures to be followed by establishments producing hotdog and deli products under Alternative 3. Under alternative 3, an establishment producing a hotdog or deli product that obtains a positive for Listeria monocytogenes or an indicator organism such as Listeria spp. in follow up testing on food contact surfaces must hold lots of product that may have become contaminated by the food contact surface and must sample and test these lots before release into commerce. In addition, establishments producing RTE products must identify conditions under which the establishment will implement hold-and-test procedures following a positive test for Listeria spp. or L. monocytogenes on a food contact surface. In response to NFPA questions, FSIS officials have indicated that the intent is not to set a minimum level of sampling, but rather to rely on the industry to identify what they individually or as a group consider to be reasonable and

scientifically supportable. The Agency encouraged the industry to consider the ICMSF tables (International Commission on Microbiological Specifications for Foods. Microorganisms in Foods 7: Microbiological Testing in Food Safety Management. Kluwer Academic\Plenum Publishers, NY. 2002). ICMSF Sampling Plans for Listeria monocytogenes ICMSF categorizes microbial hazards according to risk \u2013 moderate, serious and severe. ICMSF ranks L. monocytogenes as either a serious hazard in foods for the general population or a severe hazard in foods for restricted populations (high risk groups). ICMSF describes 15 different cases of sampling plans, with sampling plan stringency based on degree of risk and the effect on risk of the conditions of use. Cases 10, 11 and 12 would apply to the serious category, and cases 13, 14, or 15 would apply to the severe category of microbial hazards. ICMSF considers cases 13, 14, and 15 to apply to foods intended specifically for highly susceptible individuals (e.g., hospitals and nursing homes) because a large proportion of the individuals would be potentially susceptible; thus, increasing the stringency of the sampling plans is appropriate. Cases 10, 11 and 12 68", "Updated Compliance Guidelines May 2006 apply to foods for the general population, where the proportion of susceptible individuals is much lower; thus, the overall risk of illness is reduced. Recent risk assessments have demonstrated that low levels of L. monocytogenes in food pose little risk, even for the highly susceptible population. For cases 10 or 13, conditions of use reduce risk (e.g., the numbers of L. monocytogenes will decrease). For cases 11 and 14, conditions cause no change in the hazard (e.g., the organism cannot grow), and for cases 12 and 15, conditions may increase the risk (e.g., foods in which L. monocytogenes can grow are subjected to conditions that allow growth). Sampling plans for the cases are given in the table below, where n is the number of samples and c=0 means that none of the \u201cn\u201d 25-g samples can be positive for L. monocytogenes. The table also provides the sampling plan performance, assuming a log-normal distribution with a standard deviation of 0.8; lots having the calculated mean concentrations or greater will be rejected with at least 95% confidence. Each of these plans achieves assurance that L. monocytogenes is present at <1 in 25 g. It is recommended that the 25 g. sample be analyzed separately and not composited. However, if compositing is to be done, composites of 25-g portions should not exceed a total of 125 g. in order to maintain the sensitivity of the method of analysis.

Conditions reduce Conditions cause no Conditions increase concern change in concern concern  
Case 10 Case 11 Case 12 n=5, c=0 n=10, c=0 n=20, c=0 Mean Concentration Mean

Concentration Mean Concentration 1 cfu\32g 1 cfu\83g 1 cfu\185g Case 13 Case 14 Case 15  
n=15, c=0 n=30, c=0 n=60, c=0 Mean Concentration Mean Concentration Mean Concentration 1  
cfu\135g 1 cfu\278g 1 cfu\526g Where RTE products must be sampled (hold and test) under  
the rule, the number of samples (randomly selected) would be as specified for these cases  
based on the risk of the product and the intended consumers. Since deli and hotdog products  
are ranked as the top causes of foodborne illness, the establishment producing these products  
should select these products to be sampled first. Sampling starts after the establishment has  
conducted corrective actions that are specifically designed to find the most likely cause of the  
contamination and controls are put in place to prevent recurrence. 69", "Updated Compliance  
Guidelines May 2006 Case 10 Case 11 Case 12 n=5, c=0 n=10, c=0 n=20, c=0 Products with  
continued Products that limit growth Products that support decline in population due to (< 1  
log) due to growth and that will be antimicrobial or other antimicrobial or other stored  
refrigerated for an formulation considerations formulation considerations extended period of

time. such as pH, aw, etc. such as pH, aw, etc. Products in Alternative 1 Products in Alternative 2 Products in Alternative 3 Case 13 Case 14 Case 15 n=15, c=0 n=30, c=0 n=60, c=0 As for case 10, but where As for case 11, but where As for case 12, but where products are produced for a products are produced for a products are produced for a hospital or nursing home or hospital or nursing home or hospital or nursing home or other higher risk population other higher risk population other higher risk population Products in Alternative 1 Products in Alternative 2 Products in Alternative 3 intended for a hospital, intended for a hospital, intended for a hospital, nursing home or other nursing home or other nursing home or other higher risk population higher risk population higher risk population. The number of samples recommended will be collected in 1 day and all affected products will be held during the testing period. Testing can be for Listeria spp. or L. monocytogenes. Any positive results from this follow-up testing (using the ICMSF approach) should lead to more significant investigations of the cause and of prevention before intensified follow-up testing. If samples tested positive for Listeria spp., the establishment should confirm for L. monocytogenes and if positive for L. monocytogenes, the product is considered adulterated. The establishment must conduct rigorous corrective actions, and other sanitation and HACCP type activities. Establishments may send a letter or certification when they ship tested products to nursing homes, hospitals and other institutions with susceptible populations. Such a letter would indicate that product has been sampled and tested according to ICMSF recommendations. Establishments supplying nursing homes, hospitals and other institutions with the susceptible populations are expected to implement whatever additional controls and verification procedures are necessary to ensure that product is not adulterated.

70", "Updated Compliance Guidelines May 2006 ATTACHMENT 6 HOLD-AND-TEST SCENARIO FLOWCHART

The following flow chart is a most likely scenario for a hold and test situation. The flowchart illustrates what an establishment could do in case of a food contact surface (FCS) testing positive for Listeria spp. or Listeria-like organisms, and when a follow-up FCS test is positive. Establishments can design their own procedures or flowchart for their hold and test program. Repeated positive FCS test would imply an inadequate sanitation system or harborage of the pathogen and establishments should investigate and reassess their sanitation program, their equipment layout and design product flow to determine the cause of the contamination. For repeated food contact surface positives for Listeria spp. or Listeria-like organisms during the hold and test period, establishments can test associated product for L. monocytogenes based on a sampling plan. This chart only addresses FCS testing with Listeria spp or Listeria-like organisms. If the establishment tests FCS for L. monocytogenes and the result is positive, product in the sampled lot is considered adulterated. The establishment can destroy the product or reprocess the product with a process that is destructive of L. monocytogenes.

71", "Updated Compliance Guidelines May 2006 ATTACHMENT 6 HOLD-AND-TEST SCENARIO FLOWCHART

Test Food Contact Surface (FCS) (Day1) FCS Listeria spp.\Listeria-like (+) (Day4) Corrective Action Intensified Cleaning and Sanitizing Continue Production Test FCS (Day 7) in sanitation program Corrective Action Intensified Cleaning and Sanitizing FCS L. spp.\L.-like (+) FCS L. spp.\L.-like(\u2013) Continue Production Test according to frequency Continue Production Hold and test product lot (Day 7) Follow-up FCS test for L. monocytogenes or L. spp.\L.-like \_ FCS L. spp.\L.-like (+) FCS L. spp.\L.-like (-) Hold and test product lots Hold Product (days 8, 9, 10) using sampling plan (Day 10) Repeat steps from Hold Product Lots (Days 8-10) Day 7 . until results of Day 7 Product Test (Days 8-10) Day 7 Product Day 7 Product Day 7

Product (Day 14) Lm (+) Lm (-) or L. spp.\L.-like (+) Release applicable L. spp.\L.-like (-) Destroy product or Continue analysis to Rework product with product lot determine if Lm (+) process destructive of Lm FCS: food contact surface L spp. or L.-like: Listeria spp. or Listeria-like organisms (test results available after 2 or 3 days) Lm: Listeria monocytogenes (test results available after 6 or 7 days) 72", "Updated Compliance Guidelines May 2006 Enforcement strategy Under 9 CFR 430, an establishment with deli and hotdog products in Alternative 3 must provide for testing of food contact surface (FCS). If the FCS tests positive for L. monocytogenes or Listeria Spp. or Listeria-like organisms, the establishment must conduct follow-up testing to verify its corrective actions. If during the follow-up testing another positive FCS occurs, the establishment must hold the applicable product lot if positive for L. spp. or L.-like, or destroy or rework with a process destructive of L. monocytogenes if positive for L. monocytogenes, and test the FCS until the establishment corrects the problem as indicated by the test result. In addition, the establishment must test held product lots for Listeria monocytogenes using a sampling plan that will provide a statistical level of confidence. The flowchart above shows a test and hold scenario which an establishment in this type of situation can use. The following section describes the likely action and reaction of inspection personnel during a hold and test situation. Day 1, 4 The testing program and the test results for food contact and non-food contact surfaces should be available to inspection program personnel. In case of a FCS testing positive for L spp. or Listeria-like organism, inspection program personnel will verify that the establishment is performing the corrective actions as specified in the HACCP plan, Sanitation SOP or prerequisite programs, including any intensified cleaning and sanitizing. For deli and hotdog products in Alternative 3, inspection personnel will verify that the establishment is conducting follow-up testing for FCS to determine the effectiveness of the corrective actions, targeting most likely source of contamination and additional tests in surrounding FCS area, and recording all these. Day 7 Results of the follow-up FCS tests are available on this day. If the FCS tests are negative, then the establishment continues with its normal production and sanitation program procedures. If the follow-up FCS tests are positive for L. monocytogenes, Listeria spp. or Listeria-like organisms, inspection program personnel will verify that the establishment is following its corrective action for a second FCS positive, including intensified cleaning and sanitizing. For deli and hotdog products in Alternative 3, inspection personnel will verify whether the establishment is holding the product produced that day and testing the product lot for L. spp or L. monocytogenes, and whether the establishment is conducting follow-up testing of FCS during each production, and holding all products until a negative follow-up FCS test is obtained. Products produced on days 8, 9 and 10 are held until the follow-up FCS test available after about 3 days is found negative. The interim rule states that products must be held until the problem is corrected as indicated by testing. For establishments in Alternative 3 producing deli and hotdog products, inspection personnel can cite the establishment if these procedures are not followed. Days 8, 9, and 10 73", "Updated Compliance Guidelines May 2006 The presence of Listeria spp. or Listeria-like organisms on a food contact surface or on ready-to-eat (RTE) product is associated with the potential for an insanitary condition to exist. FSIS expects an establishment to develop a compelling justification for concluding that product produced on days in which insanitary conditions may have existed is not adulterated. Thus, FSIS would further expect that the establishment, on days 8-10 would conduct verification testing on the food contact surfaces to demonstrate that the potential insanitary condition was adequately

redressed via the corrective and preventative actions. In addition, to further develop a compelling justification to support the establishment's decision, FSIS would expect a prudent establishment to also compile data on product testing to confirm and verify that the corrective and preventative actions were effective in preventing product from becoming adulterated.

Day 10 If Day 7 FCS Test is Positive Inspection program personnel will verify that if the follow-up FCS test taken on Day 7 is positive, then the day's production lots of deli and hotdog products in Alternative 3 are held and tested for Listeria spp. /Listeria-like or L. monocytogenes and the same procedures are followed as in the second FCS (+) test as in Day 7. If FCS samples taken on day 7 are found positive for L. spp. /L.-like on day 10, the establishment should hold and test product produced on days 8, 9 and 10 unless the establishment has supporting documentation to justify that product produced on days 8, 9 and 10 would not be contaminated with L. monocytogenes. The sampling plan must provide a level of confidence that each product is not contaminated with L. monocytogenes. Because of 3 consecutive positive FCS, the establishment should conduct intensive cleaning and sanitizing and reevaluate its sanitation program. If FCS is positive for L. monocytogenes, affected product lots are considered adulterated. The establishment should also hold and test products produced on days 8, 9 and 10 because a FCS positive for L. monocytogenes shows that the corrective action may not have been effective in removing the contamination and products produced on succeeding days may also be contaminated. If Day 7 FCS Test is Negative If FCS samples taken on day 7 are found negative for Listeria spp. /Listeria-like on day 10, the establishment should wait for the results of the FCS tests conducted on days 8, 9, and 10 as detailed above, and results of the Day 7 product test before releasing these products. Products produced on days 8 and 9 may be released without waiting for product testing results if the establishment has a compelling justification for concluding that products produced on those days are not adulterated.

Day 14 If day 7 product was found positive for L. monocytogenes on day 14, affected product lots produced on day 7 are considered adulterated. The establishment must destroy the product lots or rework them with a process destructive of L. monocytogenes. The establishment should continue holding product lots produced on days 8, 9, and 10 until results of products tests are available, unless the establishment has supporting "Updated Compliance Guidelines May 2006" documentation for why product produced on days 8, 9 and 10 would not be contaminated with L. monocytogenes. Establishment should also test and hold product produced before day 7 and recall them if already in commerce or provide compelling evidence that product produced before day 7 was not adulterated. For a product sample that tests positive for L. monocytogenes, inspection personnel will verify that the product lots affected are disposed properly, i.e., destroyed, or reworked with a process destructive to L. monocytogenes. Establishments should have supporting documentation that products lots produced before Day 7 are not contaminated with L. monocytogenes, so that these will not be included as adulterated. A product that is positive for Listeria. spp. or Listeria-like is not summarily determined to be adulterated, although it can lead to a determination that an insanitary condition exists and without compelling documentation, the establishment may not be able to conclude that the product is not adulterated. This also indicates that corrective and preventative actions taken may not have been effective, or that the sanitation program is inadequate and ineffective and therefore, the establishment needs to take actions to prove otherwise. The establishment needs to have compelling documentation that the product is not

adulterated and needs to determine that its sampling plan provides a level of confidence that each product is not contaminated with *L. monocytogenes*. If the establishment is using a post-lethality treatment or antimicrobial agent and the product tests positive for *Listeria* spp., *Listeria*-like organisms, or *L. monocytogenes*, according to 417.6(e), the HACCP plan may be found inadequate. In determining whether the HACCP plan is inadequate, the Agency will take into account all available information and consider the entire situation. The cause and significance of a positive result varies from case to case depending on the circumstances of processing involved, and the pathogen found. FSIS will consider whether some or all products produced under the same or a substantially similar HACCP plan are affected, whether there have been other incidents of product contamination with the pathogen, and whether incidents of product contamination have been persistent or recurring. Establishments are required to take corrective and preventive actions in accordance with 9 CFR 417.3. The Agency will expect the same rigor for testing and sanitation at the point that product testing is reached for products in Alternative 3 and in Alternative 2, using an antimicrobial agent or process. For products in Alternative 1, and in Alternative 2 using post-lethality treatment, if FCS is positive for *Listeria* spp. or *Listeria*-like organisms, product holding and testing may not be necessary as long as the post-lethality treatment is validated to reduce *L. monocytogenes* by at least 1 log, and the establishment verifies the effectiveness of the post-lethality treatment.

"Updated Compliance Guidelines May 2006" 76 ATTACHMENT 7 PROCEDURES FOR THE EVALUATION OF ESTABLISHMENT CONTROL PROGRAMS FOR LISTERIA MONOCYTOGENES

FSIS is conducting an evaluation of the effectiveness of the post-lethality treatment, antimicrobial agent or process and the sanitation program used by establishments to control *Listeria monocytogenes* (LM) in their post-lethality exposed ready-to-eat (RTE) meat and poultry products. Results of this evaluation will be used to determine the risk of LM contamination and the frequency of risk-based verification sampling for LM. This document includes procedures and questionnaires for evaluating an establishment's control measures for LM. The document also contains an Appendix that includes definitions, explanation of terms, and examples of validation studies with highlighted information that are important for control.

Background: *L. monocytogenes* is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation Standard Operating Procedures (SOP) or other prerequisite program.

9 CFR Part 430 \u201cControl of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products: Final Rule, June 6, 2003\u201d with implementation starting on October 6, 2003, mandates establishment compliance with one of three postlethality alternatives. For establishments that produce RTE products that are post-lethality exposed, FSIS needs your assistance in providing information that will answer the following questions.

1. Has the establishment selected one of the three alternatives per 430.4(b) of the regulations?
2. For establishments electing to use Alternative 1, the following questions apply: (a) Does the establishment use a post-lethality treatment for product AND an antimicrobial agent or process that suppresses or limits the growth of LM? (b) How effective is that process?
3. For establishments electing to use Alternative 2, the following questions apply: (a) Does the establishment use a post-lethality treatment for product OR an antimicrobial agent or process that suppresses or limits the growth of LM? (b) How effective is that process?
4. For establishments electing to use Alternative 3, the following questions apply: (a) Does the establishment have a sanitation program that addresses testing of food contact

surfaces: How effective is that program? You will evaluate the establishment's level of effectiveness in implementing Alternatives 1, 2 and 3 through a set of questions for each Alternative. The set of questions for each Alternative are provided in separate Evaluation Sections in the Procedures. The Evaluation Sections are numbered I, II, III and IV. Step 4 in the Instructions matches each Alternative with the appropriate Evaluation Sections. INSTRUCTIONS (If you have any questions regarding this survey, please contact Amelia K. Sharar (202-205-0009, Amelia.Sharar@FSIS.USDA.gov ) or Paul Uhler (202-205-0438, Paul.Uhler@FSIS.USDA.gov ) Step 1: Have the following documents ready and available for review: the establishment's HACCP plan, Sanitation SOP, and prerequisite programs addressing post-lethality exposed RTE product associated with 9 CFR 430. Use the establishment's completed FSIS Form 10, 240-1 as reference ONLY. Do not simply restate what is on the form." "Updated Compliance Guidelines May 2006 77 For determination of risk-based verification testing, FSIS needs to have this evaluation completed without participation of establishment personnel. All information needed should be readily available for review, in accordance with HACCP requirements. FSIS will follow-up in circumstances in which there are significant discrepancies between these procedures and the information provided by the establishment on FSIS Form 10,240-1. NOTE: FSIS is not asking the establishment personnel to participate by responding to the checklist questions because FSIS has not sought approval from OMB to conduct such information gathering from industry. However, FSIS does have authority to assess and document the information relative to the checklist that is available as part of the establishment's food safety system FSIS can share with the establishment the checklist and the FSIS assessment that was completed as part of the checklist. Step 2: Answer preliminary questions in Guide to Selecting Evaluation Sections. Step 3: Read through the evaluation sections and accompanying tables prior to completing the preliminary question related to the control programs for each applicable product(s): Section I: Post-lethality Treatment (PLT) Section II: Antimicrobial Agent or Process (AMAP) Section III: Sanitation Program Section IV: On-going Verification Step 4: For each Alternative, use the following sections to rate the evaluation of that control program: Alternative 1, use Section I, II, III and IV Alternative 2 (PLT), use Section I, III and IV Alternative 2 (AMAP), use Section II, III and IV Alternative 3, Section III and IV Step 5: Follow the instructions provided on how to score the establishment's validation and on-going verification documentation in your assessment for each product.

**GUIDE TO SELECTING EVALUATION SECTION PRELIMINARY QUESTIONS**

Establishment Number: \_\_\_\_\_ 1. Does the establishment produce post-lethality exposed ready-to-eat product covered by 9 CFR 430? YES NO (STOP, product is not covered by 9 CFR 430) 2. Did the establishment develop control measures that meet one of the three Alternatives for the product, as required in 9 CFR 430.4? YES NO (STOP and consult with front-line supervisor) 3. In the chart below, list the products covered by 9 CFR 430 and the Alternative chosen by the establishment. NOTE: There can be only one Alternative chosen for each product group. If needed, please refer to the establishment's FSIS Form 10,240-1 to answer these questions and use your best judgment based on how the process is being controlled in accordance with 9 CFR 430. Group the products that are controlled by the same Alternative and treatment. Use separate evaluation forms for products or product groups with unique situations, such as having the same", "Updated Compliance Guidelines May 2006 78 alternative and treatment but with different methods\sources of validation or with different

log reduction or suppression. For example, for the same product in Alternative 2 using AMAP and the same antimicrobial agent used, such as hotdog treated with sodium lactate validated by a challenge study, and hotdog treated with sodium lactate validated using a modeling program, separate evaluation forms should be used. Conduct one evaluation for each product group, using the questions in the appropriate Evaluation Sections for that group\ufe0f Alternative (See Step 4 Instructions). Include the name of each product within the group in the entry for product name in the Preliminary Questions section. Complete as many Evaluation Sections to cover all products produced by the establishment that are associated with 9 CFR 430. PRODUCT(GROUP) NAME ALTERNATIVE 4. Complete the sections that correspond to the chosen alternative. Alternative 1 (PLT and AMAP) Sections I, II, III and IV Alternative 2 (PLT only) Sections I, III and IV Alternative 2 (AMAP only) Sections II, III, and IV Alternative 3 (Sanitation) Sections III and IV", "Updated Compliance Guidelines May 2006 79 SECTION I \ufe0f Post-Lethality Treatment (PLT) Product (Group) Name:

Post-lethality Treatment used:

For the following questions, please place an X in the appropriate response column. (NOTE: If needed, please refer to the establishment\ufe0f FSIS Form 10,240-1 to answer these questions and use your best judgment based on how the process is being controlled in accordance with 9 CFR 430. Rate and score responses using the scoring instructions at the end of these questions.) Questions Yes No Not Sure N/A 1. Is the post-lethality treatment validated and documented? (Note: See APPENDIX for examples of validation.) 2. Has the establishment identified the critical variables (e.g., time, temperature, pressure, concentration, pH, etc.) used in the validation? (Note: Examples of validation methods that can be used are challenge study for the product, published study, modeling program.) 3. If the critical variables have been identified for PLT, are they being applied in the HACCP plan in a similar manner? 4. Is the product or product formulation used in the validation the same as or similar to the product or product formulation for which the establishment is using the PLT? 5. Is the establishment using the PLT as described in the validation with regards to equipment and procedures? 6. If the critical variables, product formulation, procedure or equipment used by the establishment are not the same as or similar to those used in the validation, did the establishment conduct additional validation that demonstrated the changes are effective? (Note: Place an X on N/A if you answered \ufe0fYES\ufe0d to questions 2-5) 7. If the establishment did not conduct additional validation, did it provide any rationale to explain why the PLT is effective and has the same impact even though the critical variables, product formulation, procedure or equipment are different? (Note: Place an X on N/A if you answered \ufe0fYES\ufe0d to questions 2-5) 8. Did the establishment conduct an initial validation to test the adequacy of the CCP, critical limits, monitoring and recordkeeping procedures, and corrective actions as stated in the HACCP plan? (This would be evident by data to demonstrate that the CCP was applied and the process was tested, e.g., product was tested prior to the treatment for presence\absence, and\or level of LM, and tested after the treatment for the same attributes in order to find low level of LM contamination using appropriate number of tests from randomly selected samples. Reliance only on tests with negative results after treatment is not considered product validation and should be marked as \ufe0fNo\ufe09- not validated.) 9. Does the establishment have a rational basis or data to show that the reduction of LM by the PLT as described is sufficient to

control the level of contamination of LM that may occur in the product? (Example: evidence of actual reduction of LM contamination on product by PLT vs. level of contamination on food contact surface) 10. Do the information in the HACCP plan, Sanitation SOP and Prerequisite programs (e.g., Alternative, PLT, AMAP, log reduction, log suppression, FCS testing frequency, etc.) corroborate the information on the survey form (FSIS Form 10,240-1) that the establishment submitted? (Note: If No, consult with the front-line supervisor and, if appropriate, inform the establishment and request it complete and submit a new Form 10,240-1 with revised information.) 11. Is the PLT treatment a pre-packaging treatment, i.e., the PLT is applied after", "Updated Compliance Guidelines May 2006 80 Questions Yes No Not Sure N\A environmental exposure but before re-packaging (e.g., infra-red treatment)? (Note: If No, stop and rate this section) 12. If the PLT is a pre-packaging PLT, does the establishment have validated control measures in place to prevent recontamination after treatment and before re-packaging? (Examples of control measures are: 1) aseptic packaging procedures; 2) packaging equipment located right after the PLT equipment; 3) use of antimicrobials; 4) positive air flow; 5) other environmental control program.) You have completed this section. Please rate this section. Rating: Conclusive: Answered \u2018yes\u2019 for #1-5, 8-10, and 12 if \u2018yes\u2019 to 11 Substantiated: Answered \u2018yes\u2019 to #1-3 and [6 or 7], [8 or 9], and 12 if \u2018yes\u2019 to 11 Inconclusive: Answered \u2018no\u2019 or \u2018not sure\u2019 to any of the following #1- 3, [6 or 7], [8 or 9] and 12 if \u2018yes\u2019 to 11, Use the conclusions obtained from the questions above (conclusive, substantiated, or inconclusive) to applicable establishment PLT in Table 1.", "Updated Compliance Guidelines May 2006 81 Table 1: Features of a Validated Post-lethality Treatment Table 1 gives numerical scores based on the method of validation and the log reduction achieved by the PLT. The more rigorous the validation method and the log reduction achieved by the PLT, the lower the risk, and the higher the scores. The risk of LM contamination goes down as the score goes from inconclusive to conclusive. Using the result from Section I, circle the score provided (in parenthesis) for the appropriate feature and criteria. For example, if the establishment\u2019s PLT as documented in its HACCP plan was derived from a manufacturer challenge study and achieves 2 log reduction of LM, and the result from SECTION I is Conclusive, circle the score provided on the appropriate row (manufacturer challenge study and equal to or greater than 2 log reduction), which in this case is 10. Control measure Feature Criteria1 Inconclusive Substantiated Conclusive Post-lethality treatment Challenge study for the product conducted by establishment or manufacturer Less than 1 log reduction (0) (0) Equal to or greater than 1 log, but less than 2 log reduction (0) (3) (5) Equal to or greater than 2 log reduction (0) (5) (10) Published challenge study Less than 1 log reduction (0) (0) (0) Equal to or greater than 1 log, but less than 2 log reduction (0) (2) (4) Equal to or greater than 2 log reduction (0) (4) (8) Modeling Program Less than 1 log reduction (0) (0) (0) Equal to or greater than 1 log, but less than 2 log reduction (0) (1) (3) Equal to or greater than 2 log reduction (0) (3) (7) 1 Criteria: Log reduction of Listeria monocytogenes (Lm)", "Updated Compliance Guidelines May 2006 82 SECTION II-Antimicrobial Agent or Process (AMAP) Product (Group) Name:

Antimicrobial Agent or Process Used:

For the following questions, please place an X in the appropriate response column. (NOTE: For products using extrinsic or intrinsic characteristics (freezing below -0.4\u00ba C (31.3\u00ba F), pH below 4.39, or water activity

below 0.92), skip questions 4-11. Also, if needed, please refer to the establishment\u2019s FSIS Form 10,240-1 to answer these questions and use your best judgment based on how the process is being controlled in accordance with 9 CFR 430. Rate and score your responses using the scoring instructions at the end of these questions.) Questions Yes No Not Sure N\A 1. Is the AMAP validated or tested, with documentation on file? (Examples: challenge study, published study, modeling program. See Appendix) (Note: Select \u201cYES\u201d if extrinsic or intrinsic characteristics such as freezing below -0.4\u00ba C (31.3\u00ba F), pH below 4.39, or water activity below 0.92r are used.) 2. Has the establishment identified the critical variables (e.g., time, temperature, pressure, concentration, moisture, pH, water activity, etc.) used in the validation? (Note: Examples of validation sources or documentation that can be used are challenge study for the product, published study, modeling program, extrinsic or intrinsic characteristics.) 3. If the critical variables have been identified, are they being applied in the application of the AMAP in the product? 4. Is the establishment using the AMAP as described in the validation with regards to equipment and procedures? 5. Is the product formulation used by the establishment the same or similar to the product or product formulation used in the validation study using the AMAP? (Examples of product formulation factors: amount of antimicrobial agent used; species [ e.g., beef, pork, chicken, turkey, etc.]; whether cured or uncured; amount of salt and moisture in finished product ) 6. If the critical variables, product formulation, procedures or equipment used by the establishment are not exactly the same as those used in the validation, did the establishment conduct additional validation that demonstrated that the changes are effective? (Note: Place an X on N\A if you answered \u201cYES\u201d to questions 2-5.) 7. If the establishment did not conduct additional validation, did it provide any rationale to explain why the treatment is effective and have the same impact even though the critical variables, product formulation, procedure or equipment are different? (Note: Place an X on N\A if you answered \u201cYES\u201d to questions 2-5.) 8. Did the validation study or validation of the model include a shelf life study, i.e., determining the growth of LM during storage? 9. Is the refrigerated shelf life (use by date on the label) shorter or the same as the recommended shelf life in the validation? Note: Place an X on N\A if no shelf life on label. 10. Did the establishment initially test for the adequacy of the AMAP in inhibiting LM growth? (Example: product was tested prior to the treatment for level of LM, and tested after the treatment and during the shelf life for the same attributes in order to find the presence of low level growth during shelf life using appropriate number of tests from randomly selected samples.)", "Updated Compliance Guidelines May 2006 83 Questions Yes No Not Sure N\A 11. Does the establishment have a rational basis or data to show that the level of growth allowed by the AMAP is sufficient to control LM growth in the product? (Example: evidence of actual inhibition of LM growth on product by AMAP vs. level of contamination on food contact surface) 12. Do the information in the HACCP plan, Sanitation SOP and Prerequisite programs (e.g., Alternative, PLT, AMAP, log reduction, log suppression, FCS testing frequency, etc.) corroborate the information on the survey form (FSIS Form 10,240-1) that the establishment submitted? (Note: If No, consult with the front-line supervisor and, if appropriate, inform the establishment and request it complete and submit a new Form 10,240-1 with revised information.) You have completed this section. Please rate this section. Rating: Conclusive: Answered \u2018yes\u2019 to #1-5, 8-11. For products using extrinsic or intrinsic characteristics (freezing, pH, water activity), \u2018yes\u2019 answers to #1- 3, and 12.

Substantiated: Answered \u2018yes\u2019 to #1 and [5 or 6], and 8. For products using extrinsic or intrinsic characteristics, \u2018yes\u2019 answers to #1- 3. Inconclusive: Answers with \u2018no\u2019 or \u2018not sure\u2019 to any of the following: #1, [6 or 7], and 8. For products using extrinsic or intrinsic characteristics, \u2018no\u2019 or \u2018not sure\u2019 answers to #1- 3. Use the conclusions obtained from the questions above (conclusive, substantiated, or inconclusive) to applicable establishment AMAP in Table 2.","Updated Compliance Guidelines May 2006 84 Table 2. Features of an Effective Antimicrobial Agent\Process This table gives numerical scores based on the method of validation and the log growth allowed by the AMAP. The more rigorous the validation method or the effectiveness and the lower the log growth allowed by the AMAP, the lower the risk, and the higher the scores. Using the result from Section II, circle the score provided (in parenthesis) for the appropriate feature and criteria. For example, if the establishment\u2019s AMAP as documented in its control program is from a published study and allows 1 log growth of LM during the refrigerated shelf life, and the result from SECTION II is Substantiated, circle the score provided on the appropriate row (published study and 1 log growth), which in this case is 4. Table 2 Control Measure Feature Criteria1 Inconclusive Substantiated Conclusive Antimicrobial growth suppressing agent or process Shelf-life study of the product using the antimicrobial agent or process Less than or equal to 1 log (0) (5) (10) More than 1 log but not more than 2 log (0) (3) (5) More than 2 log (0) (0) (0) Modeling program specific to the AMAP used in the product (e.g. Purac) Less than or equal to 1 log (0) (5) (10) More than 1 log but not more than 2 log (0) (3) (5) More than 2 log (0) (0) (0) Published study using an antimicrobial agent Less than or equal to 1 log (0) (4) (8) More than 1 log but not more than 2 log (0) (2) (4) More than 2 log (0) (0) (0) Extrinsic and Intrinsic characteristic Frozen at <4\u00ba C (31.3\u00ba F) (0) (5) (10) Aw < 0.92 (0) (5) (10) pH < 4.39 (0) (5) (10) 1 Criteria: Log growth of Listeria monocytogenes (Lm)","Updated Compliance Guidelines May 2006 85 SECTION III-Sanitation Program Product (Group) Name: \_\_\_\_\_ For the following questions, please place an X in the appropriate response column. Please note that the \u201cN\A\u201d response only applies to certain questions. (NOTE: Review establishment Sanitation program or prerequisite program for the sanitation procedures used and the food contact surface (FCS) testing program (testing frequency, number of sites, hold and test, etc). If needed, please refer to the establishment\u2019s FSIS Form 10,240-1 to answer these questions and use your best judgment based on how the process is being controlled in accordance with 9 CFR 430). Rate and score responses using the scoring instructions at the end of these questions.) A. Sanitation Procedures Questions Yes No Not Sure N\A 1. Are employee hygiene procedures available in a written document? 2. Are employees trained in hygiene procedures? 3. Are gloves used properly (e.g., are they disposed of when leaving processing line and when touching anything other than product or food contact surface)? 4. Are outer garments removed when leaving RTE area? 5. Do the employees use a 20 second hand wash (or comparable method of sanitizing) before starting and returning to work? 6. Are food and operator hand tools stored in a sanitary manner? 7. Are traffic patterns established to eliminate movement of personnel between the raw and RTE areas or controlled to prevent crosscontamination? 8. Are traffic patterns established to eliminate movement of equipment between the raw and RTE areas or controlled to prevent crosscontamination? 9. Are the raw and RTE areas physically separated (e.g., by a wall, etc.)? 10. If raw and RTE areas are not

physically separated, is the potential for cross contamination minimized? (Note: If \u2018yes\u2019 to question 9 above, place an X on N\A.) 11. Are different utensils used in the raw and RTE areas, or if different utensils are not used, are utensils washed and sanitized between raw and RTE processing? 12. Are garments worn in RTE areas readily distinguished from those used in the raw areas? 13. Are maintenance employees restricted from the RTE areas during operation or are hygienic practices followed if access is needed during operation? 14. Do tools and equipment for maintenance used in the RTE area remain in the RTE area or are tools used in another area sanitized before use in another area? 15. Are the thermometers, maintenance tools and equipment cleaned and sanitized before use? 16. Are all materials for discard (trash and waste) removed at clean up (mid-shift, end-shift, etc.)? 17. Is equipment cleaned at the end of operation to remove food and other debris? (Note: In establishments conducting extended operations, clean-up operations may occur at a frequency of less than daily.) 18. Is equipment such as slicers and dicers with blades disassembled for thorough cleaning at the end of the operation? (Note: If slicers or dicers", "Updated Compliance Guidelines May 2006 86 Questions Yes No Not Sure N\A are not used, place an X on N\A.) 19. Are equipment and floors sanitized after being rinsed? 20. Is sanitizer for equipment and floors used in the concentration specified where used? 21. Are operations discontinued during construction, or are the areas under construction or remodeling isolated to prevent contamination of other areas of operation? (Note: Place an X on N\A only if there is no construction.) B. Sanitation Testing Questions Yes No Not Sure N\A 1. Does the sanitation program or prerequisite program provide for testing FCS in the post-lethality processing environment? 2. Does the sanitation program or prerequisite program identify the conditions under which the establishment will implement hold-and-test procedures following a FCS test that is positive for Listeria-like, Listeria spp., or L. monocytogenes? 3. Does the sanitation program or prerequisite program state the frequency for testing? 4. Does the sanitation program, prerequisite program or other recordkeeping system identify the location of sites for sampling? 5. Does the sanitation program or prerequisite program identify the size of sites for sampling? 6. Are the selected locations of the sites the most probable area for contamination? 7. Is the size of the sampling area at least 1-square foot if surface allows? 8. Are all possible FCS sampling sites identified? 9. Does the sanitation program or prerequisite program explain why the testing frequency is sufficient to ensure effective control of Listeria-like, Listeria spp., or L. monocytogenes? 10. If a FCS tested positive for Listeria-like, Listeria spp., or L. monocytogenes, were the hold-and-test procedures implemented as written in the sanitation program? (Note: If FCS tested negative, place an X on N\A.) 11. If FCS tested positive for Listeria-like, Listeria spp., or L. monocytogenes, were measures taken to prevent recurrence? (Note: If FCS tested negative, place an X on N\A.) 12. If FCS tested positive for Listeria-like, Listeria spp., or L. monocytogenes, were corrective actions taken to identify and eliminate the source of contamination? (Note: If FCS tested negative, place an X on N\A.) 13. If a FCS tested positive for L. monocytogenes, was the lot of product affected destroyed or reworked with a process that eliminates L. monocytogenes? (Note: If FCS tested negative, place an X on N\A.) 14. Were the results of the product testing documented? 15. Were non-FCS tested for Listeria-like, Listeria spp., or L. monocytogenes? 16. Was follow up testing conducted on all non-FCS that tested positive for Listeria-like, Listeria spp. or L. monocytogenes? (Note: Place an X on N\A only if there is no positive follow-up non-FCS test or no positive non-FCS test.)", "Updated

Compliance Guidelines May 2006 87 Complete the next table only for an establishment that produces deli or hotdog product in Alternative 3. (Questions reflect regulatory requirements for these products.) Questions Yes No Not Sure N\A 17. Was follow-up testing conducted on the FCS site that tested positive for Listeria-like, Listeria spp., or L. monocytogenes to verify that the corrective actions after an initial positive test on a FCS were effective? Note: Place an X on N\A only if there is no positive follow-up FCS test. 18. Was follow-up testing conducted on the FCS area surrounding the FCS site that tested positive for Listeria-like, Listeria spp., or L. monocytogenes to verify that the corrective actions after an initial positive test on a FCS were effective? Note: Place an X on N\A only if there is no positive follow-up FCS test. 19. If a second follow-up FCS tested positive for Listeria-like or Listeria spp. on follow-up testing, were lots of affected product held? Note: Place an X on N\A only if there is no second follow-up positive FCS test. 20. If the second follow-up FCS tested positive for Listeria-like, Listeria spp. on follow-up testing, were the affected lots of product tested for Listeria-like, Listeria spp. or L. monocytogenes? Note: Place an X on N\A only if there is no second follow-up positive FCS test. 21. If a second follow-up FCS tested positive for L. monocytogenes on follow-up testing, were the affected lots of product destroyed or reworked with a process that is destructive of L. monocytogenes? Note: Place an X on N\A only if there is no second follow-up positive FCS test. 22. If the second follow-up FCS tested positive for Listeria-like or Listeria spp. on follow-up testing, did the sampling method and frequency provide a level of statistical confidence that ensured that each lot was not adulterated with L. monocytogenes? (e.g., is the sampling method and frequency based on a statistical sampling plan such as the ICMSF) Note: Place an X on N\A only if there is no second follow-up positive FCS test. You have completed this section. Please rate this section. Rating: Conclusive: A. Sanitation Procedures For all establishments, \u201cYes\u201d or \u201cN\A\u201d answers to all questions B. Sanitation Testing. For establishments producing deli or hot dog products under Alternative 3: Answered \u201cYes\u201d to questions 1 to 9 and \u201cYes\u201d or \u201cN\A\u201d for questions # 10 \u2013 22 For establishments under Alternative 2 Choice 2 (AMAP), or those producing non-deli or non-hotdog products under Alternative 3: Answered \u201cYes\u201d to questions 1 to 9 and \u201cYes\u201d or \u201cN\A\u201d for questions # 10 - 16 For establishments producing products under Alternative 1, or Alternative 2 Choice 1 (PLT): Answered \u201cYes\u201d or \u201cN\A\u201d to questions # 1-16 Substantiated: A. Sanitation Procedures. For all establishments, \u201cYes\u201d or \u201cN\A\u201d answers to at least 17 of the 21 questions", "Updated Compliance Guidelines May 2006 88 B. Sanitation Testing For establishments producing deli or hot dog products under Alternative 3: Answered \u201cYes\u201d to questions # 1 \u2013 9, except 6, 7, 8 and \u201cYes\u201d or \u201cN\A\u201d to questions # 10- 22 except 15 and 16. For establishments producing products under Alternative 2 Choice 2 (AMAP) or nondeli or non-hotdog products under Alternative 3: Answered \u201cYes\u201d to questions # 1- 14 except 6, 7, and 8 For establishments producing products under Alternative 1, or Alternative 2 Choice 1 (PLT): Answered \u201cYes\u201d or \u201cN\A\u201d to questions # 1- 14 except 6, 7, and 8 Inconclusive: A. Sanitation Procedures. All establishments answered \u201cYes\u201d or \u201cN\A\u201d to less than 17 of the 21 questions B. Sanitation Testing For all establishments producing deli or hot dog products under Alternative 3: Answered \u201cNo\u201d or \u201cNot Sure\u201d to any question # 1- 22 excluding 6, 7, 8, 15 and 16.

For establishments producing products under Alternative 2 Choice 2 (AMAP), or nondeli or non-hotdog products under Alternative 3: Answered \u201cNo\u201d or \u201cNot Sure\u201d to any questions # 1- 14 excluding 6, 7, and 8 For establishments producing products under Alternative 1, or Alternative 2 Choice 1 (PLT): Answered \u201cNo\u201d or \u201cNot Sure\u201d to any questions # 1- 14 excluding 2 -8 Use the conclusions obtained from the questions above (conclusive, substantiated, or inconclusive) to applicable establishment sanitation criteria in Table 3." "Updated Compliance Guidelines May 2006 89 Table 3. Features of a Sanitation Program Table 3 gives the numerical scores based on the rigor of the testing. Higher frequency of testing suggests more rigorous control, lower risk, and higher scores. These scores will be used in the risk-based verification model. Using the result from Section III, circle the score provided (in parenthesis) for the appropriate criteria. To obtain the score, apply the conclusions obtained from the questions above (conclusive, substantiated, or inconclusive) to the applicable establishment sanitation control program listed in Table 3. For example, if the establishment\u2019s FCS testing is 1\line\month for Alternative 3 as documented in its control program and the result from the SECTION III was substantiated, circle the value in the space provided in the appropriate row, which is 3 in this example. Control Measure Feature Criteria Inconclusive Substantiated Conclusive Sanitation FCS testing frequency Alt 1 (AMAP & PLT) <1\line\6 month (0) (1) (2) Alt 1 (AMAP & PLT) 1\line\6 month (0) (4) (6) Alt 1 (AMAP & PLT) >1\line\6 month (0) (7) (10) Alt2 (AMAP or PLT): <1\line\3month (0) (0) (0) Alt2 (AMAP or PLT): = 1\line\3month (0) (3) (5) Alt2 (AMAP or PLT): >1\line\3month (0) (5) (10) Alt 3: <1\line\month (non-deli, non-hotdog, or v sm. vol. deli or hotdog) (0) (0) (0) Alt 3: = 1\line\month (non-deli, non- hotdog, or v sm. vol. deli or hotdog) (0) (3) (5) Alt 3: >1\line\month (non-deli, non- hotdog, or v sm. vol. deli or hotdog) (0) (5) (10) Alt 3: <2\line\month (sm. vol., deli or hotdog) (0) (0) (0) Alt 3: =2\line\month (sm. vol., deli or hotdog) (0) (3) (5) Alt 3: >2\line\month (sm. vol. deli or hotdog) (0) (5) (10) Alt 3: <4\line\month (lg. vol., deli or hotdog) (0) (0) (0) Alt 3: =4\line\month (lg. vol., deli or hotdog) (0) (5) (10) SECTION IV- On-Going Verification System Product (Group) Name \_\_\_\_\_,""Updated Compliance Guidelines May 2006 90 For the following questions, please place an X in the appropriate response column. \ufffd If Alternative 1 was chosen for the product(s), complete sections A, B and C. \ufffd If Alternative 2 using a PLT (choice 1) was chosen for the product(s), complete sections A and C only. \ufffd If Alternative 2 using an AMAP (choice 2) was chosen for the product(s), complete sections B and C only \ufffd If Alternative 3 was chosen for the product(s), complete section C only (NOTE: Review establishment HACCP plan, Sanitation program or prerequisite program depending on the Alternative chosen for the product. If needed, please refer to the establishment\u2019s FSIS Form 10,240-1 to answer these questions and use your best judgment based on how the process is being controlled in accordance with 9 CFR 430. Score responses using the scoring instructions at the end of these questions.) A. Post-lethality Treatment (for Alternative 1, and Alternative 2 using PLT) Questions Yes No Not Sure N/A 1. Is the PLT validation rating conclusive or substantiated (from SECTION I and Table 1)? 2. Are CCPs, CLs or critical variables for the PLT reassessed annually or when a change may affect the hazard analysis or HACCP plan per 417.4(a)(3)? 3. Is recurrence of positive product or FCS controlled at zero or prevented within the last 12 months? (Note: If there is no positive product or FCS, place an X on N/A) 4. Are corrective actions conducted

when CCP is not achieved? (Note if CCP is achieved, place an X on N\A) 5. Are corrective actions conducted if positive products or positive FCS are found? (Note if no positive products or FCS are found, place an X on N\A) 6. Does the establishment persist or succeed in determining the cause and source of the positive product or positive FCS? (Note: If there is no positive product or FCS, place an X on N\A.) 7. Was the last Food Safety Assessment for cause (for Listeria rule noncompliance or positives) conducted in the establishment prior to implementation of the rule in October 2003? (Note: If no assessment[(for cause, for Listeria] has ever been conducted, place an X on N\A). 8. Was the last Intensified Verification Testing for the establishment conducted prior to implementation of the rule in October 2003? (Note: If no IVT has ever been conducted, place an X on N\A.) You have completed this section. Please rate and score for PLT (Table 4). B. Antimicrobial Agent or Processes (for Alternative 1, and Alternative 2 using AMAP) Questions Yes No Not Sure N\A 1. Is the rating for validation\effectiveness of AMAP conclusive or substantiated (from SECTION II and Table 2)? 2. Are the CCPs, CLs (if AMAP is in the HACCP plan) or critical variables (if AMAP is in the SSOP or Prerequisite Programs) reassessed annually or when a change may affect the hazard analysis or HACCP plan per 417.4(a)(3)? 3. Does the labeling of product shelf life agree with the shelf life determined from the AMAP study or model? (Note: If the label does not","Updated Compliance Guidelines May 2006 91 Questions Yes No Not Sure N\A indicate a shelf life ,place an X on N\A 4. Are corrective actions conducted when the CCP or critical variables are not achieved? (Note if CCP or critical variables are achieved, place an X on N\A) 5. Are corrective actions conducted if positive products or positive FCS are found? (Note: If there is no positive product or FCS, place an X on N\A) 6. Is the recurrence of positive product or FCS controlled at zero or prevented within the last 12 months? (Note: If there is no positive product or FCS, place an X on N\A) 7. Does the establishment persist or succeed in determining the cause and source of the positive product or positive FCS? (Note: If there is no positive product or FCS, place an X on N\A.) 8. Was the last Food Safety Assessment for cause (for Listeria rule noncompliance or positives) conducted in the establishment prior to implementation of the rule in October 2003? (Note: If no assessment [for cause, for Listeria] has ever been conducted, place an X on N\A.) 9. Was the last Intensified Verification Testing for the establishment conducted prior to implementation of the rule? (Note: If no IVT has ever been conducted, place an X on N\A.) You have completed this section. Please rate and score for AMAP (Table 4). C. Sanitation Program (for Alternative 1, Alternative 2 and Alternative 3) Questions Yes No Not Sure N\A 1. Is the rating for effectiveness of the sanitation program conclusive or substantiated (from SECTION III and Table 3) 2. Is the establishment following the sanitizing procedures as stated in its Sanitation SOP or prerequisite programs? 3. Does the establishment follow procedures for taking at least the minimum number of samples at designated areas for FCS testing as described in its control program? 4. Is recurrence of positive product or FCS controlled at zero or prevented within the last 12 months? (Note: If there is no positive product or FCS, place an X on N\A) 5. Are sanitation corrective actions conducted promptly and effectively, e.g., when product or FCS tests positive? 6. Does the establishment persist or succeed in determining the cause and source of the positive result? (Note: If there is no positive product or FCS, place an X on N\A.) 7. Does the establishment use more rigorous sanitizing to prevent recurrence of positives? (Note: If there is no positive product or FCS, place an X on N\A.) 8. Was the last Food Safety Assessment for cause (for Listeria rule noncompliance or positives) conducted in the

establishment prior to implementation of the rule in October 2003? (Note: If no assessment [for cause, for Listeria] has ever been conducted, place an X on N/A.) 9. Was the last Intensified Verification Testing for the establishment conducted prior to implementation of the rule in October 2003? (Note: If no IVT has ever been conducted, place an X on N/A.) You have completed this section. Please rate and score for Sanitation (Table4).", "Updated Compliance Guidelines May 2006 92 Rating: A. Post-lethality Treatment Conclusive: Answered \u2018yes\u2019 to # 1-2 and \u2018yes\u2019 or \u2018N/A\u2019 for # 3-8 Substantiated: Answered \u2018yes\u2019 to # 1-2 and \u2018yes\u2019 or \u2018N/A\u2019 to # 4-6 Inconclusive: Answers with \u2018no\u2019 or \u2018not sure\u2019 to # 1-2 B. Antimicrobial Agent or Process Conclusive: Answered \u2018yes\u2019 to # 1-2 and \u2018yes\u2019 or \u2018N/A\u2019 for # 3-9 Substantiated: Answered \u2018yes\u2019 to # 1-2 and \u2018yes\u2019 or \u2018N/A\u2019 for # 3-5 Inconclusive: Answers with \u2018no\u2019 or \u2018not sure\u2019 to # 1-3 C. Sanitation Program Conclusive: Answered \u2018yes\u2019 to #1-3 and \u2018yes\u2019 or \u2018N/A\u2019 for # 4-9 For establishments producing products under Alternative 1, and Alternative 2 (Choice 1, PLT), can be N/A in # 3 Substantiated: Answered \u2018yes\u2019 to # 1-3 and \u2018yes\u2019 or \u2018N/A\u2019 for # 4, 5 and 7 For establishments producing products under Alternative 1 and Alternative 2 (Choice 1, PLT), can be N/A in # 3 Inconclusive: Answers with \u2018no\u2019 or \u2018not sure\u2019 to # 1-2 Table 4. Features of an on-going verification system Use the rating obtained from the questions above to establish PLT, AMAP or Sanitation program as applicable, and circle the score provided (in parenthesis) . Control measure Feature Criteria Inconclusive Substantiated Conclusive On-going verification system Post-lethality treatment (0) (5) (10) Antimicrobial agent or process (0) (5) (10) Sanitation program (0) (5) (10) Add scores for PLT, AMAP or Sanitation depending on the control program that the establishment has.", "Updated Compliance Guidelines May 2006 93 APPENDIX DEFINITION/EXPLANATION OF TERMS Antimicrobial Agent A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as LM, or that has the effect of suppressing or limiting growth of a pathogen such as LM in the product throughout the shelf life of the product (9 CFR430.1). Examples: potassium lactate, sodium diacetate, which limit the growth of LM. Antimicrobial Process An operation, such as freezing that is applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as LM, in the product throughout the shelf life of the product, (9CFR 430.1). Other examples are processes that result in a pH or water activity that suppresses or limits microbial growth. Challenge Study A study that documents the adequacy of control measures in a process. This involves inoculating the target organism (e.g., LM) into a product to determine the effect of control measures such as post-lethality treatment or antimicrobial agent or process on the reduction or growth of the organism. Challenge studies are usually performed in a laboratory to avoid the possible spread of contamination in an establishment. They are also performed under laboratory conditions, which means that the scale of the study is adjusted, based on the capacity of the laboratory (i.e. fewer products may be tested, and a water bath may be used rather than a hot-water pasteurizer). The number of organisms before and after the application of the control measure is counted to determine the effect of the control measure. The study determines the effect using different processing variables such as time, temperature, pressure, concentration, acidity, pH and others. If challenge studies are

used as supporting documentation by the establishment, it is important that they use product that has similar physical characteristics to that being produced by the establishment (i.e., pH, Aw, etc.) and processing (and intervention) steps that are similar to those utilized by the establishment. For example, for a post-lethality treatment like steam pasteurization or hot water pasteurization, the time and temperature of treatment similar to that used for the product itself may be critical components of a challenge study. For high pressure pasteurization, pressure is a critical variable. For the use of chemical additives as antimicrobial agents, pH, acidity, and concentration may be additional critical variables. Challenge studies used for validation may or may not be published in scientific journals, and can be 1) conducted for any product; 2) conducted for an establishment's specific product or processing; or 3) conducted by the manufacturer of an equipment or chemical additive for use in the processing of a product. Challenge studies conducted for an establishment's specific product or a manufacturer's equipment or chemical additives have the advantage of using the same formulation, procedure and critical factors of moisture, pH, time, temperature, pressure, etc. as those used in the establishment. However, most of these challenge studies are not published. Published studies have the advantage of being peer-reviewed before publication, but may not be specific for an establishment's product or processing. Microbial Pathogen Computer Modeling (MPCM) Program A modeling program is a mathematical model describing the growth characteristics of pathogens in foods subjected to different environmental (product factors such as pH, salt, phosphates, nitrites, and water activity, and extrinsic factors such as temperature and culture atmosphere) and processing conditions. Computer-based microbial modeling programs may be used to provide an estimate of the influence of each limiting agent or combination of agents during processing. A computer model is a predictive tool and must be evaluated in terms of relevance and validity to the product in question. An establishment should verify the model's predictions for the establishment's product and conditions of processing by conducting tests, such of product and food contact surfaces, to confirm whether conditions are adequately controlled, as predicted. Of note, some modeling programs may identify zero growth as allowing up to 1 log growth, as a consequence of measurement error. Establishments should be aware of this when relying upon such assumptions." "Updated Compliance Guidelines May 2006 94 Products Covered by 9 CFR 430 All post-lethality exposed RTE meat and poultry Examples: deli meat, hotdog, jerky, chicken nuggets Products Not Covered by 9 CFR 430 Cook-in bag and shipped products Hot-filled products Partially cooked products Commercially sterile, thermally processed products Post-lethality Exposed Product Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment (9 CFR 430.1). Examples of post-lethality exposed products: hotdogs after the casings are removed; cooked roast beef after removing the cooking bag. Post lethality Processing Environment The area in an establishment into which product is routed after having been subjected to an initial lethality treatment (CFR 430.1). Examples are the production area where hotdog casings are peeled, or products are sliced and re-bagged. Post-lethality Treatment (PLT) A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure (9 CFR 430.1). Examples: hot water pasteurization, steam pasteurization, high pressure processing. Pre-packaging Post-lethality

**Treatment** This is a post-lethality treatment that is conducted prior to packaging. Most PLT are conducted after the product is repackaged. Because the PLT is applied before packaging, the product can be exposed to recontamination after the treatment. The establishment has to include methods to demonstrate, with high confidence, that recontamination does not occur. Some of the methods include placing packaging right after the treatment by physically placing the packaging equipment next to the treatment equipment, having aseptic environmental controls, including micro-filtered air flow and positive\ negative air pressure, as well as mechanisms for ensuring equipment does not become contaminated within the packaging room. Published Study A challenge or inoculated pack study conducted by scientists, subsequently reviewed by other scientists knowledgeable in the subject (peer-reviewed), before publishing in a scientific journal. Shelf life Study A shelf life study is one that measures the increase or decrease in the number of the target organism or pathogen during storage. For an antimicrobial agent or process (AMAP), a shelf life study is important because it determines the time (in days) at a slightly abusive refrigerated storage temperature (e.g., at 45 degrees Fahrenheit) that the number of LM increases, signifying growth. A slightly abusive temperature is used in order to ensure that if LM is present and viable, growth will occur and can be measured throughout shelf-life. This slightly abusive temperature also represents the worse-case conditions that could occur during cold-chain storage and handling. Validation Validation is a process of demonstrating that the HACCP system, if operated as designed, can adequately control identified hazards to produce a safe product. Validation consists of a scientific or technical justification or documentation of control, and an initial demonstration proving that the system will perform as expected. Validation can be derived from a challenge study, a published study from a peer-reviewed scientific journal, modeling program, data underlying published guidelines, or establishment data.", "Updated Compliance Guidelines May 2006 95 The documentation must identify the hazard and the pathogen, including the level of hazard prevention or pathogen reduction to be achieved, and all associated factors or conditions should identify which processing steps will achieve the specified reduction or prevention, and how these processing steps will be monitored. The scientific or technical basis should be related to the specific hazard or pathogen and should identify specific control parameters. The demonstration should be conducted in the plant using the parameters in the validation. As part of the demonstration, the establishment should observe, measure, and record results and should show that the plant can routinely meet the parameters in order to control the hazards.

**EXAMPLES OF CHALLENGE STUDIES** When faced with a challenge study on file to document validation, it is important to look at the title and the abstract or summary first. The abstract at the beginning of the document always give the most important findings of the study. Look for the objective, the procedure or conditions used and the results. Sometimes the equipment used is also included in the abstract. The abstract usually gives the critical factors (e.g., time, temperature, pH, concentration, pressure), the initial level of pathogens or organisms and how these factors affected the level of pathogens or organisms, and whether there was reduction, suppression or no effect. For important information not found in the abstract, look or read the other sections of the document. The Materials and Methods section includes the microorganisms used and microbial inoculation method, postlethality treatment procedure, and data analysis. The Results and Discussion section gives the results, tables, graphs, pictures, and the authors\u2019 explanation and discussion of the results. The Conclusions section gives

the overall result of the study, conclusions based on the conditions of the study and recommendations. Sometimes the conclusions are included in the end of the Results and Discussions section. The following are summaries of challenge studies for post-lethality treatment and antimicrobial agents taken from the Compliance Guidelines for the Listeria rule (FSIS website). The summaries include the conditions for post-lethality treatments or addition of antimicrobial agents and the resulting time, temperature pressure or concentration to control *L. monocytogenes*. The critical variables of time, temperature, pressure, concentration or pH, as well as the procedure or equipment that are bolded are the important information that needs to be determined when reading or scanning a challenge study. These variables are the ones used for the CCP and critical limit. Noting down the information gathered from the abstract or summary as shown for the first challenge study would help in determining if the establishment is using the same or similar procedure, equipment and critical factors as the challenge study.

**A. Steam Pasteurization and Hot Water Pasteurization (Important information for validation are bolded)**

Studies by Murphy et al. (2003) showed that post-cook hot water pasteurization and steam pasteurization resulted in a 77 log reduction of *L. monocytogenes* in surface inoculated vacuum packaged fully cooked chicken fillets and strips. The reduction was effective when single packaged breast fillets, 227 g- packaged strips and 454 g-packaged strips were heat treated at 90°C in a pilot scale steam cooker or hot water cooker for 5, 25 and 35 minutes, respectively.

Information gathered from the summary or abstract:

Post-lethality treatment: hot water pasteurization or steam pasteurization

Products: fully cooked chicken breast fillets and strips

Procedure: fully cooked products were surface inoculated with *L. monocytogenes*, vacuum packaged and pasteurized

Equipment used for the pasteurization treatment: Steam pasteurization: pilot-scale steam cooker

Hot water pasteurization: pilot-scale hot water cooker

Temperature of pasteurization: 90°C

Reduction of *L. monocytogenes*: 7 log reduction

Products and time of pasteurization that resulted in 7 log reduction", "Updated Compliance Guidelines May 2006

96 Product Time of pasteurization (min)

Single-packaged breast fillets 5 227g-package strips 25 454 g-packaged strips 35

Murphy, R.Y., L. K. Duncan, K.H. Driscoll, B.L. Beard, M. E. Berrang and J.A. Marcy. 2003. Determination of thermal lethality of *Listeria monocytogenes* in fully cooked chicken breast fillets and strips during post cook in-package pasteurization. *J. Food Protect* 66:578-583.

**B. High Hydrostatic Pressure Processing (Important information for validation are bolded)**

High pressure processing (HPP) is one of the new technologies used for food processing. This technology provides a means of ensuring food safety for those products that are difficult to be heat treated due to organoleptic effects. HPP was shown to inactivate pathogens without any thermal or chemical effects and at the same time preserve the quality of the product. Raghubeer and Ting (2003) evaluated the efficacy of high hydrostatic pressure processing in inactivating *L. monocytogenes* in retail-packaged samples of sliced ham, turkey and roast beef obtained from a manufacturer and repackaged in 25-g portions. Results show that an inoculum of about 10<sup>4</sup> *L. monocytogenes* cocktail in these 3 products and HPP treatment at 87,000 psi for 3 minutes showed no recovery of *L. monocytogenes* after 61 days of storage at 34°F. There were no pressure-injured cells detected. There were no adverse organoleptic effects detected on the 3 HPP treated products during the 61-day shelf life study. No signs of spoilage were seen on all 3 products after 61 days of storage, and for 100 days for ham and turkey. According to the investigators, the normal shelf life of these products is 30 days, so the HPP treatment extended

the shelf life of the products. Raghubeer, E.V. and E.D. Ting. 2003. The Effects of high hydrostatic pressure (HPP) on Listeria monocytogenes in RTE meat products. Avure Technologies, Inc. Submitted for publication. C. Studies on the Use of Antimicrobial Agents (Important information for validation are bolded) Bedie et al., (2001) evaluated the use of antimicrobials, included in frankfurter formulations, on *L. monocytogenes* populations during refrigerated storage. Fully cooked and cooled frankfurters were inoculated with 103 to 104 CFU /cm<sup>2</sup> of *L. monocytogenes* after peeling and before vacuum packaging. Samples were stored at 4°C for up to 120 days and sampled for testing on assigned days. Results are as follows: ANTIMICROBIAL LEVEL (%) L. MONOCYTOGENES GROWTH INHIBITION Sodium lactate 3 70 days no pathogen growth Sodium diacetate 0.25 50 days no pathogen growth Sodium acetate 0.25, 0.50 20 days no pathogen growth Sodium lactate 6 120 days no growth and reduced pathogen growth Sodium diacetate 0.5 120 days no growth and reduced pathogen growth Inoc. Control 0.0 Increased to 6 logs in 20 days Note: Sodium acetate is approved as a flavor enhancer, not as an antimicrobial agent. No pathogen growth refers to zero increase in the number of inoculated *L. monocytogenes* cells (bacteriostatic); while reduced pathogen growth refers to a decrease in the number of inoculated *L. monocytogenes* cells (bactericidal) in the product. In this study, tables showed the reduction varied with storage days, but was up to 1.0 log on some days. Levels of sodium lactate at 6.0 % and sodium diacetate at 0.5 % showed a reduction of the pathogens, however these levels are above the permitted levels.", "Updated Compliance Guidelines May 2006 97 Bedie, B. K., J. Samelis, J.N. Sofos, K. E. Belk, J. A. Scanga, and G. C. Smith . 2001. Antimicrobials in the formulation to control *Listeria monocytogenes* postprocessing contamination on frankfurters stored at 4°C in vacuum packages. *J. Food Protect.* 64:1949-1955 This study by Samelis et al., (2002) used similar treatments, processing and inoculation procedures and frankfurter formulations as the previous study described above. However, in this study combinations of antimicrobials were used, and in combination with hot water treatment. Therefore this is a combination of post-lethality treatment and antimicrobial agent. Hot water treatment involved immersion of frankfurters, with two product links in a package to 75 or 80°C for 60 s. Storage at 4°C shows: TREATMENT LEVELS (%) L. MONOCYTOGENES GROWTH INHIBITION Sodium lactate 1.8 35-50 days no growth Sodium lactate + sodium acetate 1.8 0.25 120 days no growth; 35-50 days growth reduction Sodium lactate + Sodium diacetate 1.8 0.25 120 days no growth; 35-50 days growth reduction Sodium lactate + Glucuno-delta-lactone 1.8 0.25 120 days no growth, 35-50 days growth reduction Hot water treatment (80°C, 60 s) + Sodium lactate 1.8 Inoc. population reduced by 0.4-0.9 log CFU/cm<sup>2</sup>, and 50-70 days growth reduction by 1.1-1.4 CFU/cm<sup>2</sup> Hot water treatment (80°C, 60 s) Increase in growth to about 6-8 logs in 50 days Inoculated Control, no treatment Increase in growth to about 6 logs in 20 days and 8 logs thereafter up to 120 days Note: Sodium lactate was used as a 3 % of a 60 % (wt/wt) commercial solution. Glucuno-delta lactone is approved as an acidifier, and a curing accelerator, but not as antimicrobial. Sodium acetate is approved as a flavor enhancer, not as an antimicrobial agent. Samelis, J. G.K. Bedie, J.N. Sofos, K.E. Belk, J.A. Scanga, and G.C. Smith. 2002. Control of *Listeria monocytogenes* with combined antimicrobials after post-process contamination and extended storage of frankfurters at 4°C in vacuum packages. *J. Food Protect.* 65: 299-307.", "Updated Compliance Guidelines May 2006 98 ATTACHMENT 8 GUIDANCE DERIVED FROM A REVIEW OF COMPREHENSIVE FOOD SAFETY ASSESSMENTS ASSOCIATED WITH

**COMPLIANCE WITH 9 CFR 430** Since 2004, FSIS conducted comprehensive Food Safety Assessments (FSA) by Enforcement, Investigations, and Analysis Officer (EIAO) in which the design and execution of the food safety systems were assessed, with a specific focus on Listeria monocytogenes in ready-to-eat (RTE) products. From June 2004 through September 2005, a total of 195 FSA reports directly related to 9 CFR 430, the Listeria monocytogenes regulations on post-lethality exposed RTE products, were further reviewed by the Office of Policy, Program and Employee Development. The OPPED review was performed in order to glean from the reports the design and execution features of the associated food safety systems that may have contributed to weak control measures. OPPED has summarized the significant features that may be helpful for the RTE industry, particularly small and very small establishments, in order for the industry to focus attention and enhance their control measures for *L. monocytogenes*.  
**Summary of Findings and Recommendations** The three failures common to most of the establishments reviewed from 2004 to 2005, regardless of the establishment-selected 9 CFR 430 control measure (i.e., Alternatives 2 or 3; there were no noted failures associated with Alternative 1), were: 1) not identifying *L. monocytogenes* in the hazard analysis; 2) not explaining how the food contact surfaces (FCS) were identified and selected and how the testing frequency was established; and 3) not providing hold and test procedures in the event of a *Listeria* spp. or *L. monocytogenes* finding by the establishment. Alternative 2: In addition to the 3 failures common to most of the establishments mentioned above, some establishments selecting Alternative 2 did not identify the control method (e.g., freezing) used, provide supporting documentation for the control method, follow the written cleaning and sanitizing frequencies, or address and control condensation problems in processing areas where product is post-lethality exposed. Alternative 3: In addition to the 3 failures common to most of the establishments mentioned above, some establishments selecting Alternative 3 were found to have a number of problems with designing and implementing a sanitation program to meet the requirements of 9 CFR 430, in addition to meeting the requirements of 9 CFR 416.

Establishments that selected Alternative 3 for their products had problems with the sampling plan described in their sanitation program to control *L. monocytogenes*, such as its implementation, identifying the location and size of their sampling sites, failure to identify and incorporate all food contact surfaces in their program, failure to include non-food contact surfaces such as cooling racks, wire trays, cooler walls, and tubs used to hold open bags of RTE products as potential sampling sites. **Corrective Actions:** For the three most common failures, the following corrective actions were identified and taken by many of the establishments and likely contributed to resolving regulatory enforcement actions: 1. *L. monocytogenes* is not identified in the hazard analysis as a hazard reasonably likely to occur. FSIS, through 9 CFR 430, believes that *L. monocytogenes* is a hazard reasonably likely to occur in post-lethality exposed RTE meat and poultry products. As such, the hazard analysis should list *L. monocytogenes* either as a hazard reasonably likely to occur or as a hazard not reasonably likely to occur. In either case, the associated control measures need to describe what control measures are in place to support this finding. This does not automatically mean that a critical control point is required. If the control measure does not eliminate, prevent, or reduce *L. monocytogenes* to an acceptable level, the controls can be addressed in the Sanitation SOP or other prerequisite program. The exception is that for application of a post-lethality treatment (as in Alternative 1 and", "Updated Compliance Guidelines May 2006 99 2), 9 CFR 430 requires the treatment to be

identified in the HACCP plan only and not in the Sanitation SOP or other prerequisite program. 2. The sanitation program does not explain how the FCS were identified and selected and how the testing frequency was established. If an establishment chooses either Alternative 2 or 3, the sanitation program for that establishment must provide for testing of FCS in the post-lethality processing environment, identify the frequency for testing, and provide an explanation of why the testing frequency is sufficient to ensure the effective control of L. monocytogenes or indicator organisms (430.4(b)(2)(iii)(A), (C), and (E) and 430.4(b)(3)(i)(A), (C), and (E)).

Identifying the FCS is simply determining the surfaces to which the product is exposed post-lethality. In addition to the equipment surfaces that contact the product post-lethality, other FCS may include knives that are used to slice the product, thermometers inserted into the product after the lethality process, or other surface that compromises the product integrity. For the testing frequency, the establishment has the options of either setting and justifying their own testing frequency or using the testing frequency recommended in the Compliance Guidelines for the control of L. monocytogenes. Whether establishments use their own or the Compliance Guideline testing frequency, the establishment still needs to have a justification on file as part of the validation support for the food safety system that provides a rationale for why the selected level of testing frequency is sufficient to demonstrate that L. monocytogenes is appropriately controlled. 3. The sanitation program did not provide hold and test procedures in the event of a FCS testing positive Listeria spp. or L. monocytogenes. If a FCS tests positive for L. monocytogenes, the product that came in contact with that surface is considered adulterated according to 9 CFR 430 and must be destroyed or treated with a process sufficient to destroy L. monocytogenes. In this case, a hold and test procedure would not be necessary for the lot in question. However, if the establishment or inspection program personnel have reason to believe that product lots other than those immediately identified may have become contaminated, the establishment should have hold and test procedures for the other product lots. On the other hand, if a FCS tests positive for an indicator organism (e.g., Listeria spp. or Listerialike organisms), the establishment producing products under Alternative 2 or non-hotdog or deli meat products under Alternative 3 must define conditions under which they will implement their hold and test procedures. Hold and test procedures for hotdog and deli meat products are described under 430.4(b)(3)(ii). For other common deficiencies in program design, the following corrective actions were identified and taken by many of the establishments and likely contributed to resolving regulatory enforcement actions:

\u2022 The establishment fails to identify the post-lethality treatment or antimicrobial treatment or process. It is the responsibility of the establishment, not the Agency, to determine the Alternative that applies to their product. However, in doing so, the establishment must provide justification for their determination. Also, the effectiveness of the post-lethality treatment or antimicrobial agent or process must be validated. For example, an establishment cannot simply declare that a process is Alternative 1 or 2 if documentation isn\u2019t available on file with the food safety system to provide the rationale for how the treatment and/or process reduces the level of L. monocytogenes and/or suppress its growth.

\u2022 The establishment\u2019s post-lethality treatment is not validated or the establishment cannot provide supporting documentation for the effectiveness of the antimicrobial agent or process or the postlethality treatment.

Validation of the post-lethality process and documentation to support the effectiveness of the antimicrobial agent or process are requirements of 9 CFR 430(b)(1)(ii) and (b)(2)(ii). The

supporting documentation can be a challenge study on the specific product, journal article on a process that is", "Updated Compliance Guidelines May 2006 100 used by the establishment, or the Compliance Guidelines with rationale to support the effect of the treatment or process. For the antimicrobial agents pH, water activity, and temperature, the Compliance Guidelines can be used as supporting documentation if these factors are below the levels listed that allow growth of L. monocytogenes. \u2022 The establishment did not identify the location and size of FCS sampling sites. The location of the sampling sites should be determined in conjunction with the requirement to provide testing of FCS. Documenting the location of the sampling sites also assists in determining the thoroughness of the sampling plan. One square foot of FCS or non-FCS, if available, is the minimum area recommended for sampling in the Compliance Guidelines. A prudent plant could use the Compliance Guidelines as the minimum testing amount to ensure the effectiveness of their sanitation program while conducting on-going verification to demonstrate that the level and frequency of testing is sufficient to find insanitary conditions and, when found, adequately controlled to prevent product adulteration. Failures in the implementation of L. monocytogenes food safety programs were attributable to either not implementing the program or not applying the program as written. Either case is comparable to not developing a program \u2013 the establishment cannot ensure the effectiveness of their control for L. monocytogenes or indicator organism in the post-lethality environment. Failures of program implementation noted in many of the establishments were: not following sampling programs as described in the establishment\u2019s plan including failure to test FCS or include all FCS, failure to document corrective actions; not isolating or separating the processing area from construction; and not following the written sanitization procedures. Failures in implementation can be addressed by effective training the employees accompanied by supervision to ensure they are performing the tasks as described in the program. If an employee is observed to be incorrectly performing their tasks, re-training may be needed. In responding to failures in program design or implementation, an establishment should not limit the corrective actions to just meeting the minimum requirements or recommendations. The establishments should strive to develop a program that is the most effective in controlling L. monocytogenes or an indicator organism. For example, one establishment responded by extending sample collection to food contact surfaces prior to the start of processing. This practice would provide the establishment with the effectiveness of their equipment cleaning and sanitizing measures to eliminate L. monocytogenes or indicator organism.", "Updated Compliance Guidelines May 2006 101 ATTACHMENT 9 GUIDANCE DOCUMENTS FOR VALIDATION 1. GUIDELINES FOR CONDUCTING LISTERIA MONOCYTOGENES CHALLENGE TESTING OF FOODS.

[www.foodprotection.org/publications/TOCarchive/2005TOC/November2005.htm](http://www.foodprotection.org/publications/TOCarchive/2005TOC/November2005.htm) 2.

CONSIDERATIONS FOR ESTABLISHING SAFETY-BASED CONSUME-BY DATE LABELS FOR REFRIGERATED READY-TO-EAT FOODS

[www.fsis.usda.gov/ops/nacmcf/2004/NACMCF\\_Safetybased\\_Date\\_Labels\\_082704.pdf](http://www.fsis.usda.gov/ops/nacmcf/2004/NACMCF_Safetybased_Date_Labels_082704.pdf)

NACMCF. 2005. J. Food Protect. 68:(8):1761-

1775"]}, {"file\_name": "FSIS\_GD\_2005\_0005", "title": "Water Reuse Questions and Answers (Q&As)", "num": "FSIS-GD-2005-", "id": "d0ce1b2794fc405d3fd262b73d736b2e6524a226324d2690c974800ce9e4fecf", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-"}]

guidelines","url":"https:\V\www.fsis.usda.gov\sites\default\files\import\Water\_Reuse\_QA.pdf","type":"pdf","n\_pages":7,"word\_count":2662,"text\_by\_page":["United States Food Safety Office of Policy, Program, Washington, D.C. Department of and Inspection and Employee Development 20250 Agriculture Service Company Name Address Address Dear Sir\Madam: This letter is in regard to approved labels for uncooked, breaded, boneless poultry products that also may be stuffed or filled, charmarked, or artificially colored that are currently manufactured by your establishment. Products of these types are similar to the products associated with the recall that was posted on the Food Safety and Inspection Service\u2019s (FSIS) website on March 10, 2006, involving frozen stuffed chicken entrees. As noted in the recall notice, the frozen state, labeling, and cooked appearance of the uncooked chicken products may have caused consumers to believe that they were precooked. What we know is that these products were not cooked by consumers to a safe internal temperature. FSIS is concerned that the labeling of products of this type be adequate to inform the public of the manner of handling required to maintain the products in a wholesome condition and to prepare them safely. Moreover, the cooking instructions need to be validated to address the intended use by the consumer. While consumers may be directed to cook the products to an internal temperature of 165 degrees Fahrenheit (F), if they are directed to use a cooking method that is not practical or not likely to achieve the necessary level of food safety (e.g., microwaving or cooking frozen product in a toaster oven), the cooking instructions may not be valid. A fundamental part of label evaluation is to ensure that labeling will be understood and followed by consumers. It is clear from the recent events that labels for other uncooked, breaded, boneless poultry products on the market, such as those that your company produces, may not be understood or followed by consumers. This lack of understanding may result in the consumers not cooking the products to the minimum internal temperature (165 degrees F) necessary for the destruction of foodborne bacteria, even though the cooking instructions on the product labeling tell them to do so. Given what the Agency learned in the recent recall and the nature of these products, the labeling of such products may not be eligible to bear the mark of inspection if the labeling does not lead consumers to provide the lethality that is necessary. The mark of inspection on poultry (and meat) products signifies that the product, as labeled, is safe and wholesome, and that the label is not misleading. It is our strong recommendation that the labeling of the types of products in question, which are currently manufactured by your establishment, be modified to emphasize that the products are not cooked. Further enhancement of the cooking instructions and validation that lethality is achieved with all the methods of cooking preparation that are declared on the labels are necessary in our view. The Agency views the statement","2 Company Name \"Uncooked: For Safety, Must be Cooked to an Internal Temperature of 165 degrees F as Measured by Use of a Thermometer\" to be the type of statement that seems appropriate on the principal display panel of the packaging to help consumers understand the need for the safe preparation of the products on their part. It is likely that, by improving the cooking instructions, as well as documenting that cooking methods are validated as part of the official labeling record, a situation like the one that led to the recent recall could be avoided. Certain to be of assistance to your company in making the necessary changes to product labeling and cooking method validation will be the work of the Subcommittee on Consumer Guidelines for the Safe Cooking of Poultry Products of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) which will meet on March

22, 2006, in Arlington, Virginia. We suggest that the recommendations that are developed by the NACMCF serve as a guide for the modifications that are needed to the labels for your products such that the subject products can be assured to result in safe and wholesome products, and that the revised labeling is not misleading. In light of the concerns outlined in this letter, we are requesting that you submit the revised labeling for the products in question to the Agency for evaluation of the necessary modifications and re-approval by May 1, 2006. If we do not receive the modified labeling submissions by that time, the labels for the subject products will be deemed to be rescinded. If you have any questions about this matter, please do not hesitate to contact me or Rosalyn Murphy-Jenkins at Area Code (202) 205-0279.

Sincerely, Dr. Robert C. Post, Director Labeling and Consumer Protection

Staff"]},{"file\_name":"FSIS\_GD\_2006\_0001","title":"Guidance for Determining Whether a Poultry Slaughter or Processing Operation is Exempt from Inspection Requirements of the Poultry Products Inspection Act","num":"FSIS-GD-2006-0001","id":"180cd9b03009189c9e9baff12c79ff90e7feff0e7d862a461c7aea6a14d7e0d9","corpus":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/import/Poultry\_Slaughter\_Exemption\_0406.pdf","type":"pdf","n\_pages":36,"word\_count":11517,"text\_by\_page":["A GUIDE TO FEDERAL FOOD LABELING REQUIREMENTS FOR MEAT, POULTRY, AND EGG PRODUCTS Edited by Post, R., Budak, C., Canavan, J., Duncan-Harrington, T., Jones, B., Jones, S., Murphy- Jenkins, R., Myrick, T., Wheeler, M., White, P., Yoder, L., Kegley, M. The Labeling and Consumer Protection Staff Office of Policy, Program, and Employee Development Food Safety and Inspection Service U.S. DEPARTMENT OF AGRICULTURE August, 2007 Work performed under contract by Hogan & Hartson, LLP Washington, DC", "DISCLAIMER This Guide is designed as a user-friendly introduction to the basic food labeling requirements for meat, poultry, and egg products. It does not represent, nor should it be relied upon as, an official or binding statement by the Labeling and Consumer Protection Staff, LCPS), Office of Policy, Program, and Employee Development (OPPED), of the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA). Users should consider changes in FSIS regulations and policies arising after the Guide\u2019s publication date. \* \* \* The impetus for the Guide was to create a user-friendly, comprehensive guide to assist food companies in the development of food labels that comply with the array of requirements policies. While not a substitute for careful review of the requirements referenced throughout, the Guide will provide the reader with a useful tool to identify and understand those requirements that shape the food label presented to consumers. Note: Guidance on egg product, labels can be found in Appendix A of this Guide. Building from the expertise and experience of the Labeling and Consumer Protection Staff, OPPED, the Agency sought to utilize a contractor who would offer an understanding of the rules in practice. The reader benefits from the day-to-day learning\u2019s of those who are involved in the review and approval of labels and others who routinely assist companies in the application of the labeling rules. LCPS developed the scope and content of this Guide under a contract with Hogan & Hartson, LLP, Washington, DC. The Agency recognizes the contributions of the staff who served as editors and provided oversight in the creation of the Guide: Robert C. Post, Ph.D. MEd., MSc., Catherine Budak, Food Technologist, Jeffery Canavan, Food Technologist, Tawana DuncanHarrington, Program Analyst, Bill Jones, Chemist, Sally Jones, Senior Technical Advisor, Rosalyn Murphy-Jenkins, Senior Technologist, Tammie Myrick, Food

Technologist, Mark Wheeler, Biological Scientist, Patricia White, Nutritionist, and Lynn Yoder, Program Analyst, Marlene Kegley, Program Analyst, served as contract coordinator. The contributions of attorneys at Hogan & Hartson, LLP in drafting the Guide are also acknowledged: Steven B. Steinborn, Ryan Shadrick-Wilson, Lorrin H. Tuxbury, Robert O. Winters, and Elizabeth B. Fawell.

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companies and consumers alike. A company\u2019s most direct (and sometimes only) way to		
communicate with the consumer is via the food label. For consumers, the food label contains a		
wealth of information, which allows for informed purchase decisions. The U.S. Department of		
Agriculture (USDA), by statute, is charged with assuring that meat and poultry products in		
interstate or foreign commerce, or that substantially affect such commerce, are wholesome,		
not adulterated, and properly marked, labeled and packaged. 1 Responsibility for the		
development and application of the labeling requirements applicable to meat and poultry		
products rests principally with USDA\u2019s Food Safety and Inspection Service (FSIS). 2 FSIS is		
charged with developing the labeling policy by which it is determined if a meat or poultry		
product is misbranded or adulterated. 3 FSIS food labeling regulations have evolved over the		
years, reflecting the evolution of the food processing industry and consumer interest. Food		
manufacturers are responsible for compliance with the FSIS labeling rules and adherence to the		
process maintained by FSIS for the evaluation and approval of meat and poultry product labels.		
This Guide provides the basic information necessary to devise a label for meat and poultry		
products and to understand the regulatory process administered by FSIS. Answers to the most		
commonly asked questions are incorporated. This Guide cannot possibly anticipate or address		
the large number of issues that may arise in developing product labeling. The FSIS - 1 -		
","website ( <a href="http://www.fsis.usda.gov">www.fsis.usda.gov</a> ) is a good source of information, providing the complete		
statutes, regulations, and policies. Included throughout the Guide are cross references to the		
relevant sources, found primarily in the End Notes. Some issues, particularly policy issues, will		
often require consultation with the Labeling and Consumer Protection Staff (LCPS), OPPED,		
within FSIS. Before delving into the details, the Guide begins with an overview of the principal		
jurisdiction over the label, labeling and advertising of foods at the federal level. The scope of		
USDA\u2019s jurisdiction and statutory reach with respect to covered and exempt meat and		
poultry products is detailed. The role of the states in regulating food labeling is also addressed,		

along with an explanation of the consistency required between state and federal law. Section II provides an overview of the basic food labeling requirements, including the prior label approval process, establishment responsibilities, temporary label approvals, and other facets of the preapproval process. Sections III through XII address in detail each of the up to eight mandatory features that must be present on a meat or poultry label and other mandatory and optional information that may be on such a label. Appended to the Guide (Appendix A) is a discussion of the labeling requirements for egg products, which are also administered by FSIS. Other useful excerpts of labeling regulations and illustrations are included in various appendices as noted throughout the Guide. This Guide cannot substitute for a careful review of the underlying statutes, regulations, policies, and guidance referenced throughout the Guide. - 2 -

","Consultation of the appropriate regulation, directive, and other guidance document, as well as the FSIS website, provides valuable information on devising an acceptable and compliant food label. I. TIPS AND PITFALLS IN DESIGNING A FOOD LABEL \u2022 Begin label design with the mandatory labeling features required by FSIS regulations. Deviation from these requirements to accommodate marketing or other communication objectives does not ensure compliance. \u2022 Ensure that placement and prominence requirements for each mandatory feature of the food label are met. \u2022 Review brand names, marketing copy, and all other information presented on the label to determine if a regulated term is included. \u2022 Make sure that foods subject to a standard of identity comply with the applicable FSIS requirement. \u2022 Make sure that ingredients\components are properly declared in the ingredients statement. \u2022 Novel or innovative products that trigger unique labeling issues should not be submitted to be evaluated by FSIS staff as part of the sketch-approval process. Instead, they should be addressed through direct contact with the staff. Firms should build into the product launch schedule the time necessary to allow for agency consideration of policy issues. \u2022 Review ingredients statement for accuracy and completeness against formulation information. Fully consult ingredient suppliers to obtain all pertinent information as part of this review. \u2022 Keep labeling files complete and current. Document generic approvals and permitted modifications along with final approvals that must be retained by the firm. \u2022 Products that are not amenable and thus not subject to FSIS inspection must still comply with applicable labeling rules. Similarly, products not subject to prior approval (e.g., retail labeling) also must comply with applicable labeling requirements. \u2022 Fully consult the resources available at the FSIS website and always consult the regulations, directives and other policies referenced in this Guide. - 3 -","\u2022 If a label is not accurate, the label should not be used unless a temporary approval is obtained. II. INTRODUCTION TO FOOD LABELING A. The Federal Agencies and Their Statutory Authority to Regulate Food Labeling The federal regulatory agencies that have jurisdiction over food products derive their authority to govern the labeling of these products from several principal statutes -- the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), the Egg Products Inspection Act (EPIA), the Agricultural Marketing Act (AMA), the Federal Food, Drug and Cosmetic Act (FFDCA), and the Fair Packaging and Labeling Act (FPLA). In addition, food advertising \u2013 which in certain instances serves as an extension of food labeling -- is subject to regulation by the Federal Trade Commission (FTC) under the Federal Trade Commission Act, which prohibits false and deceptive advertising.

1. The United States Department of Agriculture\u2019s Food Safety and Inspection Service (FSIS) FSIS has primary responsibility for the regulation of food labeling for meat and poultry

products under the FMIA 4 and the PPIA 5 and is also authorized to regulate food labeling for exotic species of animals under the Agricultural Marketing Act of 1946. The FMIA and PPIA define the food \u201clabel,\u201d in pertinent part, as \u201ca display of written, printed, or graphic matter upon the immediate container of any article,\u201d and define \u201clabeling\u201d as \u201call labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.\u201d 6 USDA is authorized under the FMIA and the PPIA to regulate marking, labeling, or - 4 - ", "packaging of meat, poultry, or processed parts to prevent the use of any false or misleading mark, label, or container. This broad definition makes FSIS regulations applicable to product labels and materials that accompany a product but are not attached to it, such as point-of purchase (POP) materials. 7 The scope of what constitutes a food label is discussed in further detail below. The FMIA specifies the circumstances when products are misbranded. The FMIA provides, in part, that any carcass, meat or meat product is \u201cmisbranded\u201d (1) if the product\u2019s labeling is false or misleading in any particular way; (2) if it is offered for sale under the name of another food; (3) if it is an imitation of another food, unless it is labeled as such; (4) if its container is misleading; (5) unless it bears a label with the name of the manufacturer, distributor, and net quantity of contents; (6) if its labeling is not prominent and conspicuous; (7) if it purports to be a food with a standard of identity without conforming to the standard; (8) if it misrepresents itself as a food with a standard of fill; (9) if it does not bear a common or usual name (provided it is not covered by a standard of identity) and declare ingredients by common or usual name; (10) if it purports to be a food for special dietary use without conforming to FDA regulations on such products; (11) if it contains artificial flavoring, artificial coloring, or chemical preservatives that are not declared (with exceptions); and (12) if it fails to bear an inspection legend and establishment number. 8 It is intended that these provisions apply within the scope of the exceptions that may exist in the act. FSIS has similar authority under the PPIA with regard to poultry products. 9 False or misleading labeling - 5 - ", "can trigger a charge of misbranding pursuant to the wide range of labeling requirements summarized in this Guide. If a product is deemed misbranded, its manufacturer faces a wide range of penalties that can be imposed by FSIS. 10 These include withholding (rescinding) the use of labeling; product retention (prohibiting shipment); product detention (prohibiting sale from anywhere in the chain of commerce); request for product recall, press releases, and\or fines; and criminal prosecution. In addition, the facility producing misbranded product faces the possibility of inspection suspension or withdrawal. 11 2. The U.S. Food and Drug Administration (FDA) FDA has primary statutory authority to establish labeling requirements for foods and food ingredients under its purview pursuant to the Federal Food, Drug and Cosmetic Act (\u201cFFDCA\u201d). 12 The FFDCA states, in a fashion similar to the statutes enforced by USDA, that a food product is misbranded, and is, therefore, in violation of the statute, if \u201cits labeling is false or misleading in any particular ....\u201d 13 Similar to the FSIS-enforced statutes, the FFDCA defines a \u201clabel\u201d as \u201ca display of written, printed, or graphic matter upon the immediate container of any article.\u201d 14 Further, the FFDCA defines \u201clabeling\u201d as: \u201clabels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.\u201d 15 This broad definition makes FDA regulations applicable to product labels and materials that accompany a product but are not attached to it. In addition, FDA has - 6 -

","regulatory authority under the Fair Packaging and Labeling Act (\u201cFPLA\u201d), a companion statute to the FFDCA. 16 3. FSIS and FDA: Distinct Approaches to Labeling and Jurisdiction Prior approval by FSIS is required for all labels used for meat and poultry products before those products may be marketed in interstate commerce. There are distinct categories of prior approval, discussed below, that dictate the precise manner in which a label is \u201capproved.\u201d FSIS derives its authority for label approval from the provision in the Acts that states that no food article \u201chall be sold or offered for sale by any person in commerce under any name or other marking or labeling \u2026but established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary.\u201d 17 USDA interprets this statutory language as mandating the preapproval of all food labels before products that bear the mark of inspection may be offered for sale. Responsibility for USDA\u2019s pre-market label approval process rests with the FSIS Administrator. 18 Regulations and policies establish requirements for the content and design of labeling to ensure that labeling is truthful, accurate, and not misleading in order to prevent products from being misbranded. 19 Annually, FSIS evaluates approximately 60,000 labels that are sent to the Agency for evaluation and approval before they may be applied to product destined for commerce. Many more new and revised labels are subject to prior approval but are not submitted first for evaluation by the Agency, provided manufacturers ensure that such final labels fall within the conditions - 7 -","specified in the generic labeling regulations (as elaborated upon below). In specified circumstances, labels that the Agency approved may be modified by manufacturers without resubmitting them to FSIS for evaluation. However, outside of these circumstances or instances where specific exceptions exist (e.g., for random weight packages), only labeling that has been approved by FSIS may be applied to meat and poultry products. In contrast, FDA does not require prior label approval for food products under its jurisdiction. 20 FDA has promulgated regulations establishing requirements for all aspects of labeling and monitors labeling compliance primarily through random post-marketing surveillance. FDA reviews only a small portion of labels on food products falling under its jurisdiction. FDA\u2019s label review generally arises in connection with an informal request for review by a manufacturer, a trade complaint by a competitor, a consumer inquiry, or an FDA on-site inspection of a manufacturing facility. Although FSIS has jurisdictional authority over food labeling for products containing meat and poultry, the FMIA and the PPIA explicitly authorize USDA (through FSIS) to exempt from its regulatory coverage food products which contain meat or poultry \u201conly in relatively small portion or historically have not been considered by consumers as products of the meat food industry \u2026.\u201d 21 By statute, the Secretary may (not, must) exempt product applying either of the two stated criterion. Therefore, the statutes have long been applied by the Agency as including all products containing meat or poultry under FSIS jurisdiction (and, therefore, inspection). By default, all - 8 -","other foods fall under the jurisdiction of FDA (and the statutes under which it operates), including the products of exotic species of livestock and kinds of poultry, (e.g., deer, elk, and pheasant.) 22 The determination of whether a product falls under the jurisdiction of FSIS or FDA is referred to as \u201camenability.\u201d Amenability decisions are based on how a product is formulated, not the composition of the finished product. USDA has set a rule that any food product containing the following is not subject to the FMIA or PPIA (i.e., to FSIS inspection): (1) 3 percent or less raw meat or less than 2 percent cooked meat, or (2) less than 2 percent

cooked poultry meat, less than 10 percent of cooked poultry skins, giblets, or fat, separately, and less than 10 percent of cooked poultry skins, giblets, fat, and meat in combination, (i.e., specific condition,) provided the poultry ingredients were prepared under domestic or foreign inspection and the product is not represented as a poultry product. 23 FSIS has formally adopted this rule with regard to poultry, but has not done so for meat products. Nonetheless, through decades-old policy, FSIS has applied a threshold level of meat that makes meat food products amenable consistent with the poultry regulations. Examples of meat products exempt from FSIS jurisdiction under one or the other criteria specified in the FMIA and implementing regulations include spaghetti sauces with less than 2 percent cooked meat, pork and beans, bagel dogs, and gravy mixes. Because the regulations state that the Secretary may exempt products, industry is strongly advised to seek clarification from FSIS in cases where the status of jurisdiction is in question. - 9 -,"As noted, by regulation, FSIS has further defined certain products as exempt from the definition of a \u201cpoultry product.\u201d 24 These exemptions include product that contains less than 10 percent of cooked poultry skins, giblets, or fat separately and less than 10 percent of cooked poultry skins, giblets, fat, and meat or \u201cmechanically separated skins of poultry,\u201d as defined, and are not represented as a poultry product. Other exemptions include product in an institutional pack and used as soup bases or flavorings containing less than 15 percent cooked poultry meat and provided the specified conditions (as noted above) of the regulation are met. 25 Bouillon cubes, poultry broths, gravies, sauces, and flavorings also are exempt under the specified conditions (as noted above). 26 These exemptions are null if the kind of poultry is listed in the product name without appropriate qualification. Appropriate qualification is using a term, such as \u201cflavored,\u201d that must be included as part of the product name (e.g., \u201cChicken Flavored Noodle Soup\u201d) to distinguish the food product as different than a \u201cpoultry product\u201d and, therefore, preserve the exemption. Products that meet the exemption factors and conditions, and that are labeled in this fashion, are subject to jurisdiction and regulation by FDA. 27 FSIS has concurrent jurisdiction with FDA over the setting of standards of identity for food products. 28 The FMIA and PPIA state that USDA\u2019s standards for any meat and poultry food products may not be inconsistent with standards established under the FFDCA. 29 - 10 -,"Finally, FDA has authority to approve the safety of food ingredients to be used in the production of food products, including meat or poultry products. 30 The meat and poultry inspection laws explicitly permit only FDA- sanctioned food ingredients (e.g., additives, GRAS substances, color additives) to be used in the production of meat and poultry products, which FSIS also must approve as suitable for use under prescribed conditions. 31 FSIS requirements regarding legal status as safe for use in food differ somewhat from FDA. FSIS has developed policies and procedures to streamline its evaluation and approval of ingredients in meat and poultry products through close coordination with FDA. 32 FSIS has provided a great deal of useful guidance governing permitted use of safe and suitable ingredients. Beyond the scope of the Guide, there are several regulatory references that should be consulted.33 4. The Federal Trade Commission (FTC) Section 12 of the Federal Trade Commission Act specifically states that the FTC shall prohibit the false advertisement of \u201cfoods, drugs, and cosmetics.\u201d 34 Although the definition of \u201cadvertisement\u201d excludes labeling, FTC has additional authority pursuant to section 5 of the FTC Act to prevent \u201cunfair or deceptive acts or practices in or affecting commerce.\u201d 35 This broad authority enables

FTC to proceed against all unfair business practices, including false and misleading labeling of food products. 36 The FTC Act makes the dissemination of any false advertisement an unfair or deceptive - 11 -,"practice for the purpose of inducing, or that is likely to induce, the purchase of food or having an effect on interstate commerce. 37 An advertising claim may be deemed false or misleading if it is not adequately substantiated pursuant to FTC guidelines. 38 FTC requires that companies that make claims about their products be able to substantiate these claims before they are made. FTC policy guidelines essentially provide that a representation of objective fact implies that the claimant has a reasonable basis for such fact. Different types of claims warrant different levels of substantiation. 39 The courts have explicitly upheld FTC's authority to proceed against false labeling of food products. 40 FTC has statutory authority to obtain injunctive relief, and in some instances, damages. 41 FTC may also require corrective advertising if necessary to remedy the effects of past deception. 42 Thus, FTC is responsible for regulating claims about food that appear in advertising and certain other forms of labeling that may also constitute advertising. FSIS and FTC, in practice, generally coordinate their activities to avoid duplication. FSIS takes the lead in addressing the labeling of meat and poultry products. Advertising of meat and poultry products is within the purview of the FTC. It is prudent to consult FSIS labeling regulations, rules and policies when developing advertising for meat and poultry products. - 12 -,"B. Role of the States -- Validity of State and Local Regulations that Affect the Food Label State requirements adopted under state law may not differ from, or conflict with, existing federal labeling laws and regulations. States are, therefore, prohibited from imposing requirements different from or in addition to federal labeling requirements. When state law directly conflicts with federal law, or attempts to regulate in an area Congress intended to be regulated solely by federal law, the state law is generally preempted, or superseded, by federal law. This is known as the federal preemption doctrine. 43 The FMIA and the PPIA explicitly preempt state laws regulating labeling of meat and poultry products by providing that marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this Act may not be imposed by any State. 44 The federal preemption established by the FMIA and PPIA was upheld by the United States Supreme Court in a case involving California net weight labeling requirements. 45 The Court held that the California law was different from the USDA net weight standard which permitted manufacturing deviations and allowances for variations caused by moisture loss. The California law was thus declared preempted by federal law, and therefore, unenforceable. Federal courts have repeatedly and consistently upheld federal preemption of FSIS labeling requirements in the face of differing state labeling rules or practices. 46 A federal district court has ruled more recently that food packages that meet federal net weight labeling requirements may not be subjected to - 13 -,"sanction by state or local weights and measures officials based on the findings of limited retail inspections. In *Kraft Foods North America v. Rockland County Department of Weights and Measures*, the court held that reliance on limited retail inspection data gathered from small retail lot inspections to support a short weight violation conflicts with federal recognition of the reasonable variation that inevitably arises over the course of a production run. As previously stated, all labels on meat and poultry products destined for commerce must be in accordance with all applicable federal rules and approved by FSIS. Therefore, if a manufacturer's product is accurately labeled under federal rules when packaged, product remains accurately labeled,

regardless of where a portion of a given production lot is ultimately offered for sale. 47 III. FSIS LABELING \u2013 SURVEY OF BASIC PRINCIPLES A. When Packaging Must Bear Required Labeling FSIS labeling authority is very broad, extending from the labels appearing on the food package, before they are applied to the product, to point-of-purchase materials, including promotional brochures and shelf-talkers. 48 As mentioned previously, a \u201clabel\u201d is a display of any printing, graphics stickers, seals or other written, printed or graphic matter upon the immediate container. 49 This regulatory authority over the food label can affect the processing and manufacturing operations of food companies. Meat and poultry products that do not bear the USDA-approved label, unless expressly exempt, may not be distributed in interstate commerce. - 14 -,"The manner in which a meat or poultry product is packaged when shipped from an inspected establishment determines what information should appear on the label of the packaged product. The rules vary depending upon whether the product is a processed or prepared meat or poultry product, or an unprocessed meat cut, or a poultry product, and upon the type of package or container in which the product is packed and shipped. Immediate containers (e.g., bags, cardboard cartons, tray packs, and film bags enclosing processed or prepared meat products) can be considered \u201cprotective coverings\u201d and exempt from marking and labeling requirements if placed within a shipping container that meets all mandatory labeling requirements (product name, handling statement, legend, establishment number, net weight, ingredients statement, signature line, nutrition facts, and safe handling instructions when required). 50 This exemption does not include the mandatory identification and marking required for the inner container of the meat food product. The shipping container that contains exempt immediate containers must be marked \u201cPacked for Institutional Use Only\u201d or with an equivalent statement of intended limited distribution from one federal establishment to another. The unlabeled product within the shipping container may not be removed for further distribution nor displayed or offered for sale at retail. For unprocessed meat cuts, transparent film bags enclosing individual meat cuts in an unprocessed state can be considered \u201cprotective coverings\u201d and exempt from the mandatory labeling requirements when - 15 -,"required information appears on the shipping container in which the immediate containers are placed. Unlike processed meats, unprocessed meats when shipped may be removed from the shipping container for resale and further distribution to retailers, hotels, restaurants, and similar institutions if the product itself or the film bag bears a legible official mark of inspection and the establishment number. Poultry whole birds or individual cuts in protective coverings for export or sold to hotels, restaurants, or institutions only are exempt from the mandatory labeling of immediate containers, and no marking or labeling is permitted except in limited situations. The shipping container is considered the immediate container and should, therefore, include all mandatory features (product name, handling statement, legend, poultry plant number, net weight statement, ingredients statement, signature line, nutrition facts, and safe handling instructions when required.) A statement of limited use is not required to appear on the shipping container. Beyond these general requirements are specific provisions for certain types of products. 51 B. The Prior Label Approval Process Prior approval of all food labels affixed to a meat or poultry product must be consistent with FSIS regulations. The evolution of the prior label approval process provides useful context for understanding the current requirements. For many years, each label affixed to a meat or poultry product had to be submitted to FSIS for

evaluation and approval. Any modifications to - 16 -,"the approved label required resubmission to FSIS for a new final approval. Only in certain instances could minor modifications be approved at the inspected establishment by the FSIS inspector. Over time, the number of label submissions for final approval grew substantially as the number of new and modified products increased. The current regulations reflect the Agency\u2019s decision to modify its prior label approval authority in a fashion that has dramatically reduced the number of labels that must actually be submitted for evaluation and approval by FSIS staff. The local inspector no longer plays a role in the preapproval process but has the authority to retain product that bears non-compliant labels. Under the current regulations, final approval has been replaced with sketch approval based on submission of a label application to FSIS. 52 A sketch-approved label can be modified unilaterally by the company consistent with the flexibility specified by regulation, discussed below. In addition, specified types of product labels can be applied to meat and poultry products according to the generic labeling regulations without the need for submittal to FSIS, as long as the labels are in conformance with all applicable statutory, regulatory, and policy requirements. [To enhance the efficiency of its prior- approval process, FSIS encourages establishments to make use of the generically-approved labeling provisions. Establishments should consult with FSIS staff to resolve any uncertainty in this regard.] - 17 - ", "1. Treatment of Retail Labels Generally, no claims may appear on retail labels unless prior approval is obtained. Although FSIS labeling policies apply at retail, FSIS does not require that point-of-purchase material receive prior approval unless it is shipped with the product (e.g., stickered-labels applied by the retailer placed in the shipping container at the establishment where product is packed.) FSIS will evaluate and seek necessary correction of such material brought to its attention or identified by routine marketplace surveillance. 53 Despite the absence of required preapproval, meat and poultry labels applied at retail must conform to all applicable FSIS labeling regulations. A notable exception arises for so-called animal production claims (e.g., \u201craised without antibiotics\u201d) whereby only claims that have been approved by FSIS through submission of a label application may appear on \u201cretail labels.\u201d The labels applied at retail are not required to have sketch approval, but the animal production claims must be preapproved by the Agency (i.e., via the label affixed to the shipping carton). A prerequisite for FSIS approval is an establishment\u2019s written protocol that sets forth the parameters of the program to ensure the accuracy of the claim. Sometimes referred to as an \u201caffidavit\u201d or \u201ctestimonial\u201d program, appropriate documentation validating adherence to the FSIS-accepted protocol must be submitted to the Agency. 54 2. Establishment Responsibilities An establishment operates under a grant of inspection and bears certain responsibilities as a part of the label approval process. The processing - 18 -,"facility must create records of all final labeling, including sketch labels that have been approved. 55 Establishment records are to reflect modifications made to a sketch approval to the label prior to printing of the final labels. Records that must be maintained include all final labeling and \u201ctemporary\u201d label approvals. The prior-approval process does not excuse an establishment from ensuring that its labeling fully complies with applicable FSIS labeling requirements. It is prudent for an establishment to contact FSIS staff directly when proposed product formulations or label claims raise policy issues or an establishment is unsure how to apply the labeling requirements. Only labeling that is approved or expressly permitted may appear on product destined for interstate commerce. One cannot

otherwise unilaterally modify labels unless a specific regulation allows for such change or addition (e.g., random weight packages.)

3. \u201cTemporary\u201d Label Approvals FSIS recognizes that in certain circumstances a manufacturer has labels that contain one or more minor errors. On a case-by-case basis, FSIS will allow for temporary use of a nonconforming label if the criteria set forth by regulation are met. Use of a label that is in error renders a product misbranded unless temporary approval is granted by FSIS for the particular label.

Temporary labels may be granted under the following conditions: (i) The proposed labeling would not misrepresent the product; - 19 -,"(ii) The use of the labeling would not present any potential health, safety, or dietary problems to the consumer; (iii) Denial of the request would create undue economic hardship; and (iv) An unfair competitive advantage would not result from the granting of the temporary approval. An application requesting temporary approval must address each of these considerations.<sup>56</sup> Temporary approvals may be granted for a period not to exceed 180 calendar days. FSIS may also grant extensions of temporary approvals if the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.

57 4. Labels Approved Under the Generic Labeling Regulations FSIS allows generically approved labels to be applied to meat and poultry products in the exercise of its broad prior label approval authority. By regulation, FSIS specifies when generic approval can be undertaken by an establishment, foregoing the need to obtain a sketch approval requiring a submission of a label application directly to FSIS.

<sup>58</sup> Products for which a standard of identity applies may be generically approved, provided that the labeling does not contain any special claims, including quality claims, nutrient content or health claims, negative claims, geographical origin claims, or guarantees. For labeling that is not for domestic product (i.e., marked \u201cfor export only\u201d), the addition or deletion of the direct translation of a foreign language may be generically approved. - 20 -,"The final rule specifies numerous other types of labeling that are generically approved and, thus, need not be submitted to FSIS for sketch approval: single-ingredient products that bear no claims; products sold under contract specifications to the Federal government; labeling of shipping containers that contain fully- and properly-labeled immediate (inner) containers; food not intended for human consumption; meat inspection legends; inserts, tags, and other materials that bear no reference to the product and are not misleading; and the labeling for consumer test products not intended for sale.

5. Modifications of Labels Made Under the Generic Labeling Regulations FSIS also specifies the changes that can be made to a sketch- approved label whereby the modified label is not resubmitted for a new \u201csketch\u201d approval.

<sup>59</sup> Any change not authorized by regulation triggers the need for submission of the revised label for sketch approval. Consultation with FSIS staff is prudent to ensure that, in a given circumstance, the flexibility afforded these requirements is fully realized. All such modifications should be documented by the establishment, similar to generic label-approval recordkeeping discussed above. Permitted modifications or changes extend to the following features of a sketch- approved label: (1) proportionately enlarged or reduced labels; (2) substitution of any unit of measurement with its abbreviation, or vice versa; (3) a master or stock label from which the name and address of the distributor are omitted but to be applied before being used; (4) wrappers or other covers - 21 -,"bearing pictorial designs or illustrations; (5) change in the language or arrangement of opening or serving directions; (6) addition, deletion or amendment of on-pack coupons, cooking instructions, packer product code information or UPC information;

(7) any change in the manufacturer's identification and address; (8) net weight statement; (9) recipe suggestions; (10) change in punctuation; (11) newly-assigned or revised establishment number; (12) open date information; (13) change in packing material; (14) brand name changes, provided there are no design changes and the name does not connote quality or other characteristics of the product; (15) deletion of the word "new"; (16) special handling statements; (17) safe handling instructions; (18) the amount of an ingredient that does not change the order in which the ingredients are declared; (19) color; (20) vignettes, provided they do not render the product labeling misleading; (21) company-initiated change in establishment number; (22) nutrition values, except that the serving size cannot be modified; (23) deletion of any claim or nonmandatory features of the label; and (24) addition or deletion of a direct translation of the English language into a foreign language for products marked "export only."

C. Regulatory References \u2013 Resource Tools

FSIS labeling requirements and policies are found in the relevant statutes, implementing regulations, FSIS directives (including Policy Memoranda), FSIS notices, and the Food Standards and Labeling Policy Book. FSIS directives and FSIS notices are the two primary types of issuances that instruct FSIS inspection workforce and technical employees on how to carry - 22 -,"out their responsibilities. FSIS directives contain instructions of an indefinite duration, while notices are temporary instructions scheduled to expire no later than one year from the issuance date. The Food Standards and Labeling Policy Book is a compilation of policy and informal standards that have been established over years of labeling decisions assembled in a dictionary format. All of these useful references are found at the FSIS website ([www.fsis.usda.gov](http://www.fsis.usda.gov)). As part of its prior-approval process, FSIS routinely reviews policy issues on an ongoing basis. Therefore, it is important to consult these resources which are updated periodically. New policy questions should be directed to the appropriate FSIS staff.

**IV. MANDATORY REQUIREMENTS --**

**INTRODUCTION** There are up to eight specific requirements for each product label: (1) product name, (2) inspection legend and establishment number, (3) handling statement, (4) net weight statement, (5) ingredients statement, (6) address line, (7) nutrition facts, and (8) safe handling instructions. Each of these requirements is discussed in detail below. The information must or may appear on specified areas of the label. In designing a label, it is important to understand what information must go where. The placement and prominence of information of the mandatory requirements are specified by regulation. Generally, any required label information must be prominent, conspicuous (as compared to other words, statements, and designs on the label), and in such terms as "to render it likely to be read and understood by the ordinary individual under customary - 23 -,"conditions of purchase and use."

To ensure that this threshold requirement is met, the regulations specify where and in what fashion certain required information must appear. These provisions vary depending on the particular required label statements, and are specified in the appropriate sections below.

**A. Principal Display Panel** [9 C.F.R. \u00a7 317.2(d) (meat); 9 C.F.R. \u00a7 381.116(b) (poultry)] The principal display panel, or "PDP," is the part of the label most likely to be displayed, presented, shown, or examined under customary conditions to the consumer.

When a label bears alternate PDPs, information required to appear on the PDP shall be duplicated on each PDP. The PDP must include the name of the product, net quantity of contents, the official inspection legend, number of the official establishment, and, if necessary, a handling statement. The PDP must be large enough to accommodate mandatory labeling information required by statute or

regulation. 62 In determining the area of the PDP, the tops, bottoms, flanges at the top or bottoms of cans, and shoulders and necks of bottles and jars are excluded. The PDP is specifically defined as follows. \u2022 For rectangular packages, one entire side, the area of which is at least the product of height times the width of that side. \u2022 For a cylindrical or nearly cylindrical container, the area that is 40 percent of the product at the height of the container times the circumference of the container or a panel, the width of which is one-third of the circumference and the height of which is as high as the container. - 24 -,"\u2022 For a container with any other shape, 40 percent of the total surface area is considered the PDP. Certain other special circumstances for placement of the PDP are specified as well. B. Information Panel [9 C.F.R. \u00a7 317.2(m) (meat); 9 C.F.R. \u00a7 381.116(c) (poultry)] The information panel typically is that part of the label immediately contiguous and to the right of the PDP. The information panel also can be the back panel or, for some boxes, any panel contiguous to the PDP. All information required to appear on the label of a package must appear either on the PDP or the information panel unless otherwise specified by regulation. 63 Certain other label information that may be placed on the information panel (unless on the PDP) includes: an ingredients statement, name and address of the manufacturer or distributor, and nutrition labeling, if required. The safe handling instructions may be placed anywhere on the label. As with the PDP, information appearing on the information panel must be prominent and conspicuous. 64 Certain exemptions are permitted by regulation where the label is below a certain size due to the overall size of the food product\u2019s package. 65 An establishment may not deviate from regulatory requirements in an effort to accommodate optional information (e.g., product name not prominent to allow for large \u201cnew and improved\u201d claim.) - 25 -,"V. PRODUCT NAME [9 C.F.R. \u00a7 317.2(c) (meat); 9 C.F.R. \u00a7 381.117 (poultry)] A. Overview 1. Determining a Product\u2019s Name All meat and poultry products must be identified by a product name on the PDP. The regulations state that the product must be identified by the name specified by the standard, if there is one, or a common and usual name, or a truthful descriptive designation of the product. The regulations are intended to ensure that the product name accurately informs a consumer of a product\u2019s identity. In addition, there are detailed requirements in the regulations and labeling policies to ensure that the product identity is clear and prominent to the consumer. In brief, if the product is represented as a product for which a standard of identity is established, the product must be identified by that name on the labeling, (e.g., \u201cChili con Carne\u201d or \u201cChicken Soup\u201d.) If no standard of identity is established for a product, one must next consider if the product is identified by a common or usual name, if one exists (e.g., \u201cBeef Shoulder Clod\u201d or \u201cPork Loin\u201d.) Such a name may be established by regulation or common usage, and it must describe the basic nature of the product or its characterizing ingredients. In the absence of either a standard of identity or appropriate common or usual name, the identity statement must be a descriptive name. The descriptive name should accurately identify or describe - 26 -,"the basic nature of the food or its characterizing properties or ingredients (e.g., \u201cBeef and Vegetables in Dough\u201d or \u201cBreaded Nugget-shaped Chicken Patty\u201d.) 2. Placement and Prominence of Product Name The product name must appear prominently on the principal display panel. Certain regulations and Policy Memoranda specify the size (or relative size) of terms that appear as part of the product name. In general, words in product names or fanciful names may be of a

different size, color, or type, but in all cases the words must be prominent, conspicuous, and legible. 66 No word in a product name (standardized name, a common or usual name, or descriptive name) should be printed in letters that are less than one- third the size of the largest letter used in any other word of the product name. This same requirement is applicable to fanciful names as well. For example, for a product labeled Chili Mac\u2014Beans, Macaroni and Beef in Sauce, \u201cChili Mac\u201d is the fanciful name, and \u201cBeans, Macaroni, and Beef in Sauce\u201d is the product name. No letter in \u201cChili Mac\u201d may be smaller than one-third the size of the largest letter in \u201cChili Mac.\u201d Furthermore, no letter in the true product name, (i.e., \u201cBeans, Macaroni, and Beef Sauce,\u201d) may be smaller than one-third of the largest letter in the true product name. Product names in certain instances must be accompanied by a qualifying statement deemed necessary to ensure that the product name is not misleading. For example, for a turkey-ham product, \u201cturkey\u201d must appear in the same size, style, and color and on the same background as the word \u201cham.\u201d The product name must be qualified with the statement \u201ccured turkey thigh - 27 -,"meat.\u201d The qualifying statement must be contiguous to the product name (when triggered), without intervening type or designs, not less than one-half the size of the product name but not less than one-eighth inch in height, and shall be in the same style and color and the same background as the product name and in the same size, style and color, and same background as the word \u201cham.\u201d 67 B. Standards of Identity [9 C.F.R. Part 319 (meat); 9 C.F.R. \u00a7 381 Subpart P (poultry)] USDA has statutory authority to establish standards of identity for meat and poultry products. Under the FMIA and the PPIA, a product is \u201cmisbranded\u201d if: It purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by regulations . . . unless (A) it conforms to such definition and standard, and (B) its label bears the name of the food specified in the definition and standard. 68 A standard of identity prescribes a manner of preparation and the ingredients of a product that is to be labeled with a particular name. Numerous product standards have been established by regulation. 69 FSIS also has established informal policy standards by Policy Memoranda and through entries in its Food Standards and Labeling Policy Book. Foods subject to a standard of identity must be labeled with the name specified in the standard. A food that bears the name of a standardized food that does not satisfy the requirements of the applicable standard is misbranded. Examples of standardized products - 28 -,"include: \u201cHam,\u201d \u201cHam Water Added,\u201d \u201cHot Dogs,\u201d \u201cChicken and Noodles,\u201d and \u201cSpaghetti Sauce with Meatballs.\u201d C. Common or Usual Name [9 C.F.R. \u00a7 319.1 (meat); 9 C.F.R. \u00a7 381.117 (poultry)] The FMIA and PPIA authorize FSIS to promulgate common or usual names for meat and poultry food products. A product is misbranded unless it bears \u201cthe common or usual name of the food, if any there be.\u201d 70 FSIS regulations state further that any product \u201cfor which there is a common or usual name must consist of ingredients and be prepared by the use of procedures common or usual to such products, insofar as specific ingredients or procedures are not (otherwise) prescribed or prohibited.\u201d Examples of common or usual names include red meat primals, (e.g., beef round,) and subprimals, (e.g., beef sirloin steak.) D. Descriptive Names [9 C.F.R. \u00a7 317.2(e) (meat); 9 C.F.R. \u00a7 381.117(a) (poultry)] Descriptive terms may be used as a product\u2019s statement of identity provided that no standard of identity or common or usual name exists. For meat products, \u201cany descriptive designation used as a

product name for a product which has no common or usual name shall clearly and completely identify the product.\u201d For poultry products, FSIS requires \u201ca truthful descriptive designation\u201d absent a standard of identity or common or usual name. Product which has been prepared by a specific method, such as salting, smoking, drying, or chopping, must be so described unless the name implies, - 29 -,"or the manner of the packaging shows, that the product is subject to the particular form of processing. Examples of descriptive names include \u201cChicken and Vegetable in Dough\u201d or \u201cBreaded Nugget-shaped Chicken Patty.\u201d Unqualified meat terms common to the industry but uncommon to consumers, such as \u201cpicnic,\u201d \u201cbutt,\u201d and \u201cloaf\u201d must not be used as product names unless accompanied by terms descriptive of the product or with a list of ingredients, if the Agency determines that this is necessary to ensure that the label is not false or misleading. This labeling convention is only true for certain (non-specific) meat products. In contrast, the poultry regulations provide that \u201ckind\u201d (poultry species) be specified in the product name. Manufacturers may also make use of a fanciful name accompanied by a descriptive term or name that is designed to ensure that consumers are not misled as to the identity, amount, or composition of a product. A product with the fanciful name \u201cFiesta Mexicana\u201d, along with the descriptive term \u201cChicken Breasts with Salsa and Peppers\u201d, is such an example. Use of fanciful names is especially common for a whole array of new or newly-formulated food products. A truly fanciful name will not convey a meaning that in any way relates to the nature of the product (e.g., Moon Pie.) E. Imitation Food Products [9 C.F.R. \u00a7 317.2(j)(1) (meat); 9 C.F.R. \u00a7 381.1(b) (poultry)] A label for a product that is an imitation of another food shall bear the term \u201cimitation\u201d immediately preceding the name of the food imitated and in the same size and style of lettering as the product\u2019s name. An ingredients - 30 -,"statement must follow the imitation product name. USDA has informally followed FDA\u2019s approach with regard to imitation labeling and products not being nutritionally inferior. Products that resemble but are not nutritionally inferior to standardized meat or poultry products need not bear the \u201cimitation\u201d designation, provided that the meat or poultry content is conspicuously disclosed. 71 If a product is nutritionally inferior to the standardized product, it must be labeled \u201cimitation\u201d as part of the product name. 72 FSIS regulatory policy permits the marketing of products that are technically imitation solely because they do not adhere to the compositional requirements established for a standardized product or other traditional food with generally recognized, established contents (e.g., Ground Beef and Textured Vegetable Protein (TVP) Product.) This policy enables a food manufacturer to make a product that is nutritionally inferior and is designed to serve consumer preferences without the use of the stigmatizing term \u201cimitation.\u201d In response to consumer preference for lower fat alternatives to standardized foods, FSIS allows products to be nutritionally modified to reduce the fat, cholesterol, or sodium content through the addition of ingredients for fat or sodium replacement precluded or restricted by applicable standards. 73 Pursuant to this policy, qualifying products may bear the standardized name in conjunction with an appropriate nutrient content claim provided that consumers are informed of the actual components through labeling and certain other guidelines are followed. For example, meat products that combine fresh sausage, ground beef, or hamburger and other safe and suitable ingredients for - 31 -,"the principal purpose of replacing fat may be descriptively labeled. Such products are

\u201cLean Ground Beef, Water, and Carrageenan Product,\u201d \u201cLow Fat Ground Beef With X% Solution of \u2026,\u201d \u201cLean Beef Sausage, Water, and Carrageenan Product,\u201d or \u201cReduced Fat Pork Sausage, Water, and Binders Product,\u201d provided, in part, that the regulatory requirements for the nutrient content claims are satisfied. 74 Breakfast sausages, cooked sausages, and fermented sausages with modified fat content also may be identified by a nutrient content claim and a standardized or traditional name, such as \u201cLow Fat Pepperoni\u201d or \u201cReduced Fat Frankfurter.\u201d 75 F. Geographic Origin [9 C.F.R. \u00a7 317.8(b)(1) (meat); 9 C.F.R. \u00a7 381.129(b)(2) (poultry)] By regulation, terms having geographic significance generally may appear without qualification on the labeling of meat only when the product is made in the geographic area mentioned. Terms of geographic significance referring to a locality other than where the product was made may appear on the label of meat products only if qualified by the words \u201cStyle,\u201d \u201cType,\u201d or \u201cBrand,\u201d accompanied by a \u201cMade In \u2026\u201d phrase that properly identifies where the product is manufactured. The provisions governing poultry products are somewhat different and are separately described below. Significant geographic areas that are qualified by the terms \u201cstyle\u201d and \u201ctype\u201d may appear on the labels of meat products when there is a generally recognized style or type of product produced in that particular geographic area. FSIS permits use of geographic terms when accompanied by the qualifying - 32 -,"term if the manufacturer can demonstrate that there is a recognized \u201cstyle\u201d or \u201ctype.\u201d 76 Therefore, a chili produced in California can be labeled \u201cCalifornia Chili con Carne,\u201d or since it is made in the southwestern United States, it could be labeled \u201cSouthwestern Chili con Carne.\u201d On the other hand, a chili made in Nebraska could be labeled \u201cNebraska\u201d or \u201cNebraska Style Chili con Carne,\u201d or since there is a recognized southwestern style, it could be labeled \u201cSouthwestern Style Chili con Carne,\u201d if it meets the style. \u201cBrand\u201d is used as part of a product name or claim when a style or a type is not recognized or met. A qualifying statement identifying the place where the product is actually made must appear in proximity to \u201cbrand\u201d when such qualifying term is required. Therefore, using the example of chili made in Nebraska above, if the products did not comply with the definition for \u201cSouthwestern Style,\u201d the product must be labeled \u201cSouthwestern Brand Chili con Carne, Made in Nebraska.\u201d The word \u201cBrand\u201d must be the same size and style of lettering as the geographic term, and it must be accompanied with a prominent qualifying statement identifying the particular locality in which the product is prepared. 77 Where a geographic term has come into general usage as a trade name and has been approved by FSIS as not being geographically significant and, thus, generic, the term may be used without qualification, such as \u201cOld El Paso.\u201d 78 The regulation specifically states that the terms \u201cVienna,\u201d \u201cGenoa,\u201d \u201cPolish,\u201d \u201cItalian,\u201d and other similar terms need not be accompanied with a qualifying descriptive term when used on the standardized product. In - 33 -,"addition, some trade names have been used so long and exclusively by a manufacturer so that it is generally understood by consumers to mean the product of a particular manufacturer, such as \u201cSwiss Chalet.\u201d 79 In contrast to the meat regulations, FSIS poultry regulations specify that a geographic term only may be used to identify a poultry product if the product was actually produced in the locality stated on the label. 80 However, as a matter of policy, FSIS

has modified its treatment of geographic terms for poultry products to parallel the policy applied to meat products. The underlying issue with respect to geographic origin is whether a product name truly connotes geographic significance to consumers or merely implies a product's style and the importance this information is to consumers. A truthful representation of geographic origin is permitted, such as "Virginia Ham" that is produced in the Commonwealth of Virginia, or "Tennessee Peppersteak," made in Tennessee. When the term "Style" is used, there must be a method of preparation or other product attributes that distinguish or characterize the product in a manner similar to products peculiar to a geographic region. An establishment must demonstrate that such a style exists in order to use the geographic claim. By informal policy, FSIS has allowed establishments to rely upon an independent third-party authority (e.g., culinary institute) to establish that a particular style is associated with a specific geographic area and that the particular product(s) bearing the claim comport with this recognized style. - 34 -,"G. Country of Origin [9 C.F.R. § 327.14-.15] FSIS requires imported meat and poultry products to bear the name of the country of origin, preceded by the words "Product of." On an immediate container, this country of origin statement must be immediately under the name of the product. 82 On an outside container, this statement accompanies the product name and establishment number in a prominent, legible manner. 83 VI. USDA INSPECTION LEGEND [9 C.F.R. § 312 (meat); 9 C.F.R. § 381.96 (poultry)] USDA regulations require a prominently displayed inspection legend and establishment or plant number on the principal display panel of all federally-inspected meat or poultry product containers unless there is a specific exception (e.g., on a metal clip.) 84 An official inspection legend is any symbol prescribed by regulations showing that a carcass or parts of carcasses were inspected and passed by FSIS in an official establishment in accordance with all federal regulations. An official establishment number is assigned to each establishment granted inspection service. The establishment number is used to identify all containers of inspected products prepared in the establishment. A product will be deemed "misbranded" if it fails to bear these features on its containers. 85 The regulations prescribe requirements for the relative dimensions and placement of the inspection legend; and this inspection legend must be of - 35 -,"a sufficient size and of such color as to be conspicuously displayed and readily legible. 86 The use of a foreign language for all aspects of a label is acceptable provided the inspection legend and establishment or plant numbers also appear in English.87 The products themselves are not required to be branded when shipped in properly-labeled containers or when shipped under an official government seal. There are regulations that specify in great detail the precise manner, method and location by which the legend must be placed on the label of an inspected product. The required official inspection legend for inspected and passed poultry products should include the following wording, "Inspected for wholesomeness by U.S. Department of Agriculture." 88 The establishment number is prefaced by a "P" designating that the product is a poultry product. This wording should be contained within a circle. The form and arrangement should be exactly as indicated in 9 C.F.R. 381.96. The appropriate official plant number (P-and the federal number) should be shown, but, if the number appears elsewhere on the labeling material, it may be omitted from the inspection mark.89 If the number appears off the exterior of the container (e.g., on a metal clip,) a statement of its location must be printed contiguous to the legend (e.g., "Est. No. on

metal clip\ufe0f.) Products consisting of mixed meat and poultry ingredients must contain either the official meat inspection legend or official poultry inspection legend, depending on which ingredients are present in greater amounts. If meat or poultry ingredients exist in equal proportions, either official legend - 36 -,"may be used. If meat and poultry ingredients exist in exact proportions and both appear in the product name, the official legend must reflect the ingredient appearing first in the product name. VII. NET QUANTITY [9 C.F.R. \u00a7 317.2(h) (meat); 9 C.F.R. \u00a7 381.121 (poultry)] USDA statutes and regulations establish specific labeling requirements governing statements of the net quantity of the food package offered for sale to the consumer in a retail setting. This information facilitates value comparisons among similar products by consumers. All labels on food sold at retail must bear an accurate statement of the quantity of the package content in terms of weight, measure, or numerical count. 90 Such a statement must appear on the principal display panel of all containers to be sold at retail intact. 91 The statement must be in terms of the package contents -- solid, liquid, semi-solid, or viscous. 92 Reasonable quantity variations from the stated weight, caused by loss or gain of moisture during the course of good distribution practices or by unavoidable deviation in good manufacturing practices, are recognized and do not render a product to be misbranded. 93 Reasonable variations are permitted because of the nature of certain foods and the impossibility of developing completely accurate means of packaging. 94 Such variation may not be unreasonably large. 95 The Supreme Court held that the federal net weight requirements preempt state law requirements that do not permit reasonable variations, including unavoidable variations caused by moisture - 37 -,"loss during the course of good distribution practice. 96 Federal courts on several occasions have ruled that state or local enforcement practices in conflict with the FMIA or PPIA are preempted. 97 A. Expression of Net Quantity Statement The statement of quantity shall be expressed in terms of avoirdupois weight or liquid measure. The use of metric measurement as it relates to the net weight statement is voluntary because the FPLA exempts meat and poultry products from metric declaration. Where there is no general consumer usage to the contrary, the net quantity of contents statement for products sold in the U.S. should be expressed in terms of liquid measure if the product is liquid, or in terms of weight if the product is solid, semisolid, viscous, or a mixture of solid and liquid. 98 For example, a chili product would be measured in ounces and pounds, while a beef broth would be measured in fluid ounces. Thus, FSIS regulations require the terms \u201cnet weight\u201d or \u201cnet wt.\u201d to appear with the net quantity of contents when expressed in terms of weight and \u201cnet contents\u201d or \u201ccontent\u201d when expressed in terms of fluid measure. 99 Packages containing at least one pound or pint, but not more than 4 pounds or 1 gallon, must be expressed as a \u201cdual declaration.\u201d 100 A dual declaration includes ounces or fluid ounces followed, in parenthesis, by the largest whole U.S. customary unit (e.g., pounds and pints or quarts and gallons.) Any remainder should be expressed in terms of ounces or common or decimal fractions of the pound for weight measure, and fluid ounces or common or decimal fractions of the pint or quart for fluid measure (e.g., \u201cNet Wt. 24 oz. (1 - 38 -,"lb. 8 oz.),\u201d \u201cNet Wt. 24 oz. (1.5 lbs.),\u201d or \u201cNet Wt. 24 oz. (1 \u00bd lb.).\u201d 101 Exceptions for random weight, small, and multi-unit packages, as well as certain packages containing margarine and bacon, are discussed below. 102 B. Placement The net quantity of contents statement must appear in the lower 30 percent of the principal display panel of containers sold at retail intact in the following

manner.103 In lines generally parallel to the base of the containers. 104 In distinct contrast with other material on the package. 105 Separated from other printed label information appearing above and below it by a space at least equal to the height of the lettering used in the statement. 106 Separated from information appearing to its right and left by a space at least equal to twice the width of the letter 'N' of the style or type of lettering used in the declaration. 107 Packages that have a principal display panel of five square inches or less do not have to place the net quantity statement in the lower 30 percent of the principal display panel, provided that the declaration meets all other USDA requirements.

108 C. Prominence Additionally, USDA prescribes specific type requirements for the net quantity statement. The declaration must be in conspicuous and easily legible boldface print or type. 109 The lettering may be no more than three times as high as it is wide. 110 - 39 -," The minimum type size for the statement is dependent on the area of the PDP, as described in the table below. 111 When both upper and lower case letters are used in the declaration, the height of the lower case or its equivalent must meet the minimum type size requirements. 112 When only upper case letters are used, the height of the upper case letters must meet the minimum type size criteria. 113 When fractions are used, each numeral of the fraction must meet onehalf the minimum height standards. 114 Area of the PDP In Square Inches Minimum Type Size In Inches < 5 1/16 > 5-25 1/8 > 25-100 3/16 >100-400 1/4 > 400 1/2 D. Exceptions and Other Special Requirements USDA permits the following exceptions from its requirements for the net quantity statement. Individually-Wrapped, Random-Weight, Consumer-Size Packages Shipped in Bulk Containers; and Certain Meat and Poultry Products Subject to Shrinkage Through Moisture Loss The above-referenced products are not required to bear a net weight statement when shipped from an official establishment, provided that the shipping container bears a net weight shipping statement that expresses accurately the net quantity of contents in the container and is not - 40 -," otherwise false or misleading. The individual, random-weight, consumer-size packages must bear a net weight statement prior to retail display and sale. The declarations on the shipping container and individual packages are exempt from the type size, dual declaration, and placement requirements described above, if an accurate net weight declaration is shown conspicuously on the principal display panel of the shipping container or package. 115 Small Packages in Shipping Containers -- Individually-wrapped and labeled packages of less than 1 ounce net weight and random weight consumer size packages are exempt from USDA's net quantity of contents labeling requirements, provided that the packages are in a shipping container that expresses accurately the net quantity of contents in the container and is not otherwise false or misleading. 116 Small Packages in General -- Individually-wrapped and labeled packages of less than 1 ounce net weight with labels declaring net weight, price per pound, and total price are exempt from the type size, dual declaration and placement requirements described above if an accurate statement of net weight is shown conspicuously on the principal display panel of the package. 117 Sliced, Shingle-Packed Bacon in Rectangular Packages; and Margarine in One Pound Rectangular Packages (except packages containing whipped or soft margarine or packages containing more than four sticks) Provided that an appropriate net quantity statement appears on the principal display panel of the above-referenced products in a conspicuous

manner,\u201d the statement is exempt from the dual declaration requirement and the requirement that the net quantity of contents declaration appear in the bottom 30 percent of the PDP. 118 \u2022 Certain Types of Consumer Packages of Poultry Products \u2013 The Administrator may approve the use of labels that do not bear a net weight statement on the above-referenced packages, provided that: (1) the shipping container bears the statement, \u201cNet weight to be marked on consumer packages prior to display and sale\u201d; (2) the total net weight of the contents of the shipping container is marked on the container; (3) the shipping container also bears the statement: \u201cTare weight of consumer package\u201d in \u201cclose proximity\u201d to the tare weight of the consumer packaging, weighed to the nearest 1\8 ounce or less. 119 - 41 -,"Special net weight labeling rules are specified for multiunit retail packages (MRPs). An MRP is defined as a package containing two or more individually-packaged units that: (1) contain the identical commodity; (2) contain the same quantity of food; and (3) are intended to be sold as part of the MRP but are capable of being individually sold in full compliance with USDA regulations. 120 A net quantity statement is required on the outside label of the MRP. The statement must comply with the same requirements applicable to net quantity statements generally, as discussed above. In addition, net quantity statements for MRPs must also include the following: 121 \u2022 The number of individual units; \u2022 The quantity of each individual unit; and \u2022 In parenthesis, the total quantity of contents of the multiunit package, except that the declaration of total quantity need not be expressed as a \u201cdual declaration\u201d (e.g., the declaration in ounces need not be followed by an additional parenthetical declaration in terms of the largest whole U.S. customary units.) Examples of products that might bear this type of information could include pizza or soups. VIII. INGREDIENTS LABELING [9 C.F.R. \u00a7 317.2 (meat); 9 C.F.R. \u00a7 381.118 (poultry)] The ingredients statement provides the consumer with detailed information as to the constituents of a meat or poultry product. The number of ingredients, the multiple functions of ingredients, and the sophisticated methods for producing some ingredients create many challenges in applying the ingredient labeling requirements. Proper ingredients labeling requires - 42 -,"regulatory and technical expertise. An understanding as to the function an ingredient plays in the food is central to proper application of the ingredient labeling requirements. A. Overview: Basic Requirements An ingredients statement is required when a product is fabricated from two or more ingredients. 122 All ingredients must be declared by their common or usual names on the label in descending order of predominance by weight.123 Order of predominance is determined based on the weight of ingredients as added to the formulation. 124 An ingredients statement is not required when the product name provides a complete identification of all ingredients in the food (e.g., \u201cChicken Breasts with Rosemary Extract\u201d.) Ingredients present in individual amounts of two percent or less may be listed in other than descending order, provided that they are listed at the end of the ingredients statement preceded by a phrase such as \u201cless than \_\_ percent of \_\_,\u201d with the blank filled in with the \u201cappropriate\u201d threshold level of two percent, 1.5 percent, one percent, or 0.5 percent. 125 These quantifying statements should start with the threshold level of 2.0% and move down in 0.5% increments, (i.e., 1.5%, 1.0%, or 0.5%) No ingredient in the quantifying statement may be greater than the stated threshold, and ingredients listed in the quantifying statement may be adjusted in the formulation without a change in the ingredients statement. When two meat ingredients comprise at least 70% of the

meat and meat by-product ingredients of a formula, and when neither ingredient is less than 30% by weight of the total meat and meat by-products used, these meat ingredients may be interchanged in the formula without a change to the ingredients statement.<sup>126</sup> In such cases, the word '\u201cand\u201d must be used in lieu of a comma between the two ingredients. This same rule applies to products containing poultry.<sup>127</sup> However, it does not apply to mixtures of meat and poultry. An ingredient that conforms to a standard of identity (discussed above in connection with product names) is identified by the name specified by the applicable standard. When FDA standardized foods are used as ingredients in the preparation of meat or poultry products, the common or usual names of all ingredients in the standardized food must be listed, in parentheses, following the name of the standardized food (so-called '\u201ccomponent listing\u201d).<sup>128</sup> The Code of Federal Regulations and the Food Standards contain definitions for various food ingredients. Absent a specific FSIS requirement, the appropriate common or usual name as set forth by FDA is appropriate.<sup>129</sup> The Food Standards and Labeling Policy Book may also be consulted for recognized ingredient names. There are two methods by which ingredients and sub-ingredients may be declared within the ingredients statement. The ingredients of a standardized food that is used as an ingredient in a food may either (1) be declared parenthetically following the name of the standardized ingredient (i.e., '\u201ccomponent\u201d labeling,) e.g., '\u201ccheddar cheese (milk, enzymes, salt)\u201d or (2) declared by dispersing each ingredient in its order of predominance in the - 44 - ", "ingredients statement of the product in which they are used without naming the standardized food specifically (i.e., '\u201ccomposite\u201d labeling). Composite listing does not name the standardized food, (e.g., '\u201cmeatballs\u201d from various sources, each having similar but different formulations.) The affected ingredients in a composite declaration must be minor in nature and should be identified using one of the following acceptable formats: 1) Pepperoni (pork, beef, water, salt, spices, sodium nitrate (may also contain lactic acid starter culture, sugar, and sodium ascorbate)); 2) Bacon bits (cured with water, salt, dextrose and/or sugar, and sodium nitrite); or 3) Pepperoni (pork, beef, water, sweeteners (contains one or more of the following: sugar, dextrose, fructose, corn syrup), salt, spices, sodium nitrate).<sup>130</sup> FSIS allows the use of both component labeling and composite labeling within a singular ingredients statement. Certain naming conventions, including the grouping of ingredients identified by a single term, are specified by FDA regulation and followed by FSIS.<sup>131</sup> The ingredient name usually must be specific as opposed to generic. Synonymous terms are interchangeable. Examples of interchangeable terms are frank, hot dog, and weiner, or corn syrup and corn syrup solids.

B. Artificial Flavorings, Colorings, and Chemical Preservatives

1. Flavors

\u2013 Specificity or Generic Identification Rules governing the labeling of artificial flavorings, colorings, and chemical preservatives are focused on ensuring that a product\u2019s ingredients statement adequately informs a consumer of the product\u2019s content.<sup>132</sup> A 1995 '\u201cQuestion and Answer\u201d document issued by FSIS remains a valuable resource - 45 - ", "to address these and other ingredient labeling issues.<sup>133</sup> FSIS permits the term '\u201cflavorings\u201d to designate natural spices and natural spice extractives.

'\u201cSpices\u201d may be used to designate natural spices.<sup>134</sup> The meat species and poultry '\u201ckind\u201d must be identified as part of a flavor (e.g., '\u201cDried (species or kind) stocks,\u201d '\u201cDried (species or kind) broth\u201d) Such ingredients may not be declared simply as '\u201cflavors\u201d because dried stocks, dried broth and extracts, and

blood fractions are of animal origin and must be so designated as \u201cDried (species) stock,\u201d \u201cDried (species) broth,\u201d \u201c(species) extract,\u201d or \u201cDried (species) plasma.\u201d Only ingredients that fall within the regulatory definition may be declared as \u201cnatural flavor,\u201d \u201cnatural flavoring,\u201d \u201cflavor\u201d or \u201cflavoring.\u201d These include essential oils, oleoresins, and spice extractives. 135 The term \u201cspice\u201d is used to refer to those spices listed in FDA regulations. 136 Certain types of ingredients that are hydrolyzed must be identified by the source and cannot be identified generically as a \u201cflavor.\u201d Examples include: hydrolyzed (source) proteins, gelatin, hydrolyzed meat and meat by- products, autolyzed yeast, and autolyzed yeast extract. The terms \u201cartificial smoke flavoring added\u201d or \u201csmoke flavoring added\u201d must be on the product label next to the product name and identified in the ingredients statement. 137 The same requirement applies with respect to meat products in several specific instances in which artificial colorings are added to the product. 138 - 46 -,"2. Color Additives FSIS requires color additives or the lake of a color additive subject to FDA certification to be identified by its common or usual name or the abbreviated names such as \u201cFD&C Red No. 40,\u201d \u201cRed 40,\u201d \u201cFD&C Blue No. 1 Lake,\u201d or \u201cBlue 1 Lake.\u201d 139 Color additives not subject to certification may be declared generically such as \u201cArtificial Color\u201d or \u201cColor Added,\u201d or they may be designated as \u201cColored with \_\_\_\_\u201d or \u201c\_\_\_\_ color,\u201d with the blank filled with the name of the color additive. 140 Products containing any artificial coloring must note that fact on the immediate container of the product or, if there is none, the product itself. 141 3. Chemical Preservatives Containers of products containing any chemical preservative must state that fact on the label. 142 Additional rules apply to antioxidants and other additives (e.g., possible product name qualifiers.) With respect to poultry products containing chemical preservatives, FSIS clarifies that the label statement must name the chemical preservative and the purpose of its use. 143 C. Incidental Additives Federal regulations require that all ingredients used to formulate a meat or poultry product must be listed by their common or usual name on labeling. There are two exceptions to the rules. An ingredient that is classified by FDA as a secondary direct additive does not need to be labeled because it has only a momentary technical effect in food by definition. The other exception is for incidental additives according to FDA\u2019s labeling regulations. 144 - 47 -,"FSIS exempts the mandatory declaration of \u201cinidental additives\u201d from an ingredients statement if they are present in insignificant amounts and serve no technical or functional effect in food, are used as a processing aid, or have migrated to food from equipment or packing materials. 145 Processing aids are a subcategory of incidental additives and are not considered ingredients since they are essentially substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any lasting technical effect in that food. FSIS does not have a definition for incidental additives or processing aids. However, if a company believes that the use of a substance in the manufacture or formulation of a meat or poultry product is consistent with FDA\u2019s labeling definition for an incidental additive processing aid, then data needs to be submitted to FSIS to substantiate conformance with the FDA regulation. FSIS will determine on a case-by-case basis whether a request for the specific use of an ingredient is consistent with FDA\u2019s labeling definition of an incidental additive processing aid and thus, exempt from labeling.

These exceptions do not apply where FDA regulations require that use of a specific substance be disclosed for health or other reasons. For example, FDA requires that sulfiting agents that qualify as incidental additives must be labeled if present at levels exceeding an established level (10 ppm). 146 - 48 -,"D. Labeling of Ingredients of Public Health Concern Because there are foods and food ingredients to which some individuals may have a sensitivity (i.e., an allergic reaction or intolerance), FSIS emphasizes the importance of accurate, informative product labeling. FSIS supports including voluntary statements on labels to alert people who have sensitivities or intolerances to the presence of specific ingredients, particularly the \u201cbig 8\u201d allergens (wheat, crustaceans (e.g., shrimp , crab, lobster), eggs, fish, peanuts, milk, tree nuts (e.g., almonds, pecans, walnuts), and soybeans) and other specific ingredients (monosodium glutamate (MSG), sulfites, lactose, and Yellow 5 (tartrazine). FSIS provides the following example: \u201cContains: milk, wheat gluten, soy.\u201d FSIS further supports identifying the source of a specific ingredient in a parenthetical statement, (e.g., \u201cwhey (from milk)\u201d.) FSIS authorizes the use of factual labeling statements about a product\u2019s manufacturing environment, (e.g., \u201cProduced in a plant that uses peanuts,\u201d) where good manufacturing practices and effective sanitation standard operating procedures (SSOPs) cannot reasonably eliminate the unintended presence of certain ingredients. In certain circumstances, the phrase \u201cmay contain (name of allergenic ingredient)\u201d may be used on meat and poultry product labeling. However, the use of factual statements about a product\u2019s manufacturing environment, (e.g., \u201cProduced in a plant that uses peanuts,\u201d) and the use of \u201cmay contain\u201d statements, (e.g., \u201cmay contain peanuts\u201d) may only be used in cases where establishments show that adequate SSOPs cannot effectively eliminate the cross-contact issue. - 49 -,"The Agency will consider any non-misleading symbols, statements, or logos to inform consumers of the presence of ingredients of public health concern in meat, poultry, or egg products. All requests must be submitted to the Agency as a policy inquiry and not as label-approval submissions.

IX. ADDRESS (SIGNATURE) LINE [9 C.F.R. \u00a7 317.2(c)(3) & (g) (meat); 9 C.F.R. \u00a7 381.122 (poultry)] FSIS requires the labels of meat and poultry products to include the name or trade name and place of business of the manufacturer, packer, or distributor for whom the product is prepared. 147 The manufacturer or packer name may appear on the label without qualification. The name of the distributor, however, must be preceded by a phrase such as \u201cPrepared for \_\_\u201d or \u201cDistributed by \_\_.\u201d If the business is listed in a telephone or city directory, the information listed for the place of business must include the city, state, and postal ZIP code. Otherwise, it must also include the street address.

X. HANDLING STATEMENTS [9 C.F.R. \u00a7 317.2(k) (meat); 9 C.F.R. \u00a7 381.125(a) (poultry)] Packaged products that require special handling to maintain their wholesome condition must have prominently displayed on the principal display panel the applicable handling statement \u201cKeep Refrigerated,\u201d \u201cKeep Frozen,\u201d or \u201cPerishable\u201d \u201cKeep Refrigerated or Frozen.\u201d 148 The FSIS Administrator may also approve additional phrases of similar importance. - 50 -,"The statement \u201cKeep Frozen\u201d must appear on shipping containers for products that are distributed frozen and thawed prior to or during display for sale. Consumer-size containers holding such products must bear the statement \u201cPreviously Handled Frozen for Your Protection, Refreeze or Keep Refrigerated.\u201d With respect to perishable canned products, this statement must appear in upper case letters,

\u00bc inch in height, for containers with a net weight of 3 pounds or less, or \u00bd inch in height for containers with a net weight over 3 pounds. XI. SAFE HANDLING INSTRUCTIONS [9 C.F.R. \u00a7 317.2(l) (meat); 9 C.F.R. \u00a7 381.125(b) (poultry)] Safe handling instructions are required if the meat or poultry component of a product is raw or partially cooked (i.e., not considered ready-to-eat (RTE)), and if the product is destined for household consumers or institutional uses. 149 Safe handling instructions may appear on products that are not ready-to-eat (RTE) but include a fully cooked meat or poultry portion. Safe handling instructions should not be used on RTE products. Meat and poultry products intended for further processing at another official establishment also are exempt from this requirement. Under the heading \u201cSafe Handling Instructions,\u201d the safe handling information must appear on the label as follows. This product was prepared from inspected and passed meat and or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions. - 51 -,"This statement is in turn accompanied by the following additional required statements. \u2022 Keep refrigerated or frozen. Thaw in refrigerator or microwave. (This statement must appear next to a graphic illustration of a refrigerator.) 150 \u2022 Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry. (This statement must appear next to a graphic illustration of soapy hands under a faucet.) \u2022 Cook thoroughly. (This statement must appear next to a graphic illustration of a skillet.) \u2022 Keep hot foods hot. Refrigerate leftovers immediately or discard. (This statement must appear next to a graphic illustration of a thermometer.) These instructions must appear in lettering no less than 1\16 inch in height and be placed on the label \u201cprominently with such conspicuousness as to render it likely to be read and understood under customary conditions of purchase and use.\u201d The heading must be set in type size larger than the rationale statement and instructions. All safe handling information must be set off by a border and appear in one color printed on contrasting background of a single color. 151 FSIS permits changes to the first statement and icon if specific handling information on the product conflicts with the safe handling instructions. For example, if the label of a frozen product states, \u201cDo not thaw product, cook from frozen,\u201d or \u201cDo not thaw,\u201d the first part of the safe handling statement may be changed to \u201cKeep Frozen.\u201d If a product is shelf stable and states, \u201cNo refrigeration necessary,\u201d or \u201cRefrigerate after opening,\u201d - 52 -,"the icon of the refrigerator and the entire statement about refrigeration can be eliminated. XII. NUTRITION LABELING A. Mandatory Nutrition Labeling - General Requirements In 1994, USDA adopted sweeping new regulations mandating that most foods bear nutrition labeling. Nutrition labeling now is required for all meat and poultry products intended for human consumption and offered for sale, except single-ingredient, raw products and other exempt products. Exempt products include products produced by small businesses, products intended for further processing, products not for sale to consumers, products prepared and sold at retail, and products in small packages (individually wrapped packages of less than \u00bd ounce net weight). 152 These exemptions are discussed more fully below, but it is important to note that with these exemptions, a nutrition claim, or any other nutrition information provided on the label or in labeling or advertising in any context and in any form, negates the exemptions and triggers the mandatory nutrition labeling requirements. The exemptions for certain other products, such as

products intended for export and custom-slaughtered products, are not negated by nutrition claims. 153 Generally, nutrition information must appear on the label of meat and poultry products. Gift packs may display nutrition information at a place other than on a product label, such as product label inserts, provided the label bears no nutrition claim. 154 Meat and poultry products in packages - 53 -,"having a total surface area greater than 40 square inches, but lacking sufficient space on the principal display panel and information panel for all required information, may use an alternate panel that customers could readily see. 155 A product\u2019s nutrients are declared on its label. Certain nutrients must be declared, while others may be declared voluntarily. 156 The order in which certain nutrients must be declared, as well as certain definitions and requirements, are set forth below (the voluntary nutrients are identified as such). 157 \u2022 Total Calories. \u2022 Calories from Fat. \u2022 Calories from Saturated Fat (voluntary). \u2022 Total Fat. Total fat is defined as the total lipid fatty acids and is expressed as triglycerides. \u2022 Saturated Fat. Saturated fat is defined as the sum of all fatty acids containing no double bonds. \u2022 Trans Fat (voluntary). \u2022 Stearic Acid (voluntary). \u2022 Polyunsaturated Fat (voluntary). Polyunsaturated fat is defined as the cis, cis-methylene-interrupted polyunsaturated fatty acids. \u2022 Monounsaturated Fat (voluntary). Monounsaturated fat is defined as the cis-monounsaturated fatty acids. \u2022 Cholesterol. \u2022 Sodium. \u2022 Potassium (voluntary). - 54 -,"\u2022 Total Carbohydrate. Total carbohydrate is determined by subtracting the sum of the crude protein, total fat, moisture, and ash from the total weight of the product. \u2022 Dietary Fiber. \u2022 Soluble Fiber (voluntary). \u2022 Insoluble Fiber (voluntary). \u2022 Sugars. Sugars are defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). \u2022 Sugar Alcohol (voluntary). Sugar alcohol is defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA. \u2022 Other Carbohydrate (voluntary). Other carbohydrate is defined as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared (even if present) other carbohydrates is defined as the difference between total carbohydrate and the sum of dietary fiber and sugars. \u2022 Protein. A statement of the number of grams of protein must be declared. Ordinarily it is not necessary to declare the percent of daily value of protein unless a protein claim is made for the product, or if the product is intended for children under 4 or infants. When the protein digestibility-corrected amino acid score (PDCAAS) of the food is less than 20 (for adults and children greater than 4,) or less than 40 (for children between 1 and 4,) either of the following shall be placed next to the protein content: (1) \u201cnot a significant source of protein,\u201d or (2) a listing of the corrected amount of protein, expressed as percent of daily value. \u2022 Vitamin A, Vitamin C, Calcium, and Iron. The percent of daily value must be declared for vitamin A, vitamin C, calcium, and iron, in that order, and any other vitamin or mineral for which a claim is made, provided FDA has established a recommended daily intake (RDI) for such vitamin and mineral. \u2022 Vitamins and Minerals (voluntary). The declaration of the percent of daily value of other vitamins and minerals is voluntary if the vitamins and minerals are required for use in a standardized food that is used as an ingredient in another food or included solely for technological purposes. (The listing of other vitamins and minerals that may be - 55 -,"declared in the nutrition facts panel can be found in Section F of this part) Generally, nutrient information must be presented using the nutrient names in the regulation, except \u201csugar

alcohol\ufe0f which may be declared by its specific name (e.g., xylitol) when there is only one sugar alcohol in the food. Detailed requirements are set forth specifying when each mandatory or voluntary nutrient must be declared. For example, nutrients whose declaration is usually voluntary must be declared when a claim is made about the nutrient.<sup>158</sup> With the exception of the core nutrients (calories, total fat, sodium, total carbohydrate, and protein), nutrients that are present in insignificant amounts may be omitted from the list of nutrients and grouped in a summary statement (e.g., \ufe0fNot a significant source of \_\_\_\_\ufe0f.) The level of a nutrient that can be declared as (rounded to) zero is specified. The regulations also state the analytical methods for measurement of each nutrient.<sup>159</sup> B. Full Format Nutrition information must be presented in a specified format and type size.<sup>160</sup> The order in which the nutrition information appears, and the headings that must be used, also are specified in regulations.<sup>161</sup> The quantitative amount of each nutrient must be declared, except for vitamins and minerals, which are expressed as a percent of daily value.<sup>162</sup> The percent of the Daily Reference Value (DRV), under the heading \ufe0f% Daily - 56 -","Value,\ufe0f must be declared for total fat, saturated fat, cholesterol, sodium, potassium (if declared), total carbohydrate, and dietary fiber. The percent of daily value must be calculated and declared in the increments specified in the regulation.<sup>163</sup> Typically, the nutrition panel also must contain a footnote, preceded by an asterisk that states: \ufe0fPercent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.\ufe0f<sup>164</sup> Additionally, the footnote must list the recommended daily values for the macronutrients on the basis of a 2,000 and 2,500 calorie diet. Calorie conversion information on a per gram basis may follow the footnote (e.g., \ufe0fCalories per gram: fat 9, carbohydrate 4, protein 4\ufe0f.)<sup>165</sup> Variations in the presentation of nutrition information are permitted under certain circumstances. For example, nutrition information may be presented for two or more forms of the food (e.g., \ufe0fas purchased\ufe0f and \ufe0fas prepared\ufe0f) per ounce\ufe0f and \ufe0fper 100 grams;\ufe0f The regulatory requirements for dual declarations must be followed. The primary column is the food as packaged.<sup>166</sup> Additionally, meat products that contain two or more products in the same package or packages that are used interchangeably for the same type of product may use an aggregate display, specifying the identity of each food next to the nutrition information.<sup>167</sup> This same format may be used to display information for two or more forms of the same product (e.g., raw and cooked.)<sup>168 - 57 -","C.</sup> Simplified Format A simplified format for nutrition information is permitted when a meat product contains \ufe0finsignificant\ufe0f amounts of any required nutrient other than core nutrients (calories, total fat, sodium, total carbohydrate, and protein.)<sup>169</sup> An \ufe0finsignificant amount\ufe0f of a nutrient is defined as that amount that may be rounded to zero in nutrition labeling, except that for total carbohydrate, dietary fiber, sugars, and protein, it is an amount that can be declared as less than 1 gram.<sup>170</sup> The simplified format must include: (1) Total calories, total fat, total carbohydrate, protein, and sodium; and (2) Calories from fat, as well as any of the mandatory nutrients that are present in the food in more than insignificant amounts. If any required nutrient, other than a core nutrient, is present in an insignificant amount, it may be omitted from the tabular listing, provided the nutrition label includes the statement \ufe0fNot a significant source of \_\_\_\_,\ufe0f (with the blank filled in with the mandatory nutrients that are present in insignificant amounts). Otherwise, this statement is not necessary.<sup>171</sup> The simplified nutrient information must be presented in essentially the same manner as required

for the general format. The simplified format must also contain the statement, \u201cPercent Daily Values are based on a 2,000 calorie diet,\u201d and, if the term \u201cDaily Value\u201d is not spelled out, a statement that \u201cDV\u201d represents \u201cDaily Value.\u201d - 58 -,"D. Tabular Format Packages with 40 square inches or less of available surface area may use a tabular label format. Extremely small labels that cannot accommodate the standard vertical column or tabular format may display the required nutrition information in a linear format specifically outlined by USDA. The use of this linear format is approved on a case-by-case basis. Because the linear format is very hard to read, companies must demonstrate that inability to fit the tabular format on the label. 172 Packages having 40 square inches or less of available labeling space may also use approved abbreviations as part of the nutrition facts panel. Below is a listing of the authorized abbreviations: Serving size- Serv size Servings per container- Servings Calories from fat- Fat cal Calories from saturated fat- Sat fat cal Saturated fat- Sat fat Monounsaturated fat- Monounsat fat Polyunsaturated fat- Polyunsat fat Cholesterol- Cholest Total carbohydrate- Total carb Dietary fiber- Fiber Soluble fiber- Sol fiber Insoluble fiber- Insol fiber - 59 -,"Sugar alcohol- Sugar alc Other carbohydrate- Other carb 173 E. Compliance Requirements Governing Nutrition Labeling In calculating and presenting nutrition information, manufacturers must follow the compliance rules established by USDA. Methods for analyses are provided in the Agency\u2019s \u201cChemistry Laboratory Guidebook.\u201d If no USDA method is available or appropriate for a nutrient, the 1990 edition of the \u201cOfficial Methods of Analysis,\u201d published by the AOAC International, should be followed. 174 F. Reference Daily Intakes and Daily Reference Values The label declaration of percent daily value of vitamins and minerals will be based on the following Recommended Daily Intake (RDI\u2019s): 175 \u2022 Vitamin A, 5,000 international units \u2022 Vitamin C, 60 milligrams \u2022 Calcium, 1.0 grams \u2022 Iron, 18 milligrams \u2022 Vitamin D, 400 international units \u2022 Vitamin E, 30 international units \u2022 Vitamin K, 80 micrograms \u2022 Thiamin, 1.5 milligrams \u2022 Riboflavin, 1.7 milligrams \u2022 Niacin, 20 milligrams \u2022 Vitamin B6, 2.0 milligrams - 60 -,"\u2022 Folate acid, 0.4 milligrams \u2022 Vitamin B12, 6 micrograms \u2022 Biotin, 0.3 milligrams \u2022 Pantothenic acid, 10 milligrams \u2022 Phosphorus, 1.0 gram \u2022 Iodine, 150 micrograms \u2022 Magnesium, 400 milligrams \u2022 Zinc, 15 milligrams \u2022 Copper, 2 milligrams The following Recommended Daily Intake (RDI) from the FDA regulations would also be permitted on a voluntary basis on USDA food products: \u2022 Selenium, 70 micrograms \u2022 Manganese, 2.0 milligrams \u2022 Chromium, 120 micrograms \u2022 Molybdenum, 75 micrograms \u2022 Chloride, 3,400 milligrams Immediately following the name of a nutrient or dietary component, the following synonyms may be used parenthetically: \u2022 Calories\u2014Energy \u2022 Vitamin C\u2014Ascorbic Acid \u2022 Thiamin\u2014Vitamin B1 \u2022 Riboflavin\u2014Vitamin B2 - 61 -,"\u2022 Folate\u2014Folic acid or Folacin (Alternatively, folic acid or folacin may be listed without parentheses in place of folate.) The label declaration of percent daily value of the following food components is based on the following Daily Recommended Value (DRV)\u2019s: \u2022 Fat, 65 grams \u2022 Saturated fatty acids, 20 grams \u2022 Cholesterol, 300 milligrams \u2022 Total carbohydrate, 300 grams \u2022 Fiber, 25 grams \u2022 Sodium, 2,400 milligrams \u2022 Potassium, 3,500 milligrams \u2022 Protein, 50 grams G. Exemptions from Mandatory Nutrition Labeling As discussed above, the regulations either exempt certain foods from the mandatory nutrition labeling requirements or subject other foods to special labeling

requirements. Generally, these exemptions only apply when a product's label and advertising make no nutrition claims and contain no nutrition information. The exemptions and the special labeling requirements, when applicable, are identified below.

176 Small Business. A company employing 500 or fewer people, specific products produced at 100,000 pounds of product per year or less qualifies for the exemption. All product based on the same formula is counted toward the 100,000-pound limit. For example, a business making pork sausage would aggregate the weight of its bulk, link, and patty products. Businesses may calculate the amount of pounds produced by averaging the most recent two years of production.

\u2022 Products Intended for Further Processing. \u2022 Products Not for Sale to Consumers. For example, a free sauce packet included with egg rolls does not require nutrition labeling. This packet, however, may not be included in the product's net weight. If the sauce packet is either included in the net weight or not free, nutrition labeling is required.

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"\u2022 Individually-Wrapped Small Packages. Individually-wrapped packages of less than \u00bd ounce net weight are exempt.

\u2022 Products Custom Slaughtered or Prepared.

\u2022 Products Intended for Export Only.

\u2022 Certain Products Prepared and Sold or Served at Retail:

- o Ready-to-eat products packaged or portioned at retail
- o Multi-ingredient products (e.g., sausage) processed at retail

\u2022 Restaurant Menus.

\u2022 Foods for Infants and Children. Foods for children less than 2 years of age must bear nutrition labeling, except that the following nutrients may not be declared: calories from fat, calories from saturated fat, saturated fat, stearic acid, polyunsaturated fat, monounsaturated fat, and cholesterol. Foods represented or purported to be for infants and children less than four years of age must bear nutrition labeling, except that such information shall not include the percent of Daily Value (DV) and the footnote information. Nutrient names and quantitative amounts by weight must be presented in separate columns.

\u2022 Small Packages. Foods in packages that have a total surface area available for labeling of less than 12 square inches are exempt, but the label must contain an address or telephone number that may be used to obtain the required nutrition information (e.g., \u201cFor nutrition information, call 1-800-123-4567\u201d). When nutrition labeling is provided, either voluntarily or because of nutrition claims, all required information must meet certain size requirements.

H. Voluntary Nutrition Labeling

The nutrition labeling of single-ingredient, raw meat and poultry products is voluntary at this time. When voluntary nutrition labeling guidelines apply, a retailer or manufacturer must follow the mandatory nutrition labeling program with a few exceptions. Nutrition labeling may be declared \u201cas consumed\u201d or \u201cas packaged,\u201d and the number of servings per - 63 -

"\u2022 container need not be included. The simplified labeling format also may be used. When a retailer provides nutrition information at the point-of-purchase (e.g., signs or brochures), the listing of percent daily values of nutrients and required footnotes may be omitted, and formatting requirements do not apply. If a nutrition claim is made, however, all mandatory requirements apply.

\u201cSignificant participation\u201d in the voluntary nutrition labeling program is required; otherwise, the products under the voluntary nutrition labeling guidelines will become mandatory. A retailer is considered to be participating at a \u201csignificant\u201d level if it provides appropriate nutrition information for at least 90 percent of the major cuts of single-ingredient, raw meat and poultry it sells.

\u201cSignificant participation\u201d is evaluated every 2 years. Since participation in the voluntary nutrition labeling program was determined to be \u201cnot-significant\u201d in 1996 and 1999, FSIS

proposed mandatory nutrition labeling for products in the voluntary program. I. Serving Sizes

This section provides an overview of FSIS regulations concerning serving sizes, followed by a more detailed description of specific regulatory requirements such as how serving sizes are expressed on a product label. This section will also address reference amounts customarily consumed (RACC) per eating occasion and the conversion of RACC to labeled serving sizes (depending on the type and size of the product) and the exceptions to - 64 -,"these requirements. A summary of the procedures for determining the number of servings per container is also made available.

1. General Requirements For the purpose of nutrition labeling, nutrients and food components must be declared based on a serving of a food. \u201cServing size\u201d is defined as the amount of food customarily consumed per eating occasion, expressed in an appropriate common household measure. 177 The serving size is based on the established RACC for the particular food. Conversion from reference amount to serving size depends upon the nature of the product. For all meat and poultry products, the declaration of nutrient- and food-component content should be based on the product \u201cas packaged,\u201d except single-ingredient, raw product may be declared \u201cas consumed.\u201d There are two exceptions to raw, multi-ingredient products declaring nutrition information on the \u201cas purchased\u201d basis. FSIS has determined that for bacon products with a cook shrink of at least 60 percent and pork sausage type products with a cook shrink of at least 24 percent, the nutrition information may be declared on the \u201cas cooked\u201d basis only, since the nutrition information on the \u201cas packaged\u201d basis will not be useful to the consumer because the nutrient profile changes dramatically upon cooking. Cooking instructions must be included on the labeling of the bacon- and pork sausage-type products. All products may be declared in a second column \u201cas consumed\u201d if preparation and cooking instructions are clearly stated. - 65 -,"2. Common Household Measure

The serving size must be expressed in a \u201ccommon household measure\u201d which is defined as a cup, tablespoon, teaspoon, piece, slice, fraction (e.g., \u00bc pizza), ounce, or other common household equipment used to package food products (e.g., jar, tray.) The regulation lists in order of preference the measure that is suitable for the individual food: (1) cups, tablespoons, or teaspoons should be used whenever possible; (2) units such as piece, slice, tray, jar, and fractions of a whole (most appropriate for products such as pizza or quiche) are used when cup, tablespoon or teaspoon measurements are not applicable; and if neither of the prior two options are appropriate; (3) ounces, which must be expressed in 0.5-ounce increments. 178 Rounding should be indicated by the use of the term, \u201cabout.\u201d 179 Permitted abbreviations are specified by regulation.180 The common household measure should be followed by the metric quantity in parenthesis (e.g., \u201c2 slice [50 grams]\u201d,) except for single-serving containers. If a manufacturer voluntarily provides the metric weight for a single-serving product in the net-weight declaration, the serving-size declaration need not include the metric conversion (e.g., \u201cserving size 1 package.\u201d) However, if the metric weight is included in both the net-weight and the serving-size declaration, they must be identical. For single-serving products and meal-type products (e.g., can, box, package, meal, or dinner,) a description of the individual container or package should be used. For other products in discrete units (e.g., chop, - 66 -,"slice, link, patty,) a description of the individual unit should be used. For unprepared products used to prepare large discrete, units (e.g., pizza kit,) a fraction or a portion should be used.181 When no other unit is applicable, the serving size is

described in ounces. FSIS also permits ounce declarations for serving size for products in units like chicken breasts, pork chops, etc., if the individual units vary by more than 100% by weight. For example, when chicken breasts weigh between 3 ounces and 6 ounces, companies are permitted to label the product by ounces as opposed to the piece. When a serving size, determined by the reference amount, falls exactly halfway between two servings sizes (e.g., 2.5 tbsp), the size should be rounded up to the next incremental size. 182 All gram and milliliter quantities equivalent to the household measure should be rounded to the nearest whole number, except quantities less than 5 g (mL). Quantities between 2 and 5 g (mL) should be rounded to the nearest 0.5 g (mL), and quantities less than 2 g (mL) should be expressed in 0.1 g (mL) increments. 183 3. Reference Amounts Customarily Consumed (RACC) Per Eating Occasion The reference amounts reflect the amount of food customarily consumed per eating occasion and are based on the edible portion of food and on the major intended use of the food. There are alternate reference amounts for food intended for infants or children under 4 years old. 184 FSIS has approved the use of the following ready-to-serve RACCs listed below that are not codified in the regulation: - 67 -,"\u2022 Appetizers (e.g., Meat (or poultry) hors d\u2019oeuvres, mini eggrolls, mini pizza rolls, bagel pizza) - 85 grams RACC \u2022 Beans with meat (or poultry), plain or in sauce - 130 grams for beans in sauce or canned in liquid and refried beans prepared; 90 grams for others prepared; 35 grams dry RACC \u2022 Meat hot dog (or poultry hot dog) chili sauce \u2013 2 tbsp RACC \u2022 Paste for garnishing - 15 grams RACC \u2022 Stuffed cherry peppers - 30 grams RACC \u2022 Vegetables, sauce, and bacon bits (or poultry bacon bits) - 110 grams RACC \u2022 Rendered poultry fat \u2013 1 tbsp RACC The reference amount of a product that requires cooking or the addition of water or other ingredients is the amount required to prepare one reference amount of the final product. The reference amount for products that represent two or more foods packaged and presented to be consumed together (e.g., lunch meat with cheese and crackers) is typically the sum of the proportional reference amounts for each individual food in the package, provided the reference amount for the combination product is not specifically listed. Reference amounts must be used to determine whether a product meets the criteria for nutrient content claims and health claims. Reference amounts may be established or amended by submitting a petition to FSIS. The petition requirements are specified by regulation. 185 - 68 -,"4. Converting Reference Amounts Customarily Consumed (RACCs) to Labeled Serving Sizes a. Products in discrete units The serving size for products in discrete units (e.g., hot dogs, sliced luncheon meats) and products consisting of two or more foods packaged to be consumed together (e.g., beef fritters and barbecue sauce) generally is the number of whole units that most closely approximates the reference amount for the product category. If a unit weighs 67 percent or more, but less than 200 percent, of the reference amount, the serving size shall be one unit. If a unit weighs more than 50 percent, but less than 67 percent, of the reference amount, the manufacturer may declare one or two units as the serving size. If a unit weighs 200 percent or more of the reference amount, the manufacturer may declare the whole unit as one serving only if it can reasonably be consumed at a single eating occasion. 186 The serving size for products in large, discrete units that are usually divided for consumption (e.g., pizza, quiche) is the fractional slice of the food that most closely approximates the reference amount for the product category. The fractions are  $1\frac{1}{2}$ ,  $1\frac{1}{3}$ ,  $1\frac{1}{4}$ ,  $1\frac{1}{5}$ ,  $1\frac{1}{6}$ , or smaller fractions that can be divisible by 2 or 3. For packages used to prepare the large, discrete unit (e.g., pizza kits), the serving size may be the

fraction of the package used to make the reference amount of the large, discrete unit.<sup>187</sup> For assortments of meat or meat food products (e.g., variety packs), nutrient content may be expressed for the entire package or individual products. - 69 -,"b. Bulk products The serving size for bulk products (e.g., whole roast beef, whole chicken, large cans of chili, Individually Quick Frozen (IQF) chicken, vegetable pasta, and sauce products) and products consisting of two or more foods packaged to be consumed together (e.g., roast beef and potatoes) is the amount in household measure that most closely approximates the reference amount for the product category. For \u201cmixed dishes measurable by the cup\u201d sold as IQF products, the serving size is the amount of frozen product it takes to make 1 cup of the ready-to-serve product. This amount of frozen product is usually slightly larger than the 1 cup, ready-to-serve serving size since the product compacts when cooked. c. Meal-type products The serving size for meal products that come in single-serving containers is the entire content (\u201cedible portion only\u201d) of the package. The serving sizes for meal products that do not have RACCs are based on the RACC of the main ingredients and a portion of the other ingredients. For example if a meal consisted of a beef roast, gravy, and a separate package of potatoes, the company would base the serving size on 3 ounces of beef with the gravy and potato component proportioned evenly among the number of servings of the beef. Meal products do not base serving size on the sum of reference amounts. Additionally, FSIS has permitted companies to label multiple-serve meal products as a \u201cmeal for X\u201d and a serving size of \u201c1\x of package.\u201d - 70 -,"For a package containing two or more foods packaged and presented to be consumed together where the main ingredient is presented in discrete units (e.g., chicken fritters and corn), the serving size is the number of discrete units of the main ingredient, plus proportioned minor ingredients used to make the reference amount. A package containing several varieties of single-serving units, or a product having two or more compartments containing different foods, must provide nutrition information for each variety of food per serving size that is based on the reference amount for each food category. For single-serving containers, the serving size must be one unit. A product that is packaged and sold individually (i.e., single- serving containers) and that contains less than 200 percent of the reference amount, must be labeled as one serving. Products that have reference amounts of 100 grams (or 100 milliliters) or larger may declare the number of servings as either one or two when the package contains more than 150 percent but less than 200 percent of the reference amount. Packages sold individually that contain 200 percent or more of the reference amount may be declared as one serving if the entire package reasonably can be consumed in one eating occasion <sup>188</sup>. d. Exceptions There are four specified exceptions to the rules for converting reference amount to serving size: weight control products, meal products, variety packages, and single-serving containers. For products intended for - 71 -,"weight control and available only through a weight control program, a serving size may be selected by the manufacturer that is consistent with the meal plan of the program. Such products must bear a statement, \u201cfor sale only through the underlying\_\_\_\_\_ program (fill in the blank with the name of the appropriate weight control program,) (e.g., \u201cSmith\u2019s Weight Control\u201d.) 5. Servings Per Container Detailed procedures are established for determining the number of servings per container, including the increments in which the serving should be declared and procedures for rounding. The number of servings should be rounded to the nearest whole number, except the number of servings between 2 and 5 servings should be

rounded to the nearest 0.5 serving. Rounding should always be indicated by \u201cabout.\u201d 189 Random weight products may be declared as \u201cvaried\u201d provided the nutrition information is based on the reference amount expressed in ounces. When the serving size is required to be expressed on a drained solids basis and the number of servings vary because of natural variations in unit size (e.g., pickled pigs feet,) the manufacturer may state the typical number of servings per container as \u201cusually 5 servings.\u201d The number of servings in packages containing single-serving containers should be the number of individual containers. For packages containing several multi-serving units, the number of servings is determined by multiplying the number of individual multi-serving units by the number of servings in each individual unit. - 72 -,"The nutrient- and food-component content should always be based on the product as packaged or purchased. Products packed in water, brine, or oil not customarily consumed, however, shall declare the content of the drained solids.190 If oil or broth is included in the net weight, nutrition information must be declared for both the oil and broth. Product that is sold \u201cbone-in\u201d must determine the average percentage of bone and deduct that amount when calculating the number of servings per container. Those products commonly combined with other ingredients or otherwise prepared before consumption may declare nutrient contents on the basis of the product alone or \u201cas-consumed,\u201d provided that the type and quantity of the ingredients to be added and the specific method of preparation is specified. For example, a cream soup mix may be labeled with one set of Daily Values for the dry mix (per serving) and another set for the soup when prepared. 191 XIII. NUTRIENT CONTENT CLAIMS GENERALLY A. General Requirements 1. Basic Principles Claims A food label may not bear an express or implied claim that characterizes the level of a nutrient in a food (nutrient content claim) unless the term has been defined by regulations. 192 An express nutrient content claim is considered to be \u201cany direct statement about the level (or range) of a nutrient in the food\u201d (e.g., \u201clow sodium\u201d.) An implied nutrient content claim includes any claim that describes the food or an ingredient therein in a - 73 -,"manner that suggests that a nutrient is absent or present in a certain amount (e.g., \u201chigh in oat bran\u201d or \u201conly 6 grams of fat\u201d,) or suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., \u201chealthy, contains 3 grams of fat\u201d.) A manufacturer must comply with the nutrient content claim regulations if a label claim statement constitutes an express or implied claim. If a product label bears a nutrient content claim, nutrition labeling is required even if the product would otherwise be exempt. The RACCs are the basis for determining the serving size of foods and are used in determining whether a product meets the criteria for a nutrient content claim, unless otherwise specified. Claims may not be based on the level of a nutrient present in the declared serving size. If the declared serving size differs from the applicable reference amount and the product does not qualify for the claim based on the stated serving size, the claim must be followed by the criteria for the claim. In addition, the panel must include a statement referring the consumer to the nutrition label for information about the nutrient that is the subject of the claim (e.g., \u201cvery low sodium, 35 mg or less per 55 grams\u201d.) The criteria for the claim must be immediately adjacent to the most prominent claim in legible print and in a size no less than that required for net weight. 193 - 74 -,"2. Various General Requirements The regulations for the nutrition

labeling of meat and poultry products describe several general labeling requirements pertaining to nutrient content claims. For example, information provided as part of the nutrition panel is not considered a nutrient content claim. However, if this information is stated elsewhere on the label (e.g., on the principal display panel,) it could be considered an implied claim and regulated as such. 194 FSIS regulations also define what constitutes a \u201bsubstitute\u201d food. 195 A \u201bsubstitute\u201d food is one that may be used interchangeably with another food that it resembles (i.e., to which it is organoleptically, physically, and functionally similar,) and to which it is not nutritionally inferior. Products that are intended to be \u201bsubstitute foods,\u201d but are nutritionally inferior, must be labeled as an imitation food. The regulations provide further guidance concerning this definition. What constitutes a \u201bsubstitute food\u201d is relevant to many of the defined claims. Foods that qualify for a \u201clow\u201d claim, or labels that represent that a nutrient is absent, without the benefit of special processing, alteration, formulation, or reformulation, must bear a qualifying statement immediately accompanying the claim (e.g., \u201clard, a sodium-free food\u201d.) In addition, FSIS takes the position that \u201cfree\u201d or \u201clow\u201d before the name of a food implies that a food is lower in the particular nutrient than other foods of the same type. Therefore, only if a food has been specially processed, altered, formulated, or reformulated to produce a lower amount of the particular nutrient may it bear - 75 -,"a \u201cfree\u201d or \u201clow\u201d claim preceding the product name (e.g., \u201clow sodium beef noodle soup\u201d.) 196 Placement and prominence requirements are specified for nutrient content claims. The type size and style of a nutrient content claim may be no larger than two times that of the statement of identity of the food for which the claim is made. The regulations setting forth the specific definitions for each of the claims explained below include detailed placement and prominence requirements. Labeling information required to accompany certain nutrient content claim, whose type size is not specified by regulation, is required to be no less than 1\16 in height.197 3. Numeric and Percent Declarations A statement about the amount or percentage of a nutrient that implicitly characterizes the level of a nutrient is permitted if the food qualifies for a defined claim (e.g., \u201cless than 10 grams of fat per serving\u201d.) 198 If the food bearing the factual claim does not qualify for an applicable claim for the nutrient that is the subject of the factual statement, it must be accompanied by a disclaimer adjacent to the statement that the food is not low in, or a good source of, the nutrient for which the claim is made (e.g., only contains 200 milligrams of sodium per serving, not a low sodium food.) This requirement is intended to avoid a misleading impression that, for example, a food that contains \u201cless than 300 calories\u201d is a low calorie food. The regulations specify prominence and placement requirements for the disclaimer statement. Finally, a factual statement that does not implicitly characterize the level of a - 76 -,"nutrient and is not false or misleading is permitted and no disclaimer is required (e.g., \u201c100 calories\u201d or \u201c5 grams of fat\u201d.) Percent fat free claims are addressed separately and are explained below. 199 4. Relative Claims -- General Requirements Relative claims are those statements that compare the level of a nutrient in a food to the level of a nutrient in an appropriate reference food. Relative claims include: \u201clight,\u201d \u201creduced,\u201d \u201cless,\u201d (or \u201cfewer,\u201d) and \u201cmore.\u201d This section of the Guide discusses the basic requirements applicable to all relative claims. Later sections of the Guide that address each of the specific claim\u2019s definitions do not repeat

these general requirements. 200 a. Appropriate Reference Food FSIS regulations governing the use of reference foods must be followed. 201 Generally, for relative claims \u201cless,\u201d \u201cfewer,\u201d and \u201cmore,\u201d the reference food may be a similar product or a dissimilar product. For \u201clight,\u201d \u201creduced,\u201d and \u201caddded\u201d claims, the reference product should be a similar product. 202 b. Information that Must Accompany a Relative Claim The following explanatory information must accompany a relative claim: \u2022 identity of the reference food and the percentage (or a fraction) of the amount of the nutrient in the reference food by which the nutrient has been modified (e.g., 50 percent less fat than (reference food) or 1\3 fewer calories than (reference food)); and - 77 -, "\u2022 a clear and concise quantitative information statement comparing the amount of the subject nutrient in the product per labeled serving with that in the reference food must appear adjacent to the most prominent claim or on the information panel contiguous to the nutrition panel (e.g., fat reduced from 10 g to 5 g or calories reduced from 200 to 120.) A relative claim describing a reduction in the level of a nutrient (e.g., \u201clight,\u201d \u201creduced,\u201d) is not permitted if the nutrient content of the reference food qualifies as \u201clow\u201d for that nutrient. This restriction is intended to avoid use of the claim to highlight trivial reductions in the level of a nutrient. Use of the term \u201cmodified\u201d is separately defined. 203 A \u201cmodified\u201d claim may be used in the statement of identity (i.e., the product name) of a food that bears a relative claim (e.g., \u201creduced,\u201d), if followed immediately by the name of the nutrient whose content has been altered (e.g., \u201cmodified fat product\u201d.) The statement of identity must be accompanied by a comparative statement such as \u201ccontains 35% less than \_\_\_\_,\u201d and provide the explanatory information required for relative claims, as explained above. 204 5. Claims for Main Dish and Meal-Type Products are Defined Separately [9 C.F.R. \u00a7 317.313(l)&(m) (meat); 9 C.F.R. \u00a7 381.413(l) &(m) (poultry)] For the purpose of making a nutrient content claim, a \u201cmain dish product\u201d must do the following: 205 \u2022 make a significant contribution to the diet by weighing at least 6 ounces per labeled serving; \u2022 contain at least two 40-gram portions of food, or combinations of foods, from two or more of the following four food groups: (1) bread, cereal, rice and pasta; (2) fruits and vegetables; (3) milk, yogurt and cheese; - 78 - ; and (4) meat, poultry, fish, dry beans, eggs and nuts; excluding most sauces, as well as gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and \u2022 be represented as, or is in a form of a \u201cmain dish\u201d (e.g., not a beverage or dessert.) For the purpose of making a nutrient content claim, a \u201cmeal-type product\u201d must do the following: 206 \u2022 make a significant contribution to the diet by weighing at least 10 ounces per labeled serving; \u2022 contain at least three 40-gram portions of food, or combinations of foods, from two or more of the following four food groups: (1) bread, cereal, rice and pasta; (2) fruits and vegetables; (3) milk, yogurt and cheese; and (4) meat, poultry, fish, dry beans, eggs and nuts; excluding most sauces, as well as gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and \u2022 be represented as, or is in a form commonly understood to be, a breakfast, lunch, dinner, meal, or entr\u00e9e. 6. Exemptions Claims contained in the brand name of a product in use before November 27, 1991, that have not been defined are exempt from these specific regulatory restrictions, provided the brand name is not otherwise deemed false or misleading. 207 An exempt brand name must still comply with the requirements pertaining to the prominence of a

claim, the referral statement, and disclosure of nutrients in the referral statement. An implied nutrient content claim may otherwise be part of a brand name if the claim has been authorized by FSIS. Claims that are part of a product name by virtue of a standard of identity, as of November 27, 1991, are not subject to - 79 -,"the nutrient content regulations, nor would the name be deemed an implied claim or subject to the referral statement or disclosure requirements. Apart from brand names, a statement that describes the percentage of a vitamin or mineral in the food in relation to a Recommended Daily Intake (RDI) level, unless the claim is specifically prohibited, is exempt from the nutrient content claims regulations. 208 B. Specific Nutrient Content Claims 1. \u201cHigh,\u201d \u201cGood Source\u201d and \u201cMore\u201d Claims [9 C.F.R. 317.354 (meat) and 9 C.F.R. 381.454 (poultry)] A claim made about the level of a nutrient in a food in relation to the Recommended Daily Intake (RDI) or Daily Recommended Value (DRV) (excluding total carbohydrate) may only be made if the claim is defined within this section of the Guide. Therefore, claims may only be stated using the terms specified by the regulation. 209 a. \u201cHigh\u201d Claims The terms \u201chigh,\u201d \u201crich in,\u201d or \u201cexcellent source of\u201d may be used if the claimed nutrient is present in the individual food at 20 percent or more of the RDI or the DRV per reference amount customarily consumed (RACC). Main dish and meal products would qualify for this claim if the 20 percent level is reached and the label identifies the food component that is the subject of the claim (e.g., \u201cthe serving of broccoli in this product is high in vitamin C\u201d.) 210 - 80 -,"b. \u201cGood Source\u201d Claims The terms \u201cgood source,\u201d \u201ctranslates,\u201d or \u201cprovides\u201d may be used if the claimed nutrient is present in the individual food between 10 to 19 percent of the RDI or DRV per RACC. Main dish and meal products would qualify for this claim if the 10 to 19 percent level is reached and the label identifies the food component that is the subject of the claim. 211 c. \u201cMore\u201d Claims The comparative claim \u201cmore\u201d may be used to describe the level of protein, vitamins, minerals, dietary fiber, or potassium present in an individual food if the claimed nutrient is present in the food at 10 percent more of the applicable RDI or DRV per RACC as compared to an appropriate reference food. The explanatory information required for relative claims (explained above) must accompany the claim. 212 A \u201cmore\u201d or similar claim may describe a main dish or meal product if the food contains at least 10 percent more of the applicable RDI or DRV than an appropriate reference food, per 100 grams. The other requirements stated with respect to an individual food similarly apply to the claim when made for a main dish or meal product. 213 2. \u201cLight\u201d and \u201cLite\u201d Claims [9 C.F.R. 317.356 (meat) and 9 C.F.R. 381.456 (poultry)] The terms \u201clight\u201d and \u201clite\u201d may be used without further qualification. If a product derives 50 percent or more of its calories from fat, its fat content must be reduced by 50 percent or more per RACC as compared - 81 -,"to an appropriate reference food. If a product derives less than 50 percent of its calories from fat, the number of calories must be reduced by at least one- third per RACC or its fat content must be reduced by 50 percent or more compared to an appropriate reference product. As required with other relative claims, the identity of the reference product must be clearly declared, and quantitative information comparing the fat and calorie content of the product must be prominent. A \u201clight\u201d or \u201clite\u201d claim may not be made on a product that meets the definition of \u201clow fat\u201d or \u201clow calorie.\u201d The terms \u201clight\u201d and

\u201clite\u201d may be used on a main dish or meal- type product if the product qualifies for the \u201clow calorie\u201d or \u201clow fat\u201d claims and if a statement on the product\u2019s PDP explains the meaning of the claim. 214 3. \u201cSodium\u201d and \u201cSalt\u201d Claims a. \u201cSodium Free\u201d Claims The terms \u201csodium free,\u201d \u201cfree of sodium,\u201d \u201cno sodium,\u201d \u201czero sodium,\u201d \u201cwithout sodium,\u201d \u201ctrivial source of sodium,\u201d \u201cnegligible source of sodium,\u201d or \u201cdietary insignificant source of sodium\u201d may be used if the individual food contains less than 5 milligrams of sodium per reference amount (or in the case of a main dish or meal product less than 5 milligrams of sodium per labeled serving size). In addition, the food may not contain any ingredient that is sodium chloride or is generally understood by consumers to contain sodium unless the ingredient, as declared in the ingredients statement, is accompanied by an asterisk that refers consumers to the - 82 - ", "statement, \u201cadds a trivial amount of sodium,\u201d or a similar specified statement. If the food meets these conditions without the benefit of special processing, it must include an appropriate qualifying statement (e.g., \u201cleaf lettuce, a sodium free food\u201d.) 215 b. \u201cVery Low Sodium\u201d Claims The terms \u201cvery low sodium\u201d or \u201cvery low in sodium\u201d may be used if the individual food has an RACC that contains 35 milligrams or less per RACC (and per 50 grams if it is a small-serving size food). If the food qualifies for this claim without the benefit of special processing, an appropriate qualifying statement must accompany the claim (e.g., \u201cpotatoes, a very low sodium food\u201d.) 216 For a main dish or meal product, the sodium content is measured per 100 grams. The requirements for an individual food are otherwise applicable. 217 c. \u201cLow Sodium\u201d Claims The terms \u201clow sodium,\u201d \u201clow in sodium,\u201d \u201clittle sodium,\u201d \u201cccontains a small amount of sodium,\u201d or \u201clow source of sodium\u201d may be used if the individual food contains 140 milligrams or less sodium per RACC (and per 50 grams if it is a small-serving size food). Individual products with an RACC greater than 30 grams, or 2 tablespoons, and containing 140 mg or less sodium per RACC also qualify. 218 If the food qualifies for the claim without - 83 - ", "the benefit of special processing, an appropriate qualifying statement must accompany the claim (e.g., \u201cspinach, a low sodium food\u201d.) 219 For main dish and meal products, the food would qualify for this sodium claim if it contained 140 milligrams or less sodium per 100 grams. d. \u201cReduced Sodium\u201d Claims The terms \u201creduced sodium,\u201d \u201creduced in sodium,\u201d \u201csodium reduced,\u201d \u201cless sodium,\u201d \u201clower sodium,\u201d or \u201clower in sodium\u201d may be used if the individual food contains at least a 25 percent reduction in sodium as compared to an appropriate reference food. The claim must be accompanied by explanatory information required for relative claims. 220 For main dish and meal products, the 25 percent reduction in sodium is measured per 100 grams as compared to an appropriate reference food. The requirements for an individual food are otherwise applicable. No food may bear a \u201creduced sodium\u201d claim if the reference food qualifies for a \u201clow sodium\u201d claim. e. \u201cSalt\u201d Claims \u201cSalt\u201d is not considered synonymous with \u201csodium.\u201d References to salt content, such as \u201cunsalted,\u201d \u201cno salt,\u201d or \u201cno salt added,\u201d are deemed potentially misleading and subject to regulation. The term \u201csalt free\u201d may only be used if the food is \u201csodium free\u201d. In addition, the terms

\u201cunsalted,\u201d \u201cwithout added salt,\u201d and \u201cno salt added\u201d may be used for a food only if: (1) no salt is added during processing; (2) the food that it resembles and for - 84 -,"which it substitutes is normally processed with salt; and, (3) if it is not \u201csodium free,\u201d the statement \u201cnot a sodium free food\u201d is declared contiguous to the nutrition information on the information panel. 221 4. \u201cNutrient Content\u201d Claims for Fat, Fatty Acids and Cholesterol Content [9 C.F.R. 317.362 (meat) and 9 C.F.R. 381.462 (poultry)] a. \u201cFat Content\u201d Claims (1) \u201cFat Free\u201d Claims The terms \u201cfat free,\u201d \u201cfree of fat,\u201d \u201cno fat,\u201d \u201czero fat,\u201d \u201cwithout fat,\u201d \u201cnonfat,\u201d \u201ctrivial source of fat,\u201d \u201cnegligible source of fat,\u201d or \u201cdietarily insignificant source of fat\u201d may be used if the food contains less than 0.5 grams of fat per RACC or in the case of a main dish or meal product less than 0.5 grams of fat per labeled serving. In addition, the food may not contain any added ingredient that is a fat or is generally understood by consumers to contain fat unless the ingredient, as declared in the ingredients statement, is accompanied by an asterisk that refers consumers to the statement, \u201cadds a trivial amount of fat,\u201d or similar specified statement. If the food meets these conditions without the benefit of special processing, it must include an appropriate qualifying statement (e.g. \u201cbroccoli, a fat free food\u201d). 222 (2) \u201cLow Fat\u201d Claims The terms \u201clow fat,\u201d \u201clow in fat,\u201d \u201ccontains a small amount of fat,\u201d \u201clow source of fat,\u201d or \u201clittle fat\u201d may be used if the individual food contains 3 grams or less of fat per RACC, and per 50 grams if it is a small serving size - 85 -,"food. If the food qualifies for the claim without the benefit of special processing, it must be accompanied by an appropriate qualifying statement. A main dish or meal must meet the 3 grams or fewer criterion per 100 grams and not derive more than 30 percent of calories from fat. The requirements for an individual food are otherwise applicable. 223 (3) \u201cReduced Fat\u201d Claims The terms \u201creduced fat,\u201d \u201creduced in fat,\u201d \u201cfat reduced,\u201d \u201cless fat,\u201d \u201clower fat,\u201d or \u201clower in fat\u201d may be used if the individual food contains 25 percent less fat than the appropriate reference food. The claim must be accompanied by the explanatory information required for relative claims. For main dish and meal products, the 25 percent reduction in the fat is measured per 100 grams as compared to an appropriate reference food. The requirements for an individual food are otherwise applicable. No food may bear a \u201creduced fat\u201d claim if the reference food qualifies for a \u201clow fat\u201d claim.224 (4) \u201cPercent Fat-Free\u201d Claims A \u201cpercent fat-free\u201d or \u201cpercent lean\u201d claim is restricted to products that qualify as \u201clow fat.\u201d The percent reduction and the words \u201cfat free\u201d must be in uniform type size. Separately, a \u201c100 percent fat-free\u201d claim may only be made on foods that meet the criteria for \u201cfat-free,\u201d contain less than 0.5 grams of fat per 100 grams, and contain no added fat. A synonym for \u201cpercent fat free\u201d is \u201cpercent lean.\u201d225 - 86 -,"b. \u201cFatty Acid Content\u201d Claims Manufacturers must disclose the level of total fat and cholesterol in immediate proximity to a saturated fat content claim. Placement and prominence requirements are specified. Declaration of cholesterol content may be omitted if the food contains less than two milligrams of cholesterol per RACC (or per labeled serving for main dish and meal products), and fat content may be omitted if fat is present at 0.5 grams or less per reference amount (or per

labeled serving for main dish and meal products). The declaration of total fat may also be omitted if the food qualifies for a \u201clow fat\u201d claim. In addition to these general requirements, the regulation sets forth detailed requirements for specific claims that are permitted.<sup>226</sup> (1) \u201cSaturated Fat-Free\u201d Claims The terms \u201csaturated fat-free,\u201d \u201cfree of saturated fat,\u201d \u201cno saturated fat,\u201d \u201czero saturated fat,\u201d \u201cwithout saturated fat,\u201d \u201ctrivial source of saturated fat,\u201d \u201cnegligible source of saturated fat,\u201d or \u201cdietary insignificant source of saturated fat\u201d may be used if the food contains less than 0.5 grams of saturated fat and less than 0.5 grams trans fatty acid per RACC (or in the case of a main dish or meal product less than 0.5 grams of saturated fat and less than 0.5 grams trans fatty acid per labeled serving size).<sup>227</sup> In addition, the food may not contain any ingredient that is a saturated fat or is generally understood by consumers to contain saturated fat unless the ingredient, as declared in the ingredients statement, is accompanied by an asterisk that refers consumers to the statement, \u201cadds a - 87 -,"trivial amount of saturated fat,\u201d or similar specified statement. If the food meets these conditions without the benefit of special processing, it must include an appropriate qualifying statement. (2) \u201cLow In Saturated Fat\u201d Claims The terms \u201clin saturated fat,\u201d \u201clow saturated fat,\u201d \u201ccontains a small amount of saturated fat,\u201d \u201clow source of saturated fat,\u201d or \u201ca little saturated fat\u201d may be used if the individual food contains 1 gram or less of saturated fatty acids per RACC and not more than 15 percent of calories from saturated fatty acids. If the food qualifies for the claim without the benefit of special processing, it must be accompanied by an appropriate qualifying statement, which clearly refers to all food of its type and not merely to the particular food to which the label is attached.<sup>228</sup> For a main dish or meal product, the food must contain 1 gram or less of saturated fat and fewer than 10 percent calories from saturated fat, measured per 100 grams. The requirements for an individual food are otherwise applicable. (3) \u201cReduced Saturated Fat\u201d Claims The terms \u201creduced saturated fat,\u201d \u201creduced in saturated fat,\u201d \u201csaturated fat reduced,\u201d \u201cless saturated fat,\u201d \u201clower saturated fat,\u201d or \u201clower in saturated fat\u201d may be used if the individual food contains 25 percent less saturated fat per RACC than an appropriate reference food. The explanatory information required for relative claims must accompany the claim.<sup>229</sup> - 88 -,"For a main dish or meal product, the food must contain 25 percent less saturated fat per 100 grams than an appropriate reference food. The requirements for an individual food are otherwise applicable. A food cannot be labeled with a \u201creduced saturated fat\u201d claim if the reference food qualifies for a \u201clow saturated fat\u201d claim. c. \u201cCholesterol Content\u201d Claims (1) \u201cCholesterol Free\u201d Claims The terms \u201ccholesterol free,\u201d \u201cfree of cholesterol,\u201d \u201czero cholesterol,\u201d \u201cwithout cholesterol,\u201d \u201cno cholesterol,\u201d \u201ctrivial source of cholesterol,\u201d \u201cnegligible source of cholesterol,\u201d or \u201cdietary insignificant source of cholesterol\u201d may be used if: \u2022 the individual food contains 2 milligrams or less of cholesterol per reference amount (or in the case of a main dish or meal product per labeled serving size); \u2022 the food contains no ingredient generally understood by consumers to contain cholesterol, unless the ingredient, as declared in the ingredients statement, is accompanied by an asterisk which refers consumers to the statement, \u201cadds a trivial

amount of cholesterol,\u201d or similar specified statement; \u2022 the food contains 2 grams or less of saturated fat per reference amount (or for a main dish or meal product per labeled serving); and \u2022 the food qualifies for the claim without the benefit of special processing, it must include an appropriate qualifying statement. A main dish or meal product may generally bear a \u201ccholesterol free\u201d claim if it meets the requirements set forth above for individual foods, - 89 -,"but the 2 milligrams cholesterol and 2 grams saturated fat criteria are measured per 100 grams, rather than per reference amount. 231 (2) \u201cLow in Cholesterol\u201d Claims The terms \u201clow in cholesterol,\u201d \u201clow cholesterol,\u201d \u201ccontains a small amount of cholesterol,\u201d \u201clow source of cholesterol,\u201d or \u201clittle cholesterol,\u201d may be used to describe food that does not exceed the applicable disclosure level for total fat if the food: \u2022 has a RACC greater than 30 g or greater than 2 tbsp; \u2022 contains 20 milligrams or less of cholesterol per reference amount and per 50 grams if it is a small-serving size food; \u2022 contains 2 grams or less of saturated fat per reference amount; and \u2022 qualifies for the claim without the benefit of special processing, it must include an appropriate qualifying statement. A main dish or meal product may generally bear a \u201clow cholesterol\u201d claim if it meets the requirements set forth above for individual foods, but the 20 milligrams cholesterol and 2 grams saturated fat criteria are measured per 100 grams, rather than per reference amount.

232 (3) \u201cReduced Cholesterol\u201d Claims The terms \u201creduced cholesterol,\u201d \u201creduced in cholesterol,\u201d \u201ccholesterol reduced,\u201d \u201cless cholesterol,\u201d \u201clower cholesterol,\u201d or \u201clower in cholesterol\u201d may be used if the food: \u2022 has been specially formulated, altered or processed to reduce its cholesterol content by at least 25 percent from the reference food it replaces and for which it substitutes if the reference food has a - 90 -,"significant market share (i.e., 5 percent or more of a national or regional market); \u2022 contains 2 grams or less of saturated fat per reference amount; and \u2022 is accompanied by information required for relative claims. The placement and prominence requirements for the fat content statement are specified. A \u201creduced cholesterol\u201d claim is not permitted for any food if the reference food qualifies for a \u201clow cholesterol\u201d claim. The \u201creduced cholesterol\u201d claim also may be used on main dish or meal products if the product has been specifically formulated to reduce cholesterol by 25 percent, or if the main dish or meal contains 2 grams or less of saturated fat per 100 grams of product. 233 The identity of the reference product and the percent that the cholesterol has been reduced must be declared in immediate proximity to the \u201creduced cholesterol\u201d claim. 234 d. \u201cLean\u201d and \u201cExtra Lean\u201d Claims The term \u201clean\u201d may be used to describe an individual food as packaged when it contains less than 10 grams of fat, 4.5 grams or less of saturated fat, and less than 95 milligrams of cholesterol per reference amount and per 100 grams. For a main dish or meal to qualify as \u201clean,\u201d it must meet these specified levels for fat, saturated fat, and cholesterol per 100 grams and per labeled serving. The term \u201cextra lean\u201d may be used to describe products that contain less than 5 grams of total fat, less than 2 grams of saturated fat, and less than 95 milligrams of cholesterol per reference amount and per 100 - 91 -,"grams. For main dish or meal products, these levels apply per 100 grams and per labeled serving size. 235 5.

\u201cFiber\u201d Claims A claim that represents the level of dietary fiber in a food is permitted if the level of the nutrient would qualify for a claim (i.e., \u201chigh,\u201d

\u201cmore,\u201d or \u201cgood source\u201d.) If the food is not low in total fat, the label must disclose the level of total fat per labeled serving (e.g., \u201ccontains 12 grams (g) of total fat per serving\u201d.) This statement must appear in immediate proximity to the claim. 236 6. \u201cHealthy\u201d Claims The term \u201chealthy\u201d or any other derivative of the term \u201chealth\u201d may be used to describe an individual food provided the food (1) meets the requirements for \u201clow fat\u201d and \u201clow saturated fat;\u201d (2) does not contain more than 60 milligrams of cholesterol per RACC and labeled serving size (per 50 grams if the RACC is less than 30 grams); (3) does not contain more than 480 milligrams of sodium per RACC and labeled serving size (per 50 grams if the RACC is less than 50 grams); and (4) contains 10 percent or more of RDI or DRV per reference for one of the following: vitamin A, vitamin C, iron, calcium, protein, or fiber. Single-ingredient, raw foods need not meet the sodium requirement, and instead of meeting the fat and cholesterol requirements, single-ingredient, raw foods may meet the total fat, saturated fat, and cholesterol criteria for \u201cextra lean.\u201d 237 A \u201chealthy\u201d main dish or meal must meet the requirements for low - 92 -,"fat and low saturated fat requirements for main dish and meal-type products (i.e., 3 grams or less of total fat per 100 grams of product and not more than 30 percent of the calories from fat, and 1 gram or less of saturated fat per 100 grams of product and less than 10 percent of the calories from saturated fat.) Main dish and meal-type products that weigh less than 12 ounces per serving (container) cannot contain more than 60 milligrams of cholesterol per labeled serving while main dish and meal-type products weighing more than 12 ounces per serving (container) may contain no more than 90 milligrams of cholesterol per labeled serving. Additionally, main dish and meal-type products may contain up to 600 milligrams of sodium. Main dish products weighing 6 to 10 ounces per serving need only meet the RDI or DRV level for two of the listed nutrients, and meal-type products weighing 10 or more ounces need only meet the level for three of the nutrients. 238 7. Claims Related to Usefulness in Reducing or Maintaining Body Weight Any food that purports to be or is represented for special dietary use because of usefulness in reducing or maintaining body weight shall bear (1) nutrition labeling, unless exempt, and (2) a conspicuous statement of the basis upon which the food claims to be of special dietary usefulness. If the food achieves its special dietary usefulness by use of a non-nutritive ingredient (i.e., one not utilized in normal metabolism), the label must contain a statement that discloses the non-nutritive ingredient and its percentage by weight, except if such ingredient is a non-nutritive sweetener, in which case the percentage by weight does not have to be declared. 239 If a nutritive - 93 -,"sweetener, as well as a nonnutritive sweetener is added, the presence of both must be declared. Foods purporting to be \u201clow calorie,\u201d \u201creduced calorie,\u201d or otherwise containing fewer calories than a reference food must comply with the nutrient content claim regulations. Except as provided below, a food may be labeled with terms such as \u201cdiet,\u201d \u201cdietetic,\u201d \u201cartificially sweetened,\u201d or \u201csweetened with non-nutritive sweetener\u201d only if the claim is not false and misleading and the food is labeled \u201clow calorie\u201d or \u201creduced calorie\u201d or bears another comparative claim according to the nutrient content claim regulations. The exemptions to the previous requirement include (1) the use of a term that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term \u201cdiet\u201d that clearly shows that the food is offered

solely for dietary use other than regulating body weight (e.g., for low sodium diets); and (2) the use of a term on a formulated meal replacement or other food that is represented to be of special dietary use as a whole meal.<sup>240</sup> 8. \u201cHealth\u201d Claims A \u201chealth\u201d claim describes a relationship between a food and a disease or health-related condition. FSIS has not issued regulations providing for the use of a \u201chealth\u201d claim. Many such claims have been authorized for use by FDA on labeling of food products subject to its jurisdiction. FSIS will consider on a case-by-case basis the use of an FDA-regulated \u201chealth\u201d claim or such a \u201chealth\u201d claim in conjunction with a - 94 - ", "third-party certification program. An example is the American Heart Association\u2019s heart-check mark, which maintains its own criteria for eligibility and includes a \u201chealth\u201d claim in conjunction with its certifying mark (e.g., \u201cMeets American Heart Association food criteria for saturated fat and cholesterol for healthy people over age 2. While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.\u201d) 9. \u201cCalorie Content\u201d Claims a. \u201cCalorie Content\u201d Claims (1) \u201cCalorie Free\u201d Claims The terms \u201ccalorie free,\u201d \u201cfree of calories,\u201d \u201cno calories,\u201d \u201czero calories,\u201d \u201cwithout calories,\u201d \u201ctrivial source of calories,\u201d \u201cnegligible source of calories,\u201d or \u201cdietary insignificant source of calories\u201d may be used if the individual food contains less than 5 calories per reference amount. If the food meets the requirements without the benefit of special processing, the claim may be accompanied by a statement such as, \u201ca low calorie food\u201d (e.g., cider vinegar, a calorie free food.)<sup>241</sup> (2) \u201cLow Calorie\u201d Claims The terms \u201clow calorie,\u201d \u201cfew calories,\u201d \u201ccontains a small amount of calories,\u201d \u201clow source of calories,\u201d or \u201clow in calories\u201d may be used if the individual food contains no more than 40 calories per reference amount (except for sugar substitutes) and per 50 grams for dehydrated products, etc., if it is a small-serving-size food. A small\u2013serving-size food is a food with a - 95 - ", "reference amount of 30 grams or less or 2 tablespoons or less (\u201csmall serving size food\u201d). If the food qualifies for the claim without the benefit of special processing, it must be labeled to clearly refer to all products of its type and not merely the particular brand to which the label attaches (e.g., \u201ccelery, a low calorie food\u201d.) The requirements for a \u201clow calorie\u201d main dish or meal product are similar. That is, these products must contain 120 calories or less per 100 grams and meet the other requirements specified above for individual foods. 242 (3) \u201cReduced Calorie\u201d Claims The terms \u201creduced calorie,\u201d \u201cred in calories,\u201d \u201ccalories reduced,\u201d \u201cfewer calories,\u201d \u201clower calorie,\u201d or \u201clower in calories\u201d may be used if an individual food contains at least 25 percent fewer calories per RACC as compared to an appropriate reference food. The claim must be accompanied by explanatory information required for relative claims. For a main dish or meal product, the 25 percent reduction in calories is measured per 100 grams as compared to an appropriate reference food. The requirements for an individual food are otherwise applicable. The claim is not permitted for any food if the reference food meets the definition of \u201clow calorie.\u201d 243 b. \u201cSugar Content\u201d Claims (1) \u201cSugar Free\u201d Claims The terms \u201csugar free,\u201d \u201cfree of sugar,\u201d \u201cno sugar,\u201d \u201czero sugar,\u201d \u201cwithout sugar,\u201d \u201c

\u201csugarless,\u201d \u201ctrivial source of sugar,\u201d \u201cnegligible source of - 96 -","sugar,\u201d or \u201cdietary insignificant source of sugar\u201d may be used if the food contains less than 0.5 grams of sugar per RACC (or in the case of a main dish or meal product per labeled serving.) In addition, the food may not contain any ingredient that is a sugar or is generally understood by consumers to contain sugars or sweeteners unless the ingredient, as declared in the ingredients statement, is accompanied by an asterisk that refers consumers to the statement, \u201cAdds a trivial amount of sugar,\u201d or a similar specified statement. The food must be labeled \u201clow calorie\u201d or \u201creduced calorie\u201d or bear a relative claim of special dietary usefulness, or the \u201csugar free\u201d claim must be accompanied by the statement, \u201cnot a low calorie food,\u201d or a similar specified statement. 244 (2) \u201cNo Added Sugar\u201d Claims The terms \u201cno added sugar,\u201d \u201cwithout added sugar,\u201d and \u201cno sugar added\u201d may be used only if: \u2022 no amount of sugars, or any other ingredient that contains sugar that functionally substitutes for added sugars, is added during processing or packaging; \u2022 the product does not contain an ingredient containing added sugars, such as jam, jelly, or concentrated fruit juices; \u2022 the sugar content has not been increased by the amount present in the ingredients by the use of enzymes or similar means, except where the intended functional effect of the process is not to increase the sugar content of a food, and a functionally-insignificant increase in sugars results; and \u2022 the food that it resembles and for which it substitutes normally contains added sugars. - 97 -","\u2022 In addition, if the food does not qualify as \u201clow calorie,\u201d a statement must direct the consumers\u2019 attention to the nutrition panel for further information on sugar and calorie content. The requirements governing \u201csugar free\u201d claims are not applicable to a factual statement that a food is unsweetened, or contains no added sweeteners in the case of a food that contains apparent substantial inherent sugar content (e.g., juices). 245 (3) \u201cReduced Sugar\u201d Claims The terms \u201creduced sugar,\u201d \u201creduced in sugar,\u201d \u201csugar reduced,\u201d \u201cless sugar,\u201d \u201clower sugar,\u201d or \u201clower in sugar\u201d may be used if the sugar content in the individual food is reduced by 25 percent per RACC as compared to an appropriate reference food. The claim must be accompanied by the explanatory information required for relative claims. For main dish and meal products, the 25 percent reduction in sugars is measured per 100 grams as compared to an appropriate reference food. The requirements for an individual food are otherwise applicable. 246 - 98 -","Appendix A Egg Products Labeling I. Egg Products Labeling Egg product labels bearing official USDA identification markers must be approved and comply with all applicable regulations. There are seven requirements for egg products labeling: product name; manufacturer\u2019s name; official identification; USDA approval number; ingredients statement; net weight statement; and nutrition information. a. Product Name Eggs are defined as the \u201cshell egg\u201d of the domesticated chicken, turkey, duck, goose, or guinea. Egg products are any dried, frozen, or liquid eggs, with or without added ingredients. 247 All egg product labels must include the name and state of the product, (e.g., dried, frozen, liquid, or whole egg, egg yolks, egg whites,) and must appear in print size similar to the most prominent printing on the label. In addition, a trade name may be used in conjunction with the product identity. Products formulated from eggs that do not meet the applicable definitions must be identified by an appropriately descriptive name that is not false or misleading. Food products

containing eggs in relatively small proportions or which historically have not been considered to be egg products may not be labeled as an egg product (e.g., omelet mix, egg nog mix, noodles, cake mixes). 248 These products, along with imitation egg products are eligible for identification with the USDA inspection legend only under the voluntary egg products inspection program. 249 Whole Eggs Liquid or frozen whole eggs are eggs of domestic hens broken from the shells with the yolks and whites in their natural proportion. 250 A combination of whites and yolks in other than natural proportions, such as accidentally broken whole eggs, may be identified as whole eggs provided the egg solids content is standardized to 24.2% or greater. 251 Whole eggs may be mixed, or mixed and strained, and must be pasteurized or otherwise treated to destroy all viable Salmonella micro-organisms. Dried eggs (or dried whole eggs) or frozen eggs are prepared by drying or freezing liquid eggs with such precautions that the finished food is free of viable Salmonella micro-organisms. If the glucose content of the eggs was reduced during the drying process, the statements "Glucose removed for stability" or "Stabilized, glucose removed" must immediately follow the product name. 252 - 99 -,"Egg Yolks Egg yolks, liquid egg yolks, yolks, and liquid yolks are yolks of eggs of the domestic hen so separated from the whites thereof as to contain not less than 43 percent total egg solids. 253 Egg yolks may be mixed, or mixed and strained, and must be pasteurized or otherwise treated to destroy all viable Salmonella micro-organisms. Egg yolks may be dried or frozen according to applicable regulations. Dried egg yolks (or dried yolks) or frozen egg yolks are prepared by either drying or freezing egg yolks with such precautions so that the finished food is free of viable Salmonella micro-organisms. Similar label statements for glucose removal must be included if necessary. Egg Whites Egg whites, liquid egg whites, or liquid egg albumen is the food obtained from eggs of domestic hens, broken from the shells and separated from the yolks. 254 Egg whites may be mixed, or mixed and strained, and must be pasteurized or otherwise treated to destroy all viable Salmonella micro-organisms. Any optional use of ingredients such as whipping aids must be named on the PDP or panels of labels prominently and conspicuously so ordinary individuals under customary conditions of purchase are likely to understand them. 255 Egg whites may be dried or frozen according to applicable regulations. If egg whites are dried, the product name may be "dried egg whites," or "egg white solids." If the lysozyme and avidin content of the product is reduced during the drying process, the product name must be immediately preceded or followed by the statement "lysozyme and avidin reduced." 256 When dried eggs are used in another fabricated food product, these statements do not need to follow the product name.

b. Manufacturer's Name Under the Fair Packaging and Labeling Act, the name and place of business of the manufacturer, packer, or distributor must be included on the PDP. 257 The statement of the place of business must include the street address, city, state and zip code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. 258

c. Official Identification The U.S. Department of Agriculture maintains inspections of all official plants and the processing of egg products under the authority of the Egg Products Inspection Act. 259 Each official egg processing plant granted - 100 -,"inspection services is assigned an official plant number. 260 A shield containing the letters "USDA" is the official identification symbol, and when it is used in connection with an egg product, it constitutes a representation that the product has

been officially inspected. Egg products that bear the inspection mark must be processed in an official plant from edible shell eggs or other edible egg products. 261\ Plants may not have more than one plant number. The official shield must be printed on the PDP of the label using the design and wording shown below. The plant number may be printed within the shield or elsewhere on the container. 262\ When the plant number is not printed within the shield, the letter \u201cP\u201d or the word \u201cPlant\u201d must precede it. When the official shield is used on more than one label panel, it must be identically printed for each use. If a label does not bear all mandatory labeling information, it may not bear the official shield. In addition, all shell eggs packaged for consumers must be labeled to indicate that refrigeration is required, (e.g., \u201cKeep Refrigerated\u201d,) or words of similar meaning. 263 d. USDA Approval Number Labels for use on egg products must be preapproved. A separate label approval number containing one letter and a three-digit number (e.g., M001) is assigned to each label that has been approved. The assigned USDA approval number must be printed within a rectangular box and needs to be no larger than the smallest printing on the label. Labels identifying imported egg products will contain a two-letter prefix, (e.g., CN001) and labels approved for identification of products for export only will have a one-letter code. Self-adhesive strip labels may be used without approval; in conjunction with previously-approved printed labels provided the strip label does not cover any required labeling information showing the packer or - 101 -,"distributor\u2019s name and address; the product identity for whole eggs, egg yolks, or egg whites; or the state of the product. duction of egg products. Each of the ingredients used in egg products must be declared on the label as required by 21 C.F.R. Parts 101 and 130. Ingredients must be or frozen egg products. The percentage of water added must be declared on the label in the ingredients statement in descending order of proportion by weight and shown gredient is used, the label must bear the statement, \u201cNot more than 1 percent silicon dioxide added as an anticaking a ed t the national office, the label must state that the additive has been added to color the product. This declaration may be made in the ingredients statement, (e.g., \u201ccannatto extract (artificial color)\u201d or \u201ccolored with annatto extract.\u201d) 267 e es in the net weight statement. A dual declaration net weight statement is only required on retail packages containing less than 4 pounds. e. Ingredients Statement Only food-grade ingredients may be used in the pro listed in order of descending proportion by weight on the PDP. When approved, potable water may be added as a carrier for certain ingredients and additives used in the formulation of liquid as either \u201c\_\_\_\_ % water\u201d or \u201cwith \_\_\_\_ % water as a carrier.\u201d 264 When optional ingredients, such as monosodium phosphate, are used as preservatives, the label must bear the statement \u201cMonosodium phosphate (or monopotassium phosphate), with \_\_\_\_ percent water as a carrier, added to preserve color.\u201d 265 The blank must be filled in with the percent by weight of water used in proportion to the weight of the finished food. This optional ingredients statement must appear on the PDP or panels prominently and conspicuously. If an optional anticaking in gent,\u201d or \u201cLess than 2 percent sodium silicoaluminate added as an anticaking agent,\u201d whichever is applicable. 266 Color may not be added to whole eggs, egg yolks, egg whites, salt or sugared whole eggs, and salted or sugared egg yolks. Any egg product tha contains an additive which imparts color, including color additives certified as being natural, are considered to be artificially colored, and the product label must state that color has been added. If the color additive is derived from a natural source and a letter of

certification is provided to f. Net Weight Statement Each egg product label must contain a net weight statement. Th net weight statement must appear in the lower 30 percent of the label in lin generally parallel to the base on which the package rests and must appear as a distinct item on the label. The statement must be separated from any other printing above, below, or to either side of it by a space at least equal to the height of the letters - 102 -,"Regulations for the declaration of net quantity of contents can be found at 21 C.F.R. \u00a7 101.105. must compl rition labeling is required when nutrients, such as proteins, r information is presented on the labeling, except if a nutrient is included in the product solely for technological purposes. If a nutrient is included solely for technological purposes it may be declared solely in the ingredients statement. 269 g. Nutrition Information Egg or egg product labels which may be distributed for retail sale y with FDA regulations governing nutrition labeling. 268 Egg products packaged for institutional use are not required to bear nutrition information, however, if a nutrient content or health claim is made, product labeling must comply with all nutrient content claim regulations. Nut vitamins, and minerals are added to the product, or when a nutritional claim o - 103 -,"End Notes 1 21 U.S.C. \u00a7\u00a7 601 et seq. (meat); 21 U.S.C. \u00a7\u00a7 451 et seq. (poultry). 2 FSIS also regulates the labeling of egg products. These separate requirements are summarized at Appendix A of this Summary. 3 A misbranded food bears false or misleading labeling, while an adulterated food contains a poisonous or deleterious substance or otherwise poses a risk to consumer health. See, 21 U.S.C. \u00a7\u00a7 453 and 601. 4 21 U.S.C. \u00a7 601 et seq. 5 21 U.S.C. \u00a7 451 et seq. 6 21 U.S.C. \u00a7 601(o) and (p) (meat); 21 U.S.C. \u00a7 453(s) (poultry). 7 21 U.S.C. \u00a7 607 (meat); 21 U.S.C. \u00a7 457 (poultry). 8 21 U.S.C. \u00a7 601(n). 9 21 U.S.C. \u00a7 453(h). 10 See, e.g., 21 U.S.C. \u00a7 672-673 (meat); 21 U.S.C. \u00a7 467(a) \u2013 467(b) (poultry). 11 21 U.S.C. \u00a7 671 (meat); 21 U.S.C. \u00a7 467 (poultry). 12 21 U.S.C. \u00a7 301 et seq. 13 Id. \u00a7 343(a). 14 21 U.S.C. \u00a7 321(k). 15 Id. \u00a7 321(m). Under the FFDCA a manufacturer can be sanctioned in several ways if it violates a labeling requirement. FDA may seek a court order preventing the production and sale of misbranded foods. Id. \u00a7 332. Misbranded foods may also be confiscated by the government. Id. \u00a7 334. Moreover persons violating the FFDCA can be imprisoned for selling or offering for sale misbranded foods. Id. \u00a7 333. 16 15 U.S.C. \u00a7 1451 et seq. The FPLA establishes requirements for package labels of all consumer commodities, including most foods. It defines the package as \u201cany container or wrapping in which any consumer commodity is enclosed for use in the delivery or display of that consumer commodity to retail purchasers.\u201d Id. \u00a7 1459(b). 17 21 U.S.C. \u00a7 607(d) (meat); 21 U.S.C. \u00a7 457(c) (poultry). USDA has similar authority over egg products under the EPIA, 21 U.S.C. \u00a7 71036(b). 18 Id. 19 9 C.F.R. Part 317 et seq. (meat); 9 C.F.R. \u00a7 381.115 et seq. (poultry). 20 FDA has not taken the position adopted by USDA nor is it clear that the FFDCA or FPLA permit implementation of a preapproval system. 21 21 U.S.C. \u00a7 601(j) (meat). 22 \u201cMeat,\u201d \u201cmeat food product,\u201d \u201clivestock,\u201d \u201cpoultry,\u201d and \u201cpoultry product\u201d are defined by the FMIA and the PPIA (21 U.S.C. \u00a7\u00a7 601 and 453), respectively, and the Federal meat and poultry inspection regulations (9 C.F.R. \u00a7\u00a7 301.2 and 381.1, respectively) and do not include species of livestock or kinds of birds other than those specifically listed. 23 Standards and Labeling Policy Book at \u201cAmenability,\u201d p.6 (meat); 9 C.F.R. \u00a7 381.15(a)(1) (poultry). 24 9 C.F.R. 381.15(a)(1)-(5). See regulation for complete listing of exempt

poultry products. 25 9 C.F.R. \u00a7 381.15(b). 26 9 C.F.R. \u00a7 381.15(c). See also 9 C.F.R. \u00a7 381.15(d) (exception for fat capsules and sandwiches containing poultry products and/or specified conditions). 27 See 9 C.F.R. \u00a7 381.15(e). 28 21 U.S.C. \u00a7 607(c) (meat); 21 U.S.C. \u00a7 457(b) (poultry). 29 Id. 30 21 U.S.C. \u00a7\u00a7 348. 31 21 U.S.C. \u00a7 601(m)(2); 21 U.S.C. \u00a7 453(g)(2). FSIS and FDA have established procedures for the joint review of ingredients that are not addressed in this Guide. See the FSIS website. 32 See 9 C.F.R. Parts 310, 318, 319, and 381. FSIS regulations establish a general prohibition on the use in a meat or poultry product of any food ingredient that would render it adulterated - 104 -,"or misbranded, or which is not approved in Parts 424, 318, and 319 of the regulations, or \"by the Administrator [of FSIS] in specific cases.\\" The Section further provides that ingredients and sources of radiation listed or approved for use in meat and poultry products in 21 C.F.R. (i.e., FDA's regulations) will be listed for such use in FSIS's regulations \"unless precluded from such use or further restricted in Parts 318 or 319 (pertaining to meat products), or Subparts O and P, of Part 381 (pertaining to poultry products). For example, a product standard might not permit the use in a particular product of an ingredient otherwise approved for use in meat or poultry. The Administrator may also list or approve for use in the new combined table of approved substances any such food ingredients or sources or radiation. 33 [ADD ingredient references] 34 15 U.S.C. \u00a7 52. 35 15 U.S.C. \u00a7 45(a)(l). 36 Fresh Grown Preserve Corp. v FTC, 125 F.2d 917 (2d Cir. 1942) (FTC has jurisdiction to prevent unfair competition by means of false labeling and misbranding, regardless of the kind of product). 37 15 U.S.C. \u00a7 45. 38 FTC\u2019s deception and advertising substantiation policy statements have been adopted in Commission decisions, and are intended to guide manufacturers as to what level of substantiation is necessary to support a claim. See Deception Policy Statement, appended to Cliffdale Associates, Inc., 103 F.T.C 110, 174-184 (1983); Ad Substantiation Policy Statement, appended to Thompson Medical Co., 104 F.T.C. 648, 839-42 (1984), aff\u2019d, 1986-1 Trade Cas. (CCH) \u00b6 67,103 (D.C. Cir. 1986). [SBS Update cites] 39 For example, claims relating to health and safety concerns, such as claims about the healthfulness of a particular product, require a relatively high level of substantiation. See National Commission on Egg Nutrition, 89 FTC 89, 192 (1976), aff\u2019d 570 F.2d 157 (7th Cir.), cert. denied, 439 U.S. 821 (1978); Thompson Medical Co., 104 FTC at 821. 40 See Houbigant v. Federal Trade Commission, 139 F.2d 1019 (2d Cir. 1944), cert. denied, 323 U.S. 763 (1944) (FDA does not have exclusive jurisdiction over false and misleading labeling); Fresh Grown Preserve Corp., 125 F.2d 917. [SBS Update cites] 41 15 U.S.C. \u00a7\u00a7 52, 53(a). Upon violation of final cease and desist orders, FTC can seek: (1) consumer redress in the form of recession or reformation of contracts, refunds, or damages, 15 U.S.C. \u00a7 57b(b); (2) civil penalties, 15 U.S.C. \u00a7 45(m); or (3) criminal penalties if a violation of section 12 was committed with intent to defraud or expose consumers to health and safety risks. 15 U.S.C. \u00a7 54(a). 42 See Warner-Lambert Co. v. FTC, 562 F.2d 749 (D.C. Cir. 1977), cert. denied, 435 U.S. 950 (1978). 43 Under the Supremacy Clause of the U.S. Constitution, U.S. Const., Art VI cl. 2., federal laws and regulations are held to preempt state legislation in two circumstances. First, federal law is intended to preempt when a state legislates in a field that Congress intended to occupy. Second, when state and federal laws are in direct conflict, and compliance with both is impossible, federal law takes precedence. 44 21 U.S.C. \u00a7 678 (meat); 21 U.S.C. \u00a7 467(e) (poultry). 45 Rath Packaging Co., 430 U.S. 519 (1977). 46 Id. See also American Meat Institute v. Pridgeon, 724 F.2d 45 (6th Cir. 1984)

(state statute requiring posting of placards indicating product's nonconformance with state ingredient standards held unconstitutional); *Armour v. Ball*, 468 F.2d 76 (6th Cir. 1972), cert. denied, 411 U.S. 981 (1973) (marking, labeling, packaging, and ingredient requirements of FMIA preempt any state-imposed labeling requirements). 47 *Kraft Foods North America, Inc. v. Rockland County*, (S.D.N.Y. Feb. 26, 2003) (Memorandum Order granting motion for summary judgment). An appeal of this decision was dismissed. 48 As noted previously, labeling includes all labels or other written, printed, or graphic matter on or accompanying the article. 21 U.S.C. \u00a7 321(m), 601(o)(p), 453(s). See *U.S. v. Jorgensen*, 144 F.3d 550, 558 (S.D. Cal. 1998)(brochures accompanying meat product are considered - 105 -,"labeling); see also *Kordell v. United States*, 335 U.S. 343 (1948); *United States v. Sene X Eleemosynary Corporation*, 479 F. Supp. 970, 979 (S.D. Fla. 1979) (neither physical attachment nor concurrent shipment of labeling is required to give FDA jurisdiction). 49 See 9 C.F.R. \u00a7 317.2(a); 9 C.F.R. \u00a7 381.1(b). 50 See 9 C.F.R. \u00a7 301.2 and 381.1(b) (definition of \u201cimmediate container\u201d); 9 C.F.R. \u00a7 317.2 (definition of \u201cprotective covering\u201d); See also Policy Memo 090B (Directive 7220.1) and the Food Standards and Labeling Policy Book at 137 (\u201cProtective Coverings, Poultry\u201d entry). 51 See, e.g., 9 C.F.R. \u00a7 316.10(b) (markings for smaller varieties of sausage); and 9 C.F.R. \u00a7 327.14 (foreign meat cuts must bear \u201cProduct of (country of origin)\u201d). 52 \u201cSketch\u201d labeling is a printer's proof or equivalent, which clearly shows all labeling features, size, location and indication of final color. Sketch labels can be hand-drawn, computer generated or by other reasonable facsimile. 53 FSIS Directive 7220.1 (including Policy Memorandum 114A (August 18, 1994)). 54 At one time, raising claims relating to the absence of antibiotic drug residues were allowed by FSIS. Now, FSIS is requiring that the few remaining programs be phased out. See FSIS website for further information on regulation of animal production and related claims. 55 9 C.F.R. \u00a7 317.4(a) (meat); 9 C.F.R. \u00a7 381.132(a), 9 C.F.R. \u00a7 320.14(b) (11)(meat); 9 C.F.R. \u00a7 381.175(b)(6) 56 9 C.F.R. \u00a7 317.4(f) (meat); 9 C.F.R. \u00a7 381.132(f) (poultry). 57 9 C.F.R. \u00a7 317.4(f)(2). 58 Under the rule, FSIS will select samples of generically-approved labeling from the records maintained by companies and institute appropriate action if false or misleading labeling is identified. 59 9 C.F.R. \u00a7 317.5 (meat); 9 C.F.R. \u00a7 381.133 (poultry). 60 9 C.F.R. \u00a7 317.2(b); 9 C.F.R. 381.115(b). 61 9 C.F.R. \u00a7 317.2(d) (meat); 9 C.F.R. \u00a7 381.116 (poultry). Various labeling rules specify particular prominence and placement requirements beyond this general requirement. 62 Such information may not be obscured by packaging or labeling design, vignettes, crowding, or lack of contrasting colors, which could be confusing and thus deemed misbranded under the labeling statutes. 9 C.F.R. 317.2 (meat); 9 C.F.R. \u00a7 381.116 (poultry). 63 9 C.F.R. \u00a7 317.2 (meat); 9 C.F.R. \u00a7 381.116 (poultry). 64 Id. 65 9 C.F.R. \u00a7 317.2 (meat); 9 C.F.R. \u00a7 381.121 (poultry). 66 See FSIS Directive 7220.1 (Policy Memorandum 87A) (September 16, 1985)). 67 9 C.F.R. \u00a7 381.171. 68 21 U.S.C. \u00a7 601(n)(7) (meat); 21 U.S.C. \u00a7 453(h)(7) (poultry). 69 9 C.F.R. \u00a7 319 et seq. (meat); 9 C.F.R. \u00a7 381.155 et seq. (poultry). FSIS follows notice and comment rulemaking procedures prescribed by the Administrative Procedure Act in promulgating these standards. 70 21 U.S.C. \u00a7 601(n)(9) (meat); 21 U.S.C. \u00a7 453(h)(9) (poultry). 71 Policy Memorandum 69 (March 23, 1984). Nutritional inferiority is defined consistent with the requirement of 21 C.F.R. \u00a7 101.3(e)(4) as any reduction in the content of an essential nutrient that is present

at 2% or more of the U.S. RDI per serving of protein or any of the vitamins or minerals for which U.S. RDIs are established. 72 9 C.F.R. \u00a7 317.2(j) (meat); 9 C.F.R. \u00a7 381.1(b) (misbranded) (iii). Note, meat pizza containing (misbranding) (iii) cheese substitutes must have a ratio of at least 1 part cheese, 9 parts cheese substitutes. Products not meeting this cheese ratio standard require additional qualification about the characterizing ingredients to be stated in the food label. See Policy Memorandum 1 (May 6, 1980); Anthony J. Pizza v. Wisconsin Dept. of Agriculture, 676 F.2d 701 (1982) (unreported; Circuit Court upheld USDA cheese policy preempting inconsistent Wisconsin regulation). 73 9 C.F.R. \u00a7 319.10(meat); 9 C.F.R. \u00a7 381.172(poultry). 74 9 C.F.R. \u00a7 319.10(meat); 9 C.F.R. \u00a7 381.172(poultry). - 106 -,"75 9 C.F.R. \u00a7 319.10(meat); 9 C.F.R. \u00a7 381.172(poultry). 76 9 C.F.R. \u00a7 317.8(b)(1). See also USDA Policy Memorandum 68 (February 9, 1984). 77 9 C.F.R. \u00a7 317.8(b)(1). 78 Id. There is a city named \u201cEl Paso,\u201d but there is no city named \u201cOld El Paso.\u201d Accordingly, FSIS does not consider \u201cOld El Paso\u201d a geographically significant location. 79 Policy Memorandum 68 (February 9, 1984). 80 9 C.F.R. \u00a7 381.129(b)(2). 81 9 C.F.R. \u00a7 327.14. 82 Id. The immediate container must also bear the establishment number assigned by the foreign meat inspection agency. 83 9 C.F.R. \u00a7 327.15. 84 The official establishment or plant number may appear in one of the following locations: (1) inside or outside of the legend; (2) anywhere on the exterior of the container; or (3) off of the exterior when a statement identifies the location of the number. When the official inspection legend is off the exterior of the container, it may be properly located on the back of a paper label of a canned product, on a metal clip used to close casings or bags, or on other packaging or labeling material in the container when a statement of its location is printed contiguous to the official legend, such as, \u201cEST no. on metal clip.\u201d See 9 C.F.R. \u00a7 317.2(1) (meat); 9 C.F.R. \u00a7 381.123 (poultry). 85 9 C.F.R. \u00a7 301.2 (12) (misbranded) (meat); 9 C.F.R. \u00a7 381.1(b)(misbranded)(xii) (poultry). 86 9 C.F.R. \u00a7 312.2(b)(1) (meat); 9 C.F.R. \u00a7 381.123(b)(2) (poultry). 87 9 C.F.R. \u00a7 317.2(b) (meat); 9 C.F.R. \u00a7 381.128 (poultry). 88 9 C.F.R. \u00a7 381.96 (poultry). This requirement is unique to poultry. 89 Id. 9 C.F.R. \u00a7 381.96 (poultry). 90 9 C.F.R. \u00a7 317.2(h) (meat); 9 C.F.R. \u00a7 381.121(a) (poultry). 91 9 C.F.R. \u00a7 317.2(h)(1) (meat); 9 C.F.R. \u00a7 381.121(c) (poultry). 92 See 9 C.F.R. \u00a7 317.2(h)(4) (meat); 9 C.F.R. \u00a7 381.121(c)(5) (poultry). 93 9 C.F.R. \u00a7 317.2(h)(2) (meat); 9 C.F.R. \u00a7 381.121(c)(6) (poultry). 94 Rath Packing, 430 U.S. at 536. See also Kraft Foods, *supra*. 95 9 C.F.R. \u00a7 317.2(h)(2) (meat); 9 C.F.R. \u00a7 381.121(b)(6) (poultry). 96 Rath Packing, 430 U.S. at 524. See also Kraft Foods, *supra*. 97 See e.g., Rath Packing, 430 U.S. at 526; Kraft Foods, *supra*; Cook Family Foods v. Voss, 781 F. Supp. 1458, 1466 (C.D. Cal. 1991)(finding express preemption under the FMIA). 98 9 C.F.R. \u00a7 317.2(h)(4) (meat); 9 C.F.R. \u00a7 381.121(c)(5) (poultry). 99 9 C.F.R. \u00a7 317.2(h)(3) (meat); 9 C.F.R. \u00a7 381.121(c)(5) (poultry). 100 9 C.F.R. \u00a7 317.2(h)(5) (meat); 9 C.F.R. \u00a7 381.121(c)(5) (poultry). 101 Id. 102 See 9 C.F.R. \u00a7 317.2(h)(9), (12) (meat); 9 C.F.R. \u00a7 381.121(c)(8), (9) (poultry). 103 9 C.F.R. \u00a7 317.2(h)(3) (meat); 9 C.F.R. \u00a7 381.121(c)(2) (poultry). 104 Id. Broth is an example of when this type of net weight declaration would be employed. 105 Id. 106 9 C.F.R. \u00a7 317.2(h)(8) (meat); 9 C.F.R. \u00a7 381.121(c)(4) (poultry). 107 Id. 108 9 C.F.R. \u00a7 317.2(h)(3) (meat); 9 C.F.R. \u00a7 381.121(c)(2) (poultry). 109 9 C.F.R. \u00a7 317.2(h)(1) (meat); 9 C.F.R. \u00a7 381.121(c)(2) (poultry). 110 9 C.F.R. \u00a7 317.2(h)(7) (meat); 9 C.F.R. \u00a7 381.121(c)(3)(vi) (poultry).

111 9 C.F.R. \u00a7 317.2(h)(6) (meat); 9 C.F.R. \u00a7 381.121(c)(3)(i)-(v) (poultry). 112 9 C.F.R. \u00a7 317.2(h)(7) (meat); 9 C.F.R. \u00a7 381.121(c)(3)(vi) (poultry). 113 Id. 114 Id. 115 9 C.F.R. \u00a7 317.2(h)(9)(i) (meat); 9 C.F.R. \u00a7 381.121(c)(9)(i) (poultry). 116 9 C.F.R. \u00a7 317.2(h)(9)(ii) (meat); 9 C.F.R. \u00a7 381.121(c)(9)(ii) (poultry). 117 9 C.F.R. \u00a7 317.2(h)(9)(iii) (meat); 9 C.F.R. \u00a7 381.121(c)(9)(iii) (poultry). - 107 -, "118 9 C.F.R. \u00a7 317.2(h)(9)(iv) and (v). 119 9 C.F.R. \u00a7 381.121(a). 120 9 C.F.R. \u00a7 317.2(h)(12) (meat); 9 C.F.R. \u00a7 381.121(c)(8)(ii) (poultry). 121 Id. 122 See 9 C.F.R. \u00a7 317.2(c)(2) (meat); 9 C.F.R. \u00a7 381.118 (poultry). 123 9 C.F.R. \u00a7 317.2(f) (meat); 9 C.F.R. \u00a7 381.118(a)(1) (poultry). 124 See Standards and Labeling Policy Book. 125 9 C.F.R. \u00a7 317.2(f)(1)(vi)(A) (meat); 9 C.F.R. \u00a7 381.118(a)(2)(i) (poultry). 126 9 C.F.R. \u00a7 317.2(f)(1)(v). 127 9 C.F.R. \u00a7 381.118(f). 128 FSIS Directive 7237.1. 129 FSIS has adopted a range of standards for certain product categories but otherwise has few defined ingredient names. FDA\u2019s regulations provide detailed criteria from which a common or usual name designation may be used. See 21 C.F.R. \u00a7 102.5. 130 Policy Memorandum 72 (May 18, 1984). 131 See 21 C.F.R. \u00a7 101.4. For example, dried whole eggs, frozen whole eggs, and liquid whole eggs may be declared as \u201ceggs.\u201d See also 9 C.F.R. \u00a7 317.2(f)(1)(ii) (corn syrup and corn starch solids deemed synonymous). 132 21 U.S.C. \u00a7 343(k) (FDA); 21 U.S.C. \u00a7 601(n)(11) (meat); 21 U.S.C. \u00a7 453(h)(11) (poultry). 133 FSIS, Consumer Labeling and Protection, \u201cProprietary Mixture Suppliers and Manufacturers Questions and Answers,\u201d March 17, 1995 available on FSIS website. 134 9 C.F.R. \u00a7 317.2(f)(1)(i) (meat); 9 C.F.R. \u00a7 381.118(c) (poultry). 135 9 C.F.R. \u00a7 317.2(f) (1)(i)(B) (meat); 9 C.F.R. \u00a7 381.118(c)(2) (poultry). 136 21 C.F.R. \u00a7 182.10, 184. 137 9 C.F.R. \u00a7 317.2(j)(3) (meat); 9 C.F.R. \u00a7 381.119 (poultry). Any other permitted artificial flavoring must be identified as \u201cartificial flavoring\u201d in the ingredients statement. 9 C.F.R. \u00a7 317.2(j)(4). 138 9 C.F.R. \u00a7 317.2(j)(5)-(7). 139 FSIS Directive 7237.1. 140 Id. 141 9 C.F.R. \u00a7 317.2(j)(9) (meat); 9 C.F.R. \u00a7 381.119(b) (poultry). See also Policy Memorandum 113 (June 24, 1988). 142 9 C.F.R. \u00a7 317.2(j)(12) (meat); 9 C.F.R. \u00a7 381.120 (poultry). 143 9 C.F.R. \u00a7 381.120. 144 21 C.F.R. 101.100(a)(3). 145 21 C.F.R. \u00a7 101.100(a)(3). USDA follows the FDA regulation as a matter of policy.

USDA\u2019s treatment of incidental additives differs from that of FDA in one respect. In declaring sulfites that are sometimes considered incidental additives, when the total product contains less than 10 ppm sulfites but a separable component contains more than 10 ppm, USDA requires that the sulfiting agent be declared in the ingredients statement. Policy Memorandum 094B (December 17, 1986). FDA provides that a sulfite is exempt from labeling as an incidental additive if it is less than 10 ppm only for the product as a whole. 21 C.F.R. \u00a7 101.100(a)(4). 146 21 C.F.R. \u00a7 101.100(a)(4). 147 9 C.F.R. \u00a7 317.2(c)(3) and (g) (meat); 9 C.F.R. \u00a7 381.122 (poultry). 148 9 C.F.R. \u00a7 317.2(k) (meat); 9 C.F.R. \u00a7 381.125(a) (poultry). 149 9 C.F.R. \u00a7 317.2(l) (meat); 9 C.F.R. \u00a7 381.125(b) (poultry). 150 Any portion of this statement in conflict with the product\u2019s specific handling instructions may be omitted. 151 9 C.F.R. \u00a7 317.2(l) (meat); 9 C.F.R. \u00a7 381.125(b) (poultry). 152 9 C.F.R. \u00a7 317.400 (meat); 9 C.F.R. \u00a7 381.500 (poultry). 153 9 C.F.R. \u00a7 317.400 (meat); 9 C.F.R. \u00a7 381.500 (poultry). 154 9 C.F.R. \u00a7 317.302(b) (meat); 9 C.F.R. \u00a7 381.402(b) (poultry). 155 9 C.F.R. \u00a7 317.302(c) (meat); 9 C.F.R. \u00a7 381.402(c) (poultry). - 108 -, "156 9 C.F.R. \u00a7 317.309(c) (meat); 9

C.F.R. \u00a7 381.409(c) (poultry). 157 9 C.F.R. \u00a7 317.309(c) (meat); 9 C.F.R. \u00a7 381.409(c) (poultry). 158 9 C.F.R. \u00a7 317.309(c) (meat); 9 C.F.R. \u00a7 381.409(c) (poultry). 159 9 C.F.R. \u00a7 317.309(c) (meat); 9 C.F.R. \u00a7 381.409(c) (poultry). 160 9 C.F.R. \u00a7 317.309(d) (meat); 9 C.F.R. \u00a7 381.409(d) (poultry). 161 9 C.F.R. \u00a7 317.309(d) (meat); 9 C.F.R. \u00a7 381.409(d) (poultry). 162 9 C.F.R. \u00a7 317.309(d)(7) (meat); 9 C.F.R. \u00a7 381.409(d)(7) (poultry). 163 9 C.F.R. \u00a7 317.309(c) (meat); 9 C.F.R. \u00a7 381.409(c) (poultry). 164 9 C.F.R. \u00a7 317.309(d)(9) (meat); 9 C.F.R. \u00a7 381.409(d)(9) (poultry). 165 9 C.F.R. \u00a7 317.309(d)(10) (meat); 9 C.F.R. \u00a7 381.409(d)(10) (poultry). 166 9 C.F.R. \u00a7 317.309(e) (meat); 9 C.F.R. \u00a7 381.409(e) (poultry). 167 9 C.F.R. \u00a7 317.309(d)(13) (meat); 9 C.F.R. \u00a7 381.409(d)(13) (poultry). 168 9 C.F.R. \u00a7 317.309(e) (meat); 9 C.F.R. \u00a7 381.409(e) (poultry). 169 9 C.F.R. \u00a7 317.309(f) (meat); 9 C.F.R. \u00a7 381.409(f) (poultry). 170 9 C.F.R. \u00a7 317.309(f) (meat); 9 C.F.R. \u00a7 381.409(f) (poultry). 171 9 C.F.R. \u00a7 317.309(f) (meat); 9 C.F.R. \u00a7 381.409(f) (poultry). 172 9 C.F.R. \u00a7 317.309(g) (meat); 9 C.F.R. \u00a7 381.409(g) (poultry). 173 9 C.F.R. \u00a7 317.309(g)(2) (meat); 9 C.F.R. \u00a7 381.409(g)(2) (poultry). 174 9 C.F.R. \u00a7 317.309(h) (meat); 9 C.F.R. \u00a7 381.409(h) (poultry). 175 9 C.F.R. \u00a7 317.309(c) (meat); 9 C.F.R. \u00a7 381.409(c) (poultry). 176 9 C.F.R. \u00a7 317.400 (meat); 9 C.F.R. \u00a7 381.500 (poultry). 177 9 C.F.R. \u00a7 317.312 (meat); 9 C.F.R. \u00a7 381.412 (poultry). 178 9 C.F.R. \u00a7 317.309(b)(7) (meat); 9 C.F.R. \u00a7 381.409(b)(7) (poultry). 179 9 C.F.R. \u00a7 317.309(b)(7) (meat); 9 C.F.R. \u00a7 381.409(b)(7) (poultry). 180 The following abbreviations for units may be used: tbsp for tablespoon, tsp for teaspoon, g for gram, mL for milliliter, and oz for ounce. For the purposes of nutrition labeling, a teaspoon means 5 mL, a tablespoon means 15 mL, a cup means 240 mL, and 1 oz means 28 g. 181 9 C.F.R. \u00a7 317.309(b)(7) (meat); 9 C.F.R. \u00a7 381.409(b)(7) (poultry). 182 9 C.F.R. \u00a7 317.309(b)(9) (meat); 9 C.F.R. \u00a7 381.409(b)(9) (poultry). 183 9 C.F.R. \u00a7 317.309(b)(9) (meat); 9 C.F.R. \u00a7 381.409(b)(9) (poultry). 184 9 C.F.R. \u00a7 317.312 (meat); 9 C.F.R. \u00a7 381.412 (poultry). 185 9 C.F.R. \u00a7 317.312(g) (meat); 9 C.F.R. \u00a7 381.412(g) (poultry). 186 9 C.F.R. \u00a7 317.309(b) (meat); 9 C.F.R. \u00a7 381.409(b) (poultry). 187 9 C.F.R. \u00a7 317.309(b) (meat); 9 C.F.R. \u00a7 381.409(b) (poultry). 188 9 C.F.R. \u00a7 317.312 (meat); 9 C.F.R. \u00a7 381.412 (poultry). 189 9 C.F.R. \u00a7 317.309(b)(10) (meat); 9 C.F.R. \u00a7 381.409(b)(10) (poultry). 190 9 C.F.R. \u00a7 317.309(b)(11) (meat); 9 C.F.R. \u00a7 381.409(b)(11) (poultry). 191 9 C.F.R. \u00a7 317.309(b)(15) (meat); 9 C.F.R. \u00a7 381.409(b)(15) (poultry). 192 9 C.F.R. \u00a7 317.313(b) (meat); 9 C.F.R. \u00a7 381.413(b) (poultry). 193 9 C.F.R. \u00a7 317.313(p) (meat); 9 C.F.R. \u00a7 381.413(p) (poultry). 194 9 C.F.R. \u00a7 317.313(c) (meat); 9 C.F.R. \u00a7 381.413(c) (poultry). 195 9 C.F.R. \u00a7 317.313(d) (meat); 9 C.F.R. \u00a7 381.413(d) (poultry). 196 9 C.F.R. \u00a7 317.313(e) (meat); 9 C.F.R. \u00a7 381.413(e) (poultry). 197 9 C.F.R. \u00a7 317.313(f)(g) (meat); 9 C.F.R. \u00a7 381.413(f)(g) (poultry). 198 9 C.F.R. \u00a7 317.313(i)(1) (meat); 9 C.F.R. \u00a7 381.413(i)(1) (poultry). 199 9 C.F.R. \u00a7 317.313(i) (meat); 9 C.F.R. \u00a7 381.413(i) (poultry). 200 9 C.F.R. \u00a7 317.313(j) (meat); 9 C.F.R. \u00a7 381.413(j) (poultry). 201 9 C.F.R. \u00a7 317.313(j) (meat); 9 C.F.R. \u00a7 381.413(j) (poultry). 202 9 C.F.R. \u00a7 317.313(j) (meat); 9 C.F.R. \u00a7 381.413(j) (poultry). 203 9 C.F.R. \u00a7 317.313(k) (meat); 9 C.F.R. \u00a7 381.413(k) (poultry). 204 9 C.F.R. \u00a7 317.313(j) (meat); 9 C.F.R. \u00a7 381.413(j) (poultry). 205 9 C.F.R. \u00a7 317.313(l),(m) (meat); 9 C.F.R. \u00a7 381.413(l),(m) (poultry). 206 9 C.F.R.

\u00a7 317.313(l) (meat); 9 C.F.R. \u00a7 381.413(l) (poultry). - 109 -,"207 9 C.F.R. \u00a7 317.313(q) (meat); 9 C.F.R. \u00a7 381.413(q) (poultry). 208 9 C.F.R. \u00a7 317.313(q) (meat); 9 C.F.R. \u00a7 381.413(q) (poultry). 209 9 C.F.R. \u00a7 317.354 (meat); 9 C.F.R. \u00a7 381.454 (poultry). 210 9 C.F.R. \u00a7 317.354(b) (meat); 9 C.F.R. \u00a7 381.454(b) (poultry). 211 9 C.F.R. \u00a7 317.354(c) (meat); 9 C.F.R. \u00a7 381.454(c) (poultry). 212 9 C.F.R. \u00a7 317.354(e) (meat); 9 C.F.R. \u00a7 381.454(e) (poultry). 213 9 C.F.R. \u00a7 317.354(e) (meat); 9 C.F.R. \u00a7 381.454(e) (poultry). 214 9 C.F.R. \u00a7 317.356 (meat); 9 C.F.R. \u00a7 381.456 (poultry). 215 9 C.F.R. \u00a7 317.361 (meat); 9 C.F.R. \u00a7 381.461 (poultry). 216 9 C.F.R. \u00a7 317.361 (meat); 9 C.F.R. \u00a7 381.461 (poultry). 217 9 C.F.R. \u00a7 317.361 (meat); 9 C.F.R. \u00a7 381.461 (poultry). 218 9 C.F.R. \u00a7 317.361(b)(4) (meat); 9 C.F.R. \u00a7 381.461(b)(4) (poultry). 219 9 C.F.R. \u00a7 317.361 (meat); 9 C.F.R. \u00a7 381.461 (poultry). 220 9 C.F.R. \u00a7 317.361(b)(6) (meat); 9 C.F.R. \u00a7 381.461(b)(6) (poultry). 221 9 C.F.R. \u00a7 317.361(c) (meat); 9 C.F.R. \u00a7 381.461(c) (poultry). 222 9 C.F.R. \u00a7 317.362(b)(1) (meat); 9 C.F.R. \u00a7 381.462(b)(1) (poultry). 223 9 C.F.R. \u00a7 317.362(b)(2),(3) (meat); 9 C.F.R. \u00a7 381.462(b)(2),(3) (poultry). 224 9 C.F.R. \u00a7 317.362(b)(5) (meat); 9 C.F.R. \u00a7 381.462(b)(5) (poultry). 225 9 C.F.R. \u00a7 317.362(b)(6) (meat); 9 C.F.R. \u00a7 381.462(b)(6) (poultry). 226 9 C.F.R. \u00a7 317.362(c) (meat); 9 C.F.R. \u00a7 381.462(c) (poultry). 227 9 C.F.R. \u00a7 317.362(c) (meat); 9 C.F.R. \u00a7 381.462(c) (poultry). 228 9 C.F.R. \u00a7 317.362(c)(2) (meat); 9 C.F.R. \u00a7 381.462(c)(2) (poultry). 229 9 C.F.R. \u00a7 317.362(c)(3) (meat); 9 C.F.R. \u00a7 381.462(c)(3) (poultry). 230 9 C.F.R. \u00a7 317.362(c)(4) (meat); 9 C.F.R. \u00a7 381.462(c)(4) (poultry). 231 9 C.F.R. \u00a7 317.362(d)(1) (meat); 9 C.F.R. \u00a7 381.462(d)(1) (poultry). 232 9 C.F.R. \u00a7 317.362(d)(2),(3) (meat); 9 C.F.R. \u00a7 381.462(d)(2),(3) (poultry). 233 9 C.F.R. \u00a7 317.362(d)(5) (meat); 9 C.F.R. \u00a7 381.462(d)(5) (poultry). 234 9 C.F.R. \u00a7 317.362(d)(5) (meat); 9 C.F.R. \u00a7 381.462(d)(5) (poultry). 235 9 C.F.R. \u00a7 317.362(e) (meat); 9 C.F.R. \u00a7 381.462(e) (poultry). 236 9 C.F.R. \u00a7 317.354(d) (meat); 9 C.F.R. \u00a7 381.454(d) (poultry). 237 9 C.F.R. \u00a7 317.363 (meat); 9 C.F.R. \u00a7 381.463 (poultry). 238 9 C.F.R. \u00a7 317.363 (meat); 9 C.F.R. \u00a7 381.463 (poultry). 239 9 C.F.R. \u00a7 317.380 (meat); 9 C.F.R. \u00a7 381.480 (poultry). 240 9 C.F.R. \u00a7 317.380(e) (meat); 9 C.F.R. \u00a7 381.480 (e) (poultry). 241 9 C.F.R. \u00a7 317.360(b)(1) (meat); 9 C.F.R. \u00a7 381.460(b)(1) (poultry). 242 9 C.F.R. \u00a7 317.360(b)(2),(3) (meat); 9 C.F.R. \u00a7 381.460(b)(2),(3) (poultry). 243 9 C.F.R. \u00a7 317.360(b)(4) (meat); 9 C.F.R. \u00a7 381.460(b)(4) (poultry). 244 9 C.F.R. \u00a7 317.360(c)(1) (meat); 9 C.F.R. \u00a7 381.460(c)(1) (poultry). 245 9 C.F.R. \u00a7 317.360(c)(2)(3) (meat); 9 C.F.R. \u00a7 381.460(c)(2)(3) (poultry). 246 9 C.F.R. \u00a7 317.360(c)(4) (meat); 9 C.F.R. \u00a7 381.460(c)(4) (poultry). 247 7 C.F.R. \u00a7 94.2 (2004). 248 7 C.F.R. \u00a7 57.5 (2004). 249 21 C.F.R. \u00a7 101.3 (2004). \u201cimitation\u201d is defined as a food product formulated to resemble another food covered by a standard of identity, when the formulated product is nutritionally inferior. 250 21 C.F.R. \u00a7 160.115 (2004). 251 Id. 252 21 C.F.R. \u00a7 160.105 (2004). 253 21 C.F.R. \u00a7 160.180 (2004). This percentage is determined by the method prescribed in \u201cOfficial Methods of Analysis of the Association of Official Analytical Chemists,\u201d 13th Ed. (1980), sections 17.006 and 17.007 under \u201cTotal Solids, Vacuum Method (3) - Official Final Action,\u201d which is incorporated by reference. 254 21 C.F.R. \u00a7 160.140 (2004). 255 21 C.F.R. \u00a7 160.145(d) (2004). - 110 -,"256 Id. Requirements for lysozyme and avidin content reduction

are found in section 160.140(a). 257 21 C.F.R. \u00a7 101.5 (2004). 258 Id. 259 7 C.F.R. \u00a7 94.2 (2004). 260 9 C.F.R. \u00a7 590.150 (2004). 261 9 C.F.R. \u00a7 590.413 (2004). 262 9 C.F.R. \u00a7 590.412 (2004). 263 9 C.F.R. \u00a7 590.410 (2004). 264 21 C.F.R. \u00a7 160.110 (2004). 265 21 C.F.R. \u00a7 160.115 (2004). 266 21 C.F.R. \u00a7 160.105 (2004). The use of anticaking agents is specified in paragraph (a). 267 21 C.F.R. \u00a7 101.22(k)(2) (2004). 268 21 C.F.R. Part 101 (2004). 269 9 C.F.R. \u00a7 590.411 (2004). - 111 -

"]},{ "file\_name": "FSIS\_GD\_1998\_0001", "title": "Letter to Industry Nonfood Compounds - July 13, 1998", "num": "FSIS-GD-1998-0001", "id": "36105b7b74500b615ae279209cc9a6bed28f21659833f7136ab9b836a564afc7", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-07/FSIS-GD-1998-0001.pdf", "type": "pdf", "n\_pages": 1, "word\_count": 346, "text\_by\_page": [ "SUPPLEMENTARY GUIDANCE ON THE USE OF ANTIMICROBIAL AGENTS TO CONTROL LISTERIA MONOCYTOGENES IN POST-LETHALITY EXPOSED READY-TO-EAT MEAT AND POULTRY PRODUCTS An investigation of a 2007 recall of ready-to-eat (RTE) cooked chicken products because of the presence of Listeria monocytogenes (LM) showed that the establishment had failed to maintain sanitary practices and had applied antimicrobial agents that failed to suppress LM growth in challenge studies. To prevent recurrence of recalls attributable to these causes, FSIS is issuing this guidance to establishments to reiterate and emphasize: 1) Resources on the validation and application of antimicrobial agents or processes for effective control of LM; 2) Recommendations on the validation and application of antimicrobial agents or processes; and 3) Sanitation practices to control Listeria in RTE operations. I. Resources on the Validation and Application of Antimicrobial Agents or Processes The FSIS \u2018Compliance Guidelines To Control Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products\u2019 (LM compliance guidelines, May 2006) provide the following guidance and resource materials on conducting challenge studies.

([http://www.fsis.usda.gov/oppde/rdad/FRPubs/97013F/LM\\_Rule\\_Compliance\\_Guidelines\\_May\\_2006.pdf](http://www.fsis.usda.gov/oppde/rdad/FRPubs/97013F/LM_Rule_Compliance_Guidelines_May_2006.pdf)) \u2022 Some published studies about challenge studies regarding the use of antimicrobial agents are available. FSIS\u2019 general observations based on these studies are found on pp. 59-67 of the LM compliance guidelines. \u2022 Attachment 7 on pp. 93-97 of the LM compliance guidelines gives definitions and an explanation of challenge studies, validation, shelf life studies, and summaries of published challenge studies. These summaries give the critical variables used in the challenge study, such as time, temperature, pH, concentration, and others, and the results of the challenge study in terms of log reduction of LM. \u2022 A link to the article (p. 101 of the Lm compliance guidelines): GUIDELINES FOR CONDUCTING LISTERIA MONOCYTOGENES CHALLENGE TESTING OF FOODS ( Scott et al., 2005) is available at [www.foodprotection.org/publications/TOCarchive/2005TOC/November2005.htm](http://www.foodprotection.org/publications/TOCarchive/2005TOC/November2005.htm) This article gives guidance on how to conduct a challenge study for antimicrobial agents and post-lethality treatments to determine suppression, reduction, or inactivation of LM. It addresses factors to be considered when conducting a challenge study, such as strains of L. monocytogenes to be used, inoculum level, inoculum preparation and method of inoculation, formulation of the product, delivery of the lethal treatment, incubation of samples, length of the study, frequency of sampling, and sample analyses. \u2022 Another resource article for

conducting challenge studies for validation of antimicrobial agents is the article on p. 101 of the compliance guidelines: CONSIDERATIONS FOR ESTABLISHING SAFETY-BASED CONSUME-BY DATE LABELS FOR REFRIGERATED READY-TO-EAT FOODS (NACMCF, 1","2004)

[www.fsis.usda.gov/ops/nacmcf/2004/NACMCF\\_Safetybased\\_Date\\_Labels\\_082704.pdf](http://www.fsis.usda.gov/ops/nacmcf/2004/NACMCF_Safetybased_Date_Labels_082704.pdf)

This article, developed by the National Advisory Committee on Microbial Criteria for Foods (NACMCF), gives guidance on how to determine the shelf-life of a RTE product containing an added antimicrobial agent that is supposed to suppress LM growth during the refrigerated shelf-life. Most studies use the temperature which the product is normally held during storage as the temperature during shelf life studies, e.g., refrigerated temperature of 38-40\u00b0 F. Shelf-life studies also should use or include a temperature of 45\u00b0 F which reflects consumer handling. The NACMCF document recommended to using a higher temperature for shelflife studies because foods can encounter a range of temperatures below and above 45\u00b0 F, with higher temperatures more likely in grocery store cases and during consumer handling. Therefore these temperatures more accurately reflect reality. A product with an added antimicrobial agent showing L. monocytogenes growth of <2 log at a storage temperature of 38-40 \u00b0 F and at 45\u00b0 F or above would be viewed by FSIS as more protective of public health than another product showing the same growth only when stored at 38-40\u00b0 F. Establishments planning to conduct shelf life studies can use the guidance for other factors important in designing a shelf life study provided in the full NACMCF report cited above. \u2022 FSIS Directive 7120.1, Amendment 13 (August 16, 2007 through October 23, 2007, i.e., the date of publication of the last amendment) is an updated list of substances, including antimicrobial agents that have been accepted by FSIS for use in the production of meat and poultry products. This list is available at:

[http://www.fsis.usda.gov/Regulations\\_&\\_Policies/7000\\_SeriesProcessed\\_Products/index.asp](http://www.fsis.usda.gov/Regulations_&_Policies/7000_SeriesProcessed_Products/index.asp) \u2022 The FSIS Web site contains new technologies, including studies and application of antimicrobial agents or processes and post-lethality treatments that may be used in post-lethality exposed RTE products.

[http://www.fsis.usda.gov/Regulations\\_&\\_Policies/New\\_Technologies/index.asp](http://www.fsis.usda.gov/Regulations_&_Policies/New_Technologies/index.asp) II. Validation and Application of Antimicrobial Agents or Processes An establishment can validate antimicrobial agents or processes in its RTE product or product formulation using a challenge study for the product, a published study or modeling program. In addition to the information from the resources listed in Section I, establishments should consider the following recommendations on the validation and application of antimicrobial agents or processes:

Conducting a Challenge Study Conducting a challenge study is one way to validate the effectiveness of an antimicrobial agent\process or any post-lethality treatment. A challenge study can determine the ability of LM to grow in a food, show the effectiveness of an antimicrobial agent in suppressing LM growth, and the ability of a post-lethality treatment to reduce LM. 2","\u2022 A challenge study should be conducted by a microbiologist trained in these studies. The challenge study should be conducted in a food microbiological laboratory and not in the establishment. \u2022 A University Extension Service may help in finding the appropriate microbiologist and laboratory for the study or provide guidance in conducting a challenge study. \u2022 There are a variety of antimicrobial agents approved for use to suppress growth of L. monocytogenes. The necessary information on the use of the antimicrobial agent can be obtained from the manufacturer. \u2022 A challenge study

conducted for the specific product of the establishment provides a better means to validate compared to the use of a published study or a modeling program. In this case, the product formulation and critical variables for the specific product are used. When using lactate or diacetate for the study as the antimicrobial agents, check the moisture content of the finished product so that it is the same as that recommended for the level of lactate or diacetate being used. One of the findings in the RTE cooked chicken product recall is that the validation showed that exceeding the product moisture content limits recommended for the use of lactates and diacetates for the particular formulation resulted in LM growth. An article by Seman et al., (2002), referred to on p. 61 of the LM compliance guidelines emphasized the importance of MOISTURE CONTENT in the application of lactates and diacetates as antimicrobial agents. The article says, "The results show that increasing amounts of potassium lactate syrup and sodium diacetate decreased the growth rate of *L. monocytogenes*, while increasing finished product moisture increased the growth rate. Sodium chloride content was not significant but was found to have a negative correlation to growth rate. This study provided a useful model in determining the target amounts of potassium lactate and sodium acetate for cured meat product formulations to inhibit the growth of *L. monocytogenes*. The calculations would also require knowledge of the finished product sodium chloride and moisture contents." Table 2 from the study shows that different finished product moisture levels, amount of sodium chloride, and lactate and diacetate result in different levels of LM growth rate. The following are excerpts from the published study. % salt % sodium T h % diacetate % potassium lactate syrup % product moisture LM growth rate (wk-1) 1.50 0.15 7.0 74.0 0.0 1.50 0.05 2.5 74.0 0.0991 2.20 0.20 4.75 64.5 0.0 2.20 0.10 0.25 64.5 0.1338 3", "The investigators advised that this validated model is specific to the products designed for the study and the *L. monocytogenes* strains used. Testing of this model in other environments and with other *Listeria* spp., and to formulations that are outside the model's limits may result in different maximum growth rates. For the shelf life study, use at least two sets of temperatures: 1) The refrigerated temperature that the product is usually maintained and stored, e.g., 40 °F; and 2) A higher temperature to reflect consumer handling, e.g., 45 °F. An antimicrobial agent or process showing less than 2 log<sub>10</sub> growth of LM when stored at these temperatures during the product's shelf-life is considered protective of public health. Note: A criterion of no more than 1 log<sub>10</sub> growth of Lm during 1.3 times the expected shelf life of the product at 8 °C (46 °F) can put the product in the no growth category. Use of a temperature at or below 8 °C was cited by the FSISFDA risk assessment to be protective of public health because this would achieve a predicted estimate of 50 % reduction in the number of cases of listeriosis in deli meats. FSIS compliance guidelines suggest the potential of reduced regulatory sampling for products in which growth is equal to or less than 1 log<sub>10</sub> throughout the product's shelf life. Verify the effectiveness of the antimicrobial agent/process used by testing for LM growth during the shelf life of the product, at a certain frequency. Maintain and monitor records of validation, verification, and corrective actions for deviations from the effective application of antimicrobial agents/processes. Using Published Studies for Validation Establishments can seek guidance from University Extension Service specialists or authors of the studies on how to apply the controls from a published challenge study. If using a published study or modeling program, use the same product or product formulation, treatment, and procedure as in the

study. Applying the treatment to a different product or product formulation may result in a different rate of growth inhibition. \u2022 Use the same critical variables of time and temperature of treatment, concentration, pH, moisture, water activity, fat, salt content, time and temperature of storage, packaging material, packaging atmosphere, and other critical variables or factors detailed in the study. \u2022 Use the same or similar product or product formulation, procedures, and equipment as those detailed in the study. \u2022 If using product, product formulation, treatments, or other critical variables that are different from those in the published study, conduct additional validation using the new variables and verify the effectiveness of the antimicrobial agent in the product after the treatment by testing for LM growth during shelf-life storage. \u2022 Use only validated studies, published studies, and modeling programs that include a shelf-life study. 4", "When using challenge studies, use only those showing that the LM growth or growth rate is lower in the product with antimicrobial agent\process than in product without antimicrobial agent\process. \u2022 Use only challenge studies showing that the antimicrobial agent\process used in the product suppressed growth of LM throughout the commercial shelf life of the product at < 2 log<sub>10</sub> growth, or better growth suppression. \u2022 Obtain the necessary information on the use of the antimicrobial agent from the manufacturer. \u2022 Verify the effectiveness of the antimicrobial agent\process used by testing for LM growth during the shelf life of the product, at a certain frequency. \u2022 Maintain and monitor records of validation, verification, and corrective actions for deviations from the effective application of antimicrobial agents\processes. Using a Modeling Program for Validation \u2022 Modeling programs can be obtained from published studies or from the manufacturer of an antimicrobial agent. Information and guidance on the application of the antimicrobial agent may be obtained from the manufacturer. \u2022 Establishments can also seek guidance from University Extension Service specialists or authors of the modeling programs on how to use a modeling program. \u2022 If using a modeling program to determine the amount of antimicrobial agent to use, follow the directions with regards to salt content, moisture level of the finished products, and other information needed. For example, a modeling program may ask to confirm that the product is a cured product because the model is only valid for cured products. It will ask for the following: Shelf life of product in days, product specification, salt content (%) and finished product moisture content (%). The program will calculate the amount of lactate\diacetate to be used and the log suppression of LM based on the information provided. \u2022 Growth models on the use of antimicrobial agents are available mostly for cured products. For uncured products where there are no growth models, validation studies need to be conducted per product. \u2022 Verify the effectiveness of the antimicrobial agent\process used by testing for LM growth during the shelf life of the product, at a certain frequency. \u2022 Maintain and monitor records of validation, verification, and corrective actions for deviations from the effective application of antimicrobial agents\processes.

### III. Sanitation Practices to Control Listeria in RTE Operations

The use of antimicrobial agents or processes in a product does not mean that control of the sanitation in the RTE operation can be neglected. The effectiveness of the antimicrobial activity is affected by the level of microbial contaminants on equipment surfaces and in the processing environment. The 2007 recall of RTE chicken breast products showed that sanitation plays a great role in controlling LM contamination in the product and in the processing environment. The FSIS LM compliance guidelines include 5", "recommendations

for sanitation controls in RTE processing plants; Section G, I-VI, of the compliance guidelines include guidance to establishments on sanitation control. Section G-VII gives guidance on testing frequencies for food contact surfaces and recommended validated methods for testing. The following recommendations are developed as a result of findings from the 2007 LM recall. Most of these are found in the guidance contained in the FSIS LM Compliance Guidelines, Section G I-VII, but are being highlighted for establishments to take extra notice. Establishments should consider the following recommendations on sanitation controls.

A. Listeria sanitation program

- \u2022 Maintain a record of all food contact surfaces and environmental surfaces in the processing area that are to be tested. Focus on the sites that are likely to be contaminated or that tested positive in the past. Make sure all of the identified surfaces are actively sampled and have an equal opportunity of being sampled during each sampling event.
- \u2022 Include the supporting documentation of the testing frequency in your LM sanitation program.
- \u2022 Include testing and monitoring of drains after an LM positive finding.
- \u2022 Do not use LM testing to support that LM is a hazard not reasonably likely to occur. LM testing is a verification of the effectiveness of the establishment's food safety program to control LM.
- \u2022 Include supporting documentation in the Sanitation SOP or other prerequisite program to support your claim in the HACCP plan that LM is a hazard not reasonably likely to occur in your RTE processing.
- \u2022 Include supporting documentation for the alternative chosen for the product.
- \u2022 When there is a repeated LM positive finding, suspend RTE operations to determine the cause or origin of the contamination and develop measures for removal of contamination and prevention of recurrence and to verify that there is no remaining contamination.
- \u2022 Sample food contact surfaces and environmental surfaces at other points of the production process, in addition to sampling at pre-op and about 3 hours after production has started.

B. Sanitation Procedures Dripping, Condensation and Standing Water

- \u2022 IMMEDIATELY address and correct problems of dripping, condensation and standing water. *L. monocytogenes* is an environmental pathogen and may be present in dripping, standing water and condensation. The moist environment caused by condensation is conducive to the growth of the pathogen.
- \u2022 Stop production of RTE products during repairs and corrective actions for these 6", "problems.
- \u2022 Clean and sanitize equipment and the processing area after all the repairs and corrective actions are finished.
- \u2022 Verify effective sanitizing of equipment and of the processing area environment after the repairs or construction by tests showing that LM or *Listeria spp.* tested negative, before resuming RTE production.
- Personnel Hygiene

  - \u2022 Train and require personnel to wash hands before putting gloves on.
  - \u2022 Train and require personnel to wash hands before resuming duties after breaks.
  - \u2022 Train personnel on hygienic practices in an RTE processing establishment once a month.
  - \u2022 Monitor personnel hygiene practices.

- Separation of RTE and Non-RTE Areas

  - \u2022 If processing both RTE and raw products, completely separate the processing areas, such as by complete wall separation or by scheduling processing on different days. If separate processing areas or scheduling on different days is not possible, schedule RTE processing first, then follow with raw products processing.
  - Always have a complete clean-up and sanitization after each processing and pre-op testing of equipment and processing area environment before starting RTE processing.
  - \u2022 Use separate equipment for RTE and raw processing. If separate equipment is not possible, schedule to use equipment for RTE processing first, then for raw processing.
  - \u2022 Assign different personnel for RTE and raw

processing areas, especially if both are conducted on the same day. If not possible, have personnel clean hands very well and use unused, clean coats, new gloves and hairnets, and sanitized boots for RTE processing. \u2022 Restrict movement of personnel from and to NRTE area during RTE processing. If necessary, use footbath, wash hands, and use new gloves and clean, unused coats and hairnets when returning to RTE area processing. \u2022 Locate coat racks for coats used in RTE processing in an identified RTE area. \u2022 Use color coded coats for use in RTE processing area, in raw processing area, and in other areas. \u2022 Maintain procedures so that personnel coming from any area common to RTE and raw processing are not transferring contamination to RTE areas. \u2022 Establish procedures for moving equipment from a non-processing area to a RTE processing area to prevent Listeria contamination from the equipment and during the moving operation. \u2022 Avoid passing raw product through RTE areas and RTE product through raw production areas. \u2022 Do not allow RTE product to come in contact with surfaces or raw products in 7", "coolers. Records of Sanitation Procedures \u2022 Keep records of sanitation procedures to be used in conjunction with processing of RTE products that are covered by the Listeria rule. \u2022 Maintain monitoring records of sanitation procedures. \u2022 Maintain records of preventive measures taken after a finding of direct product contamination, including the steps taken to clean the affected equipment or environmental surface, or to modify the procedure affected; other corrective actions employed, verification that the corrective action will prevent recurrence of the deviation; dates of the deviation, corrective action, and verification; and identification of personnel involved in addressing the contamination. Room Temperature \u2022 Maintain temperature in processing areas and packaging rooms as stated in the HACCP plan, Sanitation SOPs, or Prerequisite Programs. \u2022 Maintain cold temperature (<50\u00ba F) in packaging room for products that are to be refrigerated or frozen, as stated in the HACCP plan, Sanitation SOPs, or Prerequisite Programs, to prevent LM growth in the RTE processing environment. \u2022 Monitor temperatures as stated in the HACCP plan, Sanitation SOPs, or Prerequisite Programs. Miscellaneous \u2022 For establishments processing deli salads and similar products, establish procedures to ensure that other non-meat or non-poultry RTE ingredients do not cause cross-contamination with Listeria. \u2022 Maintain an effective rodent and insect infestation preventive and control program. Rats, mice and insects are sources of Listeria and other microbial contamination. \u2022 Develop and maintain procedures to ensure that sanitizer concentrations in footbaths are adequately maintained. \u2022 Maintain records and verify the correct procedures for the concentrations and mixing of sanitizers. \u2022 Maintain a rotation of sanitizers used. \u2022 Avoid the creation of aerosols and airborne dust when cleaning equipment or surfaces during operation. \u2022 Discard products that touch environmental surfaces, such as products falling on the floor or on the conveyor belt. \u2022 During cleaning and sanitizing, make sure food residues are not left on the equipment. \u2022 Maintain procedures for routine cleaning and develop procedures for intensified cleaning. 8", "\u2022 When adding ingredients to second container, do not to bang or contact the first container against the interior of the other container. C. Facilities and Equipment \u2022 IMMEDIATELY FIX leaky roof, broken and cracked equipment, floors, doors, windows, etc. Suspend operations during leakage and during repairs. Test the environment for Listeria spp. after repairs are finished and resume operation only after tests are negative. \u2022 DISCARD rusty, pitted, peeling tools or parts of equipment and replace with new, smooth-surfaced ones. These rusty,

pitted tools and equipment parts serve as ideal places for LM to grow and multiply. \u2022 Always dismantle equipment for cleaning and sanitizing. \u2022 Remove equipment not in use from the RTE processing area. \u2022 Use equipment according to the intended use, with the recommended cleaning and sanitizing procedures. \u2022 Document equipment maintenance and monitoring to check for broken, pitted, rusty, peeling, or dirty equipment needing replacement, repair, cleaning, etc. \u2022 Choose equipment that is designed to be easily assembled, cleaned and sanitized. D. Dual-Jurisdiction Establishments FDA regulated products produced in dual jurisdiction establishments are not subject to FSIS regulations. Therefore they do not have to comply with 9 CFR Parts 416, 417, or 430. FSIS and FDA entered into a Memorandum of Understanding in 1999 regarding inspection coordination in dual jurisdiction establishments. The MOU can be accessed at:

<http://www.fda.gov/oc/mous/domestic/225-99-2001.html> FSIS developed FSIS Directive 5730.1, Responsibilities in Dual Jurisdiction Establishments providing instruction to its inspection program personnel about their responsibilities in dual jurisdiction establishments. Establishments producing FDA and FSIS regulated products should consider the differences in regulatory requirements between the two agencies when designing their food safety systems. The following list of recommendations could be used by establishments to prevent postlethality exposed RTE meat and poultry products from becoming adulterated with LM. \u2022 Completely separate processing areas for FSIS regulated products and FDA regulated products, such as by complete wall separation, or scheduling processing on different days. If not possible, schedule FSIS product processing first, then FDA product processing. Always have a complete clean-up and sanitization after each processing and pre-op testing of equipment and processing environment before starting FSIS product processing. \u2022 FSIS and FDA product processing areas should each have separate equipment. If not possible, schedule to use equipment for FSIS product processing first, then for FDA processing.

9",\u2022 Assign different personnel to FSIS product and FDA processing areas, especially if both are conducted on the same day. If not possible, have personnel clean hands thoroughly, and use unused, clean coats, new gloves and hairnets, and sanitized boots for FSIS and FDA processing. \u2022 Maintain a list of FSIS and FDA products processed to avoid confusion. \u2022 Maintain the same sanitation procedures for LM in both FSIS and FDA processing to avoid LM cross-contamination or growth in the processing environment.

10"]},{"file\_name":"FSIS\_GD\_1999\_0002","title":"Packing Dates on Poultry Labeling","num":"FSIS-GD-1999-0002","id":"e7ef2d25080bebad737f0c38d629cc4830f221d7563e0283e882e8e132f01e63","corpus":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/media\_file/2021-07/FSIS-GD-1998-0002.pdf","type":"pdf","n\_pages":3,"word\_count":1129,"text\_by\_page":["April 8, 2008 Food Safety and Inspection Service (FSIS) Compliance Guide on the Determination of Processing Aids Purpose of the Compliance Guide The intent of this guidance is to convey FSIS\u2019 approach to determining whether an ingredient may be considered a processing aid. Processing aids do not have to be declared in the ingredients statement on the label of the meat or poultry food product in which they are used. Regulatory Requirements for Processing Aids Ingredients that are present in a meat or poultry product in an insignificant amount and that have no functional

or technical effects in the finished meat or poultry product are considered to be processing aids. Processing aids are not required to be listed in the ingredients statement for a meat or poultry product. Although the Federal meat and poultry inspection regulations do not define \u201cprocessing aid,\u201d FSIS, in evaluating whether a substance is a processing aid, uses the Food and Drug Administration\u2019s (FDA) definition of this term, which is in 21 CFR 101.100(a)(3). According to the FDA definition, processing aids are substances that have no technical or functional effect in a finished food but may be present in that food by having been used as ingredients of another food in which they had a technical effect. For example, sodium silicoaluminate will provide a technical effect as an anti-caking agent in a dry seasoning mix. However, once the seasoning mix is used in the formulation of a meat sausage, the sodium silicoaluminate will no longer provide a technical effect in the finished food (i.e., the sausage). Processing aids are defined as: (a) substances that are added during the processing of a food but are removed in some manner from the food before it is packaged in its finished form; (b) substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food; or (c) substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food. Whether a substance meets these conditions is determined by FSIS on a case-by-case basis by considering the proposed use of the substance and the specific meat or poultry product to which it is added. Self-determination by manufacturers that a substance is a processing aid is not acceptable. Data must be submitted to FSIS\u2019 Labeling and","April 8, 2008 Program Delivery Division (LPDD) to show that the proposed use of the substance is consistent with FDA\u2019s definition of a processing aid. Manufacturers may contact LPDD at (202) 205-0623 for guidance concerning what information needs to be submitted to support their assertion that a particular use of a substance in a meat or poultry product is a processing aid."}],{"file\_name":"FSIS\_GD\_1999\_0003","title":"Update - 416.2(g): Water supply and water, ice, and solution reuse","num":"FSIS-GD-1999-0003","id":"06d3c60c0a6d0c6e91676507de0e714d422b1103eed222f1a3d2ad5ed63addb3","corpus":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/import/san\_update1.pdf","type":"pdf","n\_pages":20,"word\_count":3662,"text\_by\_page":["April 8, 2008 Guidance on Meaning of \u201cProhibited Substances\u201d in FSIS Actions on the Use of Ingredients in Meat and Poultry Products Purpose of the Compliance Guide This document is intended to provide guidance on \u201cprohibited substances\u201d to interested parties who wish to use new food ingredients (hereafter referred to as \"substances\") in the manufacture of meat and poultry products. Prohibited Substances Title 9 of the Code of Federal Regulations (CFR), Section 424.23, specifically prohibits the use of any substance in or on any meat or poultry product if it conceals damage or inferiority, or makes the product appear to be better or of greater value than it is. One example of this would be the addition of paprika to ground beef or cuts of meat. While the use of paprika in some meat and poultry products is acceptable and expected (e.g., the use of paprika in chorizo, Italian sausage, or barbecued chicken), the addition of paprika to ground beef or cuts of meat is prohibited because it would impart a permanent color to the meat. The addition of paprika in this manner would misrepresent the leanness of the meat (e.g., making it appear to have less fat than a similar package of ground

beef or cut of beef without paprika). For this reason, 9 CFR 424.23 specifically prohibits the use of paprika or oleoresin paprika in or on fresh meat, such as steaks; on comminuted fresh meat, such as chopped and formed steaks or patties; or in any other meat consisting of fresh meat (with or without seasoning). The Food Safety and Inspection Service's (FSIS) regulation on prohibited substances covers any potential use of a substance that could be used to conceal damage or mislead consumers. FSIS considers 9 CFR 424.23 each time it evaluates the suitability of a new substance, or a new use of a previously approved substance, under the joint Food and Drug Administration (FDA) and FSIS ingredient approval process. Suitability relates to the effectiveness of the substance in performing the intended technical purpose of use, at the lowest level necessary, and the assurance that the conditions of use will not mislead consumers. For example, the use of preservatives (e.g., sorbic acid) are not permitted on fresh meat because their use could mask spoilage indicators (i.e., make spoiled meat appear fresh). Therefore, FSIS requires data to be submitted on the organoleptic properties (e.g., odor, taste, color and feel) of treated meat whenever the Agency is asked to evaluate a new use of a substance. While the new or expanded use of a substance may not require rulemaking under the joint FDA and FSIS approval process, rulemaking may be necessary where a standard of identity or other Federal regulation prohibits or limits the use of a substance. Currently, for example, potassium sorbate may be added only to dry sausages to retard mold growth. If the addition of potassium sorbate to ground beef is sought, rulemaking might be necessary to include that use.", "April 8, 2008 Ingredient Approval Background On December 23, 1999, FSIS published in the Federal Register (64 FR 72167) a final rule titled, "Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products." This final rule explained how FDA and FSIS will work together regarding future requests for approvals of substances to be used in or on meat and poultry products. The final rule streamlined the process for approving the use of substances in meat and poultry products by providing for the simultaneous review by FDA and FSIS of requests and petitions. A Memorandum of Understanding (MOU) was implemented in January 2000 that outlines the procedures for such reviews. The final rule and the MOU may be accessed through the FSIS Web Site at:

[http://www.fsis.usda.gov/Regulations\\_&\\_Policies/ingredients\\_guidance/index.asp](http://www.fsis.usda.gov/Regulations_&_Policies/ingredients_guidance/index.asp) The Risk Management Division (RMD) and the Labeling and Program Delivery Division (LPDD) in the Office of Policy and Program Development (OPPD) serve as FSIS' key offices on the use and labeling of substances and on the implementation of the MOU with FDA on joint review and approval of substances. The Office of Food Additive Safety (OFAS) in the Center for Food Safety and Applied Nutrition (CFSAN) at FDA is responsible for leading that agency's regulation of food ingredients and additives, as well as for working collaboratively with FSIS in the implementation of the MOU. Additional Guidance Additional guidance on prohibited substances may be obtained from the Labeling and Program Delivery Division at (202) 205-0623."]}, {"file\_name": "FSIS\_GD\_2005\_0001", "title": "Compliance Guidelines for Retained Water", "num": "FSIS-GD-2005-0001", "id": "25f083e51fcb13201ae016b04a58dae8f9eca3ff7f938010063fe938538d7fe7", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Retained-water-guidance.pdf", "type": "pdf", "n\_pages": 18, "word\_count": 6291, "text\_by\_page": ["Questions and"]}

Answers FSIS DIRECTIVE 6100.4 VERIFICATON INSTRUCTIONS RELATED TO SPECIFIED RISK MATERIALS Note: FSIS Directive 6100.4 is arranged in chapters. The following Q&As are grouped according to the chapters where they most readily apply. Additional sections not specifically addressed in the directive are included. Chapter I: General Introduction I.

Identification of SRMs Chapter 2: Slaughter and Processing Verification Activities I. General verification activities (design and execution) for HACCP, SSOP, and PR programs II. Verification activities for age determination III. Post-mortem on-line verification duties IV. Verification of sanitation procedures V. Verification of SRM removal, segregation, and disposition; general recordkeeping VI. Verification activities for tonsil removal, segregation, and disposition VII. Verification activities for distal ileum removal, segregation, and disposition VIII. Disposal and rendering of SRMs IX. Verification activities for the prohibition of air-injection stunning X.

Verification activities for the prohibition of mechanically separated beef. Chapter 3:

Transportation of Carcasses and Parts that Contain SRMs I. Verification at slaughter establishments II. Verification at receiving establishments Chapter 4. Documentation and Enforcement I. Documentation II. Enforcement Chapter 5. Addendum: I. Handling of SRMs in custom plants 1", "Chapter 1 General Introduction Identification of SRMs Q1. What are Specified Risk Materials (SRMs)? A1. Per 9 CFR 310.22(a), except when derived from beef imported from countries that demonstrate their status to meet or exceed the food safety status in the USA having prohibited SRMs for use in human food, the following materials from cattle 30 months of age and older are SRMs: the brain, skull, eyes trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) and dorsal root ganglia. SRMs also include the tonsils and distal ileum from cattle of all ages. Q2. Why does FSIS prohibit the use of SRMs for human food? A2. Scientific and epidemiological studies have linked the fatal human disease variant Creutzfeldt-Jacob Disease (vCJD) to exposure to BSE, most likely through human consumption of beef products contaminated with the BSE agent. The tissues designated as SRMs in 9 CFR 310.22(a) are those tissues that are known to contain the BSE agent in cattle infected with BSE, as well as materials that are closely associated with these potentially infective tissues. These materials may harbor the infectious agent before the animal shows any clinical signs of disease. Therefore, FSIS prohibits SRMs from use as human food to minimize potential human exposure to the BSE agent. Canada took similar actions when a single case of BSE was discovered there in May 2003. Q3. How will FSIS ensure that SRMs are not present in human food? A3. Per 9 CFR 310.22(e), slaughter and processing establishments are required to develop, implement, and maintain written procedures to ensure that SRMs are removed from the carcasses of cattle, segregated from edible product, and disposed of as inedible. To ensure that SRMs are not present in edible product, FSIS inspectors will verify that establishments are properly implementing their procedure for the removal, segregation, and disposition of SRMs. The vertebral column and the skull of cattle 30 months of age and older are SRMs and, as such, must be disposed of as inedible. Vertebral columns are also prohibited for use in AMR systems per 9 CFR 318.24. Q4. Must all SRMs be removed at the slaughter establishment? A4. Per 9 CFR 310.22(e), all SRMs must be removed before the product can leave the slaughter establishment except for the vertebral column from cattle 30 months and older. 9 CFR 310.22(g) permits slaughter establishments to ship carcasses or parts of carcasses that contain vertebral columns from cattle 30 months of age and older to another federally 2", "inspected facility for further

processing and removal if both establishments have controls in place to ensure that the SRM portions of the vertebral column are removed and properly disposed of by the processing establishment. For cattle, 9 CFR 310.22(c) specifically states spinal cord must be removed at the slaughter establishment. All SRMs must be removed before the carcass or parts can enter commerce. Q5. Regarding the diagram in FSIS Directive 6100.4, Page 22, Attachment 2, can you clarify what the circled area includes that should not be intended for food? A5. All tissues identified as SRMs in 9 CFR 310.22(a) are designated as inedible and not for human food. The circled area is a stylized representation demonstrating only the bony portion of the vertebral column prior to splitting that is not eligible for human food. It does not mean that all the muscle portions adjacent to the vertebral column (not shown) under the circled area must always also be removed. Chapter 2: Slaughter and Processing Verification Activities General Verification Duties (Design and execution) of HACCP, SSOP and PR Programs Q6. Can a processing establishment control SRMs through a prerequisite program? A6. Yes. Per 9 CFR 310.22(e), the removal, segregation, and disposal of SRMs may be addressed one of three ways under the HACCP system. Establishments may incorporate their procedures for the removal, segregation, and disposition of SRMs into a HACCP, SSOP, or other pre-requisite (PR) program. If the establishment determines in the hazard analysis that the hazard (of SRMs) is not reasonably likely to occur because of a SSOP or other PR program, the removal of SRMs is effected as part of the written SSOP or PR program. According to HACCP requirements in 9 CFR 417.2(a), if a plant determines in its hazard analysis that SRMs are a hazard reasonably likely to occur, control of the hazard by a CCP is required. Q7. Must processing establishments that use boneless beef (beef trimmings, ground beef, etc.) from other inspected facilities develop written procedures for the removal, segregation, and disposal of SRMs and reassess their HACCP programs? A7. Yes. Per 9 CFR 310.22(e) and 9 CFR 417.4(a)(3), all establishments that slaughter cattle and all establishments that process the carcasses or parts of cattle must reassess their HACCP plan and develop, implement, and maintain written procedures for the removal, segregation, and disposal of SRMs. 3", "Verification of Sanitation Procedures regarding SRMs Q8. May an establishment slaughter mixed aged groups of cattle (i.e., those containing animals less than 30 months of age and those 30 months of age or older) without segregating if they clean and sanitize equipment after they process cattle 30 months of age and older before they process cattle less than 30 months of age? A8. Yes. Under 9 CFR 310.22(f), if an establishment slaughters cattle and does not segregate the two age groups, the establishment must either: 1) use dedicated equipment to cut through SRMs or 2) clean and sanitize equipment after it comes in contact with SRMs from the cattle 30 months of age and older, and before it is used on cattle less than 30 months of age. Q9. When cleaning and sanitizing equipment between cattle of different age classes, what is required for equipment to be considered \u201ccleaned and sanitized\u201d? A9. Equipment that comes in contact with SRMs from cattle 30 months of age and older must be cleaned (i.e., washed to remove visible contamination) and then sanitized (i.e., 180\u00b0F degree water) before it can be used on carcasses or parts of carcasses from animals less than 30 months of age. Cleaning means the removal of organic debris that is adhering to the equipment prior to sanitization (this precludes the transfer of SRM to product from cattle less than 30 months of age). However, it is not expected that \u201cclean and sanitize\u201d would be taken to the preoperational state of cleanliness. Q10. Does the splitting saw blade housing area need to be opened and cleaned, or

is just dipping adequate? A10. The \u201cclean and sanitize\u201d procedure must be adequate to remove visible tissue residue and followed by sanitizing with 180\u00b0F water. If the plant can demonstrate the interior surfaces of the saw are maintained in a clean condition to be effectively sanitized by the 180\u00baF water without opening the saw door, it may be an acceptable procedure. Equipment need not be cleaned to a pre-operational state before sanitizing. Q11. When establishments slaughter cattle of mixed ages (both less than 30 months as well as 30 months and older) and slaughters the older and younger animals separately, what is the required intervention for cleaning the equipment (e.g., splitting saw) between animals? A11. All plants that slaughter cattle or process cattle carcasses or parts have the responsibility of developing, implementing, and maintaining written procedures for the removal, segregation, and disposition of Specified Risk Materials (SRMs). These procedures must be incorporated into the plant's HACCP plans, SSOPs, or other prerequisite program. 4", "Under 9 CFR 310.22(f), if an establishment segregates older (30 months and older) from younger (less than 30 months) cattle, and slaughters and processes the younger cattle first, the establishment may use routine operational sanitation procedures to prevent cross contamination of SRMs between all cattle 30 months and older. If cattle 30 months and older are slaughtered, all equipment should be cleaned and sanitized before slaughtering the younger animals to prevent cross-contamination of the edible portions of the carcasses and parts of younger cattle with SRMs from the older cattle. Q12. FSIS notice 7-04 directed that readily identifiable SRM contamination be removed from the carcass. However, for establishments that are splitting carcasses (down the vertebral column) from cattle 30 months of age and older, did the final rule change the requirements for dealing with vertebral bone dust? A12. The final rule does not change the agency\u2019s position on bone dust. The information in FSIS Notice 7-04 has been incorporated into FSIS Directive 6100.4 \u201cVerification Instructions Related to Specified Risk Materials,\u201d which became effective October 1, 2007. The Agency expects readily identifiable SRM material to be removed from the carcass; knife trimming is an accepted method. Q13. Our state inspection program has an establishment that does not identify or segregate carcasses according to age and treats all animals as 30 months and older. Its SSOP states that it will remove all SRMs as if the carcass and parts are from beef animals over 30 months. At what point would the inspector verify sanitation procedures for this establishment once it has removed the spinal column with the band saw? A13. If the establishment does not segregate between beef carcasses less than 30 months of age and carcasses equal to or greater than 30 months of age (in other words, treats all carcasses as 30 months and older), then normal or regular sanitation requirements are expected. Normal sanitation requirements require that any grossly identifiable SRM that can end up in the meat be removed as it is considered to be inedible contamination and not for human food. Since all carcasses are being processed on the processing floor as 30 months and older, then all tissues that are considered SRMs are removed and disposed of as inedible regardless of the age of the animal. Q14. Assuming that the spinal cord has been properly removed by the slaughter establishment, is it permissible for the vertebral column of a carcass or sub-primal, i.e., chuck, to come in contact with edible tissue from another carcass or subprimal? A14. Contamination of meat or meat products by SRMs is based on identification of readily or grossly identifiable (e.g. a piece of spinal cord) SRM tissue. No further action is required so long as the plant has implemented all procedures it deems necessary to prevent potential contamination of meat by readily identifiable SRMs. 5", "Note:

Be aware that additional requirements may apply if the plant is participating in an AMS Export Verification (EV) program. Also, other monitoring, verification, record keeping, or corrective actions may apply depending on how the plant addresses SRMs under the HACCP umbrella (HACCP, SSOP, or PR programs). Q15. Is it permissible to bone a chuck on a table given that the vertebral column will come into contact with food contact surfaces, i.e.. conveyor belts and cutting boards? A15. Yes, the vertebral column may touch food contact surfaces provided the plant has implemented procedures to prevent cross contamination of meat with readily identifiable SRMs. For example, the plant may include in their written SRM control procedures (HACCP, SSOP, or PR program) employees will monitor the spinal cord has been completely removed from each vertebral column of each carcass quarter prior to dropping on the table for breaking. Q16. Is a knife used to cut through SRM material considered contaminated? A16. A knife used to cut through SRMs is a potential source of contamination. FSIS expects the plant to implement whatever procedures it deems necessary to prevent the contamination of meat with SRMs. Any knives used to split SRMs, specifically vertebral columns from cattle 30 months and older, must be cleaned and sanitized before being used on carcasses or products of cattle less than 30 months of age unless the establishment uses dedicated equipment to cut through SRMs. See 9 CFR 310.22(f). Q17. How would FSIS personnel verify that water being re-cycled in a carcass wash cabinet or steam pasteurization cabinet is free of SRM? A17: In operations that utilize re-cycled water in carcass wash cabinets and steam pasteurization cabinets, FSIS personnel would periodically verify that carcasses are washed free of visible bone remnants before the carcass enters the wash cabinet or steam pasteurization cabinet. In addition, FSIS personnel would ensure that the water being recycled is being filtered in accordance with the standard for reuse of water in 9 CFR 416.2(g)(3) to remove any build-up of biological material.

Post-mortem On-Line Verification Activities Q18. Can an establishment collect spinal cord for sale for edible product for human consumption from cattle younger than 30 months of age? A18. Spinal cord material from cattle younger than 30 months of age is not a specified risk material as listed in 9 CFR 310.22. There is no regulation that prohibits an establishment from harvesting spinal cord from cattle younger than 30 months of age for human consumption, provided it is wholesome, unadulterated, and properly labeled. However, 9 CFR 318.6(b)(4) limits the manner in which spinal cord may be used for human food. 9 CFR 318.6(b)(4) provides:

6","(4) On account of the invariable presence of bone splinters, detached spinal cords shall not be used in the preparation of edible product other than for rendering where they constitute a suitable raw material. Detached spinal cords from cattle 30 months of age and older shall not be used as raw materials for edible rendering. Verification of SRM Removal, Segregation, and Disposition; General Recordkeeping Q19. How much of the back bone or vertebral column from cattle 30 months and older needs to be removed? A19. Per 9 CFR 310.22(a) and (c), before beef product can enter commerce outside a federal establishment, the entire vertebral column (back bone) has to be removed except for the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum. The cuts are just beyond both sides of the back bone. This cut will not be through the vertebrae themselves but will go through the transverse processes and ribs. See the two diagrams in Attachment 2 of FSIS Directive 6,100.4 that illustrate transverse processes and ribs in relation to the vertebrae. Q20. If the establishment is removing the meat from around the vertebral column with electric ("wizard\") knives, is this a potential problem when used around the transverse processes of

the thoracic and transverse vertebrae? A20. Based on the diagram in Attachment 2 of FSIS Directive 6100.4, the use of a wizard knife above the transverse processes (non-SRM) appears to be of little risk. The use of a wizard knife below the transverse process of the lumbar vertebrae may be of greater risk. The regulations require each plant to develop effective procedures for the removal, segregation, and disposal of SRMs. It is up to the plant to develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. These procedures must be incorporated into the plant's HACCP plans, SSOPs, or other pre-requisite program. Q21. Can I cut steaks from the loins of cattle 30 months of age or older first and then remove the SRMs associated with the vertebral column? A21. No. Plants are expected to develop procedures in the HACCP plan, SSOP or other pre-requisite program that ensure the effective removal of all SRMs and ensure that SRMs do not contaminate edible product. FSIS has determined that the removal of SRMs from cut steaks increases the potential for contamination of edible tissue with SRMs and presents an unacceptable and unnecessary risk to consumers. Q22. Are very small plants that address SRM removal, segregation and disposition in a prerequisite program (or SSOPs) required to keep daily records

7", "documenting monitoring, verification, recordkeeping and corrective actions, including reassessment? A22. Yes. In the case of SRMs, 9 CFR 310.22 has specific recordkeeping requirements that apply regardless of whether the establishment addresses its procedures for the removal of SRMs in its HACCP plant, SSOP, or other prerequisite program. Records are only required for the days when the plant is in operation and producing product that has SRM tissues. If the establishment chooses to address SRMs in a prerequisite program, then that prerequisite program must meet all the requirements of 9 CFR 310.22 that specify daily recordkeeping. Verification Activities for Tonsil Removal, Segregation and Disposal Q23. How do FSIS inspectors verify that 5 mm of tissue is removed from tongues to ensure removal of lingual tonsils? A23. Inspection program personnel should verify that the establishment has appropriately addressed the use of a skinning machine through verifiable equipment settings and procedures so that a minimum of 5mm, or more, of tissue is removed, and that visible tonsillar tissue (i.e., the SRM) does not remain on the blade or any part of the skinning machine in a manner that may cross-contaminate edible product with SRM material. Q24. In addition to boneless beef, the plant saves head meat and tongues. The rest of the head is condemned. The plant identifies various SRMs except for tonsils. Does the plant need to address removal of tonsils in its hazard analysis? A24. Yes. Tonsils are a SRM in cattle of all ages. The establishment must consider all SRMs in their hazard analysis. SRM hazards should be addressed in the HACCP, SSOP, or PR program. Since tonsils are SRMs, the establishment must remove the tonsils from the edible tongue tissue and address tonsil removal in their written procedures as described in 9 CFR 310.22(e). Verification Activities for the Prohibition of Air-Injection Stunning Q25. The regulations prohibit the use of stunning devices that inject air into the cranial cavity of cattle. Does this include stunning devices which merely use air to power the bolt (as with the more common explosive charge bolt stunners) and may incidentally inject air? A25. No. The regulations do not specifically prohibit pneumatic stunning devices. 9 CFR 310.13(a)(2)(iv)(C) prohibits the use pneumatic stunning devices that inject compressed air into bovine skulls during stunning. This regulation would apply to malfunctioning captive bolt stunners that use compressed air. 9 CFR 313.15(b) specifically prohibits the use on cattle of captive bolt stunning devices that deliberately inject air into the cranial cavity at the end of the penetration cycle.

8", "Verification of Disposal and Rendering of SRMs Q26. What are the record keeping requirements for disposal of SRMs to inedible rendering? Specifically, do we need a separate vertebral column weight with the rendering company providing a record stating that a given weight of SRMs were received and subjected to inedible rendering, or can the establishment maintain a weight ticket for the weight of all bones received and subjected to inedible rendering? A26. Plants are required to maintain daily records sufficient to document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs. Plant records must demonstrate that the plant is following its procedures to remove and dispose of SRMs per 9 CFR 310.22(c) and 310.22(e)(4). Plant records may show separate specific weights of SRMs, but they are not required to do so. The records of plants that receive product with SRMs must show that the SRMs in the specific product have been removed and disposed of per 9 CFR 310.22(g)(4). (4) Maintains records that verify that the official establishment that received the carcasses or parts removed the portions of the vertebral column designated as specified risk materials in paragraph (a)(1) of this section and disposed of them in accordance with Sec. 314.1 or Sec. 314.3 of this subchapter. Q27. Can SRMs be rendered or must they be sent to an approved landfill? A27. SRMs from any bovine that passes AM inspection may be sent to inedible rendering or disposed of in an approved landfill after denaturing as per 9 CFR 314.1 or 314.3. SRMs are not restricted from being rendered unless the animal was condemned by FSIS on AM and samples were collected on-site and are being tested for BSE. When any condemned carcass is being tested on-site for the presence of BSE, FSIS inspection personnel should request that the any part of the carcass or SRMs not go into inedible rendering until a negative BSE result is obtained. Any carcasses or parts from condemned animals that are being tested for BSE may be disposed of in a lined landfill or incinerated in accordance with state or local sanitary codes when a test result has not yet been received. The establishment must maintain accurate records documenting the location of carcass or parts disposal. Chapter 3: Transportation of Carcasses and Parts that Contain SRMs A. Verification at Slaughter Establishments B. Verification at Receiving Establishments Verification at Slaughter (Shipping) Establishments 9", "Q28. Is the shipping establishment required to provide documentation with every shipment? A28. The shipping establishment must include in its hazard analysis decisions on food safety hazards that can occur before, during, and after entry into the establishment. The shipping establishment can ship bone-in product with SRMs (e.g., vertebral columns) as long as it verifies their removal by the receiving establishment. In addition, the shipping establishment must provide documentation to account for all product on every shipment of product containing SRMs (e.g., vertebral columns from cattle 30 months and older) to the receiving establishment. Q29. If the shipping establishment is shipping only boneless product or is removing all SRMs, is there a need to certify every shipment? A29. No. If the establishment is shipping only boneless product or bone-in products from cattle under 30 months, it should provide adequate documentation to the receiving establishment that verifies its SRM control programs are on-going and still in effect. The plant need not necessarily provide such documentation for each shipment. See Question 27 and 37. Q30. Are there any specific requirements for the use of company seals, as described in prior notices dealing with SRMs or FSIS Directive 6100.4? For example, can they simply use a padlock to seal the trailer in transport with specified risk materials (SRMs) on board? A30. The plant is responsible for developing its own controls. Such controls should be effective and may include the use of company seals or

padlocks. The use of a padlock alone does not provide adequate control unless it can be demonstrated that the identity of the product is maintained, or the shipment cannot be opened during transit before reaching the receiving official establishment. Inspection personnel are to ensure that the method of control is equivalent to use of tamper-evident seals and does not allow diversion for other purposes. Any unloading of the controlled products without the knowledge of the establishment, and without providing clear evidence (allowing FSIS verification) that control has been maintained, would not be considered adequate. Q31. FSIS Directive 6100.4 clarifies that beef carcasses from cattle 30 months of age and older can be shipped with vertebral columns still in. Can these carcasses be shipped with spinal cord still present within the vertebral column? These carcasses are shipped split, but there are often mis-splits where the spinal cord is still present. A31. No. 9 CFR 310.22(c) states the following: the spinal cord from cattle 30 months of age and older must be removed from the carcass at the establishment where the animal was slaughtered. 10", "Q32. EST A slaughters cattle and provides carcasses containing the vertebral column to EST B, located in the next town. EST B transports the carcasses from EST A to EST B in a transport vehicle owned and controlled by EST B. The carcasses are further processed at EST B. The Public Health Veterinarian is satisfied that both EST A and EST B have documentation to demonstrate that all carcasses leaving EST A arrive at EST B, and that EST B removes and disposes of all SRM. Based on this, is the establishment required to use company seals? A32. The regulations specify plants must be able to demonstrate \u201ccontrol\u201d of SRMs. The use of company seals is only one of several means to control SRMs. If the establishment has developed an alternative means to maintain control of the adulterated products, the use of company seals is not specifically required. Inspection personnel are to ensure that the method of control is equivalent to use of tamper-evident seals, does not allow diversion for other purposes or unloading of the controlled products without the knowledge of the establishment, and provides clear evidence (allowing FSIS verification) that control has been maintained. Q33: How specific must the records be to verify that the receiving establishment removed and properly disposed of the SRMs? Does the shipping establishment need to receive specific records for each carcass, part, load, etc, or would a blanket letter from the receiving establishment expressing their intent to remove the SRMs be appropriate? A33. Yes. Blanket letters are not an acceptable means to verify removal and disposal of SRMs in bone-in or other products with SRMs by the receiving plant since they typically do not contain specific identifying information. The shipping establishment must have records that demonstrate that the receiving establishment removed and properly disposed of the SRMs from specific products through lot numbers, dates, or other specific product identifying information. Q34. Previously, we used a blanket letter from the receiving plant to document that all SRMs were removed. If a blanket letter that accompanies each shipment of beef products with SRM is no longer acceptable, what information must be included? A34. By blanket letter, we presume you mean a letter of guarantee without specific information identifying the product or shipment. Per 9 CFR 310.22(e)(4), plants are required to maintain daily records sufficient to document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs. Establishments that transport carcasses or parts from cattle 30 months of age and older for further processing will have to obtain these records from the receiving establishment in order to verify that the receiving establishment removed and properly disposed of the SRMs. Records that document the removal of SRMs at

the receiving plant need to identify the specific product. Examples of records that might identify specific product containing SRMs requiring removal may include some or all of the following: 1. date shipped, load number 11","2. date arrived, 3. purchase order (PO) number, 4. product description; number of carcasses\parts, lot number 5. date\shift when processed or SRMs removed 6. product description indicating removal and disposal of SRMs meets requirements in 9 CFR 310.22 and 9 CFR 314. Q35. Is the mark of inspection applied to carcasses from cattle 30 months and older with vertebral columns intact at the shipping facility or only after removal of SRMs? A35. In the preamble discussion of the final SRM rule in Federal Register, Vol. 72, No. 134, July 13, 2007, FSIS announced, \u201clf establishments have implemented appropriate controls, FSIS inspection personnel at the shipping establishment will apply the mark of inspection to carcasses or parts that contain SRM vertebral bones as an accommodation to facilitate their transport to a processing facility where the SRMs can be removed and properly disposed of.\u201d Verification at Receiving Plants Q36. Is it permissible to break the company seal and off-load other products (other than parts which contain vertebral columns) prior to arriving at the final destination with the parts which contain SRMs? A36. Plants need not utilize company seals provided they can implement other controls to maintain identity of product and ensure the effective removal of all SRMs from the specific product before that enters commerce. Q37. Must a receiving establishment have certification from the shipping establishment if it is receiving bone-in products? A37. Each establishment that receives bone-in product must consider what steps, if any, are necessary to ensure that the supplier has properly identified SRMs, if present, for removal or that the product does not contain SRMs because it is from an animal that was younger than 30 months at the time of slaughter. Without adequate supplier documentation demonstrating the on-going identification, segregation, and removal of all SRMs, the products with vertebral column will be deemed from cattle 30 months and older per 9 CFR 310.22(h) and require removal. A prudent establishment may incorporate additional procedures or programs that include purchase specifications or supplier certification. Daily records are required. 9 CFR 310.22(e)(4) states: (4) Recordkeeping requirements. (i) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must maintain daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of the materials listed in paragraph (a) of this section, and any corrective actions taken.

12","Q38. Must a receiving establishment have certification from the shipping establishment if it is receiving only boneless beef products? A38. Plants that only receive only boneless-beef must reassess their hazard analysis for SRMs in their process. Written procedures are not required if the plant determines and can support that SRMs are not a hazard likely to occur in its process. The use of general documentation (e.g., \u201cblanket\u201d letters of guarantee) identifying shipment of only beef products from cattle less than 30 months of age is acceptable here. The written hazard analysis and supporting documentation from the shipping establishment attesting to origin of beef from cattle less than 30 months of age or the complete removal of SRMs in the boneless beef products shipped satisfy the requirements in 9 CFR 310.22(e) and 9 CFR 310.22(h). See Questions 27 and 30. Q39. Assuming that the receiving processing establishment must account for all bone-in beef with (SRM) vertebral column received as identified on the purchase order (PO), and knowing the receiving establishment may take over two days to bone all the product on the purchase order, must the record

verifying that the receiving establishment handled the SRMs correctly be generated after the entire PO is fabricated? A39. Not necessarily. Plants are required to maintain daily records sufficient to document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs. A plant may be able to subdivide lots and produce a record for a partial lot provided the plant can ultimately account for all product listed on a single purchase order (PO). Q40. FSIS permits establishments to transport carcasses that contain vertebral columns from cattle 30 months of age and older (SRMs) to another official establishment. Can an establishment that is inspected under a participating state meat program be the recipient of such carcasses? A40. No. Beef products containing SRMs can not move from a federal establishment to a state-inspected establishment. Such products moving from an establishment under Federal inspection to a plant under a non-Federal inspection system are considered to be in commerce. Beef products containing specified risk material (e.g., vertebral column) are not permitted to move unrestricted in commerce. Addendum Handling of SRMs in Custom Plants Q41. Do the SRM regulations apply to custom slaughter? 13", "A41. Yes. By authority of the FMIA, the Secretary has designated SRMs as inedible and are not eligible for human food. This rule applies to custom as well as inspected animals and products. Q42. Can cattle be farm slaughtered and processed in custom facilities? A42. Only cattle that are healthy, wholesome, and ambulatory (not non-ambulatory disabled) can be farm slaughtered and processed at a custom processing facility. Q43. If a federally inspected establishment has a non-ambulatory disabled cow that it mistakenly or inappropriately intends to slaughter as \"custom exempt,\" should the on-site FSIS inspector segregate it and call a PHV so it can be condemned? A43. If the federally inspected establishment is preparing to custom slaughter a nonambulatory disabled cow (cattle) at a federally inspected establishment, then the animal should be controlled by the inspector using a suitable retain tag with a FSIS padlock (if necessary) until the PHV can condemn it. If the animal has not been presented for inspection and could possibly be removed from the premises without FSIS permission, and there is reason to believe it will be taken elsewhere for slaughter, FSIS inspection program personnel should promptly identify the animal as \u201cUS Inspected and Condemned,\u201d retain it in a pen using a US Retained Tag and a FSIS padlock, if necessary, and notify the PHV, FLS, and District Office (DO). If the establishment is non-federally inspected custom-exempt only operation, the reviewing officer should contact the OPEER via the DO for assistance. Q44. Are custom operations eligible to process cattle 30 months of age and older? A44. Yes, custom operations are allowed to slaughter and process cattle 30 months of age or older, provided they remove and handle the SRMs appropriately as required by 9 CFR 310.22. The SRMs listed in 9 CFR 310.22(a) will be considered to be from cattle 30 months of age or older unless the custom operator can demonstrate that they are from cattle under 30 months of age as stated in 9 CFR 310.22(h). Q45. Can a plant keep custom SRM records in the same records used for SRMs under inspection? A45. Yes. Custom establishments may keep custom records with records for activities that are under federal inspection provided that they are clearly identified as custom records. Q46. Are custom exempt operators required to have written procedures for the removal, segregation and disposition of SRMs and associated records and to keep records as described in 9 CFR 310.22(e)(4)? 14", "A46. No. FSIS does not require custom operator to keep records documenting written procedures describing the removal, segregation, and disposal of SRMs for federally inspected establishments per 9 CFR 310.22(e)(4), unless the custom

operation is subject to all of 9 CFR 416 and uses SSOPs to document removal, segregation, and disposal in inspected beef. Q47. What are the minimum recordkeeping requirements regarding SRMs for custom operations? A47. 9 CFR 303.1(b)(3) describes recordkeeping requirements for custom operators. To facilitate identification of SRMs, FSIS Directive 5930.1, based on 9 CFR Part 320, states that custom operations must keep records that document the following: 1) cattle slaughtered or processed are less than 30 months of age; 2) cattle are ambulatory at time of slaughter per 9 CFR 310.22(h). Custom operations that fail to document the age of cattle slaughtered or processed and the ambulatory status of animals at slaughter are expected to handle the carcass as 30 months and older and remove all SRMs. Be aware custom operations conducted in official establishments are subject to all of 9 CFR Part 16 including SSOPs per 9 CFR 303.1(a)(2)(i). If the official establishment includes its written procedure to remove, segregate, and dispose of SRMs in its SSOP, it must meet all the requirements of 9 CFR 416, including SSOP recordkeeping for its custom operations. Q48. Can T-bones, brains, etc. be saved from older animals (30 months and older) in custom exempt facilities? A48. No. SRMs from custom slaughtered or processed animals are considered adulterated and ineligible for use as human food. All SRMs must be removed before delivering the product to the owner.

15"]},{"file\_name":"FSIS\_GD\_2005\_0002","title":"Label Submission and Approval System (LSAS) Enrollment Process","num":"FSIS-GD-2005-

0002","id":"fa8f13f4c5e54a2f7a373117027902523b1bb1faa2eeb33c5019be3343c443a6","corp\_us":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/import/LSAS\_Enrollment\_Screen\_Guide.pdf","type":"pdf","n\_pages":5,"word\_count":919,"text\_by\_page":["United States Department of Agriculture Food Safety and Inspection Service Import Permit Guide for Products with Small Amounts of Meat and Poultry April 2009","2 Table of Contents Introduction Background Import Permit Overview How We Will Proceed Supporting Documentation How to Apply for an APHIS Permit Next Steps Appendix Examples of Supporting Documentation Selected Sections of FSIS Statutes Notice of Enforcement by the USDA, FSIS, Regarding Imported Food Products Containing a Small Amount of Meat, Poultry, or Processed Egg Product Ingredients Letter to Importers, Brokers, Customs and Border Protection (CBP) and Other Interested Parties Sample VS Form 16-3 and VS Form 16-6A","3 Introduction FSIS is committed to protecting public health and is taking action to strengthen its efforts with regard to imported food products that contain small amounts of meat, poultry, and processed egg products ingredients to ensure food safety and food defense. This guide will help importers comply with the requirements for bringing these products into the United States. Importers that do not follow this guide may not be able to get products of this type into the United States.

Background The Food Safety and Inspection Service (FSIS) regulates meat, poultry, and processed egg products under statutory authority of the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA). Recent food safety incidents involving what are traditionally considered low-risk food products, including the intentional contamination of powdered milk with melamine distributed worldwide, means that FSIS must be vigilant to protect American consumers by ensuring the safety of all products under its jurisdiction. Under the FMIA, PPIA and the EPIA, those attempting to import food products into the U.S. that contain meat, poultry, or egg product ingredients must ensure that these ingredients are from an approved source. To be from an

approved source, the meat, poultry, or egg product ingredient must have been prepared under FSIS inspection or under a foreign inspection system that has been found to be equivalent by FSIS. FSIS has recently discovered that, for various reasons, products containing small amounts of cooked meat or poultry ingredients have entered the country without an assurance that the products are from an approved source. Beginning on June 22, 2009, importers of food products that contain small amounts of meat or poultry will not be granted an import permit by the USDA Animal and Plant Health Inspection Service (APHIS) unless a determination is first made by FSIS that the meat, poultry, or egg product ingredient was prepared under specific conditions that will ensure that these ingredients are not adulterated. Once the determination has been made, food products that contain only a small amount of a meat, poultry, or egg product ingredient are no longer subject to the jurisdiction of FSIS and are then subject to the jurisdiction of the Food and Drug Administration." , "4 Import Permit Overview This guide has been prepared to inform you about how products containing very small amounts of meat, poultry, or processed egg products will be treated when offered for import to the United States. The meat, poultry, or egg product ingredient has always needed to come from an approved source. FSIS, however, has always played a secondary role to the U.S. Department of Homeland Security\u2019s Customs and Border Protection and the U.S. Department of Agriculture\u2019s APHIS in ensuring that this is the case. Recent developments have pointed to a problem with this approach. Beginning on June 22, 2009, FSIS will play a direct role in verifying that product comes from an approved source. This guide is designed to help you understand what FSIS will be looking for in the way of documentation of the source of the meat or poultry product ingredient, and how the process for importing your products to the United States will be affected by FSIS involvement. Beginning on June 22, the following two steps will apply to product containing a small amount of meat or poultry products.

1. The meat or poultry ingredient must originate from an approved source, i.e., must be prepared under FSIS inspection or prepared in a certified establishment in an equivalent foreign inspection system.
2. APHIS restricts some products from entering the United States because of animal disease conditions in the country of origin. Therefore, it will continue to be necessary to contact the APHIS Veterinary Services, National Center for Import and Export, for information on restrictions related to animal diseases and to obtain a permit from APHIS. APHIS regulates imports under statutory authority of the Animal Health Protection Act to ensure that they do not pose a risk to U.S. animal health, and issues a veterinary permit to import meat, poultry, or processed egg products into the United States. An application is made through USDA VS Form 16-3. There are some countries that have no animal disease concerns and therefore do not require an APHIS permit. Nevertheless the product must still originate from equivalent countries and establishments certified to export to the United States. For those products for which a new permit is being sought after June 22, APHIS will not approve the permit until the importer provides assurance for food products that contain a small amount of meat or poultry that the meat or poultry ingredient was produced from an approved source (i.e., prepared under either FSIS inspection in the United States or from a certified establishment from a country approved as having a system equivalent to that of the United States). If documentation can be provided that the meat or poultry ingredient included in a food product comes from an approved source, it can be imported to the United States. APHIS will issue permits for these types of products once FSIS determines that the conditions for import are met. Although some

food products containing a small amount of meat, poultry, or processed egg product ingredient may not pose a threat to animal health, and would be approved for an APHIS-issued veterinary permit (VS Form 16-6A), they may", "5 still not be approved for entry into the United States because these ingredients were not prepared under inspection systems designed to ensure that these ingredients are not adulterated. In other words, they may meet APHIS entry requirements but not meet FSIS entry requirements. While a permit may have been issued based on an attestation by the importer of an approved source of the meat or poultry ingredient, it is still the responsibility of the importer to possess documentation for every shipment of product. FSIS will continue to seek and detain imported products that contain a small amount of meat or poultry ingredient from non-approved sources that have entered the United States. This has been and will continue to be FSIS\u2019 enforcement strategy. How We Will Proceed A transition period of 90 days that began on March 19, 2009, and will extend until June 22, 2009, is being provided before instituting the new import permit application procedure. During this 90-day period, APHIS will provide a 90-day extension for any currently expired import permits, and permits that expire before June 22, 2009, without modification of the current APHIS permit language referencing the need to consult with FSIS regarding compliance with regulatory requirements. After June 22, 2009, importers must be able to provide documented evidence to support the origin of the meat and\or poultry ingredient used in the food product before the APHIS permit is issued. Also after June 22, 2009, in accordance with normal surveillance procedures of product that has entered the United States (for both products that require APHIS permits and products that do not require an APHIS veterinary permit), the importer will need to provide upon request documentation to demonstrate that the meat or poultry ingredient used in the specific product was derived from an approved source. Beginning on June 23, 2009, which is after the 90-day extension granted by APHIS, APHIS will forward the permit application, VS Form 16-3, to FSIS to verify that the meat or poultry ingredient is from an approved source. FSIS will review the application and work with the applicant to ensure that the applicant fully understands what documentation is needed. It is the applicant\u2019s responsibility to provide documented evidence of an approved source to FSIS. The APHIS system allows supporting documentation to be attached. The applicant may save time in the application process by submitting the proper documentation at the time application for a permit is made. As stated above, FSIS will review the documentation and verify that the meat or poultry food product ingredients originated from an approved source. If importers can provide documented evidence that the meat or poultry ingredient included in a food product comes from an approved source, it can be imported into the United States, regardless of the equivalency status of the country producing or exporting the final product. If this condition is not met, the imported food", "6 will not be considered approved for importation into U.S. commerce, and APHIS will deny approval of the permit. Questions may be directed to FSIS at permits@fsis.usda.gov or at (888)-287-7194. Supporting Documentation The importer will be expected to attest to FSIS that the meat or poultry product ingredient is from an approved source. To do so, the importer will need to support the attestation with evidence that the meat or poultry product ingredient came under FSIS inspection or from a certified establishment in an equivalent country. The documentation used to provide this support can take various forms. An importer may provide a bill of lading, an invoice from the producing establishment, or a statement to this effect from a government agency in the country in which

the ingredient originated or the finished product originated. At a minimum, however, the documents will need to provide a basis for determining: \u2022 The country of origin of the meat or poultry product ingredient, and \u2022 The establishment where the meat or poultry product ingredient was processed In addition, if the importer has applied for an APHIS permit, the valid APHIS Permit Application Reference Number needs to be referenced on all supporting documentation. FSIS provides additional examples of the types of documents that may be used to demonstrate that a product is from an approved source in the Appendix. Once again, if there are any questions regarding the type of documentation needed, please contact FSIS at permits@fsis.usda.gov or at (888)-287-7194. How to Apply for an APHIS Permit Importers may apply for an APHIS import permit by completing and submitting the permit application (VS Form 16-3) to APHIS. The application form may be found on the APHIS Web site at <http://www.aphis.usda.gov/>. Importers may complete the application manually by downloading and faxing the form to (301) 734-8226. The application may also be completed and submitted via ePermits. ePermits is a Web-based system that allows users to apply for a permit online, check the status of the application, view issued permits or other responses, and more. It uses a USDA-wide system for login called USDA eAuthentication. To use ePermits for most application permit types, you will need to register for an eAuthentication account with Level 2 access. For more information, go to the \u201cRegister to Use ePermits\u201d page at <http://www.eauth.egov.usda.gov/eauthCreateAccount.html>.,"7 VS import permit applications, VS Form 16-3, may also be obtained by writing to the Import\Export Animal Products Program at: USDA, APHIS, VS National Center for Import and Export Products Program 4700 River Road, Unit 40 Riverdale, MD 20737-1231 For further information or questions concerning import applications, contact the Animal Products Program at (301) 734-3277 or by facsimile at (301) 734-8226. User fees are charged for all import services for restricted animal products. All applications for a veterinary permit to import materials or transport organisms and vectors must be accompanied by payment before processing can begin. Acceptable methods of payment are: check, money order (payable to USDA, APHIS), VISA, MasterCard, American Express, or an APHIS User Fee Credit Account. User fee credit accounts are recommended if there are more than six fee activities per year. To establish a User Fee Credit Account, you will need to complete a User Fee Credit Application. You can obtain the User Fee Credit Application online; by telephone: (877) 777-2128 (U.S. and Canada only) or (612) 370-2291 (User Fee Help Line); or by writing to USDA, Marketing and Regulatory Programs-Business Services, Minneapolis Business Site, Accounts Receivable Team, P.O. Box 3334, Minneapolis, MN 55403. Next Steps For products containing processed egg products as ingredients, FSIS expects to not implement procedures for several months due to the more complicated process of ascertaining whether processed eggs or shell eggs are used in the food products. For the next 12-18 months, FSIS will conduct outreach to importers, manufacturers of products containing small amounts of meat and poultry ingredients, industry associations, and other interested parties. FSIS also intends to evaluate trade impacts and publish a Federal Register document that will solicit public comments with respect to the requirement that importers shipping food products to the United States that contain small amounts of meat, poultry, or processed egg ingredients ensure that these ingredients are from an approved source, produced under sanitary conditions, and in a secure environment."8 Appendix", "9 Examples of Supporting Documentation The following are some examples of the documentation that importers will

need to submit to FSIS and APHIS.", "10 A Product Formulation May Be Used to Provide Evidence of the Proportion of Meat, Poultry, or Processed Egg Product Ingredients in the Product Formulation", "", "11 An Export Certificate or a Health Certificate May Be Used to Identify the Country of Origin of Meat, Poultry, or Processed Egg Product Ingredients and to Identify the Establishment Where the Meat, Poultry, or Processed Egg Product Ingredients Were Processed", "", "", "", "", "", "", "", "", "", "", "", "12 A Product Label May Be Used to Provide Evidence that the Product Labeling Does Not Represent the Finished Product as a Meat Food Product, Poultry Food Product, or Egg Product", "", "13 Selected Sections of FSIS Statutes Poultry Products Inspection Act Title 21 of the United States Code, Section 453 (21 U.S.C. 453) Sec. 453. Definitions (f) The term \"poultry product\" means any poultry carcass, or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof, excepting products which contain poultry ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the poultry food industry, and which are exempted by the Secretary from definition as a poultry product under such conditions as the Secretary may prescribe to assure that the poultry ingredients in such products are not adulterated and that such products are not represented as poultry products. Federal Meat Inspection Act Title 21 of the United States Code, Section 601 (21 U.S.C. 601) \u00a7601. Definitions (j) The term \"meat food product\" means any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products. This term as applied to food products of equines shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats. Egg Products Inspection Act Title 21 of the United States Code, Section 1033 (21 U.S.C. 1033) \u00a71033. Definitions (f) The term \"egg product\" means any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and which may be exempted by the Secretary under such conditions as he may prescribe to assure that the egg ingredients are not adulterated and such products are not represented as processed egg products. Links to the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act may be found on the FSIS Web site at

[http://www.fsis.usda.gov/regulations\\_&\\_policies/acts\\_&\\_authorizing\\_statutes/index.asp](http://www.fsis.usda.gov/regulations_&_policies/acts_&_authorizing_statutes/index.asp)", "14 Notice of Enforcement by the USDA, FSIS, Regarding Imported Food Products Containing a Small Amount of Meat, Poultry, or Processed Egg Product Ingredients", "Notice of Enforcement by the United States Department of Agriculture, Food Safety and Inspection Service Regarding Imported Food Products Containing a Small Amount of Meat, Poultry, or Processed Egg Product Ingredients The Food Safety and Inspection Service (FSIS) regulates domestic and imported meat, poultry, and egg products under statutory authority of the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA).

All food products for human consumption made using a small amount of meat, poultry or processed egg product ingredients for which these ingredients were not prepared under the U.S. inspection system or a certified establishment from an approved foreign food regulatory system are not eligible to enter the United States. USDA\U2019s Animal and Plant Health Inspection Service (APHIS) regulates imports of products of animal origin under statutory authority of the Animal Health Protection Act (AHPA) to ensure they do not pose a risk to U.S. animal health. Although some food products containing a small amount of meat, poultry, or processed egg product ingredient may not pose a threat to animal health and would be eligible for an APHIS-issued permit (VS Form 16-6A), they may remain ineligible for entry into the United States because these ingredients were not prepared under inspection systems designed to ensure that these ingredients are not adulterated. While FSIS statutes provide authority to exempt certain foods containing relatively small amounts of meat, poultry or processed egg product ingredients from FSIS inspection, FSIS must ensure that these ingredients are not adulterated. Accordingly, the meat, poultry, and\or processed egg product ingredient(s) used in FSIS-exempted products must be prepared under USDA\FSIS inspection or under a foreign inspection system approved by FSIS. A list of countries eligible to export meat, poultry or egg products to the United States (i.e., amenable food products generally composed of more than a small amount of meat or, poultry, or processed egg product ingredient, or is represented as a meat food product or poultry food product) is published on the FSIS web site at the following address: [http://www.fsis.usda.gov/PDF/Countries\\_Products\\_Eligible\\_for\\_Export.pdf](http://www.fsis.usda.gov/PDF/Countries_Products_Eligible_for_Export.pdf) The eligibility of the origin of the meat or poultry ingredient is a condition stated on the permit(s) issued by APHIS Veterinary Services (VS). Effective March 19, 2009, any permit issued on and after this date by APHIS will have the following condition included: Importer is also responsible for obtaining any required authorization from the USDA, Food Safety and Inspection Service (FSIS). Meat, poultry, or egg product ingredients used in FSIS-exempted products must be prepared under USDA, FSIS inspection or under a foreign inspection system approved by FSIS. Contact FSIS via e-mail at: [permits@fsis.usda.gov](mailto:permits@fsis.usda.gov) or by telephone at: 888 287 7194 for information regarding approved foreign inspection systems and foreign establishments approved by FSIS to export to the United States. A list of countries eligible to import meat, poultry or egg products is published on the FSIS web site at the following address: [http://www.fsis.usda.gov/PDF/Countries\\_Products\\_Eligible\\_for\\_Export.pdf](http://www.fsis.usda.gov/PDF/Countries_Products_Eligible_for_Export.pdf) Importers must be able to provide documented evidence, upon request by FSIS, to support the origin of the meat and\or poultry ingredient used in the food product(s) identified on the APHIS permit.", "FSIS Notice of Enforcement for Exempted Products Page 2 As part of an enhanced enforcement program for food products containing a small amount of meat or poultry, any new permit application submitted to APHIS after June 19, 2009, will be reviewed and approved by FSIS to ensure the meat and\or poultry ingredient originates from an eligible source. The importer will provide to FSIS the supporting documentation that is necessary to allow the food product to enter the United States. If this condition is not met, the imported food will be considered ineligible for importation into U.S. commerce. Ineligible product found in commerce may be subject to destruction. Note that APHIS is providing a 90-day extension for any permit that expires on or before June 19, 2009. At the end of the 90-day extension, the importer will be required to submit a new application, which will comply with the conditions outlined above. Further, the implementation of the enhanced enforcement program for products containing a

small amount of processed egg products will be forthcoming and likely reflect those for product containing a small amount of meat or poultry. The effective date for food products containing small amounts of processed egg products will be provided by USDA prior to implementation. Supporting documentation can take various forms, but as a minimum, FSIS will need documents that (1) evidence the proportion of meat, poultry, or processed egg product ingredients in the product formulation, (2) identify the country of origin of these ingredients, (3) identify the establishment where these ingredients were processed, (4) provide assurance that no other meat, poultry, or processed egg product ingredient is incorporated into the finished product, (5) evidence that the product labeling does not represent the finished product as a meat food product, poultry food product, or egg product, (6) identify of the facility where the finished product, as represented by the labeling, was manufactured, and (7) for products labeled as flavored, provide assurance that such products do not actually contain a meat, poultry, or processed egg ingredient. In addition, the valid APHIS Permit Number [or Application Reference Number] needs to be referenced on all supporting documentation. It should be noted that this enhanced enforcement program does not include food products flavored to resemble meat, poultry or processed egg products if such food products do not actually contain a meat, poultry or processed egg product ingredient. Also, the program does not include products not intended for use as human food such pet feed or pharmaceuticals. Questions concerning this enforcement notice may be directed to FSIS at the following e-mail address:

permits@fsis.usda.gov or at Toll Free number (888-287-7194). March 19, 2009", "15 Letter to Importers, Brokers, Customs and Border Protection (CBP) and Other Interested Parties", "United States Department of Agriculture Marketing and Regulatory Programs Animal and Plant Health Inspection Service Veterinary Services National Center for Import and Export 4700 River Road Unit 40 Riverdale, MD 20737 Phone: 301-734-3277 Fax: 301-734-8226 Subject: Changes to the US Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) Import Permitting Process for Food Safety and Inspection Service (FSIS) Exempted Food Products containing Meat and Poultry Ingredients. To: Importers, Brokers, Customs and Border Protection (CBP) and Other Interested Parties On January 30, 2009, the USDA, APHIS, VS at the request of the USDA, FSIS cancelled certain import permits for FSIS exempted food products containing poultry ingredients. At the same time, VS suspended the issuance of permit applications submitted to APHIS, VS, National Center for Import and Export (NCIE) for all FSIS exempted food products containing small amounts of meat and poultry ingredients. As you are aware, USDA, APHIS regulates products of animal origin under statutory authority of the Animal Health Protection Act to ensure they do not pose a risk to U.S. animal health. USDA, FSIS regulates domestic and imported meat, poultry, and processed egg products under statutory authority of the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act for public health. Together, APHIS and FSIS have implemented several policy changes to ensure that imported animal origin products do not pose a risk to either US animal health or public health. For those importers of FSIS exempted food products that contain small amounts of meat and poultry ingredients, FSIS and APHIS have revised how such permits will be issued. The recent suspension of the permitting process has caused a backlog in processing applications and we regret the inconvenience. We are currently processing all permit applications that we receive. Please be advised that all permit applications for FSIS exempted food products containing small amounts of meat and poultry ingredients

submitted to APHIS after June 19, 2009, will be reviewed by FSIS prior to APHIS issuing permits. As part of the new process, after permit applications are submitted to APHIS, they must be reviewed and approved by FSIS to ensure the meat and\or poultry ingredients in such food products originate from an eligible source, i.e., prepared under FSIS inspection or in a foreign establishment certified by a foreign inspection system approved by FSIS. Importers will be required to provide documented evidence directly to FSIS to support the origin of the meat and\or poultry ingredient used in the food product(s) identified on the APHIS permit application. If this condition is not met, FSIS will advise APHIS that the imported food product is ineligible for importation into U.S. commerce, and a permit will not be issued. VS - Safeguarding Animal Health <http://www.aphis.usda.gov> National Center for Import and Export An Equal Opportunity Employer Phone (301) 734-3277, FAX (301) 734-8226","A list of countries eligible to export meat, poultry or processed egg products to the United States (i.e., amenable food products generally composed of more than a small amount of meat or, poultry, or processed egg product ingredients, or is represented as a meat food product or poultry food product) can be found on the FSIS web site at the following address:

[http://www.fsis.usda.gov/PDF/Countries\\_Products\\_Eligible\\_for\\_Export.pdf](http://www.fsis.usda.gov/PDF/Countries_Products_Eligible_for_Export.pdf) Questions for FSIS may be directed to FSIS at the following e-mail address: [permits@fsis.usda.gov](mailto:permits@fsis.usda.gov) or at Toll Free number (888-287-7194). Question for APHIS may be directed to Dr. Christopher Robinson at [Christopher.c.robinson@aphis.usda.gov](mailto:Christopher.c.robinson@aphis.usda.gov) or at phone number (301) 734-3277. Karen A. James-Preston Assistant Director Technical Trade Services National Center for Import-Export VS - Safeguarding Animal Health <http://www.aphis.usda.gov> National Center for Import and Export An Equal Opportunity Employer Phone (301) 734-3277, FAX (301) 734-8226","16 Sample VS Form 16-3 and VS Form 16-6A

[http://www.aphis.usda.gov/import\\_export/index.shtml](http://www.aphis.usda.gov/import_export/index.shtml)","Failure to supply all applicable information can delay the processing of this application. PLEASE TYPE OR PRINT CLEARLY No controlled material, organisms or vectors may be imported or moved interstate unless the data requested on this form is furnished and certified (9 CFR 94, 95, and 122). According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The time required to complete this information collection is estimated to average .0166 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The valid OMB control number for this information collection is 0579-0015, 0094, 0183, 0213, and 0245. U.S.

DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
VETERINARY SERVICES National Center for Import-Export, Products Program 4700 River Road, Unit 40 Riverdale, MD 20737-1231 1. MODE OF TRANSPORTATION (Please \"X\"): AIR SEA LAND ANY 2. U.S. PORTS OF ENTRY APPLICATION FOR PERMIT TO: IMPORT OR TRANSPORT

CONTROLLED MATERIAL OR ORGANISMS OR VECTORS 4. SHIPPER(s): (Name and Address of producer\shipper) 3. IMPORTER (Name, organization, complete address, telephone and fax number of individual who will receive and be responsible for the imported material) 5.

DESCRIBE THE MATERIAL TO BE IMPORTED (Provide the following information, as applicable: Animal species and tissue of origin of animal product, country of origin of the animals from which the raw animal product was sourced, processing country, recombinant system and genetic inserts, antibody immunogens, stabilizers, nutritive factors of animal origin in media.)

(COMPLETE VS FORM 16-7 for cell cultures and their products.) 6. QUANTITY, FREQUENCY OF IMPORTATION, AND EXPECTED COMPLETION DATE (estimate) 7. PROPOSED USE OF MATERIAL AND DERIVATIVES (Also, for animal pathogens or vectors, describe facilities\biosafety procedures) 8. IF FOR USE IN ANIMALS, SPECIFY THE ANIMAL SPECIES 9. TREATMENT OF MATERIAL PRIOR TO IMPORTATION INTO THE U.S. (Processing\bis\purification methods, including time at specific temperatures, pH, other treatments, disease safeguards, etc.) 10. METHOD OF FINAL DISPOSITION OF IMPORTED MATERIAL AND DERIVATIVES I CERTIFY AS AUTHORIZED BY THE COMPANY\bINSTITUTION THAT I REPRESENT, THAT THIS MATERIAL WILL BE USED IN ACCORDANCE WITH ALL RESTRICTIONS AND PRECAUTIONS AS MAY BE SPECIFIED IN THE PERMIT. 11. SIGNATURE OF APPLICANT 12. TYPED NAME AND TITLE 13. DATE 14. APHIS USER FEE CREDIT ACCOUNT NO. OR METHOD OF USER FEE PAYMENT (for VISA or Mastercard include number and expiration date). VS FORM 16-3 (NOV 99) Print Clear Form", "U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE VETERINARY SERVICES RIVERDALE, MARYLAND 20737 UNITED STATES VETERINARY PERMIT FOR IMPORTATION AND TRANSPORTATION OF CONTROLLED MATERIALS AND ORGANISMS AND VECTORS PERMIT NUMBER C-109257 Commercial DATE ISSUED 04/29/2009 DATE EXPIRES 04/29/2010 NAME AND ADDRESS OF SHIPPER(S) We Got Chicken 1234 Long Beak Road Shanghai CHINA CC: AVIC, VS, MD (Annapolis, MD) FSIS, DC (Washington, DC) FDA (Rockville, MD) NAME AND ADDRESS OF PERMITTEE INCLUDING ZIP CODE AND TELEPHONE NUMBER Simone J Dedrick Chicke Crosses The Road, Inc. 4700 River Road, Unit 40 Riverdale, Maryland 20737 301-734-5890 U.S. PORT(S) OF ARRIVAL AS APPLICABLE MODE OF TRANSPORTATION ANY AS REQUESTED IN YOUR APPLICATION, YOU ARE AUTHORIZED TO IMPORT OR TRANSPORT THE FOLLOWING MATERIALS Avian - Moon Cakes containing eggs RESTRICTIONS AND PRECAUTIONS FOR TRANSPORTING AND HANDLING MATERIALS AND ALL DERIVATIVES THIS PERMIT IS ISSUED UNDER AUTHORITY CONTAINED IN 9 CFR CHAPTER 1, PARTS 94,95 AND 122. THE AUTHORIZED MATERIALS OR THEIR DERIVATIVES SHALL BE USED ONLY IN ACCORDANCE WITH THE RESTRICTIONS AND PRECAUTIONS SPECIFIED BELOW (ALTERATIONS OF RESTRICTIONS CAN BE MADE ONLY WHEN AUTHORIZED BY USDA, APHIS, VS). oAdequate safety precautions shall be maintained during shipment and handling to prevent dissemination of disease. o\*\*\* THIS PERMIT IS INVALID WITHOUT PERMITTEE'S SIGNATURE \*\*. \I, Simone J. Dedrick, certify that this material will be used in accordance with all restrictions and precautions as are specified in this permit, o\*\*\* o\*\*\* signed: \_\_\_\_\_ . \\*\*\* o\*\*\*Each shipment must be accompanied by an ORIGINAL certificate endorsed by a full-time, salaried veterinarian of the agency responsible for animal health of the GOVERNMENT OF XXXXXXXXXXXX certifying that: 1) egg is the only ingredient of animal origin in the exported product, and 2) the egg material in the exported product was heated to a minimum internal temperature of 80\u00b0C, OR heated at a minimum of 180\u00b0C for at least 15 minutes OR the yolks were heated inside the cakes at a minimum of 180\u00b0C for at least 30 minutes. o[This certification must CLEARLY correspond to the shipment by means of an invoice number or shipping marks or lot number or other identification method. An English translation must be provided.] continued on subsequent page(s)..... TO EXPEDITE CLEARANCES AT THE PORT OF ENTRY, BILL OF LADING, AIRBILL OR OTHER DOCUMENTS ACCOMPANYING THE SHIPMENT SHALL BEAR THE PERMIT NUMBER SIGNATURE Christopher Robinson TITLE National Center - Import - Export NO. LABELS VS FORM 16-6A (MAR 95) Replaces VS Form 16-3A and 16-28 which

are obsolete Page 1 of 2 SAMPLE", "U.S.DEPARTMENT OF AGRICULTURE APHIS \V VETERINARY SERVICES, RIVERDALE, MARYLAND 20737. ATTACH TO U.S. VETERINARY PERMIT - C-109257 RESTRICTIONS AND PRECAUTIONS: (continued from Permit Form VS 16-6) o\*\*\*Products imported into the United States in compliance with this permit may be released and shipped from the U.S. port of arrival to any address in the United States. The permittee name and address must appear on shipping invoice\manifest. olmporter is also responsible for obtaining any required authorization from the USDA, Food Safety and Inspection Service (FSIS). Meat, poultry, or egg product ingredients used in FSIS-exempted products must be prepared under USDA, FSIS inspection or under a foreign inspection system approved by FSIS. Contact FSIS via e-mail at: permits@fsis.usda.gov or by telephone at: (888) 287-7194 for information regarding approved foreign inspection systems and foreign establishments approved by FSIS to export to the United States. A list of countries eligible to export meat, poultry or egg products to the U.S. is published on the FSIS web site at the following address:

[http://www.fsis.usda.gov/PDF/Countries\\_Products\\_Eligible\\_for\\_Export.pdf](http://www.fsis.usda.gov/PDF/Countries_Products_Eligible_for_Export.pdf) olimported material may be subject to regulations enforced by the United States Food and Drug Administration (FDA). Importer must contact the Division of Import Operations and Policy at Area Code (301) 443-6553. oThis permit does not exempt the permittee from responsibility for compliance with any other applicable federal, state, or local laws and regulations. oA copy of this permit must be included with the shipping documents. For imported materials, these documents must be presented to CBP Agricultural Specialists upon arrival at the U.S. port of entry.

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Page 2 of 2 SAMPLE", "United States Department of Agriculture Food Safety and Inspection Service The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or a part of an individual\u2019s income is derived from any public assistance program. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA\u2019s TARGET Center at (202) 720-2600 (voice and TDD). To file a complaint of discrimination write to USDA, Director, Office of Civil Rights, 1400 Independence Avenue, S.W., Washington, DC 20250-9410 or call 1-800-795-3272 (voice) or (202) 720-6382 (TDD). USDA is an equal opportunity provider and employer. Office of Outreach, Employee Education and Training April 2009  
17"]}, {"file\_name": "FSIS\_GD\_2006\_0002", "title": "Compliance Guidelines to Control Listeria Monocytogenes in Post-Lethality Exposed Ready-To-Eat Meat and Poultry Products", "num": "FSIS-GD-2006-

0002", "id": "9a025b2bf5bce23f21b52514253bb6e3b10d2fabe57bf819be7633ae81f8be42", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Lm\_Rule\_Compliance\_Guidelines\_May\_2006.pdf", "type": "pdf", "n\_pages": 100, "word\_count": 41278, "text\_by\_page": [{"Peer Reviewed Articles of Antimicrobials Approved by the FDA and FSIS as Safe and Suitable Ingredients Title Author Chemical Website Address Acidified Sodium Chlorite Chemical and Technical Assessment Madduri V. Rao Acidified Sodium Chlorite"}]

<http://www.fao.org/ag/agn/agns/files/jecfa68/CTA%20Acidified%20Sodium%20Chlorite%20%20Final2%202007.pdf> Acidified Sodium Chlorite N/A Acidified Sodium Chlorite <http://www.meatupdate.csiro.au/new/ACidified%20Sodium%20Chlorite.pdf> Application of Acidified Sodium Chlorite in the Drinking Water to Control Salmonella serotype Typhimurium and Campylobacter jejuni in Commercial Broilers P. Mohyla, S. F. Bilgili, O. A. Oyarzabal, C. C. Warf, and G. K. Kemp Acidified Sodium Chlorite <http://www.auburn.edu/~oyerzoa/publications/2007JAPR/u20101.pdf> Monochloramine Versus Sodium Hypochlorite as Antimicrobial Agents for Reducing Populations of Bacteria on Broiler Chicken Carcasses Scott M. Russell And Stephen P. Axtell Calcium Hypochlorite and Sodium Hypochlorite <http://www.zentox.com/PathX/PathX/u2010JFP.pdf> Effect of Cetylpyridinium Chloride (Cecure\u00ae CPC Antimicrobial) on the Refrigerated Shelf Life of Fresh Boneless, Skinless Broiler Thigh Meat Y. Bai, K.R. Coleman, C.W. Coleman and A.L. Waldroup Cetylpyridinium Chloride <http://www.pjbs.org/ijps/fin809.pdf> Microbiological Impact of Spray Washing Broiler Carcasses Using Different Chlorine Concentrations and Water Temperatures J. K. Northcutt, D. P. Smith, M. T. Musgrove, K. D. Ingram, and A. Hinton, Jr. Chlorine <http://ps.fass.org/cgi/reprint/84/10/1648.pdf> Chemical carcass decontamination to control Salmonella and Campylobacter in poultry meat N.M. Bolder , F.F. Putirulan and L.J.A. Lipman Chlorine Dioxide <http://iba.zwans.com/fullpapers/10853.pdf> Effectiveness of 1,3\u2010Dibromo\u20105,5 Dimethylhydantoin on Reduction of Escherichia coli O157:H7\u2010and SalmonellaInoculated Fresh Meat Norasak Kalchayanand, Terrance M. Arthur, Joseph M. Bosilevac, Dayna M. Brichtaharhay, Michael N. Guerini, Steven D. Shackelford, Tommy L. Wheeler, And Mohammad Koohmaraie DBDMH [http://www.ars.usda.gov/SP2UserFiles/Place/543805\\_30/2009720151.pdf](http://www.ars.usda.gov/SP2UserFiles/Place/543805_30/2009720151.pdf) Comparison of Electrolyzed Oxidizing Water with Various Antimicrobial Interventions to Reduce Salmonella Species on Poultry K. A. Fabrizio, R. R. Sharma, A. Demirci, and C. N. Cutter Electrolytically Generated Hypochlorous Acid <http://ps.fass.org/cgi/reprint/81/10/1598.pdf> Efficacy of Electrolyzed Oxidizing Water for Inactivating Escherichia coli O157:H7, Salmonella enteritidis, and Listeria monocytogenes K. S. Venkitanarayanan, G. O. Ezeike, Y. Hung, and M. Doyle Electrolytically Generated Hypochlorous Acid <http://aem.asm.org/cgi/reprint/65/9/4276.pdf> Inactivation of Escherichia coli O157:H7 in Poultry Chiller Water Using Combined Ultraviolet Light, Pulsed Electric Field and Ozone Treatments Michael Ngadi, Xue Jun, James Smith and G.S.V. Raghavan Ozone <http://www.pjbs.org/ijps/fin186.pdf> The Microbial and Quality Properties of Poultry Carcasses Treated with Peracetic Acid as an Antimicrobial Treatment L. J. Bauermeister, J. W. J. Bowers, J. C. Townsend, and S. R. McKee Peracetic Acid <http://ps.fass.org/cgi/content/abstract/87/11/2390> Validating the Efficacy of Peracetic Acid Mixture as an Antimicrobial in Poultry Chillers Laura J. Bauermeister, Jordan W. J. Bowers, Julie C. Townsend, And Shelly R. McKee Peracetic Acid [http://apt.allenpress.com/perlserv/?request=getabstract&doi=10.1043%2F0362028X\(2008\)071%3C1119%3AVTEOPA%3E2.3.CO%3B2&ct=1](http://apt.allenpress.com/perlserv/?request=getabstract&doi=10.1043%2F0362028X(2008)071%3C1119%3AVTEOPA%3E2.3.CO%3B2&ct=1) Effectiveness of trisodium phosphate, lactic acid, and acetic acid in reduction of E .coli and microbial load on chicken surfaces F. M. Bin Jasass Trisodium Phosphate <http://academicjournals.org/AJMR/PDF/Pdf2008/Mar/Jasass.pdf> }, {"file\_name": "FSIS\_GD\_2005\_0003", "title": "Food Standards and Labeling Policy Book", "num": "FSIS-GD-2005-0003", "id": "f601e1546c3cb502aa1fafd55f2924db1d2bfde8d7c815c15db557fdb09dcdef", "corp": "corporation"}]

us": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Labeling-Policy-Book.pdf", "type": "pdf", "n\_pages": 188, "word\_count": 60446, "text\_by\_page": ["LESS THAN DAILY SANITATION PROCEDURES COMPLIANCE GUIDELINE 10-19-09 I. PURPOSE This guidance document was developed to help establishments that are considering or planning to implement less than daily (LTD) sanitation procedures. These guidelines provide an overview of the planning, development, implementation and maintenance of LTD sanitation procedures. These guidelines address FSIS\u2019 expectations with respect to regulatory requirements, especially those relative to Sanitation SOPs in 9 CFR 416.11416.16 and for prerequisite programs under 9 CFR 417.2 and 417.5. II. BACKGROUND As a common practice, establishments have conducted complete cleaning and sanitizing of their operations on a daily basis. However, there have never been FSIS regulations that required an establishment to conduct cleanup every twenty-four hours or within any other specified period. For the purposes of this document, \u201ctraditional\u201d cleaning addresses the complete cleaning that is typically performed every twenty-four hours and includes procedures such as: \u2022 Removing the gross contamination from equipment and production areas either by hand or with water of a suitable temperature; \u2022 Applying chemicals (detergent, acid or alkali soap) to emulsify or dissolve the food (protein) materials and fats adhering to the equipment; \u2022 Scrubbing the soiled surfaces, if necessary; \u2022 Rinsing to remove the dissolved food and fat materials with water of a suitable temperature; or \u2022 Applying a sanitizer (e.g., chemical disinfectant) to the cleaned food contact surfaces, in accordance with the label instructions to address any remaining microorganisms. Establishments can choose to extend their production operations without conducting \u201ctraditional\u201d cleaning every twenty-four hours. They can select an alternative cleaning frequency provided they ensure that, as a result of the methods utilized, insanitary conditions are not being created that may result in adulteration or contamination of product. Establishments utilizing an alternative sanitation frequency would still conduct \u201ctraditional\u201d cleaning except it would be less frequent, for example one time per week. In addition, they typically will conduct more frequent operational sanitation procedures that may include: - 1 -,"Less Than Daily Sanitation Procedure- Compliance Guideline \u2022 Removing the gross contamination from equipment and production areas either by hand or with water of a suitable temperature; \u2022 Applying chemicals (detergent, acid or alkali soap) to emulsify or dissolve the food (protein) materials and fats adhering to the equipment; An establishment using LTD sanitation procedures must meet all of the sanitation regulatory requirements . 9 CFR 416.1 through 416.5, Sanitation Performance Standards (SPS), and 9 CFR 416.11 through 416.16, Sanitation SOP, set out those requirements. In addition, establishments that implement these procedures as part of a prerequisite program will need to ensure that they address the prerequisite programs in their ongoing verification activities as a means to ensure that the prerequisite programs are being implemented such that they continue to support the decisions made in the hazard analysis (9 CFR 417.1(a)). NOTE: Establishments that develop a LTD sanitation program but continues to conduct their complete pre-op sanitation procedures daily would not be considered to have a LTD sanitation program. These establishments would still be subject to FSIS pre-op sanitation procedures (01B01 and 01B02) as they are scheduled in PBIS III. IMPLEMENTING LESS THAN DAILY SANITATION PROCEDURES When developing an LTD sanitation program, an establishment should consider all factors that

may impact its program. In most cases, FSIS expects that microbial factors affecting sanitary conditions will be the primary focus of LTD sanitation programs. It is well known that bacterial growth is a function of time, temperature, and environmental factors (available nutrients and moisture). In addition, bacteria found on food contact surfaces will affect the condition of the product. Microbes cannot be directly observed by organoleptic methods; therefore, it is likely that most LTD sanitation programs will need to include sampling methods to measure levels of bacterial contamination on food contact surfaces. As guidance for the development of procedures of this type, this document will address the following issues:

- \u2022 Risk considerations
- \u2022 Direct food contact surfaces
- \u2022 Indirect food contact surfaces
- \u2022 Non-food contact surfaces
- \u2022 Lot size or recall implications
- \u2022 Consistency of operation and potential impact on product
- \u2022 Pathogens
- \u2022 Chemicals
- \u2022 Allergens
- \u2022 Collection of Meaningful Data
  - \u2022 Initial (i.e., Baseline)
  - \u2022 Less Than Daily Sanitation Procedure- Compliance Guideline
  - \u2022 Ongoing
- \u2022 Analysis of Data
  - \u2022 Initial (i.e., analysis of baseline data before implementation of LTD sanitation procedures)
  - \u2022 Ongoing (data collected after implementation of LTD sanitation procedures)
- \u2022 Maintenance of the Sanitation SOP (9 CFR 416.14)
- \u2022 Use of analysis to evaluate the effectiveness of the LTD sanitation procedures
- \u2022 Documentation Demonstrating Effectiveness of the Sanitation SOP, including LTD sanitation procedures (9 CFR 416.16)
- \u2022 Maintenance of Sanitation SOP records that demonstrate that the sanitation procedures, including LTD sanitation procedures, are effective in preventing contamination of product.

\u2022 Addressing Noncompliances

A. RISK CONSIDERATIONS

Before implementing LTD sanitation procedures, establishments should consider multiple factors that might have the potential to contaminate product, such as:

- \u2022 Direct Food Contact Surfaces: Surfaces that routinely contact products directly during the course of operations can be the site of growth of bacteria, including spoilage organisms, and these bacteria can contaminate the product when contact occurs. The establishment needs to consider the risk of cross-contamination when designing its LTD sanitation procedures. EXAMPLES: saws, cutting boards, table tops, inside surfaces of choppers, grinders and other equipment.
- \u2022 Indirect Food Contact Surfaces: These areas have a reasonable likelihood of product contact through the course of normal production. Under proper conditions, bacterial growth and spoilage growth are likely in areas where incidental food contact occurs because these surfaces typically are not thoroughly cleaned as often as direct food contact surfaces. The establishment should consider such areas when designing LTD sanitation procedures. EXAMPLES: doorways and posts, employee clothing, outside surfaces of equipment, and rail pull switches.
- \u2022 Non-Food Contact Surfaces: Growth of pathogens and spoilage organisms may be present in areas where incidental food contact accidentally occurs. These

3", "Less Than Daily Sanitation Procedure- Compliance Guideline

surfaces may become a source of direct product contamination or create insanitary conditions that ultimately may affect sanitary conditions in the rest of the establishment. The establishment should consider such areas when designing LTD sanitation procedures.

EXAMPLES: floors, walls, and undersides of tables and work platforms.

\u2022 Lot Size or Recall Implications: The establishment should consider how its sanitation procedures and frequencies affect the determinations of lot size and amount of product represented by any FSIS or company sample. The effectiveness of sanitation may greatly affect the amount of product involved if a recall of product became necessary.

\u2022 Consistency of Operations and Potential Impact on Product: The establishment should consider whether changes to

operational sanitation procedures for extended periods between complete operational sanitation procedures would affect its ability to maintain sanitary conditions, thereby preventing the contamination or adulteration of product \u2022 Pathogens: In addition to the general microbial growth, the establishment should consider pathogen growth on surfaces that might ultimately contaminate the final product. For example, Listeria monocytogenes can form microscopic biofilms on equipment surfaces that the establishment may find difficult to remove during LTD sanitation procedures and that may later affect product through direct contact.

\u2022 Chemicals: Detergents and sanitizers (chemicals) can be toxic at certain levels. The establishment should consider accumulation of residual chemicals on surfaces. \u2022

Allergens: the establishment may wish to consider other information such as the effects allergens might have on all products produced between complete sanitation cleaning procedures. The allergenic proteins can become fixed to food contact surfaces during on-going operations (i.e., between complete sanitation procedures) and potentially become a labeling issue in other foods being processed that would not otherwise contain the ingredient. B.

COLLECT MEANINGFUL DATA After an establishment has considered the risks associated with its operation, the establishment will need to consider what information it should collect. The initial data collected likely will be related to microbiological conditions of the equipment.

However , many factors (e.g. ph, water activity, product characteristics) could affect the product and therefore affect the type, and amount , of data that the establishment ultimately decides is needed to ensure that the alternative cleaning procedures are effective and that sanitary conditions are maintained. 4", "Less Than Daily Sanitation Procedure- Compliance Guideline 1. Initial Testing (i.e. baseline data collection) When developing a sanitation program, the establishment should consider all factors that may have an impact on the program and address them when developing a Sanitation SOP. A microbiological baseline study may provide a starting point for such consideration. Baseline testing, while not required, is highly recommended as a means to develop criteria that can be used to evaluate the ongoing effectiveness of a LTD sanitation program. Using the criteria developed from the baseline study, ongoing microbial testing may be an effective means to demonstrate that all food contact surfaces are cleaned often enough to prevent the creation of insanitary conditions and adulteration of product. If the establishment chooses not to conduct a baseline study, it may be difficult to demonstrate that the use of a LTD sanitation procedure will meet the sanitation regulatory requirements. 2. Microbiological Baseline Studies: The regulations do not require baseline studies, nor are there any requirements for levels of testing in a baseline study.

However, a baseline study can serve as a basis from which the establishment can determine the microbiological operating levels and limits for its facility under normal operating conditions. A baseline study would include evaluating the establishment\u2019s sanitary conditions following \u201ctraditional\u201d pre-operational and operational sanitation procedures before implementation of any changes in sanitation procedures or frequencies. The generation of baseline microbial data provides a mechanism that enables the establishment to determine where it started under normal operating conditions. The data then forms the basis for comparison of the alternative procedures to the \u201ctraditional\u201d procedures. In establishments planning on implementing LTD sanitation procedures, baseline studies can provide information for the establishment to use to compare the efficacy of LTD sanitation procedures in controlling microbial levels to those of its traditional sanitation procedures. The

establishment can use the data obtained from the traditional operations to develop acceptable tolerance levels that would become part of a statistical process control (SPC) monitoring program. When designing a microbial sampling program, the establishment should survey its operation to determine what measurements of its process can provide an accurate assessment of overall sanitation. Because of the number of variables that could exist, adequate time should be taken to collect enough data to account for all the variables. Some attempt should be made to determine \u201cworst case\u201d scenarios. For example, a \u201cworst case\u201d scenario would consider: \u2022 When to sample (e.g., at the end of the last production shift during the time of day or year when the ambient temperature is the hottest or most humid)  
5,"Less Than Daily Sanitation Procedure- Compliance Guideline \u2022 Where to sample (e.g., areas on the equipment where microbial contamination is most likely to occur; are most likely to affect products; or most likely to harbor bacteria) 3. Baseline Study: Example There is no required format for baseline studies. Establishments may develop baseline studies following the steps below:

- 1) Describe testing protocol
- a) Describe the focus of testing (for example)
- b) Aerobic Plate Count (APC)
- c) Total Plate Count (TPC)
- 2) Identify sample collection methodology
- a) Sponge
- b) Swab
- c) SpongeSicle
- d) Product
- i) Type (pre or post packaged as applicable)
- ii) Amount
- 3) Identify frequency of testing
- a) How many times per day or week or month
- b) How many pieces of equipment or product per test
- 4) Identify sample sites
- 5) Sampling of each identified food contact surface should be conducted using a statistically validated sampling plan so that adequate baseline data are collected for each food contact surface throughout the baseline study.
- 6) Randomized patterns for sampling each food contact surface are recommended.
- 7) Define any relevant measurements that are used by the establishment. For example:
- a) CFU/in<sup>2</sup>
- b) CFU/cm<sup>2</sup>
- c) CFU/g
- 8) Describe analysis of results
- a) Identify statistical methods
- b) Initial analysis
- c) On-going analysis
- 9) Describe comparison of microbial results (for example)
- a) Traditional daily sanitation vs. LTD sanitation
- b) Start of operation vs. end of operations
- c) Start of operations vs. during operations
- d) Comparison of results at different sample sites to determine most effective sites for ongoing monitoring
- 10) Determine operational limits
- a) sanitary vs. insanitary
- 11) Determine actions to be implemented when limits are exceeded

a) Initial 6,"Less Than Daily Sanitation Procedure- Compliance Guideline b) On-going 4. On-going testing Once the establishment determines the microbial conditions that exist under traditional operating conditions, it may decide to conduct on-going microbial testing as part of the LTD sanitation procedures. These data will enable the establishment to compare the initial baseline test results to the on-going test results in order to ensure that the procedure is effective over time. The establishment could then demonstrate that the alternative sanitation procedures are effective, and that product is not contaminated. Ideally, the establishment has collected baseline data so that it knows the sanitation conditions under normal operational conditions. The establishment should conduct ongoing testing after it makes the change to LTD sanitation procedures for comparison with the baseline results. This verification testing provides the establishment with an indication of continued success of the LTD sanitation procedures after initial implementation. In order to demonstrate the effectiveness of the sanitation procedures, the ongoing testing program should be designed to make comparisons with the baseline program. \u2022 Ongoing testing should use methods that are the same as those used to collect baseline data \u2022 Ongoing testing should use similar sample sites or a relevant subset, as the baseline sites \u2022 Initially, ongoing testing should be conducted at a

high frequency in order to demonstrate that the establishment is consistently maintaining sanitary conditions Over time, if the data demonstrate that the program is effective, the establishment may be able to support a reduced sampling frequency. C. ANALYSIS OF DATA Demonstrating the ongoing effectiveness of alternate frequency sanitation procedures requires more than simply collecting raw data. The data should be meaningful (i.e., it provides a basis to assess whether the LTD sanitation procedures and the Sanitation SOP are effective in ensuring food safety, whether product is being contaminated or adulterated, and whether insanitary conditions are being created). The establishment should consider what the data mean, and how they relate to the ongoing effectiveness of the sanitation procedures. Records should document that the results of the baseline study and ongoing testing (or other information) demonstrate compliance with sanitation requirements. Valid conclusions can only be made if the establishment has adequately developed and implemented the design of their cleanup program.

7", "Less Than Daily Sanitation Procedure- Compliance Guideline 1. Initial (i.e. baseline or pre-implementation data): The establishment should analyze its findings in order to establish the effectiveness of its LTD sanitation procedures. Establishments should gather the information and data and put them together in a clear concise format that ties all the information together. Ultimately, the establishment\u2019s records should show that it is maintaining sanitary conditions, and that product is not contaminated or adulterated.

2. Ongoing (data collected once procedure implemented): It is very important that the establishment compare the data collected during ongoing testing to the initial baseline data. The data analysis should demonstrate that, over time, after the procedures have been implemented, microbial levels on equipment are no higher than the baseline levels obtained before the implementation of the new procedures. The comparison of these data should consider general trends over an extended period of time. While small daily variations may be insignificant and are to be expected, the data analysis should demonstrate that over time, microbial levels on equipment have not increased (i.e. are not statistically significant) because of the implementing of the new procedures. The establishment should monitor microbial levels on equipment surfaces as a means of demonstrating that the new procedures are effective. Ultimately, the indicator of success in the use of the procedures of this type is an establishment's ability to demonstrate, by means of data or other documentation, the continual effectiveness of the new procedures and frequencies to maintain sanitary conditions and prevent direct contamination or adulteration of product.

D. MAINTAINING THE SANITATION SOP (9 CFR 416.14) Regardless of where establishments choose to incorporate their LTD sanitation procedures (Sanitation SOP, GMP or other prerequisite program), 9 CFR 416.14 requires that establishments maintain their Sanitation SOP and ensure that it continues to be effective. The establishment needs to routinely evaluate the effectiveness of the Sanitation SOP as a means to ensure that the procedures and frequencies continue to prevent the contamination or adulteration of product. There are no regulations that specify how an establishment is to determine whether the Sanitation SOP is effective. Typically, the establishment will periodically review Sanitation SOP records to evaluate the effectiveness of the Sanitation SOP. As previously stated, microbial testing is not a regulatory requirement in Sanitation SOPs; however, it can be one means used by an establishment to demonstrate the effectiveness of its sanitation program. In the absence of microbial data to support the baseline or ongoing testing, the establishment would need to provide other records to document

sanitary effectiveness. Ideally, an establishment's comparison of microbial testing data should indicate that the microbial levels in the facility resulting from the use of the LTD sanitation procedures are the same as, or lower, than those resulting from the use of the establishment's traditional sanitation procedures and frequencies. 8", "Less Than Daily Sanitation Procedure- Compliance Guideline If the data show that the microbial levels associated with the LTD sanitation program are significantly higher than those of the traditional program, the efficacy of the program in preventing product contamination or adulteration would be in question. An establishment would want to review as many available establishment records as possible, including FSIS Noncompliance Records (NR), in order to provide a basis that would assure the establishment that the Sanitation SOP is effective. However, the establishment should not claim that the lack of FSIS NRs demonstrate that the Sanitation SOP is effective. NRs address specific regulatory noncompliances. The absence of NRs provides little assurance of the overall efficacy of the establishment's sanitation procedures and frequencies in preventing product contamination or adulteration. The most important aspect of the evaluation of the Sanitation SOP is that when the establishment determines that there are issues of concern, it responds to those issues. Operations within an establishment rarely remain unchanged. Without periodic adjustments to the Sanitation SOP, or any sanitation related program, it may be difficult to demonstrate that the procedures in place continue to prevent the contamination or adulteration of product. The following is a summary of what an establishment may do to ensure that the Sanitation SOP remains effective:

- 1) Routinely review and evaluate the Sanitation SOP as required in 416.14 (i.e., not simply when FSIS suggests it)
- a) Evaluate Sanitation SOP records and consider what did or did not work
- i) Evaluate monitoring procedures and frequencies and consider if they are working
- ii) Evaluate previous corrective actions
- (1) Consider if they have been fully implemented and effective
- (2) Consider if or how they could be improved
- b) Consider whether the Sanitation SOP procedures have prevented the contamination or adulteration of product (e.g., have there been situations where contamination or adulteration of product, or contamination of food contact surfaces occurred?)
- c) Review the results of any microbiological testing and consider whether those results reflect an environment that will not contaminate or adulterate product
- d) Review any SOP, GMP or prerequisite sanitation related programs that are in use and consider what effect they appear to be having on the Sanitation SOP (e.g., have they been implemented as written? Does their implementation help ensure that product is not contaminated or adulterated?)
- i) Employee Hygiene
- ii) Employee Training
- iii) Product Reconditioning

2) Revise Sanitation SOPs as often as necessary. Sign and date the Sanitation SOP if changes are made (9 CFR 416.12(b))

9", "Less Than Daily Sanitation Procedure- Compliance Guideline

E. DOCUMENTATION DEMONSTRATING THE EFFECTIVENESS OF THE SANITATION SOP AND LESS THAN DAILY SANITATION PROCEDURES

FSIS believes that sanitation is, as addressed in the Pathogen Reduction\HACCP Final Rule (Federal Register, Thursday July 26, 1996, Page 38805 \u2013 38855), essential for food safety, and that sanitary facilities or equipment create an environment suitable to prevent the contamination or adulteration of products. As a result, establishments are required to develop Sanitation SOPs as a prerequisite to effective operation of their food safety system and as a means to minimize the risk of direct product contamination and adulteration. Documentation related to the implementation of the Sanitation SOP, as required by 9 CFR 416.16, provides verifiable evidence that the establishment's Sanitation SOP is effective at maintaining

sanitary conditions, which prevents the adulteration of product. The establishment is required to maintain records associated with the implementation of the Sanitation SOP. If the LTD sanitation procedures are part of the Sanitation SOP, then the records generated by the implementation of the Sanitation SOP, and all the procedure therein, are subject to FSIS review under 9 CFR 416.17. Because the Sanitation SOP and any additional sanitation programs are a prerequisite to food safety, it is essential that documentation be available to demonstrate that these programs are achieving their goals, and that establishments are verifying that the implementation of these programs continue to support any decisions related to food safety. FSIS will review those records in order to verify that the establishment is implementing the program as written and that it is effective.

**F. ADDRESSING NONCOMPLIANCES**

The LTD sanitation procedure should include the means by which the establishment will address noncompliances. If the LTD sanitation procedure is incorporated into the Sanitation SOP, the establishment would be expected to implement corrective actions in accordance with 9 CFR 416.15. 10"]}, {"file\_name": "FSIS\_GD\_2006\_0007", "title": "Letter to Industry about the Safe Handling Labeling of Uncooked, Breaded, Boneless Poultry Products", "num": "FSIS-GD-2006-0007", "id": "b597783a5d5473350f531df6f96636384dd54797bd595b1d17ba1cea3a5a657a", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Letter\_to\_Industry\_on\_Frozen\_Uncooked\_Poultry.pdf", "type": "pdf", "n\_pages": 2, "word\_count": 780, "text\_by\_page": ["1 MOBILE SLAUGHTER UNIT COMPLIANCE GUIDE This guidance document follows the procedures for guidance documents in the Office of Management and Budget\u2019s (OMB) \u201cFinal Bulletin for Agency Good Guidance Practices.\u201d More information on OMB\u2019s policies and procedures can be found on the FSIS Web page: [www.fsis.usda.gov/Significant\\_Guidance/index.asp](http://www.fsis.usda.gov/Significant_Guidance/index.asp) FSIS encourages those who own or manage mobile slaughter units to avail themselves of this guidance in meeting the pertinent regulatory requirements. This document includes recommendations rather than regulatory requirements. FSIS requests that all interested persons submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days. The document will be updated in response to comments. Comments may be submitted by either of the following methods:

**eRulemaking Portal:** This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov> Follow the online instructions at that site for submitting comments.

**Mail, including floppy disks or CD-ROMs, and hand- or courier-delivered items:** Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Room 2-2127, George Washington Carver Center, 5601 Sunnyside Avenue, Mailstop 5474, Beltsville, MD 20705-5474.

**Instructions:** All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2010-0004. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

**2 I.DEFINITION** Mobile slaughter unit: A mobile slaughter unit (MSU) is a self-contained slaughter facility that can travel from site to site.

**II.PURPOSE** This guideline is intended for owners and managers of a new or existing red meat or poultry MSU who want their establishment to come under Federal inspection and continue operations in accordance with Food Safety and Inspection Service (FSIS) regulations. MSU operators are

subject to the same regulatory requirements that apply to a fixed (\u201cbrick and mortar\u201d) facility. This guideline includes the procedures necessary to receive a Federal grant of inspection, unique concerns that may arise with mobile slaughter units, and links to review regulatory requirements and resources.

**III. ADVANTAGES OF MOBILE SLAUGHTER**

The meat and poultry industries have become increasingly consolidated, while consumer interest in locally grown and specialty products has continued to expand<sup>1</sup>. The industry consolidation has resulted in a lack of U.S. Department of Agriculture (USDA) or State-inspected establishments available to small producers of livestock and poultry in some remote or sparsely populated areas. These small producers often serve the needs of their community and the growing demand for forage-fed, natural, and organic meat and poultry products. MSUs can serve multiple small producers in areas where slaughter services might be unaffordable or otherwise unavailable. Therefore MSUs can help small producers meet this demand, expand their businesses and create wealth in rural communities.

The advantages of a MSU versus a fixed structure include lower processing costs, reduced stress on animals, lower capital investment, and less resistance from municipalities and neighbors<sup>2</sup>.

**IV. WHAT IS NEEDED TO OPERATE A MSU UNDER FEDERAL INSPECTION**

A. Grant of Inspection

Contact the District Office (DO) that has jurisdiction over the geographic area in which you will primarily operate the MSU. The DO will send you an information packet and an Application for Federal Meat, Poultry or Import Inspection, FSIS Form 5200-2. A list of DO locations and contact information is available (see [http://www.fsis.usda.gov/Contact\\_Us/Office\\_Locations\\_&\\_Phone\\_Numbers/index.asp](http://www.fsis.usda.gov/Contact_Us/Office_Locations_&_Phone_Numbers/index.asp)).<sup>3</sup>

There are seven basic steps required for obtaining Federal meat and poultry inspection in the Federal Grant of Inspection Guide (see [http://www.fsis.usda.gov/Regulations\\_&\\_Policies/Grant\\_of\\_Inspection\\_Guideline/index.asp](http://www.fsis.usda.gov/Regulations_&_Policies/Grant_of_Inspection_Guideline/index.asp)). By clicking on each bullet heading under the Steps Required for Obtaining Federal Meat and Poultry Inspection, you will see a detailed description of each step, including regulatory citations, forms, and sample forms. The steps are:

1. File an Application for Inspection
2. Facilities Must Meet Regulatory Performance Standards
3. Obtain Approved Labels or Brands
4. Obtain Approved Water Source Letter
5. Obtain Approved Sewage System Letter
6. Provide a Written Standard Operating Procedure for Sanitation
7. Provide a Written Hazard Analysis and HACCP Plan

Only the application for a Federal grant of inspection is to be submitted to the DO. All other documents relative to the above list are to be maintained on file at the facility and made available for review by inspection program personnel (IPP) upon request. DO representatives are available to assist you with the application process and to answer any additional questions you might have concerning regulatory requirements. Upon receipt of your application and completion of all preliminary items, a designee of the DO will review the MSU. If all documentation and the facility comply with regulatory requirements, then a conditional grant of inspection will be issued to allow you 90 days to validate your HACCP program.

**Operating in Several Districts:** For a MSU that will operate in more than one district, the owner is to first file an application for inspection in the Headquarters district in which the unit will primarily operate. The Headquarters DO will assign the primary establishment number (e.g. Est. 00). A separate application is then sent by the MSU owner to each additional district in which operations will be conducted. The remaining districts will use the same establishment number, but with an additional alphabetical suffix (e.g. 00 A, 00 B, etc.) that identifies the establishment when it operates within that specific district. Plant profiles in each district will record that the

MSU is \u201cding business as\u201d 00, 00 A, 00 B. The Headquarters DO may designate a liaison or case specialist to coordinate information sharing between districts regarding MSU activities and regulatory compliance trends. This will also facilitate food safety assessments which will be the primary responsibility of the Headquarters DO. (A food safety assessment considers all food safety aspects that relate to an establishment and its environment, the nature and", "4 source of all materials received, and the plant\u2019s processes and products.) The grant holder is to ensure that IPP have access to the MSU at all times whenever a request for access is made, in accordance with the Federal Meat Inspection Act, Sec. 606 (\u201caccess at all times, day or night, whether the establishment be operating or not\u201d) and the Poultry Products Inspection Act, Sec. 11 (\u201caccess to their places of business and opportunities to examine\u2026\u201d). Scheduling: Every time the MSU moves to a different location, and before conducting any slaughter operations, the respective DO with oversight of that location will be notified by the MSU operator. FSIS realizes that ordinary schedules described in the regulations may not be applicable to most MSUs. However, the MSU operator needs to provide to any district in which he or she will operate a schedule of days and hours of operation in accordance with Title 9 of the Code of Federal Regulations (9 CFR) 307.4(d)(1) for meat or 381.37(d)(1) for poultry. The operations schedule needs to be provided as much in advance as possible, allowing adequate time for the DO to arrange staffing and inspection procedure schedules necessary for FSIS services. At least two to four weeks advance notice is recommended, depending upon the degree of predictability and consistency of MSU operations. The submitted work schedule is to specify the daily clock hours of operations and lunch periods. Any changes in the schedule must be approved by the DO. If the MSU will operate on a seasonal basis only, the dates of operation are to be specified for the DO. Voluntary suspension of operations to cover temporary inactive periods not to exceed 120 calendar days can be requested in writing through DO channels. NOTE: The staffing of mobile slaughter units may present a challenge to FSIS. It may be difficult for the Agency to find personnel to provide inspection at the location at which a unit intends to operate. Thus, communication with the DO by the operator of the mobile unit is particularly important. B. Sanitation Requirements Meat and poultry establishments with a grant of inspection from FSIS are to conduct operations under all of the provisions of 9 CFR Part 416--Sanitation (see [http://www.access.gpo.gov/nara/cfr/waisidx\\_07/9cfr416\\_07.html](http://www.access.gpo.gov/nara/cfr/waisidx_07/9cfr416_07.html)).", "5 A detailed explanation of the sanitation regulations, including methods already proven to meet the regulatory requirements, is in the Sanitation Performance Standards Compliance Guide (see [http://www.fsis.usda.gov/Regulations\\_&\\_Policies/Sanitation\\_Performance\\_Standards/index.asp](http://www.fsis.usda.gov/Regulations_&_Policies/Sanitation_Performance_Standards/index.asp)). 1. Sanitation Performance and Unique Considerations for MSUs a. Water In order to receive a grant of inspection all Federal establishments must provide FSIS personnel with documentation certifying that the supply of water, no matter what the source, complies with the National Primary Drinking water regulations (40 CFR Part 1410). The MSU may operate at a location where it can directly utilize either a municipal water supply or private well water. Alternatively, it is permissible to transport water in a tank to the slaughter location as long as there is a water report certifying the potability of the water source. This documentation needs to be made available for FSIS review at all operational locations before initiating slaughter activities at that specific site. For a private well, this documentation is to be renewed semiannually for any recurring slaughter location (e.g., a specific ranch or farm where the MSU

operates at various times throughout the year). Some MSUs will be working in conjunction with a FSIS inspected (official) fabrication facility where they obtain their water. In all cases, the availability of documentation certifying that water sources are potable is a continuing requirement. Water supply requirements are covered in the sanitation regulations in 9 CFR 416.2(g)(1). IPP will verify that the MSU meets these requirements in accordance with FSIS Directive 5000.1(see

<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5000.1Rev3.pdf>). b. Sewage and Waste Water Disposal The MSU operator is to provide FSIS with a letter of approval from the local health authority for any specific slaughter site. A MSU will usually not have traditional sewage facilities unless there is access to a private septic system provided at the slaughter location. Some MSUs may have a holding tank and will haul waste water for discharge at a MSU docking station. Alternatively, waste water disposal might be adapted for the specific situation. For example, blood and waste water might be dispersed on the producer's property well away from any stream or drainage, provided the local health authority permits this. In any case, the MSU operator is to provide a letter", "6 from the local health authority relating to waste water handling at any specific operational site. This is required to obtain and uphold terms of the grant. c. Grounds and Facilities The walls, floors, and ceilings of the MSU are to be built of durable materials impervious to moisture which can be cleaned and sanitized as necessary to prevent product adulteration or creation of insanitary conditions (9 CFR 416.2(b)(1and 2)). Adequate heat and insulation will help prevent freezing of water pipes during cold weather operation. The operator is to maintain the MSU and implement a program to prevent harborage or entry of pests. Methods to prevent pest entry could include: 1) Keep doors and windows closed as much as possible. 2) Use high output fans to prevent entry of flying insects. 3) Spray and bait for flies prior to the day of slaughter. 4) Apply a spray-on surfactant or a mixture of water and mineral oil to the hide of livestock before skinning to reduce the risk of flies contaminating edible product. 5) Control of rodents around docking stations or any other operational areas, and where the MSU will be stored during non-operational hours. Pest control substances must be approved by the Environmental Protection Agency (EPA) for use in food processing environments and be used in a manner that does not adulterate product or create insanitary conditions. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA reviews pesticide formulation, intended use, and other information; registers all pesticides for use in the United States; and prescribes labeling, use, and other regulatory requirements to prevent unreasonable adverse effects on the environment, including humans, wildlife, plants, and property. Any meat or poultry establishment using a pesticide must follow the FIFRA requirements. The grounds immediately surrounding the MSU operational site are to be maintained to prevent creation of insanitary conditions that could lead to adulteration of product. Positioning the MSU on a well-draining concrete or gravel pad can be helpful for controlling manure, mud, pooling water, and other sanitation problems. Bleeding animals on a sloped concrete pad equipped with lines to a drain field is recommended, or alternatively, a gravel bed can allow blood and water to drain and prevent pooling. The position of doors into the MSU should be considered relative to prevailing winds to help control airborne dust, agricultural chemicals, or odors associated with the operational site. If a combustion engine generator is used as a power source for the MSU, then exhaust emissions should not create odors which affect sanitary operation of the MSU.", "7 Adequate ventilation in the small space

of a MSU is of utmost importance to control odors, vapors, and condensation to prevent adulteration of product (9 CFR 416.2(d)). b. Sanitary Facilities and Office Accommodations for Inspection Personnel Hand washing and toilet facilities are required for IPP and MSU employees (9 CFR 416.2(h)(1-2)). While these provisions may not be located inside the MSU, they should be available within a \u201creasonable\u201d distance. For example, portable toilets and hand sanitizer outside the MSU with hand washing facilities available inside the unit would be considered reasonable accommodations. Some MSUs will operate on the producer\u2019s property and farm toilet facilities may suffice if within a reasonable distance. Other MSUs may operate in close proximity to a public building, or an associated official fabrication facility, where these accommodations are located. In all cases, the DO will determine what constitutes \u201creasonable\u201d accommodations. Inspectors need not have an official office within a MSU if it operates as part of a combination or patrol assignment. Alternatively, the USDA inspector may have access to an office in an associated official fabrication facility. Any other arrangements for the equivalent of office space and required facilities in accordance with 9 CFR 307.1 and .2, or 381.36, are acceptable if approved by a designee of the DO. However, it is recommended that the MSU provide a desk with adequate lighting, chair, cooler or refrigerator space for storing laboratory samples (e.g., residue or microbiological specimens) collected by IPP, and a cabinet that can be padlocked for storing USDA brands and official documents. The DO will determine the logistics on a case-by-case basis for IPP phone communications (e.g., use of cell phones) as well as arrangements for FSIS shipment of laboratory samples (either directly from the MSU operational site or by means of inspector transport of samples to a central package pick-up location).

2. Sanitation Standard Operating Procedures (Sanitation SOPs)

A federally inspected MSU is to comply with 9 CFR 416.11 and 416.12 requiring establishments to develop, implement, and maintain written standard operating procedures for sanitation. All recordkeeping requirements of 9 CFR 416.16 apply to a MSU. Records are to be kept in the MSU and made available to IPP upon request. Additional information regarding Sanitation SOPs is available through Commonly Asked Questions from Small and Very Small Plants on Sanitation Standard Operating Procedures (see

[http://www.fsis.usda.gov/Help/FAQs\\_SSOP\\_3/index.asp](http://www.fsis.usda.gov/Help/FAQs_SSOP_3/index.asp)).

"8 C. Hazard Analysis and Critical Control Point (HACCP) Systems

A written hazard analysis and slaughter HACCP plan tailored to your MSU will need to be developed by an individual trained in HACCP principles before you will be granted Federal inspection (9 CFR 304.3(b) or 381.22(b)), and thereafter you will need to implement and maintain them in order to continue operations. A hazard analysis is the process used to determine the food safety hazards reasonably likely to occur in the production process and to identify the measures that the establishment can apply to control those hazards. Whenever a hazard analysis identifies a food safety hazard that is reasonably likely to occur, a written HACCP plan must be developed. Typical slaughter hazards might include, but are not limited to: 1) Control of feces, ingesta, or milk contamination; 2) Disease-producing microorganisms (E. coli O157:H7; Salmonella); and 3) Chemical, pesticide, or drug residues. Chilling and cold storage of product may occur within the MSU or in an associated fabrication facility, depending upon hazard analysis decisions. The MSU operator is not restricted to producing only whole or partial carcasses, but any further processing activities are to be included in the HACCP plan and associated supporting documents. Additionally, all 9 CFR 417.5 recordkeeping requirements apply to a MSU. The hazard analysis and HACCP plan for a

MSU need not be overly complicated. However, a MSU operator may want to utilize an outside consultant who is not employed by the establishment to develop its food safety system. The FSIS Outreach office (see [http://www.fsis.usda.gov/About\\_FSIS/OOEET/index.asp](http://www.fsis.usda.gov/About_FSIS/OOEET/index.asp)) can provide information on HACCP workshops, as well as a self-study guide and video. They can also assist in directing you to contacts for the Small Business Regulatory Enforcement Fairness Act (SBREFA). Additionally, each State assigns HACCP Coordinators to assist establishments with the development of HACCP programs (see

[http://www.fsis.usda.gov/contact\\_us/state\\_haccp\\_contacts\\_&\\_coordinators/index.asp](http://www.fsis.usda.gov/contact_us/state_haccp_contacts_&_coordinators/index.asp)). D. Slaughter Regulatory Concerns 1. Meat (Livestock) -- MSU operators are to comply with all livestock slaughter regulations described in 9 CFR Parts 307 through 314. This includes microbiological testing requirements such as generic E. coli testing (9 CFR 310.25(a)). Humane Slaughter of Livestock is addressed in 9 CFR Part 313. FSIS recommends that slaughter facilities, including MSUs, use a systematic", "9 approach to humane slaughter, with a focus on treating livestock in a way that includes minimizing excitement, discomfort, and accidental injury when unloading or driving animals. The MSU operator is responsible for meeting all regulatory requirements for humane slaughter of livestock and should carefully consider the design of any holding pens, driveways, and ramps available at any specific operational site, as well as the methods used to adequately restrain animals and produce immediate insensibility upon stunning. In most circumstances, if a firearm is used then the head cannot be saved for edible product, except for the tongue. FSIS authority for enforcing humane handling requirements commences when animals begin being handled by either the MSU operator or livestock owner as they are staged for slaughter. FSIS Directives 6900.1 and 6900.2 contain additional information on humane handling (see

<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/6900.1Rev1.pdf>

<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/6900.2Rev1.pdf>). Each MSU operational site is to provide an ante-mortem pen for IPP to observe live animals at rest and in motion, as well as a holding pen for animals designated as U.S. Suspects. Any diseased or disabled animals requiring further inspection are to be provided a covered pen sufficient to protect them from adverse weather conditions. Livestock carcasses of varying species, or custom slaughtered carcasses held and transported in the MSU, are to have adequate separation or protective wraps in order to minimize potential cross-contamination caused by carcass-to-carcass contact. Inedible articles are to be denatured and handled in accordance with 9 CFR 325.11 and 325.13. 2. Poultry -- MSU operators are to comply with all poultry slaughter regulations in 9 CFR Part 381, including slaughter in accordance with good commercial practices as described in 9 CFR 381.65(b). Generic E. coli testing requirements apply in accordance with 9 CFR 381.94(a). Inedible articles are to be denatured and handled in accordance with 9 CFR 381.95 and 381.193. 3. Special labeling claims (such as \u201call natural\u201d) for meat and poultry products require prior-approval by the Labeling and Policy Development Division (LPDD) (ph: 301-504-0878, FAX: 301-504-0873). You are to submit to this office a copy of the label plus supporting documentation or statements to substantiate any special claims. Links are included in the [www.fsis.usda.gov](http://www.fsis.usda.gov) Website for: Animal Raising Claims, Natural and Organic Claims, and \u201cCertified Organic\u201d. (see", "10

[http://www.fsis.usda.gov/Regulations\\_&\\_Policies/claims\\_guidance/index.asp](http://www.fsis.usda.gov/Regulations_&_Policies/claims_guidance/index.asp)). 4. Proper carcass and offal disposal may be accomplished in a variety of ways. Please contact your local

health regulatory authority for more information about alternatives in your area. For example, denatured meat or poultry offal might be allowed to remain on the farm to be composted for use as a soil amendment when permitted by local regulations. Many producers prefer this practice because soil nutrients will be increased, and the higher cost of rendering will be avoided.

5. If FSIS retained product held for further examination is to be transported in the MSU to an official facility for a Public Health Veterinarian\u2019s determination of product disposition, then the establishment needs to obtain FSIS approval of the means used to secure the carcass and parts in accordance with 9 CFR 307.2(h) and 310.3, or 381.77.

6. Exotic animals (e.g., bison, elk) or poultry (e.g., migratory waterfowl, game birds) slaughtered under voluntary Federal inspection are to comply with 9 CFR Part 352 or Part 362, respectively.

V. Additional Information The Niche Meat Processor Assistance Network, sponsored in part by USDA\u2019s Rural Development Agency and the Cooperative State Research, Education, and Extension Service (CSREES) provides additional helpful information about designing a unit, workforce management issues, and other non-regulatory information (see [http://www.extension.org/pages/Mobile\\_Slaughter/Processing\\_Units](http://www.extension.org/pages/Mobile_Slaughter/Processing_Units)).

References

1. Federal States Marketing Improvement Program Grant. \u201cMobile Slaughter Unit for Wyoming. Assessment of Need and Values\u201d July 1, 2004.
2. Simon, Ken. \u201cIs a Mobile Slaughterhouse Coming to Connecticut?\u201d <http://www.workingtheland.com/feature-mobile-slaughterhouse.htm>
3. {"file\_name": "FSIS\_GD\_2007\_0001", "title": "A Guide to Federal Food Labeling Requirements for Meat, Poultry, and Egg Products", "num": "FSIS-GD-2007-0001", "id": "26b6af3f0dc369460b4af1bb3b4f0c129deb050dc0f6a5b746a765efbed128c1", "corp\_us": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-07/Labeling\_Requirements\_Guide.pdf", "type": "pdf", "n\_pages": 117, "word\_count": 31312, "text\_by\_page": ["1 Updated Questions and Answers Food Safety and Inspection Service (FSIS) Labeling Compliance Policy Guide on Poultry Food Product Dating Purpose of the Compliance Guide The intent of this guidance is to convey current practices and clarify the requirements of the regulations with regard to the appropriate use of pack dates and slaughter dates on poultry food products because of an increasing number of requests for clarification. This guidance provides a summary on the date of slaughter and date of packing required in Title 9 of the Code of Federal Regulations (9 CFR), Section 381.126(a) and (b). Additionally, there are questions and answers at the end of the Notice to help clarify the issue. The product dating requirements are first and foremost related to the quality of the product and not an issue regarding food safety. Slaughter dates, pack dates, and date codes were originally intended for use by retailers for inventory control and for determining other dates voluntarily provided on consumer package labeling, e.g., \u201csell by\u201d and \u201cuse by\u201d dating, in compliance with 9 CFR 381.129(c)(2) of the regulations. Lastly, in order to consolidate all poultry product dating information in one location, the Constituent Update that was published in 1999 regarding the options available for compliance with 9 CFR 381.126 requirements has been updated and included in this Notice, in addition to the 2002 FSIS web guidance document entitled \u201cChanging Dates on Labeling.\u201d Current Regulatory Requirements Title 9 CFR Section 381.126(a) requires that either the immediate container or the shipping container of all poultry food products be marked by code or otherwise with the date of packing. The date of packing is

the date when the finished product is packed into the immediate container, i.e., consumer package. Historically, the slaughter date, process date, and pack date were generally the same date since most poultry was slaughtered, processed, and packaged on the same day. In today's market, we recognize that products are often subjected to additional processing and may be slaughtered and further processed over a period of time. Thus, the pack date (date product is packaged) may not be the same as the slaughter or processing date. Although the pack date is related to product quality rather than product safety, it may not be misleading. In addition, the pack date is not used to convey the date that consumer packaged products are placed in the shipping container nor is the pack date used to convey a date when finished packaged products are simply removed from the package and repackaged into a new container. To simply unwrap and rewrap products for the purposes of including a new pack date would be false and misleading and, thus, would misbrand the product under the Poultry Products Inspection Act (PPIA). In contrast, if products are packaged, stored, then further processed and repackaged, a new pack date is acceptable on the repackaged product."

"Section 381.126(b) of the regulations requires the immediate containers of dressed poultry to be marked with a lot number which shall be the number of the day of the year on which the poultry was slaughtered or a coded number. 'Dressed poultry,' for the application of this section of the regulations, means slaughtered, defeathered, eviscerated whole birds with the head and feet removed, i.e., a ready-to-cook whole bird. Further processed poultry, e.g., cut-up, marinated, breaded, etc., products are not considered to be dressed poultry and fall under section 381.126(a) not (b) of this regulation.

Packing Dates on Poultry Labeling (Revised Policy Previously Conveyed in FSIS Constituents Update Dated 12/17/99) Since 1972, FSIS has required poultry products to include a date of packing, either as a calendar date or a code (9 CFR Section 381.126(a)). FSIS has permitted the use of a sellby or use-by date in lieu of the required date of packing. Several years ago, an issue regarding the appropriate application of the Federal poultry products inspection regulations on "date of packing" (9 CFR 381.126(a)) arose. The circumstances involved a processor who packages poultry food products in consumer-ready film-wrapped packages that are in refrigerated storage awaiting shipment to customers when orders are received. At the time an order is received, a price label and sell-by date are applied to the consumer packages, which are then placed in master shippers to which box end labeling, including a "pack date," is applied. The pack date that has been applied, however, has been the date the consumer packages are placed in the shipper, not the original pack date on which the poultry was placed in the consumer packaging. As stated above, the application of the date the consumer packages are placed in the shipper does not meet the intent of the "pack date" that is required by Federal regulations. The regulations state that the pack date can be applied to the shipper or immediate containers of poultry food products using either a code or the actual calendar date of packing. The date of packing, however, must be the original date the poultry is placed in the consumer packaging (immediate container); the use of any other calendar date will mislead consumers. After discussions with the company and the National Chicken Council, it was resolved that, perhaps, misinterpretation of the pack date provisions has occurred within industry. Understanding that the immediate containers, i.e., consumer package, or the shipping containers of poultry food products, must be marked with the original pack date, there are actually four options available to poultry processors to comply with the packing date provisions,

one of which must be used. These options are: \u2022 a code is applied that represents the original pack date of the poultry food product in the consumer package, or \u2022 the original pack date of the poultry food product is applied to the consumer package or the shipping container accompanied by an explanatory statement, e.g., "packing date" (per 9 CFR 381.129 (c) (2)), or \u2022 the original pack date of the poultry food product is applied to the consumer package or the shipping container along with a date representing when the,"3 consumer packages are placed in shippers. In this case, each date must be accompanied by an explanatory statement in accordance with 9 CFR 381.129 (c) (2), e.g., "packing date," and "date put in shipping container," or \u2022 the use of a calendar date, e.g., \u201csell-by,\u201d \u201cu01cuse-by,\u201d etc. (per 9 CFR 381.129 (c) (2)), in lieu of the original pack date of the poultry food product is applied to the consumer package or the shipping container. Changing Dates on Labeling An issue that has recently been raised is the legality of changing calendar dates, e.g., sellby dates, use-by dates, etc., that appear on meat or poultry products. Poultry products are required to include a date of packing, either as a calendar date or a code. A food retailer may not modify a "packing\pack" date on a product packaged under Federal inspection. Additionally, FSIS has permitted the use of a sell-by or use-by date in lieu of the required date of packing. Therefore, since the pack date\code is mandatory, and a sell-by or use-by date may be used in lieu of the pack date\code, retailers may not modify a sell-by or use-by date on poultry products packaged under Federal inspection. FSIS has no regulations requiring calendar dating on red meat products. However, if a federally inspected establishment has voluntarily placed a calendar date on red meat products, such a date cannot be removed or changed by a retailer. There are likely a number of factors that manufacturers have considered about safety in preparing products and the inclusion of a calendar date that a retailer may not be aware of. Moreover, similar to other labeling features applied at Federally inspected establishments, they should not be removed or modified unless returned and repackaged\reprocessed under Federal inspection. On the other hand, if a food retailer places a calendar date on red meat or poultry products, the retailer may change that date on products that remain wholesome, provided that the change in the date is identified on the label, e.g., "original sell-by date" and "new sell-by date." A local jurisdiction (e.g., a State authority) may, however, have a requirement against changing these dates at the retail level. Lastly, if a product has an expired date and the food remains wholesome, the product may continue to be offered for sale.

Poultry Product Dating -- Frequently Asked Questions

1. Question: What is the general rule about pack dates on poultry food products produced in a federally inspected facility? Answer: FSIS requires all immediate containers or shipping containers of poultry food products to be clearly and permanently marked by code or otherwise with the date of packing. If a calendar date is used, it must be accompanied by a statement explaining the meaning of the date. The calendar date must include the month of the year and the day of the month for all products and also the year in","4 the case of products hermetically sealed, dried, or frozen products, for example, \u201cpacked on May 22, 2005.\u201d For further information, see the regulations at 9 CFR 381.126 (b) and 381.129 (c) (1).
2. Question: What are the definitions of \u201ccconsumer packaging,\u201d \u201cimmediate container,\u201d and \u201cshipping container\u201d in reference to poultry product pack dates? Answer: "Consumer package" is defined in 9 CFR 381.1. A consumer package means any container in which a poultry product is enclosed for the purpose of display and sale to household consumers. Therefore, the consumer

package is synonymous with \"immediate container.\" The immediate container (9 CFR 381.1) includes any consumer package; or any other container in which poultry products, not consumer packaged, are packed. Furthermore, immediate containers are required by 381.116 to bear all required features applicable in Subpart N of 9 CFR, Part 381, in other words, an immediate container is a fully labeled package. In some cases, the immediate container is also the shipping container. 9 CFR 381.116, states that the labeling requirements in that part apply to shipping containers; that is, when the shippers are also the immediate container. However, a true shipper is only required to include the inspection legend, plant number, and a handling statement, if the product is perishable. A true shipping container would always contain fully labeled product inside; thus, there is not a requirement for shippers to be fully labeled.

3. Question: Does the date of pack \u201clabel requirement\u201d apply to fresh, raw product only, OR does it apply to frozen, thawed, partially cooked, or cooked product? Answer: Section 381.126(a) of the regulations applies to all poultry food products not covered by other sections of this regulation. These products require a pack date. Dressed poultry and canned poultry are covered by other paragraphs in that section of the regulations -- 381.126 (b) and (c), respectively. Dressed poultry requires the slaughter date, and canned poultry requires the date of canning or a code to represent the date of canning.

4. Question: What is the definition of a pack date? Answer: The pack date is the date that a product is packaged.

5. Question: How can the pack date be expressed? Answer: Understanding that the immediate containers or the shipping containers of poultry food products must be marked with the original pack date, there are actually four options available for poultry processors to comply with the pack date provisions, one of which must be used. These options are:

- \u2022 a code is applied that represents the original pack date of the poultry food product in the consumer package, or
- \u2022 the original pack date of the poultry food product is applied to the consumer package or the shipping container accompanied by an explanatory statement, e.g., \"packing date\" (per 9 CFR 381.129 (c) (2)), or
- \u2022 the original pack date of the poultry food product is applied to the consumer package or the shipping container along with a date representing when the consumer packages are placed in shippers. In this case, each date must be accompanied by an explanatory statement in accordance with 9 CFR 381.129 (c) (2), e.g., \"packing date,\" and \"date put in shipping container,\" or
- \u2022 the use of a calendar date, e.g., \u201csell-by,\u201d \u201cuse-by,\u201d etc., (per 9 CFR 381.129 (c) (2)) in lieu of the original pack date of the poultry food product is applied to the consumer package or the shipping container.

6. Question: Can a \u201csell-by\u201d or \u201cuse-by\u201d date be used in lieu of the \u201crequired date of packing\u201d? Answer: Yes, in accordance with longstanding FSIS policy, \u201csell-by\u201d or \u201cuseby\u201d dating can be used in lieu of pack dates on poultry food products.

7. Question: How does the \u201csell-by\u201d or \u201cuse-by\u201d date correspond with the pack date? Answer: There is no single, numerical correlation between the pack date and other dates placed on labeling. Manufacturers must determine these dated based on the length of time that their product will remain wholesome.

Updated Question and Answer 8. Question: Can a pack date on a poultry product be changed? Answer: No. The pack date for a poultry food product packaged under Federal inspection can not change unless the poultry product is further prepared or processed, e.g., chopped, smoked, ground, etc. and repackaged. The date that the product is further processed and packaged could then be used as the new pack date. For the purpose of this policy, freezing the product can be considered to be

a further preparation or process. Therefore, a new pack date can be applied to refrigerated poultry food products if they are frozen and repackaged or repackaged and frozen. It is not sufficient to simply freeze product, it must be repackaged as well to change the pack date. Similarly, if a frozen poultry food product is thawed and repackaged, a new pack date can be applied to the product. In this situation, thawed and repackaged product would include the use of the handling statement, \u201cPreviously handled frozen; for your protection keep refrigerated or refreeze.\u201d This is needed to ensure that the labeling of such product is not misleading to consumers.", "6 9. Question: Can retail stores change the sell by\use by dates that a Federal facility applied to labeling? Answer: No. Because a pack date is required for a poultry food product, and a sell-by\use-by date can be used in lieu of the pack date, a retailer cannot change the date applied by the Federal plant unless the poultry product is further processed, e.g., chopped, smoked, ground, and then repackaged. 10. Question: Can the time of day be placed under the pack dates of labels? Answer: FSIS would not take issue if the time of day is placed on the labels under the pack date as long as the pack date complies with FSIS regulations. 11. Question: Does the requirement for pack dates depend on who is receiving the product (consumer vs. HRI)? Answer: No. According to 9 CFR 381.126(a), a pack date is required on either the immediate container or shipping container of all poultry food products. 12. Question: Can raw product that is slaughtered on a particular day and then stored until further processed on a subsequent day be labeled with a \u201cdate of pack\u201d corresponding to the date it was \u201cfurther processed,\u201d e.g., deboned, marinated, cut-up, etc?. Answer: If the product has been further processed, e.g., cut-up, deboned, etc., and then packaged, it is acceptable to use the date of the packaging as the pack date required by 381.126(a). 13. Question: How is product that is slaughtered at one establishment and processed, e.g., cut-up, at a receiving establishment to be labeled (relative to \u201cdate of pack\u201d)? Answer: When the birds are processed and packaged at a second plant, the date of packaging is the acceptable pack date. 14. Question: What is the general rule about slaughter dates on poultry food products produced in a federally inspected facility? Answer: Slaughter dates are only required on dressed poultry. As specified by 9 CFR 381.126(b), \u201cdressed poultry\u201d is to be marked with a lot number which shall be the number of the day of the year on which the poultry was slaughtered or a coded number. \u201cDressed poultry,\u201d for the application of this section of the regulations, is slaughtered, defeathered, eviscerated whole birds with the head and feet removed, i.e., a ready-to-cook whole bird. \u201cDressed poultry\u201d would also include slaughtered, defeathered, whole birds slaughtered under various religious or other exemptions, e.g., Chinese Buddhist exempt poultry that requires the head and the feet remain on eviscerated poultry. Prepared or processed poultry, e.g., "7 cut-up, marinated, breaded, etc., products are not considered to be dressed poultry and fall under subsection (a) not (b) of this regulation. 15. Question: Can the slaughter date and the pack date be the same? Answer: Yes, if the birds are slaughtered, processed, and packaged in immediate containers on the same day. 16. Question: Does the slaughter date have to be on the immediate container of all poultry? Answer: A slaughter date is only required by 9 CFR 381.126(b) on the immediate containers of \u201cdressed\u201d poultry. 17. Question: What is the definition of \u201cdressed poultry?\u201d Does it include ALL raw poultry (whole birds, cut-up parts, giblets, deboned product, marinated product, necks, paws, etc.)? Answer: \u201cDressed poultry,\u201d for the application of this section of the regulations, is

slaughtered, defeathered, eviscerated whole birds with the head and feet removed, i.e., a ready-to-cook whole bird. Prepared or processed poultry, e.g., cut-up, marinated, breaded, etc., products are not considered to be dressed poultry and would be governed under subsection (a) not (b) of 381.126. 18. Question: Frozen dressed poultry (e.g., frozen whole turkeys) are slaughtered on various dates and placed in consumer ready packages prior to being placed in frozen storage. When needed, the establishment removes frozen whole turkeys from frozen storage for shipment. Prior to shipment, the frozen whole turkeys have a price label applied that bears a code. The establishment has documentation to show that the code can be used to identify birds\u2019 date of slaughter. Does this practice comply with the date of packing labeling requirements described in 9 CFR 381.126(b)? Answer: In this case, 9 CFR 381.126(b) specifies that the immediate container for dressed poultry shall bear the number of the day of the year on which the poultry was slaughtered or a coded number. An "explanatory statement" statement as described in 9 CFR 381.126(a) is only required when a calendar date is used. 9 CFR 381.12(c) requires that the Inspector be informed as to the meaning of any coded number that is used. In this case, the code can be linked to the slaughter date through an establishment\u2019s documentation and recordkeeping. Therefore, the code is in compliance with the requirements of 9 CFR 381.126 (b) because it can be linked to the date of slaughter. If the birds are commingled in frozen storage, and the actual slaughter date of each bird cannot be determined, the coded number would have to be linked to the oldest date of slaughter." , "8 19. Question: What is a code date? Answer: A code or code date should be information that has meaning to the manufacturing or packing plant for tracking purposes of a product, specifically, a means of identification of product slaughtered, prepared, processed, or packaged on a certain date in the case of a recall. If the code links to a production date, that is sufficient; that is actually the purpose of the code to identify the date of production or a lot from a specific date. However, codes should not have meaning that is misleading to a consumer. If a plant is using "codes" that appear to be dates, it should revise its coding system or apply the proper use of calendar dating in accordance with 9 CFR 381.129(c). For example, we believe that \u201c051305\u201d and \u201cMay1305\u201d do not represent codes but calendar dates that should be identified properly. A Julian date of \u201c13305\u201d (133rd day of the year 2005) would be considered to be an acceptable code since most consumers would not immediately associate such numbers with a calendar date. New Questions and Answers 20 and 21 20. Question: Can a \u201cuse-by\u201d or \u201ccell-by\u201d date be used in lieu of the slaughter date required on \u201cdressed\u201d poultry as described in 9 CFR 381.126(b). \u201cDressed poultry,\u201d for the application of this section of the regulations, means slaughtered, defeathered, eviscerated whole birds with the head and feet removed, i.e., a ready-to-cook whole bird. Answer: No, a \u201cuse-by\u201d or \u201ccell-by\u201d date may not be used in lieu of the slaughter date. However, the regulations do permit the use of a code to identify the slaughter date. 21. Question: If a plant operates a shift that begins late in the evening and runs past midnight, can the end of the shift, i.e., the next day\u2019s date be used as the slaughter or pack date for the entire shift? Answer: No, it is misleading to use a later date for a slaughter or pack date. Product slaughtered or packed until midnight would have to use the accurate date of slaughter or pack. However, we would permit product slaughtered or packed after midnight to include the date the shift started if a company cannot change dating equipment in the middle of a shift. For additional information about poultry food product

dating and labeling, contact the Labeling and Program Delivery Division at 301-504-0878 or 0879."],{"file\_name":"FSIS\_GD\_2008\_0001","title":"Supplementary Guidance on the use of Antimicrobial Agents to Control Listeria Monocytogenes in Post-Lethality Exposed Ready-To-Eat Meat and Poultry Products","num":"FSIS-GD-2008-0001","id":"a9c90411b46b30ae6f3e6fb7356e2627a9dacc7435a724ffe61fbcd0292cdf0d","corp\_us":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/import/Lm\_Supplementary\_Guidance.pdf","type":"pdf","n\_pages":10,"word\_count":3743,"text\_by\_page":["FSIS Guidance for Evaluating Test Kit Performance 10/15/10 Page 1 of 22 FSIS Guidance for Test Kit Manufacturers, Laboratories: Evaluating the Performance of Pathogen Test Kit Methods Table of Contents I. Introduction II. General Guidance for Evaluation of Pathogen Test Kit Performance 1. Purpose, Scope and Audience 2. General Considerations 3. Inoculum - Number of strains - Strain selection (Table 1) - Preparation of inoculum - Inoculation of matrix 4. Matrix - Choice of matrix (Tables 2a, Table 2b) - Decision Criteria Illustrating When New Validation Studies Should be Conducted for an Existing Method - Characterization of matrix 5. Study Design and Analysis - Paired and Unpaired studies (Figure 1) - Data Analysis - Levels of validation (Figure 2, Table 3) - Reference method 6. Sample size - Unpaired studies (Figure 3) - Paired studies (Figure 4) 7. Study report Attachment. Example of Pearson Chi-square statistic Statistic Calculation for Unpaired Samples","FSIS Guidance for Evaluating Test Kit Performance 10/15/10 Page 2 of 22 I. Introduction FSIS-regulated establishments rely on results from pathogen testing programs to comply with regulatory requirements and to support decisions made in their HACCP systems to ensure the production of safe unadulterated products. FSIS does not maintain a list of acceptable methods to be used in these testing programs. However, the Agency's overall expectation is that any test used by an establishment is appropriate for its intended use, that the test performance is comparable to the FSIS method (if applicable), and that the laboratory performing the test did not introduce modifications that could compromise test's performance. FSIS believes that a robust validation study must be performed on any method used by establishments to detect microbiological hazards in FSIS-regulated foods. A validation study is an experimental process to measure performance characteristics of a particular test, with the goal of determining whether the test is equivalent to the reference test. 'Equivalent' is defined as the designated relationship between two tests indicating that, for the intended conditions of use, the performance characteristics are statistically indistinguishable. This guidance document (section II) provides an example of how to design a robust pathogen method validation study that may be used to demonstrate equivalence. The performance characteristics addressed in this guidance are described in Box 1. The guidance provided in this document primarily focuses on measuring relative recovery and sensitivity (false negative rate). Measurement of specificity (false positive rate), inclusivity, exclusivity, repeatability, reproducibility, and ruggedness should be performed through the direction of an independent organization, or by following guidance provided by the AOAC International Official Methods of Analysis Program. The FSIS guidance should be useful to organizations that design or conduct validation studies for foodborne pathogen testing methods. These organizations include test kit manufacturers, laboratories, and independent validation organizations. The FSIS guidance is not intended to conflict with or supplant existing guidance from independent organizations (AOAC and ISO). The FSIS guidance could be used to

evaluate the performance of a candidate alternative method for Escherichia coli O157:H7 or non-O157 Shiga toxin producing E. coli (nonO157 STEC). NOTE: The use of validation in this document is not intended to have any application to the implementation of 9 CFR 417.4(a)(1) on initial validation of HACCP plans. This document deals exclusively with the evaluation of pathogen test kit methods.","FSIS Guidance for Evaluating Test Kit Performance 10\15\10 Page 3 of 22 Box 1. Performance Characteristics Used to Evaluate Pathogen Test Kit Methods Relative Recovery measures the proportion of true positive samples recovered from the new test compared to the reference test when similarly inoculated. Sensitivity\False Negative Rate measures the probability that a test will correctly detect a true positive sample. A false negative (FN) result occurs when a test does not correctly detect a true positive sample, so 1 minus the sensitivity equals the FN rate. Specificity1\False Positive Rate measures the probability that a test will correctly detect a true negative sample. A false positive (FP) result occurs when a test does not correctly detect a true negative sample, so 1 minus the specificity equals the FP rate. Inclusivity measures the ability of a test to detect a wide variety of strains representing the target pathogen. Exclusivity measures the ability of a test to resist interference by cross-reactivity with non-target organisms likely to be found in the tested food. Reproducibility is a measure of test performance in different laboratories with different equipment and personnel. Repeatability is a measure of test performance in the same laboratory with the same equipment and personnel. Ruggedness testing is performed to determine if small changes to the procedure or environmental factors influences test performance. Validation studies are designed to evaluate the performance of a new test (referred in this document as the alternative method, or A) against a reference method (referred to as R) that provides a definitive result. The typical study design can not be applied to methods which do not have an available authoritative R. Additionally, the study design described in this document (section II) would not determine if the performance of A exceeded R. Validation studies performed through the Association of Analytical Communities (AOAC) or other recognized independent organizations that perform or organize validation studies on behalf of test developers, follow the traditional design and rely on culture based reference methods. FSIS believes that any method used to detect foodborne pathogens in meat, poultry, and egg products should be as sensitive as the FSIS method. Other recognized cultural methods, fit for the purpose of detecting low levels of stressed cells in food, also may be an appropriate reference method. Alternative methods should be re-validated when significant changes affecting performance are introduced to the reference method. Re-validation should be performed within one year of the introduced changes. 1 Also referred to as Selectivity.","FSIS Guidance for Evaluating Test Kit Performance 10\15\10 Page 4 of 22 From a food safety perspective, methods to detect foodborne pathogens should be validated using a robust study design with special attention to sensitivity (false negative rate) and inclusivity to limit or prevent false negative results. From an economic perspective, methods should be validated with special attention to specificity and exclusivity to prevent or limit false positive results and to reduce the time to obtain results, thus allowing product disposition to be rapidly determined. Sensitivity, specificity and timeliness are related, so an increase in one parameter may lead to a reduction of the other. Robust validation methodology implies that A should be evaluated under the most challenging conditions to provide confidence that the method likely will perform well under most situations. In practical terms, a robust validation methodology should address the following

parameters: 1. The inoculum level should be low enough to achieve fractional recovery of positive results by R. In FSIS\u2019 experience, pathogens subjected to zero tolerance testing in meat, poultry, and egg products often are found at low levels, close to one viable organism per analytical unit. Because it is practically impossible to place a single organism in a testable unit of food, the best approach taken in validation studies is to inoculate foods at low levels so that a fraction of the analyses (defined as 20-80% of the inoculated samples analyzed by R) are confirmed positive for the target pathogen. \u201cFractional recovery\u201d is a well-established concept used by AOAC and other organizations performing validations, and was recognized as a preferred method for defining test performance by the Presidential Task Force for Best Practices in Microbiology<sup>2,3</sup>. 2. The study should evaluate the ability of the test to detect potentially stressed or injured cells. Foods prepared for commercial distribution often are exposed to conditions injurious to bacterial contaminants. Foods often are processed at reduced temperatures to prevent pathogen growth and avoid spoilage. In other situations, food properties are modified by the application of antimicrobial agents such as organic acids, salt, curing agents, or other preservatives or by the modification of pH and water activity. In addition, the presence and level of resident microflora in the sample, (which is related to the age and handling of the product sample) could interfere with target pathogen growth. Any of these treatments may negatively affect the growth properties of the target pathogen, by extending lag phase or exponential growth rate. Injured cells would be more difficult to detect, but could retain their ability to cause illness. 3. The study should evaluate the ability of the test to detect target organisms in the products likely to be tested; however, foods that present a challenge to the test\u2019s performance should be evaluated, even if they are not as likely to be tested. 4. The study should evaluate a target strain with limited growth potential in the product to be tested; this would present a challenge to the sensitivity of the test kit.

2 Feldsine et al., AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Qualitative and Quantitative Food Microbiological Official Methods of Analysis. Journal of the AOAC International 85(2): 1187-1200. 3AOAC International Presidential Task Force, Best Practices in Microbiological Methodology (August 10, 2006), accessed at:  
<http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/ucm124900.htm>, "FSIS Guidance for Evaluating Test Kit Performance 10/15/10 Page 5 of 22

5. The study should evaluate the test\u2019s performance against a cultural method. For most FSIS-regulated products, the current FSIS method, found in the microbiology laboratory guidebook (MLG), is the most appropriate reference cultural method<sup>4</sup>.

6. The study should evaluate a sufficient number of samples. The number of samples should be chosen to provide adequate statistical assurance that a false negative conclusion will not be reached (i.e., that A and R were equivalent when, in reality, the methods were not equivalent). This guidance document in section II provides a robust validation experimental design that addresses the above mentioned parameters. The document can be used by test kit developers, laboratories, or independent validation organizations to determine whether a new alternative method A would be appropriate for testing programs conducted in FSISregulated establishments. Two criteria should be considered:

1. Demonstration that recovery rates for A and R are statistically indistinguishable using an unpaired trial with fractional recovery of positive results<sup>5</sup>.
2. Evaluate the sensitivity of A using a paired trial and a minimum of 29 positive samples. FSIS will use these data to evaluate a manufacturer\u2019s claim that a new method was equivalent to a

reference method, including the FSIS method.<sup>4</sup> When minimal changes have been introduced, validation against a non-cultural method may be appropriate.<sup>5</sup> A different study design would be needed to demonstrate that recovery rates for A were superior to R. This situation is not addressed in this guidance document.", "FSIS Guidance for Evaluating Test Kit Performance 10\15\10 Page 6 of 22 II. General Guidance for Evaluation of Pathogen Test Kit Performance The following guidance is provided to assist the design of effective validation studies that are likely to meet FSIS\u2019 expectations.

**1. Purpose, Scope and Audience**

This guidance document is intended to assist the design of validation experiments for methods used to detect bacterial pathogens in matrices such as meat, poultry, and egg products, and environmental samples (sponges, swabs, brines). In particular, the document could be used to evaluate the performance of a candidate alternative method for *E. coli* O157:H7 or non-O157 Shiga toxin producing *E. coli* (non-O157 STEC) strains. The document is not applicable to methods for enumerating microorganisms. This guidance document focuses on procedures to measure sensitivity (and false negative rate), specificity (and false positive rate), and to compare positive recovery rates for an alternative and reference method (abbreviated as A and R, respectively). These measures of test performance should be evaluated when any modification is introduced to A, including, for example, changes to test portion size, enrichment media, enrichment time, enrichment temperature, sample to media ratio, or test matrix. If a major modification is introduced to A, then Inclusivity, Exclusivity, Repeatability, Reproducibility and Ruggedness Testing should also be performed, either through the direction of an independent organization, or by following guidance provided by the AOAC International Official Methods of Analysis Program<sup>2</sup>. A major modification to A would include significant changes in the design or the component reagents for a screening test, for example, the introduction of a new antibody or oligonucleotide primer. This guidance document is not intended to conflict with or supplant existing guidance from independent organizations (AOAC and ISO), and is not intended to have any application to the initial validation of HACCP plans described in 9 CFR 417.4(a)(1). The intended audience for this document includes test kit manufacturers, laboratories as well as independent organizations that evaluate test kit performance.

**2. General Considerations**

The work should be carried out in a laboratory that is independent of the manufacturer\u2019s economic interest. For example, the study may be carried out under contract to an academic laboratory, or a publicly-, or privately-owned laboratory that is not controlled by the test manufacturer. Alternatively, the validation may be performed through an independent organization such as AOAC, AFNOR, ISO, or NordVal. To avoid handling bias, the identity of the samples should be blinded to the analysts. The study design should be reviewed by an outside party before initiating work. FSIS can review and comment on study design<sup>6</sup>. Finally, all study reports as well as the associated raw data should be available for review by FSIS.

**6 Submit proposals for FSIS comment through the sampling queue at askFSIS (<http://askfsis.custhelp.com>).** ", "FSIS Guidance for Evaluating Test Kit Performance 10\15\10 Page 7 of 22

**3. Inoculum Number of strains:** The number of strains to be used for inclusivity and exclusivity studies is referenced in the AOAC guidelines<sup>2</sup>. Experiments to determine method equivalence should be conducted under conditions that result in fractional recovery of positive samples. Therefore, the use of multiple strain cocktails is not recommended, because individual strains would segregate to different samples.

**Strain selection:** Strains used to measure test performance should be available from public collections (e.g., ATCC, DSMZ, JCM), academic

government reference laboratories, or other collections that are available to the scientific community. For inclusivity and exclusivity studies, the strain set should include strains that do and do not meet the FSIS regulatory definition based on the current FSIS MLG method (Table 1). For validation of test performance characteristics, the target strain should be associated historically with the matrix, or an outbreak. These should be the first strains of choice for conducting the validation study. Strains demonstrating reduced growth potential in particular matrices also should be chosen to challenge the validation. A validation experiment using a challenging target strain would provide additional information on the robustness of the alternative procedure. If FSIS had evidence that certain strains or serotypes consistently were not detected by a commercially available method, it may request additional validation data. Recommendations for typical strains of *E. coli* O157:H7, *Listeria monocytogenes*, *Listeria* species, and *Salmonella* strains are provided in Table 1. FSIS welcomes recommendations for typical and challenging strains to be considered for validation studies in specific meat, poultry, egg product, and environmental matrices.

**Inoculum preparation:** To insure the purity of the target strain, a single, isolated colony is picked from a non-selective plating medium. For experiments to determine method equivalence, the isolated colony is used to inoculate an appropriate liquid medium, and it is incubated until the culture reaches stationary phase. Following incubation, the stationary phase culture should be cold-stressed ( $4^{\circ}\text{C}$ , 18-24 hours).<sup>7</sup> After 24 hours at  $4^{\circ}\text{C}$ , the culture can be diluted and plated on a non-selective medium to determine colony forming units per milliliter (CFU/mL). Sufficient measurements should be made to determine that the target strain is uniformly distributed in the culture to ensure that the inoculum in the tested samples is distributed as a Poisson distribution. These results should be reported. The 24 hour CFU/mL value can be used to determine the volume of inoculum to be added to the matrix to achieve the desired target strain concentration.

Alternatively, the target strain level in the inoculated matrix can be estimated by most probable number (MPN) analysis. FSIS welcomes recommendations for alternative procedures for preparing target strains for validation experiments and for inoculating test matrices.<sup>7</sup> This is a minimum recommendation for stress conditioning of the inoculum. The study design should consider the typical conditions used to manufacture the matrix of interest at the typical point of sampling. These may include temperature extremes, salt, water activity, pH, or the presence of residual antimicrobial compounds like organic acids. In some cases, the inoculum can be exposed to extreme conditions simply by exposure to the test matrix.<sup>7</sup> "FSIS Guidance for Evaluating Test Kit Performance 10/15/10 Page 8 of 22

**Inoculation of the matrix:** The inoculation level should be sufficient to result in fractional recovery of positive samples per test portion, defined as a range of 20-80% confirmed positive results for R. The inoculation level merely refers to the average level of target organism delivered to each test portion that would result in fractional recovery of positive results. The level may be different based on the choice of R or target organism, and higher inoculation levels may be required if the fractional recovery rate does not meet the recommended range. If possible, the matrix should be well mixed before inoculation to reduce potential variation in composition including intrinsic interfering factors. For example, high fat (e.g., 50% lean) beef trim can be sliced into small pieces or ground to distribute the fat and background microflora before inoculation. The experimental portions should be prepared and inoculated with the necessary volume of inoculum preparation to ensure the inoculum is well distributed. If a multicomponent product is to be

evaluated, the non-FSIS and FSIS-regulated components should be likewise well distributed before inoculation. If multiple portion sizes are to be evaluated, a portion of the matrix can be inoculated at X CFU per 25 grams, and then 25 gram portions of inoculated matrix are combined with additional, uninoculated matrix to create alternative portion sizes containing X CFU per portion. For validation of environmental testing methods, the inoculum may be added directly to the collection device (swab or sponge). However, the typical conditions of use should be simulated including the presence of competitive microflora. For example, before adding the inoculum, the device should be used to swab a surface. The device and inoculum should be combined with sample collection media before enrichment. The same concept of low level inoculation and fractional recovery apply to the validation of tests for environmental samples. A number of samples (5-10 per trial) should be uninoculated to serve as negative controls.

4. Matrix Choice of Matrix: Validation studies should use matrices typical of the samples likely to be tested. Food matrices can be mixed before inoculation and enrichment to reduce potential for experimental variation. The choice of the matrix and the decision to initiate a validation study for a new matrix should be based as much as possible on the intrinsic properties of the matrix that are likely to affect the growth of the target pathogen. These properties include: levels of indigenous microflora, fat content, pH, salt content, water activity, the presence of antimicrobial compounds including additives found in ready-to-eat products, and the presence of residual antimicrobial compounds typically used for treating environmental surfaces or raw products. The intrinsic properties should be evaluated at a location in the process when the sample is likely to be collected. For example, beef trim is typically sampled after fabrication, so a validation study intended for beef trim should use trim collected at that point. Primal cuts purchased at retail would not be a suitable substitute. Similarly, a *Salmonella* test intended for raw egg yolk may not be suitable for testing pasteurized egg yolk product containing additives that may interfere with *Salmonella* growth. A scheme for determining meat, poultry, and egg matrix categories based on water, fat, spice, salt, or sugar content, and cooking was created by the Presidential Task Force on Best Practices in Microbiological Methodology (BPMM)3.

Additional factors described above should be considered as well. Examples", "FSIS Guidance for Evaluating Test Kit Performance 10\15\10 Page 9 of 22 illustrating this concept are found in Box 2. Tables 2a and 2b provide some examples of matrix categories for FSIS-regulated meat, poultry, and egg products. Box 2. Decision Criteria Illustrating When New Validation Studies Should be Conducted for an Existing Method A commercially available test for *E. coli* O157:H7 was AOAC-validated for ground beef products. The test matrix was 80% lean ground beef. Customers would like to use the test for lean beef trim of comparable fat level. There is no need to re-validate the test for this matrix, since there is minimal difference in fat content, an important intrinsic property that may affect test performance. No other intrinsic properties (such as residual antimicrobial compounds) distinguish these matrices. Customers want to use the above mentioned test for 50% lean trim, a validation experiment should be designed for this matrix since the fat content is significantly different and may affect test performance. A commercially available test for *Listeria monocytogenes* was validated for ready to eat turkey roll with 5% salt added. It was concluded that there is no need to revalidate the test for use with low fat beef hot dogs because the fat and salt content were similar and are not expected to have a differential effect on test performance based on comparative information about growth kinetics within turkey and beef matrices. However, use of the test with dry fermented

salami would require additional validation because the reduced water activity and presence of added microbial flora (lactic acid bacteria) in the salami could affect test performance. The above mentioned *L. monocytogenes* test should be validated for use with sponge samples collected from environmental surfaces. Characterization of matrix: Intrinsic properties of concern for the specific matrix (e.g., APC to evaluate microbial flora, water activity, pH, antimicrobial residues or additives) should be measured in the material chosen for the study, and the values should be compared to published or unpublished ranges for the product type. The values (as well as the methods for determining the values) should be presented in the study report or should be otherwise available for review by FSIS.

## 5. Study Design and Analysis.

**Paired and Unpaired studies:** Validation studies should measure performance characteristics of an alternative method (A) relative to a reference method (R). Figure 1 illustrates validation study designs. Microbiological methods typically involve sequential sample preparation and enrichment, screening, and confirmatory procedures. Figure 1 depicts these procedures using the numbers P, S, and C respectively. For example, AP refers to the alternative sample preparation and enrichment procedure, while RP refers to the sample preparation and enrichment procedures indicated in the reference method. AC refers to the reference confirmatory procedure applied to A.," "FSIS Guidance for Evaluating Test Kit Performance 10\15\10 Page 10 of 22 Validation studies should rely on two components to determine the equivalency of A and R: relative recovery and sensitivity (false negative rate). FSIS believes that the recovery A and R should be statistically indistinguishable, and that a robust estimate of sensitivity should be determined. FSIS has not determined that a specific sensitivity criterion is appropriate for all situations. Manufacturers should evaluate sensitivity estimates on a case by case basis. Test kit manufacturers can use this guidance document to evaluate sensitivity for a test kit, or to demonstrate that a test kit met a specific sensitivity criterion. Two study designs in Figure 1 illustrate how relative recovery and sensitivity are determined and calculated. An unpaired study design is intended to compare the recoveries of A and R. It is performed using independent samples that are randomly assigned to either the A or R procedure8. A paired study design is intended to measure the sensitivity of A9. The paired study is performed by taking two or more measurements from the same sample to which A is applied10. Evidence from both unpaired and paired studies is used to evaluate a manufacturer\u2019s claim that a new method was equivalent to a reference cultural method, including the FSIS method. 8 Care must be taken to avoid biased selection of samples for the A or R protocol. 9 Specificity (false positive rate), can also be estimated using a paired experiment as the ratio of negative tests at AS divided by AC. 10 For example, a sample is prepared by the A method and is sampled after 15 hours of enrichment with AS (the alternative screening test) and AC (the reference confirmatory procedure).," "FSIS Guidance for Evaluating Test Kit Performance 10\15\10 Page 11 of 22 Figure 1. Validation Experiment Design. A is the alternative method, R is the reference method. P is the sample preparation and enrichment procedure, S is the screening procedure, and C is the reference confirmatory procedure. AC refers to the reference confirmatory procedure applied to A. RS refers to a screening procedure applied to R. In an unpaired trial, recovery (% positive) at AS is compared to recovery at R2. Results at AS should be confirmed at AC, and recovery at RC and AC should not be statistically distinguishable. In a paired trial, a false negative or false positive rate is calculated as the ratio of positive tests at AS divided by AC.

**Data Analysis.** Data analysis from an unpaired study typically involves a comparison of recovery

rates (proportion of positive results) at AS and RC, but only if fractional recovery is achieved. In other words, the proportion of positive samples using A is compared to the proportion of confirmed positives using R. Because some of the AS results may in fact be false, all AS results used in this comparison are confirmed (AC). A simple Pearson chi-square test without continuity correction should be used to determine if the recovery rates from the two procedures are statistically distinguishable. The associated P-value for significance (alpha) provides the probability that the methods are found not to be equivalent by chance, assuming the true proportions were identical. FSIS\u2019 concern is that the performance of A should not be inferior to R. Therefore, the statistical test should decide between the null hypothesis (that is, the performances of A and R are identical) and the alternative hypothesis (that the performance of A is inferior to R). Thus, a 1-sided statistical test should be used. By convention, alpha is set to 0.05 (meaning that there is a 5% probability that the statistical evidence would lead to accepting the alternative hypothesis when in fact the null hypothesis is true). A Pearson chi-square test without correction factors is recommended because this method is commonly used for statistical testing and does not rely on access to, or knowledge of, sophisticated computer programs that may not be available to all<sup>11</sup> (see attachment). The Pearson Chi square statistic is made using the familiar  $(O-E)^2/E$  formula: where O is the observed result, E is the expected value of the result, assuming the truth of the null hypothesis, summing over the 4 cells of a 2 x 2 table that has entries equal to the number of positive and negative results for the two methods. The expected value under the null hypothesis is the average of the two corresponding method specific results. The statistical significance (p- value) of the result of this calculation is equal to the<sup>12</sup>, "FSIS Guidance for Evaluating Test Kit Performance 10/15/10 Page 12 of 22 one-sided chi-square test at an alpha of 0.05 is essentially the same as the two-sided chisquare at an alpha of 0.10. Thus, rejection of the null hypothesis and acceptance of the alternative hypothesis occurs when the chi-square statistic exceeds 2.7055 and the number of positive results for R is greater than that for A. Data analysis from a paired study involves a comparison of paired results from the same sample determined by AS and AC. Sensitivity and specificity are determined from the ratio of AS to AC for positive results (to determine sensitivity) or for negative results (to determine specificity)<sup>12</sup>. These ratios are point estimates, and unless a large number of samples test positive or negative, the associated confidence intervals would be very wide, and would be used to provide a robust estimate of sensitivity or specificity (see below for discussion of sample size). FSIS Levels of validation. FSIS believes that all alternative methods should be validated using robust studies such as those described above. However, the Agency realizes that modifications to methods may not always require the same level of validation. Therefore, FSIS proposes four levels of validation that may be appropriate for some circumstances (Figure 2, Table 3). Note that a minimum of 60 samples per method are recommended for all levels. FSIS level 1 validation includes unpaired and paired studies, and all samples are confirmed using the reference confirmatory procedure (RC for R or AC for A). Level 1 is recommended for any novel A, or when a major modification, or two or more non-major modifications are introduced to A (e.g., new matrix, new screening test, or new enrichment broth). Comparison of recovery of the screening device with the A and R methods is optional. FSIS level 2 validation could be used when a single non-major modification is made to A. Like level 1, level 2 also includes an unpaired and paired study, but would allow a screening test to substitute for the full reference

method. This screening test (referred to as RS) would be recommended only if the performance is determined using a level 1 validation. In this situation, the apparent equivalency of A is determined by comparing recovery rates for AS with RS FSIS level 3 validation could also be used when a single non-major modification is made to A. Level 3 only includes an unpaired study, and would allow substitution of a screening test (AS and RS) for confirmed results provided that the same screening test was used for A and R, and the performance of AS and RS were determined using level 1 validation. Level 2 is preferable to level 3 validation. FSIS level 4 validation would be appropriate only when a full reference method does not exist. Level 4 only includes a paired study in which recovery at AC and AR is compared. probability that a chi-square-distributed random variable (with 1 degree of freedom) exceeds the result. The attachment describes how the Pearson chi-square test statistic is calculated. 12 Unlike the paired experiment, AS results are not corrected by AC results.", "FSIS Guidance for Evaluating Test Kit Performance 10\15\10 Page 13 of 22 Figure 2. FSIS levels of Validation. A is the alternative method, R is the reference method. P is the sample preparation and enrichment procedure, S is the screening procedure, and C is the reference confirmatory procedure. AC refers to the reference confirmatory procedure applied to A. RS refers to an alternative screening procedure applied to R. In an unpaired trial, recovery (% positive) at AS is compared to recovery at R2. Results at AS should be confirmed at AC, and recovery at RC and AC should not be statistically distinguishable. In a paired trial, a false negative or false positive rate is calculated by comparing results at AS and AC. Comparison of recovery by RS and AS is optional for FSIS level 1 validation. Reference method: For FSIS regulated products, the current FSIS method, which is found in the Microbiology Laboratory Guidebook (MLG), is the most appropriate reference cultural method for validating methods used by FSIS-regulated establishments. Other cultural methods also may be appropriate, including methods described in FDA\u2019s Bacterial Analytical Manual (BAM), or reference methods defined by the International Standards Organization (ISO), or the Codex Alimentarius. In certain circumstances, as indicated in Table 3 and figure 2, a non-cultural method may be appropriate for validation studies when minimal changes have been introduced to A, and the non-cultural method is well-defined (see Levels of Validation). Alternative methods should be revalidated when significant changes affecting performance are introduced to the reference method. Re-validation should be performed within one year of the introduced changes. 6. Sample size To provide robust estimates of method equivalency, as well as estimates of sensitivity and specificity, sample size needs to be addressed. Unpaired studies: The number of samples tested per method, the anticipated recovery rates, and the confidence level (alpha), are used to calculate statistical power, defined as the probability of detecting a true difference between A and R. That is, the number of samples that would provide high probability of detecting a difference in the recovery rates of A and R. FSIS calculated statistical power for experiments with different sample", "FSIS Guidance for Evaluating Test Kit Performance 10\15\10 Page 14 of 22 sizes and underlying differences in recovery rate13. In these calculations, FSIS assumed alpha to be 0.05, and a 50% recovery rate for R. Figure 3 presents calculated statistical power as a function of A and R recovery rates and sample size. FSIS would not accept as equivalent a candidate A performing at 50% relative to R. In other words, the recovery of R is 50% and that of A is 25%. Thus, in this scenario, there should be a high probability of rejecting the null hypothesis and accepting the alternative hypothesis. For an experiment with N = 20 (i.e., 20 samples tested per method), the

power is 49.5%. That is, in over one-half of the experiments, the null hypothesis would not be rejected and the recovery rate for A and R would be judged as indistinguishable. If N = 40, the power is 75.4%, an almost 25% chance of not detecting what FSIS would consider to be a large difference between the recovery rates of A and R. When N = 60, the power is 89%, almost 90%; that is, an almost 9:1 odds of detecting such a true difference; for N = 80, there is a 95% power, that is, about a 19:1 chance of detecting the difference. For these reasons, FSIS recommends a minimal sample size of 60 per method (and preferably 80 samples per method) to determine robustly if the recovery rates of A and R are indistinguishable. 13 Using PROC POWER procedure of SAS\u00ae version 9.1","FSIS Guidance for Evaluating Test Kit Performance 10\15\10 Page 15 of 22 Figure 3. Statistical Power as Determined by Sample Size, Recovery Rate, and Minimal Difference between the Alternative and Reference Methods. Statistical power was calculated using PROC POWER program of PC SAS\u00ae version 9.13, assuming 50% recovery rate for the reference method, 10% significance (i.e., a 1-sided test with 5% significance), and 5-45% reduced recovery for the alternative method compared to the reference method. The probability of determining that the methods are statistically distinguishable is shown. Paired studies: As indicated above, a large number of samples would be needed to provide a robust estimate of sensitivity. FSIS recommends that validation studies include a large number of paired trials of A that confirm positive by AC. Figure 4 shows the probability of finding at least one false negative result among 12 to 50 confirmed positive samples assuming a hypothetical alternative test with 90% sensitivity (i.e., a 10% false negative rate). There should be a high level of assurance that the validation study would detect at least one false negative result from this hypothetical test. The curve indicates that 29 or greater positive samples would provide high (95% or higher) assurance that at least one false negative result would be detected from the hypothetical test. Zero false negative results from 29 confirmed positives would be consistent with a test having a sensitivity that met or exceeded 90% and zero negative results from 50 confirmed positives would be consistent with a test with a sensitivity that met or exceeded 94%.","FSIS Guidance for Evaluating Test Kit Performance 10\15\10 Page 16 of 22 These calculations are provided for illustrative purposes; FSIS has not determined that a specific sensitivity criterion is appropriate for all situations. The key point is that a larger number of confirmed positive samples provide greater assurance of detecting an unacceptable false negative rate. Figure 4. Probability of Finding at Least One False Negative Result for a Hypothetical Test with a 10% False Negative Rate Versus Number of Samples. Twenty-nine samples provide 95% probability (confidence) of detecting at least 1 false negative with this test. 7. Study Report Preferably, validation study reports should be published in an appropriate peer-reviewed journal, such as the Journal of the AOAC International. In any case, a study report containing experimental details and format similar to a scientific article format should be provided to FSIS for review. This would include abstract, introduction, materials and methods, results, discussion, and references sections. For new methods or modifications to existing methods that have not been validated by a recognized independent body, a study report and all associated raw data should be available to FSIS for review. Any recommended changes to the validated test protocol should be communicated as soon as possible to new and existing end users as part of a package insert, on the manufacturer\u2019s web site, and in the manufacturer\u2019s technical literature.","FSIS Guidance for Evaluating Test Kit Performance 10\15\10 Page 17 of 22 Table 1. Typical and Challenging Strains for use with Validation

Studies.", "FSIS Guidance for Evaluating Test Kit Performance 10\15\10 Page 18 of 22 Table 2a. Typical and Challenging Meat and Poultry Matrices for use with Validation Studies.", "FSIS Guidance for Evaluating Test Kit Performance 10\15\10 Page 19 of 22 Table 2b. Typical and Challenging Egg Product Matrices for use with Validation Studies", "FSIS Guidance for Evaluating Test Kit Performance 10\15\10 Page 20 of 22 Table 3. FSIS Levels of Validation. A is the alternative method, R is the reference method. S is the screening procedure, and C is the reference confirmatory procedure. AC refers to the reference confirmatory procedure applied to A. RS refers to an alternative screening procedure applied to R. In an unpaired trial, recovery (% positive) at AS is compared to recovery at R2. Results at AS should be confirmed at AC, and recovery at RC and AC should not be statistically distinguishable. In a paired trial, a false negative or false positive rate is calculated by comparing results at AS and AC.", "FSIS Guidance for Evaluating Test Kit Performance 10\15\10 Page 21 of 22 Attachment: Example of Pearson Chi-square Statistic Calculation for Unpaired Samples The results of a fractional recovery experiment can be given in a table, represented in Table A-1. Table A-1: Representation of Results A, B, C, and D from a Fractional Recovery experiment. Alternative Reference Positive A C Negative B D Percent Positive  $100\% \frac{A}{(A+B)}$   $100\% \frac{C}{(C+D)}$  For example, suppose 60 samples are inoculated at fractional recovery and tested using the reference method (R) and 46 are determined to be positive using the reference confirmatory procedure (RC). Another 60 samples are inoculated and tested with the alternative method (A), and 37 are determined to be positive using the alternative screening test (AS) and are confirmed subsequently using the reference confirmatory procedure applied to the alternative method (AC). Table A-2 depicts the hypothetical results. Table A-2: Hypothetical Results of a Fractional Recovery Experiment.

Alternative Reference Positive 37 46 Negative 23 14 Percent Positive 61.7% 76.7% Calculation: The Pearson chi-square test statistic formula is popularly known as the sum of terms  $(O-E)^2/E$ , where O is the observed number of results in the cell; E is the expected number of results in the cell when the null hypothesis is true. The sum of these terms over all cells of the table that contain the results (Table A2) gives the value of the chi-square statistic. The expected numbers of results in the cells, E, are calculated under the assumption that the null hypothesis is true. The null hypothesis states that the recovery of positive results by the two methods is the same. The \u201cxpected\u201d numbers of positive results in the four cells are shown in the following table as expected cell values E(A), E(B), E(C), and E(D), if two procedures have the same fractional recoveries. Table A-3: Expected Number of Cell-Specific Results, E, used in the Calculation of the Chi-Square test, based on Table A1-1. Alternative Reference Positive  $(A+C)/2$   $(A+C)/2$  Negative  $(B + D)/2$   $(B + D)/2$  Percent Positive  $100\% \frac{(A+C)}{(A+B+C+D)}$   $100\% \frac{(A+C)}{(A+B+C+D)}$ ", "FSIS Guidance for Evaluating Test Kit Performance 10\15\10 Page 22 of 22 In the example given above the table of expected values are given in Table A-4. Table A-4: Expected Number of Cell-Specific Results, E, based on Actual Results in the Example, given in Table A1-2. Alternative Reference Positive 41.5 41.5 Negative 18.5 18.5 Percent Positive 69.2% 69.2 The chi-square statistic is computed as the sum of the terms  $(O-E)^2/E$  over the four cells of the numbers of results, as shown in formula (1). Formula (1):  $\text{Chi-sq} = (A-E(A))^2/E(A) + (B-E(B))^2/E(B) + (C-E(C))^2/E(C) + (D-E(D))^2/E(D)$  For the example:  $\text{Chi-sq} = 0.48795 + 1.09459 + 0.48795 + 1.09459 = 3.16509$  Note: Because of the symmetry of the calculations for A and R, it is only necessary to compute the first two terms. A simpler equation can be used, as shown in formula (2). Formula (2):  $\text{Chi-sq} = (A-C)^2/(A+C) + (B-D)^2/(B+D)$  (2) For the example:  $\text{Chi-sq} =$

(9)2\83 + (9)2\37 = 0.9759 + 2.1892 = 3.1651 The Pearson chi-square result of 3.1651 is greater than the cut-off value and the number of positive results for R is greater than that for A. Thus, the null hypothesis is rejected, and thus, based on these results the recovery of A and R cannot be considered the same."}],{"file\_name":"FSIS\_GD\_2013\_0016","title":"Guidance on the Procedures for Joint FSIS and Food and Drug Administration (FDA) Approval of Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products","num":"FSIS-GD-2013-

## Equipment

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## V. Use of Video or Other Electronic Monitoring or Recordings for Food Defense

Purposes\u2026\u2026\u2026\u2026\u2026\u2026\u2026\u2026..page 8 A.

## Systems Used for Creating Video or Other Electronic Monitoring or Recording Records

Maintenance and Retention of Records Generated Using Video or Other Electronic Monitoring or Recording Equipment\u2026\u2026\u2026\u2026\u2026\u2026.page 12","3 I. Purpose This compliance guide was written in response to U.S. Department of

Agriculture's Office of the Inspector General (OIG) recommendations (December 2008) to provide information to industry on the use of video or other electronic monitoring or recording equipment to help it maintain compliance with federal regulations, including humane treatment of livestock and the use of good commercial practices in poultry. This document includes recommendations rather than regulatory requirements. FSIS is providing this guidance to advise establishments that video or other electronic monitoring or recording equipment can be used in federally inspected establishments. This guide informs establishments of the Agency's expectations if they decide to use this type of equipment to create records to meet requirements of the Hazard Analysis of Critical Control Points (HACCP) regulations or the regulations governing Sanitation Standard Operating Procedures (Sanitation SOPs) or associated prerequisite programs. In addition, this guide provides information on issues establishments should consider if they use this equipment for any other purpose, such as part of their food defense plans. Most importantly, this guide provides information and encourages industry to use this technology, particularly as part of its systematic approach to ensure that livestock are handled humanely and that poultry good commercial practices are followed.

Although FSIS recognizes that the use of video or other electronic monitoring or recording equipment may assist establishments in meeting federal requirements or for other purposes it cannot be used in a manner to harass, intimidate or interfere with FSIS Inspection Program Personnel (IPP) in the performance of their duties. II. Background Video or other electronic monitoring or recording technology is rapidly changing to meet increasing needs of businesses to become more efficient, increase productivity, and maintain security. Before the 1990s, traditional video technology was analog-based and was used for simple surveillance of premises with a closed circuit television camera and a video cassette recorder (VCR). With the VCR this video system could preserve information (or evidence) which allowed review of past events captured on the video. Further developments improved video capabilities and their applications, but the most revolutionary change, enabled by Internet and local area network

(LAN) availability, was full digitization of both camera and recorder. In these digital video surveillance systems, a digitized camera signal travels over a LAN line to a computer or server. The server or computer in turn manages and analyzes all incoming information resulting in an array of capabilities. A fully digitized system can encrypt data and integrate with other systems or multiple locations. It can retrieve data from remote locations, and use software that enhances or,"4 manipulates images for better viewing and detection of adverse events. It can also direct the video surveillance cameras on-site to detect specific criteria developed to measure process control or compliance. One application of a system of this type in the food industry is video auditing. This application allows the operator to select criteria or risk areas for video monitoring from a remote location to determine whether the selected activities or procedures are indeed taking place. This application is called remote video auditing (RVA). These types of systems, from early traditional to fully digital, are forms of electronic records if they provide permanent evidence or information about past events as do other electronic recordings, such as data loggers or continuous recording devices.<sup>1</sup> However, \u201clive feed video\u201d from a surveillance camera would not be a record if it is not recorded or maintained.

**III. Recordkeeping Requirements for Video or Other Electronic or Recording Equipment**

When video or other electronic monitoring or recording equipment provides permanent evidence of or information about past events, an electronic record is created. Electronic records may substitute for paper and handwritten records and are subject to the same statutory and regulatory requirements. As with paper records, video or other electronic monitoring or recording records may be designated as a record to meet HACCP and Sanitation SOP requirements or may be used for other purposes, such as Food Defense plans. Records not designated for HACCP or Sanitation SOPs are not subject to 9 CFR Parts 416 or 417 recordkeeping regulations; however, any monitoring or verification activities that have an impact on the hazard analysis are subject to 9 CFR Part 417. Additionally, FSIS may request access to all applicable establishment records in the event of an official investigation related to issues such as food defense, food safety, unlawful actions, or provisions of 9 CFR 320. For example, if potential product tampering has been detected, FSIS may request access to an establishment\u2019s recordings used in carrying out their Food Defense plan in the course of that investigation. The FMIA (21 USC 642), PPIA (21 USC 460(b)), and Egg Products Inspection Act (EPIA) (21 USC 1040) contain broad authority requiring certain classes of persons, firms, and corporations in the meat, poultry, and processed egg products business to maintain and provide FSIS with access to records related to their operations. Recordkeeping requirements apply to persons, firms, and corporations that prepare, freeze, pack, label, buy, sell, transport, store, and import meat food products (21 USC 1). Other digital imaging include the following: scanning (bar code scanners); software for scanning items; storage media, such as magnetic or optical disks; programs that can convert images into text-searchable files such as optical character recognition programs; indexing software, for making images more accessible; and storage devices, such as CD jukeboxes or hierarchical storage management (HSM) systems."<sup>5</sup> 642(a) (1), (2)). The statutes require that these businesses maintain production records, bills of sale, invoices, shipping and receiving records, and related business records.

**IV. Use of Video or Other Electronic Monitoring or Recording Equipment to Verify Livestock Humane Slaughter Activities or Poultry Good Commercial Practices**

FSIS encourages federally inspected establishments to consider using video or other electronic monitoring or recording equipment

as part of an overall systematic approach to maintain humane handling or good commercial practices to comply with regulatory and statutory requirements.<sup>2</sup> FSIS encourages establishments to use video technology not as a substitute, but as a supplement to enhance their hands-on activities. The use of video technology should be effectively implemented to result in trustworthy and accurate information that helps to prevent inhumane treatment or inadequate good commercial practices. Video or other electronic monitoring or recording equipment provides an establishment with continuous information on what is occurring with humane handling, instead of relying on periodic observations or spot checks. Establishments should strategically place cameras to provide continuous multi-dimensional views of an establishment's processes, such as from unloading through stunning. Some systems can bring together information in regards to humane handling, food safety, compliance, and product quality at one time. Thus, video or other electronic monitoring or recording equipment can provide new information for establishments to improve process control, as well as to provide feedback for employee training. A type of video or other electronic monitoring or recording equipment that has been developed specifically to verify humane handling or good commercial practices is RVA. In a RVA system the video feed or recording from cameras placed to continuously monitor critical live animal handling and stunning areas, is linked through a computer server to allow the records to be viewed on the web at a remote location by an auditor. The auditor views the video daily and generates reports, containing statistical summaries, web hyperlinks to the video and still images captured through the RVA systems. Such systems may also supply immediate notification to the establishment when pre-determined activities or increased incidences of activities occur. Establishments may determine that the records from using video or other electronic monitoring or recording equipment can help them develop and maintain a systematic approach to humane handling and good commercial practice. The systematic approach means one in which establishments focus on treating livestock or poultry in such a *Humane Handling and Slaughter Requirements and the Merits of a Systematic Approach to meet such Requirements*,<sup>6</sup> (69 FR 54625, September 9, 2004) and *Treatment of Live Poultry Before Slaughter*<sup>7</sup> (70 FR 56624, September 28, 2005).<sup>8</sup> "6 manner as to minimize excitement, discomfort, and accidental injury for the entire time that live livestock or poultry are held in connection with slaughter. The systematic approach involves specific steps (four in livestock and three in poultry) to ensure that there is an integrated approach to humanely handling the animals and good commercial practices in poultry. The steps are: 1. Identify where and under what circumstances livestock may experience excitement, discomfort, or accidental injury while being handled in connection with the slaughter process. Assess circumstances in which poultry may experience excitement, discomfort, or accidental injury while being handled. 2. Design facilities and implement practices that will minimize livestock discomfort and injury in accordance with existing regulations. Take steps to minimize the possibility of excitement, discomfort, and accidental injury of poultry. 3. Periodically evaluate the system to see whether there is any excitement, discomfort, or injury as livestock move from being unloaded from trucks to the knock box. Evaluate periodically how poultry are being handled and slaughtered to ensure (a) that any excitement, discomfort, or accidental injury is being minimized; (b) that all poultry are slaughtered in a manner that results in thorough bleeding of the poultry carcass; and (c) that breathing has stopped before scalding. 4. Improve or adjust operations in livestock to minimize

the excitement, discomfort, or possibility of accidental injury. A livestock establishment in Step 3, for example, might use video monitoring of the holding pens to determine whether employees are in fact minimizing excitement, discomfort, and accidental injury of animals. Similarly poultry establishments may use video or other electronic monitoring or recording equipment to monitor live areas to determine whether employees are taking actions to minimize excitement, discomfort, and accidental injury, as they position the birds for stunning and slaughter. Thus, the use of video or other electronic monitoring or recording equipment to support an overall systematic approach can provide assurance that the establishment intends to meet the requirements for humane handling and good commercial practices. Although FSIS encourages establishments to use appropriate video or other electronic monitoring or recording equipment, video surveillance from a remote location would not provide an effective method for FSIS to assess the consciousness of animals, as the Agency is required to do.

Assessing consciousness of animals involves direct observation from several visual perspectives and sometimes touching the animal's eyes or other parts. The use of video technology does not replace FSIS on-site verification activities of humane handling and good commercial practices. IPP need to conduct hands-on verification activities to assess whether an establishment's handling and slaughter", "7 activities comply with 9 CFR Part 313, 21 USC 603(b), and section 1902 of the HMSA (7 USC 1902). Similarly for poultry, IPP need to assess by hands-on verification whether birds are handled and slaughtered in a manner consistent with good commercial practices ( 9 CFR Part 381.65 (b)), and whether they are dying other than by slaughter (9 CFR Part 381. 90) (PPIA) 21 US 453(g) (5)). FSIS IPP are trained in humane handling and understand that they are obligated to take immediate action when they directly observe an egregious humane slaughter violation. If IPP were to observe an egregious event on an establishment's live feed video for example, IPP are expected to go directly to the place at the establishment where the event was occurring and ensure that the event has ended and does not persist. They are also expected to document appropriately the observation, even when the event witnessed is no longer occurring and to take any appropriate actions according to instructions in relevant FSIS Notices and Directives. NOTE: IPP are not to focus on the live feed video since it does not have a recording component and therefore cannot create a record. While the live feed may, on a rare occasion, point to a problem, it is a much more efficient use of IPP's time to perform the assigned tasks than to specifically focus on the live feed video, on the off chance that an egregious situation will be shown. For similar reasons, FSIS believes that IPP need to conduct hands-on verification activities for ante-mortem inspection (9 CFR Part 309 and Part 381.70 - 75). V. Use of Video or Other Electronic Monitoring or Recordings for Food Defense Purposes FSIS has prepared guidance documents for food processors to use to assist federally and State-inspected establishments that produce meat, poultry, and processed egg products in identifying ways to strengthen their biosecurity protection. FSIS recognizes that inspected plants may also be aware of, and may be adopting, guidelines from other government and private sector organizations and agencies. FSIS designed "Food Defense Guidelines for Slaughter and Processing Establishments" to meet the particular needs of meat and poultry establishments and processed egg products plants. These guidelines are available on the FSIS Web site at [http://www.fsis.usda.gov/Food\\_Defense\\_&\\_Emergency\\_Response/FSIS\\_Security\\_Guidelines\\_for\\_Food\\_Processors](http://www.fsis.usda.gov/Food_Defense_&_Emergency_Response/FSIS_Security_Guidelines_for_Food_Processors). While the guidelines are voluntary, and establishments may

choose to adopt measures suggested by many different sources, it is vital that all food businesses take steps to ensure the security of their operations. Video surveillance equipment can be used to meet many different and varied food defense concerns. Establishments may not cover every element of their Food Defense Plan with video cameras and may choose short, moderate, or long recording durations. A common use of video surveillance is", "8 monitoring the exterior of the buildings and premises to enhance the perimeter security of the establishment. Videos or other electronic monitoring or recordings used by establishments for food defense purposes to maintain active monitoring and surveillance of process points of highest concern (vulnerable nodes) in food systems represent a credible countermeasure against intentional contamination. Providing FSIS access to the videos regarding food defense activities is voluntary, unless the video includes information relevant to an official investigation, such as a suspected case of food tampering. In those situations, FSIS may request access to all applicable establishment records. If in the future, the Agency decides to propose mandatory development and implementation of functional food defense plans, access to video records is one of the issues that FSIS will consider in the rulemaking.

**VI. Use of Video or Other Electronic Monitoring or Recording Equipment to Meet HACCP and Sanitation SOP Recordkeeping Regulatory Requirements or for Other Purposes.**

Establishments are required to keep records related to their HACCP plan, including all decision-making with its operation (i.e., monitoring, verification, and corrective action). This documentation includes the results of any testing and of any monitoring or verification activities, such as in prerequisite programs that are performed by the establishment that may have an impact on the establishment\u2019s hazard analysis, whether or not such testing or monitoring is incorporated into an actual HACCP plan, referenced in a HACCP plan, or considered as separate activities. Records of these activities, that may have an impact on the establishment\u2019s hazard analysis, as well as designated HACCP records, are subject to FSIS review and are to be available to FSIS personnel (9 CFR 417.5 (e) and (f)). Establishments are required to develop and maintain a recordkeeping system that documents the monitoring of the critical control points (CCPs) (9 CFR 417.2(c) (6)).

Establishments need to decide in advance how they will document their monitoring of and verification activities for their CCPs. If an establishment determines and designates a video or other electronic monitoring or recording equipment to record the required HACCP information, this information is to be included as part of its recordkeeping system description. Accessibility of electronic or digital records is the same as for any other record, and establishments will need to comply with the applicable regulatory requirements for record retention and availability (9 CFR 320, 416.16, and 417.5). Establishments would need to provide appropriate methods or means for FSIS to view the video or digital records used for the purposes listed in 9 CFR Part 320. The regulations (9 CFR 417.4(a) (2)) require ongoing verification activities, including the review of records generated and maintained in accordance with 417.5(a) (3). FSIS", "9 would not anticipate that establishments can use video recordings to accomplish the purposes of 9 CFR 417.4(a) (2) (i) or (iii). However, an establishment may use video or other electronic monitoring or recording equipment as an ongoing verification activity by direct observation of the monitoring activities (9 CFR 417.4(a) (2) (ii)). If the establishment does so, it must have documents supporting the verification procedures and frequency of using the video for this purpose. This documentation would include support that the video or other electronic monitoring or recording equipment captures all of the observable activities at the CCP. For

example, if a recording, observed at a remote location, is used instead of physically walking to the monitoring point and observing the person, as they perform the monitoring procedures, then the establishment would have to demonstrate that the information and data recorded are accurate and that no food safety issues are missed. Recordkeeping requirements in 9 CFR 417.5(a) (3) include monitoring and verification procedures and their results, as well as the initials or signature of the individual making the entry, the time and date of entry, and the product identification (e.g. name, code, lot). For example, initials or signature of an individual might be achieved by a time stamp on the video corresponding to a specific company employee with specific access to that record. Establishments will also need to conduct activities designed to determine whether their automated recordkeeping systems are functioning as intended and to conduct verification activities on these systems. For video or other electronic monitoring or recording equipment, this means that the establishment will need to consider factors discussed in Section A \u201cSystems Used for Creating Video or Other Electronic Monitoring or Recording Records.\u201d The Sanitation SOP regulations (9 CFR 416.16 (a) (b)) require maintaining daily records to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken. Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data. Establishments need to decide in advance how they are going to document Sanitation SOP implementation and monitoring activities, such as observing performance of sanitation tasks and identifying noncompliance. Establishments that designate and choose to use video records to meet Sanitation SOP regulatory requirements need to ensure that the video or other electronic monitoring or recording equipment they use meets the regulatory requirements of 9 CFR 416.16, that is, showing that the video records document the monitoring of the Sanitation SOP and any corrective actions that were taken. The establishment would need to determine how noncompliance would be identified, and what corrective actions it would need to take to restore sanitary operating conditions. If a video record is to be generated in addition to a paper monitoring or verification record, establishments should determine in advance and designate whether they plan to rely on the video recording or other electronic monitoring or recording or the paper", "10 record to meet regulatory requirements. Once the establishment designates the records from this type of equipment then the records would be available to the establishment and to FSIS, as are other records, according to 9 CFR 320, 416, and 417, for verification purposes. Establishments may choose to submit non-HACCP, non-Sanitation SOP, or other management or surveillance video records to appeal a decision in a Noncompliance Record (NR). The validity of those records would be determined on a case-by-case basis. For example, an electronic surveillance record may demonstrate that monitoring of the CCP took place, but the results of the monitoring were not recorded. Establishments should be aware that all information on video or other electronic equipment records used in an appeal may be considered by FSIS in making a final appeal decision.

A. Systems Used for Creating Video or Other Electronic Monitoring or Recording Records

When video or other electronic monitoring or recording equipment is used to produce records that meet regulatory requirements, an establishment needs to design, maintain, and validate its system so that the records generated will be trustworthy, accurate, and a true representation of the process. In the absence of controls, electronic records can be easily manipulated. For example, FSIS would consider the absence of a record showing who has

accessed a computer system, and what operations he or she has performed during a given period of time (audit trail) to be highly significant if there are data or record entry discrepancies. Similarly, lack of operational system checks to ensure that the correct order of manufacturing steps occurs (event sequencing) would be significant if such a deviation results in an adulterated or misbranded product. FSIS recommends that establishments consider the following factors and design elements when establishing this type of recordkeeping system:

1. A recordkeeping system involving video or other electronic monitoring or recording equipment should be compatible with commercial industry standards and allow migration to new technologies and standards. For example, data generated on an older software system should be moveable to a newer version software file format, which enables the user to easily view a clear and complete copy that is legible or what is called \u201chuman readable\u201d during the required record retention period for the applicable record. (See Section B \u201cMaintenance and Retention of Records Generated Using Video or Other Electronic Monitoring or Recording Equipment.\u201d)
2. A recordkeeping system involving video or other electronic monitoring or recording equipment that is designated as a record to meet HACCP or Sanitation SOPs should be based on consideration of the following elements:
  - Access: Access to record systems should be limited to authorized individuals.
  - "11 Accurate copy: Systems should be able to generate accurate and complete copies of records in human readable and electronic form suitable for inspection and review.
  - Audit trail: Systems should use secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes should not obscure, previously recorded information. Audit trail information should be retained throughout the record retention period and be available for review and copying. The system needs to be designed so that sufficient information is retained to facilitate audits and resolve disputes.
  - Authority checks: Systems should have a protocol or mechanism in place to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system, alter a record, or perform a required operation; and, there should be a means to ensure that the protocol or mechanism is rigorously followed in order to preserve original information and signatures reliably.
  - Education: Persons who develop, maintain, or use electronic record and signature systems should have the education, training, and experience to perform their assigned tasks.
  - Operator entry checks: Systems should include some mechanism that determines and records the validity of the source of any data entered manually. Appropriate controls over systems documentation should be established.
  - Policies: Establishments should establish and adhere to written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures.
  - Establishments need to set standards for how data is entered and recorded by automated systems.
  - Protection: Systems should contain an adequate means to protect records for accurate and ready retrieval throughout the record retention period, including maintaining appropriate backup records.
  - System checks: Systems should allow use of operational checks to enforce permitted sequencing of steps and events.
  - Systems documentation: Systems should have adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance. Revision and change control procedures should be in place to maintain an audit trail that documents the development and modification of systems documentation.
  - "12 Validation: Systems should be validated to ensure that they are accurate,

reliable, consistent, and able to discern invalid or altered records. Note: If an establishment contracts with a vendor to provide video or other electronic services, the vendor would need to meet or exceed the defined requirements of the components described above. Establishments should validate their electronic\computerized systems. 9 CFR 417.4(a) (1) states, \u201cValidation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.\u201d Consequently, establishments should consider the impact that the system itself might have on the accuracy, reliability, integrity, availability, and authenticity of all required records. FSIS recommends that an establishment base its approach upon a risk assessment and a determination of the potential of the system itself to affect product safety and record integrity. Some establishments may have an existing system in place. If that system does not meet the criteria noted above, then that system would likely need to be upgraded to address adequately the system components noted above.

B. Maintenance and Retention of Records Generated Using Video or Other Electronic Monitoring or Recording Equipment

FSIS believes that it is important to understand the factors unique to the maintenance of electronic records that need to be controlled to use the record. When needed, establishments should be able to accurately and readily retrieve and use the recorded information. Accessibility of electronic or digital information should follow established industry guidance, and establishments will need to comply with all applicable regulatory requirements for record retention and availability (9 CFR 320, 416.16 and 417.5). FSIS regulations in 9 CFR 320 contain basic requirements for records, including record retention time and types of records such as bills of lading, production records, invoices, shipping and receiving records, and related business records. The following principles and practices provide guidance for the industry to meet this objective:

1. Establishments should employ procedures and identify controls for the protection of records that permit their accurate and ready retrieval throughout the records retention period.
2. Establishments should update their documented procedures and controls as they make changes.
3. Establishments should identify and control factors that could affect the reliability of electronic records during their retention periods.

"13 Procedures should describe and include the following factors: How will the video surveillance or other electronic records be maintained? How is the data encoded within an electronic record (e.g., computer readable representations of information)? On what type of media (e.g., disk, tape, or flash memory devices) will the data be recorded? What hardware will be used to retrieve and display the electronic record? What software (both application programs and operating systems) will be used to read, process, and display electronic records? What are the storage conditions under which the records will be maintained? What environmental precautions are needed to maintain data (controlled environment)? What retrieval and access restrictions are there for data stored and maintained in electronic record storage (e.g., if personnel or software programs change or are upgraded can the stored data still be accessed)? Which personnel are responsible for maintaining the records? What processes are necessary to extract and present the information in human readable form? If these factors are not controlled properly, then the information that the electronic records convey might not be complete, accurate, or usable."]}, {"file\_name": "FSIS\_GD\_2013\_0017", "title": "Guidance on Ingredients and Sources of Radiation Used to Reduce Microorganisms on Carcasses, Ground Beef, and Beef Trimmings", "num": "FSIS-GD-2013-

0017","id":"9a2dea7e1c9e47fe5e8462816ca3c6c461d4094b2e78b72cace379e8008f58ed","corpus":"fsis\_guidelines","source\_page\_url":"https:\V\www.fsis.usda.gov\policy\fsis-guidelines","url":"https:\V\www.fsis.usda.gov\sites\default\files\media\_file\2021-07\FSIS-GD-2013-0017.pdf","type":"pdf","n\_pages":3,"word\_count":1668,"text\_by\_page":["Examples of Nutrition Facts Panels for Ground Products Beef, ground, 95% lean \V 5% fat, raw Nutrition Facts Serving Size 4 oz (112g) raw, as packaged. Servings Per Container varied Amount Per Serving Calories 150 Calories from Fat 50 % Daily Value\* Total Fat 6g 9% Saturated Fat 2.5g 13% Cholesterol 70mg 23% Sodium 75mg 3% Total Carbohydrate 0g 0% Protein 24g 48% Iron 15% \u2022 Not a significant source of dietary fiber, sugars, vitamin A, vitamin C, and calcium \* Percent Daily Values are based on a 2,000calorie diet Beef, ground, 90% lean \V 10% fat, raw Nutrition Facts Serving Size 4 oz (112g) raw, as packaged. Servings Per Container varied Amount Per Serving Calories 200 Calories from Fat 100 % Daily Value\* Total Fat 11g 17% Saturated Fat 4.5g 23% Cholesterol 75mg 24% Sodium 75mg 3% Total Carbohydrate 0g 0% Protein 22g 45% Iron 15% \u2022 Not a significant source of dietary fiber, sugars, vitamin A, vitamin C, and calcium \* Percent Daily Values are based on a 2,000calorie diet","Beef, ground, 80% lean \V 20% fat, raw Nutrition Facts Serving Size 4 oz (112g) raw, as packaged. Servings Per Container varied Amount Per Serving Calories 280 Calories from Fat 200 % Daily Value\* Total Fat 22g 34% Saturated Fat 9g 43% Cholesterol 80mg 27% Sodium 75mg 3% Total Carbohydrate 0g 0% Protein 19g 38% Iron 10% \u2022 Not a significant source of dietary fiber, sugars, vitamin A, vitamin C, and calcium \* Percent Daily Values are based on a 2,000calorie diet Beef, ground, 75% lean \V 25% fat, raw Nutrition Facts Serving Size 4 oz (112g) raw, as packaged. Servings Per Container varied Amount Per Serving Calories 330 Calories from Fat 250 % Daily Value\* Total Fat 28g 43% Saturated Fat 11g 53% Cholesterol 85mg 28% Sodium 75mg 3% Total Carbohydrate 0g 0% Protein 18g 35% Iron 10% \u2022 Not a significant source of dietary fiber, sugars, vitamin A, vitamin C, and calcium \* Percent Daily Values are based on a 2,000calorie diet","Beef, ground, 70% lean \V 30% fat, raw Nutrition Facts Serving Size 4 oz (112g) raw, as packaged. Servings Per Container varied Amount Per Serving Calories 370 Calories from Fat 300 % Daily Value\* Total Fat 34g 52% Saturated Fat 13g 63% Cholesterol 85mg 29% Sodium 75mg 3% Total Carbohydrate 0g 0% Protein 16g 32% Iron 10% \u2022 Not a significant source of dietary fiber, sugars, vitamin A, vitamin C, and calcium \* Percent Daily Values are based on a 2,000calorie diet Veal, ground, raw Nutrition Facts Serving Size 4 oz (112g) raw, as packaged. Servings Per Container varied Amount Per Serving Calories 160 Calories from Fat 70 % Daily Value\* Total Fat 8g 12% Saturated Fat 3g 16% Cholesterol 90mg 31% Sodium 90mg 4% Total Carbohydrate 0g 0% Protein 22g 43% Iron 6% \u2022 Not a significant source of dietary fiber, sugars, vitamin A, vitamin C, and calcium \* Percent Daily Values are based on a 2,000calorie diet","Pork, ground, 91% lean, 9% fat, raw Nutrition Facts Serving Size 4 oz (112g) raw, as packaged. Servings Per Container varied Amount Per Serving Calories 190 Calories from Fat 90 % Daily Value\* Total Fat 10g 15% Saturated Fat 2g 10% Cholesterol 80mg 26% Sodium 65mg 3% Total Carbohydrate 0g 0% Protein 23g 46% Iron 6% \u2022 Not a significant source of dietary fiber, sugars, vitamin A, vitamin C, and calcium \* Percent Daily Values are based on a 2,000calorie diet Chicken, ground, 89% lean, 11% fat, raw Nutrition Facts Serving Size 4 oz (112g) raw, as packaged. Servings Per Container varied Amount Per Serving Calories 210 Calories from Fat 110 % Daily Value\* Total Fat 12g 19% Saturated Fat 3.5g 18% Cholesterol 75mg 25% Sodium 75mg 3% Total

Carbohydrate 0g 0% Protein 23g 45% Iron 6% \u2022 Not a significant source of dietary fiber, sugars, vitamin A, vitamin C, and calcium \* Percent Daily Values are based on a 2,000calorie diet","Ground turkey, 92% lean, 8% fat, raw Nutrition Facts Serving Size 4 oz (112g) raw, as packaged. Servings Per Container varied Amount Per Serving Calories 170 Calories from Fat 80 % Daily Value\* Total Fat 9g 14% Saturated Fat 2.5g 12% Cholesterol 85mg 28% Sodium 75mg 3% Total Carbohydrate 0g 0% Protein 21g 42% Iron 8% \u2022 Not a significant source of dietary fiber, sugars, vitamin A, vitamin C, and calcium \* Percent Daily Values are based on a 2,000calorie diet Tabular Format","Note: These tabular formats are just examples. The nutrition facts values for ground product an establishment manufactures may differ depending on the fat content of the trimmings or parts used as starting material.", "Additional Information Regarding Nutrition Facts Formats 1. How large must the Nutrition Facts label be? Answer: There are no specific size requirements for the nutrition label. However, the \u201cNutrition Facts\u201d heading must be in a type size larger than all other print size in the nutrition label and generally set the full width of the nutrition facts label (9 CFR 317.309(d) and 381.409(d)). Minimum type sizes of 6 point and 8 point are required for the other information in the nutrition label, and there are minimum spacing requirements between lines of text. 2. What are the minimum type sizes and other format requirements for the Nutrition Facts label? Answer: The illustration below indicates an example of the graphics FSIS uses to display the Nutrition Facts label. Format requirements are specified in 9 CFR 317.309(d) and 381.409(d). Overall Nutrition Facts label is boxed with all black or one color type printed on a white or neutral background Typeface and Size 1. The Nutrition Facts label uses 6 point or larger Helvetica Black and\or Helvetica Regular type. In order to fit some formats the typography may be kerned as much as -4 (tighter kerning reduces legibility). 2. Key nutrients & their % Daily Value are set in 8 point Helvetica Black (but \u201c%\u201d is set in Helvetica Regular). 3. Nutrition Facts is set in either Franklin Gothic Heavy or Helvetica Black to fit the width of the label flush left and flush right.", "4. Serving Size and Servings per container are set in 8 point Helvetica Regular with 1 point of leading. 5. The table labels (for example, \u201cAmount per Serving\u201d) are set in 6 point Helvetica Black. 6. Absolute measures of nutrient content (for example, \u201c1g\u201d) and nutrient subgroups are set in 8 point Helvetica Regular with 4 points of leading. 7. Vitamins and minerals are set in 8 point Helvetica Regular, with 4 points of leading, separated by 10 point bullets. 8. All type that appears under vitamins and minerals is set in 6 point Helvetica Regular with 1 point of leading. Rules 1. A 7 point rule separates large groupings as shown in the example. A 3 point rule separates calorie information from the nutrient information. 2. A hairline rule or 1\4 point rule separates individual nutrients, as shown in the example. The top half of the label (nutrient information) has 2 points of leading between the type and the rules, the bottom half of the label (footnotes) has 1 point of leading between the type and the rules. Box All labels are enclosed by \u00bd point box rule within 3 points of text measure. 3. Must all of the type specifications shown with the nutrition format example (above) be followed? Answer: No. The mandatory type specifications are listed in 9 CFR 317.309(d) and 381.409(d). Unlike the illustrative example of section (above): 1. Any legible type style may be used, not just Helvetica. 2. The heading Nutrition Facts must be the largest type size in the nutrition label (i.e., it must be larger than 8-point, but does not need to be 13-point). 3. There is no specific thickness required for the three bars that separate the central sections of the nutrition label. 4. Can I use type sizes larger than 8 point and 6 point? Answer:

The requirement for 6 and 8 point type sizes are minimum requirements. Larger type sizes may be used. 5. What can be done if the regular Nutrition Facts label (i.e., the vertical format) does not fit the package? Answer: On packages with more than 40 square inches available to bear labeling, the \u201cside-by-side\u201d format may be used if the regular Nutrition Facts label does not fit. In this format, the bottom part of the Nutrition Facts label (following the vitamin and mineral information) is placed immediately to the right and separated with a line. If additional vitamins and minerals are listed after iron and the space under iron is inadequate, they may also be listed to the right with a line that sets them apart from the footnotes.", "Also, if the package has insufficient continuous vertical space (i.e., about 3 inches) to accommodate the above format, the nutrition label may be presented in a tabular (i.e., horizontal) display.

Bilingual Format 6. On labels that have two languages, may nutrition information be provided in one bilingual Nutrition Facts label? Answer: When nutrition labeling must be presented in a second language, the nutrition information may be presented in separate nutrition labels for each language or in one label with the second language, translating all required information, following that in English. Numeric characters that are identical in both languages need not be repeated.", "Simplified Format 7. What are the special labeling provisions for one or more mandatory nutrients being declared as \u201c0?\u201d Answer: The footnote after

\u201c\*Percent Daily Values are based on a 2000 calorie diet\u201d can be deleted.", "Small Packages and Intermediate-Sized Packages 8. What are the special labeling provisions for small and intermediate-sized packages? Answer: Food packages with a surface area of 40 sq. in. or less available for labeling may place the Nutrition Facts label on any label panel (not limited to the information panel), may omit the footnote required in 9 CFR 317.309(d) and 381.409(d) if an asterisk is placed at the bottom of the label with the statement \u201cPercent Daily Values are based on a 2,000 calorie diet,\u201d and, may also use the tabular display label format. 9.

Are abbreviations permitted in Nutrition Facts labels for small and intermediate-sized packages? Answer: Food packages with a surface area of 40 sq. in. or less available for labeling may use the following abbreviations in the Nutrition Facts label: Label Term Abbreviation Label Term Abbreviation Serving size Serv size Cholesterol Cholest Servings per container Servings Total carbohydrate Total carb Calories from fat Fat cal Dietary fiber Fiber Calories from saturated fat Sat fat cal Soluble fiber Sol fiber Saturated fat Sat fat Insoluble fiber Insol fiber Monounsaturated fat Monounsat fat Sugar alcohol Sugar alc Polyunsaturated fat Polyunsat fat Other carbohydrate Other carb 9 CFR 317.309(g)(2) and

381.409(g)(2")], {"file\_name": "FSIS\_GD\_2013\_0018", "title": "Extraordinary Circumstances-Procedures for Evaluating Labeling", "num": "FSIS-GD-2013-0018", "id": "963107ea5c7d5125dc971c66117b6d0bc9b9efbdb9b51ffa20a406f04b6b680b", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-07/FSIS-GD-2013-0018\_0.pdf", "type": "pdf", "n\_pages": 1, "word\_count": 186, "text\_by\_page": ["United States Department of Agriculture Food Safety and Inspection Service Undeclared Allergen Prevention Webinar Labeling and Program Delivery Division (LPDD) Office Policy and Program Development", "United States Department of Agriculture Food Safety and Inspection Service Big Eight Allergens \u2022 Wheat \u2022 Crustacean shellfish (e.g. shrimp, crab, lobster)", "\u2022 Eggs \u2022 Fish \u2022 Peanuts \u2022 Milk \u2022 Tree Nuts (e.g. almonds, pecans,"]}

walnuts) \u2022Soybeans", "United States Department of Agriculture Food Safety and Inspection Service Ingredient Labeling and Allergen Statements \u2022 Agency regulations require all ingredients to be declared in descending order of predominance in the ingredients statement \u2022 Food Allergen Labeling and Consumer Protection Act (FALCPA) did not amend the FMIA, PPIA, and EPIA \u2022 FSIS supports voluntary use of allergen statements, e.g., \u201ccontains: soy\u201d

[http://www.fsis.usda.gov/Regulations\\_&\\_Policies/Labeling\\_Allergens/index.asp](http://www.fsis.usda.gov/Regulations_&_Policies/Labeling_Allergens/index.asp) \u2022 LPDD evaluates \u201cmay contain\u201d type statements on a case by case basis", "United States Department of Agriculture Food Safety and Inspection Service 4 4\19\2012 12 7 13 18 40 58 54 69 70 103 0 20 40 60 80 100 120 2007 2008 2009 2010 2011 No. of Allergen Recalls Compared to Total Recalls # of Undeclared Allergen Recalls Total Number of Recalls that Year SOURCE: OFO\RMS", "United States Department of Agriculture Food Safety and Inspection Service 5 0% 20% 40% 60% 80% 100% 120% 2007 2008 2009 2010 2011 57% 59% 39% 39% 33% 21% 13% 19% 26% 39% 3% 9% 7% 10% 5% 19% 19% 35% 26% 23% % of Recalls by Reason from 2007 to Present % of Recalls associated with Pathogens % of Undeclared Allergen Recalls % of Foreign Material Recalls % of Recalls in All Other Categories SOURCE OFO\RMS", "United States Department of Agriculture Food Safety and Inspection Service 6 0 5 10 15 20 25 2007 (12 Total) 2008 (7 Total) 2009 (13 Total) 2010 (18 Total) 2011 (40 Total) 4 2 4 14 25 5 5 7 4 6 3 2 5 3 1

What or Who Initiated Allergen Recalls? # Discovered by FSIS Verification Activities # Discovered by EST # Discovered by a Consumer # Discovered by a 3rd Party # Discovered by FDA in dual jurisdiction EST SOURCE: OFO\RMS", "United States Department of Agriculture Food Safety and Inspection Service What Caused Allergen Recalls in 2011? \u2022New Ingredient and\or New Supplier \u2022Misprinted Label \u2022Product in wrong package \u2022Product reformulated \u2022Ingredient reformulated ALWAYS make SURE ALL ingredients and sub-ingredients are declared on the finished product label 7 SOURCE: OFO\RMS", "United States Department of Agriculture Food Safety and Inspection Service Allergen Recalls \u2022The occurrence of a recall indicates the establishment has failed to: \u2013address the chemical (allergen) food safety hazard in its hazard analysis; \u2013to support a decision in the hazard analysis; \u2013reassess its hazard analysis; \u2013effectively implement the controls to support a decision (see 9 CFR 417.2, 417.3, 417.4, 417.5, 417.8).", "United States Department of Agriculture Food Safety and Inspection Service Establishment Responsibilities \u2022Identify \u2022Prevent \u2022Declare", "United States Department of Agriculture Food Safety and Inspection Service Identify \u2022All ingredients going into a product must be identified before the assembly process. \u2022Inspect incoming non-meat ingredients by matching component labels, specification sheets, etc.", "United States Department of Agriculture Food Safety and Inspection Service Prevent \u2022Equipment \u2022HACCP plan \u2022Sanitation Standard Operating Procedures \u2022Allergen Control Plan \u2022Packaging and storing meat products containing allergens and those that do not.", "United States Department of Agriculture Food Safety and Inspection Service Declare \u2022Labeling procedures", "United States Department of Agriculture Food Safety and Inspection Service FSIS Actions \u2022Issued notice, Verification Activities Related to the use of Ingredients of Public Health Concern, FSIS Notice 35-11

\u2022Notice was issued for instructions for inspection activities for in plant personnel, FSIS Notice 54-11", "United States Department of Agriculture Food Safety and Inspection Service Is the product manufactured from raw materials that contain allergens? If allergens are contained

in the product, you must declare on the label all allergens contained in the product. Is the product manufactured on a production line or with equipment that comes in direct contact with allergenic substances? If no allergens are present in the product, no special labeling is needed. Implement all necessary measures to eliminate the risk for allergens on the production line and equipment! HACCP and good manufacturing principles should be used. Can it be documented through cleaning controls, test results, or other means that no allergens are present on the production line or equipment or in the product? If it can be documented that no allergen residue is in the product, no special labeling is needed. If it cannot be documented that no allergen residue is in the product, and cross contact is unavoidable, special labeling should be considered. In some cases, \u201cmay contain\u201d labeling may be applied. Be specific, such as \u201cmay contain peanuts.\u201d Allergen Risk Evaluation and Labeling Yes No No Yes Yes","United States Department of Agriculture Food Safety and Inspection Service \u201cMay Contain\u201d Statement \u2022Notice 54-11 explained Agency\u2019s position on carrying through \u201cmay contain\u201d type statements from incoming product labels to final labels \u2022Statement not required to be carried through provided the establishment contacts supplier and: (1) confirms, preferably in writing, that the statement is a cautionary statement, and no such ingredient is in the product; and (2) includes a written statement in its hazard analysis documentation to support why the \u201cmay contain\u201d or \u201cproduced in a facility\u201d statement is not carried forward to the finished meat or poultry product label","United States Department of Agriculture Food Safety and Inspection Service Recap \u2022Verify labels match the product through pre-shipment review of records. \u2022Work with FSIS in plant personnel.", "United States Department of Agriculture Food Safety and Inspection Service Ask FSIS Submit additional questions to: askfsis.custhelp.com"]}, {"file\_name": "FSIS\_GD\_2013\_0022", "title": "Compliance Guide for a Systematic Approach to the Humane Handling of Livestock", "num": "FSIS-GD-2013-0022", "id": "922249d53a00271418c1a93eb902b464dc6fc2b96bdb3d5040b6b47b581c275f", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Comp-Guide-Systematic-Approach-Humane-Handling-Livestock.pdf", "type": "pdf", "n\_pages": 21, "word\_count": 6819, "text\_by\_page": ["Updated: April 13, 2012 QUESTIONS & ANSWERS ON NUTRITION LABELING Q1. When will FSIS start scheduling webinars and meetings? A.FSIS plans to have a webinar within a month or two that discusses the general requirements of the nutrition labeling final rule and some Q&As. Once FSIS has prepared point-of-purchase materials and labels, FSIS also plans to schedule additional webinars and meetings. Q2. When FSIS provides the point-of-purchase materials, will they be different than the current posters and will they take into account the change in the values in the ARS database? A.The format will be similar to the existing posters. FSIS will continue to be in touch with ARS and the posters will include the new ARS values. Q3. Will the point-of-purchase materials be in high resolution quality on FSIS\u2019s website, so you can print larger posters? A.Yes, we plan to make the point-of-purchase materials in high resolution quality so that they can be enlarged, similar to the ones on the FDA website. Q4. Does the Agency intend to research the format of the point-of-purchase materials for better readability? The Industry is willing to work with FSIS on improving the format. A.FSIS is looking into and researching consumer readability. FSIS may conduct research on these issues in the future, provided

resources are available. Q5. Currently some posters include nutrition information for ground product. Will this nutrition information on posters disqualify businesses from using the small business exemption? A.No. Q6. Who has the burden of complying with the rule, e.g. the packer or the producer? A.Normally, the packer is considered the producer because the packer produces the final product. For ground or chopped product, the producer of the final packaged product is required to provide nutrition labels on the product, unless an exemption applies. The producer of the final packaged product may be a Federal establishment or retail facility. Retailers are required to provide point-of-purchase materials or nutrition labels for major cuts, unless an exemption applies.", "Q7. Will the inspectors be checking labels at the Federal establishments? A. As part of label verification activities, inspectors at establishments that produce ground or chopped products will periodically review labels to verify that establishments meet labeling February 9, 2011 requirements, including the requirement that the product bears a nutrition label, unless an exemption applies. Q8. If an establishment produces a mixed package of white meat and dark meat and both are major cuts, does the package need to carry 2 nutrition labels (one for white meat and one for dark meat)? A. The nutrition information for each of the major cuts could be provided at point-of purchase. Alternatively, the establishment could composite the nutrition facts panels or include two separate nutrition facts panels on the label for each product in the package. Q9. Is the leeway on values still 20%? A. Yes. The regulations in 9 CFR 317.309(h) and 381.409(h) specify that certain nutrient values are not out of compliance, unless they are more than 20% above the labeled value. That rule applies to the labeled values for calories, sugars, total fat, saturated fat, cholesterol, or sodium. These regulations also specify that certain nutrient values are not out of compliance, unless they are 20% below the labeled value. That rule applies to the labeled values for vitamins, minerals, protein, total carbohydrates, dietary fiber, other carbohydrates, polyunsaturated or monounsaturated fat or potassium. Q10. Will FSIS be doing educational sessions around the country like AMS did for country of origin labeling? A. This final rule is consistent with voluntary labeling regulations that have been in place since 1993. Therefore, FSIS thinks webinars and other meetings should be sufficient. Q11. If a producer is not sure of the lean and fat percentage of a ground or chopped product, could the producer label it with a worse lean and fat percentage? For example, could a producer label a product that is actually 80% lean and 20% fat, with a 70%lean\30% fat label? A. FSIS would not take action against producers estimating that their products are higher in fat than they actually are. Q12. Will State officers be doing any sampling for nutrient analysis? A. States that have their own meat and poultry inspection program are required to have programs at least equal to the Federal inspection program. Therefore, when FSIS begins conducting sampling for nutrient analysis of ground or chopped product, states with their own inspection program will have to conduct \u201cat least equal\u201d sampling and analysis.", "Q13. How will sampling work at retail? Will it be as complicated as with pathogens (microsampling)? How will establishments or retailers be notified? A. The details of the sampling program have not yet been worked out. However, product would not be considered adulterated if nutrition labeling information is inaccurate. Therefore, when February 9, 2011 FSIS begins sampling ground or chopped product at retail for nutrient content, FSIS does not anticipate providing establishments advance notice. Q14. Will the webinars include opportunities to ask questions? Will they be archived on the FSIS Website? A. We plan on having question and answer sessions in the webinars. Webinars are

typically posted on FSIS's website for 30 days. Q15. Will there be a label review process for retailers with unique needs? A. FSIS does not anticipate the need for this. LPDD does not pre-approve labels applied at retail unless they are shipped with the product from a Federal establishment. Retailers can submit questions concerning labeling through askFSIS. Q16. Will FSIS personnel be available to participate at industry conferences that are coming up in the next 90 days? A. Yes. Q17. How will retailers know the lean/fat content of ground products, and how will they determine the other nutrients in the nutrition facts panel? A. Retailers need to know that ground or chopped beef labeled as ground beef or hamburger does not contain more than 30% fat. Typically, they can get information concerning the lean and fat percentage from their suppliers or they can analyze the levels of fat at retail with an anal-ray or other device for measuring the fat content of ground beef. If the product does not contain AMR or low temperature rendered product, once the fat content is known, retailers can obtain information for the nutrition facts panel from the ground beef calculator available from the Agricultural Research Service at the Nutrient Database for Standard Reference, Release 23. This is available at: [www.ars.usda.gov/nutrientdata](http://www.ars.usda.gov/nutrientdata). Q18. Which cuts come under this rule? A. The final rule requires that nutrition information for the major cuts of single- ingredient, raw meat and poultry products be provided on the label or at point-of-purchase, unless an exemption applies. All ground or chopped products are also covered by the final rule (e.g., ground beef, ground pork, ground turkey). Nutrition", "information for all ground or chopped products must be provided on the label of the products, unless an exemption applies. The major cuts of single-ingredient, raw meat products covered by the rule are: Beef chuck blade roast, beef loin top loin steak, beef rib roast large end, beef round eye round steak, beef round top round steak, beef round trip roast, beef chuck arm pot roast, beef loin sirloin steak, beef round bottom round steak, beef brisket (whole, flat half, or point half), beef rib steak small February 9, 2011 end, beef loin tenderloin steak, pork loin chop, pork loin country style ribs, pork loin top loin chop boneless, pork loin rib chop, pork spareribs, pork loin tenderloin, pork loin sirloin roast, pork shoulder blade steak, pork loin top roast boneless, lamb shank, lamb shoulder arm chop, lamb shoulder blade chop, lamb rib roast, lamb loin chop, lamb leg (whole, sirloin half, or shank half), veal shoulder arm steak, veal shoulder blade steak, veal rib roast, veal loin chop, and veal cutlets. The major cuts of single-ingredient, raw poultry products covered by the rule are: Whole chicken (without neck and giblets), chicken breast, chicken wing, chicken drumstick, chicken thigh, whole turkey (without necks and giblets; separate nutrient panels for white and dark meat permitted as an option), turkey breast, turkey wing, turkey drumstick, and turkey thigh. Q19. In light of the new nutritional labeling regulations for ground product, is something like "\u201c85%\u201d still allowed on labels for retail sale with no qualifiers? A. No, under the 1993 nutrition labeling regulations that established the mandatory and voluntary nutrition labeling programs, in order for the term "\u201c\_percent lean\u201d to be used on the label or in labeling of the product, the product must have met the criteria for "\u201clow fat\u201d (9 CFR 317.362(b)(6) and 381.462(b)(6)). Most ground beef and hamburger do not qualify as "\u201clow fat.\u201d Therefore, the regulations precluded the use of the term "\u201c\_percent lean\u201d on these products. On May 24, 1994 (59 FR 26916) FSIS proposed to amend its regulations to permit a statement of the lean percentage on the labeling of ground beef and hamburger if it were contiguous to a statement of the fat percentage. On August 5, 1994, FSIS published a notice of extension of the date that it would enforce

compliance with the nutrition labeling requirements for ground beef and hamburger (59 FR 39941). The Agency extended the compliance enforcement date for these products indefinitely, pending publication of a final rule on percentage labeling for lean and fat on ground beef and hamburger. Since then, the Labeling and Program Delivery Division has approved many different labels, including use of a ratio like \u201c85\u201d without any qualifiers or words like \u201clean\u201d or \u201cfat\u201d on the label, because FSIS did not have a regulation in effect on the nutrition labeling of ground beef. FSIS has now published the nutrition labeling final rule, which permits a statement of lean percentage on the label or in labeling of ground or chopped meat and poultry products that do not meet the regulatory criteria for \u201clow fat.\u201d provided that a "statement of fat percentage is also displayed on the label or in labeling. The required statement of fat percentage must be contiguous to, in lettering of the same color, size, and type as, and on the same color background as, the statement of lean percentage. A ratio like \u201c85\u201d without the words \u201cpercent lean\u201d and \u201cpercent fat\u201d or \u201c%lean\u201d and \u201c% fat\u201d is not a statement of the lean and fat percentage. Without a complete statement of the percent fat and percent lean, consumers may not understand the meaning of the ratio. After the effective date of the nutrition labeling final rule, \u201c85\u201d and other ratios that are not complete statements should no longer be used on chopped or ground products for retail sale to consumers. Once the nutrition labeling final rule becomes effective on January 1, 2012, the Labeling and Program Delivery Division will no longer approve labels with only a ratio like \u201c85\u201d for retail products without the words \u201cpercent lean\u201d and \u201cpercent fat\u201d or \u201c%lean\u201d and \u201c% fat\u201d also on the label. A statement of percent lean and percent fat (e.g., \u201c85% lean\u201d/\u201c15% fat\u201d) will be permitted on the label for ground products that do not meet the regulatory criteria for \u201clow fat.\u201d Q20. If a Federal establishment is producing ground beef for distribution to another Federal establishment for further processing or to hotels, restaurants, and similar institutions (HRI) where it will be consumed on the premises, and the ground beef will not be distributed for sale to consumers at retail, can the establishment continue to label non-retail ground beef product with ratios or codes such as, \u201c90\u201d/\u201c10,\u201d \u201c70\u201d/\u201c30\u201d and \u201c80\u201d/\u201cup\u201d which are commonly used as ratios or codes by industry and food service establishments? A. Yes, ground meat and poultry products that are not for sale to consumers may continue to be labeled with ratios or codes such as, \u201c80\u201d/\u201c20\u201d and \u201c70\u201d/\u201cup\u201d provided: (1) the labels bear no nutrient content claims and (2) a statement of limited use is displayed on the label (e.g., \u201cfor further processing,\u201d \u201cnot for retail sale\u201d). FSIS believes that ratios or codes of this type are commonly used and understood by industry and food service establishments for ground meat and poultry products. Ratios or codes are not full statements, so their use doesn\u2019t violate the nutrition labeling final rule if they are only used by businesses for further processing. However, FSIS does not believe that consumers may always understand the meaning of ratios of this type without a complete statement of the percent fat and percent lean. Therefore, once the final rule titled, \u201cNutrition Labeling of Single-Ingredient Products and Ground or Chopped Meat and Poultry Products\u201d becomes effective on January 1, 2012, the Labeling and Program Delivery Division (LPDD) will not approve labels for ground meat and poultry products for retail sale with a ratio or code (e.g.,

\u201c85%\u201d); such codes will no longer be acceptable on product for sale to consumers. Labels for retail sale to consumers with this type of information without the words \u201cpercent lean\u201d and \u201cpercent fat\u201d or \u201c%lean\u201d and \u201c%fat\u201d should not be used and will not be approved after December 31, 2011. Labeling for retail sale to consumers may instead include a statement of the percent fat and percent lean as provided for in the regulation (e.g., \u201c85%lean/\u201d 15%fat\u201d).", "Q21: Will a small retail business, like a butcher shop, be exempt from the rule? A. Probably, it is likely that a small retail business, like a butcher shop, will qualify for the small business exemption for ground or chopped products under \u00a77317.400(a)(1) and 381.500(a)(1). There is no small business exemption for the \u201cmajor cuts\u201d of singleingredient, raw meat and poultry products. Therefore, a small retail business will be required to provide nutrition information for the major cuts of single-ingredient, raw meat and poultry products on labels or on point-of-purchase materials (e.g., signs, posters, or pamphlets). Nutrition information for the major cuts of single-ingredient, raw meat and poultry products are currently available at or [www.fmi.org/consumer/nutrifacts/](http://www.fmi.org/consumer/nutrifacts/) or [www.ars.usda.gov/nutrientdata](http://www.ars.usda.gov/nutrientdata). FSIS is also going to make point-of-purchase materials for the major cuts of single-ingredient, raw meat and poultry products available on the FSIS website. Q22: Will farmers that slaughter beef at small plants be exempt from this rule for products sold at farmers\u2019 markets? A. No, for major cuts, probably for ground beef products. If they sell major cuts of singleingredient, raw meat and poultry products at farmers\u2019 markets, they will be required to provide nutrition information for these products on labels or on point-of-purchase materials (e.g., signs, posters, or pamphlets). There is no small business exemption for the major cuts of single-ingredient, raw meat and poultry products. It is likely that a farmer that slaughters beef at a small plant will qualify for the small business exemption under \u00a77317.400(a)(1) from the nutrition labeling requirements for ground or chopped products. However, the small business exemption applies to the facility that slaughters, fabricates, packages and labels the product. Q23: Is a branded beef program (e.g., Angus Beef) that sells whole carcasses directly to approximately 20 independent retailers exempt from the nutrition labeling final rule? Is a supplier that only sells whole carcasses, not case-ready cuts, required to provide its retail customers with nutrition information? A. Yes, if the producer does not package products, this rule does not affect it. Additionally, the supplier who sells whole carcasses is not required to provide nutrition information to retail customers based on this regulation. Q24: Does a plant under USDA inspection that sells directly to consumers have to test each product so that it can be labeled with nutrition information? A. No, there is no requirement that an establishment has to test each product. The plant can obtain nutrition information and materials for the major cuts of single-ingredient, raw meat and poultry products that can be used at point-of-purchase from The Food Marketing Institute at [www.fmi.org/consumer/nutrifacts/](http://www.fmi.org/consumer/nutrifacts/). FSIS will also be making point-of-purchase (POP) materials available on its website. The National Cattlemen\u2019s Beef Association also has a website available at [www.beefretail.org/nutritionlabeler/](http://www.beefretail.org/nutritionlabeler/) that can be used to develop labels as well as POP materials for retail.", "If a retailer knows the fat content of the ground or chopped product, they can obtain information for the nutrition facts panel from the ground beef calculator available from the Agricultural Research Service at the Nutrient Database for Standard Reference, Release 23. This is available at [www.ars.usda.gov/nutrientdata](http://www.ars.usda.gov/nutrientdata). For more information regarding testing the fat content of

ground product, please see the answer to question 28. Also, if the plant qualifies for the small business exemption (\u00a7317.400(a)(1) or \u00a7381.500(a)(1)), then it would be exempted from the nutrition labeling requirements for ground and chopped products. Q25: Will meat that is sliced and weighed at the deli have to bear nutrition labels under the nutrition labeling final rule? A. No, the most recent nutrition labeling rule applies to \u201cmajor cuts\u201d and ground or chopped products, which are not typically deli products. Under current nutrition labeling regulations, product produced or packaged at retail (and not ground or chopped) is exempt from the nutrition labeling requirements (\u00a7317.400(a)(7) and \u00a7381.500(a)(7)). Q26: Will a full service meat counter, where none of the meat is packaged until a customer selects the product and then it is weighed and wrapped for the customer, have to comply with the nutrition labeling final rule? A. Yes, if the full service meat counter sells the major cuts of single-ingredient, raw meat and poultry products listed in the nutrition labeling final rule, it will need to provide point-of-purchase materials for the \u201cmajor cuts\u201d it sells. Ground product, unless it is ground at a customer's request, will require on-package nutrition facts panels, unless the business qualifies for the small business exemption or other exemptions. Q27: What is the small business exemption? A: The small business exemption is in \u00a7\u00a7317.400 and 381.500. The small business exemption applies to any establishment (or retail facility) that has 500 or fewer employees. Any product they produce at less than 100,000 lbs per year is exempt from nutrition labeling as long as the product includes no nutrition information or claims. Ground \u201cProduct\u201d would be designated by different formulas/different nutrient profiles. For example, 10% fat ground beef is a different product and has a different nutrient profile than 20% fat ground beef. Therefore, each would be counted separately toward 100,000 lbs of product. Different forms of the same product are counted together toward the 100,000 lbs. For example, 10% fat ground beef sold to hotels, restaurants, and similar institutions (HRI), 10% fat ground beef sold in 1 lb chubs, 10% fat ground beef sold as 4-ounce patties, and 10% fat ground beef sold in bulk, would all be counted together, since they all have the same nutrient profile." "Q28: When meat is ground at small and very small establishments and retail exempt facilities, how is the fat content supposed to be measured? A. It is the establishment's or retailer's responsibility to truthfully label the products. The regulations under 9 CFR 317.8(a) and 319.15(a) require a product labeled as \u201cground beef\u201d to contain no more than 30 percent fat. Therefore, it is up to the establishment to support that the product is not misbranded. Q29: Will random documentation be required to \u201cverify\u201d the processors' claims of 80% lean/20% fat or 90% lean/10% fat, etc.? A. No, there is no regulatory requirement that defines how the establishment needs to support the label, and there is no requirement that it test each lot. If they have a consistent process, using the same source materials, then the establishment could develop and implement a written program to periodically verify compliance with the label standard by ensuring that suppliers consistently provide the source materials necessary to produce the labeled product. Although, the nutrition labeling regulations do not specify how an establishment determines the nutrient content of products, \u00a7317.309(h) specifies how FSIS will sample/analyze product for compliance. Q30: Does the nutrition labeling final rule require nutrition labeling of seafood? Is the nutrition labeling program an FDA or an FSIS program? A. No, the nutrition labeling final rule does not require nutrition labeling of seafood. Seafood is regulated by the FDA. The nutrition labeling final rule is

an FSIS final rule. Q31: Are nutrition facts on posters at point-of-purchase required to be in 8pt font or larger, and the details on the bottom of the poster be in 6pt font or larger? Is there a requirement that the heading cannot be larger in font than the rest of the font on the poster? A. No, those are the specifications for a nutrition facts panel or point-of-purchase materials (POP) when a nutrient content claim is made. For POP without claims, there are no format requirements (see \u00a7317.345(a)(3)). Q32: Should the nutrition information used on point-of-purchase materials be based on Release 23 of the USDA National Nutrient Database for Standard Reference? A. Yes, that is the most current information from the Agricultural Research Service. Q33: When utilizing the USDA National Nutrient Database for Standard Reference to search for nutrient values for single-ingredient products to include on nutritional labels, options are given for \u201cSeparable Lean Only\u201d or \u201cSeparable Lean and Fat\u201d for the products in the database. What is the correct descriptor and subsequent value to choose for the product for accurate and acceptable nutrient information? For example, should \u201cPork, fresh, loin, top loin (chops), boneless, separable lean and fat, raw\u201d or \u201cPork, fresh, loin, top loin (chops), boneless, separable lean only, raw\u201d be chosen?", "A. The correct descriptor is NOT separable lean only. \u00a7317.345(d) specifies that the nutrient data should be based on meat cuts with external cover of fat at trim levels reflecting current marketing practices. 1\u20448 inch trim best reflects current market practices at this time and information available in the nutrient database. Q34: What are the minimum nutritional elements that have to be shown on the label? A. The basic mandatory information - serving size, servings per container, calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, iron. The servings per container statement does not need to be provided for the \u201cmajor cuts,\u201d but is required for ground and chopped products (servings per container may be stated as \u201cvaried\u201d for random weight products like ground products). There are voluntary nutrients as well (\u00a7\u00a7317.309(c) and 381.409(c)). Q35: Is there a required format for the nutrition facts panel? For example, can nutrition information be presented in script? A. Yes, the nutrition facts panel format is regulated. See 9 CFR 317.309(c)-(f) and 381.409(c)-(f). Meat and poultry products would probably qualify to use the simplified format. Additionally, if the total square inches of labeling space (for the entire package) is less than 40 sq. in., then the tabular format may be used. Nutrition information cannot be presented in script because the regulations stipulate that letters in the nutrition facts panel should never touch (\u00a7\u00a7317.309(d)(1)(ii)(D) and 381.409(d)(1)(ii)(D)). Q36: Can a simplified nutrition facts panel be used for \u201cmajor cuts\u201d or ground or chopped products? A. Yes, a simplified nutrition panel is acceptable since single-ingredient meat and poultry products do not generally contain carbohydrates. Q37: Does nutrition information have to be presented on top of the package, or, can it be presented as a separate label on the bottom of each package? A. No, the nutrition facts panel may be on the principle display panel (the front), or on the information panel (the first usable panel to the right of the principle display panel), which oftentimes is the back panel or the bottom of the package \u2013 see 9 CFR 317.2(m). The panel may either be part of the overall printed label or applied as a separate sticker. The following labeling guide book may be helpful: A Guide to Federal Food Labeling Requirements for Meat and Poultry Products Q38: Are establishments that only produce meat intended for hotels, restaurants, and similar institutions (HRI) (e.g., in 5 or 10lb bags) exempt

from the nutrition labeling requirements for ground and chopped products?","A. Yes, if the ground and chopped products are only produced for HRI, then the products qualify for an exemption from the nutrition labeling final rule and nutrition information is not required on the products, as long as the labeling bears no nutrition information or nutrition claims (\u00a7\u00a7317.400(a)(3) and 381.500(a)(3)). Q39: Will packages of meatloaf meat (e.g. raw ground beef and raw ground pork combined) be required to be labeled under the rule? A. If the product includes ground pork and ground beef, it would be a multi-ingredient product. Therefore, under current regulations, it would have to bear nutrition labeling unless it is subject to an exemption. Q40: Regarding the meatloaf meat, if the ground pork and ground beef are in separate portions on the same tray, could the package have two nutrition labels, one for the ground beef and one for the ground pork? A: Yes, if the ground beef and ground pork were separate, there could be two nutrition facts panels. Q41: Is sausage processed at a retail store exempt under 9 CFR 317.400(a)(7)(ii) from nutrition labeling? A. Yes, as long as there are no nutrition information or nutrient content claims on the labeling. Q42: Does the total carbohydrate value have to be listed on point-of-purchase materials? A. Yes, total carbohydrate is a core nutrient and must be listed on labels or point-of-purchase materials. For meat or poultry, total carbohydrates will generally be declared as \u201c0\u201d. Q43: Are \u201cmajor cuts\u201d that are marinated required to have nutrition labeling? A. No, nutrition labeling is not required for the major cuts of meat or poultry products marinated at the store (\u00a7\u00a7317.400(a)(7)(ii) and 381.500(a)(7)(ii)). If the meat and poultry products come to the store already marinated, packaged and labeled for the consumer, they require nutrition information, unless the supplier qualifies for the small business exemption on that product. Q44: Is a cube steak considered a chopped product or is it a muscle cut since the meat isn't chopped into separate pieces? A. A cubed steak is not considered a chopped product. It is a muscle cut. Q45: Can the required nutrition facts panel be added with a sticker label or insert label as a permanent solution to being compliant? A. Yes, a nutrition facts panel can be added as a sticker or insert."Q46: Can a food grade coated nutritional panel label be inserted with the chicken before being shrink wrapped and a sticker label that carries weight, price, product name etc. applied to the product once it is wrapped? A. Yes, as long as all the information remains visible at the time of purchase. Q47: Should the definition of the \u201cmajor cuts\u201d in \u00a7\u00a7317.344 and 381.444 be interpreted to include boneless fillets, tenderloins, thigh meat etc. or does it strictly include bone-in product only? A. Yes, since nutrition information is based on the edible portion of the product, it doesn't matter if the product is boneless or bone-in, the same product would have to have the same nutrition information on the raw 4-ounces edible portion or cooked 3-ounce edible portion. Q48: To what extent do nutritional claims on point-of-purchase (POP) materials have to be supported with on-pack nutritional labeling? For example, if a retailer states \u201cmake lean beef part of your diet\u201d does all the beef in the case have to be labeled as \u201clean\u201d or do the POP materials or on-pack labels have to identify specifically which items are \u201clean?\u201d A. If you make a statement about \u201cLean Beef\u201d on your POP materials, the POP materials would need to indicate which cuts of beef meet the lean definition. However, if a nutrition claim is made on POP materials, all of the format and content requirements of \u00a7317.309 apply. If only nutrition information-and not a nutrition claim-is supplied on POP materials, the requirements of \u00a7317.309 apply, but (i) the listing of percent Daily Value for nutrients

(except vitamins and minerals in \u00a7317.309(c)(8)) and footnote required by \u00a7317.309(d)(9) may be omitted, and (ii) the POP materials are not subject to any of the format requirements. Q49: Can nutrition facts for single-ingredient products be presented as raw or cooked on labels or point-of-purchase materials? If cooked, what is the correct description to use from the USDA National Nutrient Database for Standard Reference (i.e. broiled, braised, or roasted)? A. Point-of-purchase (POP) materials for non-ground single-ingredient, raw products can be based on nutrition information for raw or cooked products. If retailers provide nutrition information for the product as cooked, a cooking method that does not add any nutrients to the product must be used and the method must be indicated on the POP materials. However, if a nutrition claim is made on the POP materials, all of the format and content requirements of \u00a7317.309 apply. If only nutrition information-and not a nutrition claim-is supplied on POP materials, the requirements of \u00a7317.309 apply, but (i) the listing of percent Daily Value for nutrients (except vitamins and minerals in \u00a7317.309(c)(8)) and footnote required by \u00a7317.309(d)(9) may be omitted, and (ii) the POP materials are not subject to any of the format requirements.", "Q50: Does a %lean\%fat statement need to be on ground products that don\u2019t qualify as \u201clean\u201d according to USDA, or is it just an option? A. No, the use of a %lean\%fat statement is voluntary. No claims are required. However, for ground products, a %lean\%fat statement can be listed even though the products do not meet the definition of \u201clow fat\u201d (3 grams of fat per reference amount). Q51: Does \u00a7317.400(a)(7)(ii) exempt store-made gourmet burger patties (e.g., raw ground beef combined with cheese and onions) from nutrition labeling? A. Yes, burgers made in the retail store with diced cheese and chopped onions do not meet the regulatory standards for \u201cChopped Beef,\u201d \u201cGround Beef,\u201d \u201cHamburger,\u201d or \u201cBeef Patties\u201d under \u00a7319.15 because the burgers are ground beef with added foods, not added seasonings, and as such, they are descriptively labeled products. Therefore, as long as the labeling does not include any nutrition information or claims, burgers made in the retail store with other food added (e.g., diced cheese and chopped onions) are exempt from nutrition labeling because they are multi-ingredient products processed at a retail store, not multi-ingredient ground or chopped meat products (\u00a7317.400(a)(7)(ii)). Q52: Is \"pumped pork\" considered a multi-ingredient product and thus exempt from nutrition labeling under the final rule? A. Yes, pumped pork is a multi-ingredient product and not covered by this final rule. However, it is covered by the 1993 nutrition labeling regulations. Q53: When the nutrition labeling final rule becomes effective, will the nutrition label that will be applied to the product be generically approved or will the establishment have to re-apply for a new sketch approval? A. The establishment will have to apply for a label approval to add the nutrition facts to its single-ingredient or other ground products. However, similar to what has been done in the past, once the establishment obtains one label approval with a 4-ounce serving size, it can generically approve others from that one approval. Q54: Is a \u201cservings per container\u201d statement required on single-ingredient, raw products that are not ground or chopped? A. No, a \u201cservings per container\u201d statement is not required on the major cuts of single-ingredient, raw meat and poultry products. A \u201cservings per container\u201d statement is required on the labels of ground or chopped products. Because ground or chopped products are often random weight products, the servings per container may be listed as \u201cvary.\u201d Q55: Based on the

final 2010 nutrition labeling rule, ground product labeled for consumers cannot be labeled with ratios or codes for fat and lean, such as \u201c90\u201d/\u201c10\u201d or \u201c80\u201d/\u201c10\u201d. Are there other situations where ratios or codes such as \u201c90\u201d/\u201c10\u201d or \u201c80\u201d/\u201c20\u201d would be permitted on meat and poultry products?" "A. Yes, if the product is NOT for consumers and will be used for ground product, you could use a ratio (e.g., \u201c72\u201d/\u201c28\u201d) as an indication of the lean to fat ratio on the labeling provided: (1) the labels bear no nutrient content claims and (2) a statement of limited use is displayed on the label (e.g., \u201cfor further processing,\u201d \u201cnot for retail sale\u201d). Ratios or codes will also be permitted on the shipping containers that hold fully labeled ground product with a %Lean/% Fat statement. The shipping container can show a ratio on the shipping container, e.g., \u201c80\u201d/\u201c20\u201d instead of the statement of lean and fat percentage\u201c80%Lean\u201d/\u201c20%Fat\u201d.

Q56: Are marinated or injected (\u201chenhanced\u201d) products covered by this new regulation? A. No. This rule establishes new nutrition labeling requirements for major cuts of raw, single-ingredient products and ground products with or without added seasonings. Labels of multi-ingredient injected products are required to include nutrition information based on the original nutrition labeling regulations published in 1993 (58 FR 632), unless they qualify for an exemption.

Q57. Can a retailer add nutrition labels to a single-ingredient product that is otherwise fully labeled at the Federal plant and includes the legend? A. No, a retailer cannot add nutrition labels to product that is fully labeled at the Federal plant. However, retailers can provide POP materials for those products. The net weight is the only mandatory labeling feature that retailers may apply to packages of meat labeled at a Federal establishment. The regulations (9 CFR 317.2(h) and 381.121) permit a retailer to apply the net weight directly to random weight consumer size packages). If a ground beef chub is fully labeled at the Federal establishment, then only the Federal establishment can apply the nutrition facts panel to the package of ground beef chub. In comparison, the retail store can apply nutrition labels to packages if, for example, the store purchases the ground beef in bulk and repackages it into consumer size packages or purchases the product in chubs, removes the product from its original packaging, and repackages it at retail. The retailer in these scenarios would be packaging and labeling the product as opposed to the Federal establishment.

Q58. Can the retailer add nutrition labels to ground product that is otherwise fully labeled at the Federal plant and includes the legend? A. No, on case ready product, the retailer cannot add nutrition labels, if it was fully labeled at the Federal plant. Even if the Federal plant is exempt from the nutrition labeling requirements, nutrition labels cannot be added by the retailer.

Q59. Do retailers need to submit labels to FSIS for label approval? A. No, retailers do not need to obtain label approval from FSIS for adding the nutrition facts panel to products packaged at retail. Only federally inspected meat or poultry plants obtain label approval through our office. Adding the nutrition facts panel is no different from all of", "the other labeling features that a retailer places on labeling of products packaged at retail, e.g., product name, handling statement, net weight, address, safe handling instructions, and the ingredients statement.

Q60. Are immediate containers of imported meat and poultry products required to bear nutritional labeling features as mandated by 9 CFR Parts 317 and 381? A. Yes. Nutritional labeling requirements apply to meat and poultry products imported into the United States in the same respect that they apply to domestically produced products. Exemptions from nutritional labeling requirements are outlined in 9 CFR 317.400 and 9 CFR 381.500.

Q61. Do

retailers and Federal plants need to test each lot of product for nutrient content? A. No, there is no requirement that an establishment or retailer has to test each product. If necessary, the plant can obtain nutrition information and materials for the major cuts of single-ingredient, raw meat and poultry products that can be used at point-of-purchase from the FSIS website at: [www.fsis.usda.gov\Regulations\\_&\\_Policies\Nutrition\\_Labeling\index.asp](http://www.fsis.usda.gov/Regulations_&_Policies/Nutrition_Labeling/index.asp) or from The Food Marketing Institute at: [www.fmi.org\consumer\nutrifacts\](http://www.fmi.org/consumer/nutrifacts/). The National Cattlemen's Beef Association also has a website available at: [www.beefretail.org\nutritionlabeler\](http://www.beefretail.org/nutritionlabeler/) that can be used to develop labels. The nutrient content of the ground or chopped beef products can be obtained from the ground beef calculator available from the Agricultural Research Service at the Nutrient Database for Standard Reference, Release 23. This is available at: [www.ars.usda.gov\nutrientdata](http://www.ars.usda.gov/nutrientdata). For more information regarding testing the fat content of ground product, see askFSIS Q&A titled 2010 Nutrition Labeling Final Rule - verifying nutrition information and 75 FR 82160-82161. Q62. Will specific documentation be required to support the processors\u2019 claims of 80% lean\%fat or 90% lean\%fat, etc. on imported products that are ground domestically? A. No, there is no regulatory requirement that defines how the establishment needs to support the label, and there is no requirement that it test each lot. If the establishment has a consistent process, using the same source materials, then the establishment could develop and implement a written program to periodically verify compliance with the label\u2019s nutrition labeling information, including claims, by ensuring that suppliers consistently provide the source materials necessary to produce the labeled product. Although the nutrition labeling regulations do not specify how an establishment determines the nutrient content of products, \u00a7317.309(h) and 381.409(h) specify how FSIS will sample\analyze product for compliance and require that the management of the establishment maintain records to support the validity of nutrient declarations contained on product labels. All ground products may be subject to random sampling by FSIS." ,Q63. Do religious exempt products fall under this regulation? A. No, it would not. Religious exempt product is not an inspected product. If a company or retailer wanted to label religious exempt product with the nutrition facts, it would be on a strictly voluntary basis. The minimal labeling requirements for religious exempt product for retail sale are the plant number, the signature line, and a statement under which religious exemption the bird falls under. No other labeling is required for religious exempt product, unless the bird is un-eviscerated, and then the labeling would have to state the religious authority under which the bird was slaughtered. (9 CFR 381.10-381.14, specifically 381.10(a)(5) & (6)) Q64. Do raw kosher, soaked and salted products fall under mandatory nutrition labeling? A. Yes, if they are major cuts, raw kosher meat and poultry products would be subject to mandatory nutrition labeling. These products are considered to fall within the definition of single-ingredient, raw products, and, thus, are subject to mandatory nutrition labeling (58 FR 639). Q65. When the nutrition panel with the mandated nutrients is on the package, is the %lean\%fat statement necessary on the package? A. No, claims such as %lean\%fat are always voluntary; claims do not need to be included on the label. Q66. If changes are made to the POP materials from the FSIS website, do I have to update my POP materials before displaying? A. No. If substantial changes are made to the USDA\ARS data for the major cuts of meat and poultry products, FSIS will update the POP materials on the FSIS website in a timely manner. If a new version of the POP materials is posted on the FSIS website, retailers should update their POP materials as quickly as feasible. However, when

substantial changes are made to the USDA\ARS data for the major cuts, as long as the retailer updates their POP materials within 2 years of the date of the new version of the FSIS POP materials, FSIS will consider the retailer to be in compliance. Additionally, other POP materials are acceptable if they are based on the USDA\ARS Nutrient Database for Standard Reference.

Q67. If a retailer wants to make nutrient content claims on the major cuts of single-ingredient, raw products, is posting the FSIS or other POP materials sufficient? A. No, if a retailer makes nutrient content claims on these products, the nutrition facts must be displayed in an acceptable regulated nutrition facts format (all of the format and content requirements of \u00a7317.309 apply). If nutrient content claims are not made, the requirements of \u00a7317.309 apply, but (i) the listing of percent Daily Value for nutrients (except vitamins and minerals in \u00a7317.309(c)(8)) and footnote required by \u00a7317.309(d)(9) may be omitted, and (ii) the POP materials are not subject to any of the format requirements.", "Q68. If a retailer adds seasonings to ground beef (e.g., salt and pepper), would the product be exempt from the nutrition labeling regulations that require nutrition labels on all ground product? A. No, nutrition labeling is still required on the product. The nutrition labeling regulations apply to both seasoned and unseasoned ground product. The ground beef product must still meet the regulatory standard for \u201cGround Beef\u201d in 9 CFR 319.15(a). Therefore, only the seasonings permitted in ground beef are acceptable (for example, dry spices and natural flavorings).

Q69. Are the other ground products permitted to be seasoned? A. Yes, FSIS has permitted all ground products (e.g., ground beef, pork, chicken, turkey, etc.) to include the same type of seasonings that are permitted by the ground beef standard in 9 CFR 319.15(a).

Q70. When does a seasoned single-ingredient grind cease to be a single-ingredient grind (i.e., not covered by this regulation)? For example, if seasonings are added to ground pork that turn it into Italian sausage, is that product now exempt from the nutrition labeling requirements or does it still require a nutritional panel on the package? A. It depends upon the added ingredients and the product. Because the ground beef standard permits seasonings (9 CFR 319.15(a)), the nutrition labeling rule was written to encompass seasoned ground beef products as well as single-ingredient ground beef. Under the rule, ground beef with added seasonings is subject to nutrition labeling requirements, unless an exemption applies. The rule does not establish new requirements for products that are ground but that fall under another standard of identity (such as sausage) or products such as beef patty mix that have always been considered multi-ingredient products. Those products are required to bear nutrition labeling based on the 1993 final nutrition labeling rule (58 FR 632).

Q71. If a retailer has ground beef that\u2019s 80% lean\20% fat, and they add salt and pepper to it, can they still advertise that the beef is 80% lean\20% fat? A. Yes, provided that the data in the nutrition facts panel supports this statement.

Q72. If a retailer has ground beef that\u2019s 80% lean\20% fat, and they add cheese or bacon to the product, can they still say that the ground beef is 80% lean\20% fat? A. No, this is a multi-ingredient product and does not meet the standard of identity for \u201cground beef.\u201d A percent lean\fat statement would not be permitted on the product unless it meets the regulatory definition of \u201clow in fat.\u201d (9 CFR 317.362(b)(6))", "Q73. If the label includes nutrition information based on the cooked product, are actual \u201ccooking instructions\u201d required on the label, or can the label just state \u201cas packaged,\u201d or \u201cbaised,\u201d or \u201cbaked\u201d? A. The nutrition data in the nutrition facts panel for ground product must be on \u201cas packaged\u201d (raw)

but a second column can be voluntarily added to the nutrition facts panel for the product \u201cas consumed\u201d (cooked). The nutrition data in the nutrition facts panel or POP materials for the major cuts of raw, single-ingredient meat and poultry products can be provided either \u201cas packaged\u201d or \u201cas consumed.\u201d Whenever the \u201cas consumed\u201d data is provided for raw product, the cooking method must be included with the serving size, e.g., 3 oz braised (84g) (317.312(b) and 381.412(b)). Also, and cooking instructions for that method need to be included (317.345(d) and 381.445(d)) on the packaging to instruct the consumer how to obtain a fully cooked product( i.e., to ensure the raw product gets to an appropriate internal temperature). Simply stating braised in the serving size without braising instructions on the label is not sufficient. If the serving size is for product \u201cas packaged\u201d (raw) only, then cooking instructions are not required by the nutrition labeling rule, but cooking instructions are recommended for general labeling purposes unrelated to the nutrition labeling rule. POP materials do not require specific cooking instructions when nutrition information is listed for cooked products; they only require the method of cooking. Q74. For the major cuts of raw, single-ingredient meat or poultry products, what does FSIS consider \u201cclaims\u201d on labels or POP that would require nutrition information on the package instead of nutrition information at the point-of-purchase? A. Any claim identified in 9 CFR 317.300-317.400 or 381.400-381.500, including implied claims, would require nutrition information on the product. Such claims include, \u201clean,\u201d \u201clow fat,\u201d \u201clower sodium,\u201d \u201chigh in protein,\u201d and \u201cgood source of iron\u201d (i.e., any mention of a nutrient or calories). Q75. The beef data on the FSIS POP materials is based on 3 oz, cooked, 1\8th inch trim, \u201call grades\" product. If a retailer has only \u201cChoice\u201d, 1\4 inch trim product in their service case, will the FSIS POP materials be acceptable for compliance with the 2010 Nutritional Labeling Regulation? A. Yes, the beef data for 3 ounces cooked, 1\8 inch trim \"all grades\" is acceptable for posting for any beef product, provided there are no nutrient content claims as stated in 317.345(e) and 381.445(e). The regulations permit this general information for POP materials because it is not on a specific package of product. When nutrient content claims are included or the nutrition facts panel is on the package the information must represent the product in the package when such data are contained in the representative data base.". Q76. For single-ingredient ground products that are packaged and sold at that retail store, can the nutritional panel be displayed in either vertical (portrait) or horizontal (landscape) formats? Are there any restrictions that would modify these requirements? A. The same criteria apply at the store as at a Federal plant. The tabular format (landscape) may be used on packages with less than 40 total square inches of labeling space (9 CFR 317.309(g) and 381.409(g)). The vertical formats, either full format or simplified format (portrait), may be used on any label (317.309(d) and (f) and 381.409(d) and (f)). Keep in mind that the criterion to use the simplified format is in 9 CFR 317.309(f) and 381.409(f). Q77. Can the nutrition facts panel or a nutrition claim be a separate hand applied label as opposed to being part of the primary label? A. Yes, the nutrition facts panel or a claim can be a separate sticker. Q78. Does the nutritional panel need to be on top of the package (or can it be on the underside, like Safe Handling Instructions)? A. The nutrition facts panel can be on the underside of the package, on the information panel, just like the Safe Handling Instructions. Q79. Can ground product simply include a %Fat statement and not a %Lean%\%Fat statement? A. Yes, that is acceptable based on 317.313(i) and 381.413(i), as

a factual statement of percentage of a nutrient."],{"file\_name":"FSIS\_GD\_2012\_0007","title":"Questions and Answers Related to the Electronic Label Submission and Approval System (LSAS)","num":"FSIS-GD-2012-0007","id":"a454efe9f131415885e8ab24d02db96d7618564c3a421b95a1719f4880063185","corpus":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/import/FAQs\_LSAS.pdf","type":"pdf","n\_pages":3,"word\_count":1322,"text\_by\_page":["**QUESTIONS AND ANSWERS RELATED TO THE ELECTRONIC LABEL SUBMISSION AND APPROVAL SYSTEM (LSAS)** Q1. What is the Label Submission and Approval System (LSAS)? A. LSAS is a secure web-based electronic label submission application. LSAS allows users who have obtained a Level 2 e-Authentication account an alternative way to submit label requests for evaluation to the Labeling and Program Delivery Division (LPDD) and the Agricultural Marketing Service (AMS) for Child Nutrition (CN) Label approval. Q2. If I use LSAS, do I still need to complete the FSIS Form 7234-1? A. No. The FSIS Form 7234-1 found on the FSIS website is strictly for paper submission. The information fields from the FSIS Form 7234-1 have all been incorporated into LSAS, which you will complete on-line. You will have the ability to attach additional documents to your application, such as your label image, supporting information, and other related documents necessary to support your label request. Q3. What if I don't want to use the Label Submission and Approval System (LSAS)? How can I send in my label application? A. If you choose not to submit your label request to LPDD using LSAS, you may continue to use the current paper submission process using the official FSIS Form 7234-1 located on the FSIS website. For paper submissions you will want to review the Questions and Answers Related to the Application for Approval of Labels, Marking or Device, FSIS Form 7234-1. Q4. After I complete all the fields required in LSAS, will I be able to make a copy of my application for my records? A. Yes. You will have the opportunity to generate a PDF of the completed 7234-1 and any supporting documentation you have attached. You can also save the file to any location for your records. Q5. How will I know if LPDD received my submission? A. Once you select 'submit application', LSAS displays a confirmation message that the application has been submitted and includes a Label Identification Number for tracking purposes. Q6. How can I check on the status of my application? A. Each submitter will have a dashboard that includes typical pools found on a submitter's dashboard are Announcements (from the LSAS Administrator), Application Messages, Drafts, and status information, including, Submitted Applications, Adjudicated Applications, Returns and Rescinded Applications, and Appeals. If your application is still in the Submitted Applications pool with a received date, it is not in the review stage yet. Once your application is in review, the status date will change to pending. Depending on the outcome of the review, your applications will move to other pools, i.e. Adjudicated Applications, Returns and Rescinded Applications, etc."], "Q7. Where can I find instructions or training for LSAS? A. LPDD has provided a user guide for industry, PowerPoint presentations, and other information on our FSIS website. Additionally, the Agency's Outreach and Training Office (OEET) will be assisting LPDD in preparing webinars and other public presentations for training relevant to LSAS. Q8. Who do I contact if I need assistance or have a technical issue concerning LSAS? The LSAS administrator will be your first contact. You may email the administrator at LSAS@fsis.usda.gov or call 301-504-0837(M-F, 8:00am to 4:00pm EST). We ask that you use these resources first, rather than calling the main LPDD lines,

so that we can track all issues and provide appropriate resolutions. Q9. Who do I contact if I need help with my e-Authentication account? A. For assistance with your Level 2 e-Authentication account or password issues, you may contact: Service Desk 1-800-457-3642, Option 1 or eAuthhelpdesk@ftc.usda.gov Q10. How will child nutrition label applications be processed in LSAS? A. AMS technical staff has access to LSAS. LSAS will direct all child nutrition label applications first to the AMS technical staff. Once AMS adjudicates the label application as approved, LSAS will re-direct to LPDD for further evaluation and adjudication. Q11. I have a child nutrition label application that I want to submit by using the paper submission process. Does the process for submitting child nutrition label paper applications change at this time? A. No. AMS will continue to evaluate paper submissions as they have done in the past. For paper submissions you will want to review the Questions and Answers Related to the Application for Approval of Labels, Marking or Device, FSIS Form 7234-1. Once AMS adjudicates the paper submission as approved, it will be routed to LPDD in the usual manner. Once received by LPDD, it will be integrated into LSAS for further evaluation by LPDD technical staff. The adjudicated label will be printed and mailed back to the submitter. Q12. I heard LSAS has a tool to help determine whether the label can be approved using the generic labeling regulations. Why would a submitter want to use this? A. That is correct. LSAS includes a feature called the Generic Label Advisor (GLA) to determine whether a label can be generically approved. LSAS has incorporated the generic labeling regulations (9 CFR 317.5 and 381.133) into the GLA, which allows the submitter to respond to a series of questions. Based on the responses given by the submitter, the GLA will determine whether the label can be generically approved. Based on the responses, if the label can be generically approved, LSAS will generate a certificate that can be included in the submitter's labeling records.", "Q13. Can an appeal be submitted using LSAS? If so, what is the process? A. Yes. LSAS allows the submitter to appeal a LPDD decision, modifications, or denials. For instance, the submitter can select from their pool an adjudicated label with the status of sketch modified, and create the appeal by following the prompts provided. To use this option, the submitter should include the reason for requesting the label appeal and should include documentation to support the appeal. Note: All uncontested modifications to labeling must be made prior to the submission of an appeal. Q14. Does LSAS require me to install or download any special software or tools? A. No. The LSAS web application does not require you to install or download any tools in order to use it. All you need is a working Internet connection, Level 2 e-Authentication, and Adobe Reader. Q15. I started working on my label application but did not finish it. Will I have to abandon it and start over? A. No. LSAS will keep a draft of your label application in the Draft Pool. You may select the draft at a later date and continue to edit where you left off. Drafts will only be maintained for a period of 30 days from the date you last saved it. Q16. When I need to request a duplicate copy of a prior approval, I need to send in a letter requesting this information. Will I be able to retrieve prior approvals in LSAS now? A. Prior approvals (before LSAS implementation) are considered legacy data in LSAS and will not be available for viewing by the submitter. Therefore, for approvals prior to LSAS, you will need to continue to send in a letter requesting this information. Only new label submissions submitted electronically through LSAS will be available for viewing by the submitter. For duplicate copies of prior approvals (before LSAS implementation) see How to Request Duplicate Copies of Approved Labels . Q17. We have an in-house software system that incorporates the FSIS Form 7234-1. If we complete the label

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## 2 IV. Ordering KIS\u2122 Test Supplies for State MPI Programs.....page 3 .

V. Training.....page 4 VI.

## Additional

Reference \u2026\u2026\u2026\u2026\u2026\u2026\u2026.\u2026.page 4", "\u201cAt Least Equal to\u201d Compliance Guideline for State Meat and Poultry Inspection (MPI) Programs for Residue Testing December 2012 I. Purpose This guidance addresses in-plant screening of residues in meat and poultry products. The Food Safety and Inspection Service (FSIS) is now using the Kidney Inhibition Swab (KISTM) as its in-plant drug residue screening test. Effective August 19, 2012, the Agency discontinued the use of the Fast Antimicrobial Screen Test (FAST) to detect antimicrobial drug residues in all livestock in federally inspected slaughter establishments. For this reason, to meet \u201cat least equal to\u201d standards, State MPI programs are required to discontinue their use of the FAST and switch to the KISTM test. II. Background In 1994, FSIS started using the FAST in-plant residue screening test to detect antimicrobial residues in animal tissues. An FSIS review of the FAST sampling data results from federally inspected establishments suggested that in-plant screening procedures could be enhanced to provide additional public health protection. To accomplish this initiative, FSIS decided to upgrade the manner in which residues are tested through the use of the KIS\u2122 test. The KIS\u2122 test is a simple-to-use antibiotic detection test for use on kidney tissue. The test can be performed on fresh or thawed kidneys and can be performed by inspection program personnel (IPP), who can also read the results in as little as 3

hours, with the test results remaining stable up to 16 hours. The KIS\u2122 test shows better detection capabilities than FAST for certain drugs, and it can screen for additional compounds, such as Tilmicosin, Tulathromycin, and Bacitracin. Also, the KISTM test can detect residues of certain drugs \u2013 including Penicillin G, Neomycin, and Sulfonamides -- at levels closer to their U.S. tolerances than the FAST. In addition to its greater detection capability, the KISTM test is easier to use in the plant and produces more consistent results, compared to those yielded by the FAST. The KIS\u2122 Test Instructions booklet contains information on the testing supplies needed and instructions on how to perform the test. The booklet is available on the FSIS website using the following link:

[http://www.fsis.usda.gov/PDF/KIS\\_Booklet\\_0710.pdf](http://www.fsis.usda.gov/PDF/KIS_Booklet_0710.pdf). III. In-Plant Testing Using the KIS\u2122 Test To be \u201cat least equal to\u201d the Federal inspection program, State MPI programs must conduct inspectorgenerated in-plant residue screening tests in accordance with current FSIS policies that provide instruction on the type and use of current testing methods. On June 26, 2012, the Agency informed IPP that it was extending the process for replacing FAST with the KISTM test in all federally inspected livestock slaughter establishments to August 19, 2012. MPI programs will stop using FAST by January 31, 2013. After December 31, 2012, FSIS will no longer produce the FAST plates nor provide FAST supplies for MPI programs. In addition, after this date, FSIS will not accept FAST plates that are prepared from outside sources. State MPI programs that historically run an average of more than one FAST per week need to obtain training materials on performing the KISTM test and purchase KIS\u2122 test supplies and equipment for each slaughter establishment. For these establishments, State MPI personnel will conduct the KIS\u2122 test and send the KIS\u2122 test positive samples to the FSIS Midwestern Laboratory (MWL) for confirmation.", "\u201cAt Least Equal to\u201d Compliance Guideline for State Meat and Poultry Inspection (MPI) Programs for Residue Testing December 2012 3 State-inspected slaughter establishments that historically run an average of less than one FAST per week will need to submit samples of kidney, liver and muscle from animals suspected of having violative residues directly to the MWL at no cost to the State rather than to a central in-State laboratory. The State MPI program will contact MWL first when it has a sample to be forwarded for residue testing. The MWL, in turn, will send three to five boxes (with FedEx air bills) as the State identifies its sample submission needs. The MWL will return the shipping containers that contained the packaged samples to the State along with fresh supplies for future sample shipments. It is acceptable for slaughter establishments that historically run an average of less than one FAST per week to purchase a Digital Dry Block Heater that holds up to four tests, instead of 20. IV. Ordering KIS\u2122 Test Supplies for State MPI Programs To perform the KISTM test , State MPI programs will need the following supplies: 1. Digital Dry Block Heater (tests up to 20 units); 2. KISTM (Kidney Inhibition Swab) Tests; 3. Negative Controls; 4. 15 ml Tube of Deionized or Distilled Water (or equivalent); 5. Timer; 6. Transfer Pipettes or equivalent device for delivering 1ml of water; and 7. Test Tube Rack (or equivalent device) to hold KISTM tests. State MPI programs can order the following KISTM test supplies directly from the vendor, Charm Sciences, Inc. (telephone number 1-800-343-2170): \u2022 Digital Dry Block Heater (holds up to 20 tests)(Order Code INC-20-110); \u2022 KISTM (Kidney Inhibition Swab) Tests (units of 25) (order code KIS-100);and \u2022 Negative Controls (units of 4) (Order Code NCKIS-4). The ancillary testing supplies listed above (items 4 \u2013 7) can be purchased by State MPI programs through a general laboratory supply

vendor.", "At Least Equal to Compliance Guideline for State Meat and Poultry Inspection (MPI) Programs for Residue Testing December 2012 4 V. Training FSIS will make training materials with instructions on performing the KISTM test available to State MPI programs. Instructional materials, entitled Performing the KISTM Test, are available in both CD-ROM and written formats. The KISTM Test Instructions booklet is also available in hard copy, upon request. Requests for KISTM Test training materials should be sent to CEDL@fsis.usda.gov . States are to include the contact person, phone number and return address for shipment of training materials. VI. Additional Information Questions regarding KIS testing can be submitted through askFSIS using the following link:  
<http://askfsis.custhelp.com/> When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided: Subject Field: Enter KIS testing Question Field: Enter your question with as much detail as possible. Product Field: Select General Inspection Policy from the drop-down menu. Category Field: Select Sampling - General from the drop-down menu. Policy Arena: Select Domestic (U.S.) Only When all fields are complete, press the Submit button. Additional information on KIS testing is available in the series of askFSIS Q&As and can be found on the askFSIS web page and by entering "KIS" in the search feature: VII. Reference FSIS At Least Equal To Compliance Guidelines for State Meat and Poultry Cooperative Inspection Programs (July 2008)"], {"file\_name": "FSIS\_GD\_2013\_0001", "title": "FSIS Compliance Guideline: Lebanon bologna", "num": "FSIS-GD-2013-0001", "id": "8ed6d48c41d569b810889c546f61d5e19cf3e7ae443cf84340096960305743e", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Compliance\_Guideline\_Lebanon\_Bologna.pdf", "type": "pdf", "n\_pages": 8, "word\_count": 3282, "text\_by\_page": [{"1": "FSIS Compliance Guideline: Lebanon bologna January 2013 Food Safety Lessons Learned from the Lebanon Bologna Outbreak What is the purpose of this Compliance Guideline? This Compliance Guideline contains information regarding lessons learned from a Food Safety Inspection Service (FSIS) investigation of a Lebanon bologna product associated with a foodborne illness outbreak of E. coli O157:H7 in 2011. During the outbreak investigation, FSIS identified that inadequate validation of the Hazard Analysis Critical Control Point (HACCP) system design may have led to the production of adulterated product. Using the findings from the investigation, this guideline articulates how industry can meet FSIS expectations regarding the production of Lebanon bologna. It is important to note that this guideline represents FSIS' current thinking on this topic and should be considered usable as of the issuance date. Who is this guidance designed for? All Lebanon bologna processors. How is this guidance being shared? This guidance document is available on the FSIS web site for establishments to use. In addition, FSIS inspection program personnel were instructed to hold an awareness meeting in May 2012 (per Notice 36-12) with establishments that produce Lebanon bologna to share the lessons learned from the Lebanon bologna outbreak (including those covered in this document), and how the establishment can comply with regulatory requirements in 9 CFR 417.4(a)(1), 9 CFR 417.5(a)(1), and 9 CFR 417.5(a)(2). Is this version of the guidance final? Yes, this version of the guidance document, dated January 2013, is considered final and replaces the previous version of the document. No comments were received during the comment period; however, a change was made to the recommendations related to relative humidity on page 6"}]}]

as a result of an askFSIS question received. Specifically, this version clarifies the circumstances under which relative humidity would not need to be monitored as part of the Hazard Analysis and Critical Control Point (HACCP) system. Guidelines will be continually updated to reflect the most current information available to FSIS and stakeholders, although comments will no longer be accepted through regulations.gov on this guidance document. In addition, this final version made changes to the recommended log reduction for Listeria monocytogenes to be consistent with other FSIS guidance documents." "2 FSIS Compliance Guideline: Lebanon bologna January 2013 Why was this guidance developed? In March 2011, there was a recall of a Lebanon bologna product that was associated with a foodborne illness outbreak of E. coli O157:H7. An FSIS investigation into the processing of the product revealed that the establishment had not properly validated their Lebanon bologna process. In particular, the establishment did not identify supporting documentation during the design of the HACCP system that closely matched the actual commercial process used. In the actual process at the establishment, raw Lebanon bologna mix was compacted in 52 to 119 mm diameter permeable casings that were placed in a large smokehouse fitted with a single source of heat and humidity that was not well-controlled. However, in the supporting documentation identified by the establishment to represent a commercial process for Lebanon bologna, raw Lebanon bologna mix was compacted in smaller 27 millimeter diameter impermeable sealed glass tubes that were immersed in a wellcontrolled water bath. The difference in the diameter and type of casing material likely led to a lower reduction in foodborne pathogens of concern in the actual process than what was demonstrated in the supporting documentation. If the diameter of the establishment's product is larger than that of the product used in the supporting documentation, it is possible that the product core will take longer to reach the desired temperature and pH. Taking a longer time than expected to reach the desired temperature and pH may lead to a lower level of pathogen reduction. Critical operational parameters such as the product diameter and type of casing material can also affect the amount of moisture exchange between the product and the environment and can play a role in the effectiveness of the fermentation. For these reasons, it is important that when an establishment designs its HACCP system during the initial validation period that it identify supporting documentation that is representative of the actual process so that the results can be repeatable. In the case of the establishment identified in the outbreak, additional supporting documentation should have been identified during initial validation demonstrating adequate reduction in pathogens would be achieved with a product of the same diameter and casing type as that used in the actual process. What are some measures establishments can take to manufacture Lebanon bologna safely? In order to manufacture Lebanon bologna safely, it is particularly important that establishments validate their processes. There are two distinct elements to validation: 1) the scientific or technical support for the HACCP system design (design) and 2) the initial practical in-plant demonstration proving the HACCP system can perform as expected (execution). The key steps to achieving these two elements are summarized on the next page:" "3 FSIS Compliance Guideline: Lebanon bologna January 2013 Element 1: Scientific or Technical Support (Design) 1. Identify supporting documentation (e.g., journal articles, challenge studies, or data gathered-in plant) that closely matches their process; 2. Identify supporting documentation that demonstrates the expected level of bacterial pathogen reduction (e.g., a 5-log<sub>10</sub> reduction of Salmonella spp. and E. coli O157:H7, and a 3-log<sub>10</sub> reduction of Listeria monocytogenes, although a 5-log<sub>10</sub> reduction or

greater is desirable for providing an even greater safety margin for ensuring that L<sub>m</sub> doesn't grow during cold storage to detectable levels); and 3. Identify the critical operational parameters from the supporting documentation relevant to their commercial process (i.e., fermentation temperature, relative humidity, come up time to low temperature heating step, hold time and temperature for low temperature heating step, equipment, pH and time to reach target pH, type and use of starter cultures, and product characteristics such as diameter, composition, and casing type). Element 2: Initial In-Plant Demonstration (Execution) 4. Implement those same critical operational parameters in their production process (e.g. as a Critical Control Point (CCP), prerequisite program, or as part of the HACCP system); 5. Identify at least one product from each HACCP category to gather in-plant validation data; and 6. Gather data demonstrating the effectiveness of the implementation of the critical operational parameters. Establishments should identify supporting documentation that closely matches their process and should identify all of the critical operational parameters from the supporting documentation relevant to their commercial production process. Critical operational parameters are the specific conditions that an intervention or process must operate under in order for it to be effective. Such critical operational parameters include pH, time, temperature, relative humidity, equipment settings or calibration, and spatial configuration. If the critical operational parameters used in an establishment's process do not closely match those in the supporting documentation, adequate lethality may not be achieved, and the establishment may not be able to support the decisions in its hazard analysis on an ongoing basis as required in 417.5(a)(1). NOTE: FSIS recommends that the supporting documentation address the worst case scenario because of variability in the actual process for the critical operational parameters identified. For example, the supporting documentation should be based on the highest expected pathogen load, shortest amount of time", "4 FSIS Compliance Guideline: Lebanon bologna January 2013 it takes the actual product to achieve the target temperature for the low temperature heat step, the longest amount of time it takes the actual product to reach the target pH, or the lowest relative humidity achieved. Such worst case scenarios can be determined by reviewing monitoring and pre-requisite records the establishment currently collects associated with the critical operational parameters identified in the supporting documentation. In some circumstances, establishments may be able to support using critical operational parameters that are different from those in the supporting documentation (e.g., higher concentrations of antimicrobials or higher thermal processing temperatures). In these cases, establishments should provide justification supporting that the levels chosen are at least as effective as those in the supporting documentation. This justification is needed because different levels of a critical operational parameter may not always be equally effective. For example, higher processing temperatures may result in the surface of the product drying out before adequate lethality is achieved. In addition to ensuring that the levels chosen are at least equally as effective, establishments should ensure the levels are also safe and suitable

(<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/7120.1.pdf>). Once all of the relevant critical operational parameters from the supporting documentation have been identified, establishments should implement and monitor those parameters in their system. During the initial set-up of their system, establishments may decide that one or more critical parameters from their scientific supporting documentation are either monitored as a CCP in

response to a hazard that the establishment has identified as reasonably likely to occur or that are verified on an ongoing basis as part of a pre-requisite program in response to a hazard that the establishment has identified as not reasonably likely to occur because of the execution of that pre-requisite program. Establishments are required to support the development of critical limits for CCPs, per 9 CFR 417.5(a)(2) used to control hazards identified as reasonably likely to occur and are required to support the development of pre-requisite programs used to prevent hazards identified as not reasonably likely to occur per 9 CFR 417.5(a)(1). Establishments may also, however, decide that a limited number of other critical operational parameters will only be verified during the initial validation period (for example, product diameter or casing type). Establishments are required to validate the design and execution of their HACCP system per 9 CFR 417.4(a)(1) which would include ensuring that critical operational parameters that are not incorporated into a critical limit of a CCP or into a pre-requisite program can be met (for example the equipment, product composition provided it does not change or spatial configuration of a system). These parameters should be included in a decision-making document but do not necessarily need to be monitored on an ongoing basis, provided they do not change over time. Further information on validation can be found in the Draft FSIS Compliance Guideline HACCP Systems Validation found at:

[http://www.fsis.usda.gov/PDF/HACCP\\_Systems\\_Validation\\_Draft\\_Guidance\\_0412.pdf](http://www.fsis.usda.gov/PDF/HACCP_Systems_Validation_Draft_Guidance_0412.pdf). "5 FSIS Compliance Guideline: Lebanon bologna January 2013 NOTE: For information that can be used to control Salmonella and E. coli O157:H7 in Lebanon bologna and other semi-dry fermented sausage products, establishments can refer to the FSIS Salmonella Compliance Guidelines for Small and Very Small Establishments that Produce Ready-to-Eat (RTE) Meat and Poultry Products (RTE Salmonella Guidelines), found at

[http://www.fsis.usda.gov/PDF/Salmonella\\_Comp\\_Guide\\_091912.pdf](http://www.fsis.usda.gov/PDF/Salmonella_Comp_Guide_091912.pdf). Finally, in addition to ensuring the critical operational parameters used in an establishment's process closely match those in the supporting documentation; establishments should also make efforts to ensure that sanitary conditions are maintained in their post-lethality processing environment. This will help ensure that RTE products are not contaminated after the lethality step. Steps should also be taken to ensure the safety of ingredients that are added to the product, to ensure that contaminated ingredients are not added after the lethality treatment. Further information on sanitation in RTE establishments and ensuring the safety of ingredients can be found in the RTE Salmonella Guidelines (referenced in the note above) and the Listeria Guidelines found at:

[http://www.fsis.usda.gov/PDF/Controlling\\_LM\\_RTE\\_guideline\\_0912.pdf](http://www.fsis.usda.gov/PDF/Controlling_LM_RTE_guideline_0912.pdf). What are the critical operational parameters for production of Lebanon bologna? Examples of critical operational parameters for the production of Lebanon Bologna include: Fermentation temperature Hold time and temperature for low temperature heating step Come up time to low temperature heating step Relative humidity Equipment Type and use of starter cultures pH and time to reach target pH Product characteristics (e.g., diameter, composition, and casing type) These parameters may also apply to other fermented, semi-dry processes. In addition to using the critical operational parameters identified in the supporting documentation, it is important for establishments to use source materials prepared under Good Manufacturing Practices (GMPs) designed to minimize contamination and the presence and growth of pathogens of public health concern. If pathogen

levels are high on source materials, the process may not be sufficient to achieve full lethality, and some pathogens could survive in the product." "6 FSIS Compliance Guideline: Lebanon bologna January 2013 Specific considerations for several critical operational parameters as related to Lebanon bologna processes are outlined below:

1. Fermentation temperature\heating come up time (CUT)\hold time and temperature for low temperature heat step \u2013 The temperature that the product is heated to, and the amount of time the product is held at this temperature, are critical to ensuring that adequate lethality is achieved. The establishment should have an understanding of factors that could affect the temperature of the product (e.g., cold spots or variation in temperature of the oven during different seasons). In addition to the hold time and temperature, the time it takes the product to reach the target temperature for the low temperature heat step (also known as the come up time or CUT) may be important. A number of factors, such as product diameter and relative humidity, affect heat transfer and the amount of time it takes the product to reach the target temperature. It is important for the establishment to understand how the actual temperature of the product, the CUT, and the amount of time the product is held at the target temperature compare to the supporting documentation. If the CUT in the establishment\u2019s process is shorter than the time it takes in the study, for example, then the establishment\u2019s process may result in a lower level of pathogen reduction.

2. Equipment \u2013 Differences in equipment (e.g., smokehouses and ovens) used in the processing of Lebanon bologna can influence the effectiveness of the process and, in particular, the speed of fermentation or acidification and heating. For this reason, the establishment should gain an understanding of the humidity profile as well as the pH and temperature profile of the product throughout the process. In addition, seasonality of atmospheric conditions, cold-spot determination, or heating consistency should be understood and used to inform monitoring and verification procedures and the frequencies at which those procedures are monitored and verified.

3. Relative humidity \u2013 Relative humidity is an important parameter in most dried meat processes. A relatively high humidity is preferred to keep the product surface moist during the fermentation and intermediate heating steps, prior to drying. Controlling humidity prevents premature and uneven drying at the surface and also shortens the time it takes for the product core to reach the desired temperature. For these reasons, it is important that the lower end of the relative humidity range in the establishment\u2019s process is at least as high as the lower end of the relative humidity range used in the supporting documentation and is applied at the appropriate process steps.

NOTE: Humidity is inherently maintained and, therefore, does not need to be monitored as part of the HACCP system for products that use an impermeable casing. This is because impermeable casings will prevent or inhibit moisture loss so that the heat resistance of pathogens is not affected by the cooking process (e.g., sausages cooked in casings). In the case of the Lebanon bologna outbreak, the product used a permeable casing which allowed moisture loss to occur during the cooking process. In that case, relative humidity was not wellcontrolled and should have been because of the nature of the product.

For more", "7 FSIS Compliance Guideline: Lebanon bologna January 2013 information on processes in which humidity is inherently maintained and does not have to be added or monitored as part of the HACCP system, see the Appendix A Guidance on Relative Humidity and Time\Temperature for Cooking\Heating and Applicability to Production of Other Ready-to-Eat meat and Poultry Products found at:

[http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95033F/Appendix\\_A\\_guidance\\_95-033F.pdf](http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95033F/Appendix_A_guidance_95-033F.pdf). 4. pH and time to reach target pH \u2013 Semi-dry sausage products like Lebanon bologna are usually fermented to a pH of between 4.4 - 4.6. The establishment should be fermenting its product to the pH that is recommended in the supporting documentation. In addition to the pH level itself, the time it takes the product to reach the desired pH is also important. If a product takes too long to reach the desired pH, the acid resistance and pathogenicity of *E. coli* O157:H7 and *Salmonella* may increase. In addition, these conditions may favor *Staphylococcus aureus* growth and enterotoxin production. Therefore, it is also important that the establishment monitor the time it takes the product to reach pH of 5.3. The American Meat Institute has determined that a process documented to reduce product pH to 5.3 within a defined number of hours at a defined temperatures (known as the degree-hours) is capable of controlling growth of *Staphylococcus aureus* (for more information on the degree-hour concept see the American Meat Institute\u2019s Good Manufacturing Practices for Fermented Dry and Semidry Sausage Products:

[http://www.meathaccp.wisc.edu/assets/Heat\\_Treated\\_Shelf\\_Stable/AMIF\\_degreehours.pdf](http://www.meathaccp.wisc.edu/assets/Heat_Treated_Shelf_Stable/AMIF_degreehours.pdf)). For these reasons, it is critically important that establishments monitor the pH of the product during fermentation as well as the time it takes the product to reach the desired pH, to ensure that the time it takes the product to reach the desired pH is consistent with the supporting documentation and is within an acceptable number of degree-hours. NOTE: According to the Food Standards and Labeling Policy Book, a Lebanon bologna product that has a Moisture Protein Ratio (MPR) of 3.1:1 or less and a pH of 5.0 or less does not require refrigeration. However, meeting these criteria does not necessarily mean that the product has received sufficient log reduction for pathogens of public health concern (e.g., *E. coli* O157:H7, *Salmonella* and *Listeria monocytogenes*). 5. Starter culture - The starter culture used in the product should be similar in composition to that used in the supporting documentation, to ensure that fermentation is achieved, and the rate of pH drop is as expected. The starter culture should be formulated to ensure microbial dominance of fermentation strains over any potential pathogens and to inhibit potential *Staphylococcus aureus* growth during fermentation. In addition, the starter culture used for fermentation can affect whether bacteriocins (toxins produced by bacteria that inhibit the growth of other similar bacteria) are produced and the type of bacteriocins produced, which can affect the level of reduction for bacterial pathogens.", "8 FSIS Compliance Guideline: Lebanon bologna January 2013 6. Product Characteristics \u2013 a. Casing diameter - Product casing size and shape are critical operational parameters in fermented, semi-dry processes because they affect heat transfer. For Lebanon bologna and other similar products, it is important that the diameter of the product used in the establishment\u2019s process is the same or smaller than that of the product used in the supporting documentation. If the diameter of the establishment\u2019s product is larger than that of the product used in the supporting documentation, it is possible that the product core will take longer to reach the desired temperature and pH, and a lower level of pathogen reduction would be achieved. b. Product formulation \u2013 Product formulation plays a role in the fermentation process and in the heat transfer during the intermediate heating step. Product formulation also may affect microbial resistance to acid or heat. The establishment should have an understanding of the critical operational parameters associated with the product formulation (e.g., % salt, moisture level, nitrite or any other preservatives, and % fat)

and should ensure that the material used in the supporting documentation is similar to their product with respect to those critical operational parameters.

c. Casing \u2013 The casing influences moisture exchange. Products with impermeable, semi-permeable, or permeable casings exchange moisture with the environment differently and can, therefore, influence the rate of product acidification, the penetration of heat into the interior of the product, and the maximum internal temperature reached by the product. Therefore, the establishment should ensure that the type of casing used in its process is the same as that used in the supporting documentation."]}, {"file\_name": "FSIS\_GD\_2013\_0007", "title": "Compliance Guide For Residue Prevention", "num": "FSIS-GD-2013-0007", "id": "534c538da5c2ae59b9946a9b32f46927ff92aacbdf1af529189cb8375e41b2e0", "corp\_us": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Residue\_Prevention\_Comp\_Guide.pdf", "type": "pdf", "n\_pages": 12, "word\_count": 3615, "text\_by\_page": ["i FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results 2013 FSIS Compliance Guideline for Controlling Meat and Poultry Products Pending FSIS Test Results Table of Contents What is the purpose of this Compliance Guideline? Page 1 Who is this Compliance Guideline designed for? 1 How can I comment on this Compliance Guideline? 1 Why is this policy being implemented? 2 Guidance for domestic establishments on controlling meat and poultry products pending FSIS test results 2 \u2022 What domestic products are subject to this policy? 2 \u2022 Can an establishment move product off-site pending final test results? 3 \u2022 What does FSIS consider adequate controls when product is moved from the establishment prior to receipt of laboratory results? 3 \u2022 When will FSIS consider domestic product to be in commerce? 4 \u2022 What is the minimum amount of time product will have to be on hold or under control for pending FSIS test results? 4 \u2022 How can an establishment determine the amount of product they need to hold? 5 \u2022 Guidance for determining lot sizes 6 Guidance for importers of record on controlling meat and poultry products pending FSIS test results 12 \u2022 What imported products are subject to this policy? 12 \u2022 Can an importer of record move product off-site pending final test results? 13", "ii FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results 2013 \u2022 What does FSIS consider adequate controls when product is moved from the official import inspection establishment prior to receipt of laboratory results? 13 \u2022 When will FSIS consider imported product to be in commerce? 13 \u2022 What actions will FSIS take on imported product that receives an unacceptable laboratory result? 14 \u2022 What is the minimum amount of time product will have to be on hold or under control for pending FSIS test results? 14 \u2022 How does an importer of record determine the amount of product they need to hold? 15", "FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results 2013 1 What is the purpose of this Compliance Guideline? The purpose of this guidance document is to help domestic establishments and importers of record comply with the Food Safety and Inspection Service\u2019s (FSIS) new policy that product FSIS tests for adulterants will not be allowed to move into commerce until acceptable results become available. Specifically, it articulates: \u2022 Which products and FSIS sampling and testing programs are subject to this policy; \u2022 How domestic establishments can meet FSIS\u2019s requirement for meat and poultry establishments to hold or control product when FSIS collects a sample; \u2022 How an establishment determines the amount of product it

needs to hold; \u2022 How importers of record can meet FSIS\u2019s requirement to hold or control product when FSIS collects a sample; and \u2022 How an importer of record determines the amount of product they need to hold. It is important to note that this Guideline represents FSIS\u2019s current thinking on this topic and should be considered usable as of its issuance. Guidelines will be continually updated to reflect the most current information available to FSIS and its stakeholders. Who is this Compliance Guideline designed for? This guidance is designed for all FSIS regulated meat and poultry establishments and importers of record whose products are subject to: \u2022 FSIS verification testing for pathogens or chemical residues considered adulterants in FSIS regulated products, and \u2022 FSIS verification of non-food safety consumer protection regulatory requirements (e.g., protein-fat-free and moisture in hams). Therefore, this guidance applies to most products subject to FSIS verification testing with the exception of raw products subject to routine FSIS verification testing for Salmonella or other pathogens (such as Campylobacter) and poultry carcasses or other raw poultry parts subject to routine FSIS verification testing for residues. The applicable domestic and import testing programs are outlined further in this document. How can I comment on this Compliance Guideline? FSIS is seeking comments on this guidance document as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days and the document will be updated in response to the comments. Comments may be submitted by either of the following methods:","FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results 2013 2 Federal eRulemaking Portal Online submission at regulations.gov: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Mail, including - CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, 8-163A, Washington, DC 20250-3700. All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title: FSIS Compliance Guideline for Meeting Test & Hold Requirements. Comments received will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>. Why is this policy being implemented? FSIS has asked, but had not required, official establishments and importers of record to maintain control of products tested for adulterants while waiting for receipt of all test results. FSIS has found, however, inconsistencies with those controls. Consequently, recalls have occurred because product was already in commerce by the time unacceptable test results came back from the laboratory. Therefore, FSIS announced that it is changing its procedures, and that products subject to this policy will not be able to enter commerce until receipt of all test results that bear on the determination as to whether those products are adulterated are received. For more information see the Federal Register Notice (77 FR 73401), announcing the final policy available at <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2005-0044FN.pdf>. Guidance for domestic establishments on controlling meat and poultry products pending FSIS test results What domestic products are subject to this policy? Under the new policy, the following products tested by FSIS under domestic sampling and testing programs cannot move into

commerce until acceptable results become available: \u2022 Raw, non-intact beef or veal products such as ground beef, hamburgers, and patties and raw products that are components of non-intact products, including beef manufacturing trimmings, bench trim, heart meat, head meat, cheek meat, weasand meat, product from Advanced Meat Recovery (AMR) systems, low temperature rendered lean finely textured beef (LFTB), partially defatted beef fatty tissue, and partially defatted chopped beef, tested for E. coli O157:H7 and non-O157 Shiga-toxin producing Escherichia coli (non-O157 STEC); \u2022 Ready-to-eat (RTE) products tested for Listeria monocytogenes and Salmonella;,"FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results 2013 3 \u2022 RTE product that passed over food contact surfaces that have been tested by FSIS for the presence of Listeria monocytogenes or Salmonella; \u2022 Livestock carcasses tested for residue by FSIS of drugs, such as antibiotics, sulfonamides, or avermectins, or the feed additive carbadox under domestic sampling and testing programs; and \u2022 Products that are tested for non-food safety consumer protection verification (e.g., protein-fat-free and moisture in hams). The policy does not cover: \u2022 Raw meat or poultry products that FSIS has tested for Salmonella or other pathogens (such as Campylobacter) that FSIS has not designated as adulterants in those products and \u2022 Poultry carcasses subject to FSIS testing for drug residues. Because of the significant number of poultry carcasses in a lot, because of the economic effect of holding such a lot, and because, historically, FSIS has not seen residue problems in poultry tested for residues, such product would not need to be held from commerce pending acceptable test results (76 FR 19955). Can an establishment move product off-site pending final test results? Yes, an establishment is not required to hold product tested by FSIS for adulterants at the establishment, provided it has effective controls in place for it to move elsewhere under its ownership so that the product does not enter into commerce until the establishment receives acceptable results. NOTE: FSIS inspectors do not retain products tested by FSIS for adulterants pending test results; however, when FSIS inspection program personnel believe an animal may contain violative levels of residues, they will continue to deem it "U.S. Suspect," retain the carcass, and submit samples for residue testing. What does FSIS consider adequate controls when product is moved from the establishment prior to receipt of laboratory results? Establishments are to maintain the integrity of the lot and use any effective mechanism to control the product. Adequate controls may include company seals. The Agency will require establishments to document and support that they can control the product pending the availability of test results. FSIS personnel will verify this documentation at the time of sample collection. If the movement of product results in a change of ownership, then the product is considered to have entered commerce.","FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results 2013 4 When will FSIS consider domestic product to be in commerce? FSIS recognizes that the mark of inspection is pre-printed on the package label of many products, and that it is most efficient to allow the product to be packaged and labeled with the printed mark of inspection as part of the production process. FSIS will continue to allow meat and poultry establishments to package and label products sampled and tested for adulterants with the mark of inspection. However, such product will not be eligible for shipment into commerce until acceptable test results for adulterants are available. In addition, to move product off-site pending FSIS test results, establishments cannot complete preshipment review or transfer ownership of the product to another entity. When a meat or

poultry establishment completes a pre-shipment review (9 CFR 417.5(c)), the establishment indicates that it takes full and final responsibility for applying its Hazard Analysis and Critical Control Point (HACCP) controls to the product that it has produced. Pre-shipment review can be accomplished if the product is at a location other than the producing establishment, as long as the review of appropriate documents and compliance with 9 CFR 417.5(c) occurs before the product leaves the control of the producing establishment. If the establishment has completed pre-shipment review pending test results, and the results are positive, the establishment has produced and shipped adulterated product into commerce. What is the minimum amount of time product will have to be on hold or under control for pending FSIS test results? The following table summarizes the minimum number of days from receipt to when the result is received, depending on whether the result is determined to be acceptable or unacceptable by analysis type. KEY QUESTION Question: Can an establishment package and label products with the mark of inspection before acceptable test results for adulterants are available? Answer: Yes, FSIS recognizes that the mark of inspection is pre-printed on the package label of many products, and that it is most efficient to allow the product to be packaged and labeled with the printed mark of inspection as part of the production process. FSIS will continue to allow meat and poultry establishments to package and label products sampled and tested for adulterants with the mark of inspection. However, such product will not be eligible for shipment into commerce until acceptable test results for adulterants are available.", "FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results 2013 5 Analysis Minimum Number of Days from Receipt When the Result Is: Acceptable Unacceptable E.coli O157:H7 and non-O157 in raw beef products 2 4 Listeria monocytogenes in RTE products 3 6 Salmonella in RTE products 1 5 Residue (antibiotics, sulfonamides, or avermectins or the feed additive carbadox) in livestock 4\* Will depend on what is screened and the number and type of additional analyses required Non-food safety consumer protection verification Will depend on the type of analysis Will depend on the type of analysis \*Does not include the time (12 \u2013 24 hours minimum) it takes to freeze the sample prior to shipping to the laboratory. FSIS begins testing of all raw beef and RTE products for microbiological pathogen analysis, and all residue testing, the day of receipt, including Saturdays. Non-food safety consumer protection verification analyses are started Monday through Friday on the day of receipt; analysis of non-food safety samples received on Saturdays are started on Mondays. In regard to sample discards, any sample that the FSIS laboratory may discard would occur the day of receipt and would not increase turnaround times in any way. Official establishments can receive lab sample results from the Agency electronically. More information on the various FSIS laboratory methodologies including time-frames for receipt of results can be found in the Microbiological Lab Guidebook and the FSIS Analytical Chemistry Laboratory Guidebook available at: [http://www.fsis.usda.gov/Science/Guidebooks\\_&\\_Methods/index.asp](http://www.fsis.usda.gov/Science/Guidebooks_&_Methods/index.asp). How can an establishment determine the amount of product it needs to hold? The establishment is responsible for having a supportable basis to define the sampled lot. The sampled lot is the product represented by the sample tested for by FSIS. In order to limit the amount of product affected by a sample result, the establishment may be able to limit the size of the sampled lot on the day FSIS collects a sample. For sampling purposes, lots should be defined so that if a positive result is found on one lot, the product from the other lot would not be implicated. Two such lots are called (mutually) independent or microbiologically-independent lots. Guidance on

how to", "FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results 2013 6 define sampled lots by product and analysis type is provided below. Guidance for Determining Lot Sizes Guidance for determining lot sizes when FSIS collects a sample is provided for each domestic sampling and testing program below. This guidance can be used by establishments to limit the amount of product on hold when FSIS collects a sample.

Determining the Sampled Lot for Raw Beef Products Subject to E. coli O157:H7 and non-O157 Testing A production lot of raw beef products can be defined in many ways. FSIS does not recognize \u201cclean-up to clean-up\u201d alone as a supportable basis for distinguishing one portion of production of raw beef product from another portion of production. This is because shiga-toxin producing Escherichia coli (E. coli) (STEC) organisms such as E. coli O157:H7, E. coli O26, O45, O103, O111, O121 and O145 are generally not environmental contaminants and, therefore, would not be completely addressed through cleaning and sanitizing. Guidance for lotting different types of raw beef products is described. Raw beef products that are components of non-intact products FSIS samples and tests the following raw beef products that are components of nonintact products for E. coli O157:H7 and in some cases, non-O157 STEC: beef manufacturing trimmings, bench trim, heart meat, head meat, cheek meat, weasand meat, product from AMR systems, low temperature rendered lean finely textured beef (LFTB), partially defatted beef fatty tissue, and partially defatted chopped beef. Considerations that may be used to determine the sampled lot (alone or in combination) for these types of raw beef products include: \u2022 Any scientific, statistically based sampling programs for shiga-toxin producing Escherichia coli (STEC) organisms, particularly E. coli O157:H7, non-STEC, or their associated virulence markers (e.g., eae and stx genes) that the establishment uses to distinguish between segments of production; \u2022 Sanitation Standard Operating Procedures (Sanitation SOPs) or any other prerequisite programs used to control the spread of STEC cross-contamination between raw beef components during production. The following may lead to the cross-contamination between raw beef components during production: o improper sanitary dressing; o insanitary product contact surfaces on equipment such as machinery and employee hand tools; o improper employee hygiene; ", "FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results 2013 7 \u2022 Processing interventions that have been validated to limit or control STEC contamination; \u2022 Beef manufacturing trimmings and raw beef components or rework carried over from one production period to another (carrying rework over from one production period to another compromises microbiological independence between lots); and \u2022 Use of same source materials during different production periods (if the components are being generated at an establishment that is not a slaughter establishment), provided product from one supplier could not have crosscontaminated the product from the other. The following are examples of ways the official establishment can limit its lot size: An establishment could produce bench trim from primals that are then mechanically tenderized and cut into steaks. In order to limit the sampled lot to the bench trim, the establishment could trim the primals, apply a validated intervention to the primals, and then tenderize the primals and cut them into steaks. In the event that FSIS collects a sample of bench trim that is found to be positive, the establishment could support that the non-intact steaks were microbiologically independent using the processing intervention validated to control STEC contamination, provided the critical operational parameters of the intervention were implemented properly. Another example of how an establishment could lot

beef manufacturing trimmings would be by using a robust sampling and testing program in which the establishment samples every combo bin (or other unit of product up to 10,000 pounds) using the N60 sampling plan and tests each sample for *E. coli* O157:H7 or their associated virulence markers (e.g., eae and stx genes). In this case, each combo bin of beef manufacturing trimmings would be considered a lot. If FSIS were to collect a sample from one combo bin of product, and the sample was found to be positive for *E. coli* O157:H7 or a nonO157 STEC , the establishment could support the release of the other lots of product using the results of their own robust testing program. Such robust testing would also be a way for establishments to support microbiological independence of finished product produced from the same production lot of source materials from a single supplier that were found positive for *E. coli* O157:H7. For other raw, intact beef products that are components of non-intact products produced at slaughter establishments such as head meat, heart meat, and cheek meat, establishments often will lot product by slaughter day because of the use of common product contact surfaces that are not cleaned and sanitized until the end of the production day. In large establishments, components such as head meat, heart meat, and cheek meat are usually transported on a moving viscera table and in small establishments a viscera truck is often used. If these product contact surfaces are not cleaned between use, all product that came in contact with that equipment since the last clean-up is considered part of the same lot due to the opportunity for crosscontamination. Cleaning and sanitizing of product contact surfaces may be used as a factor in defining lot size in this case because the components were produced from one", "FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results 2013 8 or more carcasses slaughtered and dressed consecutively or intermittently within a defined period of time (e.g., production day). Therefore, any contamination should be limited within that defined period of time. In limited cases, a single carcass may be considered a stand-alone lot. This may occur in the limited cases when FSIS collects follow-up samples directly from the carcass in response to an FSIS positive sample. For example, FSIS will collect follow-up samples directly from the carcass at an originating slaughter establishment if that establishment sent carcasses to a receiving establishment that produced bench trim from those carcasses that was then used in ground beef which FSIS tested and found positive. Product from different carcasses can be considered as independent lots provided the meat from the carcasses from each lot was handled so as to not cross-contaminate one another. This includes having assurances that the carcasses were not co-mingled. In those cases only the sampled carcass would be held. If the establishment does not prevent carcasses from being commingled or does not have adequate controls to prevent cross contamination among carcasses, it will not be able to designate one carcass as a stand-alone lot for sampling. Raw non-intact beef products FSIS samples and tests raw non-intact beef products that meet the standard of identity for ground and chopped beef (9 CFR 319.15(a)), hamburgers (9 CFR 319.15(b)), and beef patties (9 CFR 319.15(c)) for *E. coli* O157:H7. The same considerations listed on pages 6-7 for determining the sampled lot of raw beef products that are components of non-intact products may be used to determine the sampled lot of raw non-intact beef products that FSIS samples and tests. NOTE: Additional guidance on sanitation practices beef grinders can implement to prevent the introduction of bacterial hazards into their process can be found on page 1 of the Sanitation Guidance for Beef grinders (available at [http://www.fsis.usda.gov/PDF/Sanitation\\_Guidance\\_Beef\\_Grinders.pdf](http://www.fsis.usda.gov/PDF/Sanitation_Guidance_Beef_Grinders.pdf)). The following are

examples of ways establishments can limit its lot size of raw ground beef products: An establishment may define lots by source materials. STEC organisms tend to contaminate source materials during the slaughter and dressing process and so any contamination in source materials would likely be supplier specific. This lotting practice would be acceptable if the product from one supplier does not cross-contaminate the product from the other. For instance, following the grinding of product from one supplier, the lines and equipment were sanitized before the product from the next supplier was processed. It is important to note that if multiple lots of raw ground beef product were produced from source materials from the same production lot of a single supplier, and some of this product was found positive for E. coli O157:H7, a scientific basis is necessary to justify why any raw ground product produced at the grinder from", "FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results 2013 9 those source materials should not be considered adulterated (67 FR 62333). Another example of how an establishment could lot ground beef would be by using a robust sampling and testing plan in which ground beef samples are collected in 65 gram grab portions every 30 minutes of processing and combined into 1 composite sample (five 65 gram samples would be combined into a 325 grams composite) to be tested for E. coli O157:H7 or their associated virulence markers (e.g., eae and stx genes). Using this plan, an establishment could lot product in 2.5 hour production segments and support microbiological independence for those segments. The recommendations and information discussed above regarding defining the sampled lot can also be found in the: \u2022 Guidance for Small and Very Small Establishments on Sampling Beef Products for E. coli O157:H7 found at: [http://www.fsis.usda.gov/PDF/Draft\\_Guidance\\_SVSP\\_sampling\\_for\\_ecoli.pdf](http://www.fsis.usda.gov/PDF/Draft_Guidance_SVSP_sampling_for_ecoli.pdf); \u2022 Compliance Guideline for Sampling Beef Trimmings for E. coli O157:H7 found at: [http://www.fsis.usda.gov/PDF/Draft\\_Guidelines\\_Sampling\\_Beef\\_Trimmings\\_Ecoli.pdf](http://www.fsis.usda.gov/PDF/Draft_Guidelines_Sampling_Beef_Trimmings_Ecoli.pdf); and the \u2022 Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers found at: [http://www.fsis.usda.gov/PDF/Compliance\\_Guide\\_Est\\_Sampling\\_STEC\\_0512.pdf](http://www.fsis.usda.gov/PDF/Compliance_Guide_Est_Sampling_STEC_0512.pdf).

QUESTION Question: If an establishment produces two lots of ground beef from the same source materials and FSIS test results from one lot of product come back as unacceptable (e.g., positive for E. coli O157:H7), will the second lot of product need to be recalled if it was released into commerce? Answer: It depends. The Recall Committee evaluates all production factors and control measures and then determines the scope of the affected product subject to recall. If multiple lots of raw ground beef product were produced from source materials from the same production lot of a single supplier, and some of this product was found positive for E. coli O157:H7, a scientific basis is necessary to justify why any raw ground product produced at the grinder from those source materials should not be considered adulterated. Such a scientific basis could include establishment test results in which the establishment tested each lot for E. coli O157:H7 using a robust sampling and testing plan and found the other lot negative for E. coli O157:H7.", "FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results 2013 10 Alternative lot definitions In addition to the parameters described above which can be used to define the sampled lot, FSIS has provided establishments that have their own sampling and testing programs the option to reduce their lot size for beef manufacturing trimmings, other raw ground beef components, or raw ground beef products to one combo bin or other unit (e.g., box) on the day that FSIS conducts sampling provided that the

establishment: 1. Has a validated intervention for E. coli O157:H7 at a Critical Control Point (CCP) in the HACCP plan that covers the product or requires an intervention for E. coli O157:H7 at a CCP for that product\u2019s source materials; and 2. Samples and tests every production lot for E. coli O157:H7 and generally collects its samples of beef manufacturing trimmings, other raw ground beef components, or raw ground beef products across multiple combo bins or other sample units. If an establishment meets these criteria and reduces its lot size to a single combo bin or sample unit when FSIS samples the product, then FSIS will collect the sample from the single combo bin or unit. Establishments may also have written procedures to grind a minimum batch of product that represents the entire lot in a smaller grinder. To ensure that the sample is representative of the lot, establishments with these written procedures need to have supporting documentation that describes how the minimum batch is representative of the entire lot (e.g., includes an appropriate proportion of all types of trim used to produce the lot). As a general guide, the minimum batch size should not be less than 50 pounds. In order to reduce the sampled lot to this minimum batch size, establishments will need to meet the 2 criteria listed above. Determining the Sampled Lot for RTE Products Subject to Listeria monocytogenes and Salmonella Testing A production lot for RTE product is typically defined as all product produced from clean-up to clean-up unless the official establishment can support a smaller lot size. Unlike E. coli O157:H7 and non-O157 STEC, Listeria monocytogenes (Lm) primarily contaminates product from the production environment. Therefore, it is difficult for establishments to support that Lm did not contaminate all product produced since the last complete clean-up. If the establishment performs a complete cleaning and sanitizing (following the procedures in its Sanitation SOP) between lots, the lot size could be reduced.

Considerations that should be taken into account when determining lot size include RTE source materials used, frequency of cleaning and sanitizing, and processing steps employed. An example of RTE source materials would be the chicken used in a chicken salad. If the chicken is received from another establishment, and product from", "FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results 2013 11 the same bag or container is used in multiple lots, then the establishment should consider whether microbiological independence is maintained between lots. If one of the lots containing a common RTE source material tests positive by FSIS, a scientific basis is necessary to justify why the other lots should not be implicated (for example, the source material was not the cause of the positive). Establishments should also consider whether the re-use of brine between lots would affect microbiological independence. In addition, establishments should consider how processing steps affect microbiological independence between lots. For example, since Salmonella contaminate RTE products as a result of under-processing, if one lot of RTE product tests positive by FSIS, and another lot of product received the same lethality treatment, a scientific basis is necessary to justify why the later lot should not be implicated. NOTE: An official establishment may reduce its lot size on a day when FSIS collects a routine RTE sample, in order to facilitate holding the product, as long as the change does not interfere with FSIS\u2019s ability to collect a representative sample. For example, decreasing the lot size could impact FSIS\u2019s ability to collect the samples because Listeria monocytogenes works its way out of the equipment after 3 hours. As a result, if the establishment produces a very small lot on the day FSIS collects a sample when it typically produces a larger lot, then FSIS may not be able to collect a representative sample. Products produced in the same room could be

considered part of the same or different processing lots, depending on how the lots are separated. If the processing lines can be considered microbiologically and physically independent of one another (i.e., equipment, personnel, utensils, and RTE source materials are not shared among the lines), then they can be considered different lots. Likewise, products produced on the same line could be considered different processing lots if they are separated by a complete cleaning and sanitization, as well as the other factors described above. NOTE: Products stored in a common cooler would not necessarily be considered part of the same lot. However, the establishment\u2019s Sanitation SOP KEY QUESTION Question: If an establishment produces two lots of RTE product from the same source materials, and FSIS test results from one lot of product come back as unacceptable (e.g., positive for Listeria monocytogenes), will the second lot of product need to be recalled if it was released into commerce? Answer: It depends. If one of the lots containing a common RTE source material tests positive by FSIS, a scientific basis is necessary to justify why the other lots should not be implicated. For example, the establishment may be able to support that source materials received a lethality treatment in the final package. Therefore, post-lethality contamination with Listeria monocytogenes would not be possible.", "FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results 2013 12 should address possible cross contamination, especially if RTE and raw products are held in the same cooler. The guidance provided for determining the sampled lot for RTE products subject to Listeria monocytogenes and Salmonella testing can also be applied to determining the sampled lot of product when FSIS collects a food contact surface (FCS) sample for Listeria monocytogenes or Salmonella. Product that passes over the tested FCS will also need to be held pending test results because the product would be considered adulterated if it passed over a FCS that tested positive for Listeria monocytogenes or Salmonella. As with product samples, products produced in the same room but on different processing lines could be considered part of the same or different processing lots, depending on how the lots are separated. If a FCS tests positive on one line, and the establishment has supporting documentation that there is not cross contamination among the lines, then lots produced on the other lines may not be implicated. The guidance provided in this section can also be found in Chapter 3, Page 15 of the revised Listeria Guidelines available at [http://www.fsis.usda.gov/PDF/Controlling\\_LM\\_RTE\\_guideline\\_0912.pdf](http://www.fsis.usda.gov/PDF/Controlling_LM_RTE_guideline_0912.pdf). Determining Product Held for Livestock Carcasses Subject to Residue Sampling and Testing For chemical residues, only the sampled livestock carcass is typically held. That is because for chemical residues, lots typically are determined on a carcass basis during the slaughter operation, unless there is evidence of flock or herd application of the treatment. Although not required under this new policy, it is also recommended that establishments hold the specific poultry carcasses that are sampled for residues. Guidance for Importers of Record on controlling meat and poultry products pending FSIS test results What imported products are subject to this policy? Under the new policy, the following products tested by FSIS cannot move into commerce until acceptable results become available: \u2022 Raw, non-intact beef or veal products such as ground beef, hamburgers, and patties and raw products that are components of non-intact products including beef manufacturing trimmings, bench trim, heart meat, head meat, cheek meat, weasand meat, product from Advanced Meat Recovery (AMR) systems, low temperature rendered lean finely textured beef (LFTB), partially defatted beef fatty tissue, and partially defatted chopped beef tested for E. coli O157:H7 and non-O157 Shiga-toxin producing

Escherichia coli (non-O157 STEC); \u2022 Ready-to-eat (RTE) products tested for Listeria monocytogenes and Salmonella; ", "FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results 2013 13 \u2022 Livestock carcasses and other products other than raw poultry carcasses and parts subject to FSIS testing for residues; and \u2022 Products that are tested for non-food safety consumer protection verification (e.g., protein-fat-free and moisture in hams). The policy does not cover: \u2022 Raw meat or poultry products that FSIS has tested for Salmonella or other pathogens (such as Campylobacter) that FSIS has not designated as adulterants in those products and \u2022 Poultry carcasses or other raw poultry parts subject to FSIS testing for residues and pesticides. Can an importer of record move product from the official import inspection establishment pending receipt of final laboratory results? Yes, the importer of record can move imported product off-site from the official import inspection establishment provided the importer has controls in place that will ensure that product does not enter commerce until the importer of record receives notification of acceptable test results. NOTE: The policy regarding product assigned reinspection at the Intensified level has not changed. Lots of imported product that are assigned reinspection at the Intensified level are under FSIS hold and are not permitted to move off-site from the official import inspection establishment. What does FSIS consider adequate controls when product is moved from the official import inspection establishment prior to receipt of laboratory results? Importers of record are to maintain the integrity of the lot and may use any effective mechanism to control the product, including the use of company seals. The Agency will require importers of record to document that they can control the product pending the availability of test results and provide that documentation to FSIS personnel prior to moving the shipment off-site. When will FSIS consider imported product to be in commerce? If the movement of product results in a change of ownership from the importer of record that presented the product for FSIS reinspection at the official import inspection establishment to any other entity prior to receipt of laboratory results, or if the importer of record relinquishes ownership of the product before receiving the laboratory results, then the product is considered to have entered commerce. Both of these actions are violations of the test and hold provision. Therefore, the product may be subject to redelivery by Customs and Border Protection (CBP) or local Customs authority and to ", "FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results 2013 14 any fines or penalties imposed by such authority, as well as to enforcement actions by FSIS. NOTE: FSIS defines the importer of record as the named individual or company on the entry made with CBP or the local Customs authority. What actions will FSIS take on imported product that receives an unacceptable laboratory result? When the importer of record has maintained control of the product, and unacceptable results are reported, FSIS will refuse the product entry. The importer of record must make appropriate arrangements with FSIS to return the product to an official import inspection establishment to have the product marked as U.S. Refused Entry. The importer of record still has the option to re-export refused entry product. When the importer of record has NOT maintained control of the product, or ownership has changed, and unacceptable results are found, the importer of record has shipped adulterated product into commerce as the product is considered to be domestic product and is subject to recall. In addition, adulterated product in U.S. commerce is no longer eligible for re-exportation, and the importer of record is subject to FSIS enforcement action or sanctions, as appropriate. What is the minimum amount of time product will have to be on hold

or under control for pending FSIS test results? The following table summarizes the minimum number of days from receipt to when the result is received depending on whether the result is determined to be acceptable or unacceptable by analysis type. Analysis Minimum Number of Days from Receipt When the Result Is: Acceptable Unacceptable E. coli O157:H7 and non-O157 in raw beef products 2 4 Listeria monocytogenes in RTE products 3 6 Salmonella in RTE products 1 5 Residue (antibiotics, sulfonamides, or avermectins or the feed additive carbadox) and pesticides in livestock and poultry other than raw poultry carcasses or parts 4\* Will depend on what is screened and the number and type of additional analyses required Non-food safety consumer protection Will depend on the type of analysis Will depend on the type of analysis", "FSIS Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results 2013 15 verification \*Does not include the time (12 \u2013 24 hours minimum) it takes to freeze the sample prior to shipping to the laboratory. FSIS begins testing of all raw beef and RTE products for microbiological pathogen analysis or for residues the day of receipt, including Saturdays. Non-food safety consumer protection verification analyses are started Monday through Friday on the day of receipt; analysis of non-food safety samples received on Saturdays are started on Mondays. In regard to sample discards, any sample that the FSIS laboratory may discard would occur the day of receipt and would not increase turnaround times in any way. Official import inspection establishments can receive lab sample results from the Agency electronically. More information on the various FSIS laboratory methodologies including time-frames for receipt of results can be found in the Microbiological Lab Guidebook and the FSIS Analytical Chemistry Laboratory Guidebook available at:

[http://www.fsis.usda.gov/Science/Guidebooks\\_&\\_Methods/index.asp](http://www.fsis.usda.gov/Science/Guidebooks_&_Methods/index.asp). How does an importer of record determine the amount of product he or she needs to hold? The sampled lot is the product represented by the sample tested by FSIS, which is the defined lot on the foreign inspection certificate. As with domestic product, for lotting purposes, lots are defined so that if a positive result is found on one lot, the product from the other lot would not be implicated. Two such lots are called independent or microbiologically-independent lots. A lot of imported product is determined by the information provided by the foreign inspection system on the foreign inspection certificate and cannot be altered at point of entry reinspection. Therefore, it is critical that the importer of record work with the foreign establishment in regard to how product is lotted."]}, {"file\_name": "FSIS\_GD\_2013\_0008", "title": "\"At Least Equal To\" Compliance Guideline for State Meat and Poultry Inspection (MPI) Programs for Laboratory Methods", "num": "FSIS-GD-2013-0008", "id": "be3bc631a2090b1766f67b59eb3e3ff6708e256384935bc93b193d3b9d673897", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/At-Least-Equal-to-Guide-MPI-Programs-Lab-Methods.pdf", "type": "pdf", "n\_pages": 6, "word\_count": 1617, "text\_by\_page": ["FSIS Hold and Test Conference Call with Industry (February 7, 2013) 1. Will FSIS be implementing new procedures so that importers of record will need to maintain control of imported meat and poultry product pending the results of FSIS tests for adulterants, including residues? Yes. FSIS has emphasized the importance of Agency port-of-entry testing for adulterants, including residues. Effective February 8, 2013, FSIS will not allow product that it tests for adulterants to enter commerce in the U.S. until test results become available. FSIS labs will expedite the"]}

availability of test results to the extent practical, and FSIS will issue any additional necessary instructions to import inspection personnel to ensure the new policy and procedures are effectively implemented. 2. Does fresh product that is subject to residue testing at reinspection need to be frozen prior to being submitted to the labs for testing? No. Import inspection personnel have the option to submit residue samples frozen or cold to the designated laboratory. FSIS will issue instructions re-emphasizing that fresh product sampled for a residue does not need to be frozen. 3. Can a lot of fresh product presented for FSIS reinspection and assigned a laboratory residue type of inspection (TOI) be withdrawn and returned to Canada, (e.g., canceling the import application)? No. The shipment would be U.S. Refused Entry because it was presented to FSIS for reinspection as required and denied the sampling TOI assigned to that lot. 4. Can a lot of fresh product presented to FSIS for reinspection and assigned a laboratory TOI be controlled by returning it to the production facility in Canada? No. However, the product could move under control of the importer to a facility in the United States for storage until acceptable results on the sampled lot are received. 5. What defines a lot? Lot groupings are based on the product species, process\product category, and product group, which are identified and certified on the foreign inspection certificate. Importers (or agents) should coordinate with the exporting establishment in the foreign country to designate lots during the certification process in the foreign country. This question was addressed in a response to question number 15 of a previous Q & A posted on the FSIS web site at:

[http://www.fsis.usda.gov/PHIS/PHIS\\_Import\\_Q&A\\_050212/index.asp](http://www.fsis.usda.gov/PHIS/PHIS_Import_Q&A_050212/index.asp) 6. Can importers of record receive LEARN results? Not at this time. The importer of record and customs broker may provide an email on the import application to receive lab results. FSIS import inspection personnel receive results and communicate them to the official import inspection establishment. 7. Are sampling rates changing? No. FSIS sampling protocols and rates of sampling are not changing with the test and hold policy. 8. Can beef product found E. coli O157 and non-O157 STEC positive at reinspection be diverted to an official establishment for thermal lethality treatment? No. That product is adulterated and cannot enter commerce in the U.S. The positive lot is U.S. Refused Entry with the standard disposition options available, including re-export.", "FSIS Hold and Test Conference Call with Industry (February 7, 2013) 9. Can U.S Refused Entry product be re-exported to a third country? Yes, however FSIS would provide notification to the competent authority where the U.S. Refused Entry shipment is destined. 10. Can the sampled lot be moved to the final destination and controlled at an official establishment pending FSIS results for adulterants? Yes, the importer of record must maintain ownership of the product and ensure the product does not enter commerce until acceptable lab results are received. Imported product destined for further processing and stored at an official establishment under control of the importer cannot be further processed until acceptable lab results are received, as this product would be considered to have entered commerce. 11. Are fully cooked products required to be held under the new policy and procedures? Yes, ready-to-eat (RTE) products are subject to the new policy and procedures when sampled for adulterants. The importer of record would need to maintain control of the product pending receipt of acceptable analysis results. 12. The change in ownership may occur prior to filing the Customs entry, though the original importer of record proceeds with filing the entry. What impact does this have on this policy? The importer of record that files the entry with CBP is the responsible party that must maintain adequate control of the product, so that it



plans: domestic and import. These plans are further divided to facilitate the management of chemical residues such as veterinary drugs, pesticides, and environmental contaminants in meat, poultry, and egg products. The domestic sampling plan includes scheduled sampling and inspector-generated sampling. The import reinspection sampling plan is separated into normal sampling, increased sampling, and intensified sampling. With the implementation of the Hazard Analysis and Critical Control Points (HACCP) system, another important component of the NRP is to provide verification of residue control in HACCP systems. As part of the HACCP regulation, slaughter and production establishments are required to identify all chemical residue hazards that are reasonably likely to occur and develop systems to guard against them. An effective chemical residue prevention program is essential to foster the prudent use of veterinary drugs and pesticides in food animals. In 1999, the NRP was modified to make residue evaluation more consistent with risk assessment principles. The USDA Office of Inspector General (OIG) determined in its review of the FSIS National Residue Program for Cattle, dated January 29, 2010, that the FSIS National Residue Program for Cattle is not meeting its objective of preventing residues from entering the food supply. The OIG report identified slaughter establishments that", "5 continue to purchase livestock from repeat violator producers as one issue contributing to the residue problem. Another issue identified as a problem is the lack of cattle identification available at slaughter that can be associated to the producer. The review further determined there are two slaughter classes of livestock (dairy cows and bob veal) that contribute 90 percent of the residues found in animals presented for slaughter. For this reason, this compliance guide is primarily focused on cull dairy cows and bob veal. Furthermore, on July 6, 2012, FSIS announced changes to the NRP (77 FR 39895). Most significantly, FSIS began analyzing fewer samples but by using multi-residue methods. FSIS now uses multi-residue techniques to quantify a larger number of analytes with greater precision and accuracy. Such methods can often be performed with faster throughput and at lower cost to the Agency than conventional single residue methods.

III. Regulatory Requirements Establishments are required, under 9 CFR 417.2 (a), to conduct a hazard analysis and consider the food safety hazards that might be expected to arise from drug residues. Establishments are also required to maintain documentation that supports the decisions made in their hazard analysis as a part of their records under 9 CFR 417.5 (a) (1). FSIS expects, as it has since HACCP was implemented, that establishments will verify the ongoing effectiveness of their residue programs under HACCP per 9 CFR 417.4 (a). Establishments that determine in their hazard analysis that the food safety hazard \u201cdrug residues\u201d is not a hazard reasonably likely to occur are required under 9 CFR 417.3 (b) (4) to reassess their HACCP plan each time a violative drug residue is found by FSIS. With repeated violations it becomes increasingly difficult for establishments to support the decision that drug residues are not reasonably likely to occur. As a part of an effective HACCP system, an establishment should consider whether the producer of the animals it is considering for purchase has a history of residue violations. Because it is not possible to know for sure whether an animal contains a drug residue that would cause FSIS to condemn the carcass, an establishment\u2019s best indicator of whether the animal may have such a residue is past practice by the producer. A producer who has had more than one residue violation in the preceding 12 months may be more likely than other producers to be selling additional animals with violative residues. Therefore, it is prudent for an establishment to purchase livestock with adequate identification to trace back to the producer. This information

will enable the establishment to determine whether the producer appears on the most recent Residue Repeat Violator List for Establishments and Livestock Auctions (Residue Repeat Violator List). The Residue Repeat Violator List is composed of suppliers who have had", "6 more than one residue violation in the preceding 12 months. FSIS began compiling and publishing the Residue Repeat Violator List in August 2009 in response to an industry request. FSIS updates the listing weekly and when properly used, this information can be a valuable tool for assisting slaughter establishments in avoiding illegal residues in animals they slaughter by identifying livestock from known producers of repeat violator animals. If an establishment regularly purchases animals from a particular livestock market, it may obtain a general certification from the market stating that market personnel check all animals sold at that market against the Residue Repeat Violator List and notify potential buyers of animals from producers whose names appear on that list. This certification may also identify those animals from a producer known to be on the Residue Repeat Violator List. As an alternative to a general certification, particularly if the establishment purchases cattle from a livestock market, establishments should obtain a letter or some other type of credible certification from the seller or livestock market or auction that states that the animals in question either are or are not from a supplier who has had more than one residue violation in the last 12 months. A person or firm that is on the Residue Repeat Violator List remains eligible to market its livestock for slaughter. An establishment may present for slaughter animals from producers on the FSIS Repeat Residue Violator List, but it must have effective controls in place to ensure that any carcasses with violative residues are not allowed into commerce. An official establishment would need to be aware of when it receives livestock from a person or firm on the Residue Repeat Violator List in order for it to be able to design and implement its food safety program to address the potential hazard of an illegal residue. An establishment that receives a certification from the seller that the animal is not from a producer with a history of residue violations should keep the certification in its HACCP records, but they should ensure each time it intends to purchase animals from the market that the market has performed an appropriate review of the list. Without producer information or appropriate certification, it is not possible for an establishment to institute effective preventive measures. If an establishment does not follow this guide and FSIS finds violative residues, the establishment\u2019s HACCP system may be inadequate under 9 CFR 417.6.", "7 IV. Residue Prevention Recommendations In a Federal Register notice entitled \u201cResidue Control in a HACCP Environment\u201d (70 FR 70809, November 28, 2000), FSIS listed four practices available to slaughter establishments to avoid slaughtering animals that contain illegal residues: ensure that all animals brought into an establishment for slaughter are identified, so that they can be traced back to the producers; notify animal producers in writing of both violative and high, though not violative, residue findings, with such notification including a discussion of the issues involved, the company\u2019s (slaughter establishment\u2019s) future expectations, and an indication that repeat violators will not be future suppliers; explore the possibilities for the establishment to require purchase specifications including voluntary residue avoidance programs; and explore live animal testing. These four preventive practices are still relevant to prudent establishments and are entailed and reaffirmed in this guide. FSIS is specifically emphasizing in this guide that establishments, especially those that slaughter dairy cows and bob veal calves, should apply five basic measures, which expand upon and further clarify the four practices listed in the

Federal Register notice, to prevent the occurrence of violative residues.

1. Confirm producer history

An establishment should have an effective residue control program that includes measures that takes into account the historical residue violation information associated with producers. A livestock producer is the individual, farm, dairy, ranch, feed yard or other firm from which the animal originates. The establishment can access the Residue Repeat Violator List to obtain the list of repeat violator producers prior to purchasing the cattle. FSIS has determined that a letter or certification from the seller, livestock market, or auction on a lot-by-lot basis demonstrating that the person issuing the letter or certification has reviewed the most recently posted Residue Repeat Violator List and determined that none of the animals in the lot came from suppliers with more than one violation in the last 12 months is a way that slaughter establishments can protect themselves. In addition, as discussed above, if an establishment regularly purchases livestock from a market, instead of getting a certification for each lot, it may decide to obtain a general certification that the market will check the list for each lot, although the establishment should regularly ensure that the market is adhering to this certification. In addition, this documentation may also identify those animals from a producer known to be on the Residue Repeat Violator List. An establishment that does not use the information in the Residue Repeat Violator List, either directly or through a letter or certification, would not be taking advantage of a tool", "8 for identifying livestock from known repeat violators. Thus, the establishment would not be taking advantage of a means of controlling a hazard that is foreseeable.

2. Purchase animals that are free from violative residues

An establishment should purchase animals from producers that have a history of providing residue-free animals, that employ an effective residue prevention program, and that use drugs judiciously by avoiding unnecessary or inappropriate use. In addition, an establishment should require documentation from the producer that the animals are \u201cfree from violative residues.\u201d The Food and Drug Administration recommends in guidance on Judicious Use of Medically Important Drugs that producers limit use in food-producing animals of medically important antimicrobial drugs to cases when such use is necessary to ensure animal health and then only with veterinary oversight or consultation.

3. Ensure animals are adequately identified

FSIS encourages slaughter establishments to purchase animals with sufficient identification, such as ear tags or back tags, to trace back to the producer and not to purchase any cattle that do not have identification that would allow them to be traced back to the farm of their origin. Cattle should be consistently identified with ear tags or back tags, and that identification has to be maintained with the cattle through the slaughter process until post-mortem inspection is complete. Maintaining proper identification of cattle enables accurate trace back to the producer that can be upheld in a court of law if necessary. FSIS acknowledges that incidental loss of back tags does occur while livestock are in transport and holding areas. If back tags do not work in certain situations, other means of identification like producer ear tags, feedlot identification tags, tattoos, and calf-hood tags (\u201cbangs\u201d) should be considered. Without adequate identification, neither the establishment nor FSIS can utilize herd history to determine how likely cattle are to have violative levels of chemicals. Cattle that do not have animal identification may have had the identification intentionally removed in an effort to obscure their origin. If someone has attempted to obscure the origin of the cattle, FSIS would be concerned about a possible higher risk that these animals contain violative residues. Because of this risk, FSIS Notice 44-12

instructs inspection program personnel to perform in-plant screening tests at an increased frequency if an establishment is not able to demonstrate that it has put in place measures designed to prevent or reduce the possibility that it will receive animals for slaughter with a violative residue. Thus, when cattle are not identified to the producer at ante-mortem inspection, given the Agency's experience with such livestock, FSIS is likely to test such animals on a more frequent basis (up to 100 percent). 4. Supply the producer information to FSIS at ante-mortem inspection When producer information or other assurances are not available at ante-mortem, or when the cattle are purchased from a producer listed on the Residue Repeat Violator List, FSIS is likely to screen test the cattle at a higher rate and may test up to 100 percent. If FSIS is presented with producer information or a letter or certification from the seller, livestock market, or auction, on a lot by lot or other appropriate basis, demonstrating that the person issuing the letter or certification reviewed the most recently posted Residue Repeat Violator List and determined that none of the animals in the lot came from suppliers with more than one violation in the last 12 months, FSIS is likely to screen test the cattle at a lower rate. 5. Notify Producers of Violative Animals Slaughter establishments are notified through the FSIS Public Health Information System (PHIS) of both violative residues and of residues that are detectable but that do not exceed the tolerance levels established by FDA and EPA. Slaughter establishments should notify animal producers in writing if their animals are found either with violative or non-violative levels of a drug residue. Persistent non-violative residues may indicate a pattern of usage that could result in violations at some point. Such notification should include a discussion of the issues involved, the company's future expectations, and an indication that repeat violators will not be future suppliers. V. Comments and Responses In April 2012, FSIS announced the availability of a compliance guide for residue prevention (77 FR 24671) and requested comment on the guide. FSIS received a total of 12 comment letters in response to the April 2012 notice from professional veterinary associations, national trade organizations, private citizens, and an animal welfare advocacy organization. In response to the comments it received, FSIS has updated the compliance guide by substituting "residue free" and "drug free" with the phrase "free from" violative residues. In addition, FSIS has included a discussion of means of livestock identification other than those discussed in the initial guidance that should be considered by livestock slaughter establishments when back tags are lost and prove ineffective in maintaining the identity of the animals. Following is a summary of the comments and FSIS's responses.

**Comment:** Several comments stated that only a small percentage of livestock receiving a back tag at the livestock market or sale barn actually retain those tags all the way to slaughter. One comment estimated that 80 percent of back tags placed on swine fall off before the animals are presented for slaughter. Several comments conjectured that if processors refuse to purchase animals without identification as recommended by FSIS, owners of animals that unwittingly lose their back tags while in transit or holding pens will be denied market access. As an alternative to back tags, two comments requested that FSIS mandate the use of permanent ear identification tags in swine.

**Response:** FSIS acknowledges that incidental loss of back tags does occur while livestock are in transport and holding areas. However, FSIS believes, in some cases, back tags prove to be an acceptable form of identification. If back tags do not work in certain situations, FSIS recommends that establishments use other means of identification, like producer ear tags, feedlot identification tags, tattoos, and calf-hood tags.

(\u201cbangs\u201d). FSIS amended the guide to address animal identification options for establishments to consider when incidental loss of back tags occurs. FSIS has limited authority to mandate the use of specific identification devices, permanent or otherwise, on livestock presented for slaughter. Therefore, FSIS does not intend to propose changes to its regulations to require specific identification devices at this time. Comment: Several comments opposed FSIS\u2019s recommendation that slaughter establishments notify animal producers if their animals are found to have non-violative levels of a drug residue because the information will likely confuse producers. Response: On November 28, 2000, FSIS informed establishments that if their HACCP plans included residue controls that incorporate the best available preventive practices for slaughter establishments, if they implement those controls effectively, and if they supply FSIS with information about violators, then the Agency will not treat violative residue findings by the establishment that are followed by appropriate corrective actions as noncompliance (65 FR 70809). The Federal Register notice went on to recommend that slaughter establishments notify animal producers in writing of both violative and non-violative residue findings as one of several \u201cbest preventive practices.\u201d As reaffirmed in the compliance guide, FSIS believes that such an approach will result in a decrease in violative residue findings because evidence of non-violative residues is an indication of lack of care in drug use by that producer. Comment: Several comments requested that FSIS resume publishing the Residue Violator List in addition to the revised Residue Repeat Violator List. According to the comments, information contained within the discontinued Residue Violator List was used by certain trade organizations to target outreach on residue avoidance to reduce the probability that a repeat violation would occur. Response: In 2011, to avoid confusion, FSIS stopped publishing the monthly Residue Violator (Alert) List that included the names of any producer, including first-time offenders, with a residue violation in the previous 12-months. FSIS replaced that list with the Residue Repeat Violator List. Published weekly, the Residue Repeat Violator List identifies producers who repeatedly (i.e., on more than one occasion) within a 12month period have sold animals for slaughter whose carcasses were found by FSIS to contain a violative level of a chemical residue.", "11 FSIS recognizes that posting the name of a livestock producer to a publicly-available list of residue violators may potentially result in significant economic harm to that producer. Moreover, the incentive of removal of the producer\u2019s name from the Residue Repeat Violator List, which motivates repeat violators to improve their operations to prevent violative residues, will be weakened if producers with only one violation are listed on the web site. Finally, FSIS notes that many first-time residue violators do not go on to become repeat violators within the designated 12-month period. Therefore, FSIS does not intend to resume publishing names of producers with a single violation within a 12month period. Comment: Because producers or suppliers can sell livestock to multiple Federal establishments, one comment suggested FSIS consolidate residue test results from the supplier or producer and set an acceptance level of non-violative samples that would trigger removal of a producer from the Residue Repeat Violator List rather than use a hard 12-month timeframe. Response: FSIS would need to evaluate existing data to set a level of acceptable non-violative residue sample results that would trigger removal of a producer from the Residue Repeat Violator List. Given the time and resources that it would take to perform this evaluation, FSIS finds that the passage of time without a violation remains the appropriate criterion for removal from the list and is not making any changes to the Residue Repeat Violator

list at this time. Comment: Two comments requested that FSIS amend the compliance guide by substituting \u201cresidue-free\u201d and \u201cdrug residue free\u201d with the phrase \u201cfree from violative residues\u201d. Response: FSIS agrees with the suggested changes and has modified the compliance guide accordingly. Comment: Two comments expressed various concerns about drug residues in horses destined to be slaughtered for human consumption. Response: In January 2010, the USDA Office of Inspector General determined in its review of the FSIS National Residue Program for Cattle that cull dairy cows and bob veal account for 90 percent of the residues found in animals presented for slaughter. Therefore, the guide focuses primarily on establishments that slaughter these livestock. However, this guide will be useful to any establishments that slaughter horses under Federal inspection in the future. By following the recommendations in the guidance, horse slaughter establishments would employ practices that help them avoid receiving horses with residues", "12 VI. References Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), Egg Products Inspection Act (EPIA), 9 CFR 310.2(a) and generally 9 CFR 300 to end, 417.3(a) and (b); Residue Repeat Violator List for Use by Livestock Markets and Establishments FSIS National Residue Program \u201cRed Book\u201d for 2010 (June 2012) FSIS National Residue Program Scheduled Sampling Plans \u201cBlue Book\u201d for 2012"]}, {"file\_name": "FSIS\_GD\_2013\_0026", "title": "Egg Products - Blueprint Guide", "num": "FSIS-GD-2013-0026", "id": "7bd68c26d6c31409fa907bb608a9f6c4b392a09e18e1653e0e6631a0d1a631e3", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Blueprint-Guide.pdf", "type": "pdf", "n\_pages": 8, "word\_count": 2366, "text\_by\_page": ["Page 1 of 6", "\u201cAt Least Equal To\u201d Compliance Guideline for State Meat and Poultry Inspection (MPI) Programs for Laboratory Methods Table of Contents I. Purpose", "\u2022 Background", "\u2022 Criteria for \u201cAt Least Equal To\u201d Laboratory Methods.....page 2 IV.", "\u2022 Submission of Laboratory Methods.....page 5 V. Additional Information", "\u2022 Purpose This Compliance Guideline supplements the \u201cAt Least Equal To\u201d Compliance Guidelines for State Meat and Poultry Inspection (MPI) programs. It specifically supplements the guidance material in Component 3 - Product Sampling, of the guideline in that it provides additional instruction and recommendations on product sampling, laboratory methods and quality assurance.", "\u2022 II. Background FSIS has entered into cooperative agreements with various states that administer their own MPI programs in a manner that is \u201cat least equal to\u201d the Federal inspection program. To be \u201cat least equal to\u201d the Federal inspection program, the State programs need to have product sampling and laboratory methods with capabilities and safeguards that are \u201cat least equal to\u201d FSIS\u2019s sampling and methods. Hence, the State MPI programs should update and maintain their", "\u2022 Page 6", "\u2022 Page 2 of 6 I."]}]

laboratory microbiological and chemical detection methods so they are \u201cat least equal to\u201d the applicable FSIS guidebook methods. FSIS has integrated ongoing documents and on-site reviews of the applicable analytical methods in its annual comprehensive review of State MPI programs. Based on these reviews, FSIS will determine whether a participating State MPI testing program is \u201cat least equal to\u201d the corresponding FSIS testing program. FSIS plans to begin using the criteria in this guidance as part of the Federal Fiscal Year (FY) 2014 review cycle. Each State MPI program needs to submit its FY 2014 self-assessment by November 15, 2013. FSIS will evaluate whether the information submitted by a State as part of the FY 2014 assessment meets the criteria in this guidance.

III. Criteria for \u201cAt Least Equal To\u201d Laboratory Methods

To achieve and maintain \u201cat least equal to\u201d laboratory methods, each State MPI program should meet the criteria in the following three areas:

- (1) Program Sampling and Reporting, (2) Laboratory Quality Assurance Programs, and (3) Laboratory Testing Methods.

Sampling methods should provide analytical results \u201cat least equal to\u201d corresponding FSIS testing programs. Each State program should provide documentation through self-assessment and on-site review to FSIS that demonstrate that its program includes the following:

- 1) Program Sampling and Reporting

The sampling methodology, including the matrices and tools used, is effective for generating meaningful and consistent data.

\u2022 The program ensures sample integrity and identity. Laboratories that analyze samples for State MPI programs should maintain procedures to ensure that samples are not compromised within the laboratory. These procedures should include a documented chain of custody as well as traceability to the sample, equipment, and critical supplies used to analyze the sample. . .", "Page 3 of 6 \u2022 The program demonstrates confidence in test results and does not re-sample or re-test pathogen-positive and non-compliant products.

\u2022 Official test results are reported directly to the State MPI program in a timely manner.

- 2) Laboratory Quality Assurance (QA) Programs

State MPI program laboratories, or contract laboratories, should have an appropriate quality assurance (QA) program \u201cat least equal to\u201d the program maintained by FSIS laboratories to ensure the reliability and integrity of analytical results. State MPI program laboratories, or contract laboratories, should ensure that each laboratory meets the criteria outlined in the attached FSIS MPI Program Laboratory Quality Management System Checklist.

Laboratory QA program assessment consists the following:

- \u2022 Documented program of quality control procedures and ensure that these procedures are followed.
- \u2022 Properly trained personnel, suitable facilities and equipment, and verified, calibrated, and maintained equipment in a manner consistent with international norms (e.g. European cooperation for Accreditation (EA) 04/10 or Analytical Laboratory Accreditation Criteria Committee (ALACC) guidance).
- \u2022 Appropriate proficiency testing schemes for food analysis.
- \u2022 Use of validated method protocols.
- \u2022 Reporting and recordkeeping capabilities that can clearly track and link a test result to the correct establishment.

- 3) Laboratory Testing Methods

Standard methods are available in the USDA FSIS Microbiology Laboratory Guidebook (MLG), USDA FSIS Chemistry Laboratory Guidebook, FDA Bacteriological Analytical Manual, International Organization for Standardization (ISO) Methods, and Association of Analytical Communities (AOAC) Official Methods of Analysis.

Methods used in support of the State MPI program should be validated for the product type sampled. State MPI programs should provide documentation necessary to explain the methods used and the scientific basis for their (or the other testing laboratory's) selection. Such

documentation should include detailed testing method protocols, supplemental testing procedures, and evidence of method validation for microbiology methods and sustained proficiency testing for chemistry methods. Method assessment by FSIS considers the following: Microbiology \u2022 Methods of analysis have been designed to detect the lowest possible level of stressed pathogens from meat, poultry, and environmental samples (e.g., the method includes an enrichment step). \u2022 Methods of analysis have been validated through an experimental study. When methods have been modified, it may be necessary to conduct a supplemental validation. For validation studies conducted outside AOAC, Association Fran\u00e7aise de Normalisation (AFNOR), the French national organization for standardization, or similar organizations, please refer to \u201cFSIS Guidance for Evaluating Test Kit Performance. 10/15/10\u201d at the following link:", "Page 4 of 6  
[http://www.fsis.usda.gov/wps/wcm/connect/966638c7-1931-471f-a79e4155ce461d65/Validation\\_Studies\\_Pathogen\\_Detection\\_Methods.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/966638c7-1931-471f-a79e4155ce461d65/Validation_Studies_Pathogen_Detection_Methods.pdf?MOD=AJPERES)

\u2022 Methods of analysis detect the same target pathogens as the corresponding FSIS MLG method. That is, alternative methods should be inclusive for strains defined as positive by the biochemical, genetic, and serological confirmation tests described in the MLG. \u2022 Methods of analysis use appropriately sized test portions or sampling methodology and frequency for samples that offer enhanced opportunity for detecting foodborne pathogen contaminations. For information on the test portions used for FSIS testing programs, refer to FSIS laboratory method protocols available from the FSIS Microbiology Laboratory Guidebook website at the following link:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook> \u2022 If additional non-validated confirmatory tests are performed by the laboratory, those tests should not be relied upon to invalidate the previous results. \u2022 Shipping enrichments to a second confirmatory laboratory should be avoided. FSIS guidance for evaluating microbiological testing methods can be found in FSIS Directive 5100.1 Rev. 3 Attachment 1 \u201cEvaluation of Microbiological Methods Used by Establishments\u201d at the following link:  
[http://www.fsis.usda.gov/wps/wcm/connect/868cc16e-8dae-48e2-a3c4898d77f4a0a0/Attachment1\\_5100.1Rev3\\_Methods.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/868cc16e-8dae-48e2-a3c4898d77f4a0a0/Attachment1_5100.1Rev3_Methods.pdf?MOD=AJPERES) Food Chemistry \u2022 Methods of analysis should be capable of measuring food chemistry components as a percentage of sample weight. Moisture, protein, fat, and salt should be included. FSIS conducts limited food chemistry analysis of products at official establishments when in-plant inspection personnel believe the product is misbranded. \u2022 Acceptable methods of analysis are available on the FSIS Chemistry Laboratory Guidebook website at the following link:  
<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook> \u2022 AOAC Official Methods of Analysis for food chemistry are also acceptable. \u2022 Alternative methods for food chemistry analysis are acceptable, provided they measure the same components with sufficient accuracy. Evidence to support use of an alternative method would include proficiency-testing data generated by the State MPI laboratories or contract laboratories completing the analysis. \u2022 The FSIS Accredited Laboratory Program (ALP) provides proficiency-testing services for food chemistry. For further information, visit the following link:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/accreditedlaboratories/accredited-laboratories> \u2022 Information on in-plant screening of residues in meat and poultry products is available at the following link:  
[http://www.fsis.usda.gov/wps/wcm/connect/c2329ec8-a3fc-4581-8302dd71aa66e0a8/Compliance\\_Guide\\_At\\_Least\\_Equal\\_to\\_Residue\\_Testing\\_122112.pdf?MOD=D=AJ PERES](http://www.fsis.usda.gov/wps/wcm/connect/c2329ec8-a3fc-4581-8302dd71aa66e0a8/Compliance_Guide_At_Least_Equal_to_Residue_Testing_122112.pdf?MOD=D=AJ PERES), "Page 5 of 6 IV. Submission of Laboratory Methods To initiate the review process, State MPI programs should submit their current laboratory methods on or before November 15, 2013, as part of the FY 2014 self-assessment submissions. In subsequent years, State MPI programs should submit a list of their current laboratory methods and copies of new or revised methods as part of the self-assessment submission process. In the submission, State MPI program Directors should divide the document submissions into Microbiology methods, Chemistry methods, and QA records. All three sections should be submitted electronically to the FSIS Outlook mailbox: [Statelabinquiry@fsis.usda.gov](mailto:Statelabinquiry@fsis.usda.gov) If hard copies must be submitted, please mail them to the following address: Director, USDA, FSIS, OPHS, Laboratory Quality Assurance Staff 950 College Station Road Athens, Georgia 30605 Phone: (706) 546-3559 FSIS also recommends that States submit a completed FSIS MPI Program Laboratory Quality Management System Checklist available at the following link:  
<http://www.fsis.usda.gov/wps/wcm/connect/b31678b7-0822-4081-bc9a-bf483403851f/State-MPI-Lab-Quality-Mgmt-SysChecklist.pdf?MOD=AJPERES> or similar information for each laboratory performing MPI-related analyses. Records related to FSIS on-site reviews should be submitted to the FSIS Outlook mailbox. NOTE: State laboratories that are accredited to ISO 17025 with all applicable methods under their scope of accreditation may provide their current certificates of accreditation in lieu of the QA checklist. While use of contract laboratories to meet analytical requirements is acceptable, the contract laboratory should meet the same requirements as described for State MPI program laboratories. The State MPI program laboratories and their contract laboratories are subject to periodic on-site reviews by FSIS to evaluate the QA program in comparison to written submissions and to verify the accuracy and implementation of the laboratory methods. V. Additional Information Questions regarding laboratory methods can be submitted through AskFSIS using the following link:  
<http://askfsis.custhelp.com/> When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided: Subject Field: Enter Laboratory Methods", "Page 6 of 6 Question Field: Enter your question with as much detail as possible. Product Field: Select General Inspection from the drop-down menu. Category Field: Select Cooperative State Inspection Programs from the drop-down menu. Policy Arena: Select Domestic (U.S.) Only When all fields are complete, press the Submit button. VI. References \u201cAt Least Equal to\u201d Compliance Guideline for State Meat and Poultry Inspection (MPI) Programs for Residue Testing  
[http://www.fsis.usda.gov/wps/wcm/connect/c2329ec8-a3fc-4581-8302dd71aa66e0a8/Compliance\\_Guide\\_At\\_Least\\_Equal\\_to\\_Residue\\_Testing\\_122112.pdf?MOD=D=AJPE RES](http://www.fsis.usda.gov/wps/wcm/connect/c2329ec8-a3fc-4581-8302dd71aa66e0a8/Compliance_Guide_At_Least_Equal_to_Residue_Testing_122112.pdf?MOD=D=AJPE RES) \u201cAt Least Equal To\u201d Guidelines For State Meat And Poultry Cooperative Inspection Program [http://www.fsis.usda.gov/wps/wcm/connect/e257c4af-2a5e-4b50-8e5e3e8da94af949/At\\_Least\\_Equal\\_to\\_Guidelines.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/e257c4af-2a5e-4b50-8e5e3e8da94af949/At_Least_Equal_to_Guidelines.pdf?MOD=AJPERES) Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory March 2012 <http://www.fsis.usda.gov/wps/wcm/connect/3d0c3eb-f09d-494d>

9830ecf4c8435bf7\Guidance\_Selecting\_Micro\_Testing\_Lab.pdf?MOD=AJPERES FSIS Analytical Chemistry Laboratory Guidebook

<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-andmethods/chemistry-laboratory-guidebook/> FSIS Microbiology Laboratory Guidebook

<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-andmethods/microbiology-laboratory-guidebook> [{"file\_name": "FSIS\_GD\_2014\_0001", "title": "Controlling Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products", "num": "FSIS-GD-2014-0001", "id": "6b006f1d080953ae877c7e51ede042885ea726e57682b7b05f2792ebf880b067", "co\_rpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Controlling-Lm-RTE-Guideline.pdf", "type": "pdf", "n\_pages": 143, "word\_count": 58448, "text\_by\_page": ["1 June 2013 Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory This Compliance Guideline is provided to establishments producing meat, poultry and processed egg products for use when they are selecting a commercial or private laboratory to analyze establishment microbiological samples. This guidance document should be particularly useful to very small operations in selecting a microbiological testing laboratory. FSIS previously issued this guidance in March 2012 with a request for comments. In response to the comments it received, FSIS has revised the guidance to: \u2022 Clarify that laboratories that meet ISO 17025 accreditation would also meet the guidelines provided by FSIS in this guidance document; \u2022 Compile a Web-based list of methods that have been externally validated for the detection of foodborne pathogens and included information and a hyperlink to this list; \u2022 State that proficiency testing (PT) should be performed on a regular basis (two to three times annually) and that PT may be used to evaluate the laboratories\u2019 accuracy, precision, and efficiency. PT may also be used as a means to evaluate individual analyst competency; \u2022 Add more questions on PT requirements to the Laboratory Assessment Checklist for establishments to ask laboratories when evaluating if a laboratory is capable of producing accurate and reliable results; \u2022 State that negative controls may be helpful in some circumstances. For example, as a negative control, laboratories may spike one or more samples with nontarget bacteria that produce a distinctly different result from the target bacterium on differential media or confirmatory tests. \u2022 State that, because of safety concerns and to prevent cross contamination, FSIS recommends that a pathogen testing laboratory be segregated from manufacturing areas and that access to the laboratory space is limited. A summary of comments and responses to the comments is included in the Federal Register notice announcing the availability of this document. 1These lists of methods that have been externally validated for the detection of foodborne pathogens are intended to be informational and are not an endorsement or approval of any particular method, regardless of its inclusion in the list.", "2 Table of Contents Chapter 1. Purpose page 3 Chapter 2. Laboratory Selection and Evaluation Criteria page 4 A. Personnel Qualifications page 5 B. Sample Receipt and Handling page 6 C. Quality Assurance Management System page 7 D. Method Selection and Implementation page 12 E. Reporting of Results and Establishment\u2019s Interpretation of Results page 16 Chapter 3. What Data Should an Establishment Have Readily Available for FSIS Personnel page 17 References page 19 Appendix I. Laboratory Assessment Checklist page"]}]

21","3 Chapter 1. Purpose FSIS is issuing this guidance document to provide criteria to establishments producing meat, poultry and processed egg products for selecting a commercial or private microbiological testing laboratory to analyze establishment samples. FSIS recognizes that the AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals is a useful technical reference for laboratory staff, and particularly as guidance for laboratories seeking to implement the ISO 17025 requirements. FSIS has included a citation for this reference in the body of this guidance document (see page 18). This FSIS document, in contrast to the Association of Analytical Communities (AOAC) document, was developed to assist industry plant managers and support staff in assessing and selecting their laboratory services at no extra charge. While FSIS acknowledges there is some technical overlap for these documents, the FSIS document provides language and content that is specific to a non-technical industry audience. A commercial laboratory refers to an outside or off-site contracting testing laboratory, while a private laboratory refers to an establishment\u2019s own in-house or on-site laboratory. Throughout this document, the term laboratory will be used to mean both types of laboratories. When outside laboratories analyze establishment samples, it is the responsibility of the regulated establishment to ensure that microbiological testing methodologies and practices meet their food safety needs. Establishments that select a laboratory that does not apply appropriate testing methods or effective Quality Control\Quality Assurance (QC\QA) practices may not receive reliable or useful testing results. FSIS-regulated establishments may perform microbiological testing (or contract with an outside laboratory) for various reasons, including, but not limited to the following: \u2022 To fulfill regulatory requirements (9 CFR 310.25, 381.94, 430.4, 590.580); \u2022 To support on-going verification of the establishment\u2019s HACCP plan (9 CFR 417.4(a)(2)); \u2022 To support decisions made in the establishment\u2019s hazard analysis ( 9 CFR 417.5(a)(1) and 417.5(a)(2)); \u2022 To evaluate the effectiveness of the establishment\u2019s sanitation program (9 CFR 416.14); or \u2022 To comply with customers\u2019 purchase specifications or requirements.","4 Ultimately, it is the responsibility of the regulated establishment to ensure that microbiological testing meets its food safety needs. Establishments should clearly communicate their needs to the testing laboratory and direct them to any necessary testing protocols or other guidance, including this document, on the FSIS Web site. It is the establishment\u2019s responsibility to understand the implication of the results from the laboratory for their program and plan corrective actions accordingly. The establishment should not assume that an unexpected result is incorrect. Resampling or retesting a sample is typically not an appropriate action. Because of safety\security concerns and to prevent cross contamination, FSIS strongly recommends that a pathogen testing laboratory be segregated from manufacturing areas, and that access to the laboratory space be limited. Pathogen testing laboratories should: \u2022 Follow requirements for Biosafety Level II laboratory operation as outlined in Biosafety in Microbiological and Biomedical Laboratories (BMBL) available at: <http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf>; \u2022 Restrict access to the laboratory to trained staff; and \u2022 Ensure the laboratory is operating under the supervision of a qualified microbiologist or equivalent. NOTE: Establishments can (and often do) analyze samples for non-pathogenic organisms such as Listeria spp., generic E. coli and aerobic plate counts (APC). Chapter 2. Laboratory Selection and Evaluation Criteria When evaluating the

services provided by a microbiological testing laboratory, it is important for the establishment to ensure that the candidate laboratory to be able to perform the analyses and report results using methods that meet the establishment's needs. Building a working relationship and initiating conversation consistent with these guidelines will help ensure that the establishment selects an appropriate laboratory. The evaluation criteria and recommended questions found in this document will assist establishments in making a determination that the results they receive from the laboratory are reliable and accurate. These criteria include what FSIS considers essential to understanding whether a laboratory is capable of producing acceptable results. For ease of use, a checklist of recommended questions for assessing laboratories is available in Appendix I. In addition, FSIS inspection personnel will use similar criteria to evaluate laboratory results during the verification of a food safety system such as a Hazard Analysis Critical Control Point (HACCP) system verification or a Food Safety Assessment (FSA). The criteria provided in this document include: A. Personnel qualifications;,"5 B. Sample receipt and handling, sample integrity maintenance, identity and chain of custody; C. Quality assurance management system; D. Method selection and implementation; and E. Reporting of results and establishment's interpretation of results. The selected laboratory should not subcontract any portion of the analyses to another laboratory without permission of the establishment management and proof that the subcontract laboratory meets this guidance. The establishment management should also verify that the conditions under which a sample is shipped to a subcontract or second laboratory for testing do not adversely affect the follow-up analysis. Each section of this document provides general information, questions to ask the laboratory manager, and items to be taken into consideration before selecting a laboratory. This information should be helpful for evaluating which laboratory best fits the needs of an establishment. For further assistance, additional information is available under the References listed in this document (page 18).

A. Personnel Qualifications KEY POINTS:

\u2022 The laboratory should have a policy and system in place for documenting and maintaining records on the background of laboratory management and analysts, which include their education, experience, and training, to establish analyst competency for a specific testing method.

\u2022 All laboratory personnel should be well versed in food microbiology, analytical methods of food sampling, and foodborne pathogens such as *Campylobacter*, *Salmonella*, *Listeria monocytogenes*, *E. coli* O157:H7, and non-O157 Shiga ToxinProducing *Escherichia coli* (STEC) in meat, poultry, and processed egg products. Analysts should be trained on new or revised methods before they perform the Questions to ask Laboratory Manager

1. Does the Laboratory Manager have an advanced degree (PhD or MS) or a 4-year degree in biology, chemistry, microbiology, food or medical technology, or other relevant science with at least 12 semester hours of course work in microbiology, or at least 4 years of experience working in a public health, medical, food, or other related laboratory?
2. Do the Laboratory analysts\technicians have a 4-year degree, or an associate degree in biology, microbiology, or relevant science with at least 10 semester hours of microbiology, or 2 years of working experience?
3. Does the Laboratory have records (certificates) documenting successful participation in applicable proficiency testing programs within the past year?
4. Can the Laboratory provide documentation demonstrating that all laboratory personnel meet the necessary education, training, and competency requirements?"

"6 method on establishment samples. Analysts should then demonstrate ongoing competency annually for each method performed.

Laboratories may use laboratory proficiency testing (PT) as a means to evaluate the individual analyst's initial and ongoing competencies to perform a method. Other options to demonstrate analyst competency include control charting and analyzing in-house blinded training or check samples. All relevant internal and external training should be documented for each staff member and records must show completed performance verifications.

B. Sample Receipt and Handling KEY POINTS:

- \u2022 The laboratory should have a documented system, such as a Standard Operating Procedure (SOP), for ensuring the integrity of samples during transportation and upon receipt, including discard criteria for unacceptable samples.
- \u2022 The laboratory should have a system for tracking samples after they have been received and accepted for analysis including procedures for maintaining the identity and integrity of the sample throughout storage, analysis, and reporting of test results.
- \u2022 The laboratory should have a system for tracing a test result to the correct sample.

Sample Receipt, Handling, Integrity Maintenance, Identity, and Chain of Custody General Principles:

Collecting and analyzing samples involves multiple steps, all of which must be successfully performed and documented to maintain the identity and integrity of the sample. It is important for the establishment to be able to collect and ship samples properly. On-site assistance or information on proper sample collection (aseptic techniques) and shipment of samples by the laboratory to the establishment is also important. The final result of the analysis will be neither accurate nor meaningful if a laboratory has not implemented procedures to prevent mishandling of samples or alteration of records. Procedures for maintaining sample integrity are particularly important when samples need to be transported from the establishment to an off-site laboratory (e.g., by a delivery service such as FedEx or courier) where they may not be under the direct control of the establishment or the laboratory for a period of time."

"7 Things to Look For:

1. Sample integrity: The laboratory should have procedures in place to ensure sample integrity is maintained. These procedures should include:
  - \u2022 Documenting sample custody during all stages of testing, from receipt of samples to reporting of results;
  - \u2022 Determining whether samples have been shipped and held at inappropriate temperatures, and ensuring that such samples are not analyzed;
  - \u2022 Preventing contamination from other samples or the environment.
2. Sample identity: The laboratory should have procedures to ensure that the history of any sample received by the laboratory is documented. Each sample should be labeled with permanent ink or another permanent labeling system. Each sample should be assigned a unique identifier that is associated with the sample from collection to test report.
3. Chain of custody: A chain-of-custody (COC) document is often used to demonstrate that the sample is always under the control of the establishment or the laboratory. COC documents record the circumstances under which the responsibility of the sample is transferred. They include the time, date, name, and signature of the individuals that are transferring the sample and a description of the sample, including the sample's unique identifier. The COC supports both the sample integrity and the accuracy of the test results. A Laboratory Information Management System (LIMS) is often utilized by laboratories to capture and store this COC information electronically.
4. Preparation and shipment of the sample: Non-intact samples should be placed in a sterile primary container (e.g. sterile Whirlpack bag) designated for collecting samples and shipped in a box containing cooling packs to maintain the proper temperature. Food samples in intact retail packs do not have to be placed in sterile containers but should be placed in a secondary container such as a sealed plastic bag. Shipping boxes

should be sealed to prevent unauthorized access to the sample. 5. Sample receipt: The laboratory should maintain a sample log-in book, computer file, or other permanent recordkeeping system with an accessible format to document the following: \u2022 Samples are inspected upon receipt and their condition is recorded; \u2022 Samples are evaluated against the laboratory\u2019s discard policy; and \u2022 Unacceptable samples are discarded and not analyzed.

C. Quality Assurance Management System KEY POINTS:

The laboratory should, on a regular basis (at least 2 to 3 times annually), evaluate its competency through participation in proficiency testing (PT) programs for", "8 each method performed. The laboratory should maintain PT records with sufficient information to show that the method was performed like a routine sample. For all samples, the testing laboratory should have routine controls with each batch of samples, including a positive control inoculated with the analytes of interest, a sterility control, and (optionally) a non-target analyte \u201cnegative\u201d control. The laboratory should not report results to establishments unless the controls support acceptable test performance. In addition, all laboratory equipment should be adequately maintained and routinely calibrated according to the appropriate guidance.

General Principles:

Quality assurance (QA) is defined as a program designed to ensure timely and reproducible results that are useful to customers through the minimization of human error. Quality control (QC) is defined as a procedure intended to verify that a system, such as a laboratory method, is working correctly. The International Organization for Standardization (ISO) (<http://www.iso.org/iso/home.htm>) developed internationally accepted quality standards for laboratory management, ISO\IEC (International Electrotechnical Commission) Standard 17025 General requirements for the competence of testing and calibration laboratories, focusing on QA and QC principles. Laboratories receive external audits to demonstrate compliance with the ISO standard. Although accreditation is not a specific requirement, accreditation provides increased confidence in the accuracy and quality of the test results produced by a laboratory. Note that FSIS laboratories are audited by an external assessment body to demonstrate compliance with the ISO 17025 Standard and the AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals, available at: <http://www.aoac.org/accreditation/faq2.htm>. Whether or not a laboratory is accredited under ISO 17025, the Analytical Laboratory Accreditation Criteria Committee (ALACC) document is a helpful reference, available at:

[http://www.a2la.org/requirements/17025\\_FOOD\\_MICRO\\_REQ.pdf](http://www.a2la.org/requirements/17025_FOOD_MICRO_REQ.pdf). This document provides guidance on the frequency of equipment maintenance, calibration, and monitoring the performance of equipment during the course of analysis (i.e., performance verification). Alternatively, the European Co-Operation for Accreditation (EA) 04\10, Accreditation for Microbiology Laboratories provides similar guidance and is available at:

<http://www.european-accreditation.org/n1/doc/ea-4-10.pdf>. The above accreditation schemes cover all the topics mentioned in this guidance document. Laboratories that meet the guidance provided in the above mentioned accreditation schemes would meet the guidelines provided in this document. All laboratories that test samples from FSIS-regulated establishments should have QA and QC programs and should be able to describe these programs to their customers. At a minimum, QA and QC programs implemented by laboratories should cover written procedures and data collection tools, sample traceability\chain of custody, equipment maintenance and calibration, validated testing methods, PT, and analysis

controls.", "9 Things to Look For: 1. Written QA Program: The laboratory should have policy and procedure documents describing the analytical and quality activities performed in the laboratory. Analysts should only have access to the current revisions of these documents. Laboratory personnel should periodically review these QA program documents for continued suitability. 2. Proficiency testing (PT) programs: PT provides evidence of laboratory competency to produce credible analytical results in a method. PT programs are designed to critically evaluate the accuracy, precision, and efficiency of the laboratory. The laboratory should regularly evaluate their laboratory competency through a PT program. PT programs are administered by an outside organization on a routine (e.g., annual, semi-annual, or thriceannual) basis. In a PT program, the outside organization sends the laboratory a set of food samples, with each sample either inoculated or free of the microorganism of interest. The laboratory analyzes the samples and submits its results for assessment. The outside organization evaluates the returned results against the target value and provides the laboratory a report stating whether the laboratory has successfully met the criteria set by the organization administering the PT program. 3. Data collection tools: The laboratory's sample worksheets should contain sufficient information to verify the proper interpretation of the test for the final result. Worksheets should be prepared by the laboratory on a daily basis to record observations, calculations, and traceable information. These and other data collection tools should contain sufficient information to facilitate the identification of factors that may affect the accuracy of the result, such as media preparation. The worksheets should record the following (as applicable): Questions to ask Laboratory Manager 1. Does the laboratory have a written Quality Assurance Program? 2. On review and verification of laboratory PT results, were all results for the past year found to be acceptable? 3. Has the performance of the method been evaluated for use in the laboratory? 4. Are the sample type, test portion, analyte, and test method captured on the laboratory's sample worksheet? 5. Does the laboratory always run positive and sterility controls at the same time as the samples? 6. Are the laboratory results approved by the laboratory director or manager before the results are released to the customer? 7. Are the calibration, operation, and maintenance of all equipment verified to be performed in accordance with international recommendations?", "10 \u2022 Method protocol name or number; \u2022 Analysts performing the method; \u2022 Unique identifier (internal laboratory number); \u2022 Start and completion dates; \u2022 Measurements from relevant equipment such as temperature from ovens, incubators, water baths, autoclaves; \u2022 Incubation or running times; \u2022 Lane or injection order; \u2022 Equipment used; \u2022 Lot number (or traceable identification) for media, reagents, standards, and controls used in the procedure; \u2022 Sample weights; \u2022 Measurements, such as pH and water activity; \u2022 Calculations performed during the procedure; \u2022 Any other relevant observation, such as the size, color, and consistency of colonies on microbiological media; \u2022 Unexpected observations; and \u2022 Results from samples and controls. 4. Controls: The laboratory should run controls with each batch of samples, and the sample results should not be reported unless the controls indicate acceptable test performance. Controls are defined as samples that are intended to verify that the method is performed correctly and produces accurate results. Microbiological controls include: \u2022 One or more positive controls, which are food samples inoculated with a well-characterized strain that is the target of the method. The positive control result verifies that the method, all media and reagents, and the analyst are

capable of achieving the correct result at the time of analysis when the organism of interest is present. Also, laboratories use positive controls to evaluate whether the food sampled interferes with the detection of the target microorganism. Care must be taken to avoid crosscontamination between the positive control and the other samples. One way that laboratories may verify that positive sample results are not caused by cross-contamination is by using an easily identifiable positive control such as one that contains an antibiotic resistance or a fluorescence strain. \u2022 A sterility control is a type of control where prepared media are not inoculated with any control organism. Laboratories use the sterility control", "11 to verify that all media and reagents, as well as the analyst, are not contributing contamination that could have an impact on the test result. The sterility control should always be negative and there should be no evidence of microbial growth. \u2022 Additional negative controls may be helpful in some circumstances. As an example, laboratories may spike one or more samples with non-target bacteria that produce a distinctly different result from the target bacterium on differential media or confirmatory tests. Such a negative control can be inoculated at the beginning of the analysis or applied later in the analysis for specific biochemical, genetic or serological confirmation tests. NOTE: Some test kits have controls built into the test. These controls should be analyzed along with the samples and method controls to verify that the kit performs according to manufacturer specifications. Results derived from control samples can be used to identify the source of problems. Controls demonstrate the following to the customer: \u2022 The entire method is performing as expected; \u2022 The specific media and reagent lots are performing as expected; \u2022 The analyst is performing all steps of the analysis correctly; and \u2022 There is a basis for documenting that the test results are valid and accurate. Because controls are important to demonstrate that the method was effective, they should be analyzed concurrently with every batch of samples, and the results from the controls should be recorded. Importantly, an unexpected result may indicate that the method is not performing effectively; therefore, the validity of sample results should be evaluated by the laboratory. The laboratory QA system should not allow the result to be reported to the customer until the issue is resolved. In addition, the laboratory should employ controls to perform lot and batch acceptance on test kits, reagents and culture media. Sterility, selectivity and the ability to support growth of target analytes should be assessed prior to using the product on customer samples.

5. Environmental Monitoring: The laboratory should implement an effective environmental monitoring program to mitigate risk of cross contaminating sample portions. Air monitoring for density of airborne microorganisms and sponge samples of work surfaces such as bench tops, stomachers, balances, and analytical instruments, for the analytes of interest are appropriate activities. The laboratory should investigate positive results to identify cross contamination of positive samples and should follow up with necessary disinfectant of work surfaces and necessary follow up testing.", "12

6. Equipment: The laboratory should have policies and procedures in place to ensure that all equipment and software used for testing, calibration, and sampling are uniquely identified, capable of achieving the required accuracy, and comply with the method specifications. The laboratory should have procedures to ensure that equipment is used properly, maintained, and performance calibrated according to the manufacturer's recommendations, and that defective equipment is removed from the service area and clearly labeled as \u201cout of service.\u201d

D. Method Selection and Implementation KEY POINTS: Methods should be

specific or fit for the intended purpose to detect the target microorganism in the sample. Methods for detecting foodborne pathogens should be designed to be adequately sensitive to detect low levels of injured cells to prevent false negative results. The method should be capable of detecting the target pathogen, as it is defined in the corresponding FSIS Microbiology Laboratory Guidebook (MLG) protocol. Confirmation methods should be specific for target organisms, so that cross reactions with closely related microorganisms or analytes do not occur. The method should be validated using a scientifically robust study by a recognized entity, as outlined in the FSIS validation guidance document for test kit manufacturers and laboratories. Internationally recognized independent organizations, including AOAC, AFNOR (Association Fran\u00e7aise de Normalisation, the French national organization for standardization), MicroVal, and NordVal organize validation studies on behalf of clients. Any modifications introduced to a validated method should also be validated using a scientifically robust study. Sample size should be comparable to those employed by FSIS, if applicable. For more guidance from FSIS on validation studies please refer to Questions to ask Laboratory Manager 1. Does the laboratory use an analytical method described in the FSIS-MLG? 2. Has the enrichment and screening method used by the laboratory to detect the target microorganism of interest, been validated and approved by an organization such as AOAC, AFNOR, ISO, NordVal, MicroVal, FDA, FSIS, or other? If yes, specify the organization. 3. Has the method used by the laboratory to confirm the target microorganism of interest been approved by an organization such as AOAC, AFNOR, ISO, NordVal, MicroVal, FDA, FSIS, or other? If yes, specify the organization. 4. Is the sample collected representative of the production lot? 5. Is the test portion representative of the entire sample collected? If yes, is it similar to the sample size provided for in the FSIS-MLG? 6. Has the method been validated for the matrix of interest (food or environmental swabs) and the test portion size? 7. Have any changes been made by the laboratory to the validated method? If yes, request additional scientific supporting documents.", "13 \u201cFSIS Guidance for Test Kit Manufacturers, Laboratories: Evaluating the Performance of Pathogen Test Kit Methods\u201d. NOTE: Laboratories that are accredited and use the same analytical methods, procedures, and sample sizes as those used by FSIS laboratories and described in FSIS\u2019s Microbiology Laboratory Guidebook (FSIS-MLG) are deemed to have met the laboratory selection and evaluation criteria described in this chapter (Chapter 2). The FSIS-MLG is posted on the FSIS Web site at:  
<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook> General Principles: All analytical methods described in the FSIS-MLG have been scientifically validated and are considered fit for their intended purpose. Thus, laboratories that analyze samples using specific instructions in the FSIS-MLG, or that have met the above evaluation criteria and are able to use the methods, would meet the evaluation criteria for laboratory selection. Validation: Laboratories may also use other validated testing methods that differ from the methods described in the FSIS-MLG. Validation as used in this document refers to a laboratory study to evaluate the performance characteristics of a testing method. Validation is typically performed by regulatory agencies or companies that develop test kits. In most cases, validation studies are designed to compare the performance of a new method (referred to as an \u201calternative\u201d method) against an older, well-characterized method (referred to as a \u201creference\u201d method). For the intended conditions of use, the performance

characteristics of the new method and the well-characterized method should be statistically indistinguishable. FSIS has also provided guidance for industry to consider when validating new microbiological methods or modifications to existing methods for foodborne pathogens. . See guidance document for more information, available at:

[http://www.fsis.usda.gov/wps/wcm/connect/966638c7-1931-471f-a79e4155ce461d65/Validation\\_Studies\\_Pathogen\\_Detection\\_Methods.pdf?MOD=AJPRES](http://www.fsis.usda.gov/wps/wcm/connect/966638c7-1931-471f-a79e4155ce461d65/Validation_Studies_Pathogen_Detection_Methods.pdf?MOD=AJPRES)

Following validated testing protocols: Establishments should verify that their laboratories follow all steps in a validated method protocol. Modifications to validated methods (whether FSIS-MLG or alternative methods) often compromise the effectiveness of the test. Verification: The laboratory should demonstrate on-going competence in performing the method at their facility, which would include participating in proficiency testing programs. In summary, establishments should determine whether a laboratory is using validated methods to test their samples, whether the methods are fit for their intended purpose, whether those methods are comparable to the methods used by FSIS (if applicable), and whether the methods have been modified from their initial validated procedure. By", "14 following these guidelines and using methods that are validated, establishments and laboratories can ensure that the results are reliable and fit for their purpose. If an establishment does not choose to use methods that have been validated, FSIS may question the support for decisions made in their hazard analysis.

Things to Look For: 1. Validated methods: The laboratory should only use validated test methods to analyze samples. Validation studies can be performed either in single or multiple laboratories. However, multiple laboratory validation studies are preferable because these studies evaluate the \u201cruggedness\u201d (comparable test performance in different laboratories with different equipment and personnel), and therefore, the likelihood that the test will have acceptable performance is greater if it has been successfully validated in multiple laboratories. 2. Fit for intended purpose: Validation by a recognized independent organization does not support that the method is appropriate for any and all situations. The laboratory and the establishment should also make a determination that the method is fit for the intended purpose. That is, the method: \u2022 Has been validated in foods or matrices representative of those likely to be sampled at the establishment; NOTE: Links to AOAC-RI Performance Tested Methods and AOAC Official Methods of Analysis are provided in the Reference section below. Manufacturers of microbiological testing products, including pathogen screening tests, often provide useful information on the validation of their products. \u2022 Has been validated to analyze the desired test portions; and \u2022 Has been validated to detect the microorganisms of concern as identified by the establishment. Additionally, laboratories and establishments should consider the following intrinsic factors: \u2022 Detection: methods intended to detect the presence of foodborne pathogens should be capable of detecting low levels (approaching one cell per test portion) of injured cells; \u2022 Raw food: the presence of fat and competitive microbiota and other factors can affect test sensitivity; \u2022 Ready- to-Eat (RTE) food: the sensitivity of methods intended for RTE food samples can be affected by properties of the product including added salt, low pH, and low water activity (in the case of dried products such as jerky); and", "15 \u2022 Environmental surface: microbial load and the presence of detergents and sanitizers typically used in RTE-producing establishments can affect method sensitivity. 3. Use of FSIS-comparable methods: If the laboratory does not use a method described in the FSIS-MLG, the analytical methods used by the laboratory should be

comparable to the methods used by FSIS. For example, for products that are tested for the foodborne pathogens E. coli O157:H7, non-O157 STECs, Salmonella, Campylobacter, or Listeria monocytogenes, the establishment should ensure that the sampling and testing methods are comparable to the appropriate FSIS methods used for these specific organisms as described in the MLG. Specifically, the methods should:

- Be validated by a recognized independent organization using an appropriate cultural method as a reference, such as the FSIS-MLG method.
- Alternatively, a validated method from a scientifically robust study using the FSIS method as a reference is acceptable but should be evaluated by FSIS. FSIS recommends submitting questions regarding the suitability of a method to askFSIS at:

<http://askfsis.custhelp.com>; and

- Be capable of analyzing a test portion similar to the FSIS test portion in terms of size and food type. The MLG provides information about the current analytical portion for each particular analysis. The test portion is the portion of the collected sample that is actually tested by the laboratory.

**4. Modifications to Validated Methods:** If the laboratory has introduced modifications to a validated analytical method, the modifications should be validated using a scientifically robust study. FSIS has encountered situations where laboratories have made significant modifications to a validated method without determining how the modification would affect test performance. Changes that should be validated include:

- Increased test portion size;
- Altered ratio of sample to enrichment broth;
- Different enrichment broth;
- Modification to established enrichment;
- Reduced enrichment time;
- Different enrichment temperature; and
- Different food sample.

If any modifications are introduced to a validated method, the method should be revalidated using a scientifically robust study and comparing it with a reference cultural method. These studies are performed by regulatory bodies or internationally recognized independent validation organizations.

**16 E. Reporting of Results and Establishment's Interpretation of Results**

**KEY POINTS:** A Certificate of Analysis (COA) or a laboratory report details data consistent with FSIS reporting results. The information provided in these reports may vary for each laboratory. FSIS recommends that establishments know what data are included in the laboratory's sample report or COA before selecting the lab.

**General Principles:** Test results should be reported in a manner consistent with the principles of quality assurance to provide useful information and to minimize human error. Laboratory reports or COAs issued for production lots should contain the following information, which is consistent with test result reports prepared by FSIS laboratories:

- Result (including the units of measurement, e.g. cfu/g, cfu/sq. in., MPN/g);
- Description of sample;
- Unique identifier of sample (internal laboratory number);
- Location of sample collection or type of product tested;
- Date of sample collection;
- Date of analysis;
- Date of result report;
- Name of method (cite AOAC, AFNOR, ISO number, if applicable);
- Name, title, and signature of individual preparing the result;
- Interpretation of results (acceptable or unacceptable); and
- Name, title, date and signature of individual reviewing result and authorizing its release.

**Things to Look For:** The laboratory's QA system should address how the combination of test results (screening vs. confirmation results) are interpreted and reported. All presumptive positive results identified by a rapid screening method should be reported. For laboratories that perform analysis of egg product samples (PEPRLab program), all presumptive positive results from official surveillance samples should also be confirmed using one of three cultural confirmed methods (AMS Laboratory Methods for

Egg", "17 Products \u2013 Section I (\u201993 rev.) and Section VII (\u201994 rev.), FSIS MLG online, Chapter 4, and FDA Bacteriological Analytical Manual (BAM) online, Chapter 5). Once analysis is started on a sample, the analysis should be completed. If the analysis is terminated before completion, the analyst should document why the analysis was not completed. The QA system should also ensure that test results that do not meet internal laboratory standards are not reported. NOTE: It is the establishment\u2019s responsibility to interpret the results for its own food safety system. Chapter 3. What Data Should an Establishment Have Readily Available for FSIS Personnel? The establishment management is responsible for testing that is conducted on its behalf and should communicate with the laboratory manager to ensure that the methods used by the laboratory are fit for purpose. The method should be validated to test the product the establishment produces. In some circumstances, such as during an outbreak investigation or FSA, FSIS will evaluate methods using similar criteria and may request additional supporting documentation from the establishment. Under the HACCP regulations, the results of any testing that is performed by an establishment that may have an impact on the establishment\u2019s hazard analysis are subject to FSIS review and are to be available to FSIS personnel. Therefore, FSIS has access to testing records and testing data related to HACCP, prerequisite programs, and good manufacturing procedures. FSIS also has access to records of testing conducted for the establishment\u2019s business customers that could bear on the hazard analysis.

Furthermore, FSIS has access to supporting documentation associated with this testing, including method protocols. Data on testing methods and results that are subject to FSIS review include, but are not limited to the following: \u2022 Testing protocol for requested analyses, including modification necessary to meet the needs of the establishment program; \u2022 Evidence of method validation; \u2022 Establishment\u2019s sampling plan, including purpose, type, and frequency of sampling; \u2022 Correspondence between the establishment and laboratory, including acknowledgement from the laboratory that it meets the criteria established in this guidance (for example, including a completed laboratory assessment checklist); \u2022 Chain of Custody (COC) documentation when samples are needed to be transported from the establishment to an off-site laboratory (e.g. by a delivery service such as FedEx or courier) where they may not be under the direct control of the establishment or the laboratory for a period of time;" "18 \u2022 Microbiological test results and reports; \u2022 Interpretation of results (acceptable\unacceptable) for use by the establishment such as applying results to determine process control or following HACCP (Hazard Critical Control Points) plan, or integrating results in conjunction with SOP; \u2022 Corrective actions related to test results, such as laboratory error, unacceptable sample temperature or failed PT; \u2022 Data and supporting documentation associated with testing; and \u2022 Testing associated with prerequisite programs and with good manufacturing procedures." "19 References 1. Ask FSIS Questions and Answers. Available at: <http://askfsis.custhelp.com> 2. AOAC Official Methods of Analysis search engine at: <http://www.eoma.aoac.org/> 3. AOAC-RI Performance Tested Methods list at: <http://www.aoac.org/testkits/testedmethods.html> 4. A2LA Food Microbiology Program Requirements. June 2001. Based upon the FLAWG document: \u201cAOAC International Accreditation Criteria for Laboratories Performing Food Microbiological Testing\u201d. Available at: [http://www.a2la.org/requirements/17025\\_FOOD\\_MICRO\\_REQ.pdf](http://www.a2la.org/requirements/17025_FOOD_MICRO_REQ.pdf) 5. Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition. Available at:

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<http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm>, "21 APPENDIX I. Laboratory Assessment Checklist The checklist is intended to assist establishments to determine whether a microbiological laboratory is capable of producing accurate and reliable results. The questions are phrased so that the appropriate response to most questions is \u201cYes,\u201d \u201cNo,\u201d or \u201cNot applicable (\u201cNA\u201d). Questions pertaining to services or procedures not routinely used by the establishment should be marked as \u201cNA\u201d. A \u201cNo\u201d response

to any of the questions would not necessarily imply that results from the laboratory are not reliable. The establishment should request additional supporting information or a justification for the \u201cNo\u201d response, or contact FSIS through askFSIS at:

<http://askfsis.custhelp.com>, for additional assistance.

**Date Laboratory Name Questions Yes No Not Applicable (NA)**

Does the laboratory manager have an advanced degree (PhD or MS) or a 4 year degree in biology, chemistry, microbiology, food or medical technology, or other relevant science with at least 12 semester hours of course work in microbiology or at least 4 years of experience working in a public health, medical, food, or other related laboratory? Does the laboratory analyst or technician have a 4 year degree, or an associate degree in biology, microbiology, or relevant science with at least 10 semester hours of microbiology, and\or 2 years of working experience? Can the laboratory provide documentation demonstrating that all laboratory personnel meet the recommended education, training, and certification requirements above? (See Chapter 2 - A: Personnel Qualifications). Is the laboratory analyst trained on a new method and found to be competent before he\she can perform the method on the establishment samples? Does the laboratory have records (certificates) documenting the analysts\u2019 or technicians\u2019 competency, such as participation in a laboratory PT program, analyzing in-house blinded training or check samples?", "22 Does the laboratory have a written Quality Assurance Program? Is the laboratory\u2019s Quality Assurance Program periodically reviewed by an external party? Questions Yes No Not Applicable (NA)

Does the laboratory have lot acceptance criteria for test kits, reagents and growth media (i.e., does the laboratory assess them for sterility, selectivity, and ability to support growth of target analyte prior to using product on customer samples)? On review and verification of laboratory PT results, were all results for the past year found to be acceptable? For any unacceptable PT result, did the laboratory perform an appropriate root cause analysis and implement effective corrective actions? If a commercial PT program is unavailable for the target analyte, does the laboratory use blinded in-house check samples to demonstrate laboratory competency\u201d? Has the performance of the method been verified for use in the laboratory? Does the laboratory subcontract any portion of the analyses to another laboratory? If yes, does the subcontract laboratory meet the recommended criteria found in this document? If portions of the analyses are subcontracted to another laboratory, has sample integrity been maintained under the conditions under which the samples are stored and shipped? If enrichments have been shipped to a second laboratory for follow-up analysis, what ensures the integrity of these analyses? Does the sample have a unique identification number (Sample ID, internal laboratory #) to be able to trace the sample results back to sample receiving and sample collection? Does the laboratory have criteria for accepting or discarding samples when samples are received at the laboratory (sample receiving)? (for example: unbroken seals on containers; acceptable temperature for raw ground beef).", "23 Are the sample type, test portion, analyte, and test method captured on the laboratory\u2019s sample worksheet? Does the laboratory run control samples (positive, sterility, or negative) at the same time as the samples? Questions Yes No Not Applicable (NA)

Does the laboratory sample result reporting tool have the name or initial of the technician or analyst carrying out the analysis? Are the laboratory results reviewed by the laboratory director or manager before the results are released to the customer? Is equipment maintained, calibrated and performance monitored during the course of analysis (verified) in accordance with international recommendations (ALACC or EA04\10) and also maintained and

calibrated as recommended by the manufacturer? Has the enrichment or screening method used by the laboratory to detect the target microorganism of interest been approved by an organization such as AOAC, AFNOR, ISO, MicroVal, NordVal, FDA, FSIS, or other? If yes, specify the organization. Has the confirmatory method used by the laboratory to confirm the target microorganism of interest been approved by an organization such as AOAC, AFNOR, MicroVal, ISO, NordVal, FDA, FSIS, or other? If yes, specify the organization. Is the sample collected representative of the production lot? Is the test portion representative of the entire sample collected? If yes, is it similar to the sample size provided for in the FSIS-MLG? Has the method been validated for the matrix of interest (food or environmental swabs) and the test portion size? Have any changes been made by the laboratory to the validated method? If changes have been made to the validated method, does the laboratory have additional scientific supporting documentation to support the modification?", "24 Does the laboratory\u2019s sample report or COA include information on the sample type, analyte, laboratory official who approved results of test?"]}, {"file\_name": "FSIS\_GD\_2013\_0003", "title": "FSIS Compliance Guideline for Controlling Meat and Poultry Products Pending FSIS Test Results", "num": "FSIS-GD-2013-0003", "id": "1455bf810124fcde91768fb3f91af3631a0a6245ffd4616d4d4e56c42cccc254", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-09/FSIS-GD-2013-0003.pdf", "type": "pdf", "n\_pages": 17, "word\_count": 6391, "text\_by\_page": ["Guidance on the Procedures for Joint Food Safety and Inspection Service (FSIS) and Food and Drug Administration (FDA) Approval of Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products Purpose of this Document This document is intended to provide guidance to interested parties who wish to use new food ingredients and sources of radiation or to make new use of approved food ingredients and sources of radiation in the manufacture of meat and poultry products. All ingredients and sources of radiation (hereafter referred to as \"substances\") must be determined to be safe and suitable before they can be used in the production of meat and poultry products. This document explains the procedures for such a determination. Background FDA is authorized to determine the safety of substances (including Generally Recognized as Safe (GRAS) substances, food additives, and color additives), as well as prescribing safe conditions of use. However, while FDA has the responsibility for determining the safety of substances, FSIS still retains, under the tenets of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), and their implementing regulations, the authority to determine that new substances and new uses of previously approved substances are suitable for use in meat and poultry products. Suitability relates to the effectiveness of the substance in performing the intended technical purpose of use, at the lowest level necessary, and the assurance that the conditions of use will not result in an adulterated product or one that misleads consumers. On December 23, 1999, FSIS published, in the Federal Register, a final rule, entitled \"Food Ingredients and Sources of Radiation Listed or Approved for use in the Production of Meat and Poultry Products.\" This final rule explained how FDA and FSIS will work together regarding future requests for approvals of substances to be used in or on meat and poultry products. The final rule streamlined the process for approving the use of substances in meat and poultry products by providing for the simultaneous review by FDA and FSIS of requests and petitions. A Memorandum of Understanding (MOU) was implemented in January 2000, which established a joint committee to coordinate the review of new substances and new uses of previously approved substances. The joint committee consists of representatives from both agencies, and its purpose is to facilitate the timely review of new substances and new uses of previously approved substances. The joint committee also provides a forum for communication and collaboration between FDA and FSIS on issues related to the safety and suitability of new substances and new uses of previously approved substances. The joint committee is responsible for developing and implementing procedures for the review of new substances and new uses of previously approved substances, and for ensuring that both agencies are working together to achieve the same goals. The joint committee is also responsible for resolving any disputes or disagreements between FDA and FSIS regarding the safety and suitability of new substances and new uses of previously approved substances. The joint committee is also responsible for developing and implementing procedures for the review of new substances and new uses of previously approved substances, and for ensuring that both agencies are working together to achieve the same goals. The joint committee is also responsible for resolving any disputes or disagreements between FDA and FSIS regarding the safety and suitability of new substances and new uses of previously approved substances."]]}

2000 that outlines the procedures for such reviews. The final rule and the MOU may be accessed through the FSIS Labeling and Additives Policy website at:

<http://www.fsis.usda.gov/oppde/larc>. The Labeling and Consumer Protection Staff (LCPS) serves as FSIS' focal point on the use and labeling of substances, and implements the MOU with FDA on the joint review and approval of substances. The Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition (CFSAN) at FDA is responsible for regulating food ingredients and additives, as well as working collaboratively with FSIS, LCPS, in the implementation of the MOU. Ingredient\Additive Classifications and the Procedures for Approval Substances added to foods are classified and defined in FDA's regulations. The classifications include Generally Recognized as Safe (GRAS) substances, food additives (direct and secondary direct), color additives, and prior sanctioned substances. (There are also other classifications, e.g., food contact materials; however, the approval of such materials is handled on a company-by company basis by FDA.) With the exception of prior sanctioned substances, the procedures for approving ingredients and additives are described as follows:","GRAS Substances (21 CFR, Parts 182 and 184) GRAS substances generally are substances for which there is consensus among the scientific community regarding their safety, and which have a history of use in foods and are derived from foods (21 CFR 170.30). There are essentially 3 ways a substance is GRAS: (a) the substance is listed by FDA in 21 CFR Parts 182 or 184 as GRAS or Affirmed GRAS; (b) the substance is determined to be GRAS by a manufacturer, supplier, or other group (i.e., a GRAS \"self-determination\"); or (c) the substance is the subject of a GRAS notice. In order to use new substances or consider new uses of previously approved substances, FSIS must have from FDA, at the very least, a written statement of no objection with regard to the safety of the use of the substance because the mark of inspection for meat and poultry products reflects a determination by FSIS that the food product is not adulterated, and thus that all substances used to make the product are safe and suitable. FSIS must have data that show that the use of new substances is suitable for the intended technical purpose(s). (Refer to the Final Rule for a more detailed explanation of these requirements.) Therefore, with regard to (b) above, the use of substances that are self-determined by a manufacturer or supplier to be GRAS is not possible. With regard to (a) and (c) above, FDA receives GRAS notifications and requests to list substances as GRAS in 21 CFR. The criteria for which data are needed to support a GRAS classification (i.e., that show the safety of the use of an ingredient under the proposed conditions of use) are described in 21 CFR 170.30. Data are needed by FSIS to support the suitability of the use of the substance. The data need to show that the use of the substance is at the lowest level necessary to achieve the intended technical effect under the proposed conditions of use. Data must be provided for each meat and poultry product category in which use is intended (e.g., comminuted livestock products, such as cooked sausages, and cured poultry products, such as turkey ham). The use of new substances can not result in the products becoming adulterated or misbranded, e.g., making products look better or of greater value than untreated products or masking normal spoilage indicators. The Agencies operate in accordance with the MOU to evaluate the data jointly within the timeframes specified. Provided FDA agrees with the GRAS classification, they will issue a written GRAS Notice (also posted on the FDA GRAS website) which includes information regarding the notifier's responsibilities under FMIA and PPIA, and the related meat and poultry regulations. In the case of a GRAS Affirmation request, FDA will need to conduct rulemaking to amend 21 CFR. Acceptability Determinations

About the Regulatory Status of the Use of GRAS Substances

The MOU between FSIS and FDA describes a procedure whereby interested parties can request from FSIS an \"acceptability determination\" of whether the new use of substance in the production of meat and poultry products is safe and suitable. As noted previously, substances currently listed in FDA regulations for use in food generally (21 CFR, Parts 172-180) or GRAS for use in food (21 CFR, Parts 182 and 184) are not automatically acceptable for use in meat and poultry products, nor are \"self-determinations\" of GRAS possible. Unless the listing specifically mentions meat and poultry products, FSIS must have from FDA, at the very least, a written statement of no objection with regard to safety of the use of the substance. Once a written opinion is obtained from FDA, FSIS still needs to determine the suitability of the use of the substance based on data provided by the requestor that support efficacy of use. Data are needed that show the lowest level of the substance necessary to achieve the intended technical purpose. Based on the merits of the data, FSIS can permit the new use of the substance under the proposed conditions of use, and in conformance with standards and labeling requirements. Thus, not all requests for the approval of new uses of substances in the production of meat and poultry products lead to regulatory action. Rulemaking may be necessary where a standard of identity prohibits or limits the use of a substance, or the substance is not expected in the product, e.g., adding milk to hamburger.

Food Additives (21 CFR, Parts 172-180)", "Food additives (direct, secondary, indirect) are essentially chemically derived, do not have a history of use in foods, and there is no general agreement among the scientific community with regard to their safety for the use that is proposed. Direct food additives are added to food for a technical purpose and have a lasting effect in the food (e.g., the antioxidants BHA\BHT). Secondary direct additives are added for a momentary technical effect and have no lasting effect in the food (e.g., the antimicrobial agents, ozone, acidified sodium chlorite). Indirect additives have the potential to become part of a food through processing or packaging, but are not intended to be added to food for an intended technical effect (e.g., coatings and adhesives).

The approval of the use of food additives requires a great deal of scientific data in the form of petition to FDA in order to establish the safety of the substance under the proposed conditions of use, as described in 21 CFR, Part 171. Rulemaking is required on the part of FDA to amend 21 CFR. Petitions for the use of new food additives and new uses of currently approved food additives, including petitions for use in meat and poultry products, are received by FDA. FDA files such petitions publicly (i.e., in the Federal Register) if they consider them to be complete after consultation with FSIS, LCPS. Filing the petition is the start of FDA's rulemaking process. Per the MOU, FDA develops regulatory amendments in consultation with FSIS, LCPS, to amend 21 CFR. As part of the food additive petition, FSIS will require data that establish the suitability of the use of the substance for the purpose intended. The data need to show that the use of the substance is at the lowest level necessary to achieve the intended technical effect under the proposed conditions of use. Data must be provided for each meat and poultry product category in which use is intended (e.g., comminuted livestock products, such as cooked sausages, and cured poultry products, such as turkey ham). The use of new substances can not result in the products becoming adulterated or misbranded, e.g., making products look better or of greater value than untreated products or masking normal spoilage indicators. FSIS input must be provided to FDA within the timeframes specified in the MOU. All food additives must be approved for use by FDA before they may be used in meat and poultry products.

Color Additives (21 CFR, Part 70)

With regard to food applications, a color additive is any material (e.g., dye, pigment, lake) that, when added to a food, is capable of imparting a color. Although there is a different procedure for approving color additives, the procedure is similar to that of food additives, e.g., a petition to FDA is required for the approval of all new color additives which includes scientific data to support safety and suitability. When FDA receives petitions for the use of new color additives in meat and poultry products, according to the MOU, they consult with FSIS regarding efficacy and implications of the use in terms of the FMIA, PPIA, and related regulations. FDA must amend 21 CFR for the new uses of all color additives. The Agencies operate in accordance with the MOU to evaluate the data jointly within the timeframes specified. Prior Sanctioned Substances (21 CFR, Part 181) Prior sanctioned substances are excepted from the definition of \"food additive\" and are substances used in accordance with a sanction or approval granted under the Federal Food, Drug, and Cosmetic Act, Federal Meat Inspection Act, or Poultry Products Inspection Act prior to 1958. Requests for publication in 21 CFR of a prior sanction must be supported by evidence to show this. Additional Guidance Additional guidance on the procedures for the approval of substances may be obtained from the Labeling and Consumer Protection Staff at [www.fsis.usda.gov/oppde/larc](http://www.fsis.usda.gov/oppde/larc) or at (202) 205-0279.", "[Return to Related Documents]"}, {"file\_name": "FSIS\_GD\_2013\_0004", "title": "FSIS Hold and Test Conference Call with Industry", "num": "FSIS-GD-2013-0004", "id": "54580d920907777a7d376a31afae40d6e115748c21dc12ab2708e757c3d66679", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/FAQ\_Hold\_\_Test\_020713.pdf", "type": "pdf", "n\_pages": 2, "word\_count": 783, "text\_by\_page": ["Guidance on Ingredients and Sources of Radiation Used to Reduce Microorganisms on Carcasses, Ground Beef, and Beef Trimmings Purpose This document is intended to provide guidance to interested parties who wish to use new antimicrobial agents, e.g. organic acids and acidified sodium chlorite or to make new use of antimicrobial agents that are already employed in the production of beef carcasses, ground beef, and beef trimmings, to reduce the presence of pathogenic microorganisms on meat products. This document will provide some background information on the ingredient approval process and the different classes of approved antimicrobial agents, and then provide guidance on the labeling of these substances."]}

Background All ingredients and sources of radiation must be determined to be safe and suitable before they can be used in the production of meat and poultry products. On December 23, 1999, the Food Safety and Inspection Service (FSIS) published, in the Federal Register, a final rule entitled \"Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products.\" This final rule explained how the Food and Drug Administration (FDA) and FSIS will work together regarding requests for approvals of ingredients and sources of radiation to be used in or on meat and poultry products. The final rule streamlined the approval process by providing for the simultaneous review by FDA and FSIS of requests and petitions. A Memorandum of Understanding (MOU) was implemented in January 2000 that outlines the procedures for such reviews. The final rule, the MOU, and a document entitled \"Guidance on the Procedures for Joint Food Safety and Inspection Service (FSIS) and Food and Drug Administration (FDA) Approval of Ingredients Used in the Production of Meat and Poultry Products,\" which describes the process for approving the use of ingredients in detail, may be accessed through the FSIS Labeling and Additives Policy website at:

[www.fsis.usda.gov\oppde\larc](http://www.fsis.usda.gov/oppde/larc). Antimicrobial Agents Some studies show that certain ingredients provide an antimicrobial effect of reducing the levels of pathogenic microorganisms, such as E. coli O157:H7, Salmonella, and Listeria. Since December 1999, FSIS and FDA have worked together to evaluate and approve or list as safe and suitable food ingredients for use in the production of meat and poultry that have an antimicrobial effect.

**Classification of Antimicrobial Agents** Antimicrobial agents can have a momentary or a lasting effect in or on the treated product and, thus, are classified by the technical effect. The technical effect will determine the approval process and the labeling. Direct Additives FSIS and FDA regulations allow various meat and poultry products, including ground beef and trimmings, to be treated with direct food additives, e.g., Lactoferrin, a Generally Recognized as Safe (GRAS) substance. Direct food additives are considered ingredients of a product and must be included in the ingredients statement on the product\u2019s labeling. Substances are considered to be ingredient if they remain in the food product and have a lasting effect on the product.

Furthermore, because, at present, the standards of identity for ground beef and trimmings are such that these are considered to be single-ingredient raw products, they are not expected by consumers to include other substances, the use of direct additives in these products must be reflected in the product\u2019s name, e.g., "Ground Beef, treated with milk-", "derived Lactoferrin." Comminuted beef products that do not have established regulatory food standards of identity may include these ingredients in their formulations without implications for product names. Secondary Direct Food Additives Acidified sodium chlorite, peroxyacids, and ozone are examples of substances that have been approved as secondary direct food additives. Secondary direct food additives provide a momentary technical effect and not a lasting effect in the treated food. These substances are ordinarily removed from the final food, and any residuals that may carry over to the final product are not expected to exhibit any technical effect. Thus, they would be considered processing aids under FDA\u2019s definition of that term in 21 CFR, 101.100(a)(3), i.e., there is no lasting functional effect, and there is an insignificant amount present in the finished product under the proposed conditions of use.

Even though FSIS has no definition of "processing aid" in its labeling regulations, the Agency, through the Labeling and Consumer Protection Staff (LCPS), which serves as FSIS\u2019 focal point on the use and labeling of food ingredients, makes judgments on a caseby-case basis using FDA\u2019s definition of a processing aid to decide whether the use of a substance is as a processing aid or as an ingredient of a food. If a substance is a processing aid, it need not be declared in the ingredients statement, nor need there be provision for its use in any standard of identity that is applicable to the finished food. The Table below reflects the currently approved substances for use in the production of meat carcasses, parts, and comminuted products for the purpose of microbial reduction.

Ingredient Name	CFR Reference	Other Reference Products for Which Application Approved
Sodium and Potassium Lactate	9 CFR 424.21 (c)	Various meat and poultry products. Direct food additive Sodium Citrate buffered with citric acid to a pH Of 5.6 Acceptability determination Non-standardized comminuted meat and poultry products. Direct food additive Sodium Diacetate
Lactoferrin	9 CFR 424.21 (c)	Various meat and poultry products. Direct food additive Lactoferrin GRAS Notice (FDA Website)
Peroxyacids	21 CFR 173.370	Beef carcasses and parts Direct food additive Peroxyacids (a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1hydroxyethylidene-1,1diphosphonic acid)
Acidified sodium	21 CFR 173.370	Beef carcasses Secondary direct food additive\Processing Aid Acidified sodium

chlorite 21 CFR 173.325 Carcasses, parts, and trimmings, as well as all processed, comminuted or formed meat food products. Secondary direct food additive\Processing Aid Ozone 21 CFR 173.368 All meat and poultry products Secondary direct food additive\Processing Aid Sources of ionizing radiation 21 CFR 179.26 Pork, poultry, and beef products as listed. Food additive", "The Use of Organic Acids One example of how FSIS\u2019 approach works is presented by the use of organic acids. Lactic acid, acetic acid, citric acid, ascorbic acid, and other organic acids are approved or listed in FDA regulations for various technical purposes, e.g., as acidulants, antioxidants, flavoring agents, pH adjusters, nutrients, and preservatives. There may also be other uses of these organic acids by non-meat and poultry food processors for which FDA has accepted a determination by the proponent of use of the substance that the use is GRAS. For these uses, FSIS must have from FDA, at the very least, a written statement of no objection with regard to the safety of the use of the substance. The USDA mark of inspection for meat and poultry products reflects a determination by FSIS that the food product is not adulterated, and thus that all ingredients used to make the product must be safe and suitable for the product to receive the mark. FSIS has specifically approved lactic acid, acetic acid, and citric acid as antimicrobial agents in the final wash that is applied to livestock carcasses after trimming and inspection but before chilling. The Agency\u2019s decision about this use of organic acids was based on industry requests that were supported by data that showed that this application of organic acids meets FDA\u2019s definition a processing aid (21 CFR 101.100 (a) (3)). Therefore, products made from the organic acid-treated carcasses do not have to declare the organic acids in the ingredients statement on the product label. Organic acids have also been approved for use in various meat food products for certain technical effects (e.g., as acidulants to adjust pH, flavoring agents, and color preservatives). These uses are listed in the table of approved substances in 9 CFR 424.21 (c). When organic acids are used for the purposes indicated in the table, they are considered to be ingredients of the product since they are in the finished meat food product at a detectable level, and they exhibit a continuing technical effect in or on the meat food product. Therefore, the organic acids must be declared on the label of the meat food product. If a company is interested in using one or more of these organic acids as an antimicrobial agent on beef trim (i.e., a postchill application) and does not want to declare the acid in the ingredients statement on the label of the meat food product, they must provide data to LCPS that show that the use complies with FDA\u2019s definition of a processing aid. The data must show that the acid is not having a continuing effect on the meat food product. Specifically, the supporting data must show that the fresh color of the meat is not preserved. The product will exhibit normal spoilage indicators (e.g., discoloration); and that there is no extension of shelf life as compared to products made from untreated trimmings. The data must also show that the nutrient composition is not affected by the treatment, e.g., protein is not denatured, and vitamins are not enhanced. The data must address the sensory characteristics (i.e., color and odor) of the product and show that the characteristics are not altered as compared to untreated trim. Finally, there must not be any detectable residues of the organic acid in the meat food product derived from the treated trim. Occasionally, processors request consideration of the use of ingredients without the need for labeling them on products, e.g., the treatment of meat cuts and ground beef with organic acids. To date, no data have been submitted to LCPS to show that post-chiller applications of these organic acids to carcasses, parts or trimmings are situations that are consistent with FDA\u2019s labeling definition of a

processing aid. Therefore, these substances would be considered ingredients that are direct food additives when used in this way, and their use in ground beef and trimmings derived from trimmings treated post-chiller would need to be identified on product labeling. Additional Information Additional guidance on the use and labeling of ingredients and sources of radiation for use in meat and poultry may be obtained from LCPS at [www.fsis.usda.gov/oppde/larc](http://www.fsis.usda.gov/oppde/larc) or at (202) 205-0279. [Return to Related

Documents"]]},"file\_name":"FSIS\_GD\_2013\_0023","title":"Compliance Guideline for Controlling Salmonella in Market Hogs","num":"FSIS-GD-2013-0023","id":"b3cd2f9b03bc23f9e9b80ddd806930f9398a4abc6bce0e56949aae6d93056838","corpus":"fsis\_guidelines","source\_page\_url":"<https://www.fsis.usda.gov/policy/fsis-guidelines>","url":"<https://www.fsis.usda.gov/sites/default/files/import/Controlling-Salmonella-in-Market-Hogs.pdf>"}, {"type":"pdf","n\_pages":42,"word\_count":10489,"text\_by\_page":["Extraordinary Circumstances - Procedures for Evaluating Labeling In extraordinary circumstances, that is, when product has been retained ("tagged") by program personnel at official establishments or when there is some other unforeseeable impediment to movement of meat or poultry product, and a temporary label approval would remove the impediment (refer to "Information Required For Requesting a Temporary Approval" and 9 CFR 317.4(f) and 381.132(f) ), an accelerated label evaluation can be requested. A submission that asserts that there are extraordinary circumstances that justify an accelerated label evaluation will need to explain why extraordinary circumstances exist, include the information required by regulations for temporary approvals, and be accompanied by information from the establishment's labeling records about prior label approvals. FSIS recommends that a contact at the establishment be identified on the request for an evaluation based on extraordinary circumstances. As part of the label evaluation, LCPS may contact the inspector at the establishment to consult on the request. Requests for an accelerated evaluation because of extraordinary circumstances should be delivered to the Distribution Unit of LCPS and marked to the attention of the Labeling Compliance Team Leader."]}, {"file\_name":"FSIS\_GD\_2013\_0024","title":"Recall Plan Booklet - How to Develop a Meat and Poultry Product Recall Plan","num":"FSIS-GD-2013-0024","id":"97fbf1540a4c2167c2922c7a13209ecaba285d0777785b9133f91e15471e0498","corpus":"fsis\_guidelines","source\_page\_url":"<https://www.fsis.usda.gov/policy/fsis-guidelines>","url":"[https://www.fsis.usda.gov/sites/default/files/import/RecallPlanBooklet\\_0513.pdf](https://www.fsis.usda.gov/sites/default/files/import/RecallPlanBooklet_0513.pdf)"}]

"type":"pdf","n\_pages":52,"word\_count":8571,"text\_by\_page":["October 2013 FSIS developed these guidelines to promote a systematic approach to achieve compliance with the 9 CFR 313 regulatory requirements for humane slaughter of livestock. The target audience is small and very small establishments because these establishments typically have limited resources. FSIS is committed to providing small and very small establishments the best assistance possible. FSIS developed this guide to promote a systematic approach to achieve compliance with the 9 CFR 313 regulatory requirements for humane slaughter of livestock. The target audience is small and very small establishments because these establishments typically have limited resources. FSIS is committed to providing small and very small establishments the best assistance possible. FSIS Compliance Guidelines for a Systematic Approach to the Humane Handling of Livestock FSIS (Food Safety and Inspection Service) of the USDA (United States Department of Agriculture) developed this guide to promote a systematic approach to achieve

compliance with the 9 CFR Part 313 regulatory requirements for humane slaughter of livestock. FSIS is committed to providing establishments the best assistance possible. FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock", "FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 2 of 21 Preface The Food Safety and Inspection Service (FSIS) has published this guide to assist establishments in complying with humane handling requirements. This guide represents the Agency\u2019s current thinking on a systematic approach to humane handling of livestock. FSIS encourages slaughter establishments to use the guide. To promote consistency and public transparency, FSIS applies the same clearance and public comment practices for guides as those required for rulemaking. FSIS encourages interested persons to submit comments on this document, including but not limited to, content, readability, applicability, and accessibility. FSIS will update guides as necessary to reflect current information and customer feedback. Interested persons can use the following methods to submit comments: 1. Federal eRulemaking Portal \u2013 <http://www.regulations.gov> This service allows interested persons to submit short comments directly to FSIS or attach a file with lengthier comments. Interested persons will find instructions for finding guides and submitting comments on the Federal eRulemaking Portal site. 2. Mail Services \u2013 US Post Office, FedEx, and UPS Interested persons can submit comments directly to FSIS in written, printed, or electronic formats. Send documents, flash drives, CD-ROMs, or DVDs to the following address: U.S. Department of Agriculture (USDA) FSIS Docket Room Manager Patriots Plaza 3 1400 Independence Avenue SW Room 8-163B, Mailstop 3782 Washington, DC 20250-3700 3. Hand- or courier-delivery to the following address: Patriots Plaza 3 355 E. Street SW Room 8-163B Washington, DC 20250-3700. Comments submitted via mail services must include the Agency name and the title of the guide. FSIS will make comments received available for public inspection and will post comments without change, including any personal information, to <http://www.regulations.gov>.", "FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 3 of 21 Preface .....

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guide through askFSIS or by telephone at 1-800-2333935. Introduction This is the first edition of the FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock. FSIS developed this guide to promote a systematic approach to achieve compliance with the 9 CFR Part 313 regulatory requirements for humane handling and slaughter of livestock. The guide also provides a sample humane handling plan and an assessment tool. FSIS is committed to providing establishments the best assistance possible. FSIS believes that a well-implemented systematic approach for humane handling is the best way to achieve the best practices for humane handling and slaughter of livestock. This guide describes a systematic approach that FSIS believes represents the current best practices. This guide does not include all items that could be included in an establishment's development and implementation of a systematic approach to humane handling and should not serve to limit the design of a systematic approach. The guide is simply a starting point for those establishments needing guidance and assistance in establishing a systematic approach.

**Background** In the Humane Methods of Slaughter Act (HMSA), Congress declared that humane handling and slaughter of livestock was public policy.<sup>1</sup> The HMSA states, "that the use of humane methods in the slaughter of livestock prevents needless suffering; results in safer and better working conditions for persons engaged in the slaughtering industry; brings about improvement of products and economies in slaughtering operations; and produces other benefits for producers, processors, and consumers which tend to expedite an orderly flow of livestock and livestock products in interstate and foreign commerce."<sup>2</sup> Congress amended the HMSA in 1978 to provide USDA the authority to inspect slaughterhouses for compliance with the HMSA and to penalize violators. The HMSA is referenced in the Federal Meat Inspection Act (FMIA) (21 USC 6032) and is implemented by FSIS humane handling and slaughter regulations found in 9 CFR Part 313. The FMIA provides that, for the purposes of preventing inhumane slaughter of livestock:

It is therefore declared to be the policy of the United States that the slaughtering of livestock and the handling of livestock in connection with slaughter shall be carried out only by humane methods.

21 USC 603(b) - For the purpose of preventing the inhumane slaughtering of livestock, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of the method by which amenable species are slaughtered and handled in connection with slaughter in the slaughtering establishments inspected under this chapter. The Secretary may refuse to provide inspection to a new slaughtering establishment or may cause inspection to be temporarily suspended at a slaughtering establishment if the Secretary finds that any cattle, sheep, swine, goats, horses, mules, or other equines have been slaughtered or handled in connection with slaughter at such establishment by any method not in accordance with the Act of August 27, 1958 (72 Stat. 862; 7 USC 1901et seq.) until the establishment furnishes assurances satisfactory to the Secretary that all slaughtering and handling in connection with slaughter of livestock shall be in accordance with such a method.

**KEY INFORMATION** What is a systematic approach to humane handling? With a systematic approach, establishments focus on treating livestock in such a manner as to minimize excitement, discomfort, and accidental injury the entire time they hold livestock in connection with slaughter." "FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 5 of 21 IS POULTRY SLAUGHTER INCLUDED IN THE SYSTEMATIC APPROACH? No, however, the PPIA (Poultry Products Inspection Act) and Agency regulations (9 CFR Part 381.65(b)) do require that live poultry be handled in a manner that is consistent with good

commercial practices, and that they not die from causes other than slaughter (Good Commercial Practices and the Federal Register Notice). (Note: The Federal Register Notice referenced here includes guidelines rather than regulatory requirements.) livestock, the Secretary of Agriculture will assign inspectors to examine and inspect the methods by which livestock are handled and slaughtered in connection with slaughter in establishments subject to inspection (21 USC 603(b)). Therefore, establishments are required to meet the humane handling and slaughter requirements in the regulations the entire time they hold livestock in connection with slaughter. On September 9, 2004, FSIS announced that livestock slaughter establishments should implement and maintain a systematic approach to humane handling and slaughter to best assure compliance with the HMAA, FMIA, and implementing regulations (69 Federal Register 54625). A systematic approach is a comprehensive way of evaluating how livestock enter and move through an establishment. Implementing a systematic approach is not a regulatory requirement. FSIS presents the systematic approach as the best way to ensure that establishments meet the requirements of the HMAA, FMIA, and implementing regulations. The 2004 notice outlined four recommended steps establishments should take to develop and maintain a systematic approach. When using the recommended systematic approach, establishments would take into account any new conditions in the establishment that warrant changes to facilities or existing handling or slaughter procedures. The four steps are presented in the section entitled Systematic Approach versus Robust Systematic Approach (page 6). In August 2011, FSIS issued FSIS Directive 6900.2 Humane Handling and Slaughter of Livestock \u2013 Revision 2. The directive included instructions for inspectors to determine whether livestock slaughter establishments have a robust systematic approach to humane handling. Establishments may choose to adopt a robust approach, although it is not required. For FSIS to consider a systematic approach to be robust, the Agency expects that the systematic approach will include a written animal handling program and program records. The records need to be available for FSIS review. If an establishment develops and implements a robust systematic approach to humane handling and slaughter, FSIS would consider this when determining enforcement actions following an egregious inhumane treatment event. Overview of Humane Handling and Slaughter of Livestock Humane handling and slaughter of livestock prevents needless suffering; results in safer and better working conditions within the slaughtering industry; improves products and slaughtering operations; and produces other benefits for producers, processors, and consumers. KEY DEFINITION Egregious inhumane treatment: An egregious situation is any act or condition that results in severe harm to animals (FSIS Directive 6900.2 Revision 2).", "FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 6 of 21 Humane handling requirements involve handling facilities and equipment, personnel practices, and slaughter equipment. Handling facilities and equipment are addressed in 9 CFR 313.1. Personnel practices are addressed in 9 CFR 313.2. Slaughter equipment is addressed in 9 CFR 313.5, 9 CFR 313.15, 9 CFR 313.16, and 9 CFR 313.30. FSIS Verification of Establishment Humane Handling Activities FSIS veterinarians and other trained Inspection Program Personnel (IPP) perform humane handling verification activities when establishments slaughter animals, or when animals are on inspected premises (FSIS Directive 6900.2 Revision 2). To verify compliance with 9 CFR Part 313, IPP make verification observations during the course of their inspection duties. FSIS records the time spent performing verification activities in the Humane Activities Tracking System (HATS). The

nine HATS categories (see text box) address all of the regulations covering the humane handling and slaughter of livestock. IPP verify specific facility, handling, or slaughter requirements for each of the categories. The table in Attachment 1 identifies each HATS category and the verification activities IPP perform. Systematic Approach versus Robust Systematic Approach A systematic approach to humane handling and slaughter takes the regulatory requirements in 9 CFR Part 313 and organizes them into a logical approach, marked by attention to detail, regular implementation, and tailoring to the operation of the establishment. Developing a systematic approach to humane handling and slaughter is the first step in ensuring that the establishment complies with the applicable humane handling and slaughter requirements. FSIS believes that the following four elements represent a systematic approach to humane handling and slaughter of livestock. Under a SYSTEMATIC APPROACH TO HUMANE HANDLING AND SLAUGHTER, establishments should 1. Assess the ability of their livestock handling and slaughter practices to minimize distress and injury to livestock. 2. Design facilities and implement handling practices that minimize distress and injury to livestock. 3. Periodically evaluate facilities and handling methods to ensure that they continue to minimize distress and injury to livestock. 4. When necessary, modify facilities and handling methods to ensure that they continue to minimize distress and injury to livestock. WHAT ARE THE HATS CATEGORIES? I. Inclement Weather II. Truck Unloading III. Water and Feed Availability IV. Ante-mortem Inspection V. Suspect and Disabled VI. Electric Prod\Alternative Object Use VII. Slips and Falls VIII. Stunning Effectiveness IX. Conscious Animals on the Rail", "FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 7 of 21 A robust systematic approach to humane handling and slaughter adds to the four elements by incorporating three additional features (Table 1). Those three features are: 1) WRITTEN PROCEDURES: \u2212 Describes procedures that the establishment will effectively implement to stay in compliance with the regulations. \u2212 Describes actions the establishment will take when it fails to implement the program as written or fails to prevent a noncompliance. 2) WRITTEN RECORDS: \u2212 Maintains records that demonstrate that the program is implemented as written. \u2212 Maintains records that demonstrate the program will effectively prevent identified potential noncompliances. 3) FSIS REVIEW: \u2212 Written procedures and records are both made available for FSIS review upon request. KEY INFORMATION How do I demonstrate that I have a systematic approach? The basic (non-robust) systematic approach does not include a written program or records. FSIS evaluates an establishment\u2019s systematic approach through observation of operations and discussion of humane handling with establishment personnel. The four elements of the systematic approach cover several topics. This set of questions can help determine whether the establishment has a systematic approach to humane handling and slaughter. To demonstrate working knowledge of humane handling issues, establishments should be able to discuss their approach to humane handling and slaughter by answering these questions. \u2212 What situations may result in livestock excitement, discomfort, or accidental injury? \u2212 What situations may result in stunning problems? \u2212 Is the livestock handling facility designed for the movement and holding of livestock? \u2212 Does the establishment implement the livestock handling practices as designed? \u2212 How often are livestock handling methods evaluated? \u2212 How do you evaluate the stunning methods? \u2212 How do you deal with problems with livestock handling and stunning practices? \u2212 How do you know your actions have solved or lessened the problem? \u2212 How and with what information do you

train employees?","FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 8 of 21 Table 1: Systematic Approach versus Robust Systematic Approach Assessment Design Facilities and Practices Periodic Evaluation Modification (as needed) Written Procedures Written Records FSIS Review Systematic Approach Yes Yes Yes Yes Yes No No No No Robust Systematic Approach Yes Yes Yes Yes Yes Yes FSIS believes that developing a written plan is a step toward a robust systematic approach to humane handling and slaughter because a written plan can effectively address the four aspects of a systematic approach. The Sample EST 38 Humane Handling and Slaughter Plan (attachment 3) provides basic features of a written program with records. The following table identifies the differences between the systematic approach and the robust systematic approach. FSIS Response to Egregious Inhumane Treatment When humane handling or slaughter noncompliance occurs, 9 CFR 500.2(a)(4) authorizes FSIS to take a regulatory control action, and 9 CFR 500.3(b) authorizes FSIS to suspend inspection without prior notification (Notice of Suspension). Although FSIS is authorized to suspend inspection without prior notification, FSIS may exercise enforcement discretion by providing an establishment prior notification (Notice of Intended Enforcement, 9 CFR 500.4) and an opportunity to implement necessary corrective actions to achieve humane handling compliance. FSIS Directive 6900.2 (Revision 2) instructs FSIS personnel on how to respond to egregious inhumane treatment. The action FSIS personnel will take when egregious inhumane treatment occurs is likely to vary depending on whether the following conditions exist in the establishment: a) The establishment does not have any recent humane handling related enforcement actions. b) The establishment has consistently been meeting the humane handling regulatory requirements. c) The establishment has been operating under a written animal handling program that is a robust systematic approach and the establishment has made the written program accessible to IPP. d) The establishment has demonstrated the robustness of the program to IPP by effectively and consistently implementing all aspects of its program. In establishments without a robust systematic approach to humane handling and slaughter, or when not all of the conditions (a. through d.) provided above exist, FSIS instructs IPP to take the following action:","FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 9 of 21 \u2022 In the case of humane handling or slaughter noncompliance with egregious inhumane treatment, the inspector in charge recommends issuance of a Notice of Suspension. In establishments maintaining a robust systematic approach to humane handling and slaughter, and when the conditions (a. through d.) provided above exist, FSIS instructs inspection program personnel to take the following action. \u2022 In the case of humane handling or slaughter noncompliance with egregious inhumane treatment \u2013 the inspector in charge recommends issuance of a Notice of Intended Enforcement rather than a Notice of Suspension. NOTE: 9 CFR Part 500 \u2013 Rules of Practice defines suspension as \u201can interruption in the assignment of program employees to all or part of an establishment,\u201d and 9 CFR Part 500.3 (b) gives FSIS the authority to impose a suspension without providing establishments prior notification for handling or slaughtering animals inhumanely; that is, the stunning and slaughter of livestock stops while under a suspension. FSIS may \u201cimpose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance\u201d (9 CFR Part 500.4). FSIS acts on this authority by issuing a Notice of Intended Enforcement. Establishment\u2019s in receipt of a Notice of Intended Enforcement are afforded time (up to 3 days) to demonstrate or achieve compliance.

If the establishment does not demonstrate or achieve compliance in 3 days, FSIS issues a Notice of Suspension.", "FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 10 of 21 Creating a Robust Systematic Humane Handling and Slaughter Plan Step 1: Conduct an assessment FSIS believes that an assessment is the best first step toward a robust systematic approach to humane handling and slaughter. FSIS considers an assessment robust if it takes into consideration the establishment\u2019s entire humane handling and slaughter infrastructure. An assessment of humane handling and slaughter determines whether any component of the establishment\u2019s infrastructure has the potential to result in inhumane handling or slaughter of livestock. The Code of Federal Regulations (9 CFR Part 313) describes three general categories of infrastructure, 1) livestock facilities, 2) personnel practices, and 3) slaughter equipment. \u2212 Livestock facilities include the following components. \u2212 Vehicles and trailers used to transport livestock. \u2212 Facilities and equipment through which livestock pass as they move from transport vehicles or trailers to holding facilities, between holding facilities, and from holding facilities to restraining devices. \u2212 Facilities used to hold livestock temporarily. \u2212 Facilities and equipment used to restrict livestock movement during slaughter. \u2212 Personnel practices address the knowledge, skills, and abilities of any person handling livestock on the official premise. \u2212 Slaughter equipment includes the equipment used to render livestock insensible to pain and induce death. The Humane Methods of Slaughter Act describes two methods of slaughter found to be humane. \u2212 Render insensible to pain by a single blow<sup>3</sup> or gunshot<sup>4</sup> or by electrical stunning,<sup>5</sup> chemical exposure<sup>6</sup> or other means<sup>7</sup>. \u2212 Slaughter in accordance with the ritual requirements of a religious faith. To facilitate an assessment, FSIS is providing a sample assessment tool for humane handling and slaughter in Attachment 2 of this document. The tool contains all humane handling requirements as statements. The assessor decides if each statement is true, false, or does not apply to the establishment. The assessor should check \u201cTrue\u201d if the item does not have the potential to result in inhumane handling or slaughter of livestock. The assessor should check \u201cFalse\u201d if the item has the potential to result in inhumane handling or slaughter of livestock. 3 9 CFR 313.15 describes the approved use of captive bolts 4 9 CFR 313.16 describes the approved use of gunshot 5 9 CFR 313.30 describes the approved use of electrical stunning 6 9 CFR 313.5 describes the approved use of carbon dioxide gas 7 9 CFR 313 does not allow other methods of humane slaughter; however, 9 CFR 303.1(h) authorizes FSIS to permit experimentation with new technologies. Compliance assistance with new technologies is available at New Technologies.", "FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 11 of 21 Step 2: Create a written plan FSIS believes that developing a written plan is the best second step toward a robust systematic approach to humane handling and slaughter because a written plan can effectively address the four aspects of a systematic approach. Without access to the written plan, FSIS will not be able to verify effective implementation of a program that the establishment believes reflects a robust systematic approach. Establishments address each item checked \u201cFalse\u201d in step one in a written plan. FSIS considers a written plan robust if it addresses each component of handling and slaughter at the establishment that could result in inhumane handling or inhumane slaughter of livestock. Establishments may consider the following elements important when developing a written plan (Attachment 3) for humane handling and slaughter: \u2212 A list of establishment humane handling and slaughter equipment and facilities

identified as having the potential to result in inhumane handling or slaughter of livestock. (Attachment 2) \u2022 A list of procedures and monitoring frequencies sufficient to maintain humane handling and slaughter process control and prevent inhumane handling or slaughter. (Attachment 4) \u2022 A list of standards for maintaining facilities. (Attachment 2) \u2022 A list of corrective actions that address noncompliances and process control. \u2022 Provides for routine verification of implementation of the plan and reassessment and update of the plan.

Step 3: Create a recordkeeping system FSIS believes that developing a recordkeeping system (Attachment 4) is the best third step toward a robust systematic approach to humane handling and slaughter. FSIS considers a recordkeeping system robust if it promotes accuracy and provides for accountability. Establishments may consider the following elements important features of a record keeping system:

- \u2022 Documents all monitoring, corrective action, verification, and reassessment activities.
- \u2022 Prevents unauthorized access, destruction, alteration, or removal of records.
- \u2022 Provides ready access and information sharing.

"FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 12 of 21 Attachment 1: HATS Categories and FSIS verification Activities Category FSIS Verification Regulations I. Inclement Weather Verify how the establishment adapts its facilities and holding practices to inclement weather to ensure the humane handling of animals. 9 CFR 313.1 and 313.2 II. Truck Unloading Verify that the establishment\u2019s livestock handling facilities are in proper repair during livestock unloading activities. 9 CFR 313.1 and 313.2 III. Water and Feed Availability Verify the accessibility of water and feed to livestock. 9 CFR 313.2 IV. Ante-mortem Inspection Verify the establishment\u2019s procedures for humanely handling livestock during ante-mortem inspection of livestock. 9 CFR 313.1 and 313.2 V. Suspect and Disabled Verify that the establishment handles US Suspect and disabled livestock humanely. 9 CFR 313.1 and 313.2 VI. Electric Prod, Alternative Object Use Verify that the establishment humanely and effectively moves livestock without excessive prodding or the use of sharp objects. 9 CFR 313.2 VII. Slips and Falls Verify that the establishment prevents livestock from slipping and falling due to inadequate footing or improper handling practices. 9 CFR 313.1 and 313.2 VIII. Stunning Effectiveness Verify the establishment\u2019s procedures to appropriately and effectively administer stunning methods that are rapid and effective and that produce unconsciousness in the animals before the animal is shackled, hoisted, thrown, cast, or stuck. 9 CFR 313.5, 313.15, 313.16, and 313.30 IX. Conscious Animals on the Rail Verify, after stunning, that livestock remain unconscious before and after they are shackled, hoisted, thrown, cast, or stuck. 9 CFR 313.5, 313.15, 313.16, and 313.30", "FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 13 of 21 Attachment 2: Sample Assessment Tool for Humane Handling and Slaughter The sample assessment tool is a starting point. Not all of the parameters listed will apply to all establishments. Some establishments may have additional parameters. Sample Assessment Tool for Humane Handling and Slaughter Check \u201cTrue\u201d if the item does not have the potential to result in inhumane handling and/or slaughter of livestock Check \u201cFalse\u201d if the item has the potential to result in inhumane handling and/or slaughter of livestock Check \u201cN/A\u201d if the item does not apply to the establishment

FACILITIES True False N/A TRANSPORTATION OF LIVESTOCK: TRANSPORT VEHICLES Transport vehicles are free from protruding objects. Transport vehicles are free from sharp metal of any kind. Transport vehicles are free from loose boards. Transport vehicles are free from splintered planking. Transport vehicles are free from broken planking.

Transport vehicles are free from openings that can trap livestock's head. Transport vehicles are free from openings that can trap livestock's feet. Transport vehicles are free from openings that can trap livestock's legs. Transport vehicles provide good footing.

FACILITY RAMPS Ramps<sup>8</sup> are in good repair. Ramps are free from protruding objects. Ramps are free from sharp metal of any kind. Ramps are free from loose boards. Ramps are free from splintered planking. Ramps are free from broken planking. Ramps are free from openings that can trap livestock's head. Ramps are free from openings that can trap livestock's feet. Ramps are free from openings that can trap livestock's legs. Ramps provide good footing. Ramps arranged to minimize sharp corners. Ramps arranged to minimize direction reversal of driven animals.

FACILITY DRIVEWAYS Driveways<sup>9</sup> are in good repair. Driveways are free from protruding objects. Driveways are free from sharp metal of any kind. Driveways are free from loose boards. Driveways are free from splintered planking. Driveways are free from broken planking. Driveways are free from openings that can trap livestock's head.

Driveways are free from openings that can trap livestock's feet. Driveways are free from openings that can trap livestock's legs. Driveways provide good footing. Driveways arranged to minimize sharp corners. Driveways arranged to minimize direction reversal of driven animals.

<sup>8</sup> The term "cramp" in 9 CFR 313, describes any facility used to transfer livestock from transport vehicles to ground level. Ramps can be fixed structures or mobile equipment.

<sup>9</sup> The terms "driveway," "alley," and "pathway" in 9 CFR 313 are synonymous. They describe a facility used to move livestock from transport vehicles to holding pens, between holding pens, and from holding pens to restraining devices. The livestock industry routinely uses other terms to describe these facilities.

"FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 14 of 21

FACILITY HOLDING PENS Holding pens<sup>10</sup> are in good repair. Holding pens are free from protruding objects. Holding pens are free from sharp metal of any kind. Holding pens are free from loose boards. Holding pens are free from splintered planking.

Holding pens are free from broken planking. Holding pens are free from openings that can trap livestock's head. Holding pens are free from openings that can trap livestock's feet. Holding pens are free from openings that can trap livestock's legs. Holding pens provide good footing. Holding pens arranged to minimize sharp corners. Holding pens arranged to minimize direction reversal of driven animals.

Covered holding pens provided for US Suspects.

FACILITY GATES Gates<sup>11</sup> are in good repair. Gates are free from protruding objects. Gates are free from sharp metal of any kind. Gates are free from loose boards. Gates are free from splintered planking. Gates are free from broken planking. Gates are free from unnecessary openings that can trap livestock's head. Gates are free from unnecessary openings that can trap livestock's feet. Gates are free from unnecessary openings that can trap livestock's legs.

FACILITY RESTRAINING DEVICES Restraining devices<sup>12</sup> are in good repair. Restraining devices are free from sharp objects. Restraining devices are free from protruding sharp metal of any kind. Restraining devices are free from protruding objects. Restraining devices are free from exposed bolt ends. Restraining devices are free from loose boards.

Restraining devices are free from splintered planking. Restraining devices are free from broken planking. Restraining devices are free from exposed wheels. Restraining devices are free from exposed gears. Restraining devices are free from openings that can trap livestock's head. Restraining devices are free from openings that can trap livestock's feet.

devices are free from openings that can trap livestock's legs. Restraining devices comfortably accommodate the livestock restrained. OTHER DEVICES Use of Video or Other Electronic Monitoring or Recording Equipment 10 The term "holding pen" describes a facility used to hold livestock temporarily. Livestock enter and exit holding pens from driveways. 11 The term "gates" means devices designed to mechanically move or drive livestock, and devices designed to keep livestock in motion or compartmentalized. "Gates" describe devices used to limit the movement of one or more livestock. Gates can be manual or mechanical. They can move horizontally, vertically, or pivot on a central axis. The livestock industry routinely uses other terms to describe these devices. 12 The terms "restraining device," "restraining mechanism," "cchute," "cstunning area," and "ccompartments" in 9 CFR 313 are synonymous. They describe a facility used to restrict livestock movement during stunning. The livestock industry routinely uses other terms to describe these facilities." "FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 15 of 21 Personnel Practices True False N/A Personnel minimize excitement of livestock during movement. Personnel minimize excitement of livestock when using electric prods. Personnel minimize excitement of livestock when using canvas slappers. Personnel minimize excitement of livestock when using other equipment. Personnel minimize excitement when using stunning equipment. Personnel are trained and the training is documented and reviewed periodically. Personnel minimize discomfort of livestock during movement. Personnel minimize discomfort of livestock when using electric prods. Personnel minimize discomfort of livestock when using canvas slappers. Personnel minimize discomfort of livestock when using other equipment. Personnel minimize discomfort when using stunning equipment. Personnel prevent injury of livestock during movement. Personnel prevent injury of livestock when using electric prods. Personnel prevent injury of livestock when using canvas slappers. Personnel prevent injury of livestock when using other equipment. Personnel prevent injury when using stunning equipment. Personnel move livestock at a normal walking speed. Personnel provide livestock in holding pens with access to water. Personnel provide livestock held longer than 24 hours with access to feed. Personnel provide livestock held overnight with sufficient room to lie down. Personnel separate non-ambulatory disabled livestock from normal animals. Personnel set electrical prods to lowest effective voltage, not to exceed 50 V AC. Personnel do not drag conscious livestock. Personnel do not use pipes to drive livestock. Personnel do not use sharp objects to drive livestock. Personnel do not use pointed objects to drive livestock. Personnel are knowledgeable and effective in humane handling methods. Personnel are knowledgeable and effective in humane slaughter methods. Personnel transporting livestock comply with 28 Hour Rule. Stunning (General) True False N/A Livestock restraint allows the stunner operator to stun accurately. Stunning equipment designed for livestock slaughtered. Single application of stunning method renders livestock insensible to pain<sup>13</sup>. Livestock are insensible to pain immediately after stunning method applied. Livestock are unconscious and insensible to pain before shackling. Livestock are unconscious and insensible to pain before hoisting. Livestock are unconscious and insensible to pain before throwing. Livestock are unconscious and insensible to pain before casting. Livestock are unconscious and insensible to pain before cutting. Livestock remain unconscious and insensible to pain throughout shackling. Livestock remain unconscious and insensible to pain throughout hoisting. Livestock remain unconscious and

insensible to pain throughout throwing. Livestock remain unconscious and insensible to pain throughout casting. 13 The term \u201cinsensible to pain\u201d is synonymous with surgical anesthesia and unconsciousness.", "FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 16 of 21 Livestock remain unconscious and insensible to pain throughout cutting. Livestock remain unconscious and insensible to pain throughout bleeding. Stunning equipment operator is skilled. Stunning equipment operator is attentive. Stunning equipment operator is aware of their responsibility. Stunning equipment operator is trained. Stunning equipment operator is experienced. Stunning (Carbon Dioxide) True False N\A Carbon dioxide does not induce death in calves and sheep. Only sheep, calves and swine are slaughtered with carbon dioxide. All carbon dioxide delivery devices are in good repair. Concentration of carbon dioxide gas delivered is uniform. Rate of carbon dioxide gas delivery is sufficient. Rate of carbon dioxide gas delivery is uniform. Mixing of carbon dioxide gas and air within the chamber is adequate. Carbon dioxide gas delivered is free from noxious or irritating gases. Atmospheric air delivered is free from noxious or irritating gases. All carbon dioxide monitoring devices are in good repair. Sampling of carbon dioxide gas within the chamber is continuous. Samples of carbon dioxide gas collected are representative from within the chamber. Monitoring of carbon dioxide gas concentration within the chamber is continuous. Recordings of carbon dioxide gas concentration are graphical. Monitoring of carbon dioxide gas exposure time within the chamber is continuous. Recordings of carbon dioxide gas exposure time are graphical. All carbon dioxide delivery and recording devices are available for inspection by FSIS. An exhaust system prevents non-uniform carbon dioxide concentrations in chamber. An exhaust system prevents carbon dioxide contamination of the ambient air. Stunning (Captive Bolt) True False N\A Captive bolt stunners that inject compressed air into the cranium not used to stun cattle. Captive bolt stunning equipment is in good repair. Compressed air delivered at constant pressure. Air pressure monitoring devices are accurate. Air pressure monitoring devices operate constantly. Air pressure monitoring devices are easy to read. Air pressure gauges are conveniently located. Captive bolt stunning equipment equipped with safety features. Operator accurately directs the captive bolt to produce immediate unconsciousness. Operator selects appropriate captive bolt stunner for size of livestock. Stunning (Gunshot) True False N\A Firearms maintained in good repair. Operator uses hollow pointed or frangible iron plastic composition bullets; powdered iron missiles Operator accurately directs the bullet to produce immediate unconsciousness. Operator selects appropriate caliber bullet for size of livestock. Stunning (Electrical) True False N\A Suitable timing, voltage and current control devices are used. Electrical stunning equipment is in good repair. Duration, voltage, and current monitoring devices are accurate.", "FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 17 of 21 Duration, voltage, and current monitoring devices are easy to read. Duration, voltage, and current monitoring devices are conveniently located. Duration, voltage, and current monitoring devices are available for FSIS inspection. Operator selects appropriate electrical stunner settings for size of livestock. Operator accurately places the electrical stunner to produce immediate unconsciousness. Ritual Slaughter True False N\A Ritual slaughter performed by the religious authority (or duly-appointed designee) Ritual slaughter performed in accordance with standard set by the religious authority. No additional dressing cuts are made until livestock are insensible to pain.", "FSIS Compliance Guide for a Systematic Approach to the Humane Handling of

Livestock Page 18 of 21 Does this example address FSIS\u2019 basic expectations for the written part of a Robust Systematic Humane Handling plan? Yes, this example is a good place to start the development of a plan. You may find over time the basic approach expands to include additional safeguards you put in place. You can access FSIS assistance using this sample through askFSIS or by telephone at 1-800-233-3935.

Attachment 3: Sample EST 38 Humane Handling and Slaughter Plan Description of our business: We are a small, family-owned business producing specialty pork products. We typically slaughter one day per week. We raise all of the pigs we slaughter on our near-by family farm and transport them to the official establishment on the day of slaughter in a family-owned livestock trailer. We hold no live swine at the official establishment longer than 10-12 hours. The rear gate of the livestock trailer doubles as the off-loading ramp. We slaughter only healthy swine and sell all unhealthy swine to a local livestock dealer.

Animal Handling Plan: Live pigs off-load from the livestock trailer directly into one of two open-air holding pens. The pens connect by a gate to a common covered alleyway that leads to the restrainer. All holding pen and alleyway floors are waffled and sloped to facilitate drainage. Holding pens have water troughs. Interior and exterior fence construction is comprised of commercial hog fence panels and gates fastened to metal posts set in concrete. We herd swine with polyethylene sorting panels purchased locally. The restrainer is a manual device. We use electrical stunning to produce cardiac arrest. We have a back-up hand-held captive bolt in case the electrical stunning equipment become inoperable. We purchased the restraining and stunning devices through a local supplier. We operate the electrical stunner and captive bolt according to the operator\u2019s manuals that came with the equipment. Each stunned pig is shackled, hoisted, cut, and bled before we slaughter the next pig.

Assessment\Reassessment: We based our initial assessment on the tool (attachment 2) in the FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock. We will reassess our plan as needed based on our monitoring results. We will document any reassessment, and summarize all changes to our plan and records, on the back of our monitoring record.

Procedures, monitoring frequencies, and target values: We will list our procedures, monitoring frequencies, and objectives on the monitoring record.

Documentation: We will record monitoring results on our monitoring record. We will create a record for each day we slaughter pigs.

\u201cWhenever the response to a monitoring question is \u201cnono\u201d or at other times when a humane handling problem is identified, we will take immediate action to resolve it and document that action on the back of the monitoring record.

Responses will follow these principles:

- 1.) If an animal is severely injured or in distress, we will immediately humanely euthanize;
- 2.) We will immediately halt or modify our operations when necessary to ensure all animals are handled humanely and not subject",

"FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 19 of 21 to injury or distress;

- 3.) We will make any necessary repairs to facilities at the earliest possible opportunity.

Within 30 days, one of the owners will review the monitoring record, verify any corrective actions, review any reassessment, and record the date verified on the monitoring record. We will maintain all completed monitoring records in the owner\u2019s office for one year and then we will destroy them. We will make monitoring records available to FSIS in a timely manner.",

"FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 20 of 21 Attachment 4: Sample EST 38 Humane Handling Monitoring Record EST 38 Humane Handling Monitoring Record for (enter date): Inspect livestock trailer first week of

each month Circle Yes or No Free from protruding objects and sharp edges. Yes\No Free from openings that can trap pig\u2019s head, feet, or leg. Yes\No Provides good footing. Yes\No Inspect pens, alleys, and gates first week of each month Free from protruding objects and sharp edges. Yes\No Free from openings that can trap pig\u2019s head, feet, or leg. Yes\No Provide good footing. Yes\No Inspect restrainer first week of each month Free from protruding objects and sharp edges. Yes\No Free from openings that can trap pig\u2019s head, feet, or leg. Yes\No Accommodates the size of pig. Yes\No Monitor handling of pigs each day we slaughter All pigs moved at walking pace with minimal excitement and discomfort. Yes\No All pigs restrained and stunned with minimal excitement and discomfort. Yes\No No pigs injured during movement, restraining, and stunning. Yes\No Trough watering devices turned on. Yes\No Monitor operation of stunner each day we slaughter Stunning equipment works properly on each pig. Yes\No Stunning equipment is properly placed on each pig. Yes\No All pigs remain insensible to pain after single application of stunner. Yes\No All pigs remain insensible to pain throughout shackling, hoisting, cutting, and bleeding. Yes\No", "FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock Page 21 of 21 References Humane Methods of Slaughter Act (7 USC, Chapter 48) Federal Meat Inspection Act (21 USC, Chapter 12) Humane Slaughter of Livestock Regulations (9 CFR, Part 313) Rules of Practice Regulations (9 CFR, Part 500) Federal Register Notice: Humane Handling and Slaughter Requirements and the Merits of a Systematic Approach to Meet Such Requirements (69 FR 54625-54627) Humane Handling and Slaughter of Livestock (FSIS Directive 6900.2) Humane Handling of Livestock and Poultry - An Educational Guidebook Based on FSIS Policies Dr. Temple Grandin\u2019s Website (<http://www.grandin.com/>) 28 Hour Rule (Title 49, Section 80502 of the US Code")]}, {"file\_name": "FSIS\_GD\_2012\_0001", "title": "Undeclared Allergen Prevention Webinar", "num": "FSIS-GD-2012-0001", "id": "39225ea7c764c16d2c1577c1cc59c643811742121dd81db6ee52299c179eebf6", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Undeclared\_Allergen\_Prevention.pdf", "type": "pdf", "n\_pages": 17, "word\_count": 932, "text\_by\_page": ["The first edition of the Compliance Guideline contains recommendations for controlling Salmonella in Market Hogs from pre-harvest through slaughter. Compliance Guideline for Controlling Salmonella in Market Hogs First Edition December 2013 1", "This is the first edition of the Compliance Guideline for Controlling Salmonella in Market Hogs. Recommendations are included for controlling Salmonella from pre-harvest through the slaughter process. This draft guideline represents FSIS\u2019s current thinking on the control of Salmonella in market hogs. Therefore, even though this is a draft document, FSIS encourages market hog slaughter establishments to incorporate information in this guidline in their decision making process. FSIS encourages further study and solutions by industry for controlling and reducing the spread of Salmonella in hog slaughter facilities. FSIS is seeking comments on this guidance document as part of its efforts to continuously assess and improve the effectiveness of policy documents. FSIS requests that all interested persons submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days. The draft will be updated in response to comments. Comments may be submitted by either of the following methods: 1. Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment"]}]}

field on this Web page or attach a file for lengthier comments. Go to:  
<http://www.regulations.gov> and follow the online instructions at that site for submitting comments. 2. Mail, including CD-ROMs, etc.: Send to Docket Room Manager, U.S. Department of Agriculture (USDA), FSIS, 1400 Independence Avenue SW, Patriots Plaza 3, Mailstop 3782, 8-163B, Washington, DC 20250-3700. 3. Hand-or courier-delivered items: Send to Docket Room Manager, U.S. Department of Agriculture (USDA), FSIS, 1400 Independence Avenue SW, Patriots Plaza 3, Mailstop 3782, 8-163B, Washington, DC 20250-3700. Instructions: All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title: FSIS Compliance Guideline for Controlling Salmonella in Market Hogs; docket number: FSIS-2012-0026. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information to:  
<http://www.regulations.gov>. 2,"Table of Contents I.

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3","I. Purpose may be used at slaughter establishments to prevent, eliminate, or reduce levels of Salmonella on hogs. This guidance also references scientific studies that indicate lairage is a significant factor in the spread of Salmonella. FSIS encourages further study and solutions by industry in controlling and reducing the spread of Salmonella in hog slaughter facilities. This guidance targets hog establishments and discusses recommended best practices that would help them better comply with the relevant regulatory requirements (9 CFR 310.7, 310.10, 310.11, 310.12, 310.18, 310.25, Part 416, and Part 417). This guidance document includes suggestions for establishments to improve their slaughter management practices to address Salmonella. When an establishment makes changes at the appropriate processing locations, process control should result in raw pork products that have less contamination with pathogens including Salmonella. This guidance document also describes steps involved in the hog slaughter process and production of raw products. Each slaughter step section targets best practice recommendations for Salmonella contamination control. The document includes information on farm The purpose of this guidance document is to provide information on best practices that This guidance provides information on best practices that may be used at slaughter to prevent, eliminate, or reduce levels of Salmonella in market hogs. rearing and transport that establishments may share with their suppliers or producers that provide market hogs to them. The guideline also includes supplemental information for controlling parasitic hazards; *Trichinella spiralis*; and *Toxoplasma gondii* (Attachment 1). The reference list at the end of the document provides resource material. Key Points: \uf0b7 This guidance references scientific studies that indicate lairage is a significant factor in the spread of Salmonella. 4","II. Introduction Establishments should slaughter and process market hogs in a manner designed to prevent or reduce contamination from occurring at every step of the processes (shown in fig. 1) and should use decontamination and antimicrobial intervention treatments as necessary to address any contamination that: (a) may result from the implementation of the slaughter process or (b) otherwise occurs on the carcasses. Key Points: \uf0b7 Maintain adequate sanitation in pens \uf0b7 Maintain adequate sanitary separation between each carcass, and between parts and viscera during dressing \uf0b7 Routinely clean and sanitize equipment and hand tools that are used to prepare for presentation prior to opening, and remove contamination after cutting into the carcass \uf0b7 Design and arrange equipment to prevent the contact of successive carcasses and carcass parts with contaminated equipment \uf0b7 Frequently wash hands and aprons that come in contact with carcasses \uf0b7 Implement decontamination and antimicrobial intervention treatments 5","vacuuming Figure 1. Hog Slaughter Processing Steps 6 Transport Lairage (slaughterhouse holding pens) Stunning Slaughter/Bleeding Scalding Dehairing Gambrelling Singeing Polishing Knife Trimming Pre-evisceration rinse or spray Head washing\Head dropping Pre-chill Final Rinse\Hot Rinse\Steam pasteurization Spray Chilling Evisceration Bung Isolation Carcass fabrication Packaging finished product storage and transport Farm Rearing Steam\Hot water","III. Public

Health Relevance Nontyphoidal Salmonella is the most common cause of bacterial food borne illness, accounting for 11% of food borne illnesses (about 1 million illnesses), 35% of hospitalizations and 28% of deaths. Campylobacter accounts for approximately 9% of food borne illnesses (about 845,000 illnesses) and 15% of hospitalizations (Scallan et al., 2011a). Swine can harbor both pathogens, though at varying levels (Zhao et al., 2001, 2010). Outbreaks resulting in human Salmonella illnesses involving pork have been consistently identified on an annual basis, Outbreaks resulting in human Salmonella illnesses involving pork have been consistently identified on an annual basis, suggesting pork as a vehicle for salmonellosis. suggesting pork as a vehicle for salmonellosis. Between 2000 and 2007, approximately four outbreaks and one hundred and two illnesses per year, on average, have been associated with pork. These estimates were calculated for outbreaks where pork was sole implicated food vehicle or identified as the sole contaminated ingredient. A yearly comparison shows from 2000 to 2007 there were five, seven, three, three, four, three, three and seven outbreaks, respectively. Among the eight years of data, 2007 had the most salmonellosis cases associated with pork consumption at 236 illnesses. For additional information please visit the Centers for Disease Control and Preventions (CDC) foodborne illness outbreak website at: <http://www.cdc.gov/foodborneoutbreaks/>. Four Campylobacter outbreaks were associated with pork (CDC, 1998 to 2008). During the Market Hog Baseline shake down period, Campylobacter was not detected. Subsequently, Campylobacter was not sampled for during the Nationwide Market Hogs Microbiological Baseline Survey baseline testing 2010 to 2011. Under the 1996 Pathogen Reduction\Hazard Analysis and Critical Control Point (PR\HACCP) final rule, FSIS established Salmonella performance standards for several raw product classes, including market hogs, as a means of verifying that establishments control food safety hazards in fresh meat processing. FSIS verifies the performance standards by conducting the Salmonella verification testing program, in which FSIS samples and analyzes sets of chilled carcasses for Salmonella. Results from Salmonella verification sets for CY 1998 to 2010 may be found at the following link:

[http://www.fsis.usda.gov/Science/Progress\\_Report\\_Salmonella\\_Testing\\_tables/index.asp](http://www.fsis.usda.gov/Science/Progress_Report_Salmonella_Testing_tables/index.asp). In 2006, FSIS announced several new policies in the Federal Register Notice (FRN), Salmonella Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection (71 FR 9772) intended to strengthen the Salmonella Verification Program including: 7," \uf0b7 Develop a more risk-based algorithm as a means to more frequently schedule sampling in the higher risk establishments. \uf0b7 Report each individual Salmonella result to each establishment as soon as it becomes available. \uf0b7 Post quarterly nationwide Salmonella data showing aggregate results of sample set results by product class. See Quarterly Salmonella Results. \uf0b7 Conduct Food Safety Assessments (FSAs) in establishments failing its Salmonella standards, or showing poor process control. \uf0b7 Provide serotype data on verification set results as soon as results are available. \uf0b7 Work more closely with other federal and state public health agencies to develop sub-typing policies. \uf0b7 Conduct additional Nationwide Microbiological Baselines to develop tightened performance standards for Salmonella (and Campylobacter if applicable). In July, 2011 FSIS implemented updated Salmonella performance standards and new Campylobacter performance standards for young chickens and turkeys. These standards were developed from Nationwide Microbiological Baselines. With these new lower standards in poultry; market hogs now have the highest permissible standard (8.7

percent) for Salmonella of all raw carcass product classes. For an establishment to meet this standard there can be no more than six Salmonella positives in the 55 analyzed samples (referred to as a \u201cset\u201d). FSIS conducted the Nationwide Microbiological Baseline Data Collection Program; Market Hog Survey, from August 2010 to August 2011. FSIS has completed two previous nationwide surveys in market hogs. The first FSIS nationwide market hog microbiological baseline data collection was in April 1995 to March 1996 and the second FSIS nationwide pork microbiological baseline data collection was in June 1997 to May 1998. FSIS designed and performed this most recent survey to estimate the percent positive and levels of microbiological pathogens and indicator bacteria on market hog carcasses. During the survey, FSIS collected sponge samples at pre-evisceration and post-chill from two separate shifts from the belly, ham, and jowl portion of market hogs slaughtered in Federal establishments. FSIS collected a total of 3,920 sponge samples (1,960 at pre-evisceration and 1,960 at post-chill) at 152 establishments. Only market hogs were eligible for testing in the survey. Boar or stag swine, feral swine, roaster swine, and sows were excluded from this survey. Through the survey, FSIS gathered data concerning the percent positives and quantitative levels of selected foodborne pathogens, and microorganisms as indicators of process control (e.g., Salmonella, generic Escherichia coli, Enterobacteriaceae, coliforms, and aerobic plate counts). Additional information regarding The Nationwide Microbiological Baseline Data 8", "Collection Program: Market Hog Survey August 2010 to August 2011 may be found at the following link: [http://www.fsis.usda.gov/wps/wcm/connect/d5c7c1d6-09b5-4dcc-93aef3e67ff045bb/Baseline\\_Data\\_Market\\_Hogs\\_2010-2011.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/d5c7c1d6-09b5-4dcc-93aef3e67ff045bb/Baseline_Data_Market_Hogs_2010-2011.pdf?MOD=AJPERES). These data collected and discussed in this document, and best practices described throughout this document will enable the Agency to work more effectively with industry to reduce the risk of foodborne pathogens in FSIS regulated products.

IV. Cross Contamination Main routes for cross contamination:

- \uf0b7 Airborne bacteria
- \uf0b7 Contamination of walls or floors by splashing of contaminated fluid
- \uf0b7 Contact with dirty surfaces (through equipment, hands, clothes)

All controls in slaughter and dressing procedures should be aimed at eliminating contamination. Slaughter establishments can reduce prevalence of pathogens by conducting operations in a manner that reduces contamination. Establishments can eliminate or reduce contamination through adequate separation of carcasses, parts, and viscera during dressing, routine cleaning and disinfection of equipment and hand tools as described in 9 CFR 416.3. In addition, establishments should use appropriate equipment and arrange equipment to prevent cross contamination of carcasses and parts. They should use equipment designed so that it can be adequately cleaned and sanitized daily. Finally, they should ensure functional lavatories are appropriately located, with hand washing and disinfection units strategically placed on the slaughter floor as described Key Point: in 9 CFR 416.2 (h). The first and paramount rule Cross-contamination occurs when pathogens are of sanitary dressing is to carried throughout the plant and adhere to carcasses avoid any contamination of and meat contact surfaces. Bolton (2002) showed that edible portions of the carcass there can be airborne bacterial contamination at levels with materials such as feces, up to  $3.5 \log_{10} \text{CFU}/\text{m}^3$  within the slaughter urine, hair, ingesta, milk, bile, establishment. McDermid and Lever (1996) showed pathological tissues or that Salmonella can survive in aerosols at  $75.2 \mu\text{m}$  (24\u00b0C) exudates, or other filth. and 75% humidity for periods exceeding 24 hours. These positive correlations with the environment suggests that contaminated air may be a source of carcass

contamination. 9", "Scalding and singeing can greatly reduce bacteria on the skin of the hog; however, the skin is often recontaminated when the carcass passes through dehairing and polishing equipment (Yu, 1999). Polishing carcasses contaminated with feces may make this contamination invisible, allowing it to go undetected during subsequent visual inspections.

Recommended Best Practices: Cross Contamination Prevention \uf0b7 Minimize airborne contamination through effective ventilation and control of air flow \uf0b7 Sanitize equipment and enforce employee hand washing to prevent contamination during processing \uf0b7 Separate from the processing areas the facilities for hand washing, access to toilet facilities, and areas where clothes and footwear are changed \uf0b7 Use walls and other separating structures, between \u201cdirty\u201d and \u201cclean\u201d processes and maximize spatial separation of activities to reduce crosscontamination

V. Farm Rearing Control of Salmonella begins on the farm. A review of Danish pork production has shown that Salmonella prevalence in the herd is a significant factor for determining the Salmonella prevalence and levels on carcasses (Alban and Stark, 2005). Limiting the commingling of piglets in the nursery from various sources, as well as rodent control, at the rearing farm has shown a decrease the incidence of Salmonella (Goldbach, 2005). Salmonella infection in hogs may not be obvious because hogs can be asymptomatic carriers (Schwartz, 1999). There is an association between Salmonella positive hogs and contaminated carcasses at the end of the slaughter line (Vieira-Pinto, 2006). One study found that carcass contamination was mainly influenced by the probability that at least one hog contributing to the pool was seropositive (Baptista, et al 2010). This finding suggests the Salmonella carcass contamination came from the incoming hogs, and that Salmonella control on the farm is desirable. Other studies have shown a correlation between increased levels of Salmonella in hogs and the use of pelleted food (Davies, et al 1997).

10", "Recommended Best Practices: Farm Rearing \uf0b7 Control rodents \uf0b7 Control co-mingling of hogs and reduce human contact \uf0b7 Use nonpelleted feed \uf0b7 Practice good sanitation, biosecurity, and dead control \uf0b7 Vaccinate herd for Salmonella where applicable

VI. Transport Stress during transport and slaughter is known to influence the physiological and biochemical processes in hogs (Benjamin, 2005). Stress is thought to affect the bacterial ecology of the gastrointestinal tract and the immunity of the animal, resulting in increased Salmonella enterica shedding (Hurd, 2003). Rapid infection after exposure to Salmonella during transport (e.g., when trailers are not cleaned between loads from different sources) is a major reason for increased Salmonella enterica prevalence in hogs (Hurd, 2002). Hurd et al. (2005) reported increased serovar diversity of isolates obtained after slaughter compared to that of isolates from pen mates necropsied on the farm. This increase in diversity suggests that hogs may be exposed to new S. enterica sources after leaving the farm.

Recommended Best Practices: Transport \uf0b7 Clean transfer trailers after each use \uf0b7 Do not mix hog herds during transportation (Boes, 2001)

11", "VII. Lairage A study of hog slaughter processing concluded that the lairage is the most cost-effective stage to prevent cross-contamination that leads to rapid infection (Vander Gaag, 2004). Prolonged transportation and holding in the lairage may induce Salmonella shedding by infected hogs (Alban, 2005). Several Hurd studies offer insight into the preharvest ecology of Salmonella during lairage. These studies suggested the following: \uf0b7 Hogs become internally contaminated with Salmonella after leaving the farm (Hurd, et al 2001) \uf0b7 Surface contamination of the holding pen

Key Point: Lairage is the most cost-effective stage to prevent cross contamination. reflects the

quality of in-plant practices and may not be a useful measure of pre-harvest prevalence (Hurd, et al 2001) There is rapid infection during holding, suggesting the holding pen as an important *S.enterica* control point in the preharvest pork production chain (Hurd et. al. 2003). In addition to the frequent contamination of holding pens, 33.3% of hog drinking water samples were contaminated with *Salmonella*. This finding indicates that more attention to the microbiological quality of water is needed and that the water may be contaminated from the environment (Hurd, 2003) Key Point: It is important to remember that lairage is a critical processing step in hog slaughter that should not be overlooked. Implementation of recommended best practices can minimize or eliminate the spread of *Salmonella* at subsequent processing steps. 12", "Recommended Best Practices: Lairage Minimize the time the hogs are held in lairage (Hurd, 2001) Prevent overcrowding during time in lairage (Hurd, 2001a,b) Keep water in lairage pens fresh and change after each herd (Rostagno, 2003) Use slatted or elevated floors in lairage pens to reduce waste and water accumulation Maintain lairage pens in order to prevent conditions that could injure animals Avoid mixing of herds (Borch, 1996; Alban, 2005) Disinfect lairage pens and alley ways, between herds, using chlorinated alkaline detergent followed by disinfection with a quaternary ammonium solution (Dehalle, 2008) Ensure that hogs are washed clean (pen shower) and dry enough to preclude dripping at the time of stunning Segregate *Salmonella* positive herds and process them at the end the production day ( Alban, 2005;Boes, 2001) VIII. Stunning Carbon dioxide (CO<sub>2</sub>) and the electro narcosis stunning methods have no effect on carcass microbiology (Dehalle, 2008). Appropriate stunning methods are required for an establishment to be in compliance with the Humane Methods of Slaughter Act (HMSA). 13", "IX. Slaughter\Bleeding The bleeding process results in a significant accumulation of body fluids, feces, and dirt on walls and floor of the area and is a significant source of cross contamination for *Salmonella* (Bolton, 2002). A study showed that stick knives have tested positive for *Salmonella* and may be a source of cross-contamination (Botteldoorn, 2003), suggesting that sanitation of knives is critical. Efficiency and control of knife use is important to prevent wounds that are too deep. Deep wounds may penetrate the oropharynx or may allow introduction of scald water and pathogens including *Salmonella*, into the pleural cavity. Key Point: The bleeding process is a significant source of crosscontamination for *Salmonella*. X. Scalding Vertical scalding using steam may improve the bacteriological quality of the meat, prevent bacterial contamination of lungs, and reduce muscular degeneration and development of pale, soft, exudative muscle (PSE) because the internal temperature of the meat does not exceed 5 °F (41 °C) (Gracey, 1992). Vertical steam scalding reduces operating costs if the cooling water from the condenser in the steam tunnel is used to flush the carcasses during the de-hairing process. Scalding may be used as a critical control point (CCP) in a HACCP system (Bolton, 2002; Hald, 1999) if the temperature of the scalding water\steam and the duration is adequate. The cleanliness of the hogs and the status of the scald water were factors significantly associated with *Salmonella* on the carcasses at the end of the slaughter process (Letellier, 2009). Key Point: Scalding may be used as a critical control point in a HACCP system if the temperature of the scald water or steam and duration of scald are adequate. 14", "Recommended Best Practices: Scalding Evacuate feces from the rectum or implement an anus bunging system (coning) Wash the evacuated carcass before scalding Scalding water should be 145 °F (62°C) for 5 minutes

Maintain sanitary conditions. Ensure that the scalding tank is easy to clean and in good condition and repair. Drain and clean the scalding tank daily. Pay particular attention to weld sites and rough, scratched areas in the interior of the tank to ensure proper cleaning. Remove or prevent accumulations of hair and protein from the scalding tank and dehairing machine both before and during operations. Control condensation as needed to maintain sanitary conditions.

Recirculation of water may affect accumulation of hair and residue and control temperature fluctuations. Maintain a clean supply of water. Change the scald water frequently to prevent organic load build up. Recommended Best Practices: Scalding Use a counter current application (fresh or recirculated scald water that flows into the scalding tank in an opposite direction from that of the carcasses) to increase heating efficiency and water cleanliness. The stick wound should be promptly trimmed, and preferably immediately after scalding. The trimmings should be discarded. A vertical steam scald at 212 °F (100 °C) allows for a constant supply of clean steam and prevents the organic load which would accumulate if a water system was used. Add an anti-foaming agent to the scald water to reduce organic load build up in foam. XI. De-hairing Care is needed when using a de-hairing machine in order to prevent recontamination and increases in bacterial load (Morgan, 1987; Gill and Jones, 1995; Gill and Bryant, 1993; Davies, 1999; Yu, 1999; FRPERC 2007). Salmonella has been detected in air samples at the locations of de-hairing and evisceration operations (Pearce, 2005). Recommended Best Practices: De-hairing Clean and disinfect de-hairing equipment, preferably using a clean-in-place (CIP) system which may be applied on an ongoing basis throughout production. At the end of the production day, remove all organic material and debris from de-hairing equipment by power hosing with water at a pressure of 290 to 435 psi. A layer of alkaline detergent should then be applied to the equipment for 15-20 minutes in order to remove any organic material prior to sanitation of the equipment using a quaternary ammonia or similar disinfectant (Bolton, 2002). Use water between 140 °F to 144 °F (60 to 62 °C) in the de-hairing machine if the water is not chemically treated (7 ICMSF, 1998). If possible, prior to de-hairing evaluate methods to prevent fecal voiding (Bolton, 2002). Have in place procedures to clean contaminated carcasses that void fecal material after de-hairing and prior to gambrelling and rehanging. Pasteurize hog carcasses using hot water sheets at 185 °F (85 °C) or higher for 20 seconds after de-hairing. This has been shown to reduce contamination (Bolton, 2002; McMullen, 2000). For hand shaving, use an extremely sharp knife. Prevent cutting through the skin in order to reduce introducing bacteria into the interior of the carcass. XII. Gambrelling Recommended Best Practices: Gambrelling Assure carcasses are not recontaminated on the gambrel table by hogs that evacuate bowels post de-hairing. XIII. Steam/Hot Water Vacuuming The decontamination of pork carcasses by steam and lactic acid reduced the surface microbial counts immediately after treatment and retarded microbial growth during storage. Such treatment can be used to prolong the shelf-life and to increase the safety of pork carcasses. (Pipek et al. 2006) Recommended Best Practices: Steam/Hot Water Vacuuming Assure carcasses are not recontaminated on the gambrel table by hogs that evacuate bowels post de-hairing. Monitor equipment temperature, pressure, and nozzle (Pipek et al, 2006). Vacuum carcasses from top to bottom using 90-95 °F (35 °C) steam ( Pipek,et al 2006). Clean the equipment frequently on a regular preventative maintenance schedule. Apply steam vacuuming to carcasses after de-

hairing, singeing, or polishing \uf0b7 Use a 2% lactic acid solution at 131\u00b0F (55\u00b0C) for more than 60 seconds, 13-23psi (VanNetten et al.1995 17","XIV. Singeing Singeing has been identified as a significant step for reducing microbial contamination on the surface of hog carcasses, including Salmonella (James, 2007; Bolton, 2002; Pearce, 2004; Alban and Stark, 2005). Various studies have shown that singeing achieves a 2.5-3.0 log<sub>10</sub> CFU/cm<sup>2</sup> reduction in total microbial load (Bolton, 2002; Pearce, 2004) and a reduction of Salmonella incidence from 7% to 0% (Pearce, 2004). A study by Dehalle showed that a single singeing process can decrease the APC (aerobic plate count) 2.2 to 2.5 log<sub>10</sub> CFU/cm<sup>2</sup>. Key Point: Singeing has been identified as a significant step for reducing microbial contamination on the surfaces of hog carcasses, including Salmonella. Recommended Best Practices: Singeing \uf0b7 Use a full (multiple heat sources) singe process \uf0b7 Ensure that the surface carcass temperature reaches 212 \u00b0 F (100 \u00b0 C) 18","XV. Polishing Polishing is a primary mode of pork carcass recontamination following reductions that were achieved during singeing (James, 2007; Bolton, 2002; Snijders, 1984; Gill, 1995; Hald, 1999). Any surviving bacteria are mechanically disseminated by stainless steel scrapers or nylon brushes used in polishing (Delhalle, 2008). Polishers must be cleaned thoroughly because they harbor and allow bacteria to multiply to high levels (Borsch, 1996; Huis in\u2019t Veld, 1992). Key Point: Polishing is a primary mode of pork carcass recontamination following reductions that were achieved during singeing.

Recommended Best Practices: Polishing \uf0b7 Use high pressure water jets instead of flail or whip wet polisher \uf0b7 Thoroughly and frequently clean the polishing equipment \uf0b7 If singeing is efficient, the polishing process may be replaced with a pressurized, 185 \u00b0 F (85 \u00b0 C) or higher hot water wash, improving carcass decontamination rather than possible recontamination during polishing. (Gill, 1995, 1998; Van Netten, 1995; Spescha, 2006) \uf0b7 Add an additional singeing step, after polishing, to reduce contamination introduced by polishing (Spescha, 2006, Dehalle, 2008); Consider whether carcasses have been adequately reconditioned in a sanitary manner, if contaminated by feces voided during the gambrelling step 19","XVI. Knife Trimming Before treating carcasses with a pre-evisceration rinse or spray, a measure should be in place to prevent visibly contaminated carcasses from being sprayed or rinsed. If steam or hot water vacuuming is not available, knife trimming can be used to remove fecal contamination and other dressing defects. Knife trimming reduces the volume of contamination that might otherwise be diluted by washing after singeing. XVII. Pre-evisceration Carcass Rinse or Spray A listing of suitable compounds that can be used for pre-evisceration rinsing or spraying is detailed in FSIS Directive 7120.1. Additional information regarding antimicrobial compounds can be found at the following web sites:

<http://foodsafety.psu.edu/movies/carcass.html>

<http://foodsafety.psu.edu/movies/intervention%20booklet%202005.pdf>. Pre-evisceration Rinse or Spray \uf0b7 Use water at a temperature greater than 160 \u00b0 F (71.1 \u00b0 C) \uf0b7 Trim open abscesses, septic bruises, parasites, and parasitic lesions before the carcass enters the cabinet \uf0b7 If pressure is used to spray, do not exceed 100 psi to prevent driving contamination into the tissue \uf0b7 Monitor concentrations and temperatures regularly to verify effectiveness \uf0b7 Minimize overspray of water or solution from the cabinet \uf0b7 Larger operations should consider using stainless steel cabinets with an arbor of spray nozzles 20","Pre-evisceration Rinse or Spray \uf0b7 Apply organic acids with a hand spray applicator assuring the carcass is totally covered \uf0b7 Consider using a post-evisceration rinse or spray

to further reduce carcass contamination \uf0b7 Verify that the cabinet is used in a manner that prevents cross contamination of adjacent carcasse; Carcasses should not be touching prior to final inspection XVIII. Head Washing\Head Dropping Recommended Best Practices: Head Washing\ Head Dropping \uf0b7 Flush the oral cavity removing ingesta, bile, or other contaminants before head dropping and head inspection \uf0b7 Sanitize knives and head dropping equipment between carcasses and whenever sectioning of the gullet occurs \uf0b7 Be aware of potential contamination of the head, neck, and carcass by knives or equipment after incision of the oral-pharyngeal cavity or from exposure to fresh stomach contents when dropping heads and processing of head and cheek meat 21", "XIX. Bung Isolation Recommended Best Practices: Bung Isolation \uf0b7 Tie bung, cut free from surrounding tissues with a single incision, and cover area with a protective covering \uf0b7 During separation prevent contact of bung with carcass or with viscera. Secure bag with tie or clip \uf0b7 Ensure employee hygiene and use of personal protective equipment (gloves and aprons) (McEvoy, 2003b, Edwards and Fund, 2006) \uf0b7 Immediately remove any contamination that results from bunging \uf0b7 If possible, use an automated bunging system called \u201cbung guns\u201d instead of manual bung tying. An automated bunging system will reduce cross-contamination, by going around the anus and evacuating the rectum (Sheridan, 1998) \uf0b7 Sanitize bung guns, knives, and hooks between each carcass \uf0b7 Prevent contaminated water from dripping down the back of the carcass 22", "XX. Evisceration Recommended Best Practices: Evisceration \uf0b7 Remove all hair, scurf, and dirt from the hooves and the carcass and thoroughly wash the carcass before evisceration (9 CFR 310.11) \uf0b7 Sanitary dressing guidelines for beef may be applied to swine \uf0b7 To prevent contamination of the carcass or viscera, tie the rectum before evisceration. Remove the pluck with gullet and viscera attached (so there is no leakage) \uf0b7 Only skilled, experienced individuals should perform the evisceration; Experienced individuals are needed at higher line speeds \uf0b7 Avoid cutting or rupturing the gut. The critical operations are: cutting around the rectum, removal of the intestinal tract, and removal of the pluck system (Alban and Stark, 2005) \uf0b7 Take care to avoid cross-contamination, which may occur when carcass splitting saw blades come in contact with the spinal column or throat (Dehalle, 2008) \uf0b7 Remove carcasses with visual contamination or bruising for reconditioning (knife trimming or steam vacuuming) before carcass splitting \uf0b7 Disinfect carcass splitting equipment after each use (9 CFR 416.3, 416.4). 23", "XXI. Pre-chill Final Rinse\Hot Rinse\Steam Pasteurization Recommended Best Practices: Pre-chill Final Rinse\Hot Rinse\Steam Pasteurization \uf0b7 When a contaminated carcass is not adequately cleaned before the final wash, the carcass should be diverted to a holding rail until cleaned \uf0b7 Clean the contaminated carcasses by removing visible contamination by trimming or steam or hot-water vacuuming prior to final inspection and final washing \uf0b7 Rinse carcasses from the top down \uf0b7 Minimize any splash onto other carcasses \uf0b7 When utilizing a thermal pasteurization system, deliver water or steam to the entire surface of the carcass at a temperature of at least 165 \u00b0 F (73.9 \u00b0 C). \uf0b7 Pressure should not be high enough to drive contamination into the tissue \uf0b7 Small operations may use cold water to wash carcasses; Improve decontamination by adding chemicals such as chlorine or trisodium phosphate (Bolton 2002) \uf0b7 A pressurized diluted 2 to 3% lactic acid or acetic acid is recommended (McMullen, 2000). Consider careful treatment of necks and inside jowls when the head is separated from the carcass \uf0b7 Monitor drains to ensure they are working

properly and prevent backup that may result in carcass and equipment contamination 24", "XXII. Spray Chilling Recommended Best Practices: Spray Chilling \uf0b7 Spray chill carcasses using an organic spray 2 days prior to fabrication to maximize reduction of Salmonella (Algino, 2009) \uf0b7 Maintain the cooler at a temperature that ensures carcasses will have an internal temperature of 40 °F (4.4 °C) 24 hours after being put in the cooler XXIII. Carcass Fabrication Recommended Best Practices: Carcass Fabrication \uf0b7 Apply organic acid antimicrobial treatment \uf0b7 Maintain boning and fabrication rooms at 50 °F (10 °C) or less \uf0b7 Maintain fabrication area and equipment in a sanitary condition 25", "XXIV. Packaging\Finished Product Storage and Transport Recommended Best Practices: Packaging\Finished Product Storage and Transport \uf0b7 Storage room and transportation vehicle temperature should be maintained at 40 °F (4.4 °C) or less \uf0b7 Maintain Internal meat temperature during storage at 40 °F (4.4 °C) or less \uf0b7 Monitor and document temperature of storage room, vehicle, and meat XXV. Validation Validation is the process of demonstrating that the HACCP system as designed can adequately control identified hazards to produce a safe, unadulterated product. Examples of some controls that would require validation are CCPs, pre-requisite program interventions preventing a hazard from being likely to occur, and product formulations when the formulation contributes to the safety of the product. There has been much confusion about which HACCP activities are on-going verification and which are initial validation. This confusion has been magnified by the fact that the NACMCF definition of the HACCP principle verification includes validation. Many agree that validation should be a distinct function from verification (Scott and Stevenson, 2006). Key Point: There are two distinct elements to validation: 1. The scientific or technical support for the HACCP system design and; 2. The initial practical in plant demonstration proving the HACCP system can perform as expected (execution) 26", "90 calendar days of initial validation takes place upon completion of the hazard analysis and development of the HACCP system. This period provides an opportunity to check the validity or adequacy of the HACCP system. Establishments are to conduct validation activities during their initial experience with a new HACCP system. Establishments are required to complete the initial validation of the new HACCP plan in accordance with 9 CFR 417.4 during a period not to exceed 90 calendar days after the date the new process is used to produce product for distribution in commerce. During these 90 calendar days, an establishment gathers data from its monitoring and on-going verification activities at an increased frequency than listed in the HACCP plan and gathers additional data to demonstrate that the process is being executed effectively. During this period an establishment should be reviewing these data and making modifications to its system as necessary. Many agree that validation should be a distinct function from verification Following the 90 calendar day period of initial validation, an establishment uses its findings during the initial validation period to fully implement its system and solidify its monitoring and on-going verification procedures and frequencies. The establishment then continues on a daily basis to perform monitoring and verification activities to ensure that the HACCP plan continues to be implemented properly. Ongoing verification activities include but are not limited to: the calibration of processmonitoring instruments; direct observation of monitoring activities and corrective actions; and the review of records generated and maintained in accordance with 417.5(a)(3). During the annual reassessment, FSIS recommends that establishments review specific food safety related records generated during ongoing verification that demonstrate

that their HACCP systems are adequate (i.e., test results and monitoring of critical operational parameters). Additional information on validation can be found in the FSIS Compliance

Guideline for HACCP Systems Validation at:

[http://www.fsis.usda.gov/wps/wcm/connect/a6a16ac5-93e0-46dc-986a557930d2209f/HACCP\\_Systems\\_Validation\\_Draft\\_Guidance\\_0412.pdf?MOD=AJPERE](http://www.fsis.usda.gov/wps/wcm/connect/a6a16ac5-93e0-46dc-986a557930d2209f/HACCP_Systems_Validation_Draft_Guidance_0412.pdf?MOD=AJPERE)

XXVI. Process Control Verification Process control is a procedure or set of procedures designed to provide control of the establishment's operating conditions that are necessary for the production of safe and wholesome food. The goal of process control in a slaughter establishment is to minimize microbial contamination of the carcasses, to reduce bacterial pathogens that may be present and injurious to health, to control the proliferation of any remaining micro-organisms, and to prevent recontamination. 27", "Process control procedures are likely to include decontamination of carcasses, adequate sanitary dressing practices, antimicrobial intervention treatments, and implementation of best practices described throughout this compliance guide. Establishments that fail to control these procedures and treatments create the potential for contamination of carcasses and products. Establishments can verify the effectiveness of their process control procedures by conducting: \uf0b7 process mapping and; Key Points: \uf0b7 conducting on-going verification activities, such as microbiological sampling and testing utilizing indicator organisms. \uf0b7 Process mapping entails conducting microbial sampling at selected points in the process where contamination levels can be assessed. Process mapping is a useful challenge study tool. Process mapping entails conducting microbial sampling at selected points in the process where contamination levels can be assessed. The assessment measures microbiological loads on carcasses against a specific target organism or class of organisms. Process mapping provides a baseline for assessing the effectiveness of certain interventions as well as the effectiveness of the overall food safety system. Process mapping shows areas where immediate improvements can be made or where there is a need for process adjustments. A process mapping (testing) protocol could include procedures for obtaining multiple samples after each processing step or slaughter period (shift). Plotting these test results can then be used as a map of the microbial reduction at each intervention step in the system. \uf0b7 Process mapping shows areas where immediate improvements can be made or where there is a need for process adjustments.

XXVII. Process Control Verification Using Indicator Organisms As Performance Criteria Microbiological sampling programs within establishments can include testing for indicator organisms. Indicator organisms are analyzed to predict the distribution, number, and response of specific pathogenic organisms on a particular product as it travels through a HACCP system. 28", "Testing for indicator organisms is less costly than testing for pathogenic bacteria. Also, indicator organisms are easier to detect and quantify. Testing for indicator organisms is a valuable tool to monitor actual in-plant processes and determine whether a process is in control. Establishments may choose from a variety of indicator organisms to measure microbial contamination and determine process control. Examples of indicator organisms that may be suitable measures of fecal contamination include aerobic plate count (APC), Enterobacteriaceae, Total coliforms, and Generic Key Points: E. coli. Advantages of using If an establishment does not have its own indicator indicator organisms: organism data, it can use the process control limits developed from the FSIS Nationwide Market Hogs \uf0b7 Less costly Microbiological Baseline Survey (MHBS) testing results (2010-2011) to help achieve this goal, \uf0b7 Easier to detect and

provide information that is easier to detect and quantify, and facilitate daily verification activities. During the MHBS, FSIS collected samples from two points during processing: pre-evisceration and monitor in plant post-chill. Pre-evisceration refers to the location early in the process prior to evisceration of the processes hog. Post-chill refers to a later point in the process after carcasses are chilled; all interventions completed, and before the hog carcasses enter coolers. The information in Table 1 below was derived from the FSIS Nationwide Market Hog Microbiological Baseline Survey (MHBS) for specific indicator organism limits that correspond to the 80th percentile. FSIS compared the presence and levels of specific microbiological targets to determine whether significant differences existed between samples taken at pre-evisceration and post-chill. Percentiles represent the percent of establishments that are below the associated number in the distribution of average bacteria indicators per plant. An establishment may use the indicator organism limits in the Table 1 to verify that the establishment is exercising process control. For example, the table demonstrates that if an establishment has APC levels above 790 CFU/cm<sup>2</sup> at post chill, its process is most likely out of control, and the establishment should immediately take corrective action to bring its process back under control. A prudent establishment should aim for results below those limits listed for each indicator organism at pre-evisceration and post chill locations. Indicator organism results below control limits shown in Table 1 indicate that the process is in control. For example, APC levels below 790 CFU/cm<sup>2</sup> demonstrates effective process control. FSIS recommends that the establishment plot data over time to determine whether its overall processes are in control and to determine the variability in its food safety system. 29", "The establishment should take appropriate actions if it determines that its process is not in control.

Table 1: Indicator Organism Criteria Limits for Market Hogs Indicator Organism APCs

Enterobacteriaceae Total Coliforms	E. coli Average CFU/cm <sup>2</sup>	Preevisceration	Postchill
110	5,500	35	3,800
110	5,500	35	3,800
30	30	30	30
Distribution	Percentile	80%	80%
Preevisceration	Postchill	80%	80%
Preevisceration	Postchill	80%	80%
Postchill	4200000	790	8,300

Given that samples collected per establishment in the MHBS were limited, and the variation within individual establishments was high, the control limits in the table are approximations. Testing for indicator organisms is a valuable tool for assessing consistent process control within an establishment and is less costly than testing for Salmonella. Moreover, indicator organisms are generally easier to quantify than Salmonella. Nonetheless, a prudent establishment would adopt a testing program that includes both indicator organisms and testing for the pathogen Salmonella at an established frequency as part of its on-going in plant verification program. The indicator organisms would provide ongoing evidence of control, while periodic testing for the pathogen Salmonella would verify that the process is successfully addressing the pathogen. Establishments may use their own sampling data if there is adequate statistical rigor to establish statistical process controls action levels. Many small and very small establishments may not have resources for a program that provides for a sampling frequency to determine statistical process control action levels. Therefore, an establishment can also use the estimated national prevalence of 1.66% for Salmonella calculated from MHBS to assess establishment Salmonella sampling results to determine whether their processes are in control. If aggregated test results over time for an establishment are above the national prevalence estimate of 1.66%, it raises questions about the adequacy of process control within that establishment. Additional information on the national prevalence estimate can be found in the baseline report at:

[http://www.fsis.usda.gov/wps/wcm/connect/d5c7c1d6-09b5-4dcc-93aef3e67ff045bb/Baseline\\_Data\\_Market\\_Hogs\\_2010-2011.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/d5c7c1d6-09b5-4dcc-93aef3e67ff045bb/Baseline_Data_Market_Hogs_2010-2011.pdf?MOD=AJPERES). The indicator organisms would provide ongoing evidence of control, while periodic testing for Salmonella would verify that the process is successfully addressing Salmonella.

30", "XXVIII. New Technologies FSIS recognizes that new technologies provide opportunities to improve and strengthen cost effective process controls. The Agency strongly recommends that all establishments be aware of new techniques, chemicals, and machinery that may be utilized to improve their ability to produce wholesome products. FSIS has reviewed submitted protocols and listed these new technologies on the FSIS Web site. For detailed information on particular technology, interested parties should contact the listed new technology provider or manufacturer's web site. This list is at:

[http://www.fsis.usda.gov/Regulations/New\\_Technology\\_Table\\_Feb\\_06/index.asp](http://www.fsis.usda.gov/Regulations/New_Technology_Table_Feb_06/index.asp). In addition, FSIS has funded Cooperative Agreement studies. From studies completed in Key Point: New technologies provide opportunities to improve and strengthen cost effective process controls. 2003, FSIS identified technologies that may reduce levels of Salmonella. These technologies may be cost-effective for small and very small plants. A list of these completed studies on new technology can be found at:

[http://www.fsis.usda.gov/regulations\\_&\\_policies/Technologies\\_Applicable\\_for\\_Small\\_Very\\_Small\\_Plants\\_FY2003/index.asp](http://www.fsis.usda.gov/regulations_&_policies/Technologies_Applicable_for_Small_Very_Small_Plants_FY2003/index.asp).

XXIX. Information from Food Safety Assessments (FSAs)

An FSA is a comprehensive evaluation of an establishment's food safety system that assesses the establishment's sanitation controls, compliance with microbiological performance criteria, adequacy of slaughter house and processing plant Hazard Analysis and Critical Control Point (HACCP) systems, the design and operation of its prerequisite programs (including sanitary dressing procedures), and its response to food safety control deviations. In 2009, FSIS began prioritizing the scheduling of FSAs based on public health decision criteria, in addition to traditional event-based scheduling. FSIS Directive 5100.4 Prioritized Scheduling of Food Safety Assessments (FSAs) Using the Public Health Information System (PHIS), provides the decision criteria that FSIS uses to schedule FSAs.

31", "An establishment that meets one or more of the decision criteria under any of the priority levels provided in Table 1 of FSIS Directive 5100.4 will receive a for cause FSA. A for cause FSA is one that is prompted by a positive sample result, production and shipment of adulterated product, or any other high priority food safety related incident. An establishment's failure to meet the Salmonella Performance standard is one of the public health decision criteria that will result in a for cause FSA. Since 2009, there has been one FSA conducted by FSIS in response to an establishment's failure to meet the Salmonella Performance Standards for market hogs. FSIS completed a Salmonella set for market hogs at this establishment on March 25, 2010, and found 7 positives in the sample set (one over the limit of 6). This finding resulted in a for cause FSA being conducted at the establishment. In response to the FSA findings, the establishment implemented the following corrective actions:

\uf0b7 Increased lactic acid concentration from 2 to 5% to a consistent 4.5 % level sprayed on carcasses just prior to entering the cooler

\uf0b7 Targeted Inspexx (antimicrobial) at 200 ppm (instead of 100 \u2013 200ppm)

\uf0b7 Retrained employees in GMPs

\uf0b7 Reviewed carcass chilling procedures and sanitary carcass dressing procedures

\uf0b7 Placed hog carcass coolers on a regular cleaning schedule

\uf0b7 Collected knives used on the kill floor at the end of the

shift and implemented cleaning by a contract sanitation company. The establishment completed its second sample set on July 23, 2010, and passed with 4 positives in the set. XXX. Conclusion Microbial contamination in the slaughter house environment can start with the delivery of Salmonella positive hogs. However, there is significant scientific evidence that a large number of hogs are exposed to Salmonella during lariage. Such awareness of potentially significant areas of contamination can serve as reinforcement to reduce Salmonella during harvest. Studies have also shown that improved pre-harvest sanitation can reduce the levels of Salmonella exposure. Sanitary maintenance of slaughter house equipment, good slaughtering practices, and effective washing and disinfection of equipment and materials at critical steps are critical to reducing Salmonella contamination. If sanitary conditions are not maintained throughout slaughter and processing, the major reductions in microbial load noted at some stages of the process can be offset by cross-contamination or recontamination at subsequent stages of the process. Decreasing the level of Salmonella during slaughter and processing can decrease the number of human cases of salmonellosis from pork consumption by 75% (Miller, 2005). 32", "FSIS recommends that intervention and control strategies be formulated based on a combination of measures that are both practical and economically feasible. A multifactorial infection such as Salmonella requires a multi-level approach of intervention and control.

Appropriate modifications of establishment operations based on information provided in this guidance should reduce the levels of Salmonella in slaughter steps. Attachment 1 Supplemental Information Controlling Parasitic Hazards in Market Hogs: (Trichinella spiralis and Toxoplasma gondii) Trichinella spiralis (T. spiralis) and Toxoplasma gondii (T. gondii) are parasites that infect both humans and warm-blooded animals. Trichina is a generic term that refers to Trichinella, and the disease caused by this parasite is referred to as trichinellosis. Humans can become infected with T. spiralis by consuming encysted larvae in the muscle tissue of an infected animal. A common source of trichinellosis in humans is the consumption of undercooked pork. Pigs are the primary host for T. spiralis (Hill et al., 2012). Felids (cat family) are the primary host for T. gondii, and they can contaminate the environment by excreting the oocyst in their feces (Jone et al., 2012). Domestic food animals, Trichinella spiralis (T. spiralis) and Toxoplasma gondii (T. gondii) are including pigs, can be infected by T. gondii, and parasites that infect both humans infected animals harbor T. gondii tissue cysts. and warm-blooded animals. Human can become infected by ingesting tissue cysts from raw or undercooked meat (Hill et al., 2010). Over the past 20 years, the occurrence of T. spiralis infection in humans and pigs has decreased significantly in the U.S., although sporadic outbreaks still persist (Burke et al., 2008). However, the perception that pork may be infected with T. spiralis continues to be a food safety concern with some consumers. One of the most common parasitic infections in humans is toxoplasmosis. Toxoplasma gondii is the second leading cause of foodborne illnesses resulting in deaths (24%), accounting for an estimated 327 deaths annually. Toxoplasma is also the fourth leading cause of foodborne illnesses resulting in hospitalizations (8%), accounting for an estimated 4,428 hospitalizations annually (Scallan et al., 2011). 33", "Establishments that produce pork products should consider whether their suppliers have taken the necessary measures to prevent Trichinella infection in their herds. Pre-harvest management practices in the U.S. pork industry should include the recommended best practices described below:

Recommended Best Practices: Pre-harvest practices: \uf0b7 Do not feed table scraps, uncooked waste products, animal carcasses, or animal waste products contaminated with trichina \uf0b7

Prevent access to rodents and wildlife infected with *T. Gondi*, or to environmental contamination with cat feces such as soil, grass, feed, or water contamination (Jones et al., 2012) \uf0b7 Prevent exposure to rodents or other wildlife infected with *Trichina*; Rodents can serve as a reservoir host for *Trichinella* \uf0b7 Establish and maintain an effective rodent control program \uf0b7 Prevent cannibalism among hogs within an infected herd Recommended Best Practices: Slaughter \uf0b7 Obtain pork from suppliers with trichina-control programs 34", "Trichinella infection can also be controlled by post-slaughter processing interventions to inactivate the parasite (i.e., heating, freezing, irradiation, and high pressure processing). Participation by swine producers in the U.S. Trichinæ Certification Program is an alternative to controlling *Trichinella* infection in their herds. The U.S. Trichinæ Certification Program is a pork safety program that provides documentation of swine production management practices that reduce, eliminate, or avoid the risk of exposure of swine to zoonotic parasite *T. spiralis* (<http://www.aphis.usda.gov/vs/trichinæ>). This is a voluntary program for those producers, slaughter facilities, and other persons that handle or process swine from pork production sites that have been certified under the program. The standards of this program establish a set of criteria that enable producers to market swine that are not considered a risk to human health because of exposure to *T. spiralis*. These program standards were developed as a cooperative effort of the USDA agencies (Animal and Plant Health Inspection Service [APHIS], Agricultural Research Service [ARS], Cooperative States Research, Education and Extension Service [CSREES], Food Safety and Inspection Service [FSIS]) the National Pork Producers Council [NPPC], and the pork processing industry (USDA\APHIS, 2008). Recommended Best Practices: Post-Slaughter Processing Interventions \uf0b7 Heating \uf0b7 Freezing \uf0b7 Multi-Hurdle Steps (drying, curing\*, salting, fermenting) \uf0b7 Irradiation \uf0b7 High pressure processing (HPP) 9 CFR 318.10 -Prescribes the treatment of pork and products containing pork to destroy trichinæ. \*The effectiveness of curing to eliminate *T. spiralis* larvae is dependent upon a combination of various processing parameters and on the product formulation; specifically on the temperature and time of fermentation\drying and the salt level, respectively. Therefore, curing alone is not recommended as a post-slaughter intervention (Porto-Fett et al., 2010). An increasing number of swine are being raised in non-confinement systems because of increased consumer demand for \u201cfree-ranging,\u201d organically raised,\u201d and \u201chumanely raised\u201d pork products (Hill et al., 2012; Honeyman et al., 2006). In the U.S., the prevalence of *Toxoplasma* in confinement raised market hogs is approximately 2.7 % (Hill et al., 2010). For hogs raised on pastures, the prevalence has been reported to be between 50-100% (Gamble et al., 2000). The risk of *Toxoplasma* infection is significantly increased in pasture raised hogs that have access to rodents and wildlife infected with *T. gondii* or to environmental contamination with cat feces, such as soil, grass, feed, or water contamination (Jones et al., 2012). 35", "Feral pigs are also reservoirs of infection for *Trichinella* and *Toxoplasma* for nonbiosecure (or non-confinement) reared domestic hogs. Raising pigs outdoors poses a major risk for hogs being infected with *Trichinella* and *Toxoplasma* because it increases exposure to potentially infected reservoir hosts and to soil contaminated with *Toxoplasma* cysts (Hill et al., 2012; Gamble et al., 2000; Pyburn et al., 2005; Hill et al., 2010). The risk of *Trichinella* and *Toxoplasma* infection in market hogs can be substantially reduced by employing swine production practices that eliminate the sources of exposures of these parasitic hazards, thereby reducing the likelihood of human infection from

consumption of pork infected with *Trichinella* and *Toxoplasma*. XXXI. References

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operators so they can produce safe food and, ultimately, ensure the success of their livelihoods. The newsletter strives to do this through: \u2714 Informing and educating small and very small plant owner\operators on FSIS news with meaningful and coherent information in an easy-to-read format. \u2714 Assisting plant owners and operators on implementing FSIS rules and regulations into their daily operational practices with \u201cplain language\u201d information. \u2714 Fostering small and very small plants\u2019 ability to stay in business and produce the safest food by providing essential tips that will encourage the highest sanitation standards, paperwork compliance, and cost-saving measures. \u2714 Honoring FSIS\u2019 obligations to small and very small plants by providing a mechanism that increases a two-way dialogue between plants and the agency. Back issues of Small Plant News are available on FSIS\u2019 Web site at [www.fsis.usda.gov](http://www.fsis.usda.gov). You may also call the Small Plant Help Desk at (877) 374-7435 or e-mail [InfoSource@fsis.usda.gov](mailto:InfoSource@fsis.usda.gov) to order back copies.", "U.S. Department of Agriculture \ Food Safety and Inspection Service Table of Contents Recall Plan Guidebook Introduction

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Introduction Recalls. A recall is a voluntary action conducted by a firm to remove adulterated or misbranded meat and poultry products from commerce. Although it is your company\u2019s decision to recall a product, the Food Safety and Inspection Service (FSIS), the public health regulatory agency within the United States Department of Agriculture (USDA), coordinates with you to ensure that you have properly identified and removed recalled product from commerce by verifying the effectiveness of your recall activities. FSIS also notifies the public about product recalls. There are three levels of meat and poultry recalls categorized by FSIS. The type of recall depends upon the potential risk to consumers. \u25ca Class I. There is a reasonable probability that eating the product will cause serious, adverse health consequences or death. Examples of a Class I recall include the presence of pathogens in ready-to-eat meat or poultry products or the presence of E. coli O157:H7 and other shiga-toxin producing E. coli O157:H7 or non-O157 STEC in raw ground beef. \u25ca Class II. There is a remote probability of adverse health consequences if the product is eaten. Examples of a Class II recall include the presence of very small amounts of undeclared allergens typically associated with milder human reactions, e.g., wheat or soy, or small-sized, non-sharp-edged foreign material in a meat or poultry product. \u25ca Class III. Eating the product will not cause adverse health consequences. An example of a Class III recall is the presence of undeclared ingredients, such as excess water in meat or poultry products. U.S. Department of Agriculture Food Safety and Inspection Service", "Small Plant News Guidebook Series INTRODUCTION A recall may be an alternative to FSIS detaining or seizing adulterated or misbranded products. However, if firms do not adequately remove a recalled product from commerce, a recall does not prevent FSIS from taking other appropriate actions, such as issuing public health alerts or detaining or seizing product to protect the public. The agency will also assess whether your recall strategy, or execution of that strategy, is effective. If it finds it is ineffective, FSIS may seek to bring an enforcement action against you or your consignees. FSIS has developed this guidebook and workbook to aid small and very small establishments that produce meat or poultry products in creating their plans for how they will conduct a recall should it become necessary for them to do so. The following information can be used to design and implement an effective recall plan. 6", "7 How to Develop A Recall Plan U.S. Department of Agriculture \ Food Safety and Inspection Service Recall Plans Title 9 of the Code of Federal Regulations, Part 418 (9 CFR 418), requires that official establishments that produce meat and poultry products prepare and maintain written recall plans. Under this regulation, your plan must specify how you will decide whether to conduct a product recall and describe the procedures that you will follow if you decide that a product recall is necessary. In addition, the regulations require that your plan be available to the FSIS inspector for review upon request. FSIS recommends that processed egg products plants also develop and maintain recall plans, although they are not explicitly required to do so by the regulation.", "How to

Develop A Recall Plan Small Plant News Guidebook Series Important Contact Information Recall Team. Your recall plan should contain a list of all your internal and external personnel who will be involved in a product recall. Include their roles and responsibilities, telephone numbers, fax numbers, and e-mail addresses. Be sure to appoint backups for each person. One person should be identified as the \u201crecall coordinator.\u201d This person may use another title, but the idea is to have one person in charge of recalls and recall planning. The recall coordinator will manage, maintain, and make changes to the recall plan as necessary. The recall coordinator should be knowledgeable about every aspect of the firm\u2019s operations, including purchasing, processing, quality assurance, distribution, and consumer complaints. The recall coordinator should be authorized to make decisions in carrying out a recall and should report to top management at regular, specified intervals. FSIS District Office. Your recall plan should include the telephone number of your local FSIS District Office. If you believe, or have reason to believe, that you have shipped adulterated or misbranded meat or poultry product into commerce, you are required to notify your local FSIS District Office within 24 hours. In addition, you must notify your local FSIS District Office if you believe that you have received adulterated or misbranded product, in accordance with 9 CFR 418.3. 8", "9 How to Develop A Recall Plan U.S. Department of Agriculture \u2014 Food Safety and Inspection Service Procedures for Determining a Recall Health Hazard Evaluation. Your plan must specify a method for determining how you will decide whether to conduct a recall if your product is adulterated or misbranded and is in commerce. Evaluating the nature and extent of the health risks associated with the product is one method for doing so. If you choose to assess the health hazards, you should take the following into account: \u25ca Whether any illness or injuries have already occurred from eating the product; \u25ca What hazards target various segments of the population, (e.g., children, the elderly, immune-compromised individuals, etc.), with particular attention paid to those individuals at greatest risk; \u25ca How serious is the health hazard to which the at-risk population would be exposed; \u25ca How likely is the hazard to occur; and \u25ca What would happen if it did. Here are some examples that you may want to consider when developing your recall plan. This list is not all inclusive, but it will help stimulate your thinking. \u25ca Undeclared allergen \u2013 What health hazards may arise if product shipped from your plant containing an undeclared allergen is consumed? \u25ca Consumer complaints \u2013 What are the health hazards if you receive a consumer complaint about a foreign material such as glass or metal in the product that has been shipped from your establishment? \u25ca Underprocessing \u2013 What are the health hazards if you discover that some of the products have been underprocessed? If your plant produces ready-to-eat product and raw product, will the hazards for these be different?", "10 How to Develop A Recall Plan Small Plant News Guidebook Series \u25ca Raw non-intact beef tests positive for E. coli O157:H7 or non-O157 STEC (both plant and FSIS test) \u25ca Ready-to-eat product tests positive for any pathogen (both plant and FSIS test) Scope of Recall. Your plan should also outline how you will determine the identity and amount of product to be recalled. It will be your responsibility to define when the problem began, when it was resolved, and what products are affected. Clean-up times do not necessarily define the scope of a recall. FSIS suggests that your plan specify how you will determine the amount of product affected by using various scenarios. Scenarios can include: the contamination of a vat of product with a foreign object, the use of an incorrect label, or the use of the same source of raw materials in other lots on other days of production.

When determining the amount of product affected, consider the following: "Your coding of product; The pathogen of concern; The processing and packaging; The equipment; The Hazard Analysis and Critical Control Point (HACCP) monitoring and verification activities (including microbiological testing) that you perform; Your Sanitation Standard Operating Procedure (SSOP) records; and Whether some, or all, of the products controlled by the same or substantially similar HACCP plans have been affected." "11 How to Develop A Recall Plan U.S. Department of Agriculture / Food Safety and Inspection Service Records. Records are vital in tracing product forwarded to consignees and back to potential suppliers. They include invoices, bills of sale, and shipping documents from each transaction in which product made with meat or poultry is purchased, sold, shipped, received, or handled by your plant in connection with any business subject to the Federal Meat Inspection Act or the Poultry Products Inspection Act. HACCP system records may also play a part in this process. Records you should have on hand include: Records needed to permit positive identification of products produced; Production records, including records on ingredients that are essential for traceback of products and ingredients of the products. All products need a system of product coding; this coding will facilitate an effective recall. Records of raw materials used in each lot of ground beef are especially important. Both you and public health authorities need to know if the problem is traceable to a supplier (refer to 9 CFR 320 and 9 CFR 381, subpart Q);" "12 How to Develop A Recall Plan Small Plant News Guidebook Series Distribution records that identify and locate shipped products that are recalled. These records should include at least the names and addresses of consignees, shipment method, date of shipment, and the amount of product shipped to each consignee. It is also useful to note which consignees are hospitals, restaurants, distributors, part of a chain, or independent retailers. Here's a practical example. If a recall of product is necessary because of contamination with Listeria monocytogenes, then a key factor in limiting the scope of the recall is whether the establishment (or retail store) is properly cleaning the equipment between lots. If not, there could be microbial contamination from one lot to another. Carefully maintained production records serve a vital public health purpose by giving the establishment and agency a means of pinpointing potential sources of contamination and providing greater accuracy in determining which products may be affected. Records that help product traceback: Production or grinding logs showing the times of each grind; Formulation or blend of raw ingredients, including amounts; Supplier lot identification; Finished product lot and subplot identification; and Any test results associated with either the raw materials or finished product. The records should indicate and track which lots or sublots of a grinding establishment's ground beef, including rework, and any other raw materials were used. The records should also track the amounts of each that were used." "13 How to Develop A Recall Plan U.S. Department of Agriculture / Food Safety and Inspection Service Recall Communications Recall Notice. FSIS recommends that your recall plan include an outline of the content of your recall notice. Please see sample recall notices on pages 16-18. When drafting the content of your recall notice, consider the following: Be brief and to the point; Clearly identify the product and any other pertinent descriptive information to enable accurate and immediate identification of the product, including: Product/brand name; Product code; Package/case size; Package/case date code; Lot number/expiration date; and Universal Product Code. Provide an

explanation of the risk if the product is eaten; \u25ca Concisely explain the reason for the recall and the hazard involved; \u25ca Provide specific instructions on what should be done with the recalled products; \u25ca Request an official, written response from consignees; \u25ca Provide a way for the recipient of the communication to report to the recalling firm whether it has any of the product, e.g., by allowing the recipient to place a collect call to the recalling operation; \u25ca The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message; and \u25ca Provide contact information for your firm (for questions). Your plan should also detail how the recall notification will be issued. For example, you can send your recall notice by e-mail, telephone, or", "14 How to Develop A Recall Plan Small Plant News Guidebook Series fax. Written notices should bear a prominent heading to indicate the importance of the communication. For example, a letter might bear a bold red declaration, such as \u201cURGENT FOOD RECALL.\u201d If communication is conducted by telephone, you should document and send a followup letter, e-mail, or fax to ensure that all bases are covered. Public Notification. FSIS recommends that you identify if and how the public will be notified of the recall. Recalls are often announced via a press release through national or local news media, or via a company website. Be sure to include contact information for all potential media, such as television stations, radio stations, and newspapers with local, State, and regional coverage areas, as well as the national wire services. If the actual contacts are not specified, then reference sources of current media contacts for all possible recall scenarios should be specified in the recall plan. The class of the recall and where the product was distributed will determine the type of notification you will use. Generally, distribution levels are categorized as wholesale, retail, hotel\restaurant\institutional (HRI) and consumer users. The more levels affected, the greater the need for different communication methods. At the wholesale level, the product is distributed to a warehouse or distribution center. This is the distribution level between the manufacturer and retailer. The retail level is when the product is received by the retailers for sale to the public. The HRI level is when the product was received by hotels, restaurants, or institutional customers. Lastly, the consumer level is when the product is sold directly to consumers. Regardless of the public notification action you take, FSIS will issue a press release for Class I and Class II recalls. FSIS will issue a Recall Notification Report if the recalled product has only been distributed at the wholesale level (and your firm is able to gain control of the product before it can be further distributed to the retail, HRI, or consumer level) and for Class III recalls. A Recall Notification Report is not distributed to the media.", "15 How to Develop A Recall Plan U.S. Department of Agriculture \ Food Safety and Inspection Service Control and Disposition of Returned Product Your recall plan should specify how the recalled product will be controlled pending disposition and disposal. If it will be destroyed after being returned, then notify FSIS prior to destroying the product in the event witnessing the product destruction is necessary. Recall Simulations The best way to test the effectiveness of your recall plan is to conduct a recall simulation that will help you identify any glitches in your recall plan. For example, you might find that a key fax or telephone number of a distributor or supplier has changed. Simulating a recall will keep your recall personnel alert and will familiarize everyone with recall procedures. A simulation will determine how quickly your company can identify and control a lot of affected product. If problems are identified during a recall simulation, then the recall plan should be revised and corrected. Simulations are necessary, and your recall plan will

falter without them. If you follow these guidelines, then you and your establishment should be ready in the event of a recall. Having a plan, familiarizing everyone with it, and implementing its procedures will keep you in control. Sample Recall Notices and Notification Letter and Worksheets. On pages 16-19, you will find sample Recall Notices and a Notification letter. You may use these as templates when designing your own Recall Notices and Notification Letters. On pages 20-24, you will find recall worksheets. You may use these for collecting pertinent information during a recall. In addition, a Recall Plan Workbook has been added to help you create a recall plan. The workbook can be found on pages 25-48. If you have any questions or concerns about developing your recall plan or need additional resources, contact FSIS\2019 Office of Outreach, Employee Education and Training through the Small Plant Help Desk at 1-877-FSISHelp (1-877-374-7435) or e-mail InfoSource@fsis.usda.gov. Also, visit the Small and Very Small Plant Web page at www.fsis.usda.gov to obtain information on training, workshops, and technical information to suit your needs. For additional information, you can also access FSIS Directive 8080.1, Recall of Meat and Poultry Products, from FSIS\2019 Web site at www.fsis.usda.gov/wps/wcm/connect/77a99dc3-9784-4a1f-b694ecf4eea455a6/8080.1.pdf?MOD=AJPERES. All information from this brochure is derived from FSIS Directive 8080.1.","16 How to Develop A Recall Plan Small Plant News Guidebook Series SAMPLE RECALL NOTICE: May Contain GLASS, PLASTIC, ETC. [STATE] FIRM RECALLS [PRODUCT] THAT MAY CONTAIN [GLASS, PLASTIC, ETC.] [CITY], [DATE] \u2013 [COMPANY], an [CITY, STATE], establishment, is recalling approximately [AMOUNT] pounds of [PRODUCT] that may contain pieces of [SPECIFY MATERIAL], [FIRM NAME]. The following products are subject to recall: [IDENTIFYING INFO: TYPE OF CONTAINER, WEIGHT, \u201cBRAND NAME AND OTHER LABEL INFORMATION,\u201d ESTABLISHMENT NUMBER, CASE AND\OR DATE CODES] The products were produced on\from [DATE] and distributed to [LEVEL OF DISTRIBUTION, i.e., RETAIL ESTABLISHMENTS, INSTITUTIONS, ETC.] in [STATES]. The problem was discovered through [SPECIFY HOW PROBLEM WAS DISCOVERED]. There have been [# or NO] reports of injury from the consumption of these products. Anyone concerned about an injury from the consumption of the products should contact a physician. Consumers with questions about the recall may contact [CONTACT TITLE AND NAME] at [TELEPHONE NUMBER]. Media with questions about the recall may contact [CONTACT TITLE AND NAME] at [TELEPHONE NUMBER].","17 How to Develop A Recall Plan U.S. Department of Agriculture \ Food Safety and Inspection Service SAMPLE RECALL NOTICE: LISTERIA [STATE] FIRM RECALLS [PRODUCT] DUE TO POSSIBLE LISTERIA CONTAMINATION [CITY], [DATE] \u2013 [COMPANY], an [CITY, STATE], establishment, is recalling approximately [AMOUNT] pounds of [PRODUCT] that may be contaminated with Listeria monocytogenes]. The following products are subject to recall: [IDENTIFYING INFO: TYPE OF CONTAINER, WEIGHT, \u201cBRAND NAME AND OTHER LABEL INFORMATION,\u201d ESTABLISHMENT NUMBER, CASE AND\OR DATE CODES] The products were produced on\from [DATE] and distributed to [LEVEL OF DISTRIBUTION, i.e., RETAIL ESTABLISHMENTS, INSTITUTIONS, ETC.] in [STATES]. The problem was discovered through [SPECIFY HOW PROBLEM WAS DISCOVERED]. There have been [# or NO] reports of illness associated with the consumption of these products. Consumption of food contaminated with Listeria monocytogenes can cause listeriosis, an uncommon, but potentially fatal disease. Healthy people rarely contract listeriosis. However, listeriosis can cause serious and sometimes fatal infections in those with weak immune systems, such as infants, the elderly, pregnant

women and persons with human immunodeficiency virus (HIV) infection or undergoing chemotherapy. Symptoms include high fever, severe headaches, neck stiffness, nausea, confusion, and convulsions. Consumers with questions about the recall may contact [CONTACT TITLE AND NAME] at [TELEPHONE NUMBER]. Media with questions about the recall may contact [CONTACT TITLE AND NAME] at [TELEPHONE NUMBER].","18 How to Develop A Recall Plan Small Plant News Guidebook Series SAMPLE RECALL NOTICE: UNDECLARED ALLERGEN [STATE] FIRM RECALLS [PRODUCT] DUE TO UNDECLARED ALLERGEN [CITY], [DATE] \u2013 [COMPANY], an [CITY, STATE], establishment, is recalling approximately [AMOUNT] pounds of [PRODUCT] due to an undeclared allergen [SPECIFY ALLERGEN]. The following products are subject to recall: [IDENTIFYING INFO: TYPE OF CONTAINER, WEIGHT, \u201cBRAND NAME AND OTHER LABEL INFORMATION,\u201d ESTABLISHMENT NUMBER, CASE AND\OR DATE CODES] The products were produced on\from [DATE] and distributed to [LEVEL OF DISTRIBUTION, i.e., RETAIL ESTABLISHMENTS, INSTITUTIONS, ETC.] in [STATES]. The problem was discovered through [SPECIFY HOW PROBLEM WAS DISCOVERED]. Anyone concerned about an allergic reaction should contact a physician. Consumers with questions about the recall may contact [CONTACT TITLE AND NAME] at [TELEPHONE NUMBER]. Media with questions about the recall may contact [CONTACT TITLE AND NAME] at [TELEPHONE NUMBER].","19 How to Develop A Recall Plan U.S. Department of Agriculture \ Food Safety and Inspection Service SAMPLE RECALL NOTIFICATION LETTER [DATE] [CUSTOMER FIRM NAME and ADDRESS] ATTN: [CONTACT PERSON NAME and TITLE] Re: [RECALL OF TYPE OF PRODUCT] Dear Sir or Madam: This letter is to confirm our telephone conversation that [Company Name] is recalling the following product because [Specify Recall Reason]: [Describe the product, including name, brand, code, package size and type, establishment number, etc.] We request that you review your inventory records and segregate and hold the above product. If you have shipped any of this product, then we request that you contact your customers and ask them to retrieve the product and return it to you. Once you have retrieved all of the product, please contact us. We will arrange to have the product shipped to our facility. Please do not destroy the product. We will credit your account for any product returned. We are undertaking this action in cooperation with the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture. FSIS officials may contact you to confirm that you have received this notice and are cooperating in this action. Your prompt action will greatly assist [Company Name] in this action. If you have any questions, please do not hesitate to contact [Company Recall Coordinator] at [Telephone Number]. Thank you for your cooperation. Sincerely, [Company Official Name] and [Title]","20 How to Develop A Recall Plan Small Plant News Guidebook Series \r \r RECALL WORKSHEET (Include attachments, additional pages, label copies and flowcharts as necessary) TODAY'S DATE: ESTABLISHMENT NUMBERS: EST. P- ESTABLISHMENT NAME: ADDRESS: COMPANY RECALL COORDINATOR (name, title, telephone) COMPANY MEDIA CONTACT (name, title, telephone) COMPANY CONSUMER CONTACT (name, title, telephone) REASON FOR RECALL: IDENTIFY RECALLED PRODUCTS SEPARATELY BY: BRAND NAME PRODUCT NAME PACKAGE (Type & Size) PACKAGE CODE (Use By\Sell By) PACKAGING DATE CASE CODE (Identifying) COUNT\CASE PRODUCTION DATE AMOUNT (lbs.\cases) PRODUCED AMOUNT HELD AT ESTABLISHMENT AMOUNT (lbs.\cases) DISTRIBUTED DISTRIBUTION LEVEL (institutional\retail\etc.) DISTRIBUTION AREA EXPORTED TO (country) SCHOOL LUNCH (CN, AMS Contract) (YES) (NO) (YES) (NO) (YES) (NO) DEPT. OF DEFENSE (DSCP, Commissary, etc.) (YES) (NO) (YES) (NO) (YES) (NO) INTERNET OR CATALOG

SALES (YES) (NO) (YES) (NO) (YES) (NO)", "21 How to Develop A Recall Plan U.S. Department of Agriculture \ Food Safety and Inspection Service \r RECALL WORKSHEET DESCRIBE THE PRODUCTION\PROCESSING OPERATION AND\OR ATTACH A PROCESS FLOW DIAGRAM: WHAT WERE THE \"CLEAN-UP TO CLEAN-UP\" TIMES (where applicable)? HAS THE SOURCE OF THE CONTAMINATION BEEN IDENTIFIED? EXPLAIN: ARE THERE DATA THAT COULD LIMIT THE AMOUNT OF PRODUCT AFFECTED? (YES) (NO) EXPLAIN: WERE THERE ANY DEVIATIONS REPORTED IN THE MEASURING AND\OR MIXING OF INGREDIENTS? (YES) (NO) EXPLAIN: DOES THE ESTABLISHMENT ROUTINELY USE METAL DETECTORS OR OTHER VISUAL IMAGING DEVICES? (YES) (NO) EXPLAIN: WERE OTHER PRODUCTS PRODUCED ON THE SAME LINE OR USING SOME OF THE SAME EQUIPMENT DURING THE \"CLEAN-UP TO CLEAN-UP\" PERIOD? (YES) (NO) EXPLAIN: "22 How to Develop A Recall Plan Small Plant News Guidebook Series RECALL WORKSHEET (Listeria monocytogenes ATTACHMENT) (READY-TO-EAT PRODUCT) DESCRIBE THE PRODUCTION\PROCESSING OPERATION AND\OR ATTACH A PROCESS FLOW DIAGRAM: \_ WHAT WERE THE \"CLEAN-UP TO CLEAN-UP\" TIMES? WAS CARRYOVER PRODUCT FROM PREVIOUS PRODUCTION PACKED WITH THIS PACKAGING CODE? (YES) (NO) WAS THERE A COMPLETE LINE CLEAN-UP AFTER THE CARRYOVER WAS RUN? (YES) (NO) WHAT DATE WAS THE CARRYOVER PRODUCT CARRIED OVER FROM? \_ WERE THERE ANY PROCESS DEVIATIONS DURING THE PRODUCTION OF THE CARRYOVER PRODUCT? (YES) (NO) EXPLAIN: WHAT WAS\WERE THE CORRECTIVE ACTION(S)? WERE OTHER PRODUCTS PRODUCED ON THE SAME LINE OR USING SOME OF THE SAME EQUIPMENT DURING THE \"CLEAN-UP TO CLEAN-UP\" PERIOD? (YES) (NO) EXPLAIN: \_ WHAT INTERNAL COOK TEMPERATURE WAS REACHED? DID THE PRODUCT REACH ANY SPECIFIED Aw OR pH REQUIREMENT? (YES) (NO) SPECIFY: \_ DOES THE FIRM HAVE AN IN-PLANT ENVIRONMENTAL MONITORING PROGRAM FOR Listeria monocytogenes? (YES) (NO) WAS THE SOURCE OF THE CONTAMINATION IDENTIFIED? (YES) (NO) EXPLAIN: IS THERE DATA THAT COULD LIMIT THE AMOUNT OF PRODUCT AFFECTED? (YES) (NO) EXPLAIN: "23 How to Develop A Recall Plan U.S. Department of Agriculture \ Food Safety and Inspection Service EXPLAIN: \r RECALL WORKSHEET (E. coli 0157:H7 ATTACHMENT) DESCRIBE THE PRODUCTION\PROCESSING OPERATION AND\OR ATTACH A PROCESS FLOW DIAGRAM: \_ DOES THE ESTABLISHMENT CONDUCT E. coli 0157:H7 TESTING? (YES) (NO) WHAT FREQUENCY? WHAT WAS\WERE THE SOURCE(S) OF THE MATERIALS PROCESSED? \_\_\_\_\_ WERE OTHER PRODUCTS PRODUCED FROM THE SOURCE MATERIALS? (YES) (NO) EXPLAIN: WAS REWORK OR CARRYOVER FROM THIS PRODUCT USED IN FUTURE PRODUCTION? (YES) (NO) IF YES, ON WHAT DATES WERE THE REWORK OR CARRYOVER USED AND WAS THERE ANY REWORK OR CARRYOVER FROM THAT DAY'S PRODUCTION USED IN FUTURE PRODUCTION? WHAT WERE THE \"CLEAN-UP TO CLEAN-UP\" TIMES? WERE OTHER PRODUCTS PRODUCED ON THE SAME LINE OR USING SOME OF THE SAME EQUIPMENT DURING THE \"CLEAN-UP TO CLEAN-UP\" PERIOD? (YES) (NO) EXPLAIN: WAS ANY MICROBIOLOGICAL TESTING PERFORMED BY THE COMPANY? (YES) (NO) EXPLAIN, INCLUDE RESULTS: ARE THERE DATA THAT COULD LIMIT THE AMOUNT OF PRODUCT AFFECTED? (YES) (NO) WERE THERE ANY PROCESS DEVIATIONS DURING THE PRODUCTION OF THE AFFECTED PRODUCT? (YES) (NO) WHAT WAS\WERE THE CORRECTIVE ACTION(S)? \_ ", "24 How to Develop A Recall Plan Small Plant News Guidebook Series \r RECALL WORKSHEET (Salmonella sp. ATTACHMENT) (READY-TO-EAT PRODUCT) DESCRIBE THE PRODUCTION\PROCESSING OPERATION AND\OR ATTACH A

PROCESS FLOW DIAGRAM: \_ WHAT WERE THE \"CLEAN-UP TO CLEAN-UP\" TIMES? WAS CARRYOVER PRODUCT FROM PREVIOUS PRODUCTION PACKED WITH THIS CODE? (YES) (NO) WAS THERE A LINE CLEAN-UP AFTER THE CARRYOVER WAS RUN? (YES) (NO) WHAT DATE WAS THE CARRYOVER PRODUCT CARRIED OVER FROM? WERE THERE ANY PROCESS DEVIATIONS DURING THE PRODUCTION OF THE CARRYOVER PRODUCT? (YES) (NO) EXPLAIN: WHAT WAS\WERE THE CORRECTIVE ACTION(S)? WERE OTHER PRODUCTS PRODUCED ON THE SAME LINE OR USING SOME OF THE SAME EQUIPMENT DURING THE \"CLEAN-UP TO CLEAN-UP\" PERIOD? (YES) (NO) EXPLAIN: \_ WHAT INTERNAL COOK TEMPERATURE WAS REACHED? DID THE PRODUCT REACH ANY SPECIFIED Aw OR pH REQUIREMENT? (YES) (NO) SPECIFY: DOES THE ESTABLISHMENT HAVE POST-PROCESSING CONTROLS? (YES) (NO) SPECIFY (include records): WAS ANY MICROBIOLOGICAL TESTING PERFORMED BY THE COMPANY? (YES) (NO) EXPLAIN, INCLUDE RESULTS: IS THERE DATA THAT COULD LIMIT THE AMOUNT OF PRODUCT AFFECTED? (YES) (NO) EXPLAIN:" "U.S. Department of Agriculture Food Safety and Inspection Service A Supplement to the Small Plant News Guidebook on How to Develop a Recall Plan A Sample AND MEAT POULTRY PRODUCT Recall Plan: THE WORKBOOK 25 Small Plant News Guidebook Series May 2013", "A Sample Meat and Poultry Product Recall Plan: The Workbook A Supplement to the Small Plant News Guidebook on How to Develop a Meat and Poultry Product Recall Plan The article titled \u201cHow You Can Prevent Recalls\u201d in the Volume 2, Number 3 issue of Small Plant News featured a fictitious individual and company \u2013 Hermann Q. Fuerschlinger, owner of Fuerschlinger\u2019s Better Meat Company, to illustrate the importance of recall preparation. A recall plan, which companies are now required to have, enables efficient preparation and prompt action that can limit the scope of a recall. To help you formulate your own plan, Small Plant News has developed this two-part supplement \u201cHow to Develop a Meat and Poultry Product Recall Plan: The Workbook.\u201d Part I features the fictitious entity, Fuerschlinger\u2019s Better Meat Company, and its recall plan. As a note, the names of individuals listed within this plan are fictitious, and any resemblance to places, names, and people are purely coincidental. Part II is the workbook portion you can use to record, gather, or compile information and begin constructing your own plan. It\u2019s important to note that no one plan can fit all companies\u2019 needs. This workbook merely serves as a guide to help you get started on this important food safety tool for your own business. 26", "Part I Fuerschlinger\u2019s Better Meat Company Meat and Poultry Product Recall Plan September 15, 2012 Approved by: Hermann Q. Fuerschlinger, Owner 27", "Small Plant News Guidebook Series Small Plant News Guidebook Series A Sample Recall Plan: The Workbook Introduction The Fuerschlinger\u2019s Better Meat Company Meat and Poultry Product Recall Plan will be reviewed biannually and revised by Fuerschlinger\u2019s Better Meat Company, as necessary, when personnel, procedures, processes, or other factors change. Identification of Recall Personnel (Recall Committee) Sally Fuerschlinger (Primary Recall Coordinator), Tel: (123) 456-7890, Fax: (123) 456-7890, E-mail: Sfuerschlinger@FuerschlingersBetterMeat.com Ralph Staff (Alternate Recall Coordinator), Tel: (123) 456-7890, Fax: (123) 456-7890, E-mail: Rstaff@FuerschlingersBetterMeat.com Alexandra Jones (Consumer Representative), Tel: (123) 456-7890, Fax: (123) 456-7890, E-mail: AJones@FuerschlingersBetterMeat.com Jeff Fuerschlinger (Public Affairs Representative), Tel: (123) 456-7890, Fax: (123) 456-7890, E-mail: Jfuerschlinger@FuerschlingersBetterMeat.com Herman Q. Fuerschlinger (Owner), Tel: (123) 456-7890, Fax: (123) 456-7890, E-mail:

Hfuerschlinger@FuerschlingsBetterMeat.com Determining Whether a Recall is Necessary The Fuerschlinger\u2019s Better Meat Company will collect and analyze all information and data it has regarding product that may be recalled. It will take into account the following factors: \u2022 Has adulterated or misbranded product been produced? \u2022 Has adulterated or misbranded product been shipped? \u2022 Where has the product been shipped? \u2022 Is the product in commerce? \u2022 Is the product available to consumers? 28", "29 U.S. Department of Agriculture \ Food Safety and Inspection Service A Sample Recall Plan: The Workbook Scope of Recall Fuerschlinger\u2019s Better Meat Company will assess the amount and type of product that is implicated in a recall. When the problem involves contamination with microbial pathogens, the recall should include all products produced under a single Hazard Analysis and Critical Control Point (HACCP) plan between performance of complete cleaning and sanitizing procedures. However, the act of sanitation does not necessarily define the scope of all product removal actions. For instance, with E. coli O157:H7, the company will also consider the use of source materials. Some examples of how to define the scope of product removal actions include: \u2022 Contamination of a vat of product with a foreign material; \u2022 Use of an incorrect label; or \u2022 Use of the same source of raw materials, in other lots, on other days of production. In addition, the Fuerschlinger\u2019s Better Meat Company will consider such factors as: \u2022 Coding of product; \u2022 Pathogen of concern; \u2022 Processing and packaging; \u2022 Equipment; \u2022 Our HACCP plan monitoring and verification activities (including microbiological testing); \u2022 Our Sanitation Standard Operating Procedure (SSOP) records; and \u2022 Whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected. The plan will specify how the company will determine the scope of the implicated product for various scenarios and contingencies.", "Small Plant News Guidebook Series Small Plant News Guidebook Series A Sample Recall Plan: The Workbook Records Company records are maintained in our office at 123 Brown Rd., Springfield, OH 12345. They are kept for a period of time that exceeds the shelf-life and expected use of our products and in accordance with FSIS regulations 9 CFR 320 and 9 CFR 381.175, and contain the following information: \u2022 Positive identification of products; \u2022 Distribution records (e.g., bills of sale, invoices, shipping papers, etc.); and \u2022 Production records that facilitate traceback of products and product ingredients. All of our records include the names and addresses of consignees, shipment methods, and dates of shipment. In addition, we maintain records of all of our suppliers of ground beef (e.g., names and lot numbers of suppliers, and production dates) in accordance with FSIS Directive 10,010.1. 30", "31 U.S. Department of Agriculture \ Food Safety and Inspection Service A Sample Recall Plan: The Workbook Depth of Recall The Fuerschlinger\u2019s Better Meat Company Recall Committee has developed a number of scenarios to determine the depth of the recall. Since they are proprietary designs, they are maintained in our office at 123 Brown Rd., Springfield, OH 12345. In the event of a recall, they will be made available to regulatory agencies upon request. The depth of a recall depends on the degree of hazard, the extent of distribution, and the level to which the recalled product was distributed. Levels of recall depth are categorized as: \u2022 Wholesale level: Product has been distributed to a warehouse or distribution center where it is not under the direct control of the producing company. \u2022 Retail level: Product has been received by retailers for sale to household consumers. \u2022 HRI level: Product has been received by hotels, restaurants, and institutional (HRI) customers. \u2022 Consumer level:

Product has been sold to consumers. Recall Communications We, at Fuerschlinger\u2019s Better Meat Company, consider the health and safety of our employees and the public our highest priority. As such, we have developed various communication methods to inform suppliers, consignees, and consumers about any product recalls we may be involved in. Please see the recall communication templates on pages 38-41. All of our communications will convey the following information: \u2022 If the product is subject to recall; \u2022 If further distribution or use of any remaining product should cease immediately;" "Small Plant News Guidebook Series Small Plant News Guidebook Series A Sample Recall Plan: The Workbook \u2022 If the direct consignee should, in turn, notify its consignees that received the product about the recall; \u2022 Instructions on what to do with the product; and \u2022 Our contact information (point of contact and telephone number). Recall Communication Implementation Fuerschlinger\u2019s Better Meat Company will attempt to contact all consignees or customers via the following methods (in this particular order) until a point of contact receives and acknowledges our communication: \u2022 Telephone; \u2022 E-mail; and \u2022 Fax. In addition, all consignees or customers shall be contacted via special delivery letters conspicuously marked (on the letter or envelope) \u201cURGENT \u2013 FOOD RECALL.\u201d Follow-up communications shall be sent to consignees or customers who fail to respond to initial recall communications within 24 hours. 32", "33 U.S. Department of Agriculture / Food Safety and Inspection Service A Sample Recall Plan: The Workbook Recall Communication Content All recall communications will be written in accordance with the following guidelines: \u2022 Be brief and to the point; \u2022 Clearly identify the product and any other pertinent, descriptive information including: o Product\brand name; o Product code; o Package\case size; o Package\case date code; o Lot number\expiration date; and o Universal Product Code (UPC). \u2022 Describe the risk involved in consuming the product; \u2022 Concisely explain the reason for the recall and the hazard involved; \u2022 Provide specific instructions on what should be done with the recalled product; \u2022 Request an official, written statement from consignees; \u2022 Provide a means for consignees (and other communication recipients) to report whether or not they have any of the product under their control; and \u2022 Include our company\u2019s contact information and a point of contact." "Small Plant News Guidebook Series Small Plant News Guidebook Series A Sample Recall Plan: The Workbook Responsibility of Recipient Consignees or customers who receive a recall communication should immediately carry out all instructions provided and, where necessary, extend the recall to their consignees or customers. Public Notification The class of a recall and the extent to which the product was distributed in commerce will determine the distribution of public notification by FSIS. Fuerschlinger\u2019s Better Meat Company will decide if the company will issue its own press release in addition to the Recall Release or Recall Notification Report issued by FSIS and how it will be issued. Public notification templates may be found on Pages 38-41. Effectiveness Checks In an effort to assess the progress and effectiveness of a recall, FSIS will conduct effectiveness checks to verify that all consignees (at the determined recall depth) have received notification about the recall and have taken appropriate action. Regardless of the recall scenario, all consignees will be contacted via the following methods (in this particular order) until we receive written acknowledgment from them: \u2022 Telephone call; \u2022 E-mail or Fax; \u2022 Special delivery letters; and \u2022 Personal visit. 34", "35 U.S. Department of Agriculture / Food Safety and Inspection Service A Sample Recall Plan: The Workbook

Fuerschlinger\u2019s Better Meat Company will consider the following information in regards to the recall effectiveness check process:

- \u2022 How much product is implicated in the recall?
- \u2022 How is the product identified to our customers\retailers (e.g., lot markings)?
- \u2022 How many locations did we ship the product to and where are they?
- \u2022 How did we communicate the product removal action to those who received it?
- o Did we document this contact?
- o Did we ask for and receive written acknowledgment from them?
- \u2022 What actions were taken with the product and by whom?
- \u2022 If product was destroyed, then was destruction witnessed and documented?
- o Were FSIS inspection program personnel present?
- \u2022 Is there a written record of:
- o When the issue was identified?
- o When customers were notified?
- o When we received notification that the product was either placed on hold or was no longer in a customer\u2019s control?
- \u2022 Can we account for most (or all) of the product?"

"Small Plant News Guidebook Series Small Plant News Guidebook Series A Sample Recall Plan: The Workbook Returned Product Control and Disposition Fuerschlinger\u2019s Better Meat Company will specify how the recalled product will be disposed of and how it will be controlled pending disposition. FSIS should be notified prior to disposition actions, which may include destruction or relabeling of product that is returned. If the product is destroyed, it will be rendered inedible for humans and animals. All labeling will be made unusable for trade.

36", "37 U.S. Department of Agriculture \ Food Safety and Inspection Service A Sample Recall Plan: The Workbook Recall Simulations Fuerschlinger\u2019s Better Meat Company will conduct biannual simulation exercises to evaluate our recall plan. The simulated recall will involve the selection, without prior notice to personnel involved in the exercise, of at least one product lot that has been distributed in commerce. A hypothetical reason for recalling the product will be specified and will involve the activation of the recall plan. The simulation will proceed at least to the point at which communication is made beyond the firm\u2019s organizational limits (full details of who will be contacted and how this will be established will be specified prior to the start of the exercise). In addition, the recall simulation exercises will include scenarios in which the recalled product has been shipped beyond the firm\u2019s initial customer to one or more of the consignee\u2019s customers. A recall simulation file is maintained by Fuerschlinger\u2019s Better Meat Company to record the details and results of all simulated recall exercises. It includes the following information:

- \u2022 Name, address and telephone number of clients (of the test lot);
- \u2022 Production records;
- \u2022 Inventory; and
- \u2022 Distribution of the test lot.

If problems are identified during a recall simulation exercise, our recall plan (and procedures) will be revised as necessary. The Fuerschlinger\u2019s Better Meat Company Recall Plan will be reviewed biannually and revised as necessary, when personnel, procedures, processes, and other factors change.

Recall Communication Templates

The enclosed recall communication templates on pages 38-41 will be used by the company to develop Letters to Customers and Press Releases relating to recalled product(s) during actual recalls and simulation exercises."

"Small Plant News Guidebook Series Small Plant News Guidebook Series A Sample Recall Plan: The Workbook RECALL COMMUNICATION TEMPLATE #1 Letter to Customers DATE CUSTOMER FIRM NAME & ADDRESS ATTN: CONTACT PERSON NAME & TITLE Re: RECALL OF TYPE OF PRODUCT Dear Sir or Madam: This letter is to confirm our telephone conversation that Fuerschlinger\u2019s Better Meat Company is recalling the following product because Specify Recall Reason: Describe the product, including name, brand, code, package size and type, establishment number, etc. We request that you review your

inventory records and segregate and hold the above product. If you have shipped any of this product, then we request that you contact your customers and ask them to retrieve the product and return it to you. Once you have retrieved all of the product, please contact us. We will arrange to have the product shipped to our facility. Please do not destroy the product. We will credit your account for returned products. We are undertaking this action in cooperation with the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS). FSIS officials may contact you to confirm that you have received this notice and are cooperating in this action. Your prompt action will greatly assist Fuerschlinder\u2019s Better Meat Company in this recall. If you have any questions, please do not hesitate to contact Sally Fuerschlinder at (123) 456-7890. Thank you for your cooperation. Sincerely, Hermann Q. Fuerschlinder, Owner 38", "39 U.S. Department of Agriculture \ Food Safety and Inspection Service A Sample Recall Plan: The Workbook RECALL COMMUNICATION TEMPLATE #2 Company Press Release

FUERSCHLINGER\u2019S BETTER MEAT COMPANY RECALLS [PRODUCT] DUE TO POSSIBLE LISTERIA CONTAMINATION [CITY], [DATE] \u2013 Fuerschlinder\u2019s Better Meat Company, a Springfield, Ohio, establishment, is recalling approximately [AMOUNT] pounds of [PRODUCT] that may be contaminated with Listeria monocytogenes]. The following products are subject to recall: \u2022 [IDENTIFYING INFO: TYPE OF CONTAINER, WEIGHT, \u201cBRAND NAME AND OTHER LABEL INFORMATION,\u201d ESTABLISHMENT NUMBER, CASE AND\OR DATE CODES] The products were produced [DATE] and distributed to [LEVEL OF DISTRIBUTION I.E. RETAIL ESTABLISHMENTS, INSTITUTIONS, ETC] in [STATES]. The problem was discovered through [SPECIFY HOW PROBLEM WAS DISCOVERED]. There have been [# or NONE] reports of illness associated with consumption of these products. Consumption of food contaminated with Listeria monocytogenes can cause listeriosis, an uncommon but potentially fatal disease. Healthy people rarely contract listeriosis. However, listeriosis can cause miscarriages and stillbirths, and can also cause serious and sometimes fatal infections in those with weak immune systems, such as infants, the elderly, persons with human immunodeficiency virus (HIV) infection, or those undergoing chemotherapy. Infection can spread to the nervous system, resulting in high fever, severe headache, neck stiffness, nausea, confusion and convulsions. Consumers with questions about the recall may contact the Fuerschlinder\u2019s Better Meat Company Consumer Representative, Alexandra Jones, at (123) 456-7890. Media with questions about the recall may contact the Fuerschlinder\u2019s Better Meat Company Public Affairs Representative, Jeff Fuerschlinder, at (123) 456-7890.", "Small Plant News Guidebook Series Small Plant News Guidebook Series A Sample Recall Plan: The Workbook RECALL COMMUNICATION TEMPLATE #3 Company Press Release FUERSCHLINGER\u2019S BETTER MEAT COMPANY RECALLS [PRODUCT] DUE TO UNDECLARED ALLERGEN [CITY], [DATE] \u2013 Fuerschlinder\u2019s Better Meat Company, a Springfield, Ohio, establishment, is recalling approximately [AMOUNT] pounds of [PRODUCT] due to an undeclared allergen [SPECIFY ALLERGEN]. The following products are subject to recall: \u2022 [IDENTIFYING INFO: TYPE OF CONTAINER, WEIGHT, \u201cBRAND NAME AND OTHER LABEL INFORMATION,\u201d ESTABLISHMENT NUMBER, CASE AND\OR DATE CODES] The products were produced [DATE] and distributed to [LEVEL OF DISTRIBUTION I.E., RETAIL ESTABLISHMENTS, INSTITUTIONS, ETC.] in [STATES]. The problem was discovered through [SPECIFY HOW PROBLEM WAS DISCOVERED]. Anyone concerned about an allergic reaction should contact a physician. Consumers with questions about the recall may contact the Fuerschlinder\u2019s Better Meat Company

Consumer Representative, Alexandra Jones at (123) 456-7890. Media with questions about the recall may contact the Fuerschlinger\u2019s Better Meat Company Public Affairs Representative, Jeff Fuerschlinger at (123) 456-7890. 40", "41 U.S. Department of Agriculture \ Food Safety and Inspection Service A Sample Recall Plan: The Workbook RECALL COMMUNICATION TEMPLATE #4 Company Press Release FUERSCHLINGER\u2019S BETTER MEAT COMPANY RECALLS [PRODUCT] THAT MAY CONTAIN [GLASS, PLASTIC, ETC.] [CITY], [DATE] \u2013 Fuerschlinger\u2019s Better Meat Company, a Springfield, Ohio, establishment, is recalling approximately [AMOUNT] pounds of [PRODUCT] that may contain pieces of [SPECIFY MATERIAL]. The following products are subject to recall: \u2022 [IDENTIFYING INFO: TYPE OF CONTAINER, WEIGHT, \u201cBRAND NAME AND OTHER LABEL INFORMATION,\u201d ESTABLISHMENT NUMBER, CASE AND\OR DATE CODES] The products were produced [DATE] and distributed to [LEVEL OF DISTRIBUTION I.E. RETAIL ESTABLISHMENTS, INSTITUTIONS, ETC] in [STATES]. The problem was discovered through [SPECIFY HOW PROBLEM WAS DISCOVERED]. There have been [# or NONE] reports of injury from consumption of these products. Anyone concerned about an injury from consumption of the products should contact a physician. Consumers with questions about the recall may contact the Fuerschlinger\u2019s Better Meat Company Consumer Representative, Alexandra Jones, at (123) 456-7890. Media with questions about the recall may contact the Fuerschlinger\u2019s Better Meat Company Public Affairs Representative, Jeff Fuerschlinger, at (123) 456-7890.", "Small Plant News Guidebook Series Small Plant News Guidebook Series A Sample Recall Plan: The Workbook Part II The Workbook RECALL PLAN Establishment name: \_\_\_\_\_

Establishment location: \_\_\_\_\_ FSIS establishment number: \_\_\_\_\_ Date: \_\_\_\_\_

42", "U.S. Department of Agriculture \ Food Safety and Inspection Service A Sample Recall Plan: The Workbook Recall Coordinator (person responsible for coordinating recalls at this firm): Name: \_\_\_\_\_

Phone: \_\_\_\_\_  
Fax: \_\_\_\_\_  
E-mail: \_\_\_\_\_  
Recall Team\Contacts Name: \_\_\_\_\_

Contact information (company, address, phone number, fax number, e-mail address) Role (in plant, supplier, distributor, customer, District Office) 43", "Small Plant News Guidebook Series Small Plant News Guidebook Series A Sample Recall Plan: The Workbook \_\_\_\_\_

Procedures for Determining a Recall Health Hazard Evaluation \u2022 Is there an undeclared allergen in the plant\u2019s product? \u274f Yes \u274f No If yes, describe the details. \_\_\_\_\_

\u2022 Was product underprocessed? \u274f Yes \u274f No If yes, describe the details. \_\_\_\_\_

\u2022 Has product tested positive for a pathogen? \u274f Yes \u274f No If yes, describe the details. \_\_\_\_\_ \u2022 Are there reports of disease or injury occurring due to product? \u274f Yes \u274f No If yes, describe the details. \_\_\_\_\_

44","45 U.S. Department of Agriculture \ Food Safety and Inspection Service A Sample Recall Plan: The Workbook

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\u2022 How did the plant receive word of a problem with the product? \u2022 How serious is the hazard? \u2022 Are some groups at more risk to the hazard in the product? \u2022 Other details:","Small Plant News Guidebook Series Small Plant News Guidebook Series A Sample Recall Plan: The Workbook

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Records What system of records will be used to manage and track the recall? \u274f Product identification, product coding, product lots \u274f Distribution records \u274f Consignee records Other details related to records: Include a copy of all records used for this recall as an Appendix to this plan. Recall Depth Check all levels that the recall includes. \u274f Wholesale (warehouse, storage) \u274f Retail \u274f Hotels, restaurants, and institutions \u274f Consumer \u274f Other (describe)

46","U.S. Department of Agriculture \ Food Safety and Inspection Service A Sample Recall Plan: The Workbook Recall Notice (See sample of Recall Notice in Guidebook.) Include a copy of the Recall Notice used as an Appendix to this plan. Recall Notice Tracking The Recall Notice was issued to the following companies or individuals. (Include all records, such as fax received receipts, copies of e-mail responses, etc.) Notice sent to (company\ individual name) Method used to send the Notice Date the Notice was sent Date response was received indicating a response from company\ individual Directions in the Notice were followed? Phone Yes Fax No E-mail Other 47","Small Plant News Guidebook Series Small Plant News Guidebook Series A Sample Recall Plan: The Workbook

Record of Returned Product and Product Disposition Company returning product Product description (lot, condition) Date returned product was received Who received the product Product disposition FSIS contacted? Date of last recall simulation: 48","49 U.S. Department of Agriculture \ Food Safety and Inspection Service A Sample Recall Plan: The Workbook To access the Introduction to Microbiology of Food Processing guidebook, go to <http://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/newsletters/small-plant-news>","Small Plant News Guidebook Series Small Plant News Guidebook Series A Sample Recall Plan: The Workbook To access the Help for Dealing With Plant Emergencies guidebook in English, Korean, and Spanish, go to <http://www.fsis.usda.gov/wps/portal/fsis/>

newsroom\meetings\newsletters\small-plant-news. 50", "How to Develop A Recall Plan U.S. Department of Agriculture \ Food Safety and Inspection Service The Small Plant Help Desk A resource for small and very small plants Call Toll-free 1-877-FSISHelp (1-877-374-7435). Knowledgeable USDA-FSIS specialists from the Outreach and Partnership office are available weekdays 8:00 AM to 4:00 PM EST to give you personal assistance on matters relating to the regulation of meat, poultry, and processed egg products. Or e-mail questions to InfoSource@fsis.usda.gov. 51", "Small Plant News Guidebook Series United States Department of Agriculture Food Safety and Inspection Service The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual\u2019s income is derived from any public assistance program. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA\u2019s TARGET Center at (202) 720-2600 (voice and TDD). To file a complaint of discrimination, write to USDA, Office of the Assistant Secretary for Civil Rights - Director, Office of Adjudication, 1400 Independence Avenue, S.W., Washington, DC 20250-9410 or call (800) 795-3272 (voice) or (202) 720-6382 (TDD). USDA is an equal opportunity provider and employer. Office of Outreach, Employee Education, and Training Slightly Revised and Reprinted September 2015"]}, {"file\_name": "FSIS\_GD\_2011\_0001", "title": "Compliance Guidelines for Use of Video or Other Electronic Monitoring or Recording Equipment in Federally Inspected Establishments", "num": "FSIS-GD-2011-0001", "id": "12a5850fa0abb52a6a13c308ac1885ad2581ba38b12dd8b1274e019e02ae2996", "co\_rpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Compliance\_Guidelines\_for\_Use\_of\_Video\_082611.pdf", "type": "pdf", "n\_pages": 13, "word\_count": 4939, "text\_b\_y\_page": ["DRAWING \u2013 BLUEPRINT GUIDE 1 I. PURPOSE This is a guide for preparing drawings or blueprints, supplemental information, and room specifications which are to be submitted for approval as outlined in 9 CFR 592.140, Regulations Governing the inspection of Eggs and Egg Products. Plant drawings are for the purpose of establishing the area of the new official plant, plant layout, types of construction, floor drainage, location and types of equipment, air systems and description of other principal facilities at the location. There are specific facility and equipment requirements provided throughout the regulations and in applicable 3-A and E-3-A Sanitary Standards and Accepted Practices. II. SUBMITTAL OF PLANS The applicant is to submit drawings and supplemental information for approval to the Frontline Supervisor responsible for oversight of the new official egg products plant as part of the Application for Federal Inspection Service for egg products. The drawings are to consist of complete floor plans and a plot plan. Supplemental information and room specifications are to accompany the drawings. Upon receipt of the submitted drawings, the supervisor will make a preliminary review to determine their accuracy and completeness. Any necessary changes or corrections will be requested by the supervisor. The supervisor will return drawings to the applicant for corrections before a final review. A final review and approval of the submitted drawings will be determined by the Frontline Supervisor. A final survey of the finished facility will also be conducted by the supervisor or a designee followed by the communication of

conformance with provisions of the approval and the regulations by the Frontline Supervisor.

III. GENERAL REQUIREMENTS The drawings may be regular blueprints or ink drawings on durable-weight drawing paper. The sheet size of the print should not exceed 34 by 44 inches. The wording on each print is to be legible, all lines sharp and clear, and drawings properly drawn to scale. When blueprints are prepared, we recommend the plant keep the original drawings for future use. If revisions then become necessary at a later date, changes can be made on the original drawing and new copies prepared and submitted. This would eliminate the need for preparing complete new drawings and also reduce the use of overlays. Each individual prints is to show: (1) the scale used; (2) the north point of the compass; and (3) the firm name, street, city, State, and ZIP code, or an accurate description of the

location.", "DRAWING \u2013 BLUEPRINT GUIDE 2 IV. PLOT PLAN The plot plan of the entire premises is to include: A. The location of all buildings, roadways, alleys, drains, catch basins, wells, reservoirs, storage tanks, and any other major structure. B. Nearby buildings and types of businesses located on adjoining property. C. The drainage and slope of terrain. D. The character and surfacing of roadways, driveways, streets, and loading areas (including the loading area for a refuse room), and the paved tanker truck bays (with drainage) for shipping and receiving tankers. The plot plan may be drawn to scale of 1\32 inch per foot. V. FLOOR PLAN A. The floor plan drawings are to include the entire plant. a drawing is required for each floor of the plant and should accurately illustrate and describe the facilities. Each room is to be identified.

Detailed prints for processing rooms should be drawn to a scale of 1\4 inch per foot. If a print includes only non-processing areas, it may be drawn to a scale of 1\8 inch per foot. Include the names of other firms, if any, occupying the building, their type of business, and the space occupied by them. If any rooms of the official plant will be used for purposes other than ones related to operation of the egg products plan, indicate this on the drawing and include a statement of explanation. B. Essential items to show on floor plans are the location of: 1. Walls, doors, hallways, stairways; 2. Intake and exhaust systems; 3. Hand washing facilities, floor drains, channel drains, toilet facilities, hose connections with hot and cold water for cleanup purposes; and 4. Storage tanks, conveyors, equipment racks, and other principal pieces of equipment. C. The prints should indicate the slope of floors to drains openings or channel drains by either grade lines or arrows. Floors which require drains shall slope more than 1\8 inch per foot to drains. Channel drains should have concave bottoms and must be self-draining. Channels should be at least 10 inches wide. They are to be provided with grates or covers designed for safety and efficient recovery of water. Prints for newly-constructed plants are to include the approximate location of all under floor or underground drainage lines. This may be added to the plot plan or floor plan of the entire plant.", "DRAWING \u2013 BLUEPRINT GUIDE 3

D. Air systems for providing a positive flow of filtered air to breaking rooms, product packaging rooms (except for dried egg white packaging rooms), and blending rooms are to be shown with the following detail: 1. Pickup points of outside air; 2. Locations of fans; 3. Locations of air filters; and 4. Air distribution points in the room 5. Including pickup points for return air The air system is to be designed to supply filtered, outside air at a reasonable working temperatures. An adequate volume of air is needed to \u2013 pressurize\u201d each processing room so that the air would move outward through any openings in the room. The filtered air should enter the room at a location which is opposite from the side where most of the air is expected to flow out of the room. Indicate the efficiency of the air filtration system. The location of all exhaust

fans is to be shown. If the exhausts are ducted, the ducts are to be shown. E. Show the location of air compressors supplying air to breaking machines, packaging equipment, vacuum systems, and all pickup points of outside air. This requirement is related only to product contact air or air for product contact surfaces. New installations (air compressors, air filters, etc.) are to meet the standards set forth in E-3-A accepted practices. F. The following require detailed drawing of equipment and facilities. Special items to be shown are:

1. Transfer rooms a. Shell egg washers connected directly to drains or piped to drains so waste water does not flow over the floor.
- b. Shell egg washers ducted or exhausted to the outside.
2. Egg breaking rooms a. The number of stations at hand breaking tables or individual breaking machines model numbers.
- b. Individual hand washing facilities.
- c. A detailed drawing of the pumping and reexamination system if liquid egg is pumped from the breaking machines. The drawing may be shown a supplemental print.
- d. The shell disposal system.
- e. Churns, strainers, and other principal pieces of equipment.

3. Equipment washing rooms or areas a. All wash tanks and the number of compartments of each which are used for cleaning equipment or containers. Indicate that these are provided with hot", "DRAWING \u2013 BLUEPRINT GUIDE 4 and cold water and have drain lines trapped and connected to the plant drainage system.

- b. Utensil and equipment drain and aeration racks.
4. Mixing, blending, and fermentation rooms a. The capacity of each liquid egg storage tank; whether each is insulated or refrigerated; horizontal or upright; whether each is equipped with an agitator, covers, and thermometers.
- b. The layout of pasteurizing system (press holding tubes, etc.).
5. Egg products packaging rooms a. Principal pieces of equipment (draw off tank, scales, etc.), hand washing facilities, floor drains, and hot and cold water outlets for cleanup purposes.
6. Edible ingredient area where ingredients are weighed and mixed
7. Egg product drier rooms a. Drier(s) and all component parts
- b. The locations of air inlets to the drier, air filters, exhaust, and heater. The type of head, i.e., steam, direct or indirect gas.
- c. The powder conveying system. If a pneumatic system, the source of air pickup, location of air filters, and type of powder cooling facilities if included as part of the system.
8. Dried egg products heat treatment room a. The location of heat sources, fans, and air distribution points.
- b. Temperature recording instrument data
9. Laboratory A11 air intake and exhaust systems and drains. The drainage system for bacteriological laboratories is not to be connected with other drainage lines within the plant. Describe briefly how laboratory wastes (dry and liquid) are handled for bacteriological laboratories. This can be added as supplemental information. (see section VI of this guide)
10. Rooms for handling and packaging of inedible egg The straining, mixing, and packing areas including hot and cold water connections for cleanup, floor drains, and a forced exhaust to the outside.
11. Shell and refuse disposal rooms Location of floor drains, hot and cold water connections for cleanup, and forced exhausts to the outside. These rooms are not to open directly into processing rooms.
12. Toilet facilities Exhaust fans, drainage lines, lockers, location of toilet bowls, etc. in new or remodeled construction, the drainage system from toilets is not to be connected with other", "DRAWING \u2013 BLUEPRINT GUIDE 5 drainage systems within the confines of the plant. Other acceptable sewage line safety devices may be acceptable in lieu of this requirement.
13. Office space for USDA inspector G. Rooms and areas requiring only layout drawing;

  1. Empty egg case storage,
  2. Shell egg cooler,
  3. Freezer,
  4. Dried product holding room or area,
  5. Edible ingredient storage room,
  6. Cleaning compound storage room or area,
  7. Insecticide and rodenticide storage room or area,
  8. Packaging material and can storage room,
  9. Hallways,
  10. Maintenance shop,
  11. Dressing

rooms and lunchrooms.

**VI. SUPPLEMENTAL INFORMATION** The following are examples of information which may be submitted as descriptive side notations on the prints or on supplemental enclosures. This is recommended as a means of clarifying the prints and to minimize information on the drawings so they can be easily read:

- A. Kind and description of pasteurizer and flow-diversion valve.
- B. Description of product contact surfaces of drying system or a statement that the product contact surfaces meet E-3-A standards for spray drying systems.
- C. Methods of adding free flowing ingredients and other edible ingredients to dried egg products.
- D. Type of temperature recording devices used for recording the temperature of dried products and heat treatment rooms.
- E. A statement that an ample supply of hot water is available for cleanup and full operation of the plant.
- F. Indicate that all floor drains are trapped.
- G. A statement that all lighting fixtures in processing rooms are fitted with protective devices.
- H. Indicate all doors of processing rooms are self-closing.
- I. Hand washing facilities in processing areas are operated by other than hand controls.
- J. For new facilities only. Submit the original and two copies of a water potability certification showing municipal water and\or each private well has been tested and found to be satisfactory under the authority of a State or municipal health agency, or by USDA.
- K. Forms will be provided for reporting information on sewage disposal and compliance with the Federal Water Pollution Control Act.
- L. Capacity of fans (CFM) for the air systems."

"DRAWING \u2013 BLUEPRINT GUIDE 6 M. A statement that the air compressor system meets E-3-A standards for product contact air.

- N. Describe what heating or air-condition facilities are provided for the plant.
- O. A statement that the drier systems meet E-3-A standards.
- P. Method of shell disposal.
- Q. Any other reference to E-3-A standards that may aid in the review of the blueprints.

**VII. ROOM SPECIFICATION SHEET** The following information is to be submitted in tabular form for each room and a copy attached to each set of prints (see enclosed sample);

- A. The height and type of ceilings.
- B. The type of floor and wall construction. If more than one type, show each type of construction. Include any appropriate information of sealing or painting of wall surfaces.
- C. The number of men and women employed at the plant for each shift and toilet facilities available.

**VIII. CHANGES AND REVISIONS OF OFFICIAL PLANT** When changes in plant construction, facilities, and equipment are planned, the proposed changes are to be discussed with a representative of the Frontline Supervisor and revised prints submitted and approved prior to making the changes. Failure to comply with this requirement can be costly to a plant in terms of operating delays or corrections to unacceptable facility changes. Proposed changes and revisions may be submitted in draft form for review by:

- A. A completely revised sheet showing existing construction, equipment, and facilities with the proposed alterations and additions, or
- B. An overlay print drawn to the same scale as existing print covering the area to be modified or revised.

**IX. APPROVAL OF PRINTS AND PLANS** If the examination of the drawings, supplemental information and room specification show that they meet regulatory requirements, approval will be given. The set of the approved prints will be maintained by the plant submitting the prints. Plant management is to make their file of approved blueprints readily available to the egg products inspector and the Frontline Supervisor when requested. A final review and approval of the submitted drawings will be determined by the Frontline Supervisor. A final survey of the finished facility will also be conducted by the supervisor or designee followed by the communication of conformance with provisions of the approval and the regulations by the Frontline Supervisor. Approved prints of a new plant requesting inspection service, or for changes in an existing plant, does not constitute

operating approval. A final survey must be made by the Frontline Supervisor or", "DRAWING \u2013 BLUEPRINT GUIDE 7 a designee to determine if the plant construction and facilities are in accordance with the approved prints and the regulations. On new and existing plants, a written communication to that effect will then be provided to the applicant by the Frontline Supervisor.", "DRAWING \u2013 BLUEPRINT GUIDE 8 ROOM SPECIFICATION SHEET FOR BLUEPRINTS OF OFFICIAL EGG PRODUCTS PLANTS ROOM HEIGHT OF CEILING CEILING CONSTRUCTION FLOOR CONSTRUCTION WALL CONSTRUCTION Men\u2019s toilet facilities: Number of lavatories \_\_\_\_\_ Urinals \_\_\_\_\_ Stools \_\_\_\_\_ Maximum number of male employees per shift \_\_\_\_\_ Women\u2019s toilet facilities: Number of Lavatories \_\_\_\_\_ Stools \_\_\_\_\_ Maximum number of female employees per shift \_\_\_\_\_

"]}, {"file\_name": "FSIS\_GD\_2011\_0006", "title": "Examples of Nutrition Facts Panels for Ground Products", "num": "FSIS-GD-2011-0006", "id": "541d3bf328d4c7119b27b393c565962b8a1cab4d61c3f6162340a096976bc67b", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Nutrition\_Panel\_Format.pdf", "type": "pdf", "n\_pages": 11, "word\_count": 1786, "text\_by\_page": ["FSIS Listeria Guideline January 2014 1 FSIS Compliance Guideline: Controlling Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products January 2014", "FSIS Listeria Guideline January 2014 2 Purpose This compliance guideline provides specific recommendations that official establishments producing post-lethality exposed ready-to-eat (RTE) meat and poultry product may follow to meet the requirements of 9 CFR part 430, the Listeria Rule. It also provides information on sanitation, testing for Listeria monocytogenes (Lm), and prevention of cross contamination of post-lethality exposed, RTE meat and poultry products. This document replaces previous versions of the FSIS Listeria Guideline and Q&As. FSIS has revised this final version of the guideline to address comments on the draft version that was issued in September 2012. It also provides new information on holding products in response to FSIS\u2019s policy and procedures on not applying the mark of inspection pending certain test results. FSIS also revised the guidance to make clear that in addition to meeting the requirements of the Listeria Rule, establishments must meet the requirements of 9 CFR 416, Sanitation, and 9 CFR 417, HACCP Systems, as well as other applicable regulations. FSIS also revised the guideline to provide additional information on labeling RTE products and clarifications to labeling guidelines (Attachment 1.1: Resource 1). In addition, FSIS revised the guideline to provide updated information on the impact of multiple processing steps (hurdle effect) on the control of Listeria growth, as well as new information regarding controls for reworked product. The updated guideline also provides information on the pros and cons of compositing food contact surface samples at the laboratory. In addition, FSIS updated the guideline to clarify actions establishments should take in response to a Listeria spp. positive result in the product when establishments choose to sample products in addition to food contact surfaces (Section 3.6). Updated information is also included on the FSIS RTEPROD sampling program. This document provides guidance to assist establishments in meeting FSIS regulations. Guidance represents best practice recommendations by FSIS, based on the best scientific and practical considerations, and does not represent requirements that must be met. Establishments may choose to adopt different procedures than those outlined in the guideline, but they would need to support why those procedures are effective in controlling hazards from

Lm in post-lethality exposed RTE products. By using the recommendations in the guideline, establishments would not need to provide further support for their procedures. Summary of Changes Chapter 1: This chapter has been revised to provide clear, easy to follow information regarding the requirements of the Listeria Rule. Although this information has not changed significantly since the May 2006 version of the Compliance Guideline, FSIS recommends that establishments review this information to ensure that they are in compliance with the regulation. The information may be useful to new establishments that are starting production. In the revised version: "Step-by-step instructions have been provided, to assist establishments in determining whether their product is covered by the Listeria Rule. The requirements and recommendations for each control alternative are described." "FSIS Listeria Guideline January 2014 3" In addition, a glossary section has been provided with each chapter to further clarify the meaning of the terms used in the guidance and the Listeria Rule. Resource 1 (Attachment 1.2) has been updated to provide information about products that receive a full lethality that are not considered RTE. Chapter 2: This chapter provides updated technical information about establishing control alternatives under the Listeria Rule. In the revised version: "More in-depth information has been provided in Appendix 2.1 regarding validation of post-lethality treatments and antimicrobial agents. In addition, sanitation guidelines have been revised to include a description of intensified sanitation conducted in response to positive results. The reference section has been updated to provide more information about new technologies to control Listeria. New information has been provided in Appendix 2.3 on developing establishment employee training programs for implementing the Listeria Rule. Chapter 3: This chapter provides new and updated information on developing a Listeria Control Program to test for Lm or an indicator organism on food contact surfaces (FCS). In the revised version: "Updated information on routine testing for Listeria spp. under the three control alternatives is provided. Although there have been no changes to sampling frequency recommendations for Listeria spp., this revised chapter provides further guidance on meeting the recommended sampling frequencies and the number of samples to collect. Also, further clarification has been provided regarding FSIS expectations for sample collection and laboratory analysis of the samples. Finally, information has been provided on product and non-food contact testing (although not required by the Listeria Rule) to provide establishments with more information about the safety of their products and sanitary conditions in their food-processing environments. Chapter 4: This chapter provides new and updated information on developing enhanced sampling programs for Listeria in response to positive results from routine sampling. In the revised version: "A new table is provided (Table 4.1), clarifying timeframes for follow-up and intensified sampling, as well as hold and test of product. Intensified sampling is defined to provide establishments with more information on how to find and address the source of positive results. In addition, new information is provided on identifying and addressing Listeria trends." "FSIS Listeria Guideline January 2014 4" Findings from Food Safety Assessments (FSA) performed by FSIS in response to Lm positives have also been provided to increase awareness of common problems and lessons learned from FSA reviews. How to Use this Document The updated information in this revision of the Compliance Guideline should help establishments find specific information on the control of Lm, as needed. A glossary has been added at the end of each chapter to provide a better understanding of terminology found

in the text. Terms in the glossary have been bolded the first time they appear in the text. Boxes have been provided giving more information about points made in the text. Appendices have also been added to the end of each section to provide more detailed information regarding concepts introduced in the text. Q&A's have been incorporated into the document to assist establishments in finding specific information. If the desired information cannot be found within the Compliance Guide, FSIS recommends that users search Listeria Q&As in the AskFSIS database or submit questions through AskFSIS. Documenting these questions helps FSIS improve and refine present and future versions of the Compliance Guideline and associated issuances." , "FSIS Listeria Guideline January 2014 5 Table of Contents Introduction Page Chapter 1: Requirements of the Listeria Rule 1.1 Background 9 1.2 How Do I Determine whether My Product is Covered by the Listeria Rule? 11 1.3 The Listeria Rule Alternatives 12 1.4 Requirements for Establishments Under all Three Alternatives 16 1.5 Labeling 18 1.6 Glossary 18 1.7 References 19 Attachments 1.1 Control Requirements for Listeria monocytogenes 21 1.2 Chart of RTE vs. NRTE Products: Resource 1 22 Appendices 1.1 Product Types 24 1.2 Labeling 27 Chapter 2: FSIS Control Measures for Listeria 2.1 Post Lethality Treatments (PLT) 30 2.2 Antimicrobial Agents and Processes (AMAP) 32 2.3 Sanitation 37 2.4 Expected Levels of Control 38 2.5 Training 39 2.6 New Technology and New Ingredient Review 40 2.7 Glossary 41 2.8 References 41 Attachments 2.1 Post-lethality Treatments 46 2.2 Antimicrobial Agents or Processes 48 Appendices 2.1 Validation 55 2.2 Sanitation 68 2.3 Training 81 Chapter 3: Listeria Control Program: Testing for Lm or an Indicator Organism 3.1 Sampling for Lm or an Indicator Organism 85 3.2 Design of the Listeria Control Program 85 3.3 Routine Sampling Program 88 3.4 Frequency of Sampling and Explanation of this Frequency 90 3.5 Sample Collection and Laboratory Testing Methods 94 3.6 Other Routine Sampling 97 3.7 Glossary 100 3.8 References 101 Attachments 3.1 Possible Food Contact and Non-Food Contact Sites 102", "FSIS Listeria Guideline January 2014 6 Appendices 3.1 FSIS RTE Sampling Program 103 3.2 FSIS Sampling Procedure 107 3.3 Sample Collection and Laboratory Testing Methods 110 Chapter 4: Enhanced Sampling Program 4.1 Follow-up Sampling 115 4.2 Intensified Sampling 117 4.3 Hold and Test 118 4.4 Reprocessing Lm Contaminated Product 121 4.5 Determining Listeria Trends 122 4.6 Glossary 124 4.7 References 125 Appendices 4.1 Sampling Scenarios by Alternative 126 4.2 Hold and Test Scenario 129 4.3 Listeria Trends Examples 134 4.4 Findings from Food Safety Assessments (FSAs) 139 4.5 Response to Comments 142", "FSIS Listeria Guideline January 2014 7 Introduction Listeria monocytogenes (Lm) is a pathogen that can contaminate ready-to-eat (RTE) meat and poultry products and causes the disease listeriosis. Listeriosis is estimated to cause approximately 1,600 foodborne illnesses, 1,500 hospitalizations, and 260 deaths in the U.S. annually (Scallan et al., 2011). In most healthy individuals, listeriosis causes flu-like symptoms; however, in highly susceptible populations (e.g., the elderly, pregnant women, and immunocompromised individuals), listeriosis can lead to spontaneous abortion, septicemia, meningitis, and even death. Several outbreaks of listeriosis have been linked to the consumption of ready-to-eat (RTE) meat and poultry products contaminated with Lm. Lm is widely distributed in the environment; it is found in the air, soil, water, dust, and plant material, including silage. As such, Lm may enter the environment of processing plants and subsequently contaminate RTE meat or poultry products, as well as other ingredients. Lm has ample opportunity to occupy and thrive in various niches in a production facility, such as on floors, in drains, or in standing water. Without proper sanitation and

employee hygiene practices, Lm can easily cross-contaminate processing equipment, gloves or aprons of employees, and product. Lm has unique growth characteristics that can make it a formidable pathogen to control in the processing environment. Specifically, Lm has the ability to grow in cool damp environments where other pathogens may not and is capable of surviving freezing temperatures. Listeria species (Listeria spp.) also exhibit heat and salt tolerance. Lm is known to form biofilms on food contact surfaces (FCSs) and non-food contact environmental surfaces and, as a result, persists on these surfaces despite aggressive cleaning and sanitizing. Once Lm has established a niche, it may persist in the environment for long periods of time until the niche is identified and eliminated. RTE products are of particular concern for contamination with Lm because they may support the growth of the pathogen during refrigerated storage. In addition, since RTE products are often consumed without further cooking, there is a greater possibility of the occurrence of foodborne illness from these products if they become contaminated. Lethality treatments such as cooking meat and poultry products generally eliminate Lm; however, RTE products can be recontaminated by exposure to the environment after the lethality treatment during peeling, slicing, repackaging, and other processing steps. By controlling sanitation in the post-lethality processing environment or implementing interventions in their products, establishments can ensure that their RTE products do not become contaminated with Lm. In 2003, FSIS issued 9 CFR part 430, Control of Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Products (Listeria Rule).

According to the Listeria Rule, RTE products are considered adulterated if they contain Lm or come in direct contact with a FCS that is contaminated with Lm. FSIS testing has shown that levels of Lm in RTE meat and poultry products have decreased as a result of science-based regulations and industry efforts. However, the pathogen continues to contaminate RTE products at low levels, and illnesses from Lm-contaminated RTE products continue to occur. Furthermore, contaminated RTE products--both those that support the growth of Lm and those that do not--have been shown to cross contaminate other RTE foods at retail, exacerbating the risk of illness. Finally, the infectious dose is thought to be low for highly-susceptible populations. Therefore FSIS has maintained a \u201czero tolerance\u201d for the pathogen in RTE products and continues to strengthen programs and recommendations to reduce or eliminate Lm from RTE products." "FSIS Listeria Guideline January 2014 8 On December 10, 2012, FSIS issued a Federal Register notice (FRN), Not Applying the Mark of Inspection Pending Certain Test Results. The FRN announced that the Agency is changing its procedures and will withhold its determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received. The policy and procedures announced in the Federal Register became effective February 8, 2013. This guideline provides information for establishments to hold RTE products when FSIS tests product or food contact surfaces for Lm. This guideline provides information that establishments may use to meet the requirements of the Listeria Rule. It also provides \u201csafe harbors\u201d that establishments can implement to help ensure that the requirements are met." "FSIS Listeria Guideline January 2014 9 Chapter 1 FSIS Listeria Guideline: Requirements of the Listeria Rule 1.1 Background 1.2 How Do I Determine whether My Product is Covered by the Listeria Rule? 1.3 The Listeria Rule Alternatives Table 1.1: Listeria Control Alternatives 1.4 Requirements for Establishments Under all Three Alternatives 1.5 Labeling 1.6 Glossary 1.7 References Attachments 1.1 Control Requirements for Lm 1.2 Chart of

RTE vs. NRTE Products: Resource 1 Appendices 1.1 Product Types 1.2 Labeling This chapter provides information establishments can use to meet the regulatory requirements of 9 CFR part 430 (the Listeria Rule). 1.1 Background After several large outbreaks of listeriosis starting in the 1980s, FSIS and FDA worked together to implement strategies to decrease foodborne illness from Listeria monocytogenes (Lm). In September 2003, FDA and FSIS published the Quantitative Assessment of Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods.\u201d This risk assessment indicated that deli meats and hotdogs posed the greatest per serving risk of illness and death from Lm. In May 2003, FSIS issued the \u201cFSIS Risk Assessment for Listeria monocytogenes in Deli Meats.\u201d This risk assessment indicated that the use of a combination of growth inhibitors and post-lethality interventions to control Lm in deli meats exposed to the environment after the lethality treatment has the greatest impact on lowering the risk of illness or death from Lm. The Agency used these risk assessments as resources in developing the regulations to control Lm in RTE meat and poultry products. In 2003, FSIS issued the interim final rule, Control of Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Products (the Listeria Rule). The Listeria Rule codified the regulations establishments are required to follow to produce safe RTE products. According to the Listeria Rule, Lm is a hazard that establishments producing post-lethality exposed RTE products must control. Establishments can control Lm in the product through their Hazard Analysis and Critical Control Point (HACCP) plans or prevent Lm in the post-lethality processing environment through a Sanitation Standard Operating Procedure (SOP) or other prerequisite program. According to the Listeria Rule, post-lethality exposed RTE products are considered adulterated if they contain Lm or come in direct contact with a food contact surface (FCS) that is contaminated with Lm. The Listeria Rule established three alternative methods establishments can use in controlling Lm contamination of post-lethality exposed RTE products.", "FSIS Listeria Guideline January 2014 10 \u2022 Under Alternative 1, an establishment applies a post-lethality treatment (PLT) to reduce or eliminate Lm and an antimicrobial agent or process (AMAP) to suppress or limit growth of Lm (see Chapter 2 for more information on PLTs and AMAP). \u2022 Under Alternative 2, an establishment applies either a PLT or an AMAP. \u2022 Under Alternative 3, the establishment does not apply any PLT, AMAP; instead it relies on its sanitation program to control Lm. These alternatives increase in the stringency of their control from Alternative 3 to Alternative 1 and FSIS samples establishments in Alternative 3 at a higher rate than those in Alternative 1. The Listeria Rule only applies to products that are RTE and exposed to the environment after the lethality step (post-lethality exposed). The lethality step can be defined as cooking or another process (such as fermentation or drying) that results in a product that is safe for consumption without further preparation. NOTE: Products that are considered RTE but not post-lethality exposed are not subject to the Listeria Rule but are still sampled under the RTEPROD\_RAND project code (see Appendix 3.1 for more information on FSIS RTE sampling projects).", "FSIS Listeria Guideline January 2014 11 1.2 How Do I Determine whether My Product is Covered by the Listeria Rule? Step 1. Determine whether the product is ready-to-eat (RTE). \u2022 A product is considered RTE if there is a standard of identity<sup>1</sup> defining it as fully cooked (e.g., hotdogs or barbecue) or a common or usual name that consumers understand to refer to RTE product (e.g., p\u00e2t\u00e9), or if it meets the definition in the Listeria Rule (9 CFR 430.1). \u2022 HACCP regulations require that the establishment support that its food safety system controls possible

hazards in the product, and that the establishment documents this support. For more information, see Section 1.4. \u2022 Examples of RTE products: deli products, hotdog products, whole hams, sausages, meat salads, and other products that have been treated with a lethality step. \u2022 See Attachment 1.2 for further determination if a product is RTE or not ready-to-eat (NRTE). \u2022 NRTE products are not covered by the Listeria Rule. Step 2. Determine whether the product is postlethality exposed. \u2022 If the product is RTE, determine whether the product is exposed to the environment after the lethality treatment (e.g., cooking) and before packaging. \u2022 Examples of post-lethality exposure: o Product that is exposed to the environment after the lethality step during processing, slicing, freezing, or packaging; o Product that is removed from the cooking bag at an official establishment and sliced or cut up and re-packaged; and o Product that is acidified\fermented or salt-cured or dried and smoked and then packaged. \u2022 Examples of post-lethality exposed RTE products may include: sliced roast beef, cooked ham for slicing, hotdogs, fermented sausages, cured ham, and jerky. Step 3. Determine whether the product is covered by the Listeria Rule. \u2022 If product is RTE and post-lethality exposed it is subject to the Listeria Rule. \u2022 If product is RTE but not post-lethality exposed it is not subject to the Listeria Rule. 1 Standards of identity for meat and poultry products can be found in 9 CFR Part 319. Product Considerations Note: See Appendix 1.1 for more examples. \u2022 Frozen products may be considered RTE if they do not contain safe handling instructions and they do not need to be cooked for safety (although they may be heated to increase palatability). \u2022 Cook-in-bag products that remain in the same bag until the product leaves the establishment are not considered post-lethality exposed. \u2022 Hot-filled products at 160\u00b0F (or other lethality temperatures), such as fats and lards, are considered RTE but not considered post-lethality exposed. \u2022 Soups and other products that are cooked to eliminate pathogens and hot packed in the final packaging are RTE but not post-lethality exposed. \u2022 Country cured ham (and other similar products) may be considered either RTE or NRTE, depending on how they are processed and labeled." "FSIS Listeria Guideline January 2014 12 1.3 The Listeria Rule Alternatives According to the Listeria Rule, Lm is a hazard that establishments producing post-lethality exposed RTE products must control through a HACCP plan or prevent through a Sanitation Standard Operating Procedure (SOP) or a prerequisite program (9 CFR 430.4(a)). To maintain the sanitary conditions to meet this requirement, establishments must comply with one of three alternatives (9 CFR 430.4(b)). The Listeria alternatives are designed to address post\u2013lethality contamination of Lm in RTE products. Each establishment must designate which alternative it intends to implement for a particular product. Each alternative consists of a single control method or combination of control methods which establishments must apply (see Table 1.1). Establishments may utilize one alternative for all of their products or produce product under multiple alternatives (see the section below on establishments under multiple alternatives). For more information on control measures (e.g., PLT and AMAP), see Chapter 2. Table 1.1 Listeria Control Alternatives Alternative 1 (Alt. 1) The establishment uses a post-lethality treatment (PLT) to reduce or eliminate Lm in the product and an antimicrobial agent or process (AMAP) to limit or suppress growth of Lm in the product. Alternative 2, Choice 1 (Alt. 2a) The establishment uses a PLT to reduce or eliminate Lm in the product. Alternative 2, Choice 2 (Alt. 2b) The establishment uses an AMAP to limit or suppress growth of Lm in the product. Alternative 3 (Alt. 3) The establishment relies on sanitation alone to control Lm in the processing environment and on

the product. There are separate requirements for deli meat and hotdogs under this alternative. Establishments may also change the production process to meet the requirements for a particular alternative. For example, if an establishment employs only sanitation procedures to control Lm (Alt. 3) but later implements an AMAP, it could then meet the requirements for Alt. 2. Establishments are encouraged to use AMAPs or PLTs, if possible, to reduce the risk of Lm. Further information describing the requirements and recommendations for the three alternatives is provided below. Attachment 1.1 outlines the 9 CFR 430.4 requirements for Alt. 1, 2, and 3. Alternative 1 (9 CFR 430.4(b)(1)) Alt. 1 requires the use of a PLT to reduce or eliminate Lm and an AMAP to suppress or limit the growth of the pathogen. NOTE: The following sections describe both requirements in the Listeria Rule and recommendations to meet these requirements. When the word \u201cmust\u201d is used, it refers to a requirement. When the word \u201cshould\u201d is used, it refers to a recommendation.", "FSIS Listeria Guideline January 2014 13 \u2022 The establishment must apply a PLT to control Lm in the product and must include the PLT in its HACCP plan.2 \u2022 The establishment must validate the effectiveness of the PLT in accordance with 9 CFR 417.4. \u2022 The PLT should demonstrate at least a 1-log decrease before the product is released into commerce. \u2022 The establishment must use an AMAP to control Lm in the product and must include the agent or process in the establishment\u2019s HACCP plan, Sanitation SOP, or other prerequisite program. \u2022 The establishment must document in its HACCP plan, Sanitation SOP, or other prerequisite program that the AMAP, as used, is effective in suppressing or limiting growth of Lm. The AMAP should demonstrate that no more than 2-logs of growth of Lm will occur over the shelf life of the product. \u2022 If Lm control measures are incorporated into the establishment\u2019s Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 9 CFR 416.14. If Lm control measures are addressed in a pre-requisite program other than the Sanitation SOP, the establishment must include the program and results of the program in the documentation that the establishment is required to maintain under 9 CFR 417.5. \u2022 Because Alt. 1 includes a combination of controls, the Agency does not require establishments using Alt. 1 to have a testing program for FCS. However, testing is recommended (see Table 3.1). Testing FCS in Alt. 1 could be minimal and primarily serve as a means to verify that the sanitary conditions in the establishment will not overwhelm the PLT. \u2022 As with all control alternatives, an establishment with products in Alt. 1 must maintain sanitation in the post-lethality processing environment in accordance with 9 CFR 416. An example of a product that would fall under Alt. 1 would be deli and hotdog products that receive a PLT (such as steam pasteurization after packaging) and has an AMAP (such as the addition of lactates or diacetates in the formulation). Alternative 2 (9 CFR 430.4(b)(2)) Alt. 2 requires the use of either a PLT (Alt. 2a) or an AMAP that controls the growth of Lm over the shelf life of the product (Alt. 2b). 1. Alternative 2, Choice 1 (Alt. 2a) \u2022 The establishment must apply a PLT to control Lm in the product and must include the PLT in its HACCP plan. 2 According to 9 CFR 417.", "FSIS Listeria Guideline January 2014 14 \u2022 The establishment must validate the effectiveness of the PLT in accordance with 9 CFR 417.14. \u2022 The PLT should demonstrate at least a 1-log decrease before the product is released into commerce. \u2022 As with Alt. 1, establishments in Alt. 2a are not required to test FCS; however, FSIS recommends that establishment test the surfaces on a regular basis to demonstrate that its system is in control (for more information on testing for Alt. 2, see Table 3.1). \u2022 As with all control alternatives, an establishment with

products in Alt. 2a must maintain sanitation in the post-lethality processing environment in accordance with 9 CFR 416 An example of a product in Alt. 2a is a hotdog or deli product that is treated with a postpasteurization treatment after packaging, such as a steam treatment, and DOES NOT contain antimicrobials, such as lactate and diacetate. 2. Alternative 2, Choice 2 (Alt. 2b) \u2022 The establishment must use an AMAP to control growth of Lm in the product and must include the agent or process in the establishment\u2019s HACCP plan, Sanitation SOP, or other prerequisite program. \u2022 The establishment must document in its HACCP plan, Sanitation SOP, or other prerequisite program that the AMAP, as used, is effective in suppressing or limiting growth of Lm. The AMAP should demonstrate no more than 2-logs of growth of Lm will occur over the shelf life of the product. \u2022 If Lm control measures are incorporated into the establishment\u2019s Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 9 CFR 416.4. If Lm control measures are addressed in a pre-requisite program other than the Sanitation SOP, the establishment must include the program and results of the program in the documentation that the establishment is required to maintain under 9 CFR 417.5. \u2022 Under Alt. 2b, the establishment must test FCS in the post-lethality environment to ensure that the surfaces are sanitary and free of Lm or its indicator organisms (e.g., Listeria spp.). It must also indicate testing frequency, identify the size and location of sites to be tested, explain why the testing frequency is sufficient to control Lm, and identify conditions for hold and test when an FCS is positive for Lm or an indicator organism. Recommended testing frequencies for this alternative are included in Table 3.1. \u2022 As with all alternatives, the establishment must maintain sanitation in the post-lethality environment according to 9 CFR 416. An example of products in Alt. 2b is deli and hotdog products with antimicrobial agent (AMA) such as lactates and diacetates added to the formulation, but with no PLT. Another example of a product under Alt. 2b would be a frozen RTE product.", "FSIS Listeria Guideline January 2014 15 Alternative 3: Non-deli or Hotdog Producers (9 CFR 430.4(b)(3)(i)) Under Alt. 3, the establishment does not apply a PLT to reduce or eliminate Lm or an AMAP to control the growth of Lm in the post-lethality exposed product. Instead, it relies on sanitation alone to control Lm in the product. \u2022 The establishment must control Lm in its post-lethality processing environment through the use of sanitation control measures, which may be incorporated in the establishment\u2019s HACCP plan, Sanitation SOP, or prerequisite program (Listeria Control Program). \u2022 If Lm control measures are incorporated into the establishment\u2019s Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 9 CFR 416.14. If Lm control measures are addressed in a pre-requisite program other than the Sanitation SOP, the establishment must include the program and results of the program in the documentation that the establishment is required to maintain under 9 CFR 417.5. \u2022 As with establishments in Alt. 2b, establishments in Alt. 3 must provide for testing FCS in the post-lethality processing area to ensure that surfaces are sanitary and free of Lm or its indicator organisms, indicate testing frequency, identify the size and location of sites to be tested, explain why the testing frequency is sufficient to control Lm, and identify conditions for hold and test when an FCS is positive for Lm or an indicator organism. Recommended testing frequencies are included in Table 3.1. An example of a product in Alt. 3 is refrigerated chicken nuggets that are not treated with a PLT and are not formulated using AMAs. Alternative 3: Deli or Hotdog Producers (9 CFR 430.4(b)(3)(ii)) In addition to meeting the above requirements for Alt. 3 products, there are special requirements for establishments that

produce deli or hotdog products under Alt. 3. Establishments must verify that the corrective actions taken after an initial positive test for Lm or its indicator organisms on an FCS in the post-lethality processing treatment are effective. This is achieved by performing follow-up testing for Lm or an indicator organism after the FCS positive test that includes a targeted test of the specific site on the FCS that is the most likely source of contamination and additional tests in the surrounding FCS area. If follow-up testing yields a second positive result, hold and test products that may be contaminated using a sampling method and frequency that will provide a level of statistical confidence that will ensure that lots are not adulterated. NOTE: According to the Listeria Rule, products and the processing environment under Alt. 3 are likely to be subject to more frequent verification testing by FSIS than products and the processing environment in Alt. 1 or 2. In fact, Alt. 3 products are sampled at a higher rate in the FSIS risk-based sampling code (RTEPROD\_RISK). See Appendix 3.1.","FSIS Listeria Guideline January 2014 16 An establishment in Alt. 3 that produces deli meat or hotdog products will be subject to more frequent FSIS verification testing than one that does not produce such products because deli and hotdog products were ranked as higher risks for Lm contamination in the 2003 FDA/FSIS risk assessment. Examples of deli and hotdog products in Alt. 3 include sliced turkey breast luncheon meat and packaged hotdogs that are not held frozen and not formulated using an AMA. Establishments under Multiple Alternatives FSIS recognizes that establishments may produce products under multiple alternatives. These products may be produced under multiple HACCP plans or grouped under a single HACCP plan. Products can be grouped in a single HACCP plan when the hazards, CCPs, and critical limits are essentially the same. Thus, a single HACCP plan could cover hotdogs formulated with and without antimicrobial agents (Alt. 2 and 3), provided that the HACCP plan clearly distinguishes any critical differences. If an establishment produces products using two (or three) alternative Control Programs, FSIS\u2019s sampling focus will be on product manufactured under Alternative 3, then 2a and b, then 1. 1.4

Requirements for Establishments Under all Three Alternatives According to the Listeria Rule (9 CFR 430.4(c)), establishments in all three alternatives: May use verification testing for Lm or an indicator organism (e.g., Listeria spp.) to verify the effectiveness of their sanitation procedures in the post-lethality processing environment. Sanitation measures for controlling Lm and AMAP\u2019s or PLT\u2019s may be incorporated into the establishment\u2019s HACCP plan (required for PLT\u2019s) or in its Sanitation SOP or other prerequisite program. When these control procedures are incorporated into the Sanitation SOP or other prerequisite programs, the establishment must have documentation that supports the decision in its hazard analysis that Lm is not a hazard that is reasonably likely to occur. The establishment must maintain sanitation in the post-lethality processing environment accordance with 9 CFR 416. NOTE: According to the Listeria Rule, RTE products are considered adulterated if they are contaminated with Lm or pass over a surface that is contaminated with Lm. Establishments are required to hold or to maintain control of RTE products that FSIS has tested for Lm, and RTE products that have passed over food contact surfaces that FSIS has tested for Lm. Establishments may move such products off site provided they maintain control of them (e.g., through company seals). NOTE: Deli salads and wraps are not considered deli products (according to the Listeria Rule) because they are not sliced and are also not typically used in a sandwich.","FSIS Listeria Guideline January 2014 17 If the Lm control measures are included in the HACCP plan, the establishment must validate and verify the measures in

accordance with 9 CFR 417.4. If the Lm control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 9 CFR 416.14. If the Lm control measures are included in a prerequisite program other than the Sanitation SOP, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5. The establishment must make verification results available upon request to FSIS personnel. Other Requirements In addition to meeting the requirements of the Listeria Rule, establishments must meet the requirements of 9 CFR 416, Sanitation, and 9 CFR 417, HACCP Systems. Producers of RTE products must support that they are maintaining sanitation in the processing environment according to 9 CFR 416, and preventing or controlling the food safety hazards in their product according to 9 CFR 417.2(a)(1) and documenting the support according to 9 CFR 417.5(a)(1). For RTE products, FSIS recommends that the establishment achieve lethality of pathogens (e.g., *Salmonella*) in the product, and stabilize the product to inhibit the growth of spore-forming bacteria (e.g., *C. botulinum* and *C. perfringens*). The establishment needs to be able to support that its product is RTE at the end of the process. The requirements of the Listeria Rule will only be effective as long as sanitation is maintained, and the HACCP plan is effective to control the hazards in the system. Sanitation problems can lead to Listeria harborage and cross contamination of RTE meat and poultry products (see Chapter 4 of this guideline). This cross contamination may overwhelm the effectiveness of the establishment's Listeria controls and impact its ability to support its decision that Listeria is not reasonably likely to occur in its products. For example, if an establishment has condensation dripping from the ceiling that is not adequately addressed in its sanitation program, harborage of Lm could occur in its post-lethality exposed processing environment. This contamination could spread to food contact surfaces and contaminate the product with Lm. If the establishment's post lethality treatment is designed to achieve a 1-log reduction of Lm, it may be overwhelmed by the additional contamination and no longer be sufficient to ensure the safety of the product. In that case, the establishment may no longer be able to demonstrate that its HACCP system is effective in controlling pathogens. Likewise, the establishment may find positive results from the food contact surface testing it performs as part of its sanitation SOP to meet the requirements of the Listeria Rule. These positive results may indicate that there are sanitation issues in the establishment's environment that need to be addressed to ensure the safety of the product. For example, the establishment has a hole in the wall, allowing insulation to become saturated with water, and a harborage point for Lm to form. Through an investigation, the establishment determines that the Lm from the hole in the wall could have spread to food contact surfaces, leading to the positive testing result. The establishment takes corrective actions (in accordance with 9 CFR 416.15(a)) by repairing the hole, while at the same time reassessing its Sanitation SOP (in accordance with 9 CFR 416.15(b)) to ensure that cross contamination to food contact surfaces does not occur. In "FSIS Listeria Guideline January 2014" 18 addition, because the establishment uses its Sanitation SOP to support its decision that Lm is not reasonably likely to occur on its product, it reassesses its HACCP plan (in accordance with 9 CFR 417.3(b)(4)) to ensure that its controls for Lm are effective in light of this issue. As these examples show, it is critical that establishments producing RTE products ensure that their systems are working together to control pathogens. A Listeria Control Program by itself will not be effective, unless it is used along with the sanitation

and HACCP programs to control the hazards from pathogens.

**1.5 Labeling** According to the Listeria Rule, an establishment that controls Lm by using a PLT or an AMAP may declare this fact on the label, provided that the establishment has validated the claim (9 CFR 430.4(e)). The purpose of such claims is to inform consumers about measures taken by the processor to ensure the safety of the product and enable consumers to make informed purchase decisions. Such claims are voluntary and may be of value to consumers, especially those in groups most vulnerable to foodborne illness. Processors need to document their validation of these claims, as described in Appendix 2.1. For further labeling resources, see Attachment 1.2 and Appendix 1.2. In addition, if an establishment labels the product as RTE (e.g., does not include safe handling instructions, see Attachment 1.1), it is required to process the product to render it RTE, in accordance with 9 CFR 317.2(l) and 381.125(b). To meet these requirements, the establishment's process must be validated to achieve at least a 6.5 log reduction of Salmonella for cooked beef, roast beef, and cooked corned beef products (9 CFR 318.17), a 5-log reduction for uncured meat patties (9 CFR 318.23), a 7-log reduction for cooked poultry products (9 CFR 381.150), or other equivalent lethality. FSIS will review the establishment's supporting documentation for its lethality and stabilization processes to verify that the establishment is meeting the requirements. Alternative means of achieving lethality may also be sufficient, as long as the establishment can support the effectiveness of its process. See the FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products for more information.

**1.6 Glossary**

**Alternative:** A method of control for Lm adopted by an establishment to meet the requirements of the Listeria Rule.

**Antimicrobial Agent (AMA):** A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as Lm, or that has the effect of suppressing or limiting growth of a pathogen, such as Lm, in the product throughout the shelf life of the product. Examples: potassium lactate and sodium diacetate, which limit the growth of Lm (9 CFR 430.1).

**Antimicrobial Process (AMP):** An operation, such as freezing, that is applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as Lm, in the product throughout the shelf life of the product. Other examples are processes that result in a pH or water activity that suppresses or limits microbial growth (9 CFR 430.1).<sup>19</sup>

**Cook-in-bag:** Product that is cooked in an impermeable package or casing and is not exposed to the environment of the establishment after the lethality treatment.

**Deli product:** A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption (9 CFR 430.1).

**Food contact surface (FCS):** A surface in the post-lethality processing environment that comes in direct contact with RTE product (9 CFR 430.1).

**Hotdog product:** A RTE meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181 (9 CFR 430.1).

**Listeria monocytogenes (Lm):** A foodborne pathogen that can cause the disease listeriosis in humans.

**Listeriosis:** A disease caused by Lm. In most healthy individuals, listeriosis causes flu like symptoms; however in the elderly, pregnant women and their fetuses, and immunocompromised individuals, listeriosis can lead to spontaneous abortion, septicemia, meningitis, and death.

**Post-lethality Exposed Product:** Ready-to-eat product that comes into direct contact with an FCS after the lethality treatment (e.g., cooking) in a post-lethality processing environment. Examples of post-lethality exposed products:

hotdogs after the casings are removed; cooked roast beef after removing the cooking bag (9 CFR 430.1). Post-lethality Processing Environment: The area in an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures (9 CFR 430.1). Post-lethality Treatment (PLT): A lethality treatment that is applied or is effective after postlethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure (9 CFR 430.1).

Ready-to-eat (RTE): A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear safe-handling instruction (as required for non RTE products by 9 CFR 317.2(1) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety and can include frozen meat or poultry products (9 CFR 430.1). 1.7 References FDA and FSIS.

Quantitative Assessment of Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods, September 2003. . Available on the FDA website:

<http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm183966.htm>" , "FSIS Listeria Guideline January 2014 20 FSIS, Risk Assessment for Listeria monocytogenes in Deli Meats, May 2003. Available on the FSIS website:

[http://www.fsis.usda.gov/wps/wcm/connect/b5027918-ee69-475e-acc9a07c642f13b6/Lm\\_Deli\\_Risk\\_Assess\\_Final\\_2003.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/b5027918-ee69-475e-acc9a07c642f13b6/Lm_Deli_Risk_Assess_Final_2003.pdf?MOD=AJPERES) Scallan, E., R. M. Hoekstra, F. J. Angulo, R. V. Tauxe, M. A. Widdowson, S. L. Roy, J. L. Jones, and P. M. Griffin. 2011. Foodborne Illness Acquired in the United States \u2013 Major Pathogens. *Emerg. Infect. Dis.* 17:7-15. 9 CFR part 430 Control of Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Products", "FSIS Listeria Guideline January 2014 21 Attachment 1.1: Control

Requirements for Listeria monocytogenes Requirements \uf0e0 Increasing Risk Levels and Frequency of FSIS Verification Testing \uf0e0 ALTERNATIVE 1 ALTERNATIVE 2 ALTERNATIVE 3 Post-lethality Treatment AND Antimicrobial Agent or Process Post-lethality Treatment OR Antimicrobial Agent or Process Sanitation and Testing Program Choice 1: Post-lethality Treatment Choice 2: Antimicrobial Agent or Process Non-deli, Non-hotdog Deli or hotdog product Validate effectiveness of post-lethality treatment (PLT). Must be included as a CCP in the establishment\u2019s HACCP Plan and should show at least a 1-log reduction in Lm prior to distribution of the product into commerce X X Document effectiveness of antimicrobial agent or process: Must be included as part of the establishment\u2019s HACCP, Sanitation SOP, or Prerequisite Program and should demonstrate no more than 2-logs growth of Lm over the estimated shelf life. X X Sanitation Program Requirements X X X Testing food contact surfaces (FCS) in the post-lethality processing environment for Lm or an indicator organism. X X X State testing frequency. X X X Identify size and location of sites to be sampled. X X X Explain why testing frequency is sufficient to control Lm or an indicator organism. X X X Identify conditions for Hold-and-Test, when FCS (+) for Lm or an indicator organism. X X X Additional Sanitation Program Requirements Follow-up testing to verify corrective actions are effective after 1st FCS (+) for Lm or an indicator organism. Includes testing of targeted FCS as most likely source and additional testing of the surrounding area. X If follow-up testing yields 2nd FCS (+), hold

products that may be contaminated until problem is corrected as shown by FCS (-) in follow-up testing. X Hold and test product lots using a sampling plan that provides statistical confidence that the lots are not contaminated with Lm or an indicator organism. Release, rework, or condemn products based on results. Document results and product disposition. X Establishments in all three alternatives must maintain sanitation in accordance with 9 CFR 416. X X X X X", "FSIS Listeria Guideline January 2014 22 Attachment 1.2: Chart of RTE vs. NRTE Products: Resource 1 TYPE CLASS HACCP CATEGORY REQUIRED LABELING WHAT THE HACCP PLAN MAY ADDRESS A meat\poultry product (in whole or in part) which has not received an adequate lethality treatment for Salmonella (i.e., raw or partially cooked product). May include cuts of meat and poultry, cured pork products, and NRTE sausage. Or A meat\poultry product (in whole or in part) which has received an adequate lethality treatment for Salmonella, that is not defined by a standard of identity or a common or usual name that consumers understand to refer to RTE product and does not meet the definition of RTE\* in 9 CFR 430.1. May include NRTE ham, casseroles, and other meat or poultry dishes. Not ready-to-eat \u2022 Raw Product Ground Raw Product Not Ground \u2022 Not Heat Treated Shelf Stable \u2022 Heat Treated \u2013 shelf stable \u2022 Heat Treated but not Fully Cooked Not Shelf Stable Products with secondary inhibitors Not Shelf Stable Product must be labeled with statements such as keep refrigerated, keep frozen, or refrigerate leftovers, if not shelf stable. Use of Safe Handling Instruction (SHI) labeling required. \u2022 Use of SHI labeling (Some establishments may have a CCP for SHI labeling application). If it is not obvious that the product is raw and needs to be cooked: \u2022 Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., \u201cCook and Serve\u201d) but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel or by a burst stating such things as \u201cneeds to be fully cooked,\u201d \u201csee cooking instructions,\u201d or \u201ccook before eating.\u201d \u2022 Validation that: a. Cooking and preparation instructions on the product are sufficient to destroy pathogens. b. Instructions are realistic for the intended consumer. \*A meat or poultry product that is edible without any additional preparation to achieve food safety.", "FSIS Listeria Guideline January 2014 23 A product containing a meat\poultry component that is RTE in combination with nonmeat\poultry components that needs to receive a lethality treatment by the intended user. The final product does not meet the definition of RTE in 9 CFR 430 because it contains raw components. May include meals, dinners, and frozen entrees. Not ready-to-eat \u2022 Heat Treated but not Fully Cooked Not Shelf Stable Product must be labeled with statements such as keep refrigerated or frozen. Use of SHI labeling is recommended. NOTE: SHI are not required because the meat or poultry component is RTE. However, FSIS recommends SHI for these products because raw nonmeat ingredients are added. \u2022 Validation that: a. The meat\poultry component received an adequate lethality treatment for pathogens (see Section 1.4). b. Cooking and preparation instructions on the product are sufficient to destroy pathogens. c. Instructions are realistic for the intended consumer. \u2022 Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety (e.g., \u201cCook and Serve\u201d). May also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as \u201cneeds to be fully cooked\u201d, \u201csee cooking

instructions\ufe0f, or \ufe0fcook before eating.\ufe0f If necessary, hazard analysis should address whether instructions on the label are needed related to cross-contamination (e.g., avoid contact of contents) and prevention of pathogenic growth (e.g., promptly refrigerate leftovers). NOTE: Inspection program personnel are to collect samples as RTE if the establishment does not follow the guidance above. A meat\poultry product that has received an adequate lethality treatment for Salmonella that may or may not be defined by a standard of identity or a common or usual name that consumers understand to refer to RTE product, and meets the definition of RTE in 9 CFR 430. RTE products that are postlethality exposed must meet the requirements of 9 CFR part 430. May include hotdogs, deli meat, and RTE sausages.

Ready -to-eat \ufe0f Not Heat Treated Shelf Stable \ufe0f Heat Treated Shelf Stable \ufe0f Fully Cooked Not Shelf Stable \ufe0f Products with secondary inhibitors Not Shelf Stable If the product is not shelf stable, labeling such as keep refrigerated or frozen is required. SHI are not required and should not be used because they could be misleading to consumers. \ufe0f Validation that the meat or poultry component received an adequate lethality treatment for pathogens (e.g., a 5-log reduction of Salmonella). \ufe0f The establishment meets the requirements of 9 CFR 430 if the product is post-lethality exposed. \ufe0f Heating (not cooking) instructions may be included. \ufe0f Statements on the principle display panel may indicate that the product is RTE and does not have to be cooked for safety (e.g., \ufe0f fully cooked,\ufe0f \ufe0fheat and serve\ufe0f)." , "FSIS Listeria Guideline January 2014 24

Appendix 1.1: Product Types Overview of products covered under Listeria Rule Establishments that produce post-lethality exposed RTE meat and poultry products are covered by the Listeria Rule. Accordingly, the establishment should determine the alternative(s) to which it will adhere to in its processes to control L<sub>m</sub> during the post-lethality exposure. The following product types, if post-lethality exposed, would fall under the Listeria Rule. The classification of deli products and hotdog products, salad\spread\p\ufe0e2t\ufe0e9 products, cook-in bag products, frozen, and hot-packed products will be described.

I. Deli and Hotdog Products As defined in 9 CFR 430.1, a deli product is \ufe01ca ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption.\ufe01d RTE hotdog (or hot dog) products are defined in 9 CFR 430.1 as \ufe01ca ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181.\ufe01d Cooked sausages (e.g., bratwurst), as defined in 9 CFR 319.140, would be considered RTE, but would not be considered to be deli or hotdog products. Post-lethality exposed whole meat and poultry products (e.g., deli loaves) that are destined for slicing at a retail establishment are also considered to be deli products. NOTE: Deli loaves that are non post-lethality exposed (e.g., cook-in bag) that are sliced at retail are not considered to be deli products because they are not covered by the Listeria Rule, see Section III below. Like all RTE products exposed to the processing environment, deli and hotdog products that are exposed to the post-processing environment are subject to the Listeria Rule. If the RTE product is not exposed to the post-processing environment, it is not subject to the Rule. Depending on the method that an establishment chooses to control L<sub>m</sub> contamination in its processing, deli and hotdog products may be in Alt. 1, 2, or 3. NOTE: The Listeria Rule definition of deli products applies only to deli products produced official establishments. Deli products produced at retail can include deli salads, meats, and other products. Deli and hotdog products that receive a PLT and AMAP fall

under Alt. 1. An example is a hotdog that includes lactates or diacetates in the formulation and is steam pasteurized after repackaging. Deli and hotdog products with antimicrobial agents such as lactates or diacetates added in the formulation, but with no post-process lethality treatment, would fall under Alt. 2b. An example of an Alt. 2a product is a hotdog product that received only a PLT, such as being Question: A scrapple product receives a full lethality treatment at the establishment. Is the product required to be RTE? Answer: No. Unless the product has a standard of identity requiring it to be RTE (9 CFR 319 and 9 CFR 381), it can be considered to be NRTE. NRTE products are required to bear safe handling instructions, and should be labeled with validated cooking instructions. In addition, if the product is NRTE but appears to be RTE, it should be labeled conspicuously so that intended user is fully aware that product must be cooked for safety (see Attachment 1.2). The establishment's HACCP plan and intended use statement should also be consistent with a NRTE product (see Appendix 1.2 part II below).", "FSIS Listeria Guideline January 2014 25 packaged in casings with an antimicrobial agent that reduces the level of Lm. If an establishment does not use a PLT or an AMAP in the processing of deli and hotdog products, these products would fall under Alt. 3. II. Salad\Spread\P\u00e2t\u00e9 Products Salads\spreads\p\u00e2t\u00e9s are also RTE post-lethality exposed, so they are covered by the Listeria Rule. RTE meats that are used in salads receive additional handling after they are removed from their packages and are mixed with other ingredients, thus exposing them to crosscontamination. An establishment producing salads with the meat and poultry components that receive a PLT or antimicrobial agent needs to have supporting documentation showing that the antimicrobial action is sufficient to control Lm in all the salad ingredients if it chooses to have its product in Alt. 1 or 2. A salad\spread\p\u00e2t\u00e9 product with a final pH below 4.39 in all ingredients of the salad (e.g., due to the salad dressing or other ingredients added) would fall under Alt. 2, if an antimicrobial agent is used. Salads\spreads\p\u00e2t\u00e9s are not considered deli products under the Listeria Rule because they are not typically sliced. III. Cook-in Bag products A cook-in-bag product such as a cooked ham or poultry roll that leaves the federal establishment intact in its cooking bag is not covered by the Listeria Rule because it is not postlethality exposed. However, once the product is removed from its package, it should be handled using good sanitary controls so that it does not become contaminated with Lm. IV. Frozen Products Frozen products are covered under the Listeria Rule if they are considered RTE and postlethality exposed. Although freezing controls the growth of Lm, the organism can still survive the freezing process. Frozen products generally fall under Alt. 2b (use of an antimicrobial agent or process to control Lm). The Listeria Rule defines an antimicrobial process as an operation, such as freezing, that is effective throughout the shelf life of the product. Therefore, to meet the definition of an antimicrobial process, and to qualify for Alt. 2b, the product would need to remain frozen throughout its shelf life. If the product is meant to be thawed and held refrigerated either at the establishment or at a retailer, the product would be considered Alt. 3. An example of a frozen product would be RTE sliced chicken strips that are frozen at the establishment and held frozen until prior to consumption. They may be heated by the consumer for palatability prior to eating. V. Hot-packed Products: Edible Oils and Fats, Lard, and Soups Edible oils and fats resulting from a rendering process that processes them to a temperature of 180\u00ba F and maintains them at 160\u00ba F are considered RTE. Rendering is intended to make this meat food product a ready-to-use ingredient in the

preparation of other foods, e.g., edible tallow and lard used as shortening. They do not require additional lethality treatment before being consumed. If these products are hot filled at a lethality temperature (e.g., Appendix A Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products) and packaged, they are not considered post-lethality exposed and therefore are not covered by the Rule. However, these products would be considered RTE and not covered by the Listeria Rule if the process calls for partial rendering of the animal fat for tallow or lard and then further processing or finishing rendering in another plant.","FSIS Listeria Guideline January 2014 26 Soups and other products that are cooked to eliminate pathogens and hot-packed in the final packaging material are RTE, but are not considered post-lethality exposed. Therefore, the Listeria Rule does not apply. VI. Dehydrated Products Dehydrated products are considered to be low risk products, because they do not support Listeria growth (as long as the water activity is below 0.92). However they may be considered RTE and post-lethality exposed, depending on their intended use. Therefore, they may be sampled under the RTEPROD\_RAND and RTEPROD\_RISK project codes. Question: Are lard products covered under the Listeria Rule? Answer: It depends. Lard products that are made from a rendering process are considered to be RTE. If they are hot-filled at a lethality temperature according to Appendix A or other scientific support, they would not be considered post-lethality exposed and would not be subject to the Listeria Rule. If they are filled at lower temperatures, then the product is considered post-lethality exposed, and subject to the Listeria Rule.","FSIS Listeria Guideline January 2014 27 Appendix 1.2: Labeling I. Post-lethality Treatments (PLT) and Antimicrobial Agents or Processes (AMAP) According to the Listeria Rule, an establishment that controls L<sub>m</sub> by using a PLT or an AMAP may declare this fact on the label, provided that the establishment has validated the claim (9 CFR 430.4(e)). The purpose of such claims is to inform consumers about measures taken by the processor to ensure the safety of the product and enable consumers to make informed purchase decisions. Such claims are voluntary and may be of value to consumers, especially those in groups most vulnerable to foodborne illness. Processors need to document their validation of these claims as described in Appendix 2.1. An example of a statement that can be made is: \u201cPotassium lactate added to prevent the growth of Listeria monocytogenes.\u201d All labeling claims and label changes to add such claims must be submitted for evaluation and approval to the FSIS Labeling and Program Delivery Division. In addition, antimicrobial agents that are added to RTE products, either to the formulation or to the finished RTE product, and those that are included in the primary packaging material of RTE products must to be listed in the ingredients statement of the product. An establishment does not need to submit a label to the Agency for evaluation and approval when it adds an antimicrobial agent (e.g., sodium diacetate) to a product formulation that is approved or listed by FDA and FSIS as safe and suitable, provided that the label can be approved in accordance with the generic labeling regulations in 9 CFR 317.5 and 381.133, (i.e., the product must have a standard of identity in Title 9 of the Code of Federal Regulations (CFR) or the Food Standards and Labeling Policy Book and the labeling must not bear special claims, guarantees, or foreign language). All ingredients including antimicrobial agents require declaration on the label. Establishments may submit for temporary approval to use existing stocks of labels with revised formulations (up to six months) in order to update and produce new labels. Approval of Labels Bearing Claims As with all claims on labels, if there is a labeling claim about the use of antimicrobial agents or lethality treatments, the labels must be

submitted to the Agency for evaluation and approval before use. Documents for validation of the effectiveness of the PLT or antimicrobial agent must be included with the label application. An establishment cannot put labeling claims of enhanced protection on RTE products that are not post-lethality exposed, such as cook-in-bag that are opened only by the consumer, because these are not covered by the Listeria Rule. Special Considerations for Antimicrobial Agents in Commminuted Beef Products The standard of identity for ground beef, chopped beef, and their cooked versions does not provide for the addition of ingredients, with the exception of non-fluid condimental seasonings, e.g., salt and pepper. Therefore, these products cannot be formulated with or treated with antimicrobial agents that are classified as having a lasting technical effect, e.g., sodium lactate and sodium diacetate, unless these products are descriptively labeled to reflect the use of the antimicrobial agents. For example, if sodium lactate is added, the product name on the label should be "Ground Beef with Sodium Lactate". However, for beef patties, which are standardized products, the regulations permit the addition of ingredients such as antimicrobial agents. Therefore, comminuted beef products formulated with antimicrobial agents and other approved or listed safe and suitable food ingredients can be labeled as "beef patties" and can be generically approved if the labeling does not bear any", "FSIS Listeria Guideline January 2014 28 special claims, guarantees, or foreign language. The labeling for other products with standards of identity that permit the addition of antimicrobial agents (e.g., luncheon meats, hotdogs, cooked whole muscle cuts (such as roast beef)) may be approved in accordance with the regulations on generic label approval to reflect the addition of new, approved safe and suitable antimicrobial agents on labeling. The addition applies provided that no special claims, guarantees, or foreign language appear on such labels, per the generic labeling regulations.

II. Differentiating Products as RTE or Not RTE (NRTE)

Some products are expected to be lethality treated and RTE as shipped as part of their common or usual name that consumers understand to refer to RTE product, e.g., pâté. Other products are defined by a standard of identity as RTE, that is, cooked, e.g., hotdogs. Some products are RTE based on labeling features, including Nutrition Facts, which declare nutrients in a product on a ready-to-serve or ready-to-eat basis. When these factors do not prevail, manufacturers may decide whether to classify products as RTE or NRTE products. However, care should be taken to ensure that it is clear whether the product is RTE or NRTE (see Attachment 1.2). The following should be taken into account when differentiating RTE from NRTE product:

- (1) Decide on the HACCP category that best fits the product based on the processing operations that are involved. The HACCP categories most often used for RTE products include fully cooked/not shelf stable, not heat treated shelf stable, heat treated shelf stable, and product with secondary inhibitors not shelf stable. In the situation where a product has been produced as an RTE product and it is not a product that is defined by a common or usual name that consumers understand to refer to RTE product (e.g., pepperoni) or standard of identity (e.g., hotdog) as a lethality-treated (e.g., cooked/fermented/dried) product, the manufacturer can decide whether the product is RTE or NRTE based on HACCP category. The establishment would need to ensure that documentation exists to support the HACCP category selected by the establishment for the product and that the appropriate category is reflected in the HACCP plan and labeling records. The establishment's hazard analysis and intended use of the product should also be consistent with a RTE or NRTE product.
- (2) Generate data that validate the cooking instructions

that appear on the labeling of NRTE products (and include in all the alternative methods of cooking the temperature that the product must reach, i.e., 160°F) to ensure that consumers provide the lethality step. When the product has historically been viewed by the consumers as a RTE product, it is especially important for the establishment to make the distinction between the RTE product and the NRTE product. In addition, the cooking instructions should not be the same "heating" instructions that may be used on the labeling for RTE products. Heating instructions for RTE products should not use the word "cooking," and should not include end temperatures (e.g. 160 °F), because it could be misleading to consumers. NOTE: It is FSIS's expectation that products in the fully cooked not shelf stable category will be considered RTE." "FSIS Listeria Guideline January 2014 29 Cooking instructions for NRTE products should include the internal temperature the product is expected to reach (e.g., 160°F), and the method of cooking (e.g., oven time and temperature) so that the product is safe for consumption by the consumer. NOTE: Specific cooking instructions are not required for NRTE products, except the instruction to cook thoroughly, included as part of safe handling instructions (SHI). However, FSIS recommends that establishments provide validated cooking instructions on labels of products that are NRTE but appear to be RTE. In addition, if the establishment chooses to label a NRTE product with cooking instructions, it should validate the instructions; otherwise, they may not provide meaningful information to consumers on how to cook the product. (3) Assess the label to ensure that it adequately reflects the features that are necessary on the principal display panel to convey that the product is a ready-to-cook product, e.g., "cook and serve," "cook and eat," "cook thoroughly," as well as safe handling instructions. It would not be appropriate to label raw products using terms such as "cooked," or broiled. FSIS regulations require SHI if the meat or poultry component is NRTE and the product is not labeled for further processing. In comparison, if the meat or poultry component is RTE, but another non-meat or poultry component requires cooking for safety, the display of safe handling instructions is not required, but highly recommended. In addition, the basis for the Nutrition Facts declarations, e.g., serving size, must be on a ready-to-cook basis, not on a ready-to-serve basis (the company has to establish a ready-to-cook basis for serving size if the regulations do not provide one). The reference amount customarily consumed (RACC) for ready-to-cook and ready-to-serve meat and poultry products are found in 9 CFR 317.312 and 381.412, respectively. Nutrition labeling is not changed by this rule, but the serving size will be affected, depending on whether the product is classified as RTE or NRTE. (4) Consider whether the label for the product can be approved consistent with the regulations on generic label approval (i.e., it is a label for a standardized product that bears no claims, special statements, guarantees, or foreign language). Such labels would not need to be sent to the Agency to be evaluated and approved prior to use. If a meat or poultry product that is processed to a time/temperature that traditionally is considered to attain a full cook, but the intended use of the product is such that the product is intended to receive a lethality treatment by the consumer, the product does not have to be labeled as RTE unless the product is defined by a standard of identity as an RTE product (e.g., hotdogs, franks, and pork with barbecue sauce). Such product may be identified as an NRTE product, provided that the labeling and validated cooking instructions (SHI) are adequate to discern that the product must be cooked for safety by the purchaser. An example of such product is a cooked,

thick-sliced, center-cut ham slice on which the labeling indicates that the product is ready-to-cook and for safety the product must be cooked to attain a minimum temperature. On the other hand, a thin sliced ham product in case-ready packaging may state that the product is RTE without additional cooking and, as such, should not be labeled with cooking instructions. Both products may have been heat treated in the same manner, but the establishment would only have control for Lm in the RTE product." , "FSIS Listeria Guideline January 2014 30 Chapter 2 FSIS Listeria Guideline: FSIS Control Measures for Listeria 2.1 Post Lethality Treatments (PLT) 2.2 Antimicrobial Agents and Processes (AMAP) Table 2.1: Growth Limits for Lm 2.3 Sanitation 2.4 Expected Levels of Control Table 2.2: Expected Control Levels for Post-lethality Treatments and Antimicrobial Agents or Processes under Alternatives 1 & 2 2.5 Training 2.6 New Technology and New Ingredient Review 2.7 Glossary 2.8 References Attachments 2.1 Post-lethality Treatments 2.2 Antimicrobial Agents or Processes Appendices 2.1 Validation 2.2 Sanitation 2.3 Training This chapter provides technical information about control measures that are used to meet the requirements for the three alternatives and provides examples establishments can use to apply these control measures to their particular product. 2.1 Post-lethality Treatments (PLT) According to the Listeria Rule, post-lethality treatments (PLT) are treatments that are designed to reduce or eliminate levels of Lm contamination on RTE products. Establishments may choose to use PLT to meet the requirements of Alt. 1 (use of a PLT and antimicrobial agent or antimicrobial process (AMAP) or Alt. 2a (use of a PLT alone). According to the Listeria Rule, establishments that use PLTs must include the treatment as a CCP in their HACCP plan and validate the effectiveness of the PLT. It is FSIS\u2019s expectation that PLTs will be designed to achieve at least a 1-log lethality of Lm before the product leaves the establishment. The PLT must be validated according to 9 CFR 417.4 and 430.4 as being effective in eliminating or reducing Lm. The establishment must also verify the effectiveness of the PLT and other control measures and make these results available upon request to FSIS personnel (9 CFR 430.4(c)(7)). Expected levels of control for PLTs and AMAPs are provided in Table 2.1. 3 Ultraviolet treatment can be used either as a post-lethality treatment or antimicrobial agent or process depending on whether it eliminates, reduces, or suppresses growth of Lm. Examples of Post-lethality Treatments (PLT) PLT for Lm may include: \u2022 Steam pasteurization, \u2022 Hot water pasteurization, \u2022 Radiant heating, \u2022 High pressure processing (HPP), \u2022 Ultraviolet (UV) Treatment, \u2022 Infrared Treatment, \u2022 Drying (Low water activity) (see example 1), and \u2022 Other validated processes.", "FSIS Listeria Guideline January 2014 31 See the section on validation and verification of PLTs below and Attachment 2.1 for more information. PLTs could be effective in any post-lethality exposed RTE product, provided a study is performed demonstrating its effectiveness in the product. PLTs can be applied as: 1) Pre-packaging treatments, e.g., infrared technology (see Example 2) 2) Post-packaging treatments, e.g., \u2022 Hot water pasteurization, \u2022 Steam pasteurization, and \u2022 High pressure processing (HPP). Some of the published studies on post-lethality treatments are reviewed in Attachment 2.1. Establishments should refer to the details of these studies if they want to use the intervention methods in their processing operations. The Compliance Guideline will be updated to include studies or other methods as they become available. For more information on using published studies or other methods of validating PLTs, see the validation of PLTs section below and Appendix 2.1. Example 1: Drying (low water activity (Aw)) as an AMAP and PLT Drying is a means to kill Lm and help make a product \u201cshelf stable\u201d. Low water

activity ( $A_w$ ) limits the amount of water available to pathogens such as Lm, which will not allow them to grow. An  $A_w$  less than or equal to 0.92 will not support the growth of Lm, and an  $A_w$  of 0.85 or less (the  $A_w$  for achieving shelf stability) can sometimes even reduce Lm numbers. FSIS will consider an  $A_w$  of 0.85 at the time the product is packed to be a post-lethality treatment and an antimicrobial treatment if the establishment provides supporting documentation that Lm is reduced by at least 1-log before the product leaves the establishment and that no more than 2logs growth of Lm occurs over the shelf life of the product. See Table 2.1 for growth limits of Lm.

**Example 2: Pre-packaging Treatment (e.g., infrared technology)** as a Post-lethality Treatment A pre-packaging treatment such as infrared technology can be used as a PLT as long as it is validated to eliminate or reduce the level of Lm by at least 1 log. Infrared technologies work by heating water inside microorganisms, causing cell death. However, if there is separation between the treatment and packaging, there is a possibility that the product could be come re-contaminated after the infrared treatment. Therefore, sufficient conditions must be met to ensure a hygienic environment after the infrared treatment step to preclude re-contamination, or the post-lethality treatment would not likely be considered effective by FSIS.

Some establishments may place the packaging machine right after the radiant heat treatment to NOTE: Some AMAs or AMPs may also act as a PLT if they reduce or eliminate the pathogen and control its growth over the shelf life of the product. An example of an AMP that also acts as a PLT is a process such as drying or fermenting, which renders an RTE product shelf stable (see Example 1 below).", "FSIS Listeria Guideline January 2014 32 reduce or eliminate product exposure. If the infrared technology or other similar technology (e.g., HPP) is validated to achieve at least a 5-log reduction of Lm and other pathogens of concern (e.g., E. coli O157:H7 and Salmonella), the process would be considered to achieve full lethality and the product would not be considered to be post-lethality exposed. Sending Product to another Establishment for a PLT Establishments that produce post-lethality exposed products may send the product to another federally-inspected establishment for PLT. If the product will not be distributed into commerce until after the PLT is applied, it should be labeled \u201cfor further processing\u201d or remain under the establishment\u2019s control. The PLT should also be considered as part of the primary establishment\u2019s HACCP program, even if it is applied at a secondary establishment. Known or suspect Lm-positive product may be treated at the establishment or shipped to another establishment for PLT or other reprocessing (see Section 4.4). If a PLT is used to reprocess Lm-positive product, the process should be validated to achieve at least a 5-log reduction of Lm or an indicator organism. If the product is shipped to another establishment for reprocessing, the product should be labeled \u201cfor further processing\u201d or remain under establishment control until the PLT is applied to the product.

**Validation of PLTs** As previously stated, the PLT must be validated to reduce or eliminate Lm from the product (9 CFR 430.4(b)(1)(ii)). The validation should demonstrate at least a 1-log reduction of Lm before the product leaves the establishment (unless the PLT is being used to treat contaminated product. See above). Establishments may use published peer-reviewed papers, challenge studies, or in-house studies to validate the effectiveness of PLTs. Published research studies may be used as a reference for validation provided the critical parameters used in the study (e.g., product type or size, the type of equipment, time, temperature, pressure and other variables) match the product or process used by the establishment. In the absence of published peer-reviewed papers, unpublished studies may be

used as reference documents, provided there is supporting documentation that the data and analysis of results demonstrate that the specific level of application on specified products or range of products is effective to produce a safe product (e.g., results in at least a 1-log decrease). FSIS expects the establishment's HACCP documentation to demonstrate that the post-lethality treatment is adequate to eliminate or reduce L<sub>m</sub> by at least 1-log. In cases of pre-packaging PLT that is applied to the finished product close to the packaging step (e.g., infrared treatment), the establishment must be able to demonstrate how the level of contamination that may occur between the treatment and the packaging is eliminated. For more information on validation of PLTs and AMAPs, see Appendix 2.1. 2.2 Antimicrobial Agents and Processes (AMAPs) According to the Listeria Rule, AMAPs must suppress or limit the growth of L<sub>m</sub> throughout the shelf-life of the product. Antimicrobial agents (AMAs) can include lactates and diacetates added in the formulation of the product and growth inhibitors added in the immediate packaging material. AMAPs must be included in the establishment's HACCP plan, Sanitation SOP, or prerequisite program and the establishment must validate that the AMA P is effective as used. It is FSIS' expectation that AMAPs are designed to allow no more than 2-logs of growth of L<sub>m</sub> over the shelf-life of the product. If the AMAP is included in the FSIS Listeria Guideline January 2014 33 the establishment's HACCP plan, the establishment must validate and verify its effectiveness in accordance with 9 CFR 417.4. If the AMAP is included in the establishment's Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 9 CFR 416.14. If the AMAP is included in a prerequisite program other than a Sanitation SOP, the establishment must ensure that the program is effective and does not cause the hazard analysis or the HACCP plan to be inadequate. The establishment must include the program and the results produced by the program in the documentation that it maintains as required in 9 CFR 417.5(a). Expectations for the efficacy of AMAPs are provided in Table 2.2. For further information on validation of AMAPs, see Appendix 2.1. 1. Antimicrobial Agents (AMAs) AMAs are defined as substances added to RTE products that have the effect of suppressing or limiting growth of L<sub>m</sub> in the product throughout the shelf life of the product (9 CFR 430.1). AMAs should allow no more than 2-logs of growth over the shelf life of the product. Examples of AMAs include: potassium lactate and sodium diacetate. Growth inhibition achieved by adding antimicrobials to product formulation depends on a variety of factors, such as: 1) The level of antimicrobial agent added, 2) pH of the product, 3) Moisture level of the product, 4) Product formulation, and 5) Whether the agent was added during formulation or to the finished product. Some published studies on AMAs are reviewed in Attachment 2.2. If establishments want to use such studies as part of their validation or support, they would need to identify all of the critical operation parameters in the study and apply them to their process. See the section below on documenting the effectiveness of AMAPs and Appendix 2.1 for more information. According to the Listeria Rule, the AMAPs must be effective throughout the shelf life of the product (9 CFR 430.1). The shelf life of the product is defined as the amount of time the product can be stored under specified conditions and still remain safe with acceptable quality. Guidance can be found in the following National Advisory Committee for Microbiological Criteria for Foods (NACMCF) report: Considerations for Establishing Safety-based Consume-by Date Labels for Refrigerated Ready-to-eat Foods. Question: Can modified atmosphere packaging (M.A.P.) be used as an AMP? Answer: M.A.P. can be used as an AMP if the establishment has documentation that it

suppresses growth of Lm and other pathogens and their toxins or toxic metabolites throughout the product's refrigerated shelf life Question: Could curing (156 ppm added nitrite) be considered an AMA? Answer: Sodium nitrite is primarily used to inhibit Clostridium botulinum growth and toxin production in cured meats. Studies have shown an inhibitory effect of nitrite, salt, and vacuum packaging on Lm growth in fish. The establishment would have to provide documentation on the inhibitory effect of nitrite on Lm in meat and poultry and indicate what other factors, such as salt concentration, are critical for the inhibitory effect." "FSIS Listeria Guideline January 2014 34 AMAs can be added to the product during formulation, to the finished product, or to the packaging material. FSIS does not require a specific concentration of inhibitor to qualify as an antimicrobial agent. However, AMAs must be generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) and also must have been found to be safe and suitable by FSIS. Approved antimicrobials for processed meat and poultry products can be found in 9 CFR 424.21 and FSIS Directive 7120.1. The addition of antimicrobials in the formulation must be included in the ingredient statement of the label (see Section 1.5). If an AMA is added to the surface of the product, it should be added as close to the final packaging step as possible to ensure the efficacy of the treatment. For example, if an AMA is applied to the surface of the product and the product is sliced, the AMA would no longer be valid as an AMA unless the sliced surface is also treated. An establishment may also use AMAs that inhibit Lm on equipment and FCSs. Using these inhibiting agents on equipment and FCSs can be considered as part of the sanitation program. The use of AMAs on the equipment alone, however, would not qualify the product for Alt. 1 or 2. The establishment would have to add the AMA directly to the product to meet the requirements for either of the alternatives. Hurdle Concept Some AMAPs may have increased effectiveness in controlling Lm growth when added in combination with other AMAPs. This synergistic effect is commonly referred to as the hurdle concept. RTE products with added salt, nitrites, and other additives achieve a water activity, pH, or moisture-protein-ratio that will reduce the level of Lm and other pathogens during processing, and continue to inhibit the growth of the pathogens during the refrigerated shelf-life. The added salts and nitrites work together to create hurdles to pathogen growth. These products may not be shelfstable because they need to be refrigerated during their shelf-life, but because of the combination of water activity and pH attained during the initial lethality treatment, these products may not support the growth of Lm during its refrigerated shelf-life. Example 1: Lactates and Diacetates as AMAs Lactates and diacetates are antimicrobials that can be added to the formulation of RTE meat and poultry products. These compounds are organic acids that serve to reduce the Aw and pH of the product. FSIS increased the permissible levels of sodium diacetate as a flavor enhancer and as an inhibitor of pathogen growth to 0.25 % (65 FR 3121-3123/2000). The Rule also permits the use of sodium lactate and potassium lactate in fully cooked meat, meat-food products, poultry, and poultry-food products, except for infant foods and formulas, at levels of up to 4.8 % of total product formulation, for the purpose of inhibiting the growth of certain pathogens. These include lactates and diacetates added in the formulation and growth Question: If an AMA is applied to a product at one establishment, and the product is sent to a second establishment for further processing, can the second establishment claim Alt. 2? Answer: Yes. The second establishment can claim Alt. 2, as long as it can demonstrate that the processing and sanitary conditions at the second establishment do not impact the effectiveness of the AMA or AMP over the shelf life of the product. To

demonstrate its effectiveness, the second establishment would need to obtain documentation from the first establishment regarding levels of the AMA or AMP and demonstrate that the further processing applied to the product does not impact the effectiveness of the AMA or AMP. The second establishment would also need to demonstrate that levels of Lm in its postlethality processing environment would not overwhelm the effectiveness of the AMA or AMP.", "FSIS Listeria Guideline January 2014 35 inhibitors in the immediate packaging material. Approved antimicrobials for processed meat and poultry products can be found in 9 CFR 424.21 and in FSIS Directive 7120.1. The addition of antimicrobials in the formulation must be included in the ingredient statement of the label. To meet the definition in the Listeria Rule, an AMA would need to be effective over the shelf life of the product (therefore, it can not be considered a processing aid), and should allow no more than 2 logs outgrowth of Lm. Example 2: Vinegar as an AMA Acidulants or added vinegars can be considered as AMAs, as long as the pH of the product is below 4.39, or the establishment can provide other supporting documentation demonstrating the effectiveness of the process. Vinegar serves to control pathogen growth by decreasing the pH of the product. However, Lm and other pathogens may still survive in a vinegar-based sauce or other products. Vinegar may also be considered a PLT if at least 1 log of Listeria death occurs before the product leaves the establishment, and the establishment can support this reduction. In addition, if the establishment can support that the vinegar results in at least a 5-log reduction of Lm after the product is placed in the final package, FSIS will consider the product to be nonpost lethality exposed.

2. Antimicrobial Processes (AMP) AMPs are operations, such as freezing, that are applied to an RTE product that have the effect of suppressing or limiting the growth of a microorganism, such as Lm, in the product throughout the shelf life of the product (9 CFR 430.1). Other examples are processes that result in a pH or water activity that suppresses or limits microbial growth. Examples of Antimicrobial Processes (AMPs) are the following:

- a. Fermentation
- b. Drying
- c. Freezing

FSIS requires establishments to provide adequate supporting documentation as part of any validation when using AMPs to control the growth of Lm (see Appendix 2.1 for more information on validation). Table 2.1 provides growth limits for Lm, which can be used to help evaluate the effectiveness of AMPs. If an AMP achieves conditions that would limit the growth of Lm based on the table, then the establishment can consider that the process has been validated to control growth of Lm.

Table 2.1 Growth Limits for Lm (ICMSF, 1996)

Temperature (°C)	Minimum	Optimum	Maximum
-0.4	31.3	37	45
\u00b0C	(31.3 \u00b0F)	(98.6\u00b0F)	(113 \u00b0F)
pH	4.39	7.0	9.4
Water activity	0.92	---	---

"FSIS Listeria Guideline January 2014 36 The establishment can place Table 2.1 on file as part of its supporting documentation, demonstrating that the AMP it has selected is sufficient to control growth of Lm, and no further scientific support for the process would be needed. However, the establishment should collect in-plant demonstration data in order to meet the second element of validation (see pages 34-35 for a discussion of in-plant demonstration data). In addition, the establishment would also be expected to conduct ongoing monitoring and verification activities to demonstrate that it is maintaining the conditions for pH, water activity, or temperature.

Example 1: Fermentation and Drying as an AMP

Fermentation and drying are processes that control the growth of Lm and other microorganisms by decreasing the pH and available moisture in the product. These processes are considered AMP if they result in finished product with pH or water activity that suppresses or limits the growth of Lm. FSIS will consider starter cultures used in dry or semi-dry fermented

sausages to be AMAs if the addition of the starter culture or vinegar results in a finished product with a pH of <4.6, and the establishment documents that this pH level in the specific product suppresses or limits growth of Lm. Although Table 2.1 lists a pH of 4.39, the pH of dry and semi dry fermented sausages may be higher (<4.6) and still control Listeria growth, because of the hurdle effect of the pH and low water activity (see Section 2.1 for more information about the hurdle effect). Example 2: Freezing as an AMP Another antimicrobial process that controls the growth of Lm in the post-lethality environment is freezing of RTE products. Freezing prevents the growth of any microorganisms in the product because their cellular activities are arrested, but depending on the method and length of freezing and other factors, some microbial kill can also result. Lm is more resistant to freezing than other foodborne pathogens and may survive freezing. Once the product is thawed, cellular activities of microorganisms may resume. It is important to note that freezing is only effective as an antimicrobial process while the product is frozen. If a product is distributed frozen and then thawed and sold as a refrigerated product, this would not meet the requirement in 9 CFR 430.1 that the antimicrobial treatment is effective throughout the shelf-life of the product. If the product is thawed as part of the preparation process by the consumer, the product will be deemed to have been frozen throughout its shelf-life. Ensuring the Effectiveness of AMAPs According to the Listeria Rule, establishments must document that the AMAP is effective in suppressing or limit growth of Lm over the shelf life of the product (9 CFR 430.4(b)(1)(ii)). The documentation should demonstrate that no more than 2-logs of growth occurs over the expected shelf-life of the product. The documentation for the effectiveness of the AMAP can be included in the establishment\u2019s HACCP plan, Sanitation SOP, or prerequisite program. Establishments may use published peer-reviewed papers, challenge studies, or in-house studies to support the effectiveness of AMAP. For more information on scientific supporting documentation, see Appendix 2.1. NOTE: Although Lm will not grow under the conditions in Table 2.1, it may still survive. In order to meet the conditions for a PLT, establishments would have to provide additional validation demonstrating that Lm is reduced or eliminated.", "FSIS Listeria Guideline January 2014 37 2.3 Sanitation All RTE establishments are required to maintain sanitation in their environment, according to 9 CFR 416. Sanitation is the foundation for an effective Listeria Control Program. Establishments in Alt. 3 rely on sanitation alone to control Lm in their post-processing environment; therefore, it is critically important that they maintain sanitary controls. They are also required to verify sanitation by testing food-contact surfaces for Lm or an indicator organism (see Chapter 3). Maintaining effective sanitation is also important for Alt. 1 and 2 establishments because PLTs and AMAPs are validated to provide certain levels of reduction or control growth of Lm. If levels of Lm are not controlled by proper sanitation, they could overwhelm the effectiveness of PLTs and AMAPs. Therefore, it is important that all establishments producing post-lethality exposed product maintain sanitation in their environments and verify its effectiveness. According to the Listeria Rule, sanitation measures for controlling Lm or an indicator organism may be incorporated into the establishment\u2019s HACCP plan, Sanitation SOP, or other prerequisite program. If Lm control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 9 CFR 416.14. If sanitation measures are incorporated into a prerequisite program other than the Sanitation SOP, the establishment must ensure that the program is effective and does not cause the hazard analysis or the HACCP plan to be

inadequate. The establishment must include the program and the results produced by the program in the documentation that the establishment maintains, as required in 9 CFR 417.5. It is expected that establishments will develop procedures for both routine and intensified sanitation in the event that Lm or an indicator organism is found on a FCS or in the product. Sanitation actions should be escalated if repeated positives are found, indicating Listeria trends. See Chapter 4 and Appendix 2. 2 for more information on Listeria trends and sanitation.

Question: How do I maintain sanitation if my establishment produces raw and RTE product in the same room? Answer: In some instances, small and very small establishments may not have the physical space to have separate RTE and raw processing areas. There are numerous sanitation considerations for separating processes by time or space, such as:

Thoroughly cleaning and sanitizing between raw and RTE processing; Scheduling RTE processing on alternate days or scheduling RTE processing before raw processing; Using separate equipment for RTE and raw processing or scheduling equipment for RTE processing first, then for raw processing; Assigning different personnel for RTE and raw processing or having personnel clean hands thoroughly and use new coats, gloves, and hairnets and sanitized boots for RTE processing; Restricting movement of personnel during RTE processing; Using color-coded coats and locating coat racks for coats used in RTE area in designated space; Maintaining procedures for movement of personnel and equipment to prevent Listeria contamination; and Not allowing RTE product to come in contact with surfaces or raw products in coolers.", "FSIS Listeria Guideline January 2014 38 Reworked Product In some cases, establishments may rework product from previous shifts. Although this is an acceptable practice, reworked products may be more likely to be contaminated than other products because of the increased handling of the products. The establishment may also rework products that are returned from another location (e.g., an off-site warehouse). The establishment should have documented procedures as part of its hazard analysis to evaluate the returned product on receipt, to ensure it has not been temperature abused or otherwise contaminated before being returned to the establishment. In addition, the establishment should have sanitary controls in place as part of its Sanitation SOP to ensure that reworked product is not contaminated during reprocessing or repackaging of the product. Establishments would also need to take into account their production of returned and reworked product when developing their Listeria Control Programs (see Chapter 3) and determining what products to hold when FSIS samples products or food contact surfaces for pathogens.

2.4 Expected Levels of Control 1. Antimicrobial Agents and Post-lethality Treatments Table 2.2 shows the expected level of control (log reduction) for establishments using PLTs and AMAPs in Alt. 1 and 2.

Establishment validation studies or supporting documentation should demonstrate that these levels of control are achieved, at a minimum, in order for the PLT, AMAP to be considered effective (see Appendix 2.1 for more information on designing validation studies). As indicated in the table, establishments that achieve higher levels of control will be sampled relatively less by FSIS than establishments that achieve a lower level of control. Table 2.2 Expected Control Levels for Post-lethality Treatments and Antimicrobial Agents or Processes under Alternatives 1 & 2. [Levels of reduction or inhibition achieved to control Lm] Level of Control\ Treatment Increased Minimum Not Accepted Post-lethality Treatment (reduction should be achieved prior to distribution of the product into commerce) 2-logs or greater reduction At least 1-log reduction Less than 1-log reduction (At this level of reduction, the PLT is not eligible unless

there is supporting documentation) Antimicrobial Agent or Processes (growth must be limited over the shelflife of the product) Allows no more than 1-log growth Allows no more than 2-logs growth Allows greater than 2-logs growth (At this level of growth, the AMAP is not eligible unless there is supporting documentation)", "FSIS Listeria Guideline January 2014 39 How to use Table 2.2 For PLTs, the expectation is that establishments will achieve a minimum of at least a 1-log reduction in L<sub>m</sub> prior to distribution of the product into commerce. If the establishment achieves an increased level of control (a 2-log or greater reduction), they will be sampled less frequently by FSIS. If they do not achieve at least a 1-log decrease, the PLT would not be eligible as a PLT under the Listeria Rule unless there is supporting documentation. In addition, an establishment using a PLT achieving less than 1-log reduction would not be eligible to apply for the labeling claim regarding enhanced protection from L<sub>m</sub> (see Section 1.5). For AMAPs, the expectation is that establishments will demonstrate a minimum of no more than 2-logs of growth over the estimated shelf-life. If the establishment demonstrates an increased level of control (1-log or less of growth over the shelf-life), then FSIS will sample the product less frequently. If the establishment demonstrates more than 2-logs of growth over the shelf-life, then the AMAP would not be considered eligible as an AMAP for purposes of the Listeria Rule, unless there is further supporting documentation.

2. Sanitation Controls Regardless of which alternative an establishment chooses, per 9 CFR 430.4(c), establishments are responsible for maintaining their sanitation programs and may use microbial testing for L<sub>m</sub> or an indicator organism to verify the effectiveness of their sanitation program by testing foodcontact surfaces (FCSs). Establishments in Alt. 2b and 3 are required to test their FCSs to verify sanitation in the environment, and FSIS recommends that establishments in Alt. 1 and 2a test their FCSs, as well. As stated previously, establishments are expected to implement intensified sanitation, and escalate their sanitation actions in response to positive results. Information on intensified sanitation can be found in Appendix 2.2, and recommended testing frequencies to verify sanitation are discussed in Chapter 3.

2.5 Training A clearly written, fully-implemented training program is critical to the success of any food safety program designed to control Listeria. A Listeria Control Program, including implementation of HACCP and Sanitation SOP, will only be effective if employees understand the program, their role, and are able to perform the duties required of them in the program. This applies to new and existing employees involved in all stages of production, from sanitation to food handling to record keeping. Individuals that develop or reassess or modify HACCP plans must be trained in accordance with 9 CFR 417.7(b); however it is important that all employees be trained in basic sanitation. An establishment's Listeria training program should include a broad, basic training program for all employees regardless of their job duties, as well as more specialized training programs for employees that handle product and staff involved in cleaning and sanitation. In some cases, employees that may be involved in more than one of these activities should be trained appropriately. The training should be tailored to meet specific needs of the establishment.

NOTE: Establishments producing products that allow greater than 1-log growth of the pathogen during its shelf life will not be eligible to apply for the labeling claim regarding enhanced protection from L<sub>m</sub>.", "FSIS Listeria Guideline January 2014 40 For more information on developing training programs, see Appendix 2.3.

2.6 New Technology and New Ingredient Review FSIS believes that the facilitation of the use of new technology and new ingredients represents an important means of improving the safety of meat, poultry, and egg products. The

Agency defines "new technology" and "new ingredients" as new ingredients or technologies or new applications of equipment, substances, methods, processes, or procedures affecting the slaughter of livestock and poultry, and processing of meat, poultry, and egg products. FSIS evaluates whether new technology and new ingredients affect product safety, inspection procedures, inspection program personnel safety, or if they would require the waiver of a regulation. Substances used as new technology or new ingredients must also meet the requirements for safety and suitability under the Agency's food ingredient approval process. While the Food and Drug Administration (FDA) has the responsibility for determining the safety of food ingredients and additives, as well as prescribing safe use, FSIS has the authority to determine that new ingredients and new uses of ingredients are suitable for use in meat, poultry, and egg products. FDA and FSIS have a Memorandum of Understanding (MOU) regarding the review, approval, and listing of food ingredients and sources of radiation used in the production of meat, poultry, and egg products. This agreement establishes the working relationship to be followed by FSIS and FDA in responding to requests for the sanctioning of the use of food ingredients and sources of radiation subject to regulation by FDA and intended for use in the production of meat, poultry, and egg products. This review is normally done simultaneously by both agencies. The MOU information can be found at: Memorandum of Understanding between FDA and FSIS

The FSIS Innovations (New Technology) Staff within the Risk, Innovations, and Management Division (RIMD) in the Office of Policy and Program Development (OPPD) reviews new technology and new ingredients that can be applied in meat, poultry, and egg processing to facilitate the introduction of the new technology in establishment or plant operations. New technology and new ingredients for use on post-lethality RTE meat, poultry, and egg products to control the growth of Lm should be sent to the New Technology Staff for review. FSIS issued the document "Guidance Procedures for Notification and Protocol Submission of New Technology" to aid in the submission of applications for review of new technology and new technologies by FSIS. Those to which FSIS has "objection" to their use in FSIS establishments are posted on the FSIS website at: New Technology Tables. A listing of ingredients that have been reviewed and approved by FDA and FSIS are available in 9 CFR Part 424, Subpart C, 424.21 "Use of food ingredients and sources of radiation." This regulatory listing of approved ingredients is now updated quarterly through revisions of FSIS Directive 7120.1 "Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products" to expedite the posting of new approved substances.

NOTE: A clearly written, fully-implemented training project is critical to the success of any Listeria Control Program. A Listeria Control Program will only be effective if employees understand the project, understand their roles, and are able to perform the duties required of them in the project."

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The above technology and ingredient reference resources should be used when considering the use of a technology or ingredient.

2.7 Glossary

Antimicrobial Agent (AMA): A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as Lm, or that has the effect of suppressing or limiting growth of a pathogen, such as Lm, in the product throughout the shelf life of the product. Examples include potassium lactate and sodium diacetate, both of which limit the growth of Lm (9 CFR 430.1).

Antimicrobial Process (AMP): An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as Lm, in the product

throughout the shelf life of the product (9CFR 430.1). Antimicrobial agents and processes are referred to together as (AMAP). Log Reduction: A 90% reduction of a pathogen. For example, a 2-log<sub>10</sub> reduction is a 99% reduction of a pathogen. Post-lethality Treatment (PLT): A lethality treatment that is applied or is effective after postlethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure (9 CFR 430.1). Prerequisite Program: A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called \u201cprerequisite\u201d because it is considered by scientific experts to be prerequisite to a HACCP plan (9 CFR 430.1). Rework: Rework is the process of recooking, reprocessing, or repackaging the product. This could also include temporary packaging of the product. FSIS considers any process that removes the product from the package and exposes it to the environment as rework. Sanitation Standard Operating Procedure (Sanitation SOP): Written procedures for sanitation that describe all of the procedures the establishment will perform daily, before, and during operations, sufficient to prevent direct contamination or adulteration of products, according to 9 CFR 416.12(a).

2.8 References

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minutes respectively. These investigators developed a model called ThermoPro that could predict the thermal lethality of pathogens in fully cooked meat and poultry products during post-cook in-package pasteurization (Murphy et al., 2001, 2003b, 2003c). The model was developed using *L. innocua* and verified for *Lm*. Information gathered from the summary or abstract: Post-lethality treatment: hot water pasteurization or steam pasteurization Products: fully cooked chicken breast fillets and strips Procedure: fully cooked products were surface inoculated with *Lm*, vacuum packaged and pasteurized Equipment used for the pasteurization treatment: Steam pasteurization: pilot-scale steam cooker Hot water pasteurization: pilot-scale hot water cooker Temperature of pasteurization: 90\u00b0C Reduction of *Lm*: 7-log reduction Products and time of pasteurization that resulted in 7-log reduction Product Time of pasteurization (min) Single-packaged breast fillets 5 227g-package strips 25 454 g-packaged strips 35 II. Pre-Package Pasteurization and Post-Package Surface Pasteurization Pre-package surface pasteurization treatment of fully cooked meat removed from its packaging wrap and inoculated with *Lm* resulted in a 1.25 to 3.5-log reduction with a treatment time of 60120 sec at 475 to 750\u00ba F air temperature (Gande and Muriana, 2003). Surface pasteurization was applied on cooked whole and split roast beef, whole corned beef, and whole and formed ham using a radiant oven. Pre-package pasteurization (60 sec) combined with post-package submerged water pasteurization using formed ham (60 or 90 sec), turkey bologna (45 or 60 sec), and roast beef (60 or 90 sec), resulted in a 3.2 to 3.9-log reduction for ham, 2.7 to 4.3-log reduction for bologna, or a 2.0 to 3.75-log reduction for roast beef. The level of reduction varied depending on the method of inoculation, type of product used, treatment temperature, and residence time." , "FSIS Listeria Guideline January 2014 47 Muriana et al., (2002) used a stainless steel water bath to submerge cooked RTE deli-style whole or formed turkey, ham and roast beef, removed from their package, inoculated with *Lm* and vacuum packaged. Results show a 2 to 4-log decrease in the levels of *Lm* in inoculated products post-cooked at 195-205\u00ba F for 2-10 min. Treatment of processed foods with acidified sodium chloride (ASC) is another example of prepackaging treatment. ASC is an antimicrobial agent that is approved for use on processed meat food products (unless precluded by standards of identity in 9 CFR 319), prior to packaging of the food for commercial purposes (21 CFR 173.325(f)). It is applied as a dip or spray at levels that result in a sodium chlorite concentration of 500 to 1,200 ppm in combination with any GRAS acid at levels sufficient to achieve a pH of 2.5 to 2.9. It is approved as a secondary direct food additive and considered as a processing aid, with very temporary or short term technical effect (bactericidal antimicrobial activity), after which it rapidly degrades to leave no long term residues or actives remaining (Kemp, Alcide Corp., personal communication, 2003). Because of this, it does not have to be included in the ingredient listing of the label. Marsden et al. (2000, unpublished), evaluated sodium chlorite (1,200 ppm) with 0.9% citric acid for its effectiveness in reducing *Lm* on retail sausages. Results show that a water wash gave a 1.2-log reduction of *Lm*. An ASC dip for 15 sec provided a 1.0-log reduction better compared to water wash. ASC exposure time of 30 sec gave 1.1 and 1.6-log reductions over the water wash control, for spraying and dipping, respectively. Spray wash or dipping was found to be comparable in antibacterial effectiveness against *Lm*. II. High-Pressure Processing High-pressure processing (HPP) is a technology that subjects food to elevated pressures, with or without the addition of heat, to inactivate microorganisms and extend microbiological shelf life. This technology provides a means of ensuring food safety for those products that are difficult to

heat treat due to organoleptic effects. HPP was shown to inactivate pathogens without any thermal or chemical effects and, at the same time, preserve the quality of the product.

Raghubeer and Ting (2003) evaluated the efficacy of HPP in inactivating Lm in retail packaged samples of sliced ham, turkey, and roast beef obtained from a manufacturer, and repackaged in 25-g portions. Results show that an inoculum of about 10<sup>4</sup> Lm cocktail in these 3 products and HPP treatment at 87,000 psi for 3 minutes showed no recovery of Lm after 61 days of storage at 34°F. No pressure-injured cells were detected. No adverse organoleptic effects were detected on the 3 HPP treated products during the 61-day shelf life study. No signs of spoilage were seen on all 3 products after 61 days of storage, and for 100 days for ham and turkey.

According to the investigators, the normal shelf life of these products is 30 days, so the HPP treatment extended the shelf life of the products.," "FSIS Listeria Guideline January 2014 48 Attachment 2.2: Antimicrobial Agents or Processes I. Use of Antimicrobial Ingredients including Bacteriophages, Lactates, Acetates, Diacetates, and Ozone Bacteriophages are viruses that infect bacteria, and cause cell death. Bacteriophage preparations may be sprayed on RTE products to reduce or eliminate Lm. These preparations (a mixture of equal proportions of six different individually purified lytic-type bacteriophages specific against Lm) are applied as a spray at a level not to exceed 1 ml of the additive per 500 cm<sup>2</sup> product surface area.

Guenther et al., (2009) showed that Lm pathogen-specific bacteriophages could reduce bacterial counts by up to 5 logs when applied to the surface of hot dogs (sausages) and sliced turkey breast (cold cuts). Ozone is an antimicrobial gas usually applied in an aqueous solution to products, food contact surfaces as a continuous spray (e.g., belts, moving tables), and non food contact environmental surfaces. Currently, the use of ozone is permitted by FDA and FSIS (21 CFR 173.368, FSIS Directive 7120.1) for use with all meat and poultry products, including RTE meat and poultry products. Buege et al., (2004) showed 1.0 to 2.4 log reductions (average 1.5) of Lm when 0.6 ppm ozone for 30 seconds was applied to ham, salami, meatloaf, natural casing wieners, and skinless wieners. Studies have shown that lactic acid and acetic acid have significant antimicrobial activity in broth and food systems. Sodium and potassium salts of these acids, when added to processed-meat formulations, are also known to potentially inhibit pathogenic bacteria, especially Lm. These antimicrobials inhibit growth of pathogens by inhibiting their metabolic activities. Seman et al., (2002) developed a mathematical model capable of predicting the growth or stasis of Lm in commercial cured meat products using a response surface method. The model can be used by manufacturers in the determination of the appropriate amounts of potassium lactate and sodium diacetate to be added to cured meat products that are organoleptically sensible and will not support the growth of Lm. Thirty products were formulated by using a variety of raw material sources such as pork trimmings, trimmed turkey breast halves, and four-muscle ham. Varying amounts of potassium lactate and sodium diacetate were added to the meat formulation and the meats were processed into different products. After chilling, the products were stripped of their casings, sliced into 25-g slices, placed into pouches, and inoculated with Lm by applying it to the surface of 100g of cured meat (four slices). Sodium chloride content was found to have a negative correlation to growth rate. The investigators provided a final regression equation predicting the growth of Lm in cured RTE meat products stored at 4°C. The investigators used predictive model performance factors and a simple linear regression analysis to evaluate the model generated in this study. They verified the accuracy of the model by comparing it with actual Lm growth data

from an independent challenge study conducted with four different commercial RTE meat products using similar storage conditions. Performance factors calculated and evaluated for control products (those","FSIS Listeria Guideline January 2014 49 not containing potassium lactate and sodium diacetate) indicated that on the average, the predicted growth of Lm exceeded those of the observed values by about 24%. The study also emphasized the importance of moisture content in the application of lactates and diacetates as antimicrobial agents. The article reports that \u201cThe results show that increasing amounts of potassium lactate syrup and sodium diacetate decreased the growth rate of Lm, while increasing finished product moisture increased the growth rate. Sodium chloride content was not significant but was found to have a negative correlation to growth rate. This study provided a useful model in determining the target amounts of potassium lactate and sodium acetate for cured meat product formulations to inhibit the growth of Lm. The calculations would also require knowledge of the finished product sodium chloride and moisture contents.\u201d Table 2 from the study shows that different finished product moisture levels, amount of sodium chloride, and lactate and diacetate result in different levels of Lm growth rate.

% Salt	% Sodium Diacetate	% Potassium Lactate Syrup	% Product Moisture	Lm Growth Rate (wk -1 )
1.50	0.15	7.0	74.0	0.0
1.50	0.05	2.5	74.0	0.0991
2.20	0.20	4.75	64.5	0.0
2.20	0.10	0.25	64.5	0.1338

The investigators advised that this validated model is specific to the products designed for the study and the Lm strains used. Testing of this model in other environments and with other Listeria spp., and to formulations that are outside the model\u2019s limits may result in different maximum growth rates. This study (Seman et. al., 2002) provided a useful model in determining the target amounts of potassium lactate and sodium acetate for cured meat product formulations to inhibit the growth of Lm. The calculations would also require knowledge of the finished product sodium chloride and moisture contents. The investigators advised that this validated model is specific to the products designed for the study and the Lm strains used. Testing of this model in other environments and with other Listeria spp., and to formulations that are outside the model\u2019s limits may result in different maximum growth rates. This study was used as the basis for the Opti.Form Listeria Control Model. The Opti.Form Listeria Control Model is a unique tool used to calculate the levels of lactate and diacetate required to retard the growth of Lm in cured meat and poultry products. The model is based on the study detailed in the paper by Seman et al., 2002, above. The model includes: \u2022 Instructions on how to use the model, \u2022 Explanation on the development of the model, \u2022 Information on the anti-microbial effects of lactate and diacetate, Recall Alert An investigation of a 2007 recall of RTE cooked chicken products contaminated with Lm showed that the establishment failed to maintain sanitation, and antimicrobial agent failed to suppress Lm. The moisture levels were higher in the product than in the establishment\u2019s supporting documentation, which could have allowed Lm growth.", "FSIS Listeria Guideline January 2014 50 \u2022 Lactates and diacetates and use of these products, \u2022 Regulations and labeling, and \u2022 Literature references. The model can be accessed by visiting the Purac website at:  
<http://www.purac.com/EN/Food/Calculators/Listeria-Control-Model.aspx>

Bedie et al., (2001) evaluated the use of antimicrobials, including in frankfurter formulations, on Lm populations during refrigerated storage. Fully cooked and cooled frankfurters were inoculated with 103 to 104 CFU /cm<sup>2</sup> of Lm after peeling and before vacuum packaging. Samples were stored at 4\u00b0C for up to 120 days and sampled for testing on assigned days. Results were

as follows: Antimicrobial Level (%) Lm Growth Inhibition Sodium lactate 3 70 days no pathogen growth Sodium diacetate 0.25 50 days no pathogen growth Sodium acetate 0.25, 0.50 20 days no pathogen growth Sodium lactate 6 120 days no growth and reduced pathogen growth Sodium diacetate 0.5 120 days no growth and reduced pathogen growth Inoc. Control 0.0 Increased to 6 logs in 20 days Note: Sodium acetate is approved as a flavor enhancer, not as an antimicrobial agent. No pathogen growth refers to zero increase in the number of inoculated Lm cells (bacteriostatic), while reduced pathogen growth refers to a decrease in the number of inoculated Lm cells (bactericidal) in the product. In this study, tables showed that the reduction varied with storage days, but was up to 1.0 log on some days. Antimicrobials were found to have no effect on pH, except for sodium diacetate, at 0.5%, which reduced the initial pH. Using the formulations and conditions in the study, establishments can add 3% sodium lactate in the frankfurter formulation and obtain no growth of Lm up to 70 days at refrigerated storage of 4°C. If the lethality treatment is adequate to eliminate Lm, then the only probable source of Lm would be from exposure of the product during peeling and repackaging. However, the establishment's sanitation program may keep the numbers to a very low level, and 3% sodium lactate included in the formulation would inhibit the growth of Lm during the product's refrigerated shelf life. Levels of sodium lactate at 6.0% and sodium diacetate at 0.5% showed a reduction of the pathogens; however, these levels are above the permitted levels. A study by Samelis et al., (2002) used similar treatments, processing, and inoculation procedures and frankfurter formulations as the previous study described above. However, in this study, combinations of antimicrobials were used, and in combination with hot-water treatment. Hot-water treatment involved immersion of frankfurters, with two product links in a package to 75 or 80°C for 60 sec. Storage at 4°C yielded the following results:

Treatment Levels (%)	Lm Growth	Inhibition	Sodium lactate	1.8	35-50 days	no growth	Sodium lactate + sodium acetate	1.8	0.25	120 days	no growth; 35-50 days growth reduction	Sodium lactate + 1.8	120 days	no growth; 35-50 days growth", "FSIS Listeria Guideline January 2014 51		
Sodium diacetate	0.25	reduction	Sodium lactate + Glucuno-deltalactone	1.8	0.25	120 days	no growth, 35-50 days growth reduction	Hot water treatment (80°C, 60 s)	+ Sodium lactate	1.8	Inoc. population reduced by 0.4-0.9 log CFU/cm <sup>2</sup> , and 50-70 days growth reduction by 1.1-1.4 CFU/cm <sup>2</sup>	Hot water treatment (80°C, 60 s)	Increase in growth to about 6-8 logs in 50 days	Inoculated Control, no treatment	Increase in growth to about 6 logs in 20 days and 8 logs thereafter up to 120 days	Note: Sodium lactate was used as a 3% of a 60% (wt/wt) commercial solution. Glucuno-delta lactone is approved as an acidifier and a curing accelerator, but not as antimicrobial. Sodium acetate is approved as a flavor enhancer, not as an antimicrobial agent. Glass et al., (2002) evaluated sodium lactate and sodium diacetate on wieners and cooked bratwurst containing both beef and pork supplied by a commercial manufacturer. Antimicrobial solutions used were sodium lactate and sodium diacetate singly or in combination at varying concentration. Wieners were repackaged in gas-impermeable pouches, then surface-inoculated with Lm mixture on multiple areas of the surface of each link. Packages were vacuum-sealed and stored at 4.5°C for up to 60 days. Two types of cooked bratwurst from a commercial manufacturer were evaluated: bratwurst that was cured and naturally smoked and bratwurst that was uncured and unsmoked. Bratwurst was stored at 3 or 7°C for up to 84 days. The surface treatment, consisting of dipping wieners into solutions containing up to 6% lactate and up to 3% diacetate for 5 seconds, did not delay

pathogen growth, indicating that dipping wieners in the lactate\diacetate solutions is not an efficient way to apply the antimicrobials. However, the inclusion of lactates and diacetates in the formulation was found effective in inhibiting growth of Lm. Results were as follows:

Product	Sodium Lactate (%)	Sodium Diacetate (%)	Lm Levels (CFU\pkg)	Bratwurst uncured, unsmoked
3.4	2.0	0.1	0.0	Growth delayed for 4-12 weeks at 7 and 3\u00b0C storage, respectively.
3.4	0.0	0.1	0.0	Growth inhibited for 12 weeks at 7 and 3\u00b0C
Wieners	3.0	1.0	0.0	Growth inhibited for 60 days at 4.5\u00b0C
				Growth inhibited for 60 days at 4.5\u00b0C

A study by Porto et al., (2002) used freshly processed peeled frankfurters in vacuum sealed packages obtained from a commercial manufacturer. Two formulations of links were used in the study: one with added 2 or 3% potassium lactate and the other without added potassium lactate. Frankfurters were aseptically removed from their original package, repackaged, and inoculated", "FSIS Listeria Guideline January 2014 52 with a mixture of Lm. The packages were vacuum-sealed to 95 kPa and incubated at 4 and 10\u00b0C. Results show that the addition of 2% or 3% potassium lactate in frankfurters can appreciably enhance safety by inhibiting or delaying the growth of Lm during storage at refrigeration or abused temperatures. The viability of the pathogen was influenced by pH and the levels of lactate added, but not by the presence of indigenous lactic acid bacteria.

Potassium Lactate (%)	Inoculum CFU\pkg	Storage Temp. (\u00b0C)	Days	Storage Lm Levels (CFU\package)
2.0	20	4	90	Remained at about 1.6 log 3.0
2.0	20	4	90	Remained at about 1.4 log 3.0
4.0	90	4	90	Remained at about 2.4 log 0.0
4.0	90	4	90	Increased to about 4.6 log 0.0
4.0	90	4	90	Increased to about 5.0 log 2.0
10	60	10	60	Remained at about 1.4 log 3.0
10	60	10	60	Remained at about 1.1 log 0.0
20	60	20	60	Increased to about 6.5 after 28 days, declined to about 5.0 after 60 days
20	60	20	60	Remained at about 2.4 log 0.0
50	20	60	60	Increased to about 6.6 log after 40 days and declined to about 5.5 log after 60 days II.

Growth Inhibitor Packaging Growth-inhibitor packaging is an intervention which delivers an active antibacterial agent to the surface of an encased sausage product. By incorporating this special coating onto the internal surface of cellulose casings, the antilisterial treatment is transferred to the surface of the processed meat\sausage during thermal processing. Upon removal of the casing, the treatment remains active on the meat surface, providing effective protection against inadvertent Listeria contamination during subsequent peeling and packaging processes. Growth-inhibitor packaging, used in conjunction with functional HACCP and Good Manufacturing Practices, provides the industry with one more tool to control the risk of Lm contamination of RTE meat and poultry products. Studies on meat formulations for hotdogs using NOJAX\u00ae AL\u2122 (Viskase Corporation, 2003) showed that the use of the casings provide a lethality hurdle to the growth of Lm, not just an inhibitory effect. The lethality impact is delivered within the first hours\days of the sausage\hotdog package life. This impact is dependent on many variables, but is generally in the range of 1 \u2013 2 log decrease of Lm at high levels of inoculation. This performance has been observed in challenge studies conducted on hotdogs drawn from commercial full-scale trials at a number of commercial processing plants. In high-inoculation trials, NOJAX AL has been combined with conventional growth inhibiting additives, and the lethality impact is obtained and then maintained throughout the product life cycle. In these same trials, without growth inhibiting additives, this casing produces lethality but in several weeks the remaining Lm begin to grow. NOJAX AL is available in the U.S., and has been approved by both FDA and USDA for its key component, nisin. This GRAS

component must be included in the ingredient statement via a label change request to the FSIS Labeling and Program Delivery Division. Because this is a", "FSIS Listeria Guideline January 2014 53 naturally derived polypeptide, there are storage and use-by criteria that will have to be adhered to by the user for maximum benefit. Casing shelf-life is about 60-90 days, with a not to exceed temperature of 85\u00ba F. This technology can be applied to most hotdogs and sausages that are encased in cellulose casing. This casing intervention can be used in any instance where casing is used as a mold for processed meat and poultry during thermal processing. This would include cellulose, plastic, and, possibly, natural casing. As part of a manufacturer\u2019s decision to use this technology, benefits are: 1) no capital costs or new equipment; 2) no change in processing steps or plant reconfigurations; 3) no impact on flavor, texture, or package appearance, and 4) minor labeling change to ingredient statement. Since this is a surface treatment, cost will be proportional to the surface to volume ratio of the product: the larger the sausage diameter, the lower the cost per pound. In general, economic analyses put the cost of this lethality intervention at about 2-3 cents per pound of finished product, with a mid-range target price of 2.5 cents per pound for a traditional 10-to-the-pound retail pack of hotdogs. Janes et al., (2002) investigated the effect of nisin added to zein film coatings (Z) coated onto cooked RTE chicken against Lm. Cooked chicken samples inoculated with Lm were dipped into Z dissolved in propylene glycol or ethanol, with or without added nisin (1,000 IU/g) and/or 1% calcium propionate and stored at 4\u00b0C or 8\u00b0C for 24 days. After 16 days at 4\u00b0C, Lm was suppressed by 4.5 to 5 log CFU/g with zein film coatings with nisin. The most effective treatment in the study for controlling Lm on the surface of RTE chicken was found when using edible zein film coatings containing nisin at a storage temperature of 4\u00b0C. A processing plant would use film coatings by fully processing the meat products, then coating them with the films. Coating can be done by spraying or dipping the processed meat products and then allowing them to dry. Zein coatings on the meat products can be dried by circulating air around the meat product using a fan. Finally, the dried coated meat products can be packaged with the usual plastic film material and refrigerated. The study by Janes et. al. has not been tested in commercial poultry processing conditions. Some general observations from the published studies on antimicrobials: \u2022 Lactates, acetates, and diacetates were found more effective in inhibiting growth of Lm when used in combination than when used singly. \u2022 These antimicrobials (described in the guideline) were found more effective when used to the maximum allowable concentration. However, higher concentrations of antimicrobials used in the formulation may affect the sensory qualities of the product, such as flavor and texture, which would necessitate sensory evaluation of treated products. \u2022 When used in combination, the amount needed to inhibit growth may be reduced. \u2022 These antimicrobials were found to have listeriostatic activity more than listericidal activity, i.e., they prevent growth of the pathogen more than reduce the number of cells of the pathogen, and therefore may not be effective against gross contamination of a product. The establishment\u2019s sanitation program should control gross contamination of", "FSIS Listeria Guideline January 2014 54 the processing environment and equipment. Addition of antimicrobials would be effective only as part of the overall HACCP strategy. \u2022 Including these antimicrobials in the formulation was found to be more effective in inhibiting listerial growth than dipping products in solutions of antimicrobials. \u2022 The antimicrobial activity of lactates and diacetates when used singly or in combination is affected by the level of

contamination of the meat product surface and processing factors such as pH, moisture, water activity, fat, nitrite, salt content, time and temperature of storage, and packaging atmosphere. \u2022 Application of the treatments used in these studies is limited to the formulations, products, and treatments used in the studies. Applying these studies to other products and formulations may result in different rates of growth inhibition. Therefore, the establishment should verify the effectiveness of the antimicrobials used in these studies for other processed meat products and other storage temperatures. \u2022 Antimicrobials used in the formulation should have an effective antilisterial activity throughout the commercial shelf life of the product. Currently, the targeted commercial shelf life of refrigerated cooked meat products in the U.S. is 75 to 90 days. \u2022 Using post-packaging thermal treatments in addition to antimicrobials was found to increase the total antilisterial effects of the antimicrobials. \u2022 These antimicrobials were found to be more effective in smoked products formulated with sodium nitrite or in products stored at strict refrigeration temperatures. \u2022 These antimicrobials may be a cost-effective antilisterial method that very small establishments can use.", "FSIS Listeria Guideline January 2014 55 Appendix 2.1 Validation I. Validation II. Scientific Support 1. Published Processing Guidelines 2. Scientific Articles from a Peer-Reviewed Journal 3. Challenge or Inoculated-Pack Studies 4. Validated Predictive Microbial-Modeling Programs 5. Establishing the Shelf-life of the Product III. In-plant Demonstration IV. Validation Examples I. Validation Validation is the process of demonstrating that the HACCP system as designed can adequately control identified hazards to produce a safe, unadulterated product. There are two distinct elements to validation: 1) The scientific or technical support for the HACCP system (design). This consists of having scientific and technical documentation that demonstrates that the designed process can control the identified hazard. In other words, will the HACCP work in theory? 2) The initial practical in-plant demonstration proving the HACCP system can perform as expected (execution). This consists of having records that demonstrate that the HACCP plan achieves what it is expected to achieve. In other words, does the plan work in practice? Validation encompasses activities that make up the entire HACCP system. Validation is an important component to the development of a HACCP system but has particular importance for products produced under the Listeria Rule. Validation, as it relates to the requirements in the Listeria Rule, will be covered in this Appendix. In particular, considerations for scientific support and in-plant data for AMAPs, and PLTs will be covered. Further recommendations can be found in the FSIS Compliance Guideline: HACCP Systems Validation, May 2013. II. Scientific Support The first element of validation is scientific support (design). There are several types of scientific support that would be considered acceptable for validating an AMAP, PLT, or other treatment. These include: \u2022 Published processing guidelines \u2022 Regulatory performance standards Question: Can establishments use the studies cited in the Compliance Guidelines for validation as they use the Compliance Guidelines in Appendices A and B in the Final Rule for certain meat and poultry products to validate cooking and cooling (stabilization) processes? Answer: Yes, provided the product, processing procedures, and ingredients are equivalent to those in the studies. For example, if the pH and concentration of antimicrobial in the study were both considered critical, then the product must have that pH and contain the antimicrobial in the concentration used in the study.", "FSIS Listeria Guideline January 2014 56 \u2022 A scientific article from a peer-reviewed journal, \u2022 A challenge or inoculated-pack study, \u2022 Unpublished data gathered in-house, and \u2022 Validated predictive microbial-

modeling program. The scientific documentation should identify: \u2022 The purpose, \u2022 The experimental procedure (including microbial testing methodology), \u2022 The hazard studied, \u2022 The product type, size, formulation, and composition (i.e., water activity, pH, fat, moisture level, salt level, and if applicable, antimicrobial level), \u2022 The processing steps that will achieve the specified reduction or prevention of growth of the pathogen, and \u2022 The critical operational parameters (i.e., the factors affecting microbial reduction in the processor\u2019s HACCP system), including: \u2022 The model and type of equipment, \u2022 Concentration, \u2022 Time, \u2022 Temperature, and \u2022 Pressure. \u2022 How the critical operational parameters can be monitored, and \u2022 The level of reduction or prevention achieved by the post-lethality treatment or antimicrobial agent applied. Question: What records would the Agency require for products with formulations that are inherently antilisterial, but that may not be formulated specifically for that purpose (e.g., BBQ and pickled meats, precooked bacon, beef snack sticks)? Would the establishment be required to make changes to the HACCP plan, Sanitation SOP, or prerequisite project to account for the antilisterial benefit of the formulation\process? Answer: FSIS would expect the establishment to have scientific support (e.g., citations to published data) that the product characteristics (e.g. moisture level, pH, or salt levels) result in at least a 1-log decrease of Listeria. Inclusion of the process in the HACCP plan would only be required for a PLT. If the process controls Listeria growth, it could be included in the Sanitation SOP or prerequisite project. Question: Does an establishment need to provide additional validation information beyond what is in the Compliance Guidelines with regard to freezing, pH and water activity to satisfy the first part of validation, scientific support? Answer: No. The establishment needs to validate the process in relation to L<sub>m</sub>, except when these values are below the limit of L<sub>m</sub> growth: pH below 4.39, water activity below 0.92, and temperature below -0.4\u00b0C, as stated in the Compliance Guidelines. However, the establishment must have the supporting documentation on-file and must conduct monitoring and verification activities.", "FSIS Listeria Guideline January 2014 57 Care should be taken to ensure that the scientific support documents are sufficiently related to the process, product, and hazard identified in the hazard analysis. The supporting documentation should be complete and available for review. Failure to take these steps would raise questions about whether the HACCP system has been adequately designed and validated. To be effective, the process procedures should relate and adhere to the critical operational parameters in the supporting documentation. Critical operational parameters are those parameters of an intervention that must be met in order for the intervention to operate effectively and as intended. Critical operational parameters include product type or size, the type of equipment, time, temperature, pressure, and other variables used in the study needed to result in equivalent levels of reduction of L<sub>m</sub>. It is important that the critical operational parameters in the establishment\u2019s actual process match those in the scientific support because such characteristics affect the PLT efficacy; for example: pH, water activity, and the presence of preservatives may all affect the PLT efficacy. If one or more of the parameters are not addressed in the process or if one or more parameters differ from those used in the scientific support, then the establishment should document a justification for the differences. 1. Published Processing Guidelines This guideline (the FSIS Listeria Guideline) is an example of a published processing guideline that can provide adequate supporting documentation for an establishment\u2019s control processes for L<sub>m</sub>. For example, Table 2.1 contains growth limits

for Lm, which can be used by establishments to help support the effectiveness of AMPs. If an AMP achieves conditions that would limit the growth of Lm based on the table, and the establishment meets the other criteria in the guidelines that would limit pathogen growth (e.g., maintaining sanitation), then the establishment can consider that the process has been validated to control growth of Lm. The establishment can place Table 2.1 on file and no further scientific support for the process would be needed. However, the establishment should collect in-plant demonstration data in order to meet the second element of validation (see pages 34-35 for a discussion of in-plant demonstration data). In addition, Attachment 2.1 and Attachment 2.2 contain summaries of journal articles that may be used to support the efficacy of PLTs or AMAPs, respectively. These attachments are not considered adequate support on their own, however, because they do not provide the details of each study that an establishment needs to determine if the study is representative of the actual process. For this reason, if an establishment chooses to use one of the articles provided in Attachment 2.1 or Attachment 2.2., FSIS expects that the establishment will have a full copy of the original article on file. Establishments may also keep Table 3.1 on file to support that they are meeting the requirements of the Listeria Rule related to Alternative 2, Choice 2 (2b) and Alternative 3 processes. Establishments can keep this table on file as part of the supporting documentation needed to explain why the testing frequency they have selected is sufficient to control Lm or an indicator organism according to 9 CFR 430.4(b)(2)(iii) (E) and (3)(i)(E). In addition, both Appendix A and Appendix B of the final rule, "Performance Standards for the Production of Certain Meat and Poultry Products", FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks, April 2009 and the Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products may be used to support the reprocessing of contaminated products, as described in Section 4.4. Although Appendix A, the FSIS Guidance on Safe Cooking of Non-intact Meat Chops, Roasts, and Steaks, and the Time-Temperature", "FSIS Listeria Guideline January 2014 58 Tables for Cooking Ready-to-Eat Poultry Products are designed to achieve reductions in Salmonella, establishments are not expected to validate that these processes also achieve reductions in Lm because Salmonella is considered an indicator of lethality for Lm. 2. Scientific Data\Information Peer-reviewed scientific data that describes a process and the results of the process can provide adequate supporting documentation for the establishment\u2019s process. This type of support could include journal articles, graduate student theses, or information found in a textbook. All of these types of scientific data go through a process of evaluation involving qualified individuals within the relevant field. In addition to describing the microbiological results of the process, the data may describe the role intrinsic and extrinsic product factors play on the growth of microorganisms. For example, a textbook may contain data on the growth limits of certain pathogens based on a food product\u2019s water activity and pH. For journal articles, the study should relate closely to the establishment\u2019s process with regards to species, product characteristics, and equipment. The establishment should use the critical operational parameters (see Section II above), cited in the journal article, that achieve the required or expected lethality or stabilization. If the establishment uses parameters that differ from those cited in the journal article, it should provide additional support for those parameters. For biological hazards, the scientific article should contain microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis. A lack of microbial data in the

scientific support could raise questions concerning whether the process design has been adequately validated. There are a number of published journal articles, theses, or textbooks available that can be accessed on-line or through a library system. Again, the establishment should ensure that the study closely relates to the establishment's process. An establishment that uses products, treatments or variables other than those used in the referenced studies should perform its own studies (or use another method of scientific support) to ensure effective reduction of L<sub>m</sub>. For example, if a published study uses a ham product, and the establishment produces a turkey product with a different formulation, the establishment should not use the study alone as its scientific support. In order to support the safety of its process, it would need to use a different study, perform its own study, or use another form of scientific support. Likewise, if an establishment uses a process such as drying for 10 days, and the study shows that drying for 20 days is effective, it would not be appropriate for the establishment to use the study, alone, as scientific support. The establishment would need to provide other support demonstrating that 10 days would be effective in controlling L<sub>m</sub> and other pathogens in their particular product type.

3. Challenge or Inoculated-Pack Studies

In the absence of a published processing guideline, published peer-reviewed paper, or predictive microbial-modeling program that would contain information needed for validation, unpublished studies may be used. In order for an unpublished paper to provide sufficient support, the study would need to be well designed, and the results would need to demonstrate that the specific level of application on specified products or range of products is effective to produce a safe product. For more information on design of challenge studies see the article "Parameters for Determining Inoculated Pack\Challenge Study Protocols" published by the National Advisory Committee on Microbiological Criteria for Foods in the Journal of Food Protection in 2010.," "FSIS Listeria Guideline January 2014 59 Examples of the effects of a post-lethality treatment and an antimicrobial process or treatment over time are shown in Figures 1 and 2, respectively: A challenge study is a study that documents the adequacy of control measures in a process. This involves inoculating the target organism (e.g., L<sub>m</sub> or an appropriate surrogate organism) into a product to determine the effect of control measures such as post-lethality treatment or antimicrobial agent or process on the reduction or growth of the organism. Challenge studies should be conducted by a microbiologist trained in performing challenge studies, in a laboratory to avoid the possible spread of contamination in an establishment. The number of organisms 0 1 2 3 4 5 6 0 4 8 12 16 20 24 28 32 36 40 44 48 Log CFU/gm Time (Hours)

Fig. 1: Effects of a Post Lethality Treatment (PLT) on Levels of Listeria monocytogenes (log CFU/gm) in an RTE Product Over Time Log CFU/gm 0 1 2 3 4 5 6 7 8 9 0 20 40 60 80 100 Log CFU/gm Storage Time, Days

Fig. 2: Listeria monocytogenes Counts for Antimicrobial Treatments 1 & 2 Treatment 1 Treatment 2 Control Note: For Treatment 1, shelf life is 80 days For Treatment 2, shelf life is 50 days", "FSIS Listeria Guideline January 2014 60 before and after the application of the control measure is counted to determine the effect of the control measure. The study determines the effect using different processing variables such as time, temperature, pressure, concentration, acidity, pH and others. Challenge studies are performed under laboratory conditions, which means that the scale of the study is adjusted, based on the capacity of the laboratory (i.e., fewer products may be tested, and a water bath may be used rather than a hotwater pasteurizer). The challenge study is often the most definitive means of scientific support. The study should be done on the same product or very

similarly formulated product, closely replicating conditions in the real production environment.

\u2022 For an antimicrobial agent or treatment, the challenge study should be designed to demonstrate that Listeria growth does not occur over the product shelf life. (see establishing a Product\u2019s Shelf-life below). \u2022 For a PLT, the challenge study should demonstrate a specific log reduction of Listeria effective from day 0 to the point before the product leaves the establishment. If challenge studies are used as supporting documentation by the establishment, it is important that they use product that has similar physical characteristics to that being produced by the establishment (i.e., pH, Aw, etc.) and processing (and intervention) steps that are similar to those utilized by the establishment. For example: \u2022 If a challenge study examines the effect of steam pasteurization or hot-water pasteurization, the time and temperature of treatment may be critical components of the study. In order for the study to be used as supporting documentation, the establishment would need to apply the same or similar time and temperature treatment. \u2022 For high pressure pasteurization, pressure is a critical variable. The establishment would need to apply the same pressure as specified in the study.

\u2022 For the use of chemical additives as antimicrobial agents, pH, acidity, and concentration may be additional critical variables. The establishment would need to demonstrate that they are applying the same levels as specified in the study. All challenge studies should be based on a sound statistical design and should also employ positive and negative controls. Listeria innocua strains are usually employed as a nonpathogenic surrogate for Lm. The inoculum level should be at least two logs greater (if possible) than the log reduction to be demonstrated. The inoculum should be composed of a cocktail of 3-5 Listeria strains, including some strains known to be relatively resistant to the Question: Many dried meat products do not support the growth of Lm, and Lm present on the product will die. If challenge studies are conducted to demonstrate the death of some identified amount of Lm, will FSIS consider the products to fall under Alt. 1? Answer: When challenge or inoculation studies incorporated into the establishment\u2019s HACCP plan demonstrate both elimination of Lm before product leaves the establishment and that Lm growth is not supported during the shelf life, those products likely will fall under Alt. 1.", "FSIS Listeria Guideline January 2014 61 treatment. The levels of Listeria should be measured at day 0 (initial level) and remaining levels measured daily or at regular intervals (Day 1, 2, 3) to the end of the shelf life (or until the point when product would leave the establishment). Listeria isolates used in challenge studies should relate to the type of meat or poultry product. They could be from foodborne illness outbreaks or from meat or poultry processing environments. If possible, one of the strains should be from a product as similar as possible to the product to be challenged, e.g., a strain isolated from a specific luncheon meat should be included in challenge studies for luncheon meats. A single strain of L. innocua may be used if the strain is known to be particularly resistant to the treatment (~2 fold more resistant) being tested (e.g., L. innocua M1 for studies evaluating heat treatments). One way of obtaining isolates is to purchase strains from culture repositories. These include the American Type Culture Collection (ATCC), the National Collection of Type Cultures (NCTC). Cornell University hosts the ILSI Lm strains collection, which provides researchers with a standard set of Lm isolates, thus allowing for comparison of data on Listeria physiological and genetic characteristics generated in different laboratories. These isolates are grouped into two separate sets, including one diversity subset (25 isolates) and one matched human and food isolate subset (17 isolates, 2 of which are also included in the diversity subset) representing

isolates from human listeriosis outbreaks and cases. More information on the ILSI Listeria strain collection, including a list of all isolates in the collection, source information, year of isolation, serotype, and ribotype information is available on Dr. Wiedmann's website at:

<http://foodscience.cornell.edu/cals/foodsci/research/labs/wiedmann/ilsi-na-strain.cfm>.

4. Validated Predictive Microbial-Modeling Programs Establishments may use the results of modeling programs to satisfy the first part of validation, scientific support. If the establishment: \u2022 Inputs accurate values into the modeling program, and \u2022 The modeling program has been validated for the type of product in question, and \u2022 The results of the modeling program show adequate control of Lm, then the establishment does not need additional scientific support such as a challenge study. If the pathogen modeling program was developed from the manufacturer of an antimicrobial agent, the establishment can contact the manufacturer to determine whether the model has been validated for their particular product and process. The following are some key points regarding the use of microbial pathogen modeling programs: \u2022 Modeling programs can be obtained from published studies or from the manufacturer of an antimicrobial agent. Information and guidance on the application of the antimicrobial agent may be obtained from the manufacturer. \u2022 Establishments can also seek guidance from University Extension Service specialists or authors of the modeling programs on how to use a modeling program. \u2022 If using a modeling program to determine the amount of antimicrobial agent to use, follow the directions with regards to salt content, moisture level of the finished products, and other information needed. For example, a modeling program may ask to confirm that the product is a cured product because the model is only valid for cured products. It will", "FSIS Listeria Guideline January 2014 62 ask for the following: Shelf life of product in days, product specification, salt content (%) and finished product moisture content (%). The program will calculate the amount of lactate\diacetate to be used and the log suppression of Lm based on the information provided. \u2022 Growth models on the use of antimicrobial agents are available mostly for cured products. For uncured products where there are no growth models, validation studies need to be conducted per product. \u2022 Verify the effectiveness of the antimicrobial agent\process used by testing for Lm growth during the shelf life of the product, at a certain frequency. \u2022 Maintain and monitor records of validation, verification, and corrective actions for deviations from the effective application of antimicrobial agents\processes.

5. Establishing the Shelf-life of the Product As stated in Section 2.2, the AMAP must be effective throughout the shelf life of the product (9 CFR 430.1). The shelf life of the product is defined as the amount of time the product can be stored under specified conditions and still remain safe with acceptable quality. In order to demonstrate effectiveness of control measures over the shelf life of the product, the establishment would need to establish their expected shelf life through a challenge study, shelflife study, or other supporting documentation such as predictive microbial modeling. This study or other supporting documentation should demonstrate that the AMAP is effective in controlling growth over the product's shelf life. Although establishments are not required to label their product with a use-by date, or other information indicating the shelf life of the product, a prudent establishment would use this labeling to help ensure that the product is not consumed after the shelf life is complete. An establishment may perform the shelf-life study or provide other supporting documentation establishing the shelf life of the product. A microbial shelf-life study is one that measures the increase or decrease in

the number of the target organism or pathogen during storage. For an AMAP, a shelf-life study is important to perform as part of the challenge study, because it determines the time (in days) the growth of Lm is controlled. Both refrigeration temperatures (e.g., 40°F) and a slightly abusive temperature (e.g., 45°F) should be used in the shelf-life study in order to ensure that if Lm is present and viable, growth will occur and can be measured throughout shelf life. This slightly abusive temperature also represents the worse-case conditions that could occur during cold-chain storage and handling. Some of the factors that should be considered in the shelf life study of a product with an added AMAP to determine that the agent or process is effective in limiting or suppressing growth of Lm are: 1. Suppression of Lm growth in product during shelf life growth should be lower in the product with added antimicrobial than growth in the untreated control. Although the Compliance Guidelines set a maximum of less than 2 log growth of Lm during the shelf life of product with added antimicrobials for the purposes of the challenge study, it is best to target a lower amount of growth than this. 2. The rate of growth of Lm in product-- the Lm growth-rate in product with added antimicrobial should be slower than the growth rate in product without added antimicrobial.", "FSIS Listeria Guideline January 2014 63 3. Temperature for holding product during the shelf life study Most studies use the temperature that the product is normally held during storage as the temperature during shelf life studies e.g., refrigerated temperature of 38-40 °F. Shelf life studies can also use or include a temperature of 45 °F to hold product since this reflects consumer handling. A resource article for conducting challenge studies for validation of antimicrobial agents is the Considerations for Establishing Safety-based Consume-by Date Labels for Refrigerated Ready-to-eat Foods(NACMCF, 2004).This article gives guidance on how to determine the shelf-life of a RTE product containing an added antimicrobial agent that is supposed to suppress Lm growth during the refrigerated shelf-life. Most studies use the temperature which the product is normally held during storage as the temperature during shelf life studies, e.g., refrigerated temperature of 38-40°F. As described above, shelf-life studies also should use or include a temperature of 45°F which reflects consumer handling. The NACMCF document recommended to using a higher temperature for shelf-life studies because foods can encounter a range of temperatures below and above 45°F, with higher temperatures more likely in grocery store cases and during consumer handling. Therefore these temperatures more accurately reflect reality. In addition, establishments should extend the time period of their study (e.g., 2.5 times the shelf-life) to determine the safety if consumers hold the product longer. NOTE: A product with an added antimicrobial agent demonstrating Lm growth of <2 log at a storage temperature of 38-40°F and at 45°F or above would be viewed by FSIS as more protective of public health than another product showing the same growth only when stored at 38-40°F.

III. In-Plant Demonstration Data The second element of HACCP systems validation is initial in-plant validation which may include in-plant observations, measurements, microbiological test results, or other information demonstrating that the Lm control measures, as written into a HACCP system, can be executed within a particular establishment to achieve the process intended result. In cases where the process specifications described in the supporting documentation are implemented in the same or similar enough way (see box below) in the establishment process, and when the scientific supporting documentation used contains microbiological data specifying the level of pathogen reduction achieved by the

intervention strategy for the target pathogen identified in the hazard analysis, the establishment should: \u2022 Identify the critical operating parameters in the scientific support, AND \u2022 Translate them in the HACCP system, AND As of the date of this guideline, FSIS realizes that some establishments may not have kept their initial in-plant demonstration documents from when HACCP was originally implemented. Those establishments that have not will be allowed the time to assemble their in-plant demonstration documents. The Agency will describe and explain these documents in a future Federal Register Notice that it intends to issue when it finalizes the Compliance Guideline on HACCP systems validation. Until the Federal Register Notice issues and further instructions are given to FSIS personnel, FSIS will not cite the lack of in-plant validation data as the only reason for the documentation of noncompliance.", "FSIS Listeria Guideline January 2014 64 \u2022 Demonstrate that the critical operating parameters are being met by gathering 90 days of execution data. By demonstrating that the critical operating parameters are being met through the collection of execution data, the establishment will have addressed the second element of validation \u2013 inplant demonstration data without the need for further microbiological data. In cases where the process specifications described in the supporting documentation are not implemented in the same or similar enough way in the establishment\u2019s process, or when the scientific supporting documentation used does not contain microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the establishment should: \u2022 Validate that the intervention as modified actually achieves the effect documented in the scientific supporting documentation (Element 1), AND \u2022 Validate that the modified critical operating parameters are being met, AND \u2022 Validate the intervention\u2019s effectiveness under actual in-plant conditions. The establishment should develop the appropriate execution data during the initial 90 days of implementing a new HACCP system, or whenever a new or modified food safety hazard control is introduced into an existing HACCP system as identified during a reassessment. During these 90 calendar days, an establishment gathers the necessary execution data to demonstrate critical operating parameters are being achieved. In essence, the establishment would repeatedly test the adequacy of the process steps in the HACCP system to establish that the HACCP system meets the designed parameters and achieves the intended result as described in the HACCP Final Rule. These execution data become part of the validation supporting documentation along with the scientific support used to design the HACCP system.

NOTE: Microbiological data (e.g., challenge studies or in-plant data) is encouraged but not required to comply with the minimum initial validation requirements provided the establishment has adequate scientific supporting documentation (e.g., journal articles) to meet the first element of validation. In addition the establishment would need to follow the parameters in the scientific support, and demonstrate that it can meet the critical parameters during operation (the second element of validation). In order to meet the second element of validation (in-plant demonstration data) the establishment would need to gather data (such as monitoring records of water temperature for a hot water pasteurization process or of water activity resulting from a drying process) over the initial 90 days demonstrating the critical operational parameters are being achieved. Generally, establishments should use the same critical operational parameters as those in the support documents. In some circumstances, establishments may be able to support using critical operational parameters that are different

from those in the support documents (e.g., higher concentrations of antimicrobials or higher thermal processing temperatures). In these cases, establishments should provide justification supporting that the levels chosen are at least as effective as those in the support documents. In addition to ensuring that the levels chosen are at least equally as effective, establishments should also ensure the levels are also safe and suitable per FSIS Directive 7120.1.","FSIS Listeria Guideline January 2014 65 For examples of the type of scientific support and in-plant demonstration data that would be expected for different types of Lm controls, please see the validation examples taken from the FSIS Compliance Guideline on HACCP Systems Validation on the following pages.","FSIS Listeria Guideline January 2014 66 IV. Validation Examples NOTE: Establishments may also collect environmental swab samples on different processing dates and at different times during the 90-day initial validation period to potentially find hard-to-control areas and niches within the establishment. Product Hazard Process Critical Operational Parameters Validation Scientific Supporting Documentation Initial In-plant documentation Postlethality exposed ready-to-eat meats Listeria monocytogenes Prerequisite program \u2013 Sanitation SOPs Listeria Control Program for food contact surfaces. Sanitary design of equipment and sanitary zone concept. Frequency for collecting samples and number of samples that should be collected per line. Joint Industry Task Force on Control of Microbial Pathogens in Ready-to-Eat Meat and Poultry Products. 1999. Interim Guidelines: Microbial Control During Production of Ready-to-Eat Meat and Poultry Products, Controlling the Incident of Microbial Pathogens. Sanitary Design Assessment Fact Sheet Tompkin, R.B. 2004. Environmental Sampling \u2013 A tool to verify the effectiveness of preventive hygiene measures. Mitt Lebens Hyg. 95:45-51. Tompkin, R.B. 2002. Control of Listeria monocytogenes in the food processing environment. J Food Prot. 65: 709-725. FSIS. 2012. Compliance Guidelines to Control Listeria monocytogenes in Post-lethality Exposed Ready-to-eat Meat and Poultry Products. In plant monitoring records for 90 day period mapping food contact surface swab results for Listeria spp. collected on different processing dates and at different times and locations a 90-day period to potentially find hard-to-control areas in the plant and to support ongoing verification testing frequency after the initial validation period\*. Assessment of sanitary design of equipment in the postlethality environment using the AMI Sanitary Equipment Design worksheet and changes to Listeria Control Program based on assessment. Identification of all possible food contact surfaces.","FSIS Listeria Guideline January 2014 67 \*NOTE: Reduction of Lm was found to be less for smoked turkey deli meat with skin-on using these time\temperature parameters than smoked turkey deli meat without skin, although the log reduction was > 1 log. For products subject to 9 CFR 430, it is FSIS expectation the post-lethality treatment will be designed to achieve at least a 1-log lethality of Lm before the product leaves the establishment. Product Hazard Process Critical Operational Parameters Validation Scientific Supporting Documentation Initial In-plant documentation Postlethality exposed ready-to-eat smoked turkey deli meat with skin on\* Listeria monocytogenes Hot water Pasteurization Hot water temperature at 195\u00b0F; product submersed for at least 6 minutes. Muriana, P.M., Quimby, W., Davidson, C.A., Grooms, J. 2002. Post package pasteurization of ready-to-eat deli meats by submersion heating for reduction of Listeria monocytogenes. J. Food Prot. 65(6): 963-969. In plant monitoring records for 90 day period demonstrating time and temperature can be consistently achieved. In plant monitoring records for 90 day period in which temperature of water is mapped and measured at increased frequencies to support monitoring procedures and

frequencies.", "FSIS Listeria Guideline January 2014 68 Appendix 2.2: Sanitation I. Introduction II. Pre Operational Sanitation Procedures III. Operational Sanitation Procedures 1. Controlling Temperature and Air Handling Units 2. Equipment Design 3. Traffic Control 4. Employee Hygiene 5. Controlling Cross Contamination IV. Sanitation During Construction V. Intensified Sanitation in Response to Positives VI. Determining the Effectiveness of the Sanitation Program I. Introduction The cornerstone of the Listeria Rule is sanitation within the post-lethality environment. All other layers of antimicrobial interventions (antimicrobial agents, post-lethality treatments, antimicrobial processes) are built upon the effective design of the establishment's sanitation program to control Lm and will not be effective if the sanitation program is poorly designed. Understanding the growth/survival characteristics is critical to the success of controlling the pathogen. Lm is more heat-resistant than most foodborne pathogens. It can survive freezing and drying. Lm resists high salt levels, nitrite, and acid and can grow in vacuum packaged products. Most importantly, the pathogen can grow in a damp, cool environment. Once the bacteria attaches to a surface it can form a biofilm and establish a niche, or harborage site, which can become more resistant to superficial cleaning regimens. Bacteria can then spread from the niches to food-contact surfaces and product. The critical components of an effective sanitation program to control Lm can be divided into the following major categories. These include: Pre-operational cleaning and sanitizing procedures that are effective in preventing Lm from forming niches or harborage sites in the processing environment. Operational sanitation procedures to prevent cross-contamination in the RTE processing environment. Intensified cleaning and sanitizing procedures in response to positive sampling results. Documentation and verification of cleaning and sanitizing procedures. Establishments are required to develop and implement the Sanitation SOP regulatory requirements, 9 CFR 416.12 through 416.16. Proper and effective sanitation involves both cleaning and sanitizing, and verifying that the cleaning and sanitizing were effective. This involves developing and implementing written sanitation standard operating procedures (Sanitation SOPs). Sanitation SOPs could be viewed as the first step to designing a total system, including the HACCP plan that will prevent, eliminate, or reduce the likelihood of pathogenic bacteria from entering and harboring in the plant environment.", "FSIS Listeria Guideline January 2014 69 Sources, Harborage, and Control of Lm Contamination An effective sanitation program should prevent contamination of food contact surfaces and prevent the formation and growth of Lm in a niche, especially in areas where the product is post-lethality exposed. A niche is an area where Listeria has grown to high numbers, such as a harborage site within the plant. Harborage sites provide an ideal place for Lm to establish and multiply. Factors that may affect the formation of niches include: equipment design, construction activities, operational conditions that move product debris into difficult to clean locations, mid-shift cleanup, high pressure during cleaning, and product characteristics that require excessive rinsing. Certain strains can become established in a processing environment for months or years. Lm can be spread from these sites and re-contaminate food or food contact surfaces between the lethality step and packaging. Therefore, the sanitation procedures should target the known reservoirs and harborage sites within the RTE processing environment. Examples of reservoirs and harborage sites of Lm in RTE processing environment Drains, hollow rollers on conveyors, on-off valves and switches, worn or cracked rubber seals around doors, vacuum/air pressure pumps, lines,

cracked tubular rods on equipment, air filters, condensate from refrigeration units, floors, standing water, open or gulley drains, ceilings and over head pipes, overhead rails and trolleys, chiller and passageway walls and doors, chiller shelving, roller guards, door handles, boots, ice makers, saturated insulation (wet or moldy), trolley and forklifts, compressed air, in-line air filters, trash cans, cracked hoses, wet, rusting or hollow framework, walls that are cracked, pitted, or covered with inadequately sealed surface panels, maintenance and cleaning tools, space between close fitting metal-to-plastic parts, and space between close fitting metal-to-metal parts. \u2022 Filling or packaging equipment, packaging film or wrappers, solutions (e.g., brine) used in chilling food, \u2022 Peelers, slicers, shredders, blenders, brine chillers, casing removal system, scales, or other equipment used after heating and before packaging, Spiral or blast freezers, conveyors, \u2022 Bins, tubs, wagons, totes, or other containers used to hold exposed product.

II. Pre-operational Cleaning and Sanitation Procedures

Typically, effective sanitation can be distilled down to the nine following steps. This is an example outline. Cleaning should be intensified during periods of construction and if repetitive positives are found.", "FSIS Listeria Guideline January 2014 70

- 1) Perform dry cleaning of the equipment, floors, conveyor belts, and tables to remove meat particles and other solid debris. Some equipment, such as slicers and dicers, will require disassembly so that parts can be cleaned thoroughly.
- 2) Wash and rinse floor.
- 3) Pre-rinse equipment (rinse in same direction as product flow). Pre-rinse with warm or cold water \u2013 less than 140\u00b0F (hot water may coagulate proteins or \u201cset soils\u201d).
- 4) Clean, foam, and scrub equipment. Always use at least the minimum contact time for the detergent\foam. Guidance should be provided concerning the location of possible niches and written instructions provided concerning the cleaning method. NOTE: Live steam for cleaning is not acceptable at this step since it may bake organic matter on the equipment.
- 5) Rinse equipment (rinse in same direction as product flow).
- 6) Visually inspect equipment to identify minute pieces of meat and biological residues.
- 7) Sanitize floor and then equipment to avoid contaminating equipment with aerosols from floor cleaning. Care should be taken in using high pressure hoses in cleaning the floor so that water won\u2019t splash on the already cleaned equipment. Use hot water, at least 180\u00b0F, for about 10 seconds to sanitize equipment. Sanitizers (e.g., acidic quaternary ammonia) may be more effective than steam for Lm control.
- 8) Rotate sanitizers periodically. Alternating between alkaline-based and acid-based detergents helps to avoid \u201csoapstone\u201d and biofilms. This also helps change the pH to prevent adaptation of bacteria to a particular environment. Portable highpressure, low volume cleaning equipment (131\u00b0F (55\u00b0C) with 20-85 kg/cm<sup>2</sup> pressure and 6- 16 liters\minute) can also be used.
- 9) Dry. Removing excess moisture can be done most safely and efficiently by air drying. Reduced relative humidity can speed the process. Avoid any possible crosscontamination from aerosol or splash if a method other than air drying (e.g., using a squeegee or towel) is used.

Recommended Frequencies for Cleaning and Sanitizing Procedures

Area Recommended Cleaning Frequency

All processing equipment, floors and drains, waste containers, totes, wagons, RTE storage areas Daily

Walls, condensation drips pans, RTE coolers Weekly

Freezers Semi-annually", "FSIS Listeria Guideline January 2014 71

Sanitizers

Cleaning and sanitizing are vital to any effective sanitation program. Thorough cleaning should be followed by sanitizing. Generally, the cleaning step is to remove all waste materials and soils, and the sanitizing step is to destroy all microorganisms. Careful consideration should be given to selecting both cleaning and sanitizing solutions. It is important

to use solutions that are compatible with the equipment materials, such as stainless steel or heavy plastics, and solutions that are effective in destroying the type of bacteria commonly associated with the type of products produced in the establishment. Rather than relying on a single sanitizer, rotating sanitizers will help prevent the development of microorganisms resistant to a particular sanitizer. The concentration and application processes for all sanitizers approved for use in meat and poultry establishments are referenced in Title 21 Code of Federal Regulations (21 CFR), Part 178, section 178.1010. All cleaners and sanitizers commercially available should have, at the minimum, the following information either on the label or available on a specification sheet that must accompany the product: Product Description \u2022 \*\* Instructions on how to use the product (concentration, method of application, contact time, temperature) \u2022 Properties \u2022 Safety Information Additional information that is sometimes available includes: \u2022 Benefits \u2022 Quality Assurance Statements \*\*Effectiveness against Listeria. Some manufacturers provide labeling in both English and Spanish, which makes the products more user friendly in various environments. At least one manufacturer also has commercially available color coded products that are easy to associate with a particular cleaning or sanitizing task. Recommendations for sanitizers inactivating Lm in biofilms on stainless and plastic conveyor belts: \u2022 Chlorine and iodophors are not effective inactivating Lm in biofilms on stainless steel. \u2022 The most effective sanitizers are acidic (not neutral) quaternary ammonium compounds, peracetic acid, and chlorine dioxide. \u2022 The less effective are the mixed halogens and acid anionics sanitizers, which were less effective than the sanitizers listed in the 2nd bullet above. \u2022 And the least effective sanitizers were chlorine, iodophors, and neutral quaternary ammonium compounds.", "FSIS Listeria Guideline January 2014 72 III. Operational Sanitation Procedures to Prevent Cross Contamination Between Raw and RTE Post-Lethality Environment 1. Controlling Temperature and air handling units \u2022 Maintain temperature in processing areas and packaging rooms as stated in the HACCP plan, Sanitation SOPs, or Prerequisite Programs. \u2022 Maintain cold temperature (<50\u00ba F) in packaging room for products that are to be refrigerated or frozen, as stated in the HACCP plan, Sanitation SOPs, or Prerequisite Programs to prevent Lm growth in the RTE processing environment. \u2022 Monitor temperatures as stated in the HACCP plan, Sanitation SOPs, or Prerequisite Programs. \u2022 Establish positive air pressure movement out of the RTE room into the raw processing areas. \u2022 Clean cooling units and air handling units at some specific frequency. \u2022 Immediately address and correct problems of dripping condensation and standing water. Production of RTE products should be stopped during repairs and corrective actions for these problems. The equipment and processing area should be cleaned and sanitized after all the repairs and corrective actions are finished. 2. Equipment Design \u2022 Evaluate the equipment to ensure that it can be easily dismantled for cleaning and is durable. \u2022 Investigate for potential Lm harborage sites, such as hollow rollers. \u2022 If new equipment is purchased, select equipment designed to enhance cleaning \u2022 All areas and parts should be accessible for manual cleaning and inspection or be readily disassembled. \u2022 Closed conveyor designs are more difficult to clean. Equipment on the processing line should be as easy to clean as possible. \u2022 Avoid hollow conveyor rollers and hollow framing. If hollow material is used, have a continuous weld seal instead of caulk. \u2022 Select food contact surfaces that are inert, smooth, and non-porous. \u2022 Equipment should be self-draining or self-emptying. \u2022 Maintain

equipment and machinery by adopting a regular preventive maintenance schedule (QA should verify performance)", "FSIS Listeria Guideline January 2014 73 \u2022 Damaged, pitted, corroded, and cracked equipment should be repaired or replaced. \u2022 Repair parts or machinery in a manner that prevents food deposits that are not easily removed with normal cleaning. \u2022 Use separate tools for RTE equipment only. Sanitize them before and after each use. \u2022 If compressed air is used, maintain and replace in-line filters regularly. \u2022 Use lubricants that contain listericidal additives, such as sodium benzoate. Lm can grow in lubricants that are contaminated with food particles. \u2022 Clean maintenance tools (including wrenches, screws, and tool boxes) on a regular basis. Consider designating certain tools for raw and RTE areas.

3. Traffic Control One critical component of an effective sanitation program is control of the movement of personnel and raw product to prevent cross-contamination of RTE finished product and FCSs within the post-lethality environment. Establishments should examine product routes from heat treatment or other antimicrobial control steps to eliminate Lm, to final packaging. The following are steps that can be used to develop control procedures. Establish traffic patterns to eliminate movement of personnel, meat containers, meat, ingredients, pallets, and refuse containers between raw and finished product areas. If possible, employees should not work in both raw and RTE areas. If they must work in both areas, they must change outer and other soiled clothing, wash and sanitize hands, and clean and sanitize footwear. \u2022 If possible, use air locks or vestibules between raw and RTE areas. \u2022 Use foam sanitizing spray systems on either side of the RTE room door on a timed system or triggered by entry\exit. \u2022 Clean, dry floors are preferable to foot baths at the point of entry because effective concentrations of disinfectant are difficult to maintain and may become a source of contamination. \u2022 If foot baths are absolutely necessary: \u2022 Wear rubber or other non-porous boots. \u2022 Maintain them properly, so that they are clean and maintain effective levels of sanitizer. \u2022 Solutions should contain stronger concentrations of sanitizer than normally used on equipment (e.g., 200 ppm iodophor, 400-800 ppm quaternary ammonia compound). \u2022 Use a minimum depth of 2 inches.", "FSIS Listeria Guideline January 2014 74 NOTE: Chlorine is NOT recommended for foot baths because of rapid inactivation, especially if cleated boots are used. The accumulation of biological material adhering to the cleats inactivates (or reduces) the bioavailability of chlorine, making it less effective. Monitor and maintain the strength of the chlorine solution, if used.

4. Employee Hygiene Development of employee hygiene procedures to prevent the contamination of FCSs should be the responsibility of management. The employee should be responsible for preventing contamination of food products and the management should be responsible for ensuring that the employee is properly trained and maintains good practices. \u2022 Employee responsibilities and actions should include:

- \u2022 Using a 20 second hand wash, allowing the soap suds to be in contact with the hands for this period of time, after using restroom facilities.
- \u2022 Washing hands before entering the work area, when leaving work area, and before handling product.
- \u2022 If gloves are worn: \u2022 Gloves that handle RTE product should be disposable. \u2022 Dispose immediately and replace if anything other than product and FCS is touched. \u2022 Dispose of gloves when leaving the processing line. \u2022 Remove coats, gloves, sleeves and other outer clothing when leaving RTE areas. \u2022 Do not wear coats, gloves, sleeves or other outer clothing inside restrooms or cafeterias. \u2022 Do not store soiled garments in lockers. \u2022 Do not eat in the locker room or store food in lockers

because food may attract insects and vermin. \u2022 Do not store operator hand tools in personal lockers. This equipment must remain in the RTE area at all times. \u2022 Do not allow employees who clean utensils and equipment for raw materials to clean RTE utensils and equipment, if possible. \u2022 The tools to clean utensils and equipment for raw materials must be different than those used to clean RTE utensils and equipment. In either case, the intent is to prevent cross contamination of finished product. \u2022 Management responsibilities should include:" "FSIS Listeria Guideline January 2014 75 \u2022 Providing hand washing facilities at proper locations. \u2022 Ensuring that the employee receives proper hygiene instruction before starting \u2013 use of hand soaps and sanitizers, no-touch dispensing systems, and boot and doorway sanitizing systems. \u2022 Developing a system for monitoring employee hygiene practices. \u2022 Developing a system for tracking the training, testing, and certification. \u2022 Retraining employees before placing them back into production if they are absent from the job or have failed to follow acceptable hygiene practices. This will help ensure that the employees are following current, acceptable hygiene habits. \u2022 Do not permit maintenance employees in RTE areas during operations if possible, primarily because they may cause direct product contamination or adulteration if they touch or lay their \u201cdirty\u201d equipment hands onto food contact surfaces. If this is not possible: \u2022 Consider the need to cease operations until a full cleaning and sanitizing is done, or, \u2022 Require maintenance personnel to change outer clothing and any other soiled clothing, use separate tools for raw and RTE areas (or wash and sanitize tools and hands prior to entering RTE areas) and wear only freshly cleaned\sanitized footwear in such areas. \u2022 Use separate equipment, maintenance tools and utensils for the RTE and raw areas. If not possible, there should be a time separation between raw processing\handling and RTE processing in order prevent cross contamination of finished product.

5. Controlling Cross Contamination

\u2022 For establishments processing RTE products, establish procedures to ensure that other non-meat or non-poultry RTE ingredients do not cause cross-contamination with Listeria.

\u2022 Maintain an effective rodent and insect infestation preventive and Control Program.

Rats, mice, and insects are sources of Listeria and other microbial contamination. \u2022 Eliminate standing water which can facilitate the spread of Lm into other areas of the plant. Sanitizer boluses can be used to sanitize standing water on a continuing basis. \u2022 Discard products that touch environmental surfaces, such as products falling on the floor, if the product cannot be properly re-conditioned (e.g., by washing). \u2022 Pallets can serve as a source of cross-contamination \u2013 pallets for raw materials should not be used in RTE areas or used for finished product. \u2022 Do not allow condensation to build up or drip over exposed RTE product." "FSIS Listeria Guideline January 2014 76 \u2022 Do not spray high pressure hoses near exposed product. Aerosols could develop that could contaminate the product. \u2022 Do not allow employees to store knives, gloves, or equipment in their lockers. Provide designated storage areas for these items. \u2022 Employees should not wear gloves, coats, or aprons in the restroom or break areas. \u2022 Drains from the \u201cdirty\u201d or \u201craw\u201d side should not be connected to those on the \u201cclean\u201d or \u201ccooked\u201d side.

Dual Jurisdiction Establishments Because FSIS-regulated products are susceptible to Lm outgrowth: It is advisable, due to the food safety nature of FSIS-regulated product, to separate processing areas for FSIS-regulated products and FDA-regulated products by time or space, such as scheduling processing on different days. If that is not possible, schedule FSIS product

processing first, then FDA product processing. If FDA product is produced first, a complete clean-up and sanitizing before starting FSIS product processing is recommended. Because of the risk for cross contamination, consider assigning different personnel for FSIS and FDA products and processing areas, if possible, especially if both are conducted on the same day. If not possible, have personnel clean hands thoroughly, and use unused, clean coats, new gloves and hairnets, and sanitized boots for FSIS and FDA processing.

**IV. Sanitation During Construction**

Dust generated by construction activities can move throughout the plant on air currents or be transferred by people or equipment traveling through the construction area into other areas of the establishment. A study by De Roin et al., (2003) showed that Lm in dust can survive and grow, once in contact with meat surfaces. Construction or maintenance activities that can result in Lm contamination of RTE product of FCS include removal of drains, removal of floor coatings, removal of a wall or ceiling that has absorbed moisture, movement of potentially contaminated materials through RTE areas or areas that directly connect with RTE processing areas, and exposure of areas typically not accessible for cleaning. Tompkin (2002) considers the potential of introduction of Lm into the RTE processing environment from an outside source or through disturbance of a harborage site (e.g., the process of replacing floor drains, walls, or cooling units) as a great concern.

**Control of the Environment during Construction**

If possible, suspend operations during construction. Otherwise:

- \u2022 Dust from construction can be difficult to detect and control. Therefore, increased monitoring of product, food-contact surfaces, and the environment is recommended during and after these disruptive events.
- \u2022 Establish negative air pressure in the construction area in order to ensure that air does not flow from the construction area into the plant.", "FSIS Listeria Guideline January 2014 77

- \u2022 Temporary partitions can be established to protect the undisturbed areas of the plant from construction dust and debris.
- \u2022 Cover any construction debris when moving out of the construction area.
- \u2022 Do not move debris through RTE processing areas or areas that directly connect to RTE processing areas, if possible.
- \u2022 Schedule construction during non-processing hours.
- \u2022 Conduct intensified cleaning and monitoring of food contact and environmental surfaces after construction is complete.
- Control of the Environment after Construction**
- \u2022 Schedule removal of all construction equipment, barriers, and final debris after production hours.
- \u2022 Perform a thorough clean-up and increased sanitation sampling at pre-operational inspection.
- Continue intensified cleaning and monitoring of food contact and environmental surfaces until food contact surfaces test negative for 3 consecutive days.", "FSIS Listeria Guideline January 2014 78

**V. Intensified Cleaning and Sanitation Following a Positive Listeria Sample**

The following are actions that can be taken during intensified cleaning. Not all steps may be necessary to address contamination. Actions should be escalated to address consecutive positives. If positives occur, consider:

- \u2022 Thoroughly cleaning and scrubbing sites where positives were found.
- \u2022 Identifying all possible harborage sites and cross contamination pathways.
- Clean and sanitize harborage points and address cross contamination.
- \u2022 Removing equipment parts and soaking overnight.
- \u2022 Increasing the frequency of all less than daily sanitation procedures (e.g., walls and ceilings).
- \u2022 Scrubbing surfaces where product residue accumulates. Pay special attention to gaps, cracks, rough welds, and crevices in equipment.
- If positives continue to occur, consider:
- \u2022 Disassembling equipment and soaking of parts in quaternary ammonia overnight.
- \u2022 After cleaning and sanitizing of larger pieces of equipment, applying steam heat via an oven at 160\u2070F and

holding for 20-30 minutes. Fogging the room with a sanitizer solution. Replacing rusty, pitted, peeling tools or parts of equipment with new, smoothsurfaced ones. These rusty, pitted tools and equipment parts serve as ideal harborage places for Lm to grow and multiply. If positives still continue to occur, consider: Identifying harborage points in equipment, such as spiral freezers and slicers, and repairing or replacing. Thoroughly cleaning all areas of the establishment, including raw and non postlethality exposed areas, to address possible harborage sites leading to contamination of RTE areas. Repairing or replacing leaky roofs, broken and cracked equipment, floors, overhead pipes, and cooling units, fans, doors, and windows. Suspend operations during repairs or replacement. FSIS recommends testing the environment for Listeria spp. after repairs are finished. Constructing new walls to separate raw and RTE areas. If drains or air handling units lead to raw areas or outside, consider rerouting.", "FSIS Listeria Guideline January 2014 79 VI. Determining the Effectiveness of the Sanitation Program Establishments can verify the effectiveness of their sanitation program through monitoring the implementation of their pre-operational and operational procedures in their Sanitation SOP. The most basic level of daily verification occurs within the post-lethality environment by monitoring the effective implementation of cleaning\sanitizing of FCSs and observing whether operational sanitation procedures are implemented to prevent cross-contamination (9 CFR 416.13(c)). Maintaining daily records to document the implementation and monitoring of the Sanitation SOP procedures targeted to the RTE environment is also a regulatory requirement to track the effectiveness of the sanitation program (9 CFR 416.16(a)). In addition, observation of employee hygiene practices within the RTE area is required to verify compliance with the Sanitation Performance Standard and prevent cross-contamination (9 CFR 416.5(c)). There are also requirements in the Listeria Rule for sampling for Lm or an indicator organism to verify sanitation. These are discussed in the main body of the Listeria Guideline. It is also important that establishments take steps to prevent future contamination events. This can include reassessing and modifying the Sanitation SOP for specific pieces of equipment or areas of the establishment, increasing cleaning and sanitation frequency, and repairing or replacing equipment or areas of the establishment that may represent harborage sites for Lm. Non-regulatory methods to verify the effectiveness of the Sanitation SOP include the use of total plate counts and ATP bioluminescence, as well as organoleptic inspection. It is important to note that these methods can not be used to replace testing performed for Lm or an indicator organism to meet the requirements of the Listeria Rule. Total Plate Counts (TPC) Visual verification combined with Total Plate Counts (TPCs) can determine both observable contamination and the level of bacterial contamination. Since TPC results are available in about 24 hours, and cannot be obtained at the time of inspection, their value lies in the measurement of the level of contamination. The level of contamination on cleaned and sanitized equipment should be very low (e.g., less than 100 CFU/in<sup>2</sup>). The level of contamination may assist the establishment in determining the source of Listeria contamination and the effectiveness of the Sanitation SOP. Establishments may be able to use the results from TPC monitoring to indicate areas where Listeria spp. testing should be performed. ATP Bioluminescence Testing \u201cLightning\u201d The use of adenosine triphosphate (ATP) bioluminescence swab testing on FCSs can also be a measurement tool to verify sanitary conditions. Most food residue and all microbes are rich in ATP and detecting microorganisms through ATP bioluminescence analysis is one method to test for sanitation

effectiveness. The more ATP present, the greater the amount of bioluminescent light emitted. A microprocessor transforms the data into a digital readout for the luminometer's display and quantifies the light output into a 2 digit zone. The product manufacturer specifies the acceptable and unacceptable zone. The ATP test can detect contamination that is not observable, is a rapid test, and results are available immediately prior to the start of operations. It is important for the establishment to verify that the cleaning and sanitizing procedures are effective. In addition, the recordkeeping should be used for data analysis and the establishment should evaluate the monitoring records for trends. 9 CFR 416.14 requires that each official", "FSIS Listeria Guideline January 2014 80 establishment routinely evaluate the effectiveness of the Sanitation SOP and the procedures therein. Therefore, trend analysis, evaluation, and appropriate revision of the Sanitation SOP, should be conducted, as necessary, to remain effective and current with respect to changes in facilities, operations, equipment, utensils, personnel, and equipment within the post-lethality environment. Records of Sanitation Procedures The following sanitation records are required by 9 CFR 416.16: \u2022 Keep records of the implementation of Sanitation SOPs. \u2022 Maintain monitoring records of Sanitation SOPs. \u2022 Maintain records of corrective actions taken if adulterated product or a direct FCS noncompliance occurs. Ensure appropriate disposition of products, restore sanitary conditions to prevent recurrence, and record the date of the noncompliance and the initials of the plant employee conducting the corrective action. \u2022 Records must be maintained for 6 months, and may be stored electronically. References De Roin, Mark, S.C. C. Foong, P. M. Dixon, J. S. Dickson. 2003. Survival and recovery of Listeria monocytogenes on ready-to-eat meats inoculated with a desiccated and nutritionally depleted dustlike vector. *J. Food Protection*. 66: (6): 962-969. Tompkin, R.B. 2002. Control of Listeria monocytogenes in the Processing Environment. *Journal of Food Protection*. 65 :709-725.,"FSIS Listeria Guideline January 2014 81 Appendix 2.3: Training I. Introduction II. Suggested Training Programs a. Hand washing b. Cross contamination c. Cleaning and sanitizing d. Equipment maintenance e. Sampling f. Facilities III. General Guidance on Training Programs IV. Reference Materials I. Introduction Basic training for all staff should include an overview that defines Lm, the differences between Listeria spp. and Lm, and an explanation of why Lm is a public health concern in post-lethality exposed ready-to-eat products. Training should also include a discussion about locations where Listeria can be found in a processing facility, with an emphasis on common harborage sites. Employees should understand why they should be concerned about Listeria, considering the perspective of both the health of the consumer and the interests of the company. Providing employees with a broad knowledge base regarding Listeria will be beneficial to any Listeria Control Program. For example, the very simple but relevant principle that employees can unknowingly bring Listeria into a ready-to-eat processing facility on their shoes may not be clear to all employees if training does not address that Listeria is ubiquitous in the environment. II. Suggested Training Programs Specific company-wide policies affecting Listeria control should be discussed in a basic training course, such as rules requiring protective smocks of a certain color to be worn in certain areas of the establishment or rules about traffic patterns in the plant. Tailoring your training program to your establishment, your products, and your needs is crucial. a. Hand Washing All personnel should be instructed in proper hand washing techniques. Adopt a descriptive hand washing policy and display clear instructions in all restrooms and at all sinks. Instructions may be for a 20-second hand wash, for example, or to wash hands as long as it

takes to sing "Happy Birthday." A thorough hand washing policy should also include instructions as to when employees should wash their hands, such as after breaks, or before gloving. b. Cross Contamination Although a basic Listeria overview training course for all employees may address cross contamination principles, a more focused cross contamination training course should be directed at employees handling product. Encouraging all employees to be aware and identifying potential harborage sites can limit lost product and reduce risk. Areas for discussion within this course should include the importance of keeping ready-to-eat and raw products separated, from receiving to storage, including food preparation, packaging, and display. General hygiene practices should be discussed, including specific requirements for outer garments, gloves, and", "FSIS Listeria Guideline January 2014 82 shoes. Training should also include common practices that can result in cross contamination, such as an employee sneezing into his or her hand and not washing his or her hands immediately afterwards. The take home message for cross contamination training is that employees must always be aware of how their actions may impact food safety. c. Cleaning and Sanitizing Just as the importance of cleaning and sanitizing cannot be overemphasized, so too is the case for an employee training program that addresses proper cleaning and sanitizing. Employees must not only be shown how to do their job, but they should understand why they are cleaning and sanitizing equipment and utensils and non-food contact surfaces, as well as understand the public health implications of improper cleaning and sanitizing. In addition to the principles of cleaning and sanitizing, the importance of following instructions as to the proper concentration and temperature when preparing chemicals, and the importance of cleaning before sanitizing should also be discussed. Employees need to know specifically what equipment and utensils to sanitize, with special emphasis placed on known harborage sites. The cleaning and sanitation training program should also include a discussion of the importance of disassembling equipment completely when cleaning, as well as instructions as to how often to clean. d. Equipment Maintenance Personnel using equipment and utensils, cleaning and sanitizing equipment and utensils, or involved in the maintenance of equipment and utensils should all be made aware of the importance of a thorough examination for cracks, rust, or pitting which result in non-smooth surfaces. While management may be aware of the importance of looking, for example, for cracks in knives or imperfections in gaskets, the employees that actually handle that equipment may not be aware of these potential Listeria harborage sites. Maintenance personnel should also have training that discusses common improper practices, such as the use of duct tape for equipment repair, which can be a source of contamination and a harborage site for Listeria. e. Sampling Every Listeria control training program should include training targeting personnel involved in the establishment's sampling program. Employees should be thoroughly trained in the "when", "where" and "how" to sample, as well as the "why". For example, the employee should understand that the environmental swabs he or she takes may lead to the identification and elimination of harborage sites. It is also critical that any employee taking samples should be trained in proper aseptic technique procedures. f. Facilities Facilities maintenance personnel should be informed that Listeria thrives in moisture and that it is important that they vigilantly look for leaking roofs, drips, standing water, and condensation. Personnel should be instructed in the procedures to follow if they observe facilities issues that can result in the presence of excessive moisture or water, such as who to notify and what action to take.

III. General Guidance on

Training Programs Training may be delivered in a variety of formats, including handouts, demonstrations, PowerPoint presentations, and on-the-job training, and should be "hands-on whenever", "FSIS Listeria Guideline January 2014 83 possible. It should be delivered in the most appropriate language or languages to meet the needs of its employees so that all employees can fully understand it. For example, training in company sanitation procedures should include a description and demonstration of the procedure to be performed, monitoring procedures, and how to respond to problems. The frequency of training is also very important: all new employees should be trained upon hiring as part of the establishment's new employee orientation prior to starting work. A refresher training course for current employees should be conducted at least once a year to ensure that each employee is properly trained for the job position held. Additional training may be necessary for employees whose duties change. Adequate time for training should be allocated, rather than attempting to fit in training during down time. It is important that all employees clearly understand their roles in the production of safe products upon completion of the training. All aspects of training should be documented, including course contents, who received the training, and when training was given. Even after training is completed, the establishment still maintains the responsibility for ensuring that the training has been implemented correctly. Establishments should verify that employees are implementing the training, as instructed, on the job. This can be accomplished by performing periodic in-house audits where employees are observed to see if they are implementing what they have been trained to do. A review of in-plant records to verify that, for example, equipment has been cleaned at the proper frequency, or that sanitizers have been mixed according to directions, will also indicate if training was effective. The establishment should also have a process in place to address employee training deficiencies, such as retraining. A final suggestion on implementing a successful Listeria training program is to identify a way to get employees involved and vested in the importance of Listeria control and the protection of public health. One way to do this is to have a rewards program where employee incentives, such as a "Food Safety Employee of the Month," are established to recognize outstanding effort in promoting the establishment's overall mission of producing a safe, wholesome product. Opening up Listeria training or the Control Program to employee suggestions may yield some very interesting and useable findings. Employees can be very insightful sources of information for improvements to your Listeria Control Program since they are often able to observe situations that managers do not.

IV.

Reference Materials These resources can be ordered from using the Food Safety Resources for Small and Very Small Plant Outreach: Order Form. FSIS Resources: 1. FSIS Compliance Guideline: Controlling Listeria monocytogenes in Post lethality Exposed Ready-to-Eat (RTE) Meat and Poultry Products (Document) 2. HACCP-10: Generic HACCP Model for Heat-Treated, Shelf-Stable Meat and Poultry Products 3. HACCP-12: Generic HACCP Model for Fully Cooked, Not Shelf-Stable Meat and Poultry Products", "FSIS Listeria Guideline January 2014 84 4. HACCP-15: Generic HACCP Model for Not Heat-Treated, Shelf-Stable Meat and Poultry Products. Pennsylvania State University Resources: 1. Control of Listeria monocytogenes in Small Meat and Poultry Establishments. DVD and booklet 2. Control of Listeria monocytogenes in Retail Establishments. DVD and booklet. 3. Implementation of a Post-Packaging Heat Treatment to Reduce Listeria monocytogenes on Ready-to-Eat Meat Products for Very Small and Small Establishments. DVD and booklet.", "FSIS Listeria Guideline January 2014 85 Chapter 3 FSIS

Listeria Guideline: Listeria Control Program: Testing for Lm or an Indicator Organism 3.1  
Sampling for Lm or an Indicator Organism 3.2 Design of the Listeria Control Program 3.3  
Routine Sampling Program 3.4 Frequency of Sampling and Explanation of this Frequency 3.5  
Sample Collection and Laboratory Testing Methods 3.6 Other Routine Sampling 3.7 Glossary 3.8  
References Attachments 3.1 Possible Food Contact and Non-Food Contact Sites Appendices 3.1  
FSIS RTE Sampling Program 3.2 FSIS Sampling Procedure 3.3 Sample Collection and Laboratory  
Testing Methods This chapter provides information on sampling and testing for Lm or an  
indicator organism and design of the Listeria Control Program. It also provides information on  
sampling frequency and other routine sampling. 3.1 Sampling for Lm or an Indicator Organism  
According to the Listeria Rule, establishments in all three alternatives may use verification  
testing for Lm or an indicator organism (e.g., Listeria spp.) to verify sanitation in their  
postlethality processing environment (9 CFR 430.4(c)(1)). Establishments in Alt. 2b and 3 are  
required to test their food contact surfaces (FCS) in order to verify sanitation in the  
environment (9 CFR 430.4(b)(2)(iii)(A) and (3)(i)(A)). Testing FCSs is encouraged for  
establishments in Alt. 1 and Alt. 2a. If a product or FCS tests positive for Lm, then the product  
will be considered adulterated and the product must be reworked or destroyed Establishments  
are required to hold or maintain control of RTE products that FSIS has tested for Lm or RTE  
products that have passed over food contact surfaces that FSIS has tested for Lm.  
Establishments may move such products off-site provided they maintain control of them (e.g.,  
through company seals). 3.2 Design of the Listeria Control Program Establishments may control  
Lm through their HACCP plan, Sanitation SOP, or prerequisite program. Establishments that  
choose to control Lm through their Sanitation SOP or prerequisite program may do so through  
the use of a Listeria Control Program. The Listeria Control Program can be incorporated as part  
of the Sanitation SOP or designed to work with the Sanitation SOP NOTE: A finding of Listeria  
spp. on a FCS indicates conditions where Lm may be present, but the product is not considered  
adulterated. However, establishments are expected to take corrective action, according to their  
control alternative, to address Listeria spp. positives so that product does not become  
adulterated.", "FSIS Listeria Guideline January 2014 86 Question: My establishment tests FCS for  
Listeria spp. and found a positive result. Are we required to further analyze the sample to  
determine if it\u2019s positive for Lm? Answer: No. There is no requirement that  
establishments further analyze Listeria spp. positives on FCS to determine if they are positive  
for Lm. However, the establishment is required to take corrective actions, depending on their  
control alternative (see Chapter 4 for more information), and HACCP plan as a prerequisite  
program. It is expected that the Listeria Control Program will be designed based on the relative  
risk of the product, depending on the alternative. It is also recommended that establishments  
take corrective and preventive actions and perform enhanced sampling in response to positives  
(see Chapter 4). If the establishment chooses to use a prerequisite program for controlling Lm  
in the environment, it must be included as part of the documentation the establishment  
maintains under 9 CFR 417.5 (see 9 CFR 430.4(c)(6)). Establishments may use the results from  
their Listeria Control Program or other prerequisite program as support for the decision in their  
hazard analysis that Lm is not a hazard reasonably likely to occur in their product. The Listeria  
Control Program should be designed to meet the requirements of the Listeria Rule. For  
establishments in Alt. 2b and 3, the Listeria Rule (9 CFR 430.4(b)(2)(iii) and (3)(i)) requires that  
establishments: \u2022 Provide for testing of FCS sites, \u2022 Identify conditions under which

the establishment will hold and test product, \u2022 State the frequency that testing will be done, \u2022 Identify the size and location of the sites that will be sampled, and \u2022 Provide an explanation of why the testing frequency is sufficient to control Lm. In addition, Alt. 3 deli and hotdog processors are required to perform follow-up sampling and hold and test product after a second positive (9 CFR 430.4(b)(3)(ii)(B)). The Listeria Control Program should also include information about the sampling and testing methods that are used to analyze the samples, and actions taken in response to positive test results, including disposition of contaminated product. Also, although not required, if non food-contact surfaces (NFCS) and product samples are collected as part of the establishment\u2019s routine sampling program, they should be described in the Listeria Control Program (Sections 3.3-3.6 and 4.1-4.3). Listeria Control Program Considerations \u2022 Listeria monocytogenes (Lm) is the foodborne pathogenic species of the bacterial genus Listeria. Most establishments choose to test for Listeria spp. (i.e., Genus Listeria) because they are indicators for Lm. \u2022 Establishments are expected to have Routine and Enhanced Sampling Programs. \u2022 Step-by-step sample collection and laboratory methods should be included. \u2022 The establishment should list all of the food contact surface (FCS) samples they will collect as part of their Listeria Control Program. \u2022 The establishment\u2019s Hold and Test program should be included as part of the Listeria Control Program. NOTE: If the establishment does decide to use its Listeria Control Program as a basis for decisions in the hazard analysis, the establishment should follow the project. If the establishment deviates from the project then FSIS may find that the establishment can no longer support its decision that Lm is not reasonably likely to occur in the product. The establishment would need to provide further justification as to why the product is unlikely to be contaminated with Lm." , "FSIS Listeria Guideline January 2014 87 Parts of the Listeria Control Program The following outline provides considerations that should be taken into account by establishments when designing a Listeria Control Program. Establishments are encouraged to include any additional considerations in designing a Listeria Control Program that are unique to its specific process. \uf0fc Types of products produced (HACCP programs considered under the Listeria Control Program). \uf0fc Listeria Control Alternative(s) used for each product. \uf0fc Organism to be sampled (Lm, Listeria spp., or Listeria-like organisms). \uf0fc Routine Sampling Program (Section 3.3). o List of sites that will be sampled (all possible food contact sites should be identified for Alt.2b and 3 establishments, see page 3-5). o Number and frequency of samples collected and explanation for this frequency (Section 3.4). o Size of each site that will be sampled. o Sampling and testing method (Section 3.5). \uf0a7 Step by step collection method. \uf0a7 Type of analysis performed (detailed laboratory analysis methods should be maintained by the lab). o Sampling for non FCS and product (if performed). See Section 3.6. \uf0a7 Number and frequency of samples collected. \uf0a7 Response to positive results. \uf0fc Enhanced Sampling Program (Chapter 4) o Follow-up testing (Section 4.1) \uf0a7 Timeframe for follow-up sampling (e.g., after the 1st FCS positive). \uf0a7 Number of samples collected. \uf0a7 Response to positive results (corrective and preventive actions (details should be included in the establishment\u2019s Sanitation SOP)). o Intensified testing (Section 4.2) \uf0a7 Timeframe for intensified testing (e.g., after the 2nd FCS positive). \uf0a7 Number of samples collected. \uf0a7 Response to positive results. \uf0a7 Intensified sanitation (details should be included in the establishment\u2019s Sanitation SOP). \uf0a7 Number of consecutive negatives to demonstrate that the process is back in control or that sanitary conditions have

been restored. \uf0a7 Conditions for re assessment of the establishment\u2019s HACCP plan in response to positives. \uf0fc Hold and Test Program for product (Section 4.3) o Conditions for hold and test. o Organism to be sampled. o Type of analysis performed. o Number and type of products to be sampled (statistically based program required for Alt. 3 deli and hotdog producers). o Product disposition in case of a positive result. NOTE: Recommended timeframes for performing follow-up sampling and intensified sampling are included in Table 4.1." , "FSIS Listeria Guideline January 2014 88 Question: Would product racks, sticks, and screens that RTE products are cooked on need to be included as product contact surfaces for Listeria sampling? Answer: Yes, the racks, sticks, and screens that are used for RTE product would be considered food contact surfaces, after the product has been cooked. Even though the racks, sticks, and screens are subjected to high temperatures along with the product, they may be handled when being removed from the oven and may be placed in a cooler as the product is cooled, so it is possible they could become contaminated after cooking.

### 3.3 Routine Sampling Program

As part of their Listeria Control Program, establishments are expected to have both routine and enhanced sampling programs. The routine sampling program should include all of the procedures the establishment will follow when collecting routine samples. As part of the routine sampling program, the establishment should identify the sites they will sample, the frequency of sampling, the number of samples they will collect, the size of the sampling sites, the sampling method, and procedures for sampling NFCS and product (if performed).

Establishments should collect samples on first and second shift if RTE post-lethality exposed product is produced on both shifts. In the routine sampling program, establishments can test for Lm or an indicator organism (e.g., Listeria spp.). For more information on testing methods, see Section 3.5. As previously stated, if a product or FCS tests positive for Lm, then the product will be considered adulterated and the product must be reworked or destroyed. A finding of Listeria spp. on a FCS indicates conditions where Lm may be present and grow, but the product is not considered adulterated. There is no requirement that establishments perform a confirmation test on samples that test positive for Listeria spp. to determine if the sample is positive for Lm. However, because many tests for Listeria spp. are screening tests for Lm, a positive result could mean that Lm is present, just not confirmed by the test. Therefore, establishments are expected to take corrective actions and to follow up on Listeria spp. positives according to their control alternative, so that product does not become adulterated.

#### Food Contact Surface (FCS) Sampling

As stated previously, according to the Listeria Rule, establishments in Alt. 2b and 3 are required to provide for testing of FCSs in the post-lethality processing environment to ensure that the surfaces are sanitary and free of Lm or an indicator organism (9 CFR 430.4(b)(2)(iii)(A) and (3)(i)(A)). Establishments are also required to identify the size and location of the sampling sites (9 CFR 430.4(b)(2)(iii)(D) and (3)(i)(D)). FSIS recommends that establishments in Alt. 1 and 2a also test their food contact surfaces. The sites that the establishment will test can be included in the Listeria Control Program. The expectation for establishments in Alt. 2b and 3 is that all possible FCSs in the post-lethality processing area will be identified. This includes surfaces which may come into contact with food on a regular basis as well as those that may come into contact on an intermittent basis. FSIS recommends that the establishment list all possible FCS in their Listeria Control Program. This means that the establishment should identify items that the product touches (e.g., NOTE: The Listeria Rule requires establishments in Alt. 2b or 3 to test their FCS for Lm or an indicator organism. Testing

product alone would not be sufficient to meet the requirements of the Listeria Rule.", "FSIS Listeria Guideline January 2014 89 equipment, utensils, and gloves). For example, it is not necessary to list each individual glove, but \u201cgloves\u201d should be listed as a sampling site. This will assist the establishment in identifying all areas that could harbor bacterial pathogens such as Lm. By including all possible FCS, the establishment could decrease the likelihood that FSIS would find the food safety system inadequate. NOTE: It would not be sufficient for establishments to collect product samples in lieu of food contact surface samples to meet the requirements for Alternative 2b or 3. The Listeria Rule requires establishments to collect food contact surface samples to meet the requirements for those alternatives (9 CFR 430.4(b)(2)(iii)(A) and (b)(3 )(i)(A)). Sample Collection Considerations Establishments should design their sampling programs so that they collect a combination of random and discretionary samples. Initially, samples should be collected at random, to ensure that all FCS have an equal probability of being sampled. Random sampling should be used after an establishment has started production or begins processing a new product to verify that their system is effective. The establishment should have plans in place so that representative samples of all FCS will be sampled over a specified period of time. Once the establishment has generated data demonstrating that their control system is effective, the establishment should adopt a more risk-based sampling program. The risk-based sampling should include discretionary samples that are collected along with the random samples. These samples can be collected at the discretion of the sample collector based on positive results or other conditions as observed at the establishment. For example, if the establishment is collecting 3-5 samples per line as part of the routine sampling program, 1-2 of the samples should be discretionary while the others should be collected randomly. Discretionary samples should be collected if the sample collector observes conditions that could lead to harborage or cross contamination in the postprocessing environment (e.g., backed-up drains, sanitation issues, and condensation dripping over equipment). Establishments should also sample more frequently in areas where sanitation issues have been identified, and use the results of their sanitation monitoring testing (e.g., APC or bioluminescence) to identify sampling sites. Discretionary samples can also be collected to demonstrate the effectiveness of the establishment\u2019s corrective actions. The results from the discretionary samples can be linked to the sample collector\u2019s Question: Each piece of equipment may have multiple sampling sites. Does the establishment need to identify every site it will sample on the equipment, or just identify the piece of equipment as a sampling site? Answer: The establishment just needs to identify the piece of equipment. However, the establishment should recognize that the equipment may have both food contact and non food contact sites, and should sample these according to their Listeria Control Program. Question: An establishment produces both FDA-regulated and USDAregulated product using the same food contact surfaces on different days. Can the establishment collect food contact surface samples as required by the Listeria Rule when FDA product is being produced? Answer: No. Collecting the samples when FDA product is being produced would not meet the requirements of the Listeria Rule, because the surfaces do not come into direct contact with FSIS product that day. However, collecting food contact surface samples when FDA product is being produced would provide the establishment with useful information regarding its overall sanitary practices.", "FSIS Listeria Guideline January 2014 90 observations, providing more information about sources of harborage or cross contamination in the establishment. If positive samples are

found, the establishment should take corrective actions and collect follow-up samples according to their alternative. In addition, the establishment should target the sites during future routine discretionary sampling, to ensure that the contamination has been addressed. For more information on follow-up sampling see Chapter 4. Examples of FCSs may include: \u2022 Conveyor belts, \u2022 Slicers, \u2022 Utensils, \u2022 Tubs, \u2022 Trays, and \u2022 Racks. A table of other possible FCSs and NFCSSs is provided in Attachment 3.1. As indicated in the table, depending on the establishment\u2019s process some surfaces that would normally be NFCSSs may be considered FCSs if they come into direct contact with the product. For example, employees\u2019 gloves should be identified as FCSs if employees directly handle the product with their gloves. Also, some NFCSSs are adjacent to products (e.g., equipment sides) and are more likely to contaminate product (see Section 3.6 for more information on sampling NFCSSs). Size of the Sampling Sites FSIS recommends that establishments sample a 12\u201dx12\u201d area, when possible. If the sampling site (e.g., tool or control button) is smaller than 12\u201dx12\u201d then a smaller size can be sampled. This sampling size is recommended to provide a representative sample of the equipment and is the same as the sample size FSIS uses when collecting samples (see Appendix 3.2). Therefore, it should help provide similar opportunity for detecting contamination as the FSIS sampling method, when used in conjunction with sampling and analysis methods meeting FSIS expectations (see Section 3.5).

3.4 Frequency of Sampling and Explanation of this Frequency According to the Listeria Rule, establishments in Alt. 2b and 3 are required to state the frequency of testing and include an explanation of why the testing frequency is sufficient to maintain control of Lm or an indicator organism (9 CFR 430.4(b)(2)(iii)(C) and (E) and (3)(i)(C) and (E)). Specifying the sampling frequency is also recommended for establishments in Alt.1 and 2a. The sampling frequency should be based on the following criteria: a) Alternative, b) Establishment size or volume (large, small, very small)<sup>4</sup>, c) Whether or not the establishment produces deli meats and hotdogs, and d) Past history and observed patterns of contamination.

4 Large establishment are those with 500 or more employees, small establishment are those with 10 or more employees, but fewer than 500 employees, and very small establishments are those with fewer than 10 employees or annual sales of less than \$2.5 million.", "FSIS Listeria Guideline January 2014 91 Other factors to consider are type of product, how often product is produced, production volume, product flow, traffic patterns, age of the processing facility, and whether raw product is produced in the same room as RTE products (or produced using the same equipment). Establishments can use the minimum sampling frequencies in Table 3.1 below to meet the requirements of the Listeria Rule. Establishments may prefer to increase their testing frequency in response to positives or Listeria trends (see Section 4.5).

Table 3.1 Minimum Routine Sampling Frequencies for Testing of Food Contact Surfaces (FCS) for Alternatives 1, 2, and 3.

Alternative	Daily Production Volume Ranges (lbs)**	Food Contact Surface (FCS) Testing Minimum Frequency*
Alternative 1	2 times/year/line (every 6 months)	2 times/year/line (every 6 months)
Alternative 2a and 2b	4 times/year/line (quarterly)	4 times/year/line (quarterly)
Alternative 3 Non-deli, non- hotdogs	1 time/month/line (monthly)	1 time/month/line (monthly)
Alternative 3 Deli, hotdogs	HACCP Size: Very small 1-6,000 1 times/month/line (monthly)	HACCP Size: Very small 1-6,000 1 times/month/line (monthly)
	Small 6,001 \u2013 50,000 2 times/month/line (every 2 weeks)	Small 6,001 \u2013 50,000 2 times/month/line (every 2 weeks)
	Large 50,001->600,000 4 times/month/line (weekly)	Large 50,001->600,000 4 times/month/line (weekly)

\*At least 3-5 samples per production line should be sampled each time (every 6 months, quarterly, monthly, biweekly or weekly). \*\*Establishments producing deli or hotdogs under Alt. 3 may decide to collect samples based on HACCP size or

production volume. Frequency Determinations: How to use Table 3.1 The table lists FSIS expectations for minimal sampling frequencies to meet the Listeria Rule. Establishments should consider these frequencies when determining their sampling frequency for their routine sampling program. Establishments can keep this table on file as part of the supporting documentation needed to explain why the testing frequency they have selected is sufficient to control Lm or an indicator organism according to 9 CFR 430.4(b)(2)(iii) (E) and (3)(i)(E). The table has been updated to provide Alt. 3 deli and hot dog Question: Can the food contact surface samples be composited (combined) at the laboratory, so that one result is obtained from all 5 samples? Answer: Yes. Establishments may request that laboratories composite food contact surface samples in order to decrease costs. However, establishments should collect the samples individually to avoid cross contamination and take corrective actions for all sites that are part of a composited sample if a positive result occurs, as described on page 95." , "FSIS Listeria Guideline January 2014 92 producers with the option of using daily production volume ranges or establishment HACCP size to determine sampling frequencies. Basing the sampling frequency on the production volume provides more risk-based sampling frequencies and is similar to FSIS sampling programs. If the establishment chooses to follow the testing frequency based on daily production volume, it is important that it modifies the documentation associated with its sampling programs. It would not be sufficient for the establishment to make modifications to its testing frequency without changing its programs and supporting documentation. When the establishment is using the sampling frequencies specified in the table, at least 3-5 FCS samples per production line should be sampled each time (every 6 months, quarterly, monthly, biweekly, or weekly). The samples should be taken at different days throughout the year, quarter, month, or week, and on different shifts (e.g., 1st and 2nd shift) to ensure that the samples are truly representative of processing conditions. The frequencies listed in the table are based on a typical processing schedule (5 days a week). Establishments that produce intermittently may be able to support sampling less frequently depending on the production schedule. Establishments operating under multiple alternatives that use the same FCS during a production day (clean-up to clean-up) should use the testing frequency for the highest risk product. For example, if an establishment produces hotdog products under Alt. 1 and deli products under Alt. 3 using the same equipment on the same processing day, they should sample at the frequency listed for Alt. 3. As stated previously, the sampling frequencies for FCS testing suggested in the Table 3.1 are recommended minimum frequencies. These sampling frequencies should be increased, or additional intensified samples should be added, based on a change in risk including the following: a) Construction activities, b) Change in the HACCP plan or addition of a new HACCP plan, c) Addition of a new product, d) Roof leaks, condensation, equipment breakdowns, or other events that could change or increase the probability of product contamination, e) Increased positives from routine sampling, or Sample Frequency Considerations \u2022 Intermittent Production: Establishments that produce RTE product intermittently may be able to justify sampling at a lower frequency, based on the number of days they produce. For example, assuming that if there are 20 production days in a typical production month (excluding weekends), and an establishment produces RTE product 1-2 days a week, then it may be able to justify sampling quarterly rather than monthly. \u2022 Representative: Samples should be representative of conditions at the establishment and collected over different shifts and seasons. \u2022 Sampling Frequency: Establishments are

expected to increase their sampling frequency in the event of a positive or other event (e.g., construction) in the establishment. NOTE: Once an establishment has identified a sampling frequency, it should follow the frequency it has selected. If sampling is not performed at the stated frequency, the establishment would need to provide support that their surfaces are sanitary and free of Lm." , "FSIS Listeria Guideline January 2014 93 f) Increased aerobic plate count (APC) or bioluminescence counts indicating sanitation issues. NOTE: Establishments operating under multiple alternatives that use the same FCS during a production day (clean-up to clean-up) should use the testing frequency for the highest risk product. For example, if an establishment produces hotdog products under Alt. 1 and deli products under Alt. 3 using the same equipment on the same processing day, they should sample at the frequency listed for Alt. 3. Question: Our establishment produces a tamale product (meat and cheese filling wrapped in a corn husk). Would this product be considered post-lethality exposed? Answer: Yes. The corn husk is not considered a sealed package. Therefore the tamale would be considered a post-lethality exposed product and FCSs that come in direct contact with the product should be sampled. Question: Our establishment produces a product that is cooked in a casing that is clipped on the ends. The product is not removed from the casing until it reaches the consumer. Would this product be considered cook-in bag, and therefore not post-lethality exposed? Answer: It depends. If the establishment can provide documentation from the manufacturer of the casing material demonstrating that it is not permeable to microorganisms and microorganisms cannot penetrate the packaging at the clip, then the product would be considered non post-lethality exposed (or cook-in bag). If the casing is considered semi-permeable (permeable to microorganisms) then the product would be considered post-lethality exposed. Question: Our establishment produces pickled pig's feet. Would this product be considered post-lethality exposed? Answer: No, pickled pig's feet are typically not considered post-lethality exposed because the product is packaged in a jar with a brine and pickle solution that causes reduction of Lm and does not allow growth. As long as the establishment can provide supporting documentation that at least a 5-log decrease of Lm is achieved by the pickle solution, the product would not be considered post-lethality exposed. Question: Our establishment uses brine to cool post-lethality exposed RTE product. Should we sample the brine? Answer: Yes. If the brine comes in direct contact with RTE product, it should be sampled as a FCS. If the product is packaged in an impermeable membrane, the brine should be sampled as a NFCs. , "FSIS Listeria Guideline January 2014 94 3.5 Sample Collection and Laboratory Testing Methods Sampling using proper collection technique is important to ensure that low levels of Lm or Listeria spp. are detected in the post-lethality processing environment. It is also important that results are accurate and reliable, so they can be used to support the decision made in the hazard analysis that Lm is not reasonably likely to occur in the product. The establishment should provide written instructions for collecting food contact, environmental surface or product samples, and the samples should be collected using aseptic techniques (see box below). The instructions can be included as part of the establishment's Listeria Control Program. In Appendix 3.2, the sampling procedures used by FSIS during IVT and RLm sampling to sample FCSs, NFCs, and brine used to chill RTE product are provided. Establishments may use these methods, or adjust the methods based on the needs of the establishment. FSIS expectations for sampling and testing methods are provided below. Further sampling and testing considerations are included in Appendix 3.3. See the box

on the next page for FSIS expectations for sampling methods." , "FSIS Listeria Guideline January 2014 95 Sampling Methods Aseptic Technique: Sampling should be performed by a person trained in aseptic technique and samples should be collected using sterile sponges or other sampling devices. Sample size: A 12\u00d712 area should be sampled, when possible, for FCS and NFCS surfaces. If the surface area is smaller than 12\u00d712, then the entire surface should be sampled. NOTE: Cotton-tip swabs and other smaller sampling devices are not recommended for sampling large areas (12\u00d712) because they may become easily saturated with microorganisms. If these devices are used, FSIS recommends collecting a smaller sampling size according to the manufacturer's instructions to equal a 12\u00d712 area. Sample collection: The sponge or sampling device should be hydrated with sterile neutralizing buffer, Dey Engley (DE) broth, or another sterile broth that contains components that can neutralize the effects of sanitizers that may be present in the sample. When to collect samples: Some samples can be collected at pre op, but most samples should be collected at least 3 hours into operations, if possible, to allow Lm to work its way out of the equipment. If the establishment typically produces RTE product for less than 3 hours then the samples can be collected less than 3 hours into operations. Sample integrity: Samples should be stored under refrigeration before analysis. Samples should be properly labeled to avoid confusion regarding testing results. Brine sampling: Some establishments use brine to cool or inject into RTE product. Depending on whether the finished product surface is directly exposed to brine after the lethality step, the brine solutions could be considered either as food contact or environmental samples. Sample compositing: FCS samples may be composited (combined) in order to conserve establishment's resources. If compositing is performed, FSIS recommends that no more than 5 samples be composited, and separate sponges (or other sampling device) be used to collect each sample, to avoid possible cross contamination. One laboratory test can then be performed on the 5 separate samples, decreasing the cost to the establishment. In addition, individual locations for the composite sample should be noted to assist in determining the site of contamination to facilitate follow-up testing. If a composited sample tests positive, the establishment should consider all the sites represented by the sample as positive and take corrective actions accordingly. During follow-up sampling of FCSs, the sites should be re-sampled individually, along with additional swabs in the area. For more information on compositing, see Appendix 3.3. Handling and shipping of samples: If the samples will be analyzed by an in-house lab, testing should be initiated immediately after collection. If not tested by an in-house lab, the testing should be initiated within 2-3 days of collection. If this is not possible, the establishment should provide evidence that another strategy does not compromise the sensitivity of the method. The samples should be stored under refrigerated conditions (33 \u00b0C to 45 \u00b0F), and in no case be allowed to freeze, which could kill organisms captured on the sampling device. Samples should be placed into insulated shipping containers and sent refrigerated to the laboratory. Lastly, the identity of the sample should be maintained during testing to ensure that sites are correctly identified." , "FSIS Listeria Guideline January 2014 96 Testing Methods Establishments may test for Lm, Listeria spp., or LLO. Testing can be performed either in-house or at a third-party laboratory (see Appendix 3.3). However, if the testing is performed at a third-party laboratory, the establishment should be familiar with the method used by the lab, have the method on file at the establishment, and know whether it meets FSIS expectations for testing methods. If an

establishment uses the testing results to support the decision made in its hazard analysis that Lm is not reasonably likely to occur in its product, then it is important that the results are reliable and accurate. Further information on testing methods can be found in Appendix 3.3. The following are FSIS\u2019s expectations for testing methods: 1) An enrichment step is used to allow for recovery of injured organisms and growth of Listeria to levels that can be detected by most testing methods. Many commonly used testing methods are unable to detect levels below 100 cells\sample. Therefore, it is important that the enrichment step be designed to allow low levels of cells that may be present in the sample to grow to detectable levels. It is also important to allow injured cells time to recover so that they can be detected by the testing method. In most cases, at least an 8-hour enrichment is needed to achieve adequate levels of Lm growth for detection. A one-hour resuscitation step is not an enrichment step, and would likely not be sufficient to detect low levels of Listeria spp. or Lm. 2) The entire sponge or sampling device is analyzed. Some methods involve testing just a small part of the broth or other diluent used to hydrate the sponge or sampling device. Studies have shown that bacteria are likely to be trapped on or in the interior of the sponge or other sampling device. Therefore, FSIS suggests that the whole sponge or sampling device be included in the enrichment step. Analyzing the entire sampling device will help ensure that cells that are present will be detected. 3) The method has been validated. All screening methods should either be used by a regulatory body (e.g., FDA Bacterial Analytical Manual (BAM)), or validated by a recognized independent body (e.g., AOAC, AFNOR, ISO, NordVal, Microval). A validated method from a scientifically robust study using the FSIS Lm qualitative method as a reference method, or other validated cultural methods is also acceptable, but would be subject to FSIS review.<sup>5</sup> In addition to guidance provided by the recognized independent bodies mentioned above, FSIS has provided guidance on the design of validation studies for pathogen testing methods in the FSIS Guidance for Test Kit Manufacturers, Laboratories: Evaluating the Performance of Pathogen Test Kit Methods. <sup>5</sup> Submit request for review of methods to AskFSIS. NOTE: Direct plating methods (e.g., media that is added directly to an agar plate or dehydrated media) that do not include an 8-hour enrichment step would be unlikely to detect low levels of Listeria spp. or Lm. NOTE: It is not sufficient for methods to be AOAC or ISO validated alone. To meet FSIS expectations for testing methods, the method should also include an enrichment step and analyze the entire sponge or sampling device." , "FSIS Listeria Guideline January 2014 97 FSIS Review of Sampling and Testing Methods As part of FSIS Food Safety Assessments (FSA), Enforcement, Investigations, and Analysis Officers (EIAs) will review the sampling and testing methods used by the establishment to determine if they meet FSIS expectations. If an establishment chooses not to use a validated methodology for food-contact and other environmental-surface testing, or if the quality of the testing results provided by the laboratory is in question, the establishment may be assuming a greater risk of allowing adulterated product into commerce. Should FSIS question the sampling or testing methodology, it may choose to review the establishment\u2019s scientific basis for using these methods. In such a circumstance, the establishment could be subject to focused verification checks, including a review of recordkeeping, observation of production, and the collection of product and environmental sampling by FSIS. 3.6 Other Routine Sampling Although not required by the Listeria Rule, establishments may choose to include sampling for indirect and NFCS and product as part of their Listeria Control Program. Sampling indirect and NFCS and product can give the

establishment more information about possible harborage and cross contamination pathways in their environment. For more information on harborage and cross contamination, see Chapter 4. Testing Indirect and Non Food Contact Surfaces (NFCS) As previously stated, establishments may choose to test indirect and NFCS samples as part of their Listeria Control Program, although they are not required by the Listeria Rule. FSIS samples indirect and NFCSs during RLm and IVT sampling, so by sampling these areas, the establishment can find harborage points before they are found by FSIS. Some examples of indirect and NFCS sites are included below. Other examples are included in Appendix 3.1. Indirect FCS sites include the following: The sides of conveyor belts, Equipment frame-work, and Table legs or other areas that are near or adjacent to food processing sites. NFCS sites include the following: Drains, Floors, Walls, and Ceilings. NOTE: If an NFCS tests positive for Lm, the product is not considered adulterated, however a positive finding could indicate insanitary conditions in the environment. Likewise, if a NFCS tests positive for Listeria spp., the product is not considered adulterated, however the establishment should address positive results to ensure that harborage and cross contamination to FCSs and product does not occur.", "FSIS Listeria Guideline January 2014 98 Establishments can set their own frequency for NFCS sampling (e.g., weekly or monthly) based on their processing schedule or past history of positives. While there is no requirement that establishments perform follow-up testing in response to indirect or NFCS samples, it is important that establishments address the source of positives (e.g., by cleaning and sanitation) to ensure that harborage and cross contamination of product does not occur. Product Testing Although product testing is not required by the Listeria Rule (except under hold and test conditions for Alt. 2b or 3), establishments may decide to test product as part of their Listeria Control Program. Product testing can be used as a verification of the effectiveness of establishments' PLTs, AMAPs, and sanitation control measures. Also, as most of FSIS testing is of product (RTEPROD\_RAND and RTEPROD\_RISK project codes), testing by the establishment can help to detect product contamination before it is found through FSIS testing. Many establishments choose to test product quarterly as part of their Listeria Control Programs. However, product testing is not a substitution for the food contact surface testing required by the Listeria Rule. Establishments that test products still need to test food contact surfaces to meet the requirements for Alternatives 2b and 3 (9 CFR 430.4(b)(2)(iii)(A) and (b)(3)(i)(A)). Product testing protocols are typically designed and validated for a 25-gram analytical portion (i.e., the portion of the collected sample that is actually tested). Before testing larger analytical portions from single or multiple composited samples, ensure that the testing method has been validated for use with the larger portion. FSIS has begun compositing 5x25 gram samples collected during RLm sampling into a 125 gram portion. The FSIS Microbiology Laboratory Guidebook (MLG) Chapter 8 methods have been updated to include validated methods for the larger sample size and may be used by establishments to analyze a 125 gram test portion. However, establishments may continue to analyze a 25 gram sample, as 25 grams is the size of the sample FSIS analyzes for the RTEPROD\_RAND and RTEPROD\_RISK project codes. Establishments can set their own frequency for product testing (e.g., quarterly or twice yearly), based on the establishment's processing schedule or past history of positive results (except in hold and test conditions). Product that tests positive for Lm would be considered adulterated and the establishment would be expected to destroy or rework the product with a process that is destructive of Lm. If

a product tests positive for Listeria spp., the establishment should provide the following documentation to demonstrate that the product is not positive for Lm: NOTE: NFCS samples may be collected anywhere in the establishment where RTE products are stored or held (e.g., coolers, freezers, loading docks, and trucks). NFCSS may also be collected in areas associated with post-lethality processing, such as equipment storage and wash rooms, spice rooms, and ingredient rooms. NOTE: The establishment should hold all product lots until its test results are received. This will prevent exposure of the consumer to a potential food hazard. Retaining the product being tested also will eliminate the cost of a recall to the establishment.", "FSIS Listeria Guideline January 2014 99 \u2022 Testing data demonstrating that the original isolate is not positive for Lm, \u2022 A sampling plan that provides a level of statistical confidence that each product is not contaminated with Lm (e.g., testing for Lm using a sampling plan recommended by the ICMSF, see Section 4.3), or \u2022 Documentation showing that the product has been reprocessed using a process validated to achieve at least a 5-log reduction of Lm. A finding of Listeria spp. in the product can indicate insanitary conditions where the product could become contaminated with Lm. Therefore, the establishment should review its Sanitation SOP and HACCP plan to ensure that Lm is controlled in its environment, and that cross contamination of the product is unlikely to occur. FSIS will review the establishment\u2019s sanitation records, observations of sanitation, and sanitation NRs, and if it finds that the establishment\u2019s Sanitation SOP is inadequate or its corrective actions are ineffective, an NR will be issued (according to 9 CFR 416.12 or 416.15), or an IVT may be scheduled at the establishment. If the establishment does not provide compelling documentation that the product is not contaminated with Lm (as described above), FSIS may not be able to determine that the product is not adulterated, and it may take a regulatory control action, under 9 CFR 500.2(a)(3). If the agency determines that product is adulterated by being produced under insanitary conditions, and the product is in commerce, the agency may request a recall.", "FSIS Listeria Guideline January 2014 100 3.7 Glossary Aseptic Technique: A sample-collection procedure performed under sterile conditions. The samples are collected using sterile sampling swabs, buffer, gloves, and other sampling supplies. Aseptic technique should be used to avoid cross contaminating samples, and keep contamination from spreading between sampling sites during sampling. Confirmation Test: A series of tests, often following a positive screening test, used to definitively identify the target organism. Food Contact Surface (FCS): An area in the post-lethality processing environment that comes in direct contact with post-lethality exposed RTE product. Production lot A production lot is the amount of product that may be impacted by a product or FCS positive test result. As previously stated, establishments are required to hold or maintain control of RTE products that FSIS has tested for Lm or RTE products that have passed over food contact surfaces that FSIS has tested for Lm. Establishments may move such products offsite provided that they maintain control of them (e.g., through company seals). A production lot is typically defined as all product produced from clean-up to clean-up unless the establishment can support a smaller lot size. If the establishment performs a complete cleaning and sanitizing (following the procedures in its Sanitation SOP) between lots, the lot size could be reduced. Factors that should be taken into account when determining lot size include RTE source materials used, frequency of cleaning and sanitizing, and processing steps. NOTE: An establishment may reduce its lot size on a day when FSIS collects a sample, in order to facilitate holding the product, as long as the change does not interfere with FSIS\u2019s ability to collect

a representative sample. Products produced in the same room could be considered part of the same or different processing lots, depending on how the lots are separated. If the processing lines can be considered microbiologically and physically independent of one another (i.e. equipment, personnel, utensils, and RTE source materials are not shared among the lines), then they can be considered different lots. An example of a common source material could be chicken in a chicken salad that is taken from the same package over multiple lots. If a FCS tests positive on one line, and the establishment has supporting documentation that there is not cross contamination among the lines, then lots produced on the other lines may not be implicated. Likewise, products produced on the same line could be considered different processing lots, if they are separated by a complete cleaning and sanitization, as well as the other factors described above. NOTE: Products stored in a common cooler would not necessarily be considered part of the same lot. However, the establishments Sanitation SOP should address possible cross contamination, especially if RTE and raw products are held in the same cooler.", "FSIS Listeria Guideline January 2014 101 Indirect Food Contact Surface: An area in the post-lethality processing environment that is adjacent to a FCS, but does not come in direct contact with the product. *Listeria monocytogenes* (Lm): A foodborne bacterial pathogen that can cause the disease listeriosis in humans. *Listeria* spp.: Members of the genus *Listeria*, which includes both pathogenic (Lm) and non pathogenic strains. The presence of *Listeria* spp. indicates conditions where Lm could be present or grow. Further confirmation tests would be needed to determine if *Listeria* spp. positive tests are also positive for Lm. *Listeria*-like organism (LLO): An indicator for Lm. LLO tests usually employ traditional *Listeria* culture enrichment and isolation media to screen for bacteria that have biochemical characteristics typical for but not necessarily exclusive to *Listeria* spp. Many LLO methods are based on the ability of *Listeria* species to hydrolyze esculin or other compounds, resulting in a color change to the broth or solid media (usually to dark brown or black). LLO could include *Enterococcus* spp. and *Lactobacillus* spp., among others. Non Food Contact Surface (NFCS): An area that does not contact product. NFCS samples may be collected from any area where RTE product is held in the establishment (e.g., coolers, freezers, loading docks, and trucks). NFCS samples may also be collected in areas associated with post-lethality processing, such as equipment storage and wash rooms, spice rooms, and ingredient rooms. Production Line: A line refers to the flow of product during production. This includes all of the equipment, personnel, and utensils that contact the RTE product. Multiple individual product lines can meet at a piece of equipment (e.g., packaging machine), but they are still considered to be different lines. Pulsed-field gel electrophoresis (PFGE): a laboratory method used for subtyping bacterial isolates below the level of species using bacterial deoxyribonucleic acid (DNA). PFGE patterns consist of DNA fragments of varying sizes resolved by passage through an agarose gel. PFGE patterns can be compared to determine their degree of relatedness. Screen test: A preliminary test to determine if a sample contains organisms that share certain characteristics (growth parameters, sensitivity to antibiotics, similar genetic make-up) as the target organism. Many tests for *Listeria* spp. are screening tests for Lm. In order to definitively define the organism as Lm, further confirmatory tests would be needed. 3.8 References Tompkin, R.B. 2002. Control of *Listeria monocytogenes* in the Processing Environment. Journal of Food Protection. 65 :709-725. Tompkin, R. B., V. N. Scott, D. T. Bernard, W. H. Sveum, and K. S. Gombas. 1999. Guidelines to Prevent Post Processing Contamination from *Listeria monocytogenes*. Dairy, Food and

Environmental Sanitation. 19 (8): 551-562. FSIS Microbiology Laboratory Guidebook, 1998.", "FSIS Listeria Guideline January 2014 102 Attachment 3.1: Possible Food Contact Surface and Non Food-Contact Sites This table provides examples of possible FCS and NFCS sites for use in developing Listeria Control Programs. The list is not all-inclusive. Careful efforts should be made to determine all possible food contact sites in an establishment\u2019s environment.

Table of Possible Food Contact and Non Food-Contact Sampling Sites	Food Contact	Non Food Contact
Aprons*		
Air blower, filter	Baggers	Boots
Band saws	Carts	Belts
Ceilings	Blades	Coat racks
Brine*	Condensation	Chiller shelving
Control buttons	Chutes	Cooling units
Coats*	Doors	
Conveyors	Drains	Cutting boards
Equipment framework	Equipment surfaces	Equipment sides
Equipment shields*	Exposed insulation	Gloves*
Fans	Grinders	Flaps
Guiding bars		Floor mats
Hopper surface	Floor\u2019/wall junctions	Knives
Mixers	Floors	Forklifts
Packaging machines	Gaskets	Paddles
Gaps between close-fitting parts	Hoses	Peelers
Packaging materials	Legs (hollow)	
Gaskets	Paddles	Plastic wrap
Hoses	Peelers	Lifters
Legs (hollow)	Plates	Machinery
Plastic wrap	Product carts	Maintenance Tools
Lifters	Machinery	Racks
Plates	Product carts	Maintenance Tools
Machinery	Maintenance Tools	Racks
Product carts	Maintenance Tools	Mops
Maintenance Tools	Racks	Saw table
Racks	Mops	
Mops	Saw table	
Saw table		
Motor housing units	Scales	Overhead pipes
Scales	Overhead pipes	Scoops
Overhead pipes	Scoops	Pallets
Scoops	Pallets	Scrapers
Pallets	Scrapers	Platforms
Scrapers	Platforms	Sealers
Platforms	Sealers	
Refrigeration units	Shredder	Roller bars (hollow)
Shredder	Roller bars (hollow)	Slicers
Roller bars (hollow)	Slicers	Rough welds
Slicers	Rough welds	Smoke sticks
Rough welds	Smoke sticks	Sinks
Smoke sticks	Sinks	Tables
Sinks	Tables	
Spiral Freezer	Thermometers	Squeegees
Thermometers	Squeegees	Tongs
Squeegees	Tongs	Standing water
Tongs	Standing water	Trays
Standing water	Trays	Stands
Trays	Stands	Trees
Stands	Trees	Trash cans
Trees	Trash cans	
Trash cans		
Tubs	Walkways	Utensils
Walkways	Utensils	Walls
Utensils	Walls	Wipers
Walls	Wipers	Wheels of carts
Wipers	Wheels of carts	*Could be considered either a food contact or a non food-contact surface, depending on if the surface comes in direct contact with the product.", "FSIS Listeria Guideline January 2014 103 Appendix 3.1: FSIS RTE Sampling Program As of August 1, 2013, FSIS combined its random ALLRTE and risk-based RTE001 product sampling projects into a single project, called RTEPROD. The RTEPROD sampling project uses two project codes: RTEPROD_RAND for product samples selected randomly, and RTEPROD_RISK for post-lethality-exposed product samples selected based on risk. The RTEPROD sampling project is expected to increase response rates and conserve laboratory resources. Under the RTEPROD_RAND project code, both postlethality exposed and non-post-lethality exposed products are tested, and samples are randomly selected by FSIS. FSIS conducts testing on non post-lethality exposed products (e.g., cook-in bag products) to verify that adequate lethality has been achieved in the products, and that they are not contaminated with Lm and Salmonella, in accordance with 9 CFR 417.8(g). Samples are scheduled for the RTEPROD_RAND project code so that all RTE establishments, regardless of plant size, production volume, or process design, have an equal chance of being sampled each fiscal year. The RTEPROD_RISK project code is used primarily to verify that establishments producing post-lethality exposed RTE meat and poultry products are controlling Lm and are in compliance with the requirements of the Listeria Rule. Establishments are identified for sampling based on a risk-ranking algorithm, which takes into account the control alternative,6 the production volume, the type of product produced, and the sampling history. Under both project codes (RTEPROD_RAND and RTEPROD_RISK), a two pound sample of the product in its final finished package is collected, and the sample is tested for Lm and Salmonella spp. Regulations and directives specific to the RTEPROD sampling program include the following: 9 CFR 430.4 \u201cControl of Listeria monocytogenes in post-lethality exposed ready-to-eat products\u201d published on June 6, 2003 (68 FR 34207); FSIS Directive 10,240.4, Revision 3, \u201cVerification Activities for 6 For Alternative 1, the establishment uses a post-lethality treatment for its product and an antimicrobial agent or process that suppresses or limits of growth of Lm. For Alternative 2, the establishment uses a post-lethality treatment for product

or an antimicrobial agent or process that suppresses or limits the growth of Lm. For Alternative 3, the establishment uses a sanitation project that controls Lm contamination in the processing environment and on the product. Question: Why does FSIS require a 2 pound sample of jerky and other RTE products? Answer: The amount of product requested depends on the type and number of tests that are performed. The Agency tests for more than one pathogen in a sample and enumerates the samples. Therefore, at least 2 pounds of product are required for most analyses. One pound of product is required for the RLm project, because only Lm is analyzed. Question: If an establishment delivered product from a sampled lot to a customer but retrieved all of it before the report of the FSIS sample result, will the product be deemed to have been shipped? Answer: Yes, once an establishment completes its pre-shipment record review, the product is considered \u201celigible for shipment\u201d or \u201cshipped.\u201d Upon report of a positive result, establishments are expected to prevent product from entering commerce in accordance with paragraphs 9 CFR 417.3(a)(4) or (b)(3) of the regulations and to process it in a manner that will make it no longer adulterated.", "FSIS Listeria Guideline January 2014 104 the Listeria monocytogenes (Lm) Regulation and Ready-to-Eat (RTE) Sampling Program,\u201d (January 10, 2014). RLm The RLm sampling project, implemented in April 2006, is a routine risk-based sampling project which consists of food contact, environmental and product samples that are taken during the production of RTE meat and poultry products that are exposed to the post-lethality environment. All samples are analyzed for Lm and are to be taken during the same day of production. In conducting the RLm project, it is anticipated that FSIS will be able to assess the compliance of establishments with regulation 9 CFR 430.1 regarding the control of Lm in postlethality exposed RTE production areas and to help ensure that RTE products are safe for consumption at the end of the production process. RLm samples are scheduled using a Food Safety Assessment (FSA) prioritization model which takes into account levels of inspection (LOI),<sup>7</sup> control alternative, and type of product produced. Starting in August 2009, RLms sampling was increased so that establishments producing post-lethality exposed RTE product are sampled at least once every four years under this project. For the RLm project, FSIS collects 3 sample units from large establishments (500 or more employees), 2 sample units from small establishments (10-499 employees) and 1 sample unit from very small establishments (< 10 employees). A sample unit consists of 10 food contact surface swabs, 5 environmental swabs (which are composited), and 5 intact product samples. FSIS laboratories composite the 5 product samples per unit. In establishments that use brine chillers, the EIAO is to collect a sample of brine from each line using a brine chiller. RLm sampling is performed in conjunction with a routine FSA, which provides an in-depth evaluation of the effectiveness of the food-safety practices employed by an establishment. The ability to use the product, contact and environmental sampling information collected from the establishments, can help identify possible risk factors that could be associated with positive results. Regulations and directives specific to the RLm sampling project include the following: 9 CFR 430.4 \u201cControl of Listeria monocytogenes in post-lethality exposed ready-toeat products\u201d published on June 6, 2003 (68 FR 34207) [includes definitions for RTE Alternatives 1, 2, and 3]; and 7 The three LOI are defined as follows: LOI 3\u2014Establishments with strong indications that they are not maintaining effective food safety process controls. LOI 2\u2014Establishments with some indication that they may not be maintaining effective food safety process controls. LOI 1\u2014Establishments that consistently demonstrate they are maintaining effective food

safety process controls. Question: If a product or food contact surface sample tests positive for a pathogen, what is the status of product(s) produced on days subsequent to the day the sample was collected? Answer: In general, FSIS does not consider product that is produced on days subsequent to the day of sampling and that is coded differently from the sampled lot to be represented by the sample. Under most circumstances, the product is not subject to retention, detention, or voluntary recall. A positive sample does call into question the adequacy of an establishment's process for producing safe product, and the establishment should take corrective actions to address the positive result.", "FSIS Listeria Guideline January 2014 105 FSIS Directive 10,240.5, Revision 3, Verification Procedures for Enforcement, Investigations, and Analysis Officers (EIAOs) for the Listeria monocytogenes (Lm) Regulation and Routine Risk-Based Listeria monocytogenes (RLm) Sampling Project published on March 28, 2013. IVT In the IVT sampling project, FSIS tests product, food contact surfaces, and environmental surfaces for Lm. An IVT is initiated after an establishment has a positive Lm result, in either finished product or on a food contact surface. An IVT can also be initiated at the discretion of the District Manager, in response to continuing sanitation non-compliances at the establishments. The IVT is performed after the establishment has taken its corrective and preventive measures in response to FSIS findings. In an IVT, FSIS collects samples in units. A unit consists of 10 food contact surface samples, 5 environmental samples, and 5 product samples per post-lethality exposed RTE processing line in operation on the day of sampling. . If the establishment uses a brine chiller, FSIS will also collect 1 brine sample per line from the brine chiller. IVTs are performed with a cause Food Safety Assessment (FSA) to provide an in-depth evaluation of food safety systems at the establishment. IVTs are scheduled according to the FSA prioritization model, with all establishments with Lm positives receiving an IVT. IVTs may also be performed in response to repetitive occurrences of non compliances because of sanitation issues or to verify corrective actions before closingout an enforcement action. The districts have 30 days in which to schedule the IVT after a product or FCS Lm positive. Regulations and directives specific to IVT include the following: 9 CFR 430.4 \Control of Listeria monocytogenes in post-lethality exposed ready-to-eat products published on June 6, 2003 (68 FR 34207) [includes definitions for RTE Alternatives 1, 2, and 3]; FSIS Directive 10,300.1, Revision 1, \Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces and Environmental Surfaces for Listeria monocytogenes, published on March 28, 2013; and FSIS Directive 10,210.1, \Unified Sampling Form published on October 14, 1997." , "FSIS Listeria Guideline January 2014 106 Question: If a RTE product tested by FSIS is found positive for Lm, is the HACCP system automatically considered inadequate? Answer: According to 417.6, the HACCP system may be found inadequate if among other things, the establishment fails to take corrective actions. In determining whether the HACCP plan is inadequate, the Agency will consider whether: 1) some or all products produced under the same or a substantially similar HACCP plan are affected, 2) there have been other incidents of product contamination with the pathogen, 3) if corrective actions have been effective, and 4) if incidents of product contamination have been persistent or recurring. FSIS will review all of this information and consider the entire situation before making a determination of HACCP plan inadequacy. Question: Can an establishment use the results of FSIS verification sampling instead of taking their own product or FCS sample if an FSIS sample is taken at the time the company is

scheduled to take their own sample? Answer: Yes, if FSIS verification sampling occurs within the same time frame as that defined in the establishment's Listeria Control Program, and the same types of samples are collected. For example, if an establishment samples its product once a quarter as part of the verification activities in their HACCP plan and FSIS takes a product sample in that same quarter, then the company can use the FSIS results as part of the verification for their HACCP plan. Likewise, if an establishment samples FCSs once a month, and FSIS samples FCSs during that month, the establishment can use the results from the FCS sampling as part of their own project. However, establishments may not use the results of FSIS product samples in lieu of taking their own FCS samples, because the sample types are different, and the FCSs samples are used to verify the sanitation in the establishment's environment. Question: If a RTE product tested by FSIS is found positive for Lm, is the establishment required to take corrective actions and reassess their HACCP plan? Answer: If Lm control is addressed as a CCP in the HACCP plan (e.g. PLT) the establishment must meet the requirements of 9 CFR 417.3(a), which requires that corrective actions are taken but does not require reassessment of the HACCP plan. If Lm is addressed in the Sanitation SOPs, then the establishment must implement the corrective actions in 9 CFR 417.3(b), which includes reassessment of the HACCP plan. In addition, they must implement the corrective action requirements for the Sanitation SOPs in 9 CFR 416.15, which includes appropriate re-evaluation or modification of the Sanitation SOP. If Lm is addressed in a prerequisite project (e.g., Listeria Control Program) that is used to support the decision that Lm is not a hazard reasonably likely to occur in the product, then the establishment must implement the corrective actions in 9 CFR 417.3(b) and comply with 417.4(a)(3). These regulations state that when there is a change in the process (e.g., a positive result) that could impact the hazard analysis, a reassessment must be performed.", "FSIS Listeria Guideline January 2014 107 Appendix 3.2: FSIS Sampling Procedure I. Sampling Using SpongeSicles" For Food Contact and Non-Food Contact Surface Sampling Equipment needed: Sterile gloves SpongeSicles 10 ml tubes of Dey Engley or other neutralizing broth Marker to label the sample bag 1. Wash and sanitize hands to the mid-forearm. 2. Using ungloved hands open the bag containing the SpongeSicle by pulling off the clear perforated strip at the top of the bag; 3. Pull apart the white tabs to open the mouth of the bag; 4. Aseptically pour 9-10 ml of sterile Dey-Engley (D/E) broth into the bag to hydrate the SpongeSicle, being careful not to contaminate the broth or sponge during the transfer. If the D/E broth is not purple, discard the tube; 5. Press the mouth of the bag back together; 6. Evenly moisten the SpongeSicle by using hand pressure on the outside of the bag to massage the sponge; 7. Position the SpongeSicle so that the handle is sticking out of the bag. Press the top of the bag back together around the handle; 8. Through the bag, squeeze the excess broth gently out of the sponge. Do not let your hand go past the thumb stop on the handle; 9. Aseptically place a sterile glove on the hand used for swabbing by: a. Positioning the glove package so that the L and R (L=left, R=right) are facing the sample collector. When the package is open, the gloves are folded, forming a cuff on the sleeve and lying palm up. Leave them in the package until ready for use; b. Holding the glove for the hand that will be used for swabbing by the inside cuff area. Inserting hand into the glove, palm side up, and lifting the glove from the package. c. Pulling the glove completely on, touching only the fold cuff with your ungloved hand. Do not touch the sterile outside surface of the glove with your ungloved hand. Unroll the fold of the glove. Do not touch any non-sterile surface (clothes, counter tops, or the

outside of the bag containing the SpongeSicle® with the sterile glove. The other hand can be left ungloved for the manipulation of non-sterile surfaces and materials. 10. Using the gloved hand, carefully take the SpongeSicle® out of the bag by grasping the handle and swab the area selected. Be careful to maintain sanitary conditions when;" , "FSIS Listeria Guideline January 2014 108 sampling and collect the samples aseptically. Do not let your hand go past the thumb stop on the handle 11. Swab at least a 1" X 1" square of food contact or environmental surface area, if possible; 12. Swab the chosen area using firm and even pressure: a. Vertically (approximately 10 times); then b. Flip the sponge and use the other side to swab horizontally (approximately 10 times); then c. Swab diagonally, using the same surface side as you used for horizontal (approximately 10 times). 13. Open the bag using the ungloved hand, and insert the sponge portion of the SpongeSicle® back into the bag; 14. Grip the SpongeSicle® through the bag and bend the handle of the SpongeSicle® back and forth with slight force, while gripping the sponge through the bag. The stick should break easily within the sponge (do not break the handle at the thumb stop). Discard the broken handle. If the handle is sticking out above the sponge, discard the sample. Take a new sample following steps 2-13. 15. Squeeze as much air out of the bag as possible and fold the top of the bag down at least 3 times. Fold in the tabs to lock the fold in place; 16. Label the bag with the date and location of the sample. 17. Ship the sample or deliver it to the laboratory as soon as possible for analysis. II. Liquid Sampling for Brine Equipment needed: Sterile gloves 500 ml sterile pitcher or other sample collection device 1000 ml sterile bottle 90 ml D/E broth Marker to label the sample 1. Wash and sanitize hands to the mid forearm. Wear sterile gloves on both hands when collecting a sample; 2. Aseptically pull a 500 ml sterile pitcher (beaker with a handle) from its packaging, being careful not to let the pitcher touch any non-sterile surface, including the exterior of the packaging; 3. Open a collection bottle and with the pitcher aseptically transfer 500 ml of the chill water or brine using the gradations on the side of the collection bottle to ensure the proper volume;" , "FSIS Listeria Guideline January 2014 109 4. Aseptically add 90 ml of D/E to each sample collected to neutralize chlorine and other disinfectants; 5. Tightly cap the collection bottle and gently mix by rotating back and forth; 6. Label the bottle with the date and sample location 7. Send or deliver to the laboratory as soon as possible." , "FSIS Listeria Guideline January 2014 110 Appendix 3.3 Sample Collection and Testing Methods According to the Listeria Rule, establishments in all three alternatives may use verification testing to verify the effectiveness of their sanitation programs (9 CFR 430.4(c)(1)). Using proper sample collection technique is important to ensure that samples provide the best measure of sanitary conditions at the establishment. It is also important that results are accurate and reliable so they can be used to support the decision made in the hazard analysis that Lm is not reasonably likely to occur in the product. Sample Collection Methods As part of its Listeria Control Program, the establishment should provide written instructions for collecting FCS samples, and product and NFCS samples (if performed). The sampling procedure used by FSIS to sample FCSs, NFCSs, and brines during IVT or RLm sampling is provided in Appendix 3.2. Establishments may use this method to sample their FCSs, or adjust the method based on the needs of the establishment. Some establishments use sentinel site programs to collect samples of FCS, NFCS, and product. An example can be requested at the following link: <http://www.tysonfoods.com/Safe-Food/Sentinel-Site-Program.aspx> The box on in Section 3.5 describes FSIS recommendations for establishment sampling methods. As stated in the box,

establishments may choose to composite food contact surface and environmental samples to save laboratory resources. Although compositing food contact surface samples is permissible, establishments should be aware that some loss of information occurs when the samples are composited. For example, if the sample tests positive, the establishment will no longer know what particular site tested positive and would be expected to take corrective actions in all of the sites represented by the composited sample. Therefore, FSIS recommends that establishments collect samples from like areas (e.g., drains in a processing room) in one set of composited samples. Likewise, all of the samples in a composited group could be from the same production line. In that case, a positive result would indicate contamination in a particular area, and establishments could tailor their corrective actions accordingly.

**Laboratory Methods**

Laboratory methods should be fit for the intended purpose, meaning that the test should effectively detect low levels of potentially injured Lm or indicator organisms on food contact or environmental surfaces, including brines, if appropriate. Testing can be performed either inhouse or by a third party laboratory, but the methods used should be reliable and accurate. In either case, it is important that the testing protocol be validated for the purpose, that the procedure is carefully followed (including time and temperature of enrichment and incubation steps), and fresh (non expired) media and testing kits be used. If a third-party laboratory is used, the establishment should be familiar with the method used by the laboratory, have the method on file at the establishment, and know whether it meets FSIS expectations for testing methods. FSIS will ultimately hold the establishment responsible for any 3rd party laboratory results; therefore, if an establishment is unsure whether a testing methodology meets FSIS expectations, it can submit a question through AskFSIS. Guidance for laboratory methods can be found in Section 3.5. Information on selecting a third-party lab can be found in the FSIS Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory.", "FSIS Listeria Guideline January 2014 111 Testing for Lm, Listeria spp., or Listeria-like organisms Establishments may choose to test for Lm, Listeria species (Listeria spp.), or Listeria-like organisms (LLO). While Listeria spp. and LLO are appropriate indicators for Lm, most establishments choose to test for Listeria spp., because it is more closely related to Lm. Establishments that test for LLO should take the same actions specified in this guideline for Listeria spp. In many cases, laboratory tests for Listeria spp. are the same initial tests that are used to screen for Lm. \u2022 Tests for Listeria spp. include immunoassays (e.g., lateral flow immunoassays, enzyme linked assay) and nucleic acid based assays (e.g., polymerase chain reaction (PCR), reverse-transcriptase PCR, DNA hybridization). \u2022 LLO tests usually employ traditional Listeria culture enrichment and isolation media to screen for bacteria that have biochemical characteristics typical for but not necessarily exclusive to Listeria spp. Many LLO methods are based on the ability of Listeria species to hydrolyze esculin or other compounds, resulting in a color change to the broth or solid media (usually to dark brown or black). \u2022 If the establishment tests for Aerobic Plate Count (APC), Total Plate Counts (TPC), Total Viable Count (TVC) or bioluminescence-based testing for organic contamination as an indicator for sanitation, they may use the results to indicate where increased Listeria testing may be needed. However, these tests cannot be used to meet sampling requirements for Lm, Listeria spp. or LLO. For more information on use of these tests to verify sanitation see Appendix 2.2.

**Compositing Samples and Pooling Enrichments**

A composited sample is defined as combining sponges from multiple sample sites into a single enrichment media for outgrowth prior to

analysis. This practice saves on the cost of media and analytic testing supplies. FSIS recommendations for compositing samples can be found on page 95. Pooling enrichments is when individual sampling sponges (or other sampling devices) are enriched separately and are combined into a single pool after incubation for analysis. Pooling can save on the cost of analytic testing supplies. However both of these practices can reduce the establishment's ability to quickly identify the source of a Listeria positive result. Pooling enrichments can make it difficult to isolate the source of the positive from the original enrichments. Typically if the result from an analysis of pooled enrichments is positive, the original enrichments are tested to identify the source of the Listeria. FSIS does not recommend going back to the original enrichments after a positive result in a pooled sample unless the follow criteria are met: NOTE: In house labs or third-party labs can be used to analyze the samples, but the sampling methods should be reliable and accurate. NOTE: If an establishment testing FCS for Listeria spp. or LLO receives a positive test result, there is no requirement that the positives are confirmed for Lm. However, establishments are required to take corrective actions according to their Alternative.", "FSIS Listeria Guideline January 2014 112 1) The enrichment times and temperatures are sufficient for the outgrowth of Listeria to levels that would ensure that pooling does not dilute the single sample to levels below the limit of detection of the test. Additional validation of the test method may be required to support this. 2) The time between taking the original enrichment for pooling and taking the individual enrichments for 'isolation' is within validated test kit specifications or can be validated not to significantly affect the detection of the analyte. 3) The enrichments have been handled appropriately during the intervening period (e.g. refrigerated and kept sterile), or a validated re-enrichment procedure is used for subsequent analyses. Re-enrichment is defined as the transfer of an older enrichment to a new enrichment broth with subsequent incubation to ensure sufficient levels of bacteria are present for analysis. Test kit manufacturers may supply guidance on this issue otherwise, a validation study may be needed to demonstrate the effectiveness of the reenrichment procedure. If the screening of the original enrichments returns negative results for all samples, then all the original samples should be considered positive since the original positive result cannot be localized to a single enrichment. Additionally the establishment may want to review the SOP for handling enrichments that may have contributed to a lack of a positive result. Similarly, as described in Section 3.5, if a composited sample tests positive, the establishment should consider all sites represented by the sample as positive. It would not be appropriate to retest individual sites and consider those sites negative, unless the retesting is being performed as a separate, follow-up sampling activity to evaluate the effectiveness of corrective actions. If these criteria are met, then FSIS recommends that no more than 5 enrichments be pooled, and that enrichments from like or similar surfaces are pooled (e.g., cutting board samples with cutting board samples). The individual locations for the pooled sample should be selected and documented to assist in determining the site of contamination to facilitate follow-up testing.

**Confirmation Methods** As stated previously, establishments are not required to confirm samples that are positive for Listeria spp. or LLO. However, if they do choose to confirm the samples, the establishment should follow the recommendations below:

- 1) Culture-based Confirmation Cultural methodology involves enrichment in one or more culture broths, subsequent isolation of a pure culture on solid media, and finally confirmation of culture identity through multiple interdependent and sequential biochemical and genetic tests. The

cultural method should always be performed on the same sample and enrichment broth as the screening test. Common appropriate enrichment-based culture isolation and confirmation methods include the FSIS Microbiology Laboratory Guidebook (MLG) Chapter 8 methods, the FDA BAM culture method and ISO 11290-1. Non-enrichment-based \u201cdirect plating\u201d methods intended for detection of higher levels of Lm, including ISO 11290-2, are not appropriate for detecting low levels of Lm contamination. The cultural method should detect", "FSIS Listeria Guideline January 2014 113 the same group of organisms as the FSIS MLG method. The laboratory procedure should indicate the specific steps taken to confirm the presence of the target microorganism. 2) Non-Culture-based Confirmation Non-cultural methodology does not involve a cultural isolation step, and consists of a single test (e.g., a PCR-based test). This type of confirmatory test is always performed on the same sample and enrichment broth as the screening test. The non-cultural test should identify a different set of characteristics than the screening test (in other words, the same test used for screening, or a similar test, may not be re-used to \"confirm\" the screening result). The non-cultural confirmation test should provide high sensitivity and enhanced specificity (ability to detect true negative results) compared to the screening test and it should be demonstrated and documented to perform acceptably under the conditions of use, which includes the enrichment conditions for the screening test (e.g., enrichment time, temperature, enrichment broth). Acceptable performance is determined by validation, preferably through an independent organization (e.g., the Association of Analytical Chemists (AOAC), Association Fran\u00e7aise de Normalization (AFNOR), ISO, or NordVal). Recording Testing Results Establishments are expected to maintain records of FCS sampling results and other sampling they may perform (product and NFCS) testing. According to the Listeria Rule, establishments must make the verification results that demonstrate the effectiveness of the measures it employs, whether under its HACCP plan, Sanitation SOP, or other prerequisite program, available on request to FSIS (9 CFR 430(c)(7)). The records should include the following: 1) Sample collection and analysis date, 2) Testing result (positive or negative), 3) Analysis that was performed (Lm, Listeria spp., or LLO), 4) Testing method (AOAC number or method name), 5) Technician or laboratory who performed the analysis, 6) Sampling site or product type analyzed. Records can be in electronic or paper format and should be maintained as described in 9 CFR 417.5. NOTE: It would not be appropriate for an establishment to rely on an \u201cinconclusive\u201d or \u201cincorrect\u201d laboratory result. If possible, further analysis should be performed on the original sample or enrichment to determine the testing result. In the absence of further information, the establishment should consider the sample to be positive. Use of Pulsed Field Gel Electrophoresis (PFGE) Data by FSIS When a sample collected by FSIS tests positive for Lm, the isolate is analyzed using Pulsed Field Gel Electrophoresis (PFGE). FSIS plans to start providing PFGE data to establishments on a routine basis, so that they can determine if harborage or cross contamination is occurring in the environment or if there are matches to clinical isolates (see below). PFGE is a laboratory method used for subtyping bacterial isolates below the level of species using bacterial deoxyribonucleic acid (DNA). PFGE patterns consist of DNA fragments of varying sizes resolved by passage through an agarose gel. PFGE patterns are compared to determine their", "FSIS Listeria Guideline January 2014 114 degree of relatedness. Establishments that test for Lm may consider using PFGE to analyze their own testing data to determine whether harborage or cross contamination is occurring in their environment.

Electronic images of PFGE patterns from FSIS and other public health organizations like the Food and Drug Administration (FDA) are uploaded to a central database (PulseNet database) maintained by the Centers for Disease Control and Prevention (CDC), where database managers evaluate and assign IDs to uploaded patterns. FSIS compares the pattern to others from the same establishment (plant comparison), to recently uploaded patterns from listeriosis cases (hotlist comparison), and to all PFGE patterns uploaded to PulseNet (pattern comparison). Because PFGE can't detect small changes in DNA, investigators focus on patterns that are indistinguishable or closely similar (1 or 2 band difference). Isolates with indistinguishable or closely similar PFGE patterns may have shared a recent ancestor and may have originated from a common source, such as a contaminated food product. PFGE data is used to supplement information gathered from other sources (epidemiological investigation, observations at an establishment) and should not be used by itself to demonstrate a definitive link between the product and the illness during outbreak investigations. Lm PFGE pattern data can be interpreted in the following way: 1. Cross contamination is suggested if an identical or highly similar PFGE pattern is found in product and surface samples collected during the same production day. If an identical pattern is found on product and a surface, the surface is more likely to be the source, unless under-processing of RTE product is suspected. 2. Harborage or ongoing contamination of the post-lethality environment is suggested if an identical or highly similar pattern is found in product and surface samples collected over multiple days, weeks, or months. 3. Food-borne exposure is suggested if the identical PFGE pattern is found in FSIS and case-patient samples, especially if the pattern is rare. Information associated with samples with indistinguishable PFGE patterns is reviewed by the FSIS Office of Public Health and Science (OPHS) staff, and may be shared with Agency staff conducting establishment-based investigations (IVT or FSA) and food-borne illnesses investigations. The PFGE data is used to supplement concurrent investigations and does not alter the regulatory implications of microbiological test results.", "FSIS Listeria Guideline January 2014 115 Chapter 4 FSIS Listeria Guideline: Enhanced Sampling Program 4.1 Follow-up Sampling Table 4.1: Timeframe for Follow-up Sampling, Intensified Sampling, and Hold and Test Performed in Response to Positive Food Contact Surface Results 4.2 Intensified Sampling 4.3 Hold and Test 4.4 Reprocessing Lm Contaminated Product 4.5 Determining Listeria Trends 4.6 Glossary 4.7 References Appendices 4.1 Sampling Scenarios by Alternative 4.2 Hold and Test Scenario 4.3 Listeria Trends Examples 4.4 Findings from Food Safety Assessments (FSAs) This chapter provides information on developing an Enhanced Sampling Program as part of the Listeria Control Program. The Enhanced Sampling Program includes follow-up and intensified sampling performed in response to a food-contact surface (FCS) result from the routine-sampling program. Sections on developing Hold and Test Programs and determining Listeria trends are also included in this chapter. 4.1 Follow-up Sampling According to the Listeria Rule, establishments in Alt. 3 (deli and hotdog producers) are required to conduct follow-up testing (sampling) in response to FCS positive sampling results (9 CFR 430.4(b)(3)(ii)(A)). If follow-up testing (sampling) yields a second FCS positive result, then products must be held and tested using a sampling plan that will ensure that products are not adulterated with Lm before they are released into commerce (9 CFR 430.4(b)(3)(ii)(B)). In response to a positive FCS result, establishments in Alt. 1, 2, and 3 (non-deli or hotdog producers) are required to perform corrective actions (9 CFR 416.15(a) and (b) and 417.3(a) and (b)). FSIS recommends that they also perform follow-up sampling in

response to a positive FCS result. By making efforts to find and address the source of contamination in the environment, establishments can take proactive steps to avoid Lm contamination of products. Appendix 4.1 Question: An establishment produces hotdog and deli products using Alt.3 and has 3 production lines in the post-lethality processing area. The establishment receives a positive result for Lm or indicator organism on line 1 FCS. Does the establishment need to sample FCSs only from line 1 or from all the 3 lines for the follow-up testing? Answer: The follow-up sampling is verification that the corrective actions taken by the establishment are effective. If the establishment can support that line 1 is using equipment, personnel and processing area that is separate and independent of the other lines (i.e., not used by other lines) and has supporting documentation that there is no history of cross-contamination among the three lines, then follow-up testing and corrective actions should be conducted on line 1.,"FSIS Listeria Guideline January 2014 116 provides step-by-step guidance for sampling in each Alternative. The establishment\u2019s follow-up testing program can be included as part of its Listeria Control Program in its Enhanced Sampling Program. In the Listeria Control Program, the establishment should specify the number of samples it will collect during follow-up sampling. FSIS recommends that 3-5 samples are collected from the site of the original FCS positive and the surrounding area. According to the Listeria Rule, establishments in Alt.3 deli and hotdog producers must conduct follow-up sampling that includes the specific FCS site that tested positive, as well as such additional tests in the FCS area as are necessary to ensure the effectiveness of the corrective actions. These may include other FCSs that are upstream from the original positive. It would be useful for the establishment to record the rationale for selecting follow-up sampling sites. For example, if a slicer tests positive, the establishment may choose to sample the conveyor or other equipment leading up to the slicer. Follow-up sampling could also include other FCSs on the same piece of equipment that were not previously tested (e.g., slicer blade or plate) or employees\u2019 gloves that come in contact with the product as it is placed on the slicer. The establishment should also include a brief description of corrective and preventive actions that will be taken in response to positive results (details can be included in the Sanitation SOP) and response to positive results (next steps). As stated previously, establishments in Alt. 3 (deli and hotdog producers) are required to hold and test product in response to a second positive test (obtained during follow-up testing) for Lm or an indicator organism. After the 2nd consecutive positive, the establishment should also enter into intensified sampling mode to find the source of positives (see Section 4.2). It is also recommended that establishments in the other alternatives enter into intensified sampling mode after the 2nd positive (although hold and test is not required at this point).

Recommendations for follow-up testing, intensified testing, and hold and test are provided in Table 4.1. Sampling scenarios by alternative can also be found in Appendix 4.1. Table 4.1 Timeframe for Follow-up Sampling, Intensified Sampling, and Hold and Test Performed in Response to Positive Food Contact Surface Results Alternative After the 1st positive After the 2nd positive After the 3rd Positive After Multiple Positives Alternative 1 Follow-up sampling Intensified sampling Hold and test recommended Alternative 2 , Choice 1 (2a) Follow-up sampling Intensified sampling Hold and test recommended Alternative 2, Choice 2 (2b) Follow-up sampling Intensified sampling Hold and test required\* (recommended after 3rd positive) Alternative 3 Follow-up sampling Intensified sampling Hold and test required\* (recommended after 3rd positive) Alternative 3 (deli or hotdog) Follow-up sampling required Intensified

sampling Hold and test required after 2nd positive. \*Establishments in Alt. 2b and 3 (non-deli or hotdog producers) are required to identify when they will hold and test product. FSIS recommends that they do so after the 3rd consecutive", "FSIS Listeria Guideline January 2014 117 positive. Establishments in Alt 3 (deli and hotdog producers) are required to hold and test product after the 2nd consecutive positive. 4.2 Intensified Sampling FSIS recommends that all establishments enter into intensified sampling mode after a 2nd FCS positive. Intensified sampling mode includes: \u2022 Intensified samples collected from FCSs, indirect and NFCSSs, and product, and \u2022 Escalated intensified cleaning and sanitation (details included in the establishment\u2019s Sanitation SOP). Intensified sampling may include the collection of FCS, NFCS, and product samples, and is performed to find sources of harborage and cross contamination in the post-lethality processing environment. Harborage is defined as the persistence of Lm in the establishment over time. Once a harborage point is formed, Lm may transfer through cross contamination onto FCSs or the product. Examples of conditions that may lead to cross contamination include condensation dripping onto product or FCSs, aerosolization from the drains, splashing from the floors, or product brushing against doors, walls, or pallets. For more examples of cross contamination and harborage, see Appendix 2.2.). Procedures for intensified sampling can be included in the establishment\u2019s Listeria Control Program. During intensified sampling, at least 3-5 samples should be collected per site that was found positive during follow-up sampling. Efforts should also be taken to find and address sources of harborage, track cross contamination in the establishment, and to find and address Listeria trends (for more information on Listeria trends, see Section 4.5). As part of its Listeria Control Program, the establishment should also include a response to positive results found during intensified testing. The finding of three consecutive positive samples for Listeria spp. from the same sampling site indicates a serious contamination issue, and increases the risk that product could be contaminated with Lm. The establishment should be taking preventive steps such as: \u2022 Increasing its routine sampling for Listeria, \u2022 Collecting intensified samples to find sources of harborage and cross contamination, \u2022 Holding and testing product (Alt. 2b and 3 non-deli or hotdog producers), \u2022 Reassessing its Sanitation SOPs to determine if sanitation issues could be leading to positive results, \u2022 Assessing the effectiveness of its PLT or AMAPs to address the increased likelihood of positives, Intensified sanitation efforts should be used in conjunction with intensified sampling after the 1st positive result to address sources of contamination. Intensified sanitation includes sanitation measures that are performed in addition to normal sanitation procedures and are escalated in response to continuing findings of positives. Intensified sanitation can include increasing the frequency of cleaning and sanitizing for certain pieces of equipment, breaking down the equipment into its parts for further cleaning, repairing or replacing broken equipment, and construction, if needed. For more descriptions of intensified sanitation, see Appendix 2.2.", "FSIS Listeria Guideline January 2014 118 \u2022 Determining whether Listeria trends exist (see Section 4.5), and \u2022 Reassessing its HACCP plan,8 to determine if the actions it is taking are effective in controlling Listeria. 4.3 Hold and Test According to the Listeria Rule, establishments in Alt. 3 (deli and hotdog producers) are required to hold product after a 2nd consecutive food contact surface positive for Lm or an indicator organism until the establishment corrects the problem indicated by the test result (9 CFR 430.4(b)(3)(ii)(B)). Further, in order to release product into commerce, the establishment must sample and test the lots of product using a method that will

provide a level of statistical confidence that the product is not adulterated (for more information see International Commission on Microbiological Specifications for Foods (ICMSF) Sampling Plans for Lm below). Alternatively, the establishment may rework or condemn the product (9 CFR 430.4(b)(3)(ii)(C)). Establishments in Alt. 3 (non-deli or hotdog producers) and Alt. 2b are required to identify when they will hold and test product ((9 CFR 430.4(b)(2)(iii)(B) and (3)(i)(B)) and FSIS recommends that they do so after the 3rd positive (see Table 4.1). As stated in the note above, the finding of three consecutive positive samples increases the risk that the product could be contaminated with Lm. If the establishment does not hold and test the product after the 3rd positive, it should provide other support demonstrating that the product is not likely to be contaminated. In addition, FSIS recommends that establishments in Alt. 1 and 2a hold and test product after multiple positives for Lm or an indicator organism. Establishments can include their hold and test procedures in their Listeria Control Program. Products can be tested for either Lm or Listeria spp.; however, if a product tests positive for Listeria spp. an establishment may be asked to provide further evidence (such as confirmatory testing results) to demonstrate that the product is not contaminated with Lm (see Section 3.6). Establishments should hold the entire product lot (and subsequent day\u2019s lots) until control is regained. For more information on defining product lots, see Section 3.5. Control is considered regained after 3 consecutive days of negative FCS results are obtained, and all other NFCS and product samples are negative. If product tests positive for Lm during hold and test (see Appendix 4.2), then the product lot represented by the sample is considered adulterated. A hold and test scenario is provided in Appendix 4.2 that provides a day-by-day description of hold and test procedures. Establishments should also describe product disposition in response to positives (procedures for reworked or condemning the product). Hold and test can only be used as a means to release product in situations where an FCS tests positive for Listeria spp. If FCSs or product tests positive for Lm the product is 8 Reassessment of the SSOP or HACCP plan is required in response to an FSIS Lm positive according to 9 CFR 417.3(b) and 416.15 (b) (see the Q&As in Appendix 3.1 for more information). NOTE: The finding of three consecutive positive samples from the same sampling site indicates a serious contamination issue, and increases the risk that product could be contaminated with Lm. NOTE: Control is regained after 3 consecutive days of negative FCS results are obtained, demonstrating that corrective actions are sufficient to address the contamination issue.", "FSIS Listeria Guideline January 2014 119 considered adulterated. In that case, testing product would not be an appropriate means of determining product safety, because even the best-designed testing program cannot detect all Lm that may be present. Therefore, product testing cannot be used as a means for the establishment to release adulterated product into the marketplace. International Commission on Microbiological Specifications for Foods (ICMSF) Sampling Plans for Lm According to the Listeria Rule, establishments in Alt. 3 producing deli or hotdog products must sample and test lots for Lm or an indicator organism using a sampling method and frequency that will provide a statistical level of confidence that ensures that each lot is not adulterated with Lm (9 CFR 430.4(b)(3)(ii)(C)). In order to meet this requirement, FSIS recommends that establishments use the International Commission on Microbiological Specifications for Foods (ICMSF) Tables. Additionally, FSIS recommends that establishments in other alternatives use these tables if they hold and test product. ICMSF categorizes microbial hazards according to risk: 1) Moderate 2) Serious 3) Severe ICMSF describes 15 different cases of sampling plans, with sampling plan

stringency based on degree of risk and the effect on risk of the conditions of use. Cases 10, 11, and 12 would apply to the serious category and cases 13, 14, or 15 would apply to the severe category of microbial hazards. ICMSF considers cases 13, 14, and 15 to apply to foods intended specifically for highly susceptible individuals (e.g., patients in hospitals and nursing homes) because a large proportion of the individuals would be potentially susceptible to foodborne illness; thus, increasing the stringency of the sampling plans is appropriate. FSIS also expects establishments that produce product for the school lunch program to use cases intended specifically for high-risk populations, because of the potential for increased risk in that population. NOTE: If a FCS or product tests positive for Lm, the product is considered adulterated. Product testing can't be used as a means to demonstrate that the product is safe. The product must be reworked or condemned, and FSIS would typically request that establishments recall such products if they have been released into the marketplace. NOTE: ICMSF ranks Lm as either a serious hazard in foods for the general population or a severe hazard in foods for restricted populations (high risk groups e.g., hospital and nursing home patients). Question: Should the ICMSF sampling plan be used for regular sampling or only for hold and test sampling? Answer: For routine sampling, the establishment can use whatever sampling plan it justifies as appropriate to demonstrate that the product is safe. For hold and test sampling for Lm, a statistically-based sampling plan should be used. The ICMSF table provides examples of statisticallybased sampling plans that are commonly used for demonstrating lot acceptance." , "FSIS Listeria Guideline January 2014 120 For cases 10 or 13, conditions of use reduce risk (e.g., the numbers of Lm will decrease). For cases 11 and 14, conditions cause no change in the hazard (e.g., the organism cannot grow), and for cases 12 and 15, conditions may increase the risk (e.g., foods in which Lm can grow are subjected to conditions that allow growth). Sampling plans for the cases are given in the table below, where n is the number of samples and c=0 means that none of the n samples can be positive for Lm. The table also provides the sampling plan performance, assuming a log-normal distribution with a standard deviation of 0.8; lots having the calculated mean concentrations or greater will be rejected with at least 95% confidence. Each of these plans achieves assurance that Lm is present at <1 CFU in the sample size. FSIS recommends analyzing a 25 g sample. If the risk of the population is unknown, FSIS recommends that establishments use cases 13-15. Conditions reduce concern Conditions cause no change in concern Conditions increase concern Case 10 n=5, c=0 Mean Concentration 1 cfu/32g Case 11 n=10, c=0 Mean Concentration 1 cfu/83g Case 12 n=20, c=0 Mean Concentration 1 cfu/185g Case 13 n=15, c=0 Mean Concentration 1 cfu/135g Case 14 n=30, c=0 Mean Concentration 1 cfu/278g Case 15 n=60, c=0 Mean Concentration 1 cfu/526g When RTE products must be sampled (hold and test) under the Listeria Rule, the number of samples (randomly selected) would be as specified for these cases based on the risk of the product and the intended consumers. Since deli and hotdog products are ranked as the top causes of foodborne illness, the establishment producing these products should select these products to be sampled first. Sampling starts after the establishment has conducted corrective actions that are specifically designed to find the most likely cause of the contamination and controls are put in place to prevent recurrence. Case 10 n=5, c=0 Case 11 n=10, c=0 Case 12 n=20, c=0 Products with continued decline in population due to antimicrobial or other formulation considerations such as pH and Aw. Products in Alternative 1 Products that limit growth (< 1 log) due to antimicrobial or other formulation

considerations such as pH and Aw. Products in Alternative 2 Products that support growth and that will be stored refrigerated for an extended period of time. Products in Alternative 3 Case 13 n=15, c=0 Case 14 n=30, c=0 Case 15 n=60, c=0 NOTE: Product samples should be analyzed separately and not composited. However, if compositing is to be done, composites of 25-g portions should not exceed a total of 125 g in order to maintain the sensitivity of the method of analysis, and a validated method should be used.", "FSIS Listeria Guideline January 2014 121 As for case 10, but where products are produced for a hospital or nursing home or for another higher risk population Products in Alternative 1 intended for a hospital, nursing home or for another higher risk population As for case 11, but where products are produced for a hospital or nursing home or for another higher risk population Products in Alternative 2 intended for a hospital, nursing home or for another higher risk population As for case 12, but where products are produced for a hospital or nursing home or for another higher risk population Products in Alternative 3 intended for a hospital, nursing home or for another higher risk population. The number of samples recommended should be collected in one day and all affected products should be held during the testing period. Testing can be for Listeria spp. or Lm. Any positive results from this follow-up testing (using the ICMSF approach) should lead to more significant investigations of the cause of the contamination. 3. Products that test positive for Listeria spp. may be considered adulterated if the establishment cannot support that the product is not adulterated, or if insanitary conditions exist, see Section 3.6. The establishment should conduct rigorous corrective and preventive actions and other sanitation activities. Establishments may send a letter or certification when they ship tested products to nursing homes, hospital, and other institutions with susceptible populations. Such a letter should indicate that product has been sampled and tested according to ICMSF recommendations. Establishments supplying nursing homes, hospitals and other institutions with susceptible populations are expected to implement whatever additional controls and verification procedures are necessary to ensure that product is not adulterated. 4.4 Reprocessing Lm Contaminated Product Product that tests positive for Lm or an indicator organism, or passes over an FCS that tests positive for Lm, or is suspected to be positive because of sanitation or processing issues at the establishment, may be reprocessed. A process that has been validated to achieve at least a 5log Lm reduction would be accepted by FSIS to reprocess the product. In order to reprocess the product, the establishment may use a processing treatment such as re-cooking and re-cooling the product (see below), applying a PLT (as described in Section 2.1), or other supportable process. An example of a PLT which has been found to achieve a 5-log Lm reduction is HPP. If an establishment chooses to use HPP to reprocess Lm-positive product, then the establishment should have scientific support that demonstrates that the process achieves at least a 5-log reduction of Lm in their particular product (see Appendix 2.1 for more information on validation). In addition, establishments may use both Appendix A and Appendix B of the final rule, \u201cPerformance Standards for the Production of Certain Meat and Poultry Products\u201d FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks and the TimeTemperature Tables for Cooking Ready-to-Eat Poultry Products, or other supportable processes to reprocess Lm-positive product. When using these guidance documents, establishments should ensure that adequate humidity is maintained during heating according to Appendix A and that C. perfringens and C. botulinum growth is controlled according to Appendix B, or other NOTE: FSIS will consider PLTs achieving at least a 5-log

reduction of Lm sufficient for reprocessing contaminated product.", "FSIS Listeria Guideline January 2014 122 scientific support. Although Appendix A and B, the FSIS Guidance on Safe Cooking of Nonintact Meat Chops, Roasts, and Steaks, and the Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products, are designed to achieve reductions in Salmonella, establishments are not expected to validate that these processes also achieve reductions in Lm because Salmonella is considered an indicator of lethality for Lm (see Appendix 2.1). 4.5 Determining Listeria Trends As described previously, establishments are expected to take corrective and preventive actions in response to positives based on their alternative. One way that establishments can ensure that their corrective actions are effective is to track sampling results. Repeated Listeria spp. positives on FCSs, NFCSSs, or product indicate positive Listeria trends in the establishment. The finding of Listeria trends could indicate that the establishment's Listeria Control Program is not effective in controlling the presence of Lm in the establishment's post-lethality processing environment. In response to a finding of Listeria trends, the establishment should perform intensified testing and sanitation, and conduct a comprehensive investigation to determine the source and the cause of the contamination (the steps in a comprehensive investigation can be found below the section on identifying and addressing Listeria trends). One way to track and address Listeria trends is through a sentinel site program. Identifying and Addressing Listeria Trends Establishments should track their sampling results over time, to identify Listeria trends. Listeria trends can consist of increases in positive samples over a particular time period (e.g., weekly, biweekly, monthly, quarterly, or 6 months) or increases in positives in particular sites or areas (see Appendix 4.3 for specific examples). By tracking their percent positive sampling results, establishments can determine if the percentage of positives in the establishments is increasing, indicating that changes in their cleaning protocols or sanitation procedures should be made. Listeria trends may also exist if positives are seen in a particular area over time. In the example provided in the tracking sheet in Appendix 4.3, positives were found on a freezer fan, wall, floor, and conveyor belt over a six month period. Although the establishment addressed each individual positive by routine cleaning and sanitizing (and the sampling site subsequently tested negative), positives still continued to occur in other areas of the freezer. The Listeria trend was not addressed until cleaning and sanitizing were escalated and repairs made to the freezer. Although every finding of Listeria trends may not require extreme steps such as equipment repairs or replacement, it is important for establishments to track their results in order to address harborage points. For more information on cleaning and sanitizing steps that can be taken to address positive results, see Appendix 2.2. Positive product results for either Listeria spp. or Lm over time could also indicate a Listeria trend. FSIS uses results from its product and RLm and IVT sampling to track trends over time, by comparing pulsed-field gel electrophoresis (PFGE) patterns. These results can be used to demonstrate possible harborage and cross contamination in the establishment (see Appendix 3.3). FSIS may use this data to take regulatory action against the establishment. By NOTE: Repeated Listeria spp. positives on FCS, NFCSS, or product (Listeria trends) could indicate that the establishment's Listeria Control Program is not effective in controlling the presence of Lm in the establishment's processing environment.", "FSIS Listeria Guideline January 2014 123 monitoring and addressing Listeria trends, establishments can take a proactive role in demonstrating that they have controlled contamination in their processing environment. When Listeria trends are identified,

establishments should take corrective actions to address the trend. Corrective actions should include intensified sampling (as described in Section 4.2) and intensified sanitation. Along with intensified sampling and sanitation, establishments should perform a comprehensive investigation to find the source of the problem (see explanation below). Preventive actions, such as increasing sanitation frequency, intensified sanitation in particular areas or equipment, repairing or replacing equipment, increasing testing frequency, and reassessing the Sanitation SOP and HACCP program, should be taken. NOTE: Continued findings of Lm in an establishment's products or contact surfaces could lead to foodborne illness and regulatory action (including suspension of inspection by FSIS). Therefore, it is important to ensure that trends are addressed before the product becomes contaminated.

**Parts of a Comprehensive Investigation** In response to findings of Listeria trends, establishments should conduct a comprehensive investigation into the source of positives, which includes:

- a. Review the cleaning and sanitizing procedures, including the types of cleaning agents.
- b. Review traffic control patterns, equipment layout and adherence to employee hygiene procedures.
- c. Locate possible niches that may represent harborage sites.

- i. Repeated, non-consecutive positives usually indicate the presence of a niche or harborage site for Lm.
- ii. Increase testing of the positive site including individual pieces of equipment to locate the source of the contamination.
- iii. Test upstream in the production area from the initial positives to find the source of contamination.
- iv. Collect at least 3-5 samples per sampling event until negatives are found.

In conjunction with the comprehensive investigation, the establishment should take preventive actions, including examining and reviewing the HACCP plan, Sanitation SOP, or prerequisite project where the sanitation and testing projects are included. As part of this review, the establishment should evaluate these projects to determine if there are any design or execution flaws, and modify them as necessary.", "FSIS Listeria Guideline January 2014 124 4.6 Glossary

**Comprehensive Investigation:** An investigation performed by the establishment to address Listeria trends. As part of this investigation, the establishment should review cleaning and sanitizing procedures, traffic control patterns, and identify sources of harborage.

**Corrective Actions:** Procedures to be followed when a deviation occurs. These include actions the establishment will take to ensure that the cause of the deviation is identified and eliminated, the critical control point (CCP) will be under control after the corrective action is taken, measures to prevent recurrence are established; and no product that is injurious to health or otherwise adulterated enters commerce (9 CFR 417.3(a)).

**Cross Contamination:** Movement of a microorganism (e.g., Lm) from one site to another. Cross contamination may occur in the post-lethality processing area when Lm moves from a harborage area, such as a drain, onto equipment and product.

**Enhanced Sampling Program:** Includes follow-up and intensified sampling, performed in response to a positive FCS result from routine sampling program. Samples should be collected in addition to those collected as part of the routine sampling program.

**Follow-up Sampling:** Collection of a 2nd FCS sample performed in response to a 1st FCS positive result. Follow-up samples should be collected from the specific site of the original positive sample, as well as additional samples of the surrounding FCS areas as necessary to ensure the effectiveness of corrective actions (required for Alt. 3 deli and hotdog processors).

**Harborage:** Persistence of Lm in a processing establishment over time. Harborage areas are areas where bacteria may survive and multiply, and are often NFCSSs that may be cleaned less frequently than FCSs.

**Hold and test:** Product samples that are held and tested by the establishment in response to a 2nd FCS

positive result (required for Alt. 3 deli and hotdog producers), according to the Listeria Rule. In addition, establishments are required to hold or maintain control of RTE products that FSIS has tested for Lm, and RTE products that have passed over food contact surfaces that FSIS has tested for Lm. Establishments may move such products off-site provided they maintain control of them (e.g., through company seals). Intensified Sampling: Sampling performed in response to a 2nd FCS positive testing result. Intensified sampling may include the collection of FCS, NFCS, and product samples, and is performed in order to find sources of harborage and cross contamination in the post-lethality processing environment. Intensified Sanitation: Intensified sanitation includes sanitation measures that are performed in addition to normal sanitation procedures and are escalated in response to continuing findings of positives. Listeria Trends: Repetitive positive FCS, NFCS, or product samples that are not addressed by routine cleaning and sanitation. Listeria trends should be addressed by intensified sanitation and investigative sampling to find sources of harborage and cross contamination. Preventive Actions: Actions taken in response to positive results to prevent further positives from occurring. These may include increased sanitation in particular areas or equipment,","FSIS Listeria Guideline January 2014 125 increased testing frequency, and review and revision of the HACCP program and Sanitation SOPs. 4.7 References International Commission on Microbiological Specifications for Foods (ICMSF). Microorganisms in Foods 7: Microbiological Testing in Food Safety Management. Kluwer Academic\Plenum Publishers, NY. 2002).","FSIS Listeria Guideline January 2014 126 Appendix 4.1: Sampling Scenarios by Alternative The following sections provide steps that establishments can take, depending on their alternative, once a positive is found. For a description of requirements by alternative, see Attachment 1.1. a) Alternative 1 i) Recommended: Conduct tests of food contact surfaces (FCS) for Lm or Listeria spp.) at least twice a year. ii) Sample at least a 12\u201dx12\u201d area for each surface, if possible. iii) Record the test results. iv) If the test results are positive for Lm or Listeria spp.: (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP, or prerequisite program), which should include intensified cleaning and sanitizing. (2) If the FCS test is positive for Lm, the product is considered adulterated. If the FCS is positive for Listeria spp., the product is not summarily considered adulterated, but corrective actions should be taken. (3) Record the corrective actions taken. (4) Collect follow-up samples from the FCS and surrounding areas (recommended). (5) Repeat corrective action and testing until samples are negative for Lm or Listeria spp. (6) Initiate intensified sampling after the 2nd consecutive positive. (7) If FCSs continue to test positive, hold and test product (recommended). v) If the product tests positive for Lm, (1) Recall the product, if already shipped, and (2) Destroy the product, or (3) Re-work the product with a process that is destructive of Lm. b) Alternative 2, choice 1 (Alt. 2a) i) Recommended: Conduct tests of FCSs for Lm or. Listeria spp. at least quarterly. ii) Sample at least a 12\u201dx12\u201d area for each surface, if possible. iii) Record the test results. iv) If the test results are positive for Lm or Listeria spp.: (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP, or prerequisite program) (2) If the FCS test is positive for Lm, the product would be considered adulterated. If the FCS is positive for Listeria spp., the product is not summarily considered adulterated, but corrective actions should be taken. (3) Record the corrective actions taken. (4) Collect follow-up samples from the FCS and surrounding areas (recommended). (5) Repeat corrective action and testing until samples are negative for Lm or Listeria spp. (6) Initiate intensified sampling after the 2nd consecutive positive. (7) If FCSs

continue to test positive, hold and test product (recommended). v) If the product tests positive for Lm, (1) Recall the product, if already shipped, and (2) Destroy the product, or (3) Re-work the product with a process that is destructive of Lm.", "FSIS Listeria Guideline January 2014 127 c) Alternative 2, choice 2 (Alt. 2b) i) Required: Conduct tests of FCSs for Lm or Listeria spp. recommended frequency: at least quarterly. ii) Sample at least a 12\u201dx12\u201d area, if possible. iii) Record the test results. iv) If the test results are positive for Lm or Listeria spp: (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP, or prerequisite program). (2) If the FCS test is positive for Lm, the product is considered adulterated. If the FCS is positive for Listeria spp., the product is not summarily considered adulterated, but corrective actions should be taken. (3) Record the corrective actions taken. (a) Collect follow-up samples from the FCS and surrounding areas (recommended). (4) Repeat corrective action and testing until samples are negative for Lm or Listeria spp. (5) Initiate intensified sampling after the 2nd consecutive positive. v) Holding and testing of product is required\* (recommended after the 3rd positive). vi) If the product tests positive for Lm, (1) Recall the product, if already shipped, and (2) Destroy the product, or (3) Re-work the product with a process that is destructive of Lm.

\*The establishment is required to identify when they will hold and test product. FSIS recommends that it hold and test product after the third consecutive positive result. d) Alternative 3 (non-deli or hotdog products) i) Required: Conduct tests of FCS for Lm or Listeria spp. Recommended frequency: once a month ii) Sample at least a 12\u201dx12\u201d area for each surface, if possible. iii) Record the test results. iv) If the test results are positive for Lm or Listeria spp.: (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program). (2) If the FCS test is positive for Lm, the product is considered adulterated. If the FCS is positive for Listeria spp., the product is not summarily considered adulterated, but corrective actions should be taken. (3) Record the corrective actions taken. (4) Collect follow-up samples from the FCS and surrounding areas (recommended). (5) Repeat corrective action and testing until samples are negative for Lm or Listeria spp. v) Initiate intensified sampling after the 2nd consecutive positive. vi) Hold and test of product is required\* (recommended after the 3rd positive). vii) If the product tests positive for Lm, (1) Recall the product, if already shipped, and (2) Destroy the product, or (3) Re-work the product with a process that is destructive of Lm.

\*The establishment is required to identify when they will hold and test product. FSIS recommends that it hold and test product after the 3rd consecutive positive result.", "FSIS Listeria Guideline January 2014 128 e) Alternative 3 (deli and hotdog products) i) Required: Conduct tests of FCSs for Lm or Listeria spp. Recommended frequency: (1) Large Establishments: four times per month per line (2) Small Establishments: two times per month per line (3) Very Small Establishments: once per month per line ii) Sample at least a 12\u201dx12\u201d area, if possible. iii) Record the test results. iv) If the test results are positive for Lm or Listeria spp.: (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP, or prerequisite program), which should include intensified cleaning and sanitizing. If the FCS test is positive for Lm, the product is considered adulterated. If the FCS is positive for Listeria spp., the product is not summarily considered adulterated, but corrective actions should be taken. (2) Record the corrective actions taken. (3) Collect follow-up samples from the FCS and the surrounding area (required). (4) Repeat corrective action and testing until samples are negative for Lm or Listeria spp. v) Initiate intensified sampling after the 2nd consecutive positive. (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP

or prerequisite program), which should include intensified cleaning and sanitizing. (2) If the FCS test is positive for Lm, the product in the sampled lot would be considered adulterated. If the FCS is positive for Listeria spp., the product is not summarily considered adulterated, but corrective actions should be taken. (3) Record the corrective actions taken. (4) Hold the product (see hold-and-test scenario below in Appendix 4.2). (5) Test product for Lm at a rate that provides a level of statistical confidence that the product is not adulterated (required after the 2nd consecutive positive result). (6) Conduct follow-up testing of the FCS each day until there are 3 consecutive negative test results for Lm or Listeria spp. (7) At the same time, continue to hold each day's production lot until the test results for the FCS are negative. (8) If the test results for the product are positive for Lm, (a) Destroy the product, or (b) Re-work the product with a process that is destructive to Lm.","FSIS Listeria Guideline January 2014 129 Appendix 4.2: Hold and Test Scenario Hold-and-Test Scenario for Deli and Hotdog Products in Alternative 3 Assuming it takes to 3 days to obtain a test result for Listeria spp.: Day 1 \u2013 Take food contact surface (FCS) samples Day 4 \u2013 If FCS samples (from Day 1) are negative for Listeria spp. \uf0fc Continue production, as the corrective action appears to have resolved the problem and test FCSs as scheduled. If the FCS samples are positive (from Day 1) for Listeria spp.: \uf0fc Take corrective action (as specified in the HACCP plan, Sanitation SOP, or prerequisite program), which should include an intensified cleaning and sanitizing. \uf0fc Collect follow-up samples of FCS\u2014target the most likely source of contamination, and also perform additional tests in the surrounding FCS area. \uf0fc Continue production. Day 7 \u2013 If the follow-up FCS sample (from Day 4) is negative for Listeria spp.: \uf0fc Continue production, as the corrective action appears to have resolved the problem and test the FCSs as scheduled. If the follow-up FCS sample (from Day 4) is positive for Listeria spp.: \uf0fc Take Corrective Action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include an intensified cleaning and sanitizing. \uf0fc Test the FCS-- target most likely source of contamination, and also take additional tests in the surrounding FCS area. \uf0fc Collect intensified samples of FCS, NFCS, and product. \uf0fc Hold and test Day 7 product lot (for Lm). \uf0fc Continue production, hold product from the day\u2019s production. Day 8 \u2013 \uf0fc Test the FCS\u2014target the most likely source of contamination, and also perform additional tests in the surrounding FCS area. \uf0fc Continue intensified sampling of FCS, NFCS, and product. \uf0fc Hold product from this day\u2019s production. Day 9 \u2013 \uf0fc Test the FCSs-- target the most likely source of contamination, and also perform additional tests in the surrounding FCS area. \uf0fc Continue intensified sampling of FCS, NFCS, and product. \uf0fc Hold product from this day\u2019s production. Day 10 \u2013 If the FCS sample (day 7 sample) is negative for Listeria spp.:","FSIS Listeria Guideline January 2014 130 \uf0fc Continue production and hold product from days 7, 8, 9 and 10 until the results from Day 7 product testing and Days 8, 9, and 10 FCS testing are available and found to be negative, unless there is compelling justification that affected products are not adulterated. \uf0fc Resume the FCS testing according to the frequency stated in the HACCP plan, Sanitation SOP, or prerequisite program. If the FCS sample (day 7 sample) is positive for Listeria spp.: \uf0fc Hold and test product from day 10 production. \uf0fc Test product from days 7, 8, 9, and 10 for Lm. \uf0fc Take corrective action. \uf0fc Intensive cleaning and sanitizing. \uf0fc Take FCS sample--target the most likely source of contamination, and also perform additional tests in the surrounding FCS area. Day 14 \u2013 If the Day 7 product is positive for Lm, destroy product, or

rework product with a process that is destructive of Lm. Recall product if already in commerce. If product is positive for Listeria spp., verify by testing that products (Days 7, 8, 9, 10), which may have been exposed to insanitary conditions are not adulterated. Product that is positive for Listeria spp. may be considered adulterated if it was produced under insanitary conditions, see Section 3.6. Question: An establishment that produces Alt. 3 deli and hotdog products tests FCSs on a Monday. The test comes back positive on Thursday. How would this affect the product produced on Monday, Tuesday, Wednesday, and Thursday? Answer: If the test is positive for Listeria spp., the result would not affect product produced on Monday through Thursday. However, on Thursday, the establishment must initiate corrective actions, intensified cleaning and sanitizing, and verify the effectiveness of the corrective actions by follow-up testing of the FCSs. If the test is positive for Lm, product that comes into direct contact with a FCS that tests positive for Lm is considered adulterated and FSIS would typically request that establishments recall such products if they have been released into the marketplace. That product must be destroyed or reworked with a process that is destructive of Lm. The establishment must have supporting documentation explaining why products produced on Tuesday, Wednesday and Thursday would not be contaminated with Lm. On Thursday, when it receives the positive result, the establishment must take corrective actions, conduct intensified cleaning and sanitizing, and test FCSs for Lm or indicator organisms to verify the effectiveness of the corrective actions.", "FSIS Listeria Guideline January 2014 131 Hold-And-Test Scenario Flowchart for Alt.3 (deli or hotdog producers) Test Food Contact Surface (FCS) (Day1) 1st FCS Listeria spp. (+) (Day4) Corrective Action Intensified Cleaning and Sanitizing Continue Production Collect Follow-up Test for FCS 2nd FCS Listeria spp. (+) FCS Listeria spp. (\u2013) (Day 7) Continue Production Test according to frequency in the Sanitation SOP. Corrective action intensified cleaning and sanitizing continue production Hold and test product lot (Day 7) (Day 10) 3rd FCS test for Lm. \_ FCS Listeria spp. or (+) FCS Listeria spp. or Repeat steps from Hold product lots (Days 8-10) Day 7. Hold product until the Day 7 product lots (Days 8-10). tests negative. Day 7 Product Day 7 Product Day 7 Product Lm (+) Lm (-) or Listeria spp. (+) Listeria spp. (-) Destroy product or Release applicable Continue analysis to Rework product with product lot. determine if Lm (+) (Day 14) process destructive of Lm. Test product Continue to hold product Test product from days 8-10. from days 8-10 until FCS from days 8-10. test negative, demonstrating control is regained (3 consecutive negative results). FCS: food contact surface Listeria spp.: Listeria species (test results available after 2 or 3 days). Lm: Listeria monocytogenes (test results available after 6 or 7 days)", "FSIS Listeria Guideline January 2014 132 Enforcement Strategy for Alternative 3 Deli and Hotdog Products Under the Listeria Rule, an establishment with deli and hotdog products in Alternative 3 must provide for testing of FCSs. If a FCS tests positive for Lm or Listeria spp., the establishment must conduct follow-up testing to verify that its corrective actions are effective. If during the follow-up testing another positive FCS occurs for Listeria spp., the establishment must hold the applicable product lot. If the product is positive for Lm, destroy or rework with a process destructive of Lm, and test the FCS until the establishment corrects the problem as indicated by the test result. In addition, the establishment must test held product lots for Lm using a sampling plan that will provide a statistical level of confidence. The flowchart above shows a hold and test scenario that establishments under hold and test can use. The days described are approximate, depending on the typical amount of time needed to obtain a positive test result (see key at bottom of the

flowchart). Establishments can adjust the flowchart based on their own process and time frame for sample results. The following section describes the likely action and reaction of inspection personnel during a hold and test situation. Day 1 and 4 The testing program and the test results for FCSs and NFCSSs should be made available to inspection program personnel (IPP). In case of a FCS testing positive for Listeria spp., IPP will verify that the establishment is performing the corrective actions as specified in the HACCP plan, Sanitation SOP or prerequisite programs, including any intensified cleaning and sanitizing. For deli and hotdog products in Alternative 3, IPP will verify that the establishment is conducting follow-up testing for FCSs to determine the effectiveness of the corrective actions, targeting the most likely source of contamination, performing additional tests in surrounding FCS area, and recording the results of all these. Day 7 Results of the follow-up FCS tests are available on this day. If the FCS tests are negative, then the establishment continues with its normal production and Sanitation SOP. If the follow-up FCS tests are positive for Listeria spp., , IPP will verify that the establishment is following its corrective action for a second FCS positive, including intensified cleaning and sanitizing. For deli and hotdog products in Alt. 3, inspection personnel will verify whether the establishment is holding the product produced that day and testing the product lot for Lm, and whether the establishment is conducting follow-up testing of FCS during each production day, and holding all products until a negative follow-up FCS test is obtained. Products produced on days 8, 9, and 10 are held until the follow-up FCS test available after about 3 days is found negative. The Listeria Rule states that products must be held until the problem is corrected, as indicated by testing. For establishments in Alt. 3 producing deli and hotdog products, inspection personnel can cite the establishment if these procedures are not followed. Days 8, 9, and 10 The presence of Listeria spp. on a FCS or on RTE product is associated with the potential for an insanitary condition to exist. FSIS expects an establishment to develop a compelling justification for concluding that product produced on days in which insanitary conditions may have existed is not adulterated. Thus, FSIS would further expect that the establishment, on days 8-10, would conduct verification testing on the FCSs to demonstrate that the potential insanitary condition was adequately redressed via the corrective and preventive actions. In addition, to further develop a compelling justification to support the establishment\u2019s decision, FSIS would expect a prudent establishment to also compile data on product testing to confirm and verify that the corrective and preventive actions were effective in preventing product from becoming adulterated.", "FSIS Listeria Guideline January 2014 133 Day 10 If the Day 7 FCS Test is Positive, IPP will verify that if the follow-up FCS test taken on Day 7 is positive, then the day\u2019s production lots of deli and hotdog products in Alt. 3 are held and tested for Lm or Listeria spp, and the same procedures are followed as in the second FCS (+) test as in Day 7. If the FCS samples taken on day 7 are found positive for Listeria spp. on day 10, the establishment should hold and test product produced on days 8, 9, and 10 unless the establishment has supporting documentation to justify that product produced on days 8, 9, and 10 would not be contaminated with Lm. The sampling plan must provide a level of confidence that each product is not contaminated with Lm. Because of 3 consecutive positive FCS samples, the establishment should conduct intensive cleaning and sanitizing and reevaluate its Sanitation SOP. If the FCS sample is positive for Lm, affected product lots are considered adulterated. The establishment should also hold and test products produced on days 8, 9, and 10 because an FCS positive for Lm shows that the corrective action may not have been effective in removing the

contamination and products produced on succeeding days may also be contaminated. If the Day 7 FCS Test is Negative If the FCS samples taken on day 7 are found negative for Listeria spp. on day 10, the establishment should wait for the results of the FCS tests conducted on days 8, 9, and 10 as detailed above, and results of the Day 7 product test before releasing these products. Control is considered regained after 3 days of negative results. Day 14 If day 7 product was found positive for Lm on day 14, affected product lots produced on day 7 are considered adulterated. The establishment must destroy the product lots or rework them with a process destructive of Lm. The establishment should continue holding product lots produced on days 8, 9, and 10 until results of products tests are available, unless the establishment has supporting documentation for why product produced on days 8, 9, and 10 would not be contaminated with Lm. Establishment should also hold and test product produced before day 7 and recall them if already in commerce or provide compelling evidence that product produced before day 7 was not adulterated. For a product sample that tests positive for Lm, inspection personnel will verify that the product lots affected are disposed properly, i.e., destroyed or reworked with a process that is destructive to Lm. Establishments should have supporting documentation that products lots produced before Day 7 are not contaminated with Lm, so that these lots will not be included as adulterated. A product that is positive for Listeria spp. may be considered adulterated if it was produced under insanitary conditions, see Section 3.6.", "FSIS Listeria Guideline January 2014 134 Appendix 4.3: Listeria Trends Examples The following are some scenarios describing how establishments can track and address Listeria trends. Establishment A Establishment A makes RTE salads, including potato salad, chicken salad, and ham salad for delicatessens in grocery stores. The establishment manufactures product in two 8-hour shifts, 6 days a week. The third shift is reserved for sanitation. It has identified three tiers in its sampling program: NFCS sampling, FCS sampling, and finished product testing. It has identified 30 NFCS sampling sites, including the walls next to the preparation tables, the exterior of the mixing kettles, the mixer shaft, and the drains under the preparation tables. Each week it randomly picks 15 of the 30 sites for testing for Listeria spp.; these 15 sites are tested twice a week ("routine monitoring") before production. Results are tracked as total number of positives over time and also by site. When a positive is detected at any site, it is given extra attention during the next sanitation. If the number of positives exceeds 10% (e.g., if there are 3 positives out of 30) during the week (two test periods, rolling window) or if the same NFCS site comes up positive more than one time in a month, these sites are given extra attention during the next sanitation shift, and the areas are re-swabbed daily until there are three consecutive days of negatives. Once this has occurred, the establishment reverts to routine monitoring. If the problem is not corrected within 5 days, the establishment enters "\u201ctrouble shooting\" mode, which includes more stringent decontamination procedures, such as disassembly and sanitizing, fogging with sanitizers, changing sanitizers, double sanitizing, and heat treatments. Establishment A also conducts routine random FCS testing and it has identified 20 FCSs, including tables, conveyor belts, and slicer blades. Each week, 10 of these are randomly selected and tested for Listeria spp., twice per week at the end of production and before cleaning. If a positive is detected, the site is given extra attention during the next sanitation shift and a follow-up sample is collected. The site is tested daily for 5 days. If the site is positive during this 5-day period, the line is shut down and, if appropriate, torn apart, taking troubleshooting swabs during the disassembly. The product contact surface and

surrounding areas receive extra sanitation and the line is re-assembled. FCS swabs are then taken every two hours during production and all products are placed on hold. If any swab tests positive, product from the 2-hour time period and from each period on either side is tested for Lm. Product that is negative is released. Product that tests positive is destroyed, since re-processing is not an option for this product. The establishment conducts random product testing of one salad product each month by taking one package every two hours from an 8-hour shift and compositing product from two packages. The product is tested for Lm. Product found to be positive for Lm is destroyed and intensified sampling of FCSs for Listeria spp. is conducted daily for a week. If positive FCS results are found, the establishment undertakes investigations to determine the cause of the problem. The Listeria Control Program is also reviewed and revised, as appropriate. Establishment B produces fully cooked, breaded chicken products. The establishment manufactures product on three separate lines in two 8-hour shifts, 6 days a week. The third shift is reserved for sanitation. The establishment's NFCS monitoring component of its Lm Control", "FSIS Listeria Guideline January 2014 135 Program targets the area where product exits the fryer, is chilled, and then packaged. There are two parts to this establishment's program: product contact surface testing and non-product contact surface testing. The establishment monitors 20 NFCSSs on a weekly basis for Listeria spp. (routine monitoring). For each line, 5 swabs are composited, resulting in 4 tests per line for a shift. If a positive is detected, the establishment investigates by re-swabbing and testing the swabs individually, as well as by taking additional swabs in the area. If there are no additional positives, the establishment considers the initial positive to be an isolated incident and returns to routine monitoring. If additional positives are detected, the establishment institutes corrective actions, which may include a review of the current Listeria Control Program, revising GMPs, changing sanitizers, enhanced sanitation in clean areas, and employee retraining. The establishment then monitors twice a week (enhanced monitoring) until there are 4 consecutive negative periods, at which point the establishment returns to routine monitoring. The establishment also monitors 15 FCSs on each line during each shift of production every other week. If the swabs are all negative, it continues routine monitoring. If there is a positive result, the establishment investigates by collecting a follow-up sample of the area, as well as by taking additional swabs in the surrounding area. In addition, it institutes corrective actions, which may include intensified cleaning and changing sanitizers. The establishment then takes swabs to confirm that the actions taken have been effective. If there are no positives, the establishment returns to routine monitoring. If there are any positives, the establishment escalates its corrective actions, which may include intensified testing, breaking down pieces of equipment and sanitizing, and heating pieces of equipment. It would also evaluate the need to conduct finished product testing based on all the existing evidence.", "FSIS Listeria Guideline January 2014 136 Example Table for Tracking Microbiological Sampling Trends This table provides an example spread sheet that establishments may use to track testing results and corrective actions for Listeria spp. over time. Tracking this information will assist establishments in identifying trends and determining whether they are taking the appropriate corrective actions in response to positives and in reaction to trends. In the scenario below, a positive testing result was found on the freezer fan and addressed by the establishment. No trend was identified because it was the first positive found in that area. However, positives continued to be found in the same general area (Line 4 freezer) leading up to a food contact surface (FCS) positive on the

belt exiting the freezer, despite progressively intensified corrective actions taken by the establishment. Negative results seen after the establishment identified a trend and took corrective action (including 3 negatives on the belt exiting the freezer) indicate that the trend was addressed. Corrective actions listed below are only examples and should not be considered the only methods to address Listeria spp. contamination. Regulatory testing for FCSs and non-regulatory testing of NFCS are shown within the table. NOTE: Establishments are NOT required to perform NFCS testing or follow-up testing in response to NFCS positives. Sampling Results for Listeria spp. in an Alternative 3 Deli and Hotdog Small Volume Establishment Date Line # FCS or NFCS Surface Shift Results Followup Test Date Followup Test Result Intensified testing

Corrective Action Trend Identified? 9Jan 4 FCS QA utensil 2 neg. 30Jan 5 FCS conveyor belt preop neg. 9Feb 1 FCS conveyor belt 1 neg. 12Feb 3 FCS eagle scale preop neg. 19Feb 1 FCS plastic film 2 neg. 19Feb 5 NFCS freezer structure preop neg. 19Feb 4 NFCS Freezer fan preop positive 24-Feb positive 3 days of Tests; (-) results Removed product, recleaned freezer and freezer fan None 23Feb 2 FCS Freezer belt 2 neg. 6Mar 1 NFCS Roller belts preop neg. 6Mar 4 NFCS Hose 2 neg. 10Mar 4 FCS product slide to freezer preop neg. 10Mar 4 NFCS freezer air handler preop neg. 18Mar 5 FCS return belt 1 neg. 18- Mar 3 NFCS wall 1 neg. 18Mar 4 NFCS stand 2 neg. 23Mar 2 NFCS drain 2 neg.", "FSIS Listeria Guideline January 2014 137 Date Line # FCS or NFCS Surface Shift Results Followup Test Date Follow- up Result Intensified testing

Corrective Action Trend Identified? 23Mar 4 NFCS freezer wall 1 positive 28-Mar positive 3 days of tests; (-) results Increase cleaning frequency for freezer, scrub freezer floors and walls. Second positive in freezer area may indicate possible harborage, addressed by increased cleaning 3Apr 6 FCS tub post- op neg. 3Apr 4 NFCS freezer floor postop positive 8-Apr positive 3 days of tests; (-) results Intensified Cleaning of Freezer, consulted freezer manufacturer, Third positive in area addressed by intensified cleaning. 3Apr 1 NFCS freezer structure post- op neg. 6Apr 4 NFCS freezer floor post- op neg. 21Apr 3 FCS conveyor belt post- op neg. 21Apr 4 NFCS freezer wall preop neg. 15May 2 FCS conveyor belt 1 neg. 18May 4 FCS line personne l preop neg. 15Jun 1 FCS product table preop neg. 15Jun 2 FCS product scoop 1 neg. 7-Jul 4 FCS belt exiting the freezer 2 positive 13-Jul positive 3 days of tests; (-) results; hold and test product (-) results Stopped production. Repaired refrigerant leak. Intensified cleaning of freezer.

Production resumed after repairs and cleaning. Freezer is identified as a harborage point and addressed by repairs and cleaning. 14 Jul 1 NFCS drain 1 neg. 14 Jul 2 NFCS wall 2 neg.", "FSIS Listeria Guideline January 2014 138 Date Line # FCS or NFCS Surface Shift Results Followup Test Date Followup Test Result Intensified testing Corrective Action Trend Identified? 30Jul 4 FCS knife blade 1 neg. 3Aug 1 FCS spiral slide 2 neg. 14Aug 4 NFCS freezer wall preop neg. 14Aug 4 NFCS product entrance facing freezer preop neg. 20Aug 4 FCS belt exiting the freezer 2 neg. 26Aug 10 FCS product rack 1 neg. 26Aug 4 NFCS freezer floor post- op neg. 12Sep 2 FCS line personne l 2 neg. 26Sep 9 NFCS condemn tub preop neg. 26Sep 7 FCS product tray preop neg. 28Sep 4 FCS belt exiting the freezer 2 neg. 1Oct 4 NFCS freezer air handler 1 neg 1Oct 4 NFCS freezer wall preop neg 1Oct 6 FCS employe e gloves 1 neg 12Oct 4 NFCS freezer floor 2 neg 12Oct 4 FCS belt exiting the freezer 1 neg Key FCS = Food contact surface NFCS = Non food contact surface", "FSIS Listeria Guideline January 2014 139 Appendix 4.4: Findings from Food Safety Assessments (FSAs) In 2009, FSIS began performing routine Food Safety Assessments (FSAs) in RTE establishments at a frequency of once every 4 years. These FSAs are performed along with routine risk-based Lm (RLm) sampling. FSIS also performs \u201cfor cause\u201d

FSAs along with Intensified Verification Testing (IVT). The purpose of the FSA is to evaluate the food safety systems (including the HACCP plan and Sanitation SOP) at the establishment to determine if they are effective in controlling the safety of the product. FSAs are performed according to FSIS Directive 5100.1 Enforcement, Investigations, and Analysis Officer (EIAO) Food Safety Assessment Methodology. FSIS reviewed the findings from for cause FSAs performed in response to IVTs on a quarterly basis. FSIS is planning to review the findings in routine FSAs performed during RLms and to include the results of those analyses in future issuances of this guidance. The findings from these reviews are used to help develop new policy and revise current policy to ensure that establishments are meeting the requirements of the Listeria Rule. By summarizing the findings FSA reports, FSIS can provide information to RTE establishments so that they can focus their attention on areas where further improvements in their food-safety systems may be needed. During the FSA review, it was found that several of the establishments had deficiencies in their Sanitation and HACCP design and record keeping systems. These problems included the following:

- \u2022 The establishment failed to follow written Listeria programs. According the Listeria Rule, establishments in Alt. 2b and 3 are required to indicate their sampling frequency and explain why the frequency they have identified is sufficient to control Lm or an indicator organism. As described in the Listeria Guideline, establishments can document the sampling frequency they have identified as part of the Listeria Control Program (Section 3.1). Once the establishment has established a frequency as part of its program, it would need to follow the sampling frequency. If an establishment does not follow the sampling frequency by not collecting a sample during the timeframe specified in their program, it would be found to be non-compliant, unless it can provide other supporting documentation demonstrating that its process is safe.
- \u2022 The establishment did not perform monitoring at frequencies specified in the HACCP plan. In some cases, establishments identified a certain frequency for monitoring the CCPs associated with RTE products (e.g., measuring lethality temperatures) and did not monitor the temperature at the specified frequency. By failing to monitor the CCPs at the specified frequency, the establishment could miss processing deviations that could occur, leading to under processing or other safety issues in the product.
- \u2022 The establishments did not document corrective actions sufficiently. If a deviation occurs from a critical limit, establishments are required to take corrective actions to bring the process under control (9 CFR 417.3). These corrective actions must include measures to prevent recurrence of the deviations. In some cases, the corrective actions written by the establishments did not provide sufficient explanation to demonstrate how future deviations would be prevented.
- ," "FSIS Listeria Guideline January 2014 140
- \u2022 The establishment did not provide supporting documentation for their PLT and AMAPs. In some cases, establishments did not support that their PLTs achieved at least a 1-log reduction of Lm in the product or that the AMAP allowed no more than 2-logs growth of Lm over the shelf-life of the product. The Listeria Guideline provides specific guidance establishments can use to ensure that the supporting documentation for the PLT and AMAP is sufficient and reflects the critical operational parameters of their process (see Appendix 2.1).
- \u2022 The establishment failed to maintain sanitary operations and failed to maintain equipment and utensils in a sanitary manner. In some cases, positive results were found during the RLm or IVT, indicating that sanitary operations were not maintained or that equipment and utensils were not maintained in a sanitary manner. In one case, condensation was dripping directly on exposed-RTE product.

The Listeria Guideline provides information establishments can use to ensure that sanitary operations are maintained (see Appendix 2.2). In addition, establishments can use verification testing to ensure that their food-contact surfaces are sanitary and free of Lm. By collecting samples of non food contact surfaces, establishments can find potential harborage points and address them before the product becomes contaminated. Establishments are required, according to 9 CFR 416.2 (b), to ensure that the facility and the equipment are sanitary and in good repair, so that potential sources of cross contamination, such as condensation, are minimized. \u2022 The establishment did not identify the location and the sites that will be sampled for testing of food contact surfaces in the post-lethality processing environment and provide an explanation of why the testing frequency was sufficient to ensure that effective control of Lm or of indicator organisms is maintained. If an establishment chooses either Alt. 2b or 3, it must test FCSs in the post-lethality processing environment, identify the frequency for testing, and provide an explanation of why the testing frequency is sufficient to ensure the effective control of Lm or indicator organisms (9 CFR 430.4(b)(2)(iii)(A), (C), and (E) and 430.4(b)(3)(i)(A), (C), and (E)). The FSIS expectation is that establishments in Alt. 2b or 3 will identify all possible FCS for testing. The Listeria Guideline provides information on site selection and a list of possible FCSs and NFCSSs the establishment could sample (see Appendix 3.1). Recommended minimum testing frequencies are also provided in the Listeria Guideline (see Section 3.3). Establishments can use the recommended frequencies or select their own frequency; however they would need to provide support that the level of testing is sufficient to demonstrate that Lm is controlled in the product. Establishments should increase their sampling frequency due to repeated positive results, construction, or sanitation issues. \u2022 The establishment did not address hazards reasonably likely to occur in the production process. Some establishments did not list all of the steps in the processing of their product in their flow chart, as required by 9 CFR 417.2(a)(2). In some cases, the establishment did not", "FSIS Listeria Guideline January 2014 141 consider possible hazards from ingredients (such as spices) added after the lethality treatment. In other cases, the establishment did not have supporting documentation on file, such as letters of guarantee or certificates of analysis (COA) demonstrating that each lot of ingredients it added to product were safe and would not cause the product to become adulterated. Information on ensuring the safety of ingredients in RTE product can be found in the FSIS RTE Salmonella Guideline. Information on avoiding sources of environmental contamination can be found in the Listeria Guideline (see Appendix 2.2). By reviewing the examples provided above and addressing deficiencies in their food-safety programs, establishments can help ensure that they meet the requirements of the Listeria Rule. In addition, by reviewing their programs to ensure that possible weaknesses are addressed, establishments can produce safe products and help protect public health.", "FSIS Listeria Guideline January 2014 142 Appendix 4.5: FSIS Response to Comments FSIS received 2 comments in response to the September 2012 \u201cFSIS Compliance Guideline: Controlling Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products\u201d (FSIS Listeria Guideline). Comment summaries and Agency responses follow. Comment: One commenter questioned why the FSIS Listeria Guideline was revised using only FSIS data and input. The commenter stated that the meat and poultry industry likely would have been able to provide additional assistance or guidance in advance of the draft being issued to field personnel. According to the commenter, revising the guideline after it is has already

been adopted may lead to confusion among the industry or FSIS field personnel. The commenter also stated that collaboration of industry and Agency efforts has lead to a decrease in positives from the FSIS RTE sampling program. Response: As FSIS has done with all guidance documents it has issued in recent years, FSIS sought industry input by seeking comment on the guidance. This practice has allowed FSIS to incorporate comments and feedback from industry and other interested parties. FSIS now adds a message to all draft compliance guidelines stating that the guideline represents FSIS\u2019s current thinking on the topic and should be considered usable as of its issuance. FSIS will routinely update guidance documents to reflect the most current information available to FSIS and its stakeholders. FSIS agrees that the success of the Listeria regulation has been the affect of efforts from industry and FSIS to control contamination of RTE products. This information has been added to the Introduction section of the revised FSIS Listeria guideline. Comment: One commenter stated that the Constituent Update article, issued on September 21, 2012, announcing the availability of the guidance and the instructions in FSIS Notice 59-12, implied that the guidelines should be considered requirements rather than recommendations to industry. Similarly, the commenter stated that instructions in FSIS Notice 59-12 stating that EIAOs are to review the information in the guideline as part of their preparation for performing FSAs, implies that that the guidelines are requirements. Response: As FSIS has stated in explaining the purpose of the FSIS Listeria Guideline, \u201cThis document provides guidance to assist establishments in meeting FSIS regulations. Guidance represents best practice recommendations by FSIS based on the best scientific and practical considerations and does not represent requirements that must be met.\u201d While it is true that the guidance can be used to assist establishments in strengthening their food-safety programs, the guidance does not represent requirements. The purpose section of the guideline has been revised to clarify that establishments may choose to adopt different procedures than those outlined in the guideline, but they would need to support why those procedures are effective in controlling hazards from Lm in RTE products. By using the recommendations in the guideline, establishments would not need to provide further support for their procedures. In FSIS Notice 59-12, FSIS instructed EIAOs not to recommend that IPP issue NRs based on establishments using previous versions of the guidelines. The purpose of this instruction is to ensure that EIAOs do not interpret the guidance as requirements, and that NRs should not be issued to establishments that fail to adopt the most recent version of the guidelines. However, EIAOs may still recommend the issuance of NRs if the establishment fails to support the efficacy of its food safety system to control pathogens. Comment: One commenter requested more information on compositing samples, including information on the pros and cons of compositing samples for both environmental and", "FSIS Listeria Guideline January 2014 143 food contact surfaces. The commenter also suggested that FSIS include provisions for the use of surrogate or indicator organisms for testing purposes in the compliance guideline. Response: FSIS added new information regarding compositing of samples and laboratory methods for analyzing the samples in Appendix 3.3, Sample Collection and Testing Methods. In addition, this section includes information on the pros and cons of compositing the samples. As stated in Appendix 3.3, establishments may choose to test for Lm, Listeria spp., or Listeria-like organisms (LLO). Listeria spp. and LLO are examples of indicator organisms for which establishments may test in lieu of testing for Lm. A finding of Listeria spp. or LLO on a food contact surface could indicate conditions where Lm could survive. FSIS has also

provided examples of the use of non-pathogenic Escherichia coli (E. coli) cultures as surrogate indicator organisms in validation studies in the following Q&A: Use of Non-pathogenic Escherichia coli (E. coli) Cultures as Surrogate Indicator Organisms in Validation Studies. As FSIS continues to revise its guidelines and to issue new guidelines, it plans to provide more information about surrogate and indicator organisms that can be used for in-plant validation studies. Comment: One commenter suggested that FSIS provide assistance to small and very small establishments concerning the changes in the guidelines by performing outreach in the form of webinars, resource documents, regional meetings, and any other form of education the Agency can provide to those establishments. Response: FSIS agrees that it would be worthwhile to conduct outreach to small and very small establishments regarding the changes in the guidelines. FSIS is planning to present a series of webinars describing the changes.

Establishments may also submit specific questions through AskFSIS, and subject matter experts will respond to their questions. Comment: One commenter asked about the use of different values in the examples and tables, the definition of \u201ccook-in bag\u201d product, and the use of Safe Handling Instructions (SHI) on RTE product. Response: With regard to the values in Table 2.1 and the values in the examples, the values in the table would be effective if used alone to control Lm growth. However, the values in Example 1 in Section 2.1 are different than the values in Table 2.1 because of the \u201churdle effect,\u201d which is the synergistic effect of parameters to control Listeria growth. FSIS revised the examples in the guideline to more clearly describe the impact of multiple factors on pathogen growth and provided a new section on the hurdle effect. In addition, FSIS revised Appendix 1.1, Product types, to further clarify that cook-in bag products are not considered deli products because they are not subject to the Listeria Rule. FSIS also revised Attachment 1.2, Chart of RTE vs. NRTE Products: Resource 1, to clarify when SHI are required and

recommended."],{"file\_name":"FSIS\_GD\_2014\_0002","title":"Generic Label Approval","num":"FSIS-GD-2014-0002","id":"8d4f0b2eed14d17170513b5ca33368afbbe76928971b391febc51d1f28c36551","corpus":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/media\_file/2021-02/Generic-Final-Rule-Overview-

Industry.pdf","type":"pdf","n\_pages":50,"word\_count":3243,"text\_by\_page":[{"FSIS Labeling and Program Delivery Staff (LPDS) January 14, 2014","The Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) require food manufacturers to obtain prior approval for labels of meat and poultry products before products may be marketed. Prior approval is granted one of two ways: Sketch approval which is approved by the Labeling and Program Delivery Staff (LPDS). Generic approval which is approved by being in compliance with applicable regulations. 2, "The Label review process by Labeling and Program Delivery Staff (LPDS). May be a printer's proof or equivalent that is sufficiently legible to clearly show all labeling features, size, and location. May be hand drawn, computer generated, or other reasonable facsimiles that clearly reflects and projects the final version of the label. Certain types of labels require sketch approval (discussed later in this presentation). 3, "Sketch approved labels reviewed by LPDS are either approved or modified. A sketch label is the concept of a label while a final label is the label that is applied to

product before distribution in commerce. Establishments are responsible for ensuring final labels applied to product are in compliance with FSIS regulations 4", "FSIS regulations approve some labels generically Generic labeling approval refers to the approval of labeling or modifications to labeling prior approved by the Agency without submitting such labeling to FSIS for sketch approval Generic labeling approval requires that all mandatory labeling features are in conformance with FSIS regulations Although such labeling is not submitted to FSIS for approval, generically approved labels are approved by being in compliance with applicable regulations, therefore Generically approved labels applied to product are consistent with the Agency's prior labeling approval system

NOTE: FSIS Inspectors do not generically approve labels. Establishments do not generically approve labels. FSIS approves labels through generic labeling regulations.

5", "By regulation, FSIS specified when a generic approval could be undertaken by an establishment (9 CFR 317.5 and 381.133) Generic approval forgoes the need to obtain sketch approval

Prior to the new rule specific labels were eligible for generic approval AND

certain changes could be made generically to sketch approved labels 6", "On November 7, 2013, FSIS published a final rule that amended the meat and poultry products inspection regulations to expand the circumstances under which the labels of meat and poultry products would be deemed to be generically approved by the Agency Effective January 2014, four categories of labels now REQUIRE sketch approval ALL OTHER labels that do not fit into one of the four categories do not require sketch approval by LPDS

7", "Final rule amended FSIS regulations to combine the previous regulations that provided for labeling approval (9 CFR 317.4 and 381.132) and generically approved labeling (9 CFR 317.5 and 381.133) for meat and poultry products into one new section New label approval regulations for meat and poultry products now in 9 CFR 412.1; approval of generic labels now in 9 CFR 412.2

8", "Only certain types of labeling require submission for evaluation by LPDS

Temporary labels for temporary approval (9 CFR 412.1(c)(4))

Labels for products produced under religious exemption (9 CFR 412.1(c)(1))

Labels for products for export with labeling deviations (9 CFR 412.1(c)(2))

Labels with special statements and claims (9 CFR 412.1(c)(3))

FSIS will continue to require the submission of such labels because they are more likely to present significant policy issues that have health or economic significance

9", "New Generic Labeling Final Rule introduces the four categories of labels that require prior approval by LPDS:

Temporary labels Religious exemption Exports with labeling deviations Special statements and claims

10", "A temporary label approval may be granted for labels with a regulatory deviation that does not pose any potential health, safety, or dietary problems to the consumer Approval not to exceed 180 days

Temporary label approval granted on a caseby-case basis

11", "Approval process unchanged by the new generic labeling rule

FSIS assesses the public health risk and potential economic adulteration when deciding to grant approval for the use of a temporary label

The regulations are not specific enough to assist establishments in determining when a temporary label may be granted

For these reasons, FSIS is not expanding the scope of generic labeling approval to include temporary label approvals and extensions.

12", "Religious-exempt product (poultry) does not receive the mark of inspection and, therefore, deviates from the general labeling requirements for meat and poultry products

Labels for religious-exempt

product must be submitted to LPDS for sketch approval \uf0d8 Ritually-slaughtered meat and poultry products receive the mark of inspection (Kosher, Halal) and may be approved generically provided that they don\u2019t meet one of the other labeling categories requiring sketch approval 13","\uf0d8 Exports of U.S. meat and poultry products occur under agreements between the U.S. government and foreign governments \uf0d8 Agreements require U.S. government approval of labels on meat and poultry products to be exported bearing labeling deviations \uf0d8 Includes ensuring that any changes made to labels on meat and poultry products are allowed per the importing country\u2019s laws (9 CFR 317.7 and 381.128) \uf0d8 Labels marked \u201cfor export only\u201d that bear labeling deviations and therefore cannot be used domestically must be sketch approved by LPDS 14","\uf0d8Detailed list of special statements and claims requiring LPDS approval and examples of claims eligible for generic approval is available on FSIS website <http://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Comp-GuideLabeling-Evaluation-Approval.pdf?MOD=AJPERES> \uf0d8List includes commonly used special statements and claims 15","Examples of special statements and claims: o3rd party raising claims or programs (i.e. Global Animal partnership, AMS Process verified or certified programs, American Heart Association (AHA) claims) oClaims regarding meat and poultry production practices (i.e. claims regarding the raising of animals such as \u201cno antibiotics administered\u201d or \u201cvegetarian fed\u201d) oBreed claims (Berkshire, Angus, Hereford, etc) oCertified claims, Certified Halal oGluten free: both certified and non certified oHealth claims defined in 21 CFR Subpart E, e.g. dietary saturated fat and cholesterol and risk of coronary heart disease (21 CFR 101.75) 16","oImplied Nutrition Claims for example Heart Smart, Baked Not Fried, Made without Butter oStatements that identify a product as \u201corganic\u201d or containing organic ingredients oInstructional or disclaimer statements concerning pathogens, such as \u201cfor cooking only\u201d; \u201cnot tested for E. coli O157:H7\u201d; or \u201cFor high pressure pasteurization at establishment ABC\u201d oNatural claims, e.g. \u201cAll Natural\u201d, \u201c100% Natural\u201d oNegative claims or \u201cfree\u201d claims (no MSG, no MSG added, no preservatives) 17","oOmega 3 factual statements o\u201cWhole Grain\u201d, \u201cMade with Whole Grains\u201d, \u201cMade with whole wheat\u201d claims oNutritional Front of Pack statements, for example \u201c0 grams trans fat per serving\u201d, Nutrition facts Up Front oClaims of the use of non-genetically engineered ingredients oClaims that are undefined in FSIS regulations or the Food Standards and Labeling Policy Book (Note: natural and negative claims are defined in the policy book but will continue to be required to be submitted for approval). 18","19 Special Claim (Breed Claim) Special Claim (Natural Claim)", "20 Special Claims (Organic Claims and logo)", "\uf0d8Some statements and claims are not considered \u201cspecial\u201d under 9 CFR 412.1 (e), e.g. statements of fact \uf0d8Statements and claims of this type may be approved generically (9 CFR 412.2(b)) \uf0d8The next two slides review examples of statements that are not considered special and may be approved generically 21","oAll, 100%, pure oAllergen or \u201cContains (name of ingredient)\u201d statements (e.g., contains soy) oAMS Grading (Prime, choice, grade A) oChild Nutrition Boxes oFlavor Profiles (e.g. made with fennel, teriyaki flavored, made with real cheese, only white meat) oForeign Language on domestic products oGeographic claims (refer to 9 CFR 317.8(b)(1)) 22","oGreen Claims\Environmental Claims oHalal, Kosher (not certified) oHand pulled style\hand pinched style oHandcrafted, handmade, hand slaughtered, hand

crafted style oHome Style oFor HRI only, Institutional use only, etc oNutrition Claims (defined) oReady in\oCooks in (number of minutes or seconds) oOven roasted or similar statements 23", "\uf0d8Expected to be a cost-saving measure for the industry: \$8.7 million over ten years \uf0d8FSIS is committed to providing guidance and resources that will help companies take advantage of this new rule without needing to hire additional personnel 24", "\uf0d8Estimate that allowing more labels to be generically approved will reduce current label approval volume by roughly 70 percent \u2022decrease from 846,000 submissions to 261,000 submissions over a 10-year period \u2022\$2.9 million saved over ten years \uf0d8Cost savings in fewer staff hours spent evaluating labels can be redirected towards other Agency initiatives 25", "\uf0d8Will enhance market efficiency by promoting a faster introduction of new products into the marketplace to meet demand \uf0d8Frees up FSIS\u2019 resources so they can be redirected to other food safety issues \uf0d8In-plant inspection personnel will continue on-site labeling evaluations 26", "\uf0d8FSIS Inspectors do not generically approve labels \uf0d8Labels will be generically approved if they meet the criteria listed in 9 CFR 412.2(b) \uf0d8FSIS in-plant inspection personnel will continue to verify labels as part of the General Labeling task \uf0d8Establishments do not generically approve labels. Generically approved labels are approved by FSIS 27", "\uf0d8Labels that do not fit into one or more of the four categories of labels requiring sketch approval are generically approved by their compliance with applicable regulations \uf0d8If an establishment elects to submit a generically approved label to LPDS for review, the label will be assigned a lower priority than those labels that require sketch approval by LPDS 28", "\uf0d8Labels which require LPDS evaluation as per 9 CFR 412.1: \u2022Temporary labels \u2022Religious-Exempt product \u2022Labels for Export bearing labeling deviations \u2022Labels bearing special statements or claims \uf0d8Will be reviewed in the order in which they are received 29", "\uf0d8Labels which do not require LPDS evaluation as per 9 CFR 412.2 \uf0d8Establishments may request voluntary evaluation by LPDS of generically approved labels \uf0d8Applications for voluntary evaluation of generically approved labels will be placed in a second priority queue and may take longer to be reviewed 30", "\uf0d8Type \u201cgeneric\u201d in the box entitled \u201cOther claim description\u201d in Step 3: Special Claims Information of the LSAS label submission process \uf0d8Generic-labels not marked as \u201cgeneric\u201d will be returned via LSAS with a note that the label may be generically approved \u2022Generic-labels may be resubmitted through LSAS for voluntary review by noting \u201cgeneric\u201d in the \u201cother claim description\u201d box \u2022When a label that may be generically approved is returned electronically, no response is necessary if voluntary review is not requested \uf0d8LSAS labels with requests for voluntary review will be added to the second priority queue 31", "\uf0d8 Type \u201cGeneric\u201d after \u201cOther claims\u201d in Block 10 of FSIS Form 7234-1 \uf0d8 Establishments submitting paper labels that may be generically approved not marked as \u201cGeneric\u201d in Block 10 will be contacted by LPDS to determine if voluntary review is requested \uf0d8 If voluntary review is requested, the paper label will be placed in the second priority queue \uf0d8 If voluntary review is not requested, the label will be returned to the establishment \uf0d8 If no contact is made with the establishment, the labels will be placed in the second priority queue 32", "\uf0d8LPDS will assess all labels to determine if label review is required \uf0d8LPDS determination that a label may be generically approved is NOT a label review \uf0d8Notification by LPDS that a label may be generically approved should not be mistaken for

LPDS approval of the label \u2022It is the establishment\u2019s responsibility to ensure that the final label meets all applicable labeling regulations \u2022Generically approved labels do not require approval by LPDS \u2022As noted earlier, generically approved labels that are voluntarily submitted for approval will be placed in the second priority queue and may take longer to be reviewed \u2022Labels that may be generically approved placed in the second priority queue may be used by the establishment provided that the labels are in compliance with applicable regulations 33", "\uf0d8Paper and LSAS labels reviewed by LPDS will be marked as either: \uf0d8Sketch Approved \uf0d8Sketch Modified, with required changes noted \uf0d8Returned \u2022Returned labels are not required to be resubmitted to LPDS for approval since they are approved generically once the noted changes are made \u2022Returned labels resubmitted to LPDS will be placed at the bottom of the second priority queue on the day they are received \u2022There is no resubmittal priority for labels that may be generically approved 34", "\uf0d8Labels that may be generically approved submitted through labeling consultants with no note of \u201cgeneric\u201d in Box 10 will be returned to the consultant for confirmation that voluntary review is requested \uf0d8Labels may be submitted back to LPDS with \u201cgeneric\u201d noted in Box 10 if voluntary review is requested \uf0d8Labels will be placed in the second priority queue on the day that they are received complete with \u201cgeneric\u201d noted in Box 10 35", "\uf0d8Labels that may be generically approved and are voluntarily submitted for review do not qualify as an extraordinary circumstance \uf0d8Any label that may be generically approved does not require LPDS approval to enter commerce, therefore emergency review will not be granted \uf0d8Special note on final product labeling \u201cTagged\u201d for labeling non-compliance \uf0d8Final label must be brought in to compliance by correcting the non-compliance \uf0d8Requests for the temporary use of final labels not in compliance with FSIS regulations and policies must be submitted to LPDS for review. Emergency reviews may be requested in this instance. 36", "\uf0d8Generic Rule does not apply to egg products \uf0d8Expanding the generic labeling criteria for processed egg products is being considered as a separate rule \uf0d8Generic Rule also does not apply to exotic species under voluntary inspection 37", "\uf0d8Available online at: [http://www.fsis.usda.gov/wps/wcm/connect/7c48be3e-e516-4ccf-a2d5b95a128f04ae/Labeling\\_Policy\\_Book\\_082005.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/7c48be3e-e516-4ccf-a2d5b95a128f04ae/Labeling_Policy_Book_082005.pdf?MOD=AJPERES) \uf0d8Provides additional guidance regarding FSIS standards outside of the regulations \uf0d8Used in conjunction with the Meat and Poultry Inspection Regulations and FSIS Directives and Notices \uf0d8Composite of policy and day-to-day labeling decisions \uf0d8Claims found in the Policy Book may be approved generically except: natural claims, negative claims 38", "\uf0d8FSIS has decided to stop adding policy guidance to the Food Standards and Labeling Policy Book \uf0d8FSIS will continue to amend or remove items in the book, as necessary, but it will no longer add new material to it \uf0d8The Agency will convey new labeling policy by other means, such as compliance policy guides 39", "Are previously approved labels containing special statements or claims eligible for generic approval when the only modification involves changes unrelated to the special statement or claim? Yes. Previously approved labels containing special statements or claims may be generically approved if the modifications to the label are unrelated to the special statement or claim. 40", "May the establishment number be changed generically from one establishment number to another in the case of a label bearing a special statement or claim? For example, may Plant B use an

approved label from Plant A by simply changing the Establishment number from A to B? Yes, this may be permitted under certain circumstances. If Plant B obtains a complete copy of the original label application and all associated supporting documentation necessary to support any special statements or claims on the original application approved for Plant A, then Plant B would have a complete label record on file and would be permitted to change the Est. number from A to B. In this case the information contained within the labeling application would be expected to remain the same (e.g. HACCP category, product formulation, processing procedures). 41", "Labels with negative claims must be submitted to FSIS for approval. How does FSIS define \u201cnegative claims\u201d ? \u201cNegative\u201d labeling claims are defined in the Food Standards and Labeling Policy Book. Negative claims refer to statements highlighting the absence of an ingredient or another constituent of the food, an example of which, \u201cgluten free,\u201d has been codified in 9 CFR 412.1 (e). \u201cNo milk\u201d is another example of a negative claim that highlights the absence of an ingredient or another constituent of a food. A negative claim may also identify the absence of certain types of ingredients e.g. \u201cno preservatives\u201d or \u201cno artificial coloring\u201d based on the product formulation. NOTE: Nutrient content claims (e.g. fat free, cholesterol free) are not considered negative claims under the Policy Book entry. 42", "Is the child nutrition (CN) box on a meat or poultry product considered a special statement or claim and require sketch approval? No. The CN information in CN boxes is reviewed and evaluated for approval by the Agricultural Marketing Service (AMS), removing it from the realm of a special statement or claim. 43", "May statements on labels that are defined in FSIS\u2019s regulations or the Food Standards and Labeling Policy Book be generically approved? With the exceptions of \u201cnatural\u201d and negative claims, yes, defined statements may be approved generically. Examples of such claims that will no longer require sketch approval by FSIS include: \u25e6A statement that characterizes a product\u2019s nutrient content that is consistent with the applicable Agency regulations, such as \u201clow fat\u201d \u25e6Addition of a nutrition facts panel to a product sold at retail \u25e6A statement that has geographical significance, such as \u201cItalian Style\u201d 44", "Do non-standardized products still require LPDS Sketch approval? The fact that a product does not have a standard described in the FSIS Food Standards and Labeling Policy Book or specified in the regulations has no bearing on whether or not the label requires sketch approval. A non-standardized meat or poultry product may be generically approved provided it does not fall into one or more of the four categories of labels requiring approval in 9 CFR 412.1(c): temporary approval, labels for export with labeling deviations, religious exempt, or labels bearing special statements or claims. 45", "Will allergen statements require approval by LPDS staff? No. FSIS will not view the addition of an allergen statement (e.g., \u201ccontains soy\u201d) applied in accordance with the Food Allergen Labeling and Consumer Protection Act (FALCPA) as a special statement or claim that requires sketch approval. 46", "Will labels containing foreign languages on products for sale in the US that do not have special statements or claims require prior approval by LPDS staff? No. While the previous meat and poultry inspection regulations did not permit the generic approval of a label adding or deleting a direct translation of the English language into a foreign language for product sold in the U.S., this final rule will allow it. These types of labels do not fall into any of the categories of labels that must be submitted to FSIS for evaluation and review. 47", "Do front-of-package labeling statements that meet the requirements for nutrient content claims, including statements of quantity,

qualify for generic approval? No. FSIS considers certain front-of-pack (FOP) labeling statements, such as those highlighting select nutrients from the nutrition facts panel placed on the principal display panel, to be nutrient content claims. However, unlike traditional nutrient content claims, such as \u201clow fat,\u201d that are defined in FSIS regulations, there are no guidelines for the multiple types of FOP labeling statements on labeling.<sup>48</sup> "What are the record keeping requirements for generically approved label? Establishments are required to keep records of all labeling, both generically approved and approved by FSIS, along with the product formulation and processing procedures, as prescribed in 9 CFR 320.1(b)(11), 381.175(b)(6), and 412.1. The final rule added the requirement that any additional documentation needed to support that the labels are consistent with the Federal meat and poultry regulations and policies on labeling also be kept.<sup>49</sup>" \u2022 FSIS Labeling Website: <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling> \u2022 Guide to Federal Food Labeling Requirements for Meat, Poultry and Egg Products: [http://www.fsis.usda.gov/wps/wcm/connect/f4af7c74-2b9f-4484-bb16fd8f9820012d/Labeling\\_Requirements\\_Guide.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/f4af7c74-2b9f-4484-bb16fd8f9820012d/Labeling_Requirements_Guide.pdf?MOD=AJPERES) \u2022 Final Rule: <http://www.fsis.usda.gov/wps/wcm/connect/3b0efaeb-9a81-4532-a1ccb4d1cdb30f4a/2005-0016F.pdf?MOD=AJPERES> \u2022 Questions submitted through askFSIS : <http://askfsis.custhelp.com> \u2022 Call LPDS at (301) 504-0878 50"]}, {"file\_name": "FSIS\_GD\_2014\_0009", "title": "Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers", "num": "FSIS-GD-2014-0009", "id": "61f130cb0c103f525b7246e84fbdbcebf6c987f9ed9746da4c720d6c3d214e09", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Compliance-Guide-Est-Sampling-STEC.pdf", "type": "pdf", "n\_pages": 40, "word\_count": 13643, "text\_by\_page": ["August 2014 FSIS Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers", "2 Table of Contents & Section Links: I. Introduction and Background Discussion Page 3 II. High Event Periods Page 5 III. Suggested High Event Period Numerical Criteria Page 12 IV. Action in a High Event Period Page 15 V. General Guidance for Verification Testing for STEC Page 17 VI. Designing Sampling Plans for Verifying Control of STEC Page 24 VII. Factors Affecting the Design of Sampling Page 29 VIII. Further Discussion Page 31 IX. Appendix 1: Detailed Explanation of FSIS\u2019s HEP Criteria Page 37 X. Appendix 2: FSIS Response to Comments Page 40", "3 Food Safety and Inspection Service (FSIS) developed this compliance guideline to assist beef slaughter\fabrication establishments that perform testing for Shiga toxinproducing Escherichia coli (STEC) organisms (or virulence markers) using the N60 sample collection method on beef manufacturing trimmings. FSIS requires that establishments perform ongoing verification activities to ensure their food safety system is functioning as intended (9 CFR 417.4(2)) and support decisions made in their hazard analysis (9 CFR 417.2 and 417.5(a)(1)). Establishment verification testing results on trimmings are likely the best available objective information a slaughter establishment can use to determine the ongoing effectiveness of its slaughter\fressing operation. Establishments can use the information to support decisions made in their Hazard Analysis and Critical Control Points (HACCP) systems. FSIS recommends that establishments incorporate statistical process control methods to monitor and control the quality of their products."]}]

control procedures into their testing programs. FSIS recommends that establishments use the test results to assess the effectiveness of their controls for preventing contamination during the slaughter operation and verify that they are reducing STEC to a non-detectable level.

Establishment sampling programs can be supplemented with other types of verification activities associated with production of other raw ground beef and patty components. The high event period (HEP) guidance provided in this document applies mainly to beef slaughter\fabrication establishments that manufacture 50,000 pounds or more of trimmings daily. Such establishments are likely to conduct sufficient verification testing on same source materials to be able to determine whether a HEP occurred. This guidance includes some general discussion at the end of Chapter III regarding how smaller establishments may choose to define a HEP. This document also includes general information on verification testing, designing sampling plans, and factors affecting the design of sampling. It also includes examples of sampling methods. These topics are covered in Chapters V through VIII and will apply to establishments of any size. This document also provides general information for non-slaughter establishments that produce or receive trimmings, although non-slaughter establishments will not know if problems with I.Introduction This guidance has been updated to reflect the Agency\u2019s recent policy developments. Since FSIS issued this compliance guideline for comments in May 2012, FSIS began testing beef manufacturing trimmings for six nonO157 STECs (O26, O45, O103, O111, O121, and O145) in addition to E. coli O157:H7. These six non-O157 STECs are capable of producing Shiga toxin (stx) and intimin (eae). FSIS declared these six non-O157 STECs adulterants in raw, non-intact beef products and product components.

(<http://www.fsis.usda.gov/wps/wcm/connect/6aa26172-2d27-4534-99d48c528b285fd2/20100023.pdf?MOD=AJPERES>).", "4 slaughter and dressing procedures have contributed to a HEP situation unless the supplier provides that information as part of a purchase specification program arrangement. This guideline reflects comments received on the Agency\u2019s Draft Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga ToxinProducing Escherichia coli (STEC) Organisms or Virulence Markers issued in May 2012. FSIS has also added an appendix that provides additional information on how FSIS developed its HEP criteria. Finally, this guidance represents current FSIS thinking. It is considered usable now. FSIS will update the guideline as needed to reflect the most current information available to FSIS and stakeholders. This document provides recommendations rather than regulatory requirements. This Compliance Guideline follows the procedures for guidance documents in the Office of Management and Budget\u2019s (OMB) \u201cFinal Bulletin for Agency Good Guidance Practices\u201d (GGP). More information on the bulletin can be found on the FSIS Web page: <http://www.fsis.usda.gov/wps/wcm/connect/fsis-content/internet/footer/policies-and-links/significant-guidance-documents/significant-guidance> ).", "5 HEP are periods in which slaughter establishments experience a high rate of positive results for STEC (or virulence markers) in trim samples from production lots containing the same source materials. That is, the trim was produced from one or more carcasses

slaughtered and dressed consecutively or intermittently within a defined period of time (e.g., shift). A HEP may mean that a systemic breakdown of the slaughter dressing operation has occurred and has created an insanitary condition applicable to all parts of the beef carcass (e.g., primal cuts in addition to the beef manufacturing trimmings and other raw ground beef and patty components). FSIS recommends that establishments identify HEP criteria so that they can

determine whether they need to withhold product from commerce when a HEP has occurred because the presence of a HEP may indicate more widespread adulteration of product, beyond the product found positive. If establishments identify and respond to HEP, they will minimize the chance that they release adulterated product into commerce. This revised guidance recommends two distinct HEP situation criteria: one type for a localized out-of-control situation, and a second type for a systemic breakdown situation. In both situations, FSIS believes that establishments should be concerned if their sampling of trimmings produce a positive rate statistically significantly greater than 5%, rather than 1.5 percent positive, as discussed in the 2008 draft guidance. In such cases the processor should review process control measures and intervention measures used during slaughter, dressing, fabrication, and grinding. The two types of HEP that may indicate out-of-control situations are: 1. A HEP that indicates a localized out-of-control event in which some specific occurrence or event causes a clustering of STEC contamination in product. 2. A HEP that indicates a systemic break-down or inherent weakness of the process or food safety system.

**KEY QUESTION** Question: What is a HEP?

Answer: High event periods (HEP) are periods in which slaughter establishments experience a high rate of positive results for STEC (or virulence markers) in trim samples from production lots containing the same source materials. A HEP situation may mean that a systemic breakdown of the slaughter dressing operation has occurred and has created an insanitary condition applicable to all parts of the beef carcass (e.g., primal cuts in addition to the beef manufacturing trimmings and other raw ground beef and patty components). This is because HEP indicate a more widespread adulteration of product, beyond any product found positive for the pathogen. By following this guidance and withholding adulterated product from commerce during HEP, establishments are more likely able to avoid costly recalls.

II. High Event Periods (HEP)<sup>6</sup>

In both situations, FSIS believes that if an establishment's sampling of trimmings during a period produced a positive rate statistically significantly greater than 5%, there was a severe loss of process control during that period. In such cases, the processor needs to thoroughly review its process control and intervention measures used during slaughter, dressing, fabrication, and grinding. One difference between a systemic break-down and a localized out-of-control situation is the amount of product that should be assessed to determine whether it may be adulterated. A localized out-of-control situation may affect only the production of one lot, while a systemic break-down may affect more products. Also, a localized HEP may indicate an isolated problem (such as improper application of an antimicrobial on one lot); a systemic HEP may indicate a broader problem (systemic failure to prevent cross contamination among carcasses or improper application of antimicrobial on many lots). When either of these trigger criteria is reached, the establishment may determine that production lots of beef manufacturing trimmings containing same source materials that were sampled, tested, and found negative should be considered as having a false negative result, depending on the reason for the HEP. If the establishment makes that determination, such product should be diverted to a full lethality treatment or otherwise destroyed. To develop recommendations for identifying a HEP, FSIS examined industry data collected in 2010 by FSIS inspection personnel from the top 33 slaughter establishments, based on production volume (heads slaughtered). Of the 33 establishments, 32 responses were received, 19 had clear definitions of a HEP, 2 had clear but incomplete definitions because they did not specify a time frame (which FSIS interpreted to be a day), 10 had unclear definitions of a HEP, and 1 did not

have a definition. Of the 21 establishments that had clear definitions (including the two FSIS interpreted), 7 were using a 5% threshold definition; there were 3 that had definitions greater than 10%. Based on these results, FSIS selected a target of 5%. That is, FSIS would consider an establishment's process to be within a HEP if the percent positive within a set time (1 day, shift, etc.) is 5% or greater. KEY QUESTION Question: Why should establishments evaluate their test results using HEP criteria? Answer: When establishments experience a HEP, FSIS believes with a high degree of confidence of poor processing or poor food safety controls. Therefore, establishments need to take extraordinary action to ensure that adulterated product does not enter commerce." "7 FSIS would not consider the establishment's process within a high event period if the percent positive is less than 5% within a given time period. FSIS developed its HEP criteria using a very high degree of statistical confidence. That way, FSIS has a very high degree of confidence that the process's percent positive truly exceeds 5%. FSIS did not select a lower target because it did not want to define HEP criteria that would be as, or more, rigorous than those of a large number of establishments. FSIS did not select a higher target (e.g., 10%) because the Agency believes such a target could result in many cases where poor processing, as defined by most of the industry, would not be detected as a HEP. The HEP criteria FSIS has provided in this guidance indicate exceptional events of poor processing. FSIS would consider an establishment's process to be within a HEP if, during the period of sampling, the (true) process percentage of positive is not less than 5%. To avoid incorrectly saying a HEP occurred, FSIS required a specified degree of statistical confidence before asserting a HEP occurred. More detailed information on how FSIS developed its HEP criteria can be found in Appendix 1: Detailed Explanation of FSIS's HEP Criteria. Industry typically makes decisions to identify HEP based on presumptive positive results (or what FSIS terms potential positive results) from initial screening tests that produce a high percentage of false positives.<sup>1</sup> Percentages of presumptive positive results are greater than percentages of confirmed results. FSIS identified a target that was in accordance with today's present industry standard. Most establishment testing methods include an enrichment step followed by differential screening specific to STEC or their virulence markers. Positive results during screening tests require further testing to detect STEC. If the establishment does not perform further testing, it should treat positive screen results as confirmed positives. FSIS considers those results positive for STEC. FSIS recognizes that many establishments test for other STEC or their associated virulence markers and treat those positive screen results as positive for STEC. Establishments can apply the guidance in this document to such positive screen results. Therefore, this document refers to E. coli O157:H7 and the six non-O157 STECs as *\u201cSTEC\u201d* and positive screening tests for STEC virulence markers. The 2008 guidance specified that an E. coli O157:H7 percent positive of greater than 1.5%, for samples collected using the N60 collection method, indicated that 1 The FSIS analysis for the presence of E. coli O157:H7 has two screening stages before confirmation. See MLG 5A.02 (10\01\10). Also see: [http://www.fsis.usda.gov/wps/wcm/connect/316b1e53-beba-4f2b-971ab587fe4744e2/MLg\\_5A\\_02.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/316b1e53-beba-4f2b-971ab587fe4744e2/MLg_5A_02.pdf?MOD=AJPERES) for a flow chart of FSIS's procedures." "8 a process may be out of control and thus in a HEP situation. Based on that percent positive, the prior guidance recommended that four positive E. coli O157:H7 results out of 91 consecutive N60 samples should be seen as indicating a loss of control. FSIS changed the recommended target from the value given in its 2008 draft guidance of 1.5% positive to 5%

positive. FSIS made this change for two primary reasons. First, FSIS recognizes that many establishments treat a potential or presumptive positive sample result as if the sample was confirmed to contain viable E. coli O157:H7. These practices result in a higher positive rate than that seen for FSIS verification testing that is specifically for viable E. coli O157:H7 that have been confirmed positive. Second, FSIS made this change to a higher target value to increase confidence that an insanitary condition likely occurred during the slaughter\ dressing operation. With a greater target value that the process is statistically significantly greater than 5%, the establishment and the Agency would have greater confidence that the food safety system is truly out of control for many situations with an identifiable cause than compared to its confidence when using a target of 1.5%. FSIS does not expect such HEP situations to happen often during any 12-month period when an establishment\u2019s slaughter dressing operation is properly functioning. FSIS did not want to recommend HEP criteria for establishments unless it can be highly confident that there are identifiable factors that contributed to the high percentage of found positive results. Establishments may choose to use the earlier guidance based on 1.5%. As is discussed below, establishments may choose to develop stricter HEP criteria than FSIS is recommending. By choosing the stricter HEP criteria, the establishment reduces its vulnerability for releasing product into commerce that could test positive at a subsequent point in processing or that could be associated with illness. Establishments should be able to support whatever HEP criteria they use. HEP criteria are most useful to establishments that have rigorous testing programs. FSIS recommends that slaughter\fabrication establishments conduct sampling and testing of trim at a frequency sufficient to find evidence of contamination surviving the slaughter and dressing operation (optimally every production lot) in an effort to ensure that adulterated product does not enter commerce. Microbiological testing is necessary because not all contamination can be seen with the naked eye. It is also important to detect all contamination because high levels of contamination may significantly reduce the safety margin afforded by antimicrobial treatments. Establishments grouping five combo bins of trimmings into production lots represented by one N60 sample may be less capable of discerning a HEP situation than establishments that collect an N60 sample from a one combo bin production lot. However, establishments that group multiple combo bins into a production lot may have a scientific basis for selecting samples or grouping samples that allows them to identify a HEP effectively; they may have had a contract study conducted for them based on their own in-plant conditions that supports their lotting practices and shows that their sampling and testing has a high probability of detecting positives when present. In addition, establishments that exclude exterior fatty trimmings from calculation of a HEP situation may be less capable of identifying a HEP situation. Additional assistance and information on these matters can be found in publications of the Beef Industry Food Safety Council, at: <http://www.bifsc.org/groundbeef.aspx> For the purpose of this document there are two types of a HEP that may indicate out-of-control situations: 1. A HEP that indicates a localized out-of-control event in which some specific occurrence or event causes a clustering of STEC contamination in product. 2. A HEP that indicates a systemic breakdown or inherent weakness of the process or food safety system. FSIS recommends that

establishments evaluate their testing results for both short term (local) and long term (systemic) periods for which the positive rate is substantially greater than that expected or typically observed within production days or shifts. Establishments can evaluate their processes during both periods by applying a set of criteria within different moving windows of testing results. If the establishment exceeds one of the HEP criteria, FSIS believes there is a high degree of confidence that particular events occurred that indicates poor processing or poor food safety controls. Below are criteria establishments may use for determining whether they have experienced a HEP.

1. For a local HEP: 3 or more STEC (or virulence markers) positive results out of 10 consecutive samples from production lots containing same source materials; that is, the trim was produced from one or more", "10 carcasses slaughtered and dressed consecutively or intermittently within a defined period of time (e.g., shift); and

2. For a systemic HEP:

- a. 7 or more STEC (or virulence markers) positive results out of 30 consecutive samples from production lots containing same source materials.
- b. Establishments that test more than 60 samples per day from production lots containing same source materials can use Table 1 below for determining criteria for a systemic HEP. Table 1 provides, for a given number of samples (window) the number of positive results that would provide close to 99% confidence that the establishment\u2019s process percentage of positive results during the period of sampling exceeds 5%. The criteria in Table 1 apply for local HEP and for systemic HEP that apply for a day (or shift) of processing (2b above). The numbers of positive results within these windows, if obtained, provide high degrees of confidence that the establishment has poor processing or poor food safety controls. The moving window method of monitoring process control is a simple and useful tracking procedure. FSIS also is recommending a HEP sample criterion based on obtaining 7 or more positive results within any 30 consecutive samples from production lots. This criterion provides a greater degree of confidence that the process percentage of positive results exceeded 5% than those for the other criteria. FSIS chose a greater degree of confidence (about 99.95%) because in this situation FSIS believes that the establishments should examine rigorously not only trim product but also other primal and subprimal products. For the other HEP criteria, Table 1 provides numbers that would result in a 99% confidence that the 5% target would have been exceeded. Table 1 also includes the observed percentage of positive samples. The reason the observed percentage of positive results is greater than the 5% target FSIS used to establish HEP is because the HEP criteria are based on a very high degree of statistical confidence that the process\u2019s percentage truly exceeds the KEY QUESTION Question: How did FSIS develop its HEP criteria? Answer: FSIS developed the HEP criteria based on a high degree of statistical confidence that the establishment exceeded 5% positive. For the local HEP criteria, FSIS used close to 99% (98.95%) confidence. For the systemic HEP guidance, FSIS used about 99.95%. FSIS expects that establishments will improve their percent positives over time, and, therefore, FSIS plans to adjust the HEP criteria accordingly. See Appendix 1 for more details.", "11 5% target. Establishments may use this table for their testing programs to determine if they have a HEP, or may develop their own. Table 1: HEP Criteria when Establishment test more than 60 samples per Day or local HEP for 10 consecutive samples

Unacceptable # Positives	Number of Samples	Confidence	Observed Percentage of Positive	3	10
98.8%	30.0%	8	61	98.9%	13.1%
9	74	98.9%	12.2%	10	86
98.9%	11.6%	11	100	98.9%	11.0%
12	113	98.9%	10.6%	13	127
98.9%	10.2%	14	141	98.9%	9.9%
15	155	98.9%	9.7%	16	169
98.9%	9.5%	17	184	98.9%	9.2%
9.1%	18	198	98.9%	8.9%	20
98.9%	8.8%	213	98.9%	8.9%	228
FSIS is not					

providing a tolerance for an acceptable number of STEC (or virulence markers) positives. Rather, FSIS is providing guidance on when the number of positive results within a certain number of samples indicates a HEP occurrence. In such situations, negative-tested production lots are possibly contaminated because they were likely produced under insanitary conditions. The establishment would need to determine whether the lots are releasable. The establishment's specific process positive rate may differ from the rate used to construct the above example. These rates may differ depending on the time of year and increase during high prevalence seasons. Consequently, a specified positive rate for a given establishment at a given time should be identified by indicating that a different positive rate was being achieved consistently and product has low likelihood of being adulterated. However, FSIS would consider an establishment to experience a HEP if it experiences a HEP according to FSIS's criteria regardless KEY QUESTION Question: Is FSIS establishing a tolerance for an acceptable number of STEC (or virulence markers) positives? Answer: No, FSIS is providing criteria that indicate exceptional events of poor processing and require extraordinary action so that adulterated product does not enter commerce.", "12 of the time of year. Further, deviations from previously obtained positive rates should be construed as presumptive evidence that the process is out of control and would warrant investigation to find and eliminate any potential causes for the positive results. As part of their supporting documentation for their hazard analysis, FSIS recommends that establishments document their criteria for identifying a HEP. One example for how establishments might develop their own criteria would be to determine an upper bound (limit) process percent positive and then determine how many actual sample results they will use to show whether they have exceeded that upper bound. FSIS expects that slaughter/fabrication establishments are subjecting 100 percent of production lots of trim to N60 verification testing. In addition, FSIS expects that establishments would have a more rigorous verification testing program during the high prevalence season (from spring into mid-autumn) in order to have greater confidence that increased contamination is not passing through the slaughter/dressing operation into the trim production lots. More rigorous verification testing programs might include more restrictive HEP criteria. In addition, small establishments or those that produce product infrequently might choose a different set of criteria from those provided by FSIS. The end of Chapter III below has specific suggestions. The following tables are provided to help establishments derive parameters for determining whether they have experienced a HEP. The tables provide specified numbers of positive results (first column) occurring within a specified number of samples (entries within the remaining columns) from production lots. Those indicate that the true percent positive of STEC findings (or virulence markers) would be greater than or equal to the specified percent positive given in the column headings, for the following percent confidence intervals: 2 There are other tracking procedures, such as calculating and graphing cumulative sums of differences of results from a specified target (CUSUM) and exponentially weighted moving averages (EWMA), which do not require such determinations. III. Sample HEP Numerical Criteria", "13 with 95 percent confidence (Table 2); close to 99 percent confidence (Table 3); and close to 99.95 percent confidence (Table 4). The latter two tables show how FSIS developed the criteria for localized or systemic HEP. In the tables below, the test result from one composite sample of multiple slices (e.g., N60 sample) is considered one positive or negative result. Table 2: Lower Bounds of Percent Positive, Based on Number of Samples Tested True positive percent of STEC

(or virulence markers) findings is greater than corresponding lower bound percentage in column with 95% confidence, given the number of positive results (rows) within corresponding number of samples (interior table entries) Number Positive 0.50% 0.68% 0.75% 1.0% 1.5% 2.0% 3.0% 3.5% 5.0% 2 71 52 47 35 24 18 12 10 7 3 164 120 109 82 55 41 27 23 16 4 274 201 182 137 91 69 46 39 28 5 395 290 263 198 132 99 66 57 40 6 523 385 349 262 175 131 88 75 53 7 658 484 439 329 220 165 110 95 67 8 797 586 532 399 266 200 134 115 81 9 940 692 627 471 314 236 158 135 95 10 1086 799 725 544 363 273 182 156 110 11 1235 909 824 618 413 310 207 178 125 Based on Table 2, if there were 4 or more positive results within 69 samples, then there would be 95% confidence that the process positive percent exceeds 2%.,"14 Table 3: Lower Bounds of Percent Positive, Based on Number of Samples Tested True positive percent of STEC (or virulence markers) findings is greater than corresponding lower bound percentage in column with about 98.85% confidence, given the number of positive results (rows) within corresponding number of samples (interior table entries) Number Positive 0.50% 0.68% 0.75% 1.0% 1.5% 2.0% 3.0% 3.5% 5.0% 2 32 23 21 16 11 8 5 5 3 3 92 68 62 46 31 23 16 13 10 4 172 127 115 86 58 44 29 25 18 5 266 196 178 133 89 67 45 39 27 6 369 272 247 185 124 93 62 54 38 7 481 354 321 241 161 121 81 70 49 8 598 440 399 300 200 151 101 87 61 9 720 530 481 361 241 181 121 104 74 10 846 623 565 424 283 213 143 123 86 11 976 718 652 489 327 246 164 141 100 Table 4: Lower Bounds of Percent Positive, Based on Number of Samples Tested True positive percent of STEC (or virulence markers) findings is greater than corresponding lower bound percentage in column with about 99.95% confidence, given the number of positive results (rows) within corresponding number of samples (interior table entries). Number Positive 0.50% 0.68% 0.75% 1.0% 1.5% 2.0% 3.0% 3.5% 5.0% 3 32 24 21 16 11 8 6 5 4 4 75 55 50 38 25 19 13 11 8 5 132 97 88 66 45 34 23 20 14 6 200 148 134 101 68 51 35 30 21 7 278 205 186 140 94 71 48 41 30 8 363 268 243 183 123 92 62 54 38 9 455 335 304 229 153 116 78 67 48 10 552 407 369 277 186 140 94 81 58 11 654 482 437 329 220 166 111 96 68 Based on Table 4, if 5 positive results occur within the set of 20 samples, then there is about 99.95% confidence that the positive percent exceeds 3.5%. The establishment may decide that if its percent positive exceeds 3.5%, then the establishment has experienced a HEP. Establishments might have reason to collect a number of samples representing product processed under similar conditions and thus is indicative of the processing during a set period. For example, an establishment might run product","15 during a given time, or for a given day (shift), and take 20 samples of that product. In that case, the tables or similar calculations used for creating the tables can be used for deciding how many positive results within sets of 20 samples would indicate a percent positive greater than that expected. Small establishments that test infrequently might decide to develop other criteria for determining whether they have experienced a HEP. For example, a small slaughter establishment may test 5 samples and find 2 of them positive. For a small establishment that does not test frequently, two positive results (or even 1) might indicate a lack of control in the production of that product and thus could be considered as a HEP. If Tables 2-4 above do not meet an establishment\u2019s needs for determining high event criteria appropriate for the establishment, the establishment should contact askFSIS at <http://askfsis.custhelp.com/> and categorize its question as \u201cSampling\u201d within the system. Through the askFSIS system, establishments can obtain expert advice on the design of HEP criteria. IV. Action in a High Event Period (HEP) In a robust testing program, negative results normally indicate that product may be released in commerce. However, during a HEP,

the establishment needs to consider whether negative-tested lots of trimmings are releasable, and whether primal and subprimal product produced from the same source materials as the trimmings may be positive for STEC. The actions taken in response to a HEP could depend upon the findings of the investigation of the positive results. If slaughter establishments experience a HEP, they should assess what happened during the slaughter and dressing process and take appropriate action that would ensure only unadulterated product is released into commerce. Studies have shown that STEC is present in the hides and intestinal contents of cattle and, therefore, can contaminate the surface of the carcass, trimmings, ground beef, and KEY

**QUESTION** Question: What actions does FSIS recommend in response to HEP? Answer: When a HEP occurs, the establishment needs to consider whether negative-tested lots of trimmings are releasable, and whether primal and subprimal product produced from the same source materials as the trimmings may be positive for STEC. For a local HEP, establishments may not need to sample, test and hold primals and subprimals. However, during systemic HEP, primal and subprimal cuts should be sampled and tested even if treated with an antimicrobial treatment. FSIS recommends that establishments test food contact surfaces for STEC (or virulence markers), and if the surface is found positive consider product that came into contact with those surfaces to be adulterated. IV. Action in a High Event Period", "16 other beef products (e.g., primals, subprimals, and mechanically tenderized or enhanced beef) during slaughter, fabrication, grinding, and processing. The process of removing the hide and intestinal tract requires care, and even under good manufacturing practices, occasional contamination of the carcass meat will occur from direct contact of the hide to the carcass, contact of the hide to equipment, hand-to-hide-to-carcass contact, aerosolization when removing the hide, or puncture of the intestinal tract. Slaughter and dressing procedures should be designed to minimize, to the maximum extent practical, crosscontamination of carcasses with the contaminants from the hide and intestinal tract. As FSIS stated in FSIS PHIS Directive 6410.1, Verifying Sanitary Dressing and Process Control Procedures by Off-Line Inspection Program Personnel (IPP) in Slaughter Operations of Cattle of any Age, the Agency expects that establishments will slaughter and process cattle in a manner designed to prevent contamination from occurring at any step in the process and will use decontamination and antimicrobial intervention treatments as necessary to address any contamination that may result from the implementation of the slaughter process or otherwise occur on the carcasses. If a slaughter establishment believes a HEP has occurred, FSIS recommends that the processor review process control measures and intervention measures used during slaughter, dressing, fabrication, and grinding. Such controls may include measures to reduce the pathogen load on incoming animals, measures to ensure that contamination of the carcass does not occur during slaughter or dressing procedures, decontamination or antimicrobial treatments, and measures to minimize carcass-to-carcass contact and cross contamination. Ensuring and verifying that such controls are indeed working is crucial to preventing future HEP. The actions taken in response to an out-of-control signal could depend upon the findings of the investigation of the positive results. If the establishment finds the cause for the HEP and takes corrective action to prevent positive results from recurring, then an increase in the sampling rate would not be needed. However, the establishment needs to have a high degree of confidence that the corrective actions will be effective before reducing the intensity of its testing. Until such a high degree of confidence is obtained, FSIS recommends that the establishment conduct increased

testing when it experiences a HEP. For example, the establishment could increase sampling rates by either defining smaller lots of trimmings (1 combo bin instead of 5 combo bins) or selecting additional samples from the 5 combo bin lots. During systemic HEP, FSIS recommends that primal and subprimal cuts be sampled and tested, even if treated with an antimicrobial treatment. In addition, during systemic HEP, FSIS recommends that establishments test food contact", "17 surfaces for the presence of STEC (or virulence markers). If they detect the pathogen, establishments should consider product that came into contact with those surfaces to be adulterated. These recommendations are not regulatory requirements. However, by taking these additional steps, establishments will be able to better ensure that they do not release adulterated product into commerce. Therefore, these additional steps may reduce the likelihood of costly recalls. During local HEP, FSIS recognizes that establishments may determine that less product may be affected or implicated by the positive results than in systemic HEP. Establishments may not need to sample, test, or hold primals and subprimals during local HEP. The prevalence of STEC has been greater in cattle coming to slaughter during the warmer months (from spring into mid-autumn \u2013 the \u201chigh prevalence season\u201d) than the colder months. Thus, HEP should be especially anticipated during the high prevalence season. Extra steps should be implemented to increase confidence that contaminated product is not released into commerce for use in raw beef during the high prevalence season compared to the low prevalence season. Such steps could include more frequent monitoring and verification of both slaughter and dressing procedures, additional antimicrobial reduction treatments, or sampling and testing additional product. FSIS also recommends increasing sampling and verification testing during the high prevalence season. During traceback activities, Enforcement, Investigations, and Analysis Officers (EIAOs) will gather information about the production of the product including the use of anti-microbials, prevention of cross-contamination, sanitary conditions, and relevant purchase specifications. Furthermore, as part of their traceback investigations, EIAOs will review slaughter establishment test results to determine whether the establishment has experienced a high event period (HEP).

Establishments are free to develop their own HEP definition as an alternative based on their unique operations. If establishments define HEP differently than FSIS, establishments should support their definition of HEP and provide the information to FSIS during traceback. For purposes of FSIS traceback activities, FSIS will identify HEP events based on the establishment\u2019s HEP criteria, provided the establishment\u2019s criteria is appropriately supported. During FSIS traceback activities, FSIS will evaluate the establishment\u2019s definition and support for defining HEP and determine whether the establishment has taken all affected product into account. If the establishment has not developed its own HEP criteria or its criteria is not supported, EIAOs will determine whether the establishment experienced a HEP based using the guidelines provided in this document. In the event the establishment has not developed or appropriated supported HEP criteria, the specific HEP criteria FSIS will use during traceback are:", "18 1. For a local HEP: 3 or more STEC (or virulence markers) positive results out of 10 consecutive samples from production lots containing same source materials; that is, the trim was produced from one or more carcasses slaughtered and dressed consecutively or intermittently within a defined period of time (e.g., shift); and 2. For a systemic HEP: 7 or more STEC (or virulence markers) positive results out of 30 consecutive samples from production lots containing same source materials. Based on the results of their traceback activities, EIAOs will

make recommendations whether regulatory and enforcement actions are warranted. The District Manager will then determine whether adulterated product entered commerce; if it has, whether to contact the FSIS Recall Management and Technical Analysis Staff; and whether enforcement actions are appropriate. When FSIS requests that establishments recall product, FSIS looks at several factors to determine the scope of a recall, including the establishment's processing and sanitation procedures, and whether there is any finished product reincorporated into fresh product (rework). Why is STEC Verification Testing Important? Because microbial contamination is not visible to the naked eye, microbiological testing is needed to verify that the slaughter and dressing procedures that are designed to prevent microbial contamination are effective. Also, an establishment may incur considerable expense if it becomes necessary to recall contaminated product from commerce<sup>3</sup>. This action becomes necessary when trimmings that have been subjected to antimicrobial interventions are later found positive for STEC or when other production lots from same source materials (i.e., fabricated from a single, common source rather than multiple, commingled sources) are found positive. For these reasons, robust sampling and testing programs that can find product containing STEC can be highly cost-effective. <sup>3</sup> FDA has estimated that a recall can cost government and industry \$3-5 million. (<sup>4</sup> Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rules to Ensure the Safety of Juice and Juice Products<sup>5</sup> (63 FR 24258; May 1, 1998). The cost covers manufacturer, retailers and State, local, and Federal authorities.

V. General Guidance for Verification Testing of STEC

**KEY QUESTION** Question: Why does FSIS recommend that establishments test beef trimmings for STEC? Answer: Establishment verification testing results on trimmings are likely the best available objective information a slaughter establishment can use to determine the effectiveness of its slaughter/dressing operation.<sup>6</sup> Extensive sampling of trimmings and careful evaluation of test results can help establishments identify areas of poor processing for corrective action. FSIS recommends that establishments continually strive to decrease STEC (or virulence markers) percent positives. FSIS expects establishments that investigate and correct problems will improve processes and decrease percent positives over time. Consequently, FSIS recommends that both slaughter establishments and receiving establishments test source product, including trimmings, for STEC (or virulence markers). FSIS recommends testing finished product even if the source material has been tested and found negative. The reason for this recommendation is that negative test results on samples of product do not imply that product is free of STEC for the following reasons: there may have been pockets of contamination in the product that were not in the actual sample tested at the slaughter establishment, the product might have become contaminated after it was sampled at the slaughter establishment, or STEC (or virulence markers) cells within the actual sample tested might not have been detected at the slaughter establishment because their numbers at the time of testing were below the limit of detection. If a receiving establishment finds incoming product intended for grinding or other raw, non-intact use positive for STEC (or positive in a screening test but not confirmed negative), that product is adulterated, although it may be treated to eliminate the pathogen. The receiving establishment should inform the supplier of the positive test results. For What Organism Should Establishments Test? It is useful to conduct verification testing for associated organisms that include STEC (e.g., a screen methodology for pathogenic STEC) and maintain records of results. Measurements of ubiquitous organisms such as Enterobacteriaceae, aerobic

plate counts (APC),<sup>4</sup> or generic E. coli can be used to evaluate the effectiveness of process controls designed to limit or eliminate microbial contamination. Frequent measurement of APC may capture a short-term trend, which would be useful for quality control, both before and after the sanitary dressing processes. However, such measurements, while helpful for ensuring 4 Measuring the level of APC on pre-eviscerated carcasses might be useful for evaluating the effectiveness of a sampling program and antimicrobial interventions (see T. A. Arthur, et al., 2004, J Food Protection 67(4): 958-665). KEY POINT FSIS recommends that both slaughter establishments and receiving establishments test source product, including trimmings, for STEC (or virulence markers).", "20 microbial process control, cannot be used as a substitute for determining the actual presence or absence of STEC in the final product. The decontamination and antimicrobial treatments applied during the slaughter and dressing operation should be designed to remove, to the maximum extent practical, contamination with pathogens. Each establishment should know the limits of capability of its slaughter and dressing operation for reducing microbial contamination as evidenced by objective data, such as for APC or other indicator organisms of process control on the carcass immediately after hide removal, before the establishment applies any antimicrobial interventions.", "21 KEY QUESTION Question: What is the significance of non-O157 STEC? Answer: The Centers for Disease Control and Prevention (CDC) estimates that there are approximately 175,905 domestically acquired foodborne illnesses associated with all Shiga toxin-producing E. coli (STEC) annually (Scallan et al, 2011)<sup>5</sup>. E. coli O157:H7 is the most well known STEC and, according to the CDC, is annually responsible for approximately 63,153 (36%) of the domestically acquired foodborne STEC illnesses. The remainder of the illnesses associated with STEC (112,752 or 64%) are caused by non-O157 STEC. While more than 50 non-O157 STEC serogroups have been associated with human illness, 70-80 % of confirmed non-O157 STEC illnesses are caused by six STEC serogroups \u2013 O26, O45, O103, O111, O121, and O145. These illnesses can be equivalent in severity to those caused by E. coli O157:H7. In the U.S, at least one outbreak and several sporadic illnesses from non-O157 STEC serogroups have been associated with ground beef products. Many establishments that produce raw, non-intact beef products, such as ground beef, incorporate antimicrobial interventions such as organic acid sprays in their processing. These methods should be effective in controlling non-O157 STEC. However, many firms will want to implement their own testing programs. A prudent establishment would use a test method that includes all hypothetical strains of E. coli O157:H7 and the target non-O157 STEC, either typical or variant organisms with these STECS serotypes, that would be identified using FSIS confirmatory testing procedures and criteria and that increases the likelihood of detecting low level contamination by these pathogens. FSIS recognizes that industry uses non-cultural methods that detect alternative target analytes for STEC including, but not limited to, eae and stx. Establishments may increase the likelihood of detecting all hypothetical strains and low levels of contamination by these pathogens in a variety of ways, including but not limited to using a test method that also is used by a regulatory body or that is validated and certified by an independent body (e.g., AOAC, AFNOR, MicroVal, or NordVal). An establishment may also opt to use a test method that is subjected to a robust validation using the FSIS cultural method as a reference. 5 Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, Jones JL, and Griffin PM. 2011. Foodborne illness acquired in the United States \u2013 major pathogens. Emerg Infect Dis. 17(1):7-15.", "22 How Frequently Should Establishments Collect a Sample? Sampling and testing

of trimmings for STEC (or virulence markers) should occur at a frequency sufficient to find evidence of contamination (e.g., pathogens) surviving the slaughter and dressing operation. Optimally, every production lot should be sampled and tested before KEY QUESTION Question: Are test kits available to test for STEC? Answer: Several companies have developed or are developing test kits to detect at least the six relevant STEC serogroups. Some kits have been submitted for review by validation bodies. In addition, some kits have been submitted for FSIS review and have received \u201cletters of no objection\u201d from the Agency. FSIS developed guidance for evaluating test kit performance and uses this criteria for evaluating test kits that have been submitted to FSIS for review. FSIS provides a summary table that describes the non-O157 STEC test methods that FSIS has received and reviewed and for which it has issued letters of no objection. The summary table is available on FSIS\u2019s website. FSIS continues to review other test kits submitted for review. For establishment testing or testing on behalf of an establishment, FSIS recognizes that other criteria, while not used specifically by FSIS for identification of a non-O157 STEC, may be a significant and expedient indicator of the presence of non-O157 STEC in products. Such tests might be applied as rapid screening procedures to expedite analyses. If an establishment uses or contracts with a laboratory that uses such rapid screening procedures, and product is found positive by that test, the regulations require the establishment to take appropriate corrective action and to ensure the proper disposition of adulterated products following a positive test result (9 CFR 417.3). The establishment will need to define and support the criteria it uses to define the sampled lot. KEY QUESTION Question: How often does FSIS recommend that slaughter establishments sample and test trim to verify their HACCP system? Answer: FSIS recommends that slaughter\fabrication establishments conduct sampling and testing of trim at a frequency sufficient to find evidence of contamination (e.g., pathogens) surviving the slaughter and dressing operation (optimally every production lot) in an effort to verify and ensure that adulterated product does not enter commerce.", "23 leaving the slaughter establishment and again before use at the receiver. Establishments that do not slaughter but do produce trimmings should report their test results back to the slaughter supplier in order for the supplier to assess the adequacy of its slaughter and dressing practices, as well as antimicrobial treatment programs. Through this feedback, an investigation of the possible reasons for the contamination getting through the slaughter and dressing operation can be conducted and could lead to the identification and correction of possible deficiencies. During the high prevalence season months (from spring into mid-autumn), the frequency of such testing should be increased compared to that of the other months in order to have increased confidence that contamination is not affecting the food safety system. Chapter VI of this document includes information on designing sampling plans. Defining a sampling plan involves establishing the procedures the establishment will use, including how it will collect a sample, the size of the units it will collect, the number of samples it will collect, the frequency with which it will collect samples, and the procedure it will use to analyze samples. What Corrective Actions Should Establishments Take in Response to Positive Test Results? Under 9 CFR 417.3, establishments are required to identify corrective actions in response to every deviation from a critical limit or a deviation not covered by specified corrective action. An STEC positive would fall into one of these two categories that require corrective actions. Corrective actions required in the regulations include identifying and eliminating the cause of the deviation (if STEC are addressed

in the HACCP plan) or reassessing the HACCP plan and determining whether changes to it are necessary (if STEC is not addressed in the HACCP plan). Process control of STEC can be evaluated by tracking past sample results, enabling establishments to tell the difference between an occasional, sporadic, positive result and a loss of process control as indicated by many positive results over time. If past sample results lead establishment management to believe the process is out of control, the establishment should carefully investigate to find all contributing causes. This type of investigation would be more involved than a follow-up investigation when an occasional positive result is found. The finding of an out-of-control process may implicate product in other production lots produced during the period that the process was out of control or from the same source material." "24 How are Corrective Actions Different in Response to a HEP? It is important to note that a HEP situation (localized and systemic) likely means that insanitary conditions occurred during the slaughter\ dressing operation such that contamination is widespread across production lots. When a HEP situation occurs, negative test results from the production lots of trimmings made from the same source materials as trimmings found positive during the HEP may not be reliable. 6 Therefore, those production lots that tested negative may not be microbiologically independent of those directly associated with the HEP. In other words, even though an N60 product sample from a production lot tested negative, trimmings produced from the same source materials as the production lots directly associated with the HEP are also potentially contaminated. When a HEP occurs, establishments should take appropriate precautionary steps to ensure adulterated lots of raw beef are not released into commerce. The establishment specifically needs to consider whether negative-tested lots of trimmings are affected and whether intact primal and subprimal product produced from the same source materials as the trimmings may be positive for STEC. Generally, if primals are not commingled before packaging, and the establishment prevents cross contamination among primals, primals can be considered independent lots. Normally, FSIS does not typically consider primal cuts designated for intact use to be adulterated if contaminated with STEC. During a HEP, however, unless the establishment has controls in place to ensure that the primals are not used for non-intact purposes, such primals may be considered adulterated because they were prepared under insanitary conditions. Establishments that subject primals to an antimicrobial treatment as part of a routine production process may be able to demonstrate 6 The statement does not imply that the usual N60 sampling and testing is not reliable regarding their sensitivity and specificity. However, it is reasonable to assume that during the HEP, the incidence and levels of contamination could be greater than normal. Negative results during a HEP could be resulting from clustered contamination within a lot. Thus, a negative result may not mean that the lot is actually negative. To suggest re-testing product that already tested negative in light of an HEP just means that FSIS is asking establishments to take action to decrease the assumed increased risk that exist in light of the HEP. KEY QUESTION Question: What does the occurrence of a HEP mean? Answer: A HEP likely means that insanitary conditions occurred during the slaughter\ dressing operation such that contamination is widespread across production lots. When a HEP situation occurs, establishments should take appropriate precautionary steps to ensure adulterated product is not released into commerce. The establishment specifically needs to consider whether negative-tested lots of trimmings are affected and whether intact primal and subprimal product produced from the same source materials as the trimmings may

be positive for STEC.", "25 that the primals are not adulterated, provided they have on-going verification testing results to affirm that contamination was not evident. It should be noted that a recent large-scale recall of beef that included primal cuts was associated with a HEP ([http://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-healthalerts/recall-case-archive/recall-case-archive2009/!ut/p/a1/jZDBC0jAEIafpQdYdlZF9CgLppa7SGS2lxjEdMFUTDz09CmdDKVmTjN8Px8zVNGMqgZHxKg2wbreVb2DRKwmcsKhr7nQyhMP3XEnoG0JC6AFw2A2kiD5yDI8w\\_8xvlwa989IfA6GMel1R1OFREN\\_eWZn2RY12THJ8FwT6v9FisLokB4NILVUsNsKknzckKImGCtL6BIT98gO1Du8c5ex0D0KG3ewMRQGX5/?1dmy&current=true&urile=wcm%3apath%3a%2Ffsis-archivescontent%2Finternet%2Fmain%2Ftopics%2Frecalls-and-public-healthalerts%2Frecall-case-archive%2Farchives%2Fct\\_index286a](http://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-healthalerts/recall-case-archive/recall-case-archive2009/!ut/p/a1/jZDBC0jAEIafpQdYdlZF9CgLppa7SGS2lxjEdMFUTDz09CmdDKVmTjN8Px8zVNGMqgZHxKg2wbreVb2DRKwmcsKhr7nQyhMP3XEnoG0JC6AFw2A2kiD5yDI8w_8xvlwa989IfA6GMel1R1OFREN_eWZn2RY12THJ8FwT6v9FisLokB4NILVUsNsKknzckKImGCtL6BIT98gO1Du8c5ex0D0KG3ewMRQGX5/?1dmy&current=true&urile=wcm%3apath%3a%2Ffsis-archivescontent%2Finternet%2Fmain%2Ftopics%2Frecalls-and-public-healthalerts%2Frecall-case-archive%2Farchives%2Fct_index286a)). Although all or most trim was diverted to cooking, including trim that tested negative for E. coli O157:H7 (or other STEC organisms or virulence markers), primal cuts that had not been treated with an antimicrobial entered commerce. Illnesses were associated with the trim derived from the untreated primal cuts. How Should Establishments Define Their Lots? Designing a sampling plan involves identifying many factors, including among others, the lot size and the amount of product from each lot that is to be sampled and analyzed. Perhaps the most important step in designing a sampling plan is the definition of a lot of product. The results (positive or negative for the presence of STEC or virulence markers) may determine the disposition of the product within the selected lot and possibly other product as well, depending on how the lots are defined.

VI. Designing Sampling Plans for Verifying Control of STEC

KEY QUESTION Question: In addition to responding to individual positive test results, what does FSIS recommend that establishments use their test results to determine? Answer: FSIS recommends that establishments monitor their test results for two distinct HEP criteria: one for a localized out-of-control situation, and a second for a systemic break-down situation. In both situations, establishments should be concerned if their sampling of trimmings produce a positive rate statistically significantly greater than 5%. "26 Trimmings from each supplier should be tested separately. Limiting product in a lot to that from a single supplier could help decrease the extent of product that would be recalled or sent for cooking when a positive test result is obtained. An establishment should be sure to always define the production lot size before sampling. An establishment should not redefine it during testing or after results are known. Lots should be defined so that if a positive result is found from one lot, the product in other lots is microbiologically independent and is not implicated. FSIS has stated (67 FR 62325; Oct. 7, 2002) that when one lot of trimmings tests positive, lots constructed from the same source material likely would be implicated. FSIS would expect the establishment to have a scientific basis that justifies why any raw ground product produced from those source materials should not be considered to be adulterated (67 FR 62325; Oct. 7, 2002, p. 62333). One way to avoid the results for one lot implicating another is to ensure that the lots are microbiologically independent. The establishment should have a sound basis for defining the lot and is responsible for determining the lot of product represented by the sample. Suggestions for defining microbiologically independent lots:

1. Product from different carcasses can be considered as independent lots provided the meat from the carcasses was handled so as not to crosscontaminate other carcasses.
2. Defining lots based on microbiological testing would be acceptable if the sample collection method is designed to have

a high confidence of detecting positive results when STEC is present in a production lot. 3. Processing interventions that limit or control STEC contamination can help to define the lot. 4. Beef manufacturing trimmings and raw beef components or rework carried over from one production period to another may expand the implicated lot in the event of a positive result. KEY POINT Lots should be defined so that if a positive result is found from one lot, the product in other lots is microbiologically independent and is not implicated." , "27 5. Sanitation Standard Operating Procedures (Sanitation SOP) or any other prerequisite programs used to control the spread of STEC crosscontamination among raw beef components during production can help to define the lot. The following may lead to cross-contamination of raw beef components during production and may expand the implicated lot in the event of a positive result: \u2022 improper sanitary dressing procedures \u2022 insanitary product contact surfaces on equipment, such as machinery and employee hand tools \u2022 improper employee hygiene

What Questions Should Establishments Consider when Designing a Sampling Plan? In designing a sampling plan, an establishment should consider the following questions.

- A. What products are to be tested? Trimmings or other source materials that are supplied to grinders, including cheek meat and head meat (see FSIS Directive 10,010.1)
- B. The size of the lot: what amount of product (i.e., the lot) is to be represented by a sample? The establishment should define how much product is going to be grouped together to constitute a \u201clot\u201d (e.g., combo bins of trimmings; boxes of packaged head meat or cheek meat). Note: FSIS strongly recommends that the lot definition not be redefined. It is unacceptable to change the lot definition based on the results of testing.
- C. How is the sample going to be collected?
  - 1. STEC (or virulence markers), when present, is not evenly distributed throughout a production lot. Therefore, a collection method that selects product at multiple sites within the lot or multiple production intervals within a given lot is more likely to detect pockets of contamination than a sampling plan that samples at fewer sites or production intervals.
  - 2. For trimmings, potential contaminants will be on the exterior surface of the product that was exposed during the slaughter and dressing process. Therefore, collection methods that provide more surface area for the test increase the sensitivity of the sampling (i.e., many thin slices of the exterior exposed fat and lean tissue)." , "28

3. For trimmings, samples can be collected by: \u2022 Obtaining 60 slices from the exterior surface of product within the lot that are as thin as possible resulting in the desired sample size (grams) to be collected. \u2022 \u201cPlug\u201d collection, where product is collected by inserting a specially designed \u201ctube\u201d between pieces of meat so as to excise the trim (exterior areas) of adjacent pieces. This procedure is performed many times, by inserting the tube at randomly selected locations, to ensure that a certain minimum number of exterior surface pieces are collected and achieving the proper weight for the sample. \u2022 Randomly selecting slices of trimmings from trim in combo bins. If the establishment produces several types of trimmings, it should include them all in the sampling program. Trim from exterior surfaces should be prioritized for collection. \u2022 Core drilling, where product is collected at several places in the combo bins by drilling a hole, approximately 25mm in diameter, into surface of meat through a template. The product is thus extracted through a coring tube and can be taken from fresh or frozen trim. \u2022 For frozen trimmings, using a sanitized band saw at 12 points around the edges of a 60-pound frozen block. To make up N60, samples should be collected from five randomly selected frozen blocks. With all these collection methods, specifications should be designed to ensure that a high percentage of the

collected product that is to be used for testing consists of exterior surface tissue. D. How much of the collected product is analyzed? 1. FSIS recommends that the entire sample be analyzed. To accommodate laboratory testing methods that limit the amount of material per analysis, subsamples could be formed and each subsample analyzed in the laboratory. Thus, multiple analyses may be needed. Not analyzing the KEY POINT With all collection methods, specifications should be designed to ensure that a high percentage of the collected product that is to be used for testing consists of exterior surface tissue." "29 entire sample could lead to a significant increase in false negative results (negative results found when the product is actually positive) compared to when the entire amount is analyzed, so that results could be misleading. Laboratory methods used should be effective in detecting the pathogen. NOTE: A sampling plan using the N60 collection method and analyzing a 325375 gram composite sample means that the weight of each of the 60 slices that is \u2018represented\u2019 in the tested material needs to be about 6.25 grams (375 grams\60 slices = 6.25 grams per slice). E. How frequently should establishments test? Optimally, every production lot should be sampled and tested. F. How effective is the testing method? 1. FSIS recommends that the establishment understand and have written documentation regarding how the laboratory is testing the sample, in regard to the size of the sample analyzed and the analytical method that is used. 2. FSIS recommends that laboratory methods be \u201cfit for purpose\u201d and ensure detection of very low levels of STEC (or virulence markers) that may have survived antimicrobial treatments. FSIS recommends that methods be approved or used by a recognized government or independent body (e.g., FSIS, FDA, AOAC, AFNOR, ISO). 3. In some circumstances, multiple samples may be \u201cpooled\u201d after enrichment to save costs for testing. Because negative broths can dilute positive broths in the pooled test broth, \u201cwet-pooling\u201d analytical methods should ensure that sensitivity is not compromised. Wet-pooling refers to combining multiple samples for a single screening test after the samples have been enriched, i.e., incubated overnight in a broth as the first stage for detecting a pathogen. 4. It is important for testing laboratories to follow the testing protocol as written to ensure the method will perform as expected. This includes prewarming the enrichment broth to the incubation temperature before incubation to help ensure the greatest sensitivity, particularly for methods using enrichment periods less than 15 hours. KEY QUESTION Question: Why is it important to analyze the entire sample? Answer: Not analyzing the entire sample could lead to a significant increase in false negative results (negative results when the product is actually positive), which increase the likelihood that adulterated product enters commerce." "30 5. In circumstances when a test result for pooled samples is positive, it may be appropriate to re-test the individual sample-specific enrichments in an attempt to identify contaminated product more accurately. In such a procedure, it is important that the storage of the enrichments does not cause a decrease in the sensitivity of the individual test as compared to the pooled test. SUMMARY: KEY ELEMENTS OF A SAMPLE PLAN A sampling plan used to verify process controls should address the following: 1. Products to be tested 2. Lot size (usually in pounds and number of combo bins) 3. Statistical sampling method for selecting lots; percentage of lots that are sampled (lot sample) 4. Slice size (dimensions) and number of slices that comprise a sample 5. Collection method for selecting samples and slices from a selected lot 6. Procedures for preparing a sample for analysis (See Chapter VIII) 7. (Sub) sample size analyzed in a laboratory 8. Laboratory testing methods used (including sample size analyzed, enrichment procedures and size of portions analyzed) 9.

Actions to take when samples are positive (See Chapter V) KEY POINT It is unacceptable to change the lot definition based on the results of testing.","31 A critical limiting factor in a sampling plan is the maximum sample size that the laboratory can analyze. Given this maximum sample size, the sample is characterized by the number of slices and the slice size. Because the contamination occurs on the surface of the meat, slices should be as thin as possible and focus on surface tissue. Because it is expected that STEC organisms (or virulence markers) when present would be distributed unevenly in clumps, in constructing samples it is advisable to use many small sample slices rather than few larger slices (all slices should be of the same thickness). Using many small slices provides a more \u201crepresentative\u201d sample of the lot and greater likelihood of finding contamination. However, the limiting factor here is the time to collect many slices. At present, an N60 sample involves collecting 60 slices of a specified dimension. An N120 sample with slices \u00bd the surface area of those used for N60 would be expected to provide a greater likelihood of finding positive results, given everything else being equal. However, the time needed to collect an N120 sample might be twice as long as needed to collect an N60 sample. With limited resources, a likely consequence of the longer time needed to collect an N120 sample would be that fewer lots or combo bins would be sampled, thus losing the advantage of N120 sampling over N60 sampling. Over the years, the N60 sample has become the standard sample for beef trim products. It is important to remember that changing the slice size of samples or the number of slices for a sample could have an impact on the expected percentage of positive findings. Several factors can guide establishments in designing their sampling plans. Two of them are discussed here: percentage of positive samples in the product and degree of confidence desired for a given sample to test positive.

A. Percentage of positive samples of STEC (or virulence markers ) in the product \u2022 The percentage of positive samples is determined as the number of positive samples for the pathogen divided by the total number of samples tested, multiplied by 100. The process percent positive is the expected percentage of positive samples over time.

B. Degree of confidence desired for a given sample to test positive \u2022 The distribution of cells of STEC (or virulence markers) will depend on the levels on the carcasses and effectiveness of the control measures used by the establishment during slaughter, dressing, and fabrication (e.g., intervention treatments, temperature, and sanitation). An establishment that has verified that its control measures (e.g., organic acid spray wash or control of incoming materials) are effective in reducing contamination by the pathogen should have lower levels of STEC (or virulence markers).

VII.Factors Affecting the Design of Sampling","32 \u2022 The percentage of contaminated slices within a contaminated lot might likely be small. Thus, large numbers of slices for a sample are needed to determine with high confidence that a sampled lot has STEC (or virulence markers) cells. Table 5 shows the number of slices that would need to be collected to have 95% confidence of detecting STEC (or virulence markers) in the sample consisting of a random collection of n slices, assuming a specified true percentage of contaminated slices within the lot.

Table 5: Calculations used to derive the number of slices given in the table assume that the \u2018sizes\u2019 of the slices are the same (based on slice size used for N60 samples). Percentage positive slices 0.5% 1% 1.7% 2.5% 5% 7.5% 10% 15% 23% Number of slices needed 598 299 178 119 59 39 29 19 12 Table 5 shows that about 60 selected slices are needed to have a 95% confidence that contamination will be detected when the percentage of potential slices within a single lot (available for selection) that are contaminated is equal to 5%.

Selecting 12 slices only provides the same degree of confidence of finding a positive when the true percentage of contamination is about 23% within the lot. The above table suggests that if sensitivity greater than that of N60 sampling is desired, more slices (i.e., more surface area) would be needed. Since each slice varies in thickness, and thus in weight, the entire N60 sample is portioned into a 325g or 375g analytical portion size, which is a requirement of the FSIS method and the portion size industry typically uses, respectively. It is possible to obtain more sensitivity by taking larger (number of slices) samples. For example, two N60 samples per lot could be collected, for a total of 120 slices (of the same size). From Table 5, this would provide about 95% confidence of detecting contamination if 2.5% of the slices within the lot were contaminated. The costs with such sampling, however, could be double that of N60 sampling, assuming that all lots were to be tested, because the time to collect the samples could be doubled, and two samples rather than one sample would be analyzed. To help mitigate the latter cost, the wet-pooled procedure for testing could be used." "33 A collection method known as N60 (mentioned above) is often used for monitoring incidence of STEC (or virulence markers) in beef trim products manufactured by the industry. The \u201860\u2019 refers to the number of slices that are used in constructing the composite sample. The slices are collected randomly from the lot in order to help ensure a good \u2018representative\u2019 sample from the product within the lot. The collection method may be as follows:

Lot size: 5 combo bins consisting of 2,000 pounds each, for a total of 10,000 pounds trim

Number of slices: 60 slices of product sliced from the surface of the meat, 12 slices from each combo bin

Slice size: Each slice is about 6.25 grams and 1\8 inch thickness

Sample size: 375 grams, composed from the 60 slices

1. Take 12 slices of product, randomly selected from and throughout each combo bin, such that each consists of product of about 6.25 grams with thickness of no more than 1\8 inch, to help ensure that the sample will consist of as many slices from the carcass surface (where the STEC organisms or virulence markers are more likely to reside) as feasible to achieve the desired sample weight (325 or 375 g). As a guide, the dimensions of the sample can be about 3 inches in length and 1 inch in width.
2. If for some reason, there are less than 5 combo bins from which product is to be collected, a total of 60 surface slices from the available combo bins would still be taken. For example, if there are 2 combo bins to be used for grinding, 30 surface slices from each combo bin to make a total of 60 surface slices would be taken; if there were 3 combo bins, 20 slices, and so forth, would be taken.
3. Combine (composite) slices for every lot \u2013 the combined 60 slices is referred to as a composite sample.

VIII. Further Discussion

KEY QUESTION Question: Why is it important to take samples originating from the exterior carcass tissue? Answer: Contamination introduced during the slaughter process occurs on the surfaces of the carcass. So collecting samples from the original surfaces of the carcass increases the likelihood of detecting contamination if it is present.

KEY QUESTION Question: Why is it important that sample slices be thin? Answer: Sample slices should be thin. This maximizes the number of slices that can be collected to achieve the desired sample weight (325 or 375g)." "34

4. Store the sample at temperatures between 7 and 10 \u00baC (44 - 50 \u00b0F), and send to the laboratory. The sample should be analyzed within 24 hours of collection.
5. At the laboratory the sample must be mixed before selecting the material to be analyzed. It is important that an approximately equal amount of material from every slice be included in the material that is being analyzed.
6. At the laboratory, if necessary, create sub-samples to be analyzed separately (typically five 75-gram sub-samples), though some

procedures allow for the whole 375 gram sample to be analyzed. 7. Incubate (enrich) each sub-sample to ensure adequate growth of any STEC cells. 8. Analyze each sub-sample for the presence of STEC \u2013 confirm as positive or negative all presumptive positive results for STEC or assume presumptive results are positive. 9. Investigate possible sources of the contamination, the process, and the controls that have been designed to prevent contamination if a result is positive. 10. Dispose of the positive lot and all other implicated product or send for full lethality. The method of analysis should be equivalent to that of the current method that the FSIS laboratories use as cited in the Microbiological Laboratory Guidebook (MLG)

(<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook> ). Some Variations of N60: The N60 collection method being used by most establishments involves 5 combo bins defining a lot. This method was designed to detect contamination slicespecific incidence at a within-lot contamination of 5%; lower percentages, averaged over the lot, would not be detected so readily. The results from Table 5 indicate a possible reason for this, namely the number of slices per combo bin (12 for N60) is too small to detect contaminated combo bins. Consequently, FSIS recommends establishments decrease the production lot size from 5 combo bins to 1 combo bin in order to provide greater assurance that contamination is detected within combo bins. That is, for the N60 method, as described above, for each combo bin there would be 60 surface slices collected. If the combo bin-specific test is positive, the product in the combo bin is sent for cooking; if negative, the product from the combo bin is sent for grinding, provided", "35 that there is no evidence that the process is out of control, based on the percent of positive results for neighboring lots that had been tested, or for any other reason known that could permit contamination not to be removed as effectively as normal. Wet-Pooling of Samples Using one combo bin as a lot may increase the cost of analysis. One way to help reduce the laboratory costs of analyses when testing each combo bin would be to enrich each N60 sample, and then pool aliquots of the individual enrichments from the five sampled combo bins. This means that the pooled aliquot represents five N60 samples. This lab method should ensure that a single positive sample pooled with multiple negative samples does not compromise the sensitivity of the testing method (the sensitivity of the test compared to the test used by FSIS). Diagram 1: The variation of N60 sampling shown (below) is an example of a wet pooled sample. In this situation, if the laboratory pooled sample is positive, then the laboratory would separately analyze the 5 enriched samples (each representing an N60 sample from each of the combo bins) to ascertain which of the combo bins represented in the laboratory pooled sample likely contributed to the positive pooled aliquot sample result. If the enrichment step is done properly, at least one of the 5 enriched samples would be found positive. The establishment would divert the one combo bin represented by the positive sample to further processing, such as cooking, to destroy the pathogen. In such a procedure, it is important that the storage of the enrichment samples does not cause a decrease in the sensitivity of the individual sample test as compared to the test on the pooled sample. If none of the individually analyzed N60 enriched samples was found positive, then this might indicate a problem with the enrichment procedure or with the sample handling. In such a case, all product within the 5 combo bins, even though they individually tested negative, would need to be cooked or disposed of because the testing did not identify the positive bin.", "36 Diagram 2:

Variation of N75 Sampling (below) depicts another variation of an STEC testing program with wet pooling. In this example, a lot is defined to be 5 combo bins, with 15 portions from each of 5 combo bins enriched. Aliquots of the enrichment from 5 combo bins are pooled and tested for an initial screening test for STEC. If the screening test for the pooled composite sample is positive, then each of the individual N15 aliquots are tested with screening tests to determine which combo may be the source of contamination. However, in this situation, further screening to determine which of the combo bins may be the source of contamination is not possible because the N15 enrichment broths do

Diagram 1: Variation of N60 Sampling N60 sample from Combo A N60 sample from Combo B N60 sample from Combo C N60 sample from Combo D N60 sample from Combo E Alliquots from Combos A-E pooled What are the results from the screening test of the composite sample? Presumptive Positive What are the results from confirmatory testing of individual alliquots? Confirmed Positive Combo A Confirmed Negative Combo B Confirmed Negative Combo C Confirmed Negative Combo D Confirmed Negative Combo E What actions should be taken in response to the confirmatory test results? Corrective Actions including appropriate product disposition (lethality treatment or landfill) and records

Combo A Released to Commerce Combos B-E Negative What is the product disposition? Released to Commerce Combos A-E", "37 not provide enough statistical confidence to rule out any one of the combo bins as the source of contamination. Therefore, the establishment should treat all 5 combo bins as positive.

Diagram 2: N75 Sampling N15 sample from Combo A N15 sample from Combo B N15 sample from Combo C N15 sample from Combo D N15 sample from Combo E Alliquots from Combos A-E pooled What are the results from the screening test of the composite sample? Presumptive Positive What are the results of a screening tests on individual alliquots from combos A-E to determine the source of the contamination? Presumptive Positive Combo A Negative Combo B Negative Combo C Negative Combo D Negative Combo E What actions should be taken in response to the screening test results? Corrective Actions including appropriate product disposition (lethality treatment or landfill) and records

Combo A-E Negative What is the product disposition? Released to Commerce Combos A-E for Presumptive Positives and Negatives", "38 IX. Appendix 1: Detailed Explanation of FSIS\u2019s HEP Criteria

FSIS assumes that, at any time, there are identifiable processing factors that have an effect on the expected percentage of found positive results. Thus, the expected percentages of found positive results can vary as these identifiable factors vary over time. By defining criteria for high event periods (HEP), FSIS is trying to identify periods of processing such that if the process as constituted during that period were to continue, the expected percentage of found contaminated samples would be greater than the expected percentage that normally is obtained. There are also factors that influence the results that cannot be identified or specifically control for and, thus, make it impossible to know how many positive results would be found among a fixed number of samples. The impact of these factors FSIS summarizes in a mathematical model by assuming that there is a random component (set of factors) of the process that affects results in a way that FSIS can only describe through a specified probability distribution, as explained in more detail below. Accordingly, for describing results associated with a processing period, the model identifies two parameter objects: 1) the expected \u201clong term\u201d percentage of found positive results (that would be found over an infinitely large number of tested samples); and 2) a probability distribution that describes the distribution of the number of positive results among a small number of tested samples. The

model's objective is to identify periods of processing (considering these to be High Event Periods) where the first parameter - the expected percentage of found positive results - is greater than some specified value. What makes this difficult is that the evidence is based on small numbers of tested samples and, thus, the results obtained from these samples might not reflect the true expected percentage of positive results associated with the process because of the randomness of the obtained results caused by factors that are not identifiable or uncontrollable. FSIS does not want to recommend declaration of a HEP unless it can be highly confident that there are identifiable factors that contribute to the high percentage of found positive results. The degree of confidence obtained for a correct inference that the process was out of control as defined here for HEP depends on the number of samples tested and the observed percentage of positive results. To compute the degree of confidence associated with results from a small number of samples, FSIS specified the probability distribution that describes random results. FSIS followed conventional procedures for doing this by assuming the number of positive results,  $m_t$ , for  $n_t$  samples in a period indexed by  $t$ , is distributed as a binomial distribution,  $b(m_t, n_t, p_t)$ , where  $p_t$  is the assumed expected percentage of found positive samples (or the probability that a specific sample will be found positive), and  $n_t$  is the number of samples being tested. If, from the results, FSIS statistically infers that  $p_t$  is greater than 5%, with a high degree of confidence,"<sup>39</sup> FSIS says that an HEP has occurred. Because of randomness, it is possible that a process during a period that has an expected percentage of positive results - the value of  $p_t$  less than 5% could have, for the few samples collected in that period, an observed percentage of positive results greater than 5%. If, however, the observed percentage of positive samples is sufficiently large, FSIS can statistically infer with high confidence that the  $p_t$  is greater than 5%. Consequently, imposing statistical criteria to provide a high degree of confidence that the (true) process percentage of positive results exceeds 5% means that the observed percentages of positive results that lead to HEPs are greater than the 5% target. The smaller the number of samples, the greater the observed percentage of positive results needed to infer that the true or expected percentage of positive results produced by the process was greater than 5%. The greater the degree of confidence desired, the greater the observed percentage of positive sample needed, for the same number of samples. Because industry is continuously testing product, FSIS set a relatively high degree of confidence of nearly 99% confidence before declaring a local HEP or a systematic HEP for a day when more than 60 samples were tested. This means that, if the expected percentage of positive results were actually 5%, there is only about a 1% probability that an HEP would be (incorrectly) declared for the period being considered. FSIS believes that when HEPs are identified, there would likely be factors that could be identifiable and controllable as causing the high percentage of positive samples. Calculations: FSIS assumed that the number of found positive results,  $k$ , in  $n_t$  samples is distributed as a binomial distribution as described above. This means the probability of  $k$  found positive results in  $n_t$  samples assumed an expected percentage of found positive samples,  $p_t$ , is given by the formula.  $P(k|n_t, p_t) = \frac{n_t!}{k!(n_t-k)!} p_t^k (1-p_t)^{n_t-k}$  (1) The degree of confidence,  $C$ , that  $m_t$  found positive samples in  $n_t$  tested samples suggests that  $p_t$  is greater than 5% is calculated as:  $C(m_t, n_t) = \sum_{k=0}^{m_t} P(k|n_t, 0.05)$  (2) where  $k$  is an index for the summation of the probabilities of  $k$  found positive results. For example, FSIS specified that in 10 samples, if 3 (or more) are found positive, there would be at least nearly 99% confidence that the expected process-specific

percentage is greater than 5%. The more exact confidence is 0.988496. If only 2 positive results were to occur, the confidence would be 0.914 which is considerably less than FSIS's approximate target of nearly 0.99. Accordingly, FSIS set its criterion for 10 samples to be 3 or more positive", "40 findings. Table 1, presented in the main document, provides the degree of confidence obtained for the set of criteria associated with the local HEP (3 or more positive results out of 10 samples) and the systemic HEP when more than 60 samples in a day are tested. Also included is the observed percentage of positive samples. In summary, FSIS built in a statistical tolerance, requiring nearly 99% confidence before considering that the process, with an observed percentage of positive test results greater than 5%, has a true expected percentage of positive results greater than 5%. In such circumstances, the establishment should take special actions. FSIS also identified a more severe type of HEP (short-term systematic), for which FSIS stated that nearly 99.95% confidence is needed to assert that the true expected percentage of positive results exceeds 5%. In such instances, the establishment should take maximum action. The criterion is 7 or more positive results in 30 samples. The confidence, based on Eq. 2, that the true expected percentage of positive results is greater than 5% when 7 positive results are found in 30 samples is 99.943%, which is near 99.95%. FSIS using tolerances (i.e., requiring a high degree of confidence) increases the likelihood that time and resources the establishment spends in response to HEP will be fruitful in finding problems that will lead to improvement. Improvement over time would lead to a lower percentage of positive results. FSIS will be monitoring the percentage positive (through its sampling programs), and expects that in the coming years, the target percentage that FSIS will use will decrease from the present 5%."]}, {"file\_name": "FSIS\_GD\_2014\_0010", "title": "FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments", "num": "FSIS-GD-2014-0010", "id": "1b0580ef82585d35ffbb20afb5e27b6fd2942f91f5e2b50d0df7b59626be991f", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Compliance-Guideline-Jerky-2014.pdf", "type": "pdf", "n\_pages": 54, "word\_count": 20124, "text\_by\_page": ["1 This guidance document is designed to help very small meat and poultry establishments that manufacture jerky identify: \u2022 The key steps in the jerky process needed to ensure safety; and \u2022 The scientific support available to help develop a safe process and product. FSIS USDA FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments 2014 Compliance Guideline", "2 This Compliance Guideline provides guidance to assist establishments in meeting FSIS regulations related to jerky processing. The guideline also contains recommendations to help industry produce a safe product based on the scientific information available in the literature. Guidance represents best practice recommendations by FSIS, based on the best scientific and practical considerations, and does not represent requirements that must be met. Establishments may choose to adopt different procedures than those outlined in the guideline, but they would need to support why those procedures are effective. It is important to note that this guideline represents FSIS's current thinking on this topic and should be considered usable as of the issuance date. This version of the guidance document, dated August 2014, replaces previous versions of the document which was last updated in July 2012. FSIS updated the guideline based on four comments from three trade associations and one individual. The following are changes made in response to comments: \u2022 Broken link on page 4 (see footnote) has been changed to a link to a report from the"]}]

New Mexico Department of Health; \u2022 Surface preparation step was added to the step-by-step guide on page 7; \u2022 Definition of shelf-stability and recommended shelf-stability parameters were clarified on page 15; \u2022 Continuously introducing steam option was clarified on page 22; \u2022 Attachment 4, which provides guidance on supporting the continuously introducing steam option, was added. A more detailed summary of the comments and FSIS\u2019 responses can be found in Attachment 1. In addition to making changes in response to public comments, FSIS also made the following changes in response to questions submitted through askFSIS: \u2022 Clarified on page 8 that the lethality treatment of poultry jerky should achieve at least a 5.0-log<sub>10</sub> reduction of *Salmonella* spp.; \u2022 Provided guidance on pages 13 \u2013 14 on how to calibrate a humidity recorder; \u2022 Clarified on page 19 that reference to the cooking time in the humidity options in Appendix A refers to the entire cooking time (including come up time), not just the time during which the temperature in Appendix A is achieved and maintained (e.g., 145\u00b0F for 4 minutes); \u2022 Clarified in the text on page 19 that if an establishment using Appendix A as support for the lethality treatment introduces steam or seals the oven, cooking time should never be less than one hour; and \u2022 Clarified the documentation that should be collected to support that humidity is being implemented consistent with Appendix A when the sealed oven or continuously introducing steam methods are used on pages 21 and 22. Although comments will no longer be accepted through regulations.gov on this guidance document, FSIS will update this document as necessary should new information become available.", "3 Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments Table of Contents Purpose 4 Background 4 Step-by-Step Guide for Jerky Processing 5 Critical Operational Parameters during the Lethality Treatment 9 Scientific Support Available for Jerky Processing 18 References 29 Helpful Websites 31 Attachment 1: FSIS Response to Comments 32 Attachment 2: Time, temperature, and humidity combinations reported in the literature for beef jerky that achieve at least a 5\u2013log<sub>10</sub> reduction in *Salmonella* and *E. coli* O157:H7 40 Attachment 3: Making Your Own Wet bulb (Reprinted with Permission from the University of Wisconsin) 49 Attachment 4: Example Time-Temperature Recorder Chart to Support Option to Continuously Inject Steam 53", "4 Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments Purpose This guideline is designed to help small and very small meat and poultry establishments that manufacture jerky to identify: \u2022 The key steps in the jerky process needed to ensure safety; and \u2022 The scientific support available to help develop a safe process and product. This guideline is not intended to set any regulatory requirements. This document replaces previous versions of the guideline last updated in July 2012. Background Meat or poultry jerky is a ready-to-eat (RTE), dried product that is considered shelfstable (i.e., it does not require refrigeration after proper processing). Following a 2003 salmonellosis outbreak from *Salmonella* Kiambu in jerky produced in New Mexico, FSIS published the first version of the Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments. The Compliance Guideline provided guidance for small and very small meat and poultry establishments on the critical steps for jerky processing and the controls needed at each of these steps to ensure a safe product is produced. One potential cause of the 2003 *Salmonella* Kiambu outbreak in jerky was the very slow drying process under low humidity conditions (1% Relative Humidity - 82\u00b0C dry bulb, 30\u00b0C wet bulb), which allowed *Salmonella* organisms to dehydrate during drying and become resistant to heat.

Therefore, the first version of the jerky compliance guidelines emphasized the need for high levels of humidity during jerky processing. Since 2003, a number of journal articles have been published that has increased scientific understanding of the critical factors during jerky processing including the role of humidity. This document updates and replaces the 2007 and 2012 versions of the guideline to reflect the most up-to-date science and understanding of jerky processing. This guideline also addresses concerns identified through Food Safety Assessments (FSAs) and askFSIS questions and responds to public comments received on the 2012 version. 1 <http://aces.nmsu.edu/ces/nmhs/documents/albanese.pdf> One potential cause of the 2003 Salmonella Kiambu in jerky outbreak was the very slow drying process under low humidity conditions", "5 Step-by-Step Guide for Jerky Processing Below is a summary of the eight (8) general processing steps used in jerky production. Although an establishment's process may not include these same steps, the lethality treatment followed by drying should be used to produce a safe product. Other steps such as the intervention and post-drying steps may be used by establishments when the lethality and drying steps do not achieve adequate lethality. Further descriptions of the key steps in the jerky process, including the microbial interventions that can be applied to ensure safety, are included in the pages that follow. \uf0d8Step 1 - Strip preparation: Whole muscle is sliced or ground; ground product is formed into strips (some jerky is formed). \uf0d8Step 2 \u2013 Marination: The strips are marinated in a solution that often contains salt, sugar, and flavoring ingredients. \uf0d8Step 3 \u2013 Interventions: Antimicrobial interventions before, during, and after marinating the strips of raw product may be added to increase the level of pathogen reduction beyond that achieved by heating alone. \uf0d8Step 4 - Surface preparation: Strips are heated using a low temperature heat step, which makes the surface tacky to aid in smoke adherence and improve product texture. \uf0d8Step 5 \u2013 Lethality: The lethality treatment is defined as the process step or steps used to destroy pathogenic microorganisms on or in a product to make the product safe for human consumption. The lethality treatment is considered to include the time when the product is placed in the heated oven (including surface preparation and color setting) until the product reaches the desired lethality time/temperature combination (also referred to as \u201cthe cooking time\u201d). In order to achieve adequate lethality, it is important that an establishment's actual process adheres to the following critical operational parameters (see Key Definitions on page 8) in the scientific support: \u2022 Product time-temperature combination \u2022 Relative humidity \uf0d8Step 6 \u2013 Drying: Drying is the process during which water (moisture) is removed from the product. After the lethality treatment, jerky is dried to meet a water activity level sufficient to prevent the growth of microorganisms, especially toxigenic microorganisms, such as *Staphylococcus aureus*. \uf0d8Step 7 \u2013 Post-drying heat step: A post-drying heat step may be added to increase the level of pathogen reduction beyond that achieved by heating alone. \uf0d8Step 8 \u2013 Handling: Product is often handled after the lethality and drying steps and prior to packaging.", "6 Jerky producers (and all producers of RTE product) are required to control the food safety hazards in their products (9 CFR 417.4(a)) and to document that their Hazard Analysis and Critical Control Point (HACCP) systems work according to 9 CFR 417.5(a). Establishments producing RTE products need to achieve lethality of pathogens (e.g., *Salmonella*) in the product, and stabilize the product to inhibit the growth of spore-forming bacteria (e.g., *C. botulinum* and *C. perfringens*). In addition, jerky producers need to ensure the growth of toxigenic microorganisms, such as

*Staphylococcus aureus*, is controlled during the process and prevented during the distribution and storage of the finished product. This guideline provides steps jerky processors can take to ensure that the jerky processes they employ effectively control these hazards. The guideline discusses each step in the jerky process in more detail below with key considerations related to pathogen reduction or control highlighted for each step. Each process is unique, so some processors may not use all 8 steps. Some may perform the steps below in different order, or some may use additional steps.

\uf0d8Step 1 - Strip preparation: Whole muscle is sliced or ground; ground product is formed into strips (some jerky is formed). It is critical for establishments to use source materials prepared under good manufacturing practices (GMPs) designed to minimize contamination and the presence and growth of pathogens of public health concern, so the initial pathogen load is not higher than what the process is designed to reduce. Establishments that choose to purchase source materials known to be contaminated with pathogens of public health concern, such as *Salmonella* or shiga toxin-producing *Escherichia coli* (E. coli) (STEC) organisms such as E. coli O157:H7 or E. coli O45, should pay special attention to the controls they put in place to ensure cross-contamination between raw and RTE product does not occur.

\uf0d8Step 2 \u2013 Marination: The strips are marinated in a solution that often contains salt, sugar, and flavoring ingredients. Establishments should use non-meat ingredients for marinades and spice mixes that are prepared under GMPs designed to minimize contamination and the presence and growth of pathogens of public health concern, so the initial pathogen load is not higher than what the process is designed to reduce. FSIS recommends that establishments use a new liquid marinade solution or dry spice mix with each production batch to reduce chances of cross-contamination from one batch of production to another. If an establishment does reuse a marinade or spice mix, it should consider and address the potential hazards associated with cross-contamination from one batch of production to another.

\uf0d8Step 3 - Interventions: Antimicrobial interventions before, during, and, after marinating the strips of raw product have been shown to increase the level of pathogen reduction beyond that achieved by heating alone. Some heating processes may not deliver an adequate lethality and, thus, may require an additional intervention step to ensure product safety. Examples of interventions that may increase the lethality of the process are:<sup>7</sup>

Preheating the meat or poultry jerky strips in the marinade to a minimum internal temperature of 160\u00b0F will provide an immediate reduction of *Salmonella* (Harrison and Harrison, 1996). Heating in marinade may produce unacceptable flavors for some products; however, other liquids such as water could be used. The times and temperatures in FSIS Appendix A: Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat and Poultry Products (referred to throughout this document as Appendix A) could be used for preheating in the liquid, although the product internal temperature should be monitored to ensure adequate lethality is achieved.

\u2013 Dipping the product in 5% acetic acid for 10 minutes before placing it in the marinade can augment the log reduction effects of drying but not enough to eliminate pathogens (Calicioglu, 2002 & 2003). This intervention may also result in an undesirable flavor.

\u2013 Dipping the product in 1:2 or 1:3 mixtures of calcium sulfate (Milonix Safe 2O\u2122) and water for 30 seconds or dipping in acidified sodium chlorite (Keeper\u00ae) at concentrations between 500 and 1,200 ppm can reduce the level of *Salmonella*, *Listeria monocytogenes* (Lm), and E. coli O157:H7 compared with no pretreatment. These pretreatments were effective in both dehydrators and smokehouse processing (Harrison

et al., 2006). \uf0d8Step 4 - Surface preparation: Strips are heated using a low temperature heat step which makes the surface tacky to aid in smoke adherence and improve product texture. Humidity is often not introduced until the next step, the lethality treatment. The lack of humidity during the initial surface preparation step is generally not a food safety concern because the step is usually too short (30 minutes or less) to dry out the product to such a degree that the heat resistance of *Salmonella* would be increased. This step may include or be followed by a color setting step during which humidity is also not introduced. This color setting step plus the surface preparation step should be 30 minutes or less in total. If an establishment uses a preparation or color setting step that is longer than 30 minutes, it should provide support for why the lack of humidity does not result in the product drying out before the lethality treatment. \uf0d8Step 5 - Lethality treatment: The lethality treatment is defined as the process step or steps used to destroy pathogenic microorganisms on or in a product to make the product safe for human consumption. The lethality treatment is considered to include the time when the product is placed in the heated oven (including surface preparation and color setting) until the point at which the product reaches the desired lethality time-temperature combination (also referred to as the \u201ccooking time\u201d). In order to achieve adequate lethality, the establishment\u2019s actual process needs to adhere to the following critical operational parameters (see Key Definitions on page 8) in the scientific support:"8 \u2022 Product time-temperature combination \u2022 Relative humidity In recent years, several jerky products have been found to be adulterated with *Salmonella* or *E. coli* O157:H7. Often the contamination has been linked to inadequate lethality treatment. The lethality treatment of meat jerky should achieve at least a 5.0-log<sub>10</sub> reduction of *Salmonella* spp. and at least a 5.0-log<sub>10</sub> reduction for shiga toxin-producing *Escherichia coli* (*E. coli*) (STEC) for products containing beef as recommended in the *Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products. The lethality treatment of poultry jerky should achieve at least a 5.0-log<sub>10</sub> reduction of *Salmonella* spp. Although poultry jerky is considered to fall under the performance standard in 9 CFR 381.150 (i.e., a 7.0-log<sub>10</sub> reduction of *Salmonella* spp.), the regulation allows for the use of an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product. Research has supported that a 5.0log<sub>10</sub> reduction in *Salmonella* is sufficient for such shelfstable products. Indeed, the FSIS Risk Assessment of the Impact of Lethality Standards on Salmonellosis from Ready-to-Eat Meat and Poultry Products found that there would not be a significant increase in the cases of salmonellosis if jerky and other shelf-stable products achieved a 5.0-log<sub>10</sub> vs. 7.0-log<sub>10</sub> lethality. In addition to *Salmonella* spp., the lethality treatment of meat and poultry jerky should achieve at least a 3.0-log<sub>10</sub> reduction in *Lm*, although a 5.0-log<sub>10</sub> reduction or greater is desirable for providing an even greater safety margin for ensuring that *Lm* does not grow to detectable levels during storage. However, establishments are not required to validate that their process achieves reduction in *Lm* (or STEC for products containing beef) if it achieves sufficient reductions in *Salmonella* because *Salmonella* is more heat resistant than other pathogens and is, therefore, considered an indicator of lethality. Establishments should make sound decisions in the hazard analysis that support that source materials were prepared using GMPs and other process controls as discussed in the previous steps of strip preparation and marination such that a 5.0-log<sub>10</sub> reduction in *Salmonella* results in the production of a safe product. Official establishments

choosing to use cooking to achieve lethality before drying may consider a number of different KEY DEFINITIONS The lethality treatment is defined as the process step or steps used to destroy pathogenic microorganisms on or in a product to make the product safe for human consumption. The lethality treatment is considered to include the time when the thermal processing begins (e.g., the product is placed in the heated oven) until the point at which the product reaches the desired lethality time-temperature combination (also referred to as the \u201ccooking time\u201d). Critical operational parameters are those parameters of an intervention that must be met in order for the intervention to operate effectively and as intended. Such parameters include but are not limited to time, temperature, water activity, concentration, relative humidity, and type of equipment (to the extent that the use of different equipment would result in an inability to achieve the critical parameters of the study).", "9 types of scientific documents to support the time-temperature-humidity combination used in the actual process. Such types of scientific support documents include: \u2022 Compliance Guidelines (e.g., Appendix A) \u2022 Journal articles \u2022 Challenge studies \u2022 In-plant data Finished product testing would not be considered adequate scientific support for the process used on its own, however, because such testing does not support that at least an adequate reduction of *Salmonella* spp. is achieved by the process. An in-depth discussion of considerations for each of these types of scientific support documents, along with examples, is discussed in the section titled: Scientific Support Documents for Jerky Processing. Critical Operational Parameters during the Lethality Treatment Regardless of the scientific support document used, it is important that an establishment's actual process and procedures relate and adhere to the critical operational parameters in the scientific support in order to achieve adequate lethality. There are several critical operational parameters that are important for jerky processing that will be reviewed. Product time-temperature combination One of the critical operational parameters during the jerky process is the time-temperature combination the product achieves. Most often the temperatures used during the lethality treatment that are reported in scientific support documents, such as the Appendix A guidelines, are the temperatures that the product should reach. FSIS has found that establishments will use these same temperatures to set critical limits for the oven temperature. However, setting the oven temperature to the temperature in the support is not appropriate because it does not ensure that the product will reach the same internal temperature, which is critical to ensure adequate lethality is achieved. For this reason, FSIS recommends that FSIS has found through FSAs that many establishments use temperatures from support documents to set critical limits for the oven temperature; however, setting the oven temperature to the temperature in the support does not ensure that the product will reach the same internal temperature which is critical to ensure adequate lethality is achieved. The FSAs show that some establishments do not measure or verify that the product has achieved the desired internal lethality temperature until after drying. FSIS does not recommended verifying product temperatures only after drying because the product may have dried out before the lethality temperature was reached, resulting in lower than expected pathogen reduction.", "10 establishments monitor the internal product temperature. Product internal temperature can be measured by inserting a thermocouple probe into the center of a beef strip. Proper insertion may be difficult because the product is so thin; therefore, FSIS recommends that establishments slice one piece of jerky twice as thick as normal so that the probe can be inserted. If this thicker piece reaches the lethality

temperature, the thinner pieces should as well. In addition, to accurately measure the product temperature, the establishment should understand factors that could affect the temperature of the product. These factors include cold spots in the oven, as well as variation in oven temperature during different seasons. Although monitoring product temperature is strongly encouraged, establishments can use the oven or smokehouse temperature in place of the product temperature, provided that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the product temperature in the scientific support. In addition to the product temperature, the amount of time the product is held at this temperature is also critical to ensuring that adequate lethality is achieved. It is important for the establishment to understand how the actual temperature of the product was taken, the time it takes the product to reach the target temperature (known as the come-up time or CUT), and the amount of time the product is held at the target temperature compared to the scientific support documentation. If the product is held at the target lethality treatment for less time than what was used in the scientific support, then adequate lethality may not be achieved.

**Relative Humidity**

In addition to the product time-temperature combination, the relative humidity (e.g., steam) in the oven is also critical to achieve adequate lethality in jerky. It is important that the establishment maintains humidity according to its scientific support. If relative humidity is not added or maintained by the process, the establishment should maintain scientific support demonstrating that humidity is not a critical operational parameter. Some jerky processors may be concerned that adding humidity will affect the ability to dry the meat or poultry and result in unacceptable product texture; however, the lethality treatment during which relative humidity is applied takes very little time. Adding humidity during the lethality treatment should accelerate subsequent drying and prevent case-hardening, which may actually improve product texture.

**KEY DEFINITIONS**

Relative Humidity is defined as the degree of saturation of the air by water (vapor), expressed as a percentage. Relative humidity describes the relation of the existing vapor pressure at a given temperature to the maximum vapor pressure at that temperature. Air at a given temperature can absorb vapor until its saturation (100%). The difference between the dry and wet bulb temperature is the relative humidity at that temperature. The following website <http://www.ringbell.co.uk/info/humid.htm> contains a function for calculating the relative humidity given the wet and dry bulb temperatures.", "11 Without sufficient humidity the product surface may dry too quickly, and the bacteria may become more heat resistant. Relative humidity around a product during the lethality treatment promotes lethality in two ways:

- \u2022 First, the humidity reduces surface evaporation and the energy or heat that evaporation removes from the product during heating. If sufficient relative humidity surrounding the product is not maintained during the lethality treatment, undesirable evaporative cooling at the surface will occur, and the product will not reach the desired temperature. Producing products under conditions of high humidity early in the cooking process reduces evaporative cooling allowing products to reach higher product surface temperatures which results in a greater reduction in microorganisms.
- \u2022 Second, the humidity keeps the product surface (and any pathogens) more moist and prevents unwanted concentration of solutes (e.g., sugar and salt) as a result of drying. Research has demonstrated that bacteria can become more heat resistant as their moisture levels decrease, and increased concentrations of solutes, especially sugars, increase the heat resistance of bacteria. Therefore,

the drying of the product surface before the pathogens are destroyed will increase pathogen heat resistance and allow them to survive the heating process. By incorporating humidity to minimize evaporation, the D values (time at a constant temperature necessary to destroy 90% or 1-log10 of the target organism) that are the basis for Appendix A and other scientific support documents remain valid (Goepfert, 1970; Goodfellow and Brown, 1978; Faith, N.G. et al. 1998). For these reasons, it is crucial that the processor prevent drying of the product until a lethal time-temperature combination is attained. In order to be most effective, the humidity should be applied during the lethality treatment and before the drying step occurs. Although the lethality treatment includes the time when the product is placed in the heated oven until the product reaches the desired lethality time and temperature combination (the \u201ccooking time\u201d), establishments may not introduce relative humidity into the process until 15 to 30 minutes after the product is placed in the heated oven. The establishment would do so because of the previous step of surface preparation that is needed to set the surface to aid in the adherence of smoke. As discussed earlier, the lack of humidity during this initial step is not a food safety concern because of its short duration. In addition to applying humidity early in the lethality treatment, FSIS also recommends that establishments treat the lethality and drying steps as separate stages to ensure that lethality is achieved before the product dries out. Therefore, the establishment should measure and verify the desired product temperature has been met before the drying stage. One way for an establishment to know that the product has not dried out before a lethal time-temperature combination is attained is to measure the water activity of the", "12 product after the lethality treatment but before drying and again after drying. Some published articles (for example, Buege et al., 2006a) report the water activity at these points in the process for comparison. Another approach is for the establishment to monitor the wet bulb temperature early in the process because it provides a good indication of product surface temperature, which strongly influences lethality (Buege, 2006a). Further explanation and directions for making a wet bulb thermometer are in Attachment 3. Although this information may be useful, establishments do not need such data to validate the process if they are able to demonstrate that their process can achieve the level of relative humidity in their scientific support. Some simple and practical measures that can be used to aid in meeting the humidity level utilized in the scientific support documents include:

- \u2022 Seal the oven: Close the smokehouse doors and oven dampers to provide a closed system and prevent moisture loss.
- \u2022 Add humidity:
  - o Place one or more shallow, wide pans of hot water in the oven to increase the humidity in the system. Conduct a test run to determine whether the water evaporates.
  - o Injecting steam or a fine water mist into the oven can also add humidity.

The use of a humidity sensor or the use of wet bulb and dry bulb thermometers (to measure relative humidity) would enable the operator to determine whether adequate humidity is being applied for either measure. In order to ensure that adequate humidity is attained, the establishment should monitor the humidity throughout the lethality treatment. The process should be monitored using wet and dry bulb thermometers (used to determine relative humidity) or a humidity sensor. The following website <http://home.fuse.net/clymer/water/wet.html> contains a function for calculating the relative humidity given the wet and dry bulb temperatures. A basic wet bulb thermometer can be prepared by fitting a wet, moisture-wicking cloth around a dry bulb thermometer. To maintain a wet cloth during the process, submerge an end of the cloth in a water supply. The

cloth must remain wet during the entire lethality treatment especially if smoke is applied. The establishment KEY DEFINITIONS The dry bulb temperature refers to the ambient air temperature. It is called \u201cdry bulb\u201d because the air temperature is indicated by a thermometer not affected by the moisture in the air or evaporative cooling that removes heat and moisture from the surface of the product. The dry bulb temperature is most commonly measured by jerky-makers. Jerky makers commonly measure the dry bulb temperature. The wet bulb temperature is the temperature indicated by a moistened thermometer bulb exposed to the air flow. A wet bulb thermometer measures the extent of cooling that happens as moisture dries from a surface, a process also known as evaporative cooling. The wet bulb temperature is always lower than the dry bulb temperature except when there is 100% relative humidity, when they will be identical. Because evaporative cooling occurs on the surface of thin jerky strips, the wet bulb temperature is a more accurate measure of product surface temperature. A sealed oven is generally defined as one in which the smokehouse doors and smokehouse oven dampers are closed to prevent moisture loss.", "13 should inspect the wet bulb sock prior to thermal processing, and the sock should be changed as necessary depending on its condition. Attachment 3 contains more details for creating a wet bulb thermometer. The use of a wet bulb thermometer is especially important for production at altitudes between 3,000 to 7,000 feet or areas of low humidity. Processing failures in the manufacture of jerky have occurred in establishments in New Mexico located between these altitudes (Eidson et al, 2000). Establishments located at higher altitudes will generally have a lower atmospheric pressure. This lower pressure leads to lower boiling points and faster evaporation from the product surface, which can lead to undesirable evaporative cooling and drying of the product surface. Furthermore, the relative humidity can be less at the higher altitude because of the lower air pressure (if the temperature at sea level and the high altitude is the same). As a result, at higher altitudes, the amount of moisture added to the smokehouse chamber necessary to achieve a given log reduction of bacteria may need to be increased to account for lower levels of humidity in the ambient (or room) air. Relative humidity in the ambient air will have an effect on the relative humidity in the smokehouse chamber, particularly when humidity is maintained by sealing the oven, because heat in the smokehouses is typically provided by heating ambient air that is passed over electrically-heated or steam-heated coils. For this reason, all establishments should also take into account variability in relative humidity in the ambient air throughout different times of year. Establishments will need to make adjustments to the amount of humidity added to the smokehouse chamber to account for changes in humidity in the ambient air at high altitudes or during dry months. These adjustments should be made on a case-by-case basis as part of the initial design of the system to ensure that the humidity in the actual process matches the level in the scientific support. FSIS recommends that establishments monitor relative humidity using wet and dry bulb thermometers or a humidity sensor with every lot or batch of product although FSIS does not require this monitoring frequency. Establishments have flexibility in how they address humidity in their HACCP systems. If relative humidity is addressed as part of a critical control point (CCP), the establishment is required to list the critical limits per 9 CFR 417.2(c)(3) and list and support the monitoring procedures and frequencies chosen for each CCP to ensure compliance with the critical limits per 9 CFR 417.2(c)(4) and 9 CFR 417.5(a)(2). Furthermore, per 9 CFR 417.4(a)(2), establishments are required to calibrate process-monitoring instruments as part of ongoing verification activities

and, per 417.5(a)(2), are required to support their verification procedures and frequencies of those procedures. If relative humidity is addressed in a prerequisite program, and the establishment determines that the implementation of that program results in potential hazards being not reasonably likely to occur, then it must have supporting documentation for the decisions made in the hazard analysis per 9 CFR 417.5(a)(1). NOTE: Accurate recordkeeping documenting the implementation of the critical operational parameters is critical to support the fact that safe products are produced. Inadequate or inaccurate recordkeeping (e.g., data entry error or unclear monitoring records) has contributed to jerky product recalls in the past, particularly when such records were associated with a lack of information regarding the implementation of all of the critical operational parameters for each batch or lot produced." "14 Often the owner's manual for humidity recorders recommends calibration on an annual basis. Establishments should follow the manual's instructions for calibration. Establishments may calibrate by comparing the temperature readouts from the microprocessor to the temperature and time plotted on the recorder charts to check for accuracy. For this procedure, FSIS recommends that the establishment calibrate the microprocessor controls before use and show that the calibration is accurate. This procedure can be performed in-house in a few simple steps: 1. The wet bulb and dry bulb probes can be placed in a bucket of hot water along with a National Institute of Standards and Technology (NIST) reference thermometer. Some establishments use a small propane burner to maintain the water at a constant temperature. 2. The NIST thermometer represents the known temperature standard, and the establishment can compare the wet and dry bulb probe readings on the microprocessor to the NIST device to verify accuracy of the probes. 3. Once the probe readings are verified on the microprocessor as being accurate, the temperature reading on the microprocessor can be compared to the chart recorder temperature. The chart recorder is then adjusted (if needed) to the microprocessor reading. These procedures for calibrating humidity recorders are provided as guidance to establishments; other procedures may be used, provided the establishment maintains support for the method chosen.

Step 6

Drying: Drying is the process during which water (moisture) is removed from the product. After the lethality treatment, jerky is dried to meet a water activity level sufficient to prevent the growth of microorganisms, especially toxicogenic microorganisms such as *Staphylococcus aureus*. Jerky is a shelf-stable product. After drying is complete, the establishment should monitor or verify the water activity to demonstrate that the product has attained shelfstability in accordance with the scientific support. FSIS does not have a standard of identity for jerky in its regulations. However, jerky has historically been dried to an MPR of 0.75:1 or below as described in the FSIS Food Standards and Labeling Policy Book. FSIS is aware that some manufacturers rely upon the MPR, rather than water activity, for determining whether their process adequately dries the jerky to produce a shelfstable product. MPR is an inappropriate indicator of shelf-stability. Water activity (also referred to as aw), measured by an instrument such as a water activity meter, is the more appropriate indicator to verify jerky is properly dried for food safety. This is because water activity is a better measure of available water (or water that is not bound by other components) for microbial growth than is MPR. Minimizing available water (e.g., achieving a sufficiently low water activity) is necessary to achieve shelf stability, provided measures are taken to address mold growth. Such measures to prevent mold growth may include using short inventory pull dates, low pH, antimycotics, coatings, packaging, or any

combination of these measures." "15 In order to achieve a shelf-stable product, a water activity critical limit of 0.85 or lower should be targeted for products stored in an aerobic or oxygen containing environment such as in ambient air, provided the establishment takes steps to prevent mold growth on the finished product. If the product is vacuum packaged in an oxygen impervious packaging (creating an anaerobic environment where no oxygen is present), then the water activity critical limit can be 0.91 or lower. These limits are based on the growth limits for *Staphylococcus aureus* with and without oxygen present (ICMSF, 1996) and FSIS\|u2019 definition of shelf-stability (see the Key Definition in the right panel). According to the International Commission on Microbiological Specifications for Foods (ICMSF), the water activity limit for *Staphylococcus aureus* growth is 0.83 under aerobic conditions and 0.90 under anaerobic conditions. However, as noted in a footnote of that book, this criterion is based on optimal conditions. FSIS recognizes that most jerky type products have other intrinsic factors, such as sodium nitrite, indigenous microflora, and salt concentration, that would also act as barriers to *Staphylococcus aureus* growth. By considering these factors, FSIS recommends an upper limit of 0.85 under aerobic conditions or 0.91 under anaerobic conditions. Establishments that choose to use these limits as support for the shelf-stability of their product may cite this guideline as scientific support for these limits and are not required to provide additional scientific support. Establishments may be able to support other water activity critical limits, provided scientific support is available to support the decision-making. The establishment needs to achieve the water activity of the finished product identified in its scientific support.

**KEY QUESTION** Question: Can a product be labeled as \u201cjerk\u201d if it meets the MPR of 0.75:1 but is not shelf-stable? Answer: No. In order to label a product \u201cjerk\u201d it must be shelf-stable. Although FSIS does not define jerk as shelf-stable in the regulatory standards of identity (9 CFR part 319), consumers consider and expect jerk to be shelf-stable.

**KEY DEFINITIONS** Shelf-stable is the condition achieved when meat and poultry products can be stored under ambient temperature and humidity conditions; if the package integrity is maintained during storage, shipping, and display at retail and in the home; and the product will not spoil or become unsafe throughout the manufacturer\|u2019s specified shelf-life. Water activity, also referred to as aw, is a measure of the concentration of moisture (i.e., water) and its availability in a food. The amount of water available in a food depends on the total concentration of all dissolved substances in the product because they bind water. Thus, if ingredients such as salt or sugar are added to food, they compete with the bacteria for available water. Moisture-protein-ratio (MPR) expresses the percent moisture divided by the percent protein. MPR is commonly used in the U.S. to classify dried sausages and other meat products. Although MPR values indicate the degree of product drying, they are not necessarily indicative of microbial safety or product shelf-stability because they do not take into account availability of the water." "16 NOTE: Vacuum packaged products with a water activity level > 0.85 and \u2264 0.91 should be kept refrigerated once the package is opened because the product would no longer be considered shelf-stable once it is exposed to oxygen. Lack of shelf-stability once the product is exposed to oxygen is mainly a concern for products that would not be consumed within a single serving as these products are not likely to be vacuum packaged by the consumer between servings. Therefore, unless the establishment has support that the product is likely to be consumed in a single serving, vacuum packaged products with a water activity in the range of > 0.85 and \u2264 0.91 should be labeled with a statement such as

\u201cRefrigerate After Opening\u201d (as described in 9 CFR 317.2(k)). Finally, it should be noted that although the establishment may control the water activity level of a product to achieve shelf-stability, controlling water activity alone would not be sufficient to assure the safety of the product. Drying the product does not necessarily result in an adequate reduction of Salmonella organisms because the pathogen can be resistant to drying. For this reason, the establishment should use a validated lethality treatment, as described in Step 5 \u2013 Lethality treatment. \uf0d8 Step 7 \u2013 Post-drying heat step: A post-drying heat step may be added to increase the level of pathogen reduction beyond that achieved by heating alone. This step may be needed for processes that do not result in an adequate reduction of Salmonella through the initial heating process. Adding a post-drying heat step has the potential to reduce Salmonella levels by approximately  $2\log_{10}\u2019s$  from the level of reduction achieved during the initial heat step. One example of a post-drying heat step that has been found to reduce Salmonella levels by approximately  $2\log_{10}\u2019s$  is to heat the dried product in a 275\u00b0F oven for 10 minutes (Harrison et al., 2001). \uf0d8 Step 8 \u2013 Handling: Product is often handled after the lethality and drying steps and prior to\//during packaging. Establishments should control their processes to prevent contamination of product with pathogens from handling after the lethality and drying steps. Such controls should KEY QUESTION Question: Should an establishment use the MPR to determine whether its process produces a shelfstable product? Answer: No. Establishments should use water activity to demonstrate that the product has attained the critical limit for shelf-stability.", "17 include ensuring that cross-contamination of product is minimized before packaging, and ensuring that the product is packaged in such a way that cross-contamination of product post-packaging is also minimized (e.g., with a good seal to maintain package integrity throughout storage, shipment, and display). Preventing cross-contamination is important even if the product is dried to a water activity such that the product is considered shelf-stable. Pathogens may still be able to survive on the product if it becomes contaminated during handling. Cross-contamination of product can occur from situations such as the following: \u2022 Using the same equipment (e.g., preparation tables, scales, or packaging equipment) for both raw and cooked products without completely cleaning and sanitizing the equipment between production lots. \u2022 Placing cooked product on the same surface (e.g., cutting table) as raw product without completely cleaning and sanitizing the surface before reuse. \u2022 Using the same utensils or containers (e.g., scoops or buckets) for both raw and cooked product without completely cleaning and sanitizing the surface before reuse. \u2022 Condensation, aerosolization, or dusting of dry ingredients into the processing environment. \u2022 Employee movement between raw and ready-to-eat areas without hand-washing or garment changing. The establishment is required to maintain sanitation in the RTE area to ensure that food contact surfaces are free of contamination from Lm and other pathogens, such as Salmonella, in accordance with 9 CFR part 430. The establishment is required to develop and implement Sanitation SOPs (9 CFR 416) to ensure that contamination and adulteration of the product is prevented after the lethality treatment. Further guidance on post-processing handling and sanitation for ready-to-eat products including jerky is in the Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and the Compliance Guidelines to Control Listeria monocytogenes in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products.", "18 Scientific Support Available for Jerky

Processing Establishments have numerous options for the types of scientific documents that can be used to support that the process achieves adequate lethality. Examples of the scientific support available to help develop a safe jerky process and product are discussed below, along with considerations for each type of support. Product sampling results, based on historical data alone, should not be used as scientific support for a jerky process because they do not provide information on the level of pathogen reduction that is achieved for the process. Compliance Guidelines FSIS has issued a number of different compliance guidelines that have application to jerky processing. It is important to note that, while FSIS considers these documents to be guidelines, if followed precisely, they are considered as validated process schedules because the guidelines contain processing methods already accepted by the Agency as effective in safely producing meat and poultry products. Some considerations for each of these compliance guidelines are outlined on the following pages. \uf0d8 FSIS Appendix A: Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat and Poultry Products For meat jerky, use of the product time-temperature combinations provided in Appendix A, including those temperatures above 158\u00b0F in which the time for the desired lethality is instantaneous, should help to ensure the safety of the product. These timetemperature combinations are based on experiments that were done with products without added salt or sugar. Added salt, sugar, or other substances that reduce water activity will increase the heat resistance of bacteria in a product. However, time and experience have shown that the time-temperature combinations in the lethality compliance guidelines have been sufficient to produce safe products even with both salt and sugar added, but the humidity during heating is a critical factor. FSIS has found through FSAs and askFSIS questions that there is confusion regarding the humidity options in Appendix A that apply to jerky, when establishments can introduce humidity by continuously introducing steam or sealing the oven, and for how long humidity should be introduced. The humidity options in Appendix A that are applicable to jerky processing are:

- o Heating jerky to a minimum internal temperature of 145 \u00b0F (62.8 \u00b0C) in an oven maintained at any temperature if the relative humidity of the oven is maintained either by continuously introducing steam for 50 percent of the cooking time or by use of a sealed oven for over 50 percent of the cooking time, or if the relative humidity of the oven is maintained at 90 percent or above for at least 25 percent of the total cooking time but in no case less than 1 hour; or
- o Heating jerky in an oven maintained at any temperature that will satisfy the internal temperature and time combinations from the chart provided in", "19 Appendix A if the relative humidity of the oven is maintained at 90 percent or above for at least 25 percent of the total cooking time but in no case less than 1 hour. The relative humidity may be achieved by use of steam injection or sealed ovens capable of producing and maintaining the required relative humidity. In order to introduce humidity by continuously introducing steam or sealing the oven, establishments should:

\uf0fe Cook the jerky product to an internal temperature-time combination of equal to or greater than 145\u00b0F for 4 minutes. It is important to note again that the temperature values in Appendix A correspond to product temperatures, not oven temperatures. If an establishment cooks its jerky product to an internal temperature-time combination of less than 145\u00b0F for 4 minutes, then the relative humidity should be maintained at 90% or above for at least one hour or 25% of the cooking time (whichever is longer). AND \uf0fe Cook the jerky product for at least one hour and in some cases longer. Cooking time should never be less than one hour. Appendix A states that the

relative humidity of the oven should be maintained either by continuously introducing steam for 50 percent of the cooking time or by use of a sealed oven for over 50 percent of the cooking time, but in no case less than one hour. This means that these options should be applied for at least one hour or 50% of the cooking time - whichever is longer. If an establishment can not apply these humidity options for equal to or more than one hour (for example because the lethality treatment takes less than one hour), then the humidity of the oven should be maintained at 90% or above throughout the lethality treatment (not just during the time and temperature combination in Appendix A) with the exception of a surface preparation step Establishments can use the flow chart on the following page to determine the humidity options when using the Appendix A guidelines as scientific support for a jerky process. The times listed in the chart do not include any surface preparation or color setting step where humidity is not introduced. So, if a process includes a 30 minute surface preparation or color setting step, the total cooking time would need to be ≥ 90 minutes in order to continuously introduce steam or seal the oven for at least 1 hour (or 50% of the cooking time, whichever is longer) as specified in Appendix A." , "20 Flow Chart to Identify Humidity Options when Using the Appendix A Guidelines as Scientific Support For a Jerky Process Is the Target Product TimeTemp One of Those in Appendix A that is ≥ 145 °F for 4 minutes? Is the total cooking time longer than 1 hour? Yes No Is the total cooking time less than 1 hour? Yes No At least 90% RH for the entire cooking time No At least 90% RH for at least 1 hour or more\* Steam injection for at least 1 hour or more\*\* Sealed oven for at least 1 hour or more\*\* Choice of \*For processes with cooking times > 4 hours, RH should be 90% for at least 25% of the cooking time which would result in more than one hour. \*\*For processes with cooking times > 2 hours, RH (introduced by steam injection, sealed oven, or at ≥ 90%) should continue to be maintained for at least 50% of the cooking time which would result in more than one hour. At least 90% RH for at least 1 hour or more\*\* Yes", "21 Specific guidance for using the sealed oven option to introduce humidity In order to support that the sealed oven option for introducing humidity is being implemented consistent with the Appendix A guidelines, establishments should: 1)Maintain documentation that supports that the jerky product achieves an internal product time-temperature combination from Appendix A of equal to or greater than 145 °F for 4 minutes. Such documentation could include: a.Records of internal product temperature and time held at that temperature (if applicable); or b.Records of the oven or smokehouse temperature in place of product temperature provided that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the product temperature in the scientific support; 2)Maintain documentation that supports that the oven dampers are closed for at least one hour or 50% of the cooking time - whichever is longer. Such documentation could include: a.Records from a computerized system that contains the time at which the oven dampers were open and were closed; or b.Records of the times at which the oven dampers were open and closed made manually; or c. Records demonstrating the relative humidity level in the oven is maintained for at least one hour or 50% of the cooking time - whichever is longer (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement) with correlation data supporting a relationship between the relative humidity level in the oven and the time at which the oven dampers were open and closed (see page 23 for guidance on minimum levels of relative humidity\wet and dry bulb temperatures to achieve); 3)Maintain

documentation that supports that when the oven dampers are closed, humidity is maintained in the ovens. Such documentation could include: a. Records demonstrating the relative humidity level in the ovens is maintained (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement), or b. Data gathered during the initial validation period along with ongoing verification which demonstrates that the relative humidity in the oven is maintained while the dampers are closed; and 4) Have an ongoing procedure for checking that the dampers are properly working along with a maintenance program to periodically monitor that the seals are intact and functional, and that when the oven dampers are closed, a tight seal is obtained. A tight seal is one in which a significant loss of humidity is prevented. FSIS acknowledges that a small amount of smoke or vapors might be seen escaping the smokehouse even when a tight seal is obtained. Establishments should also consider whether there are other openings, particularly in older smokehouses, such as drain valves or air intake valves, that need to be closed in order to ensure that a seal is obtained. Finally, some older ovens may have a stack or other opening that cannot be closed. For those establishments with older ovens that cannot be completely closed, the sealed oven method should not be used. However, the establishment may choose to close what they are able to and add moisture in the system either by continuously introducing steam or another validated method.", "22 Specific guidance for using the continuously injecting steam option to introduce humidity In order to support that the continuously introducing steam option for introducing humidity is being implemented consistent with the Appendix A guidelines, establishments should: 1) Maintain documentation that supports that the jerky product achieves an internal product time-temperature combination from Appendix A of equal to or greater than 145\u00b0F for 4 minutes. Such documentation could include: a. Records of internal product temperature and time held at that temperature (if applicable); or b. Records of the oven or smokehouse temperature in place of product temperature provided that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the product temperature in the scientific support; 2) Maintain documentation that supports that steam is continuously introduced for at least one hour or 50% of the cooking time - whichever is longer. Such documentation could include: a. Records from a computerized system that contains the time at which the steam is turned on and off; or b. Records of the times at which the steam is turned on and off made manually; or c. Records demonstrating the relative humidity level in the oven is maintained for at least one hour or 50% of the cooking time - whichever is longer (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement) along with correlation data supporting a relationship between the relative humidity level in the oven and the time steam is turned on or a letter from the manufacturer stating that when the relative humidity is rising it is because of live steam injection (see page 23 for guidance on minimum levels of relative humidity\wet and dry bulb temperatures to achieve); 3) Maintain documentation that supports that when steam is injected, humidity is maintained in the ovens. Such documentation could include: a. Records demonstrating the relative humidity level in the ovens is maintained (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement), or b. Data gathered during the initial validation period along with ongoing verification which demonstrates that the relative humidity in the oven is maintained while steam is being injected. NOTE: The

\u201ccontinuously introducing steam\u201d option refers to the use of live steam, although it may also apply to establishments that spray water onto hot heating elements, which creates steam that in turn produces humidity in the smokehouse. \u201cContinuous\u201d does not mean that the steam is injected for at least one hour during one stage; rather, steam could be injected during stages or time intervals during the lethality (cooking) treatment as long as the total amount of time the steam is introduced adds up to at least one hour or 50% of the cooking time - whichever is longer. Furthermore, the establishment may turn the steam on and off throughout the cooking time when the target humidity is reached. Attachment 4 has an example of a temperature chart, with wet and dry bulb temperatures, that an establishment could use to demonstrate it is meeting the option to continuously inject steam on an ongoing basis using monitoring records.", "23 It is important that establishments maintain and monitor the humidity levels in the oven. Establishments using either the sealed oven or continuously introducing steam options for introducing humidity can support that humidity is being introduced consistent with Appendix A following the guidance on the previous two pages. Establishments do not need to achieve a specific humidity level in the oven if Appendix A is used as the scientific support. However, FSIS recommends that establishments that monitor relative humidity try to achieve a wet bulb temperature of at least 125-130\u00b0F for 1 hour or more along with a corresponding dry bulb temperature needed to achieve at least 27-32% relative humidity or more. FSIS is making this recommendation based on expert opinion and a review of the literature that suggests that the wet bulb temperature should reach at least 125-130\u00b0F for an hour or more during the lethality process, and that at least 27-32% relative humidity should be present to ensure that adequate lethality is attained. Wet bulb temperature is generally a strong indicator of product surface temperature early in the process. Therefore, maintaining the wet bulb temperature at a high enough level to cause lethality (125-130\u00b0F) is recommended (Buege, 2006a; Harper, 2009). Although establishments using either the sealed oven or continuously introducing steam option for introducing humidity are not required to achieve a specific humidity level, the values provided in this document are listed so that establishments have further guidance concerning minimum levels to achieve as recommended by experts at FSIS. Establishments should be aware that achieving a low wet bulb temperature for a short time (i.e., below 125-130\u00b0F for less than one hour) or low relative humidity for a short time (below 27-32% for less than one hour) may indicate that the jerky process may not be achieving sufficient lethality at the product surface which could represent a vulnerability in the establishment\u2019s process to control food safety hazards of concern. NOTE: Achieving a wet bulb temperature of at least 125-130\u00b0F and at least 27-32% relative humidity for 1 hour or more is not adequate on its own to support that the process is being implemented consistently with Appendix A. Rather, establishments should ensure that all critical operational parameters from Appendix A are met (i.e., product time-temperature combination and humidity). Guidance for introducing humidity for the options that require less than 90% relative humidity (continuously introducing steam or sealing the oven) is provided on the previous two pages. Processes for which Appendix A is not appropriate as scientific support Finally, although Appendix A is commonly used as scientific support for jerky processes, the time-temperature-humidity combinations can not be applied in every scenario. For example, establishments should not use Appendix A: \uf0fe To support a process in which the drying step comes before the cooking step. Appendix A was not developed for such processes. \uf0fe To

support a process that uses a home-style dehydrator. The humidity parameters in Appendix A cannot be maintained in a home-style dehydrator. Processes that can achieve an adequate reduction of *Salmonella* and *E. coli* O157:H7 using home-style dehydrators are described in studies by Borowski et al. (2009b), and Harrison et al. (2006).,"24 \uf0d8 FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks To support the safe production of meat jerk, establishments can use the timetemperature combinations provided in the FSIS Guidance on Safe Cooking of NonIntact Meat Chops, Roasts, and Steaks. Humidity should be considered when using this time-temperature table; therefore, the same options for humidity in Appendix A should be used with this guidance. In addition, the same recommendations regarding maintaining and monitoring humidity for Appendix A apply for establishments that use the FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks for time-temperature combinations. \uf0d8 Time-Temperature Tables For Cooking Ready-To-Eat Poultry Products To support the safe production of poultry jerk, establishments can use the minimum internal temperatures listed in Appendix A of 160\u00b0F for uncured poultry or 155\u00b0F for cured and smoked poultry. Establishments should not use the time and temperature combinations provided in Appendix A for cooked beef, roast beef, and corned beef for poultry jerk. NOTE: If highly pathogenic avian influenza (HPAI) virus H5N1 is identified as a hazard reasonably likely to occur, cured and smoked poultry should be cooked to at least 158\u00b0F or a time and temperature combination that achieves a 7-log 10 reduction of *Salmonella*. The required reduction of *Salmonella* can also be achieved by using one of the timetemperature combinations listed in the Time-Temperature Tables for Cooking Ready-toEat Poultry Products. As stated in the Time-Temperature Tables guidance document, the tables reflect newer data on the temperatures needed to control *Salmonella* in poultry than the data used in developing Appendix A. The Agency has not rescinded the guidance for poultry in Appendix A, but an establishment needs to take into account the data in the Time-Temperature Tables regarding increased time at a specific temperature to achieve a given level of reduction of *Salmonella*. An establishment that utilizes Appendix A within its process should conduct on-going verification to confirm that the process is being effectively controlled. If an establishment is using Appendix A, and the Agency collects an RTE sample that is positive for *Salmonella*, the establishment would be required under 9 CFR 417.3(b), among other things, to support its decision within its hazard analysis. Regardless of which time-temperature combinations an establishment uses, humidity during heating is a critical factor. As with meat jerk, the time-temperature combinations would be sufficient to produce safe products with both salt and sugar additives if the processor uses the humidity parameters applicable to beef as described in Appendix A. The same recommendations regarding maintaining and monitoring humidity for Appendix A apply for establishments that use the Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products."25 Journal articles Journal articles are a primary type of support used for jerk processes. A number of studies have been conducted to determine time-temperature-humidity combinations that result in adequate lethality for jerk. Attachment 2 contains a summary of timetemperature-humidity combinations, along with other critical operational parameters from published studies that have been found to result in adequate lethality. If an establishment chooses to use a journal article as scientific support, it should ensure that all of the critical operational parameters (i.e., product time-temperature combination and relative humidity) used in the study match those used in the actual process. If one or more of the parameters are

not addressed or do not match the level used in the support, then the establishment's process may not achieve the same level of lethality as cited in the journal article. In that case, the establishment should document a justification as to why that parameter does not need to be met or measured, or why it differs from the support. When identifying a journal article, the establishment should consider whether it is using the same: Product (e.g., species, type-whole muscle or ground); Product formulation; Product time-temperature combination; Relative humidity at each stage (including, if reported, using the same humidity levels at the beginning and end of each stage); Type or pH of marination (if applicable); and Smoke (if applicable) as used in the article. The establishment should also ensure that the composition of the product (% salt, % fat) used in the study is the same as the composition of the actual product being produced. A prudent establishment should have knowledge of the products it produces. Because meeting the critical operational parameters is essential to achieve lethality in the product, the parameters used or measured in the article should be addressed in the process.","26 KEY QUESTION Question: Can an establishment's process use a different level of a critical operational parameter (for example, a higher concentration of an antimicrobial or a higher processing temperature) than what was used in the scientific support? Answer: Generally, establishments should use the same critical operational parameters as those in the scientific support. In some circumstances, establishments may be able to support using critical operational parameters (e.g., higher concentrations of antimicrobials or higher thermal processing temperatures) that are different from those in the scientific support. In these cases, establishments should provide justification supporting that the levels chosen are at least as effective as those in the scientific support. This justification is needed because higher levels of a critical operational parameter may not always be equally effective. For example, antimicrobial agents may only be effective within a range of concentration after which point efficacy may decrease. Similarly, higher processing temperatures may result in the surface of the product drying out before adequate lethality is achieved. In addition to ensuring that the levels chosen are at least equally as effective, establishments should ensure the levels are also safe and suitable (FSIS Directive 7120.1 Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products and 9 CFR 424.21(c)). Key Considerations for Journal Articles in Attachment 2 Attachment 2 contains a summary of processes, and the critical operational parameters of those processes, that have been found to achieve adequate lethality for jerky in the published literature. The Attachment is provided to help establishments identify alternatives to the Appendix A guidelines. This Attachment is not considered adequate support on its own because it does not provide the details of each study that an establishment needs to determine if the study is representative of the actual process. For this reason, if an establishment chooses to use one of the articles provided in Attachment 2 for scientific support, the establishment will need to have a full copy of the original article on file.","27 Challenge Studies In cases where an establishment's process does not match available scientific support documents, such as a Compliance Guideline or published journal article, an establishment may decide to conduct an inoculation challenge study to support that its process achieves adequate lethality (e.g., for meat and poultry jerky at least a 5.0-log<sub>10</sub> reduction of *Salmonella* spp.). A challenge study is a study that documents the adequacy of control measures in a process. Obtaining this documentation involves inoculating the target organism (e.g., *Salmonella* spp. or an appropriate surrogate organism such as certain

Pediococcus strains) into a product to determine the effect of control measures such as cooking and drying to reduce the organism. Challenge studies should be conducted by a microbiologist trained in performing challenge studies in a laboratory to avoid the possible spread of contamination in an establishment. In a challenge study, the number of organisms before and after the application of the control measure is counted to determine the effect of the control measure. The challenge study should be designed to closely match the critical operational parameters (e.g., time, temperature, and relative humidity) in the establishment's actual process. Challenge studies should be based on a sound statistical design and should also employ positive and negative controls. As recommended by the National Advisory Committee on Microbiological Criteria of Foods (NACMCF), the number of samples to be analyzed initially and at each time interval during processing or storage should be at a minimum two; however, analysis of three or more samples is preferred. Replicates should also be conducted. Replicates should be independent trials using different batches of product and inoculum to account for variations in product, inoculum, and other factors. Generally, the number of samples and replicates should be increased in situations of higher variability or uncertainty. When the number of samples analyzed at each time interval is only two, it is better for the study to be repeated (replicated) more than two times. In studies with three or more samples tested at each time interval, two replicates are usually adequate. In addition, the inoculum level should be at least two logs greater than the log reduction to be demonstrated. FSIS recommends that establishments use *Salmonella* (or an appropriate surrogate of *Salmonella*) as an indicator of lethality because it tends to be more heat resistant than other pathogens (Goodfellow & Brown, 1978; Line et al, 1991). FSIS considers all *Salmonella* serotypes to be pathogens of public health concern. At a minimum, a study for a microbiological food safety hazard should identify: "The hazard (including the specific strains studied), The expected level of hazard reduction or prevention to be achieved, The processing steps that will achieve the specified reduction or prevention, All critical operational parameters or conditions (e.g., time, temperature, and humidity) necessary to achieve the reduction, How these processing steps/parameters can be monitored, The critical ingredients (e.g., salt, sugar, and cure), and The critical product characteristics (e.g., pH, water activity, and fat content)." "28 FSIS does not require establishments to validate that their process achieves reduction in *E. coli* O157:H7 or Lm if they achieve sufficient reductions in *Salmonella* because *Salmonella* is an indicator of lethality. Without further scientific support, establishments should not use pathogens other than *Salmonella* as indicators of lethality. For example, establishments should not use reductions in Lm to support similar reductions in *Salmonella* without support that Lm is at least equally as heat resistant as *Salmonella* under the conditions being studied. If an establishment chooses to conduct a challenge study in a testing laboratory, the study should use at least five strains of *Salmonella*, including strains associated with human illness and strains isolated from meat and poultry products. Ideally, some of the strains selected should be those with known heat-resistance properties. One good choice, for example, might be *Salmonella enterica* serovar Senftenberg strain 775W, which displays heat resistance properties (Ng et al., 1969). *Salmonella enterica* serovar Senftenberg occurs in the top 10 serotypes seen in FSIS testing for both cow/bull carcass testing and ground beef, as well as in turkeys (carcass and ground) (FSIS testing data, 2012), so it would also be an appropriate choice for what might be seen in these products being tested. If an establishment chooses to conduct a challenge

study in a plant environment, to best represent actual processing conditions for example, then the establishment should choose surrogate organisms that have been found to respond similarly to the pathogens of interest (e.g., *Salmonella*, and if applicable, *E. coli* O157:H7). For example, the University of Wisconsin has conducted research with ground-and-formed jerky and found that two *Pediococcus* strains (Saga 200 and Biosource) have similar heatresistance to *Salmonella* and can be used in in-plant validation studies (Borowski et al., 2009a). FSIS has identified four surrogate organisms that have been shown to respond similarly to *E. coli* O157:H7 during cooking (the following askFSIS Q&A has more information) for use in in-plant validation studies. For the reasons explained above, establishments also should not use surrogate organisms that have been shown to respond similarly to *E. coli* O157:H7 to support similar reductions in *Salmonella* without support that the organisms are at least as heat resistant as *Salmonella*. Challenge studies should be equivalent to peer-reviewed scientific literature. All of the critical elements listed above for a study above need to be included to permit evaluation or confirmation of the results. More information on conducting challenge studies is found in the article published by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) in the Journal of Food Protection in 2010.," "29 References Borowski, A.G., Ingham, S.C., Ingham, B.H. 2009a. Validation of ground-and-formed beef jerky processes using commercial lactic acid bacteria starter cultures as pathogen surrogates. *J. Food Prot.* 72(6): 1234-1247. Borowski, A.G., Ingham, S.C., Ingham, B.H. 2009b. Lethality of home-style dehydrator processes against *Escherichia coli* O157:H7 and *Salmonella* serovars in the manufacture of ground-and-formed beef jerky and the potential for using a pathogen surrogate in process validation. *J. Food Prot.* 72(10): 2056-2064. Buege, D. R., Searls, G. Ingham, S.C. 2006a. Lethality of commercial whole-muscle beef jerky manufacturing processes against *Salmonella* serovars and *Escherichia coli* O157:H7. *J. Food Prot.* 69(9): 2091-2099. Buege, D.R., Searls, G., Mohanan, S., Buege, D.R. 2006b. Survival of *Staphylococcus aureus* and *Listeria monocytogenes* on vacuum-packaged beef jerky and related products stored at 21\u00b0C. *J. Food Prot.* 69(9) 2263-2267. Calicioglu, M., Sofos, J.N., Samelis, J., Kendall, P.A., Smith, G.C. 2002. Destruction of acid-adapted and non-adapted *Salmonella* during drying and storage of beef jerky treated with marinade. Animal Sciences Research Report. Colorado State University. Calicioglu, M., Sofos, J.N., Samelis, J., Kendall, P.A., Smith, G.C. 2003. Effects of acid adaptation and modified marinades on survival of post drying *Salmonella* contamination on beef jerky during storage. *J. Food Prot.* 66(3):396-402. Centers for Disease Control (CDC). 1995. Outbreak of Salmonellosis Associated with Beef Jerky \u2013 New Mexico, 1995. MMWR 1995; 44(42); 785-788. Eidson, M., Sewell, C. M., Graves, G, Olson, R. 2000. Beef jerky gastroenteritis outbreaks. *Environ. Health.* 62:9-13. Faith, N.G., Le-Coutour, N.S., Alvarenga, M.B., Calicioglu, M., Buege, D.R., Luchansky, and J. B. 1998. Viability of *Escherichia coli* O157:H7 in ground and formed beef jerky prepared at levels of 5 and 20% fat and dried at 52, 57, 63, or 68 degrees C in a homestyle dehydrator. *Int. J. Food Microbiol.* 41(3):213-221. FSIS. 2005. Risk Assessment of the Impact of Lethality Standards on Salmonellosis from Ready-to-Eat Meat and Poultry Products. Final Report. Available at:

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Measurements Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products Time-Temperature Tables For Cooking Ready-To-Eat Poultry Products", "32 Attachment 1: FSIS Response to Comments The following is a summary of FSIS\u2019 response to the comments received during the comment period.

1. Need for guidance Comment: One commenter questioned the need for the guidance given the limited information publicly available on the causes of past outbreaks in jerky and the importance of humidity in the production of jerky. The commenter also identified a broken link to a reference to one of the past outbreaks in the 2012 version of the guidance. Response: FSIS initially issued this guidance in 2007 to clarify the importance of introducing humidity to jerky processors given the lack of humidity control identified in past outbreaks. One potential cause of the 2003 Salmonella Kiambu outbreak in jerky was the very slow drying process under low humidity conditions (1% RH - 82\u00b0C dry bulb, 30\u00b0C wet bulb), which allowed Salmonella organisms to dehydrate during drying and become resistant to heat. This information was gathered by FSIS during the course of the investigation. Research has demonstrated that bacteria can become more heat resistant as their moisture level decreases, and increased concentrations of solutes, especially sugars, increase the heat resistance of bacteria. Therefore, drying of the product surface before the pathogens are destroyed will increase pathogen heat resistance and allow them to survive the heating process. By incorporating humidity to minimize evaporation, the D values (time at a constant temperature necessary to destroy 90% or 1-log10 of the target organism) that are the basis for Appendix A and other scientific support documents remain valid (Goepfert, 1970; Goodfellow and Brown, 1978; Faith, N.G. et al. 1998). For this reason, the low humidity conditions were considered to be a plausible cause of the outbreak. The low humidity conditions were likely related to the location of the processing establishment in Albuquerque, New Mexico, which is at an elevation of greater than 4,000 feet<sup>2</sup>. As described on page 13 of the guidance, the relative humidity in the ambient (or room) air is lower at higher altitudes, which affects the relative humidity in the smokehouse chamber. Prior to the 2003 outbreak, at least six other salmonellosis outbreaks occurred in New Mexico between 1966 and 1995 suggesting the high altitude\low ambient humidity conditions in the state played a role, among other factors (CDC, 1995; Eiden, 2000). Since the 2003 outbreak, FSIS has continued to refine the guidance document based on the most upto-date science and lessons learned from FSAs. Finally, the broken link provided in the previous version of the guideline has been replaced with a functioning link to an Epidemiology Presentation from the New Mexico Department of Health

(<http://aces.nmsu.edu/ces/nmhs/documents/albanese.pdf>). Comment: One commenter questioned why the Jerky Compliance Guidelines focused on small and very small establishments. According to one commenter, small and very small meat processors in the U.S. represent 5 percent of the total meat production volume, but 95 percent of the total meat processing businesses in the U.S. 2

<http://egsc.usgs.gov/ib/pubs/booklets/elvadist/elvadist.html>", "33 This commenter suggested that the guidelines not be limited to small and very small establishments but rather should be addressed to the whole industry. Response: FSIS focused the Jerky Compliance Guidelines on small and very small establishments in support of the Small Business Administration\u2019s initiative to provide small and very small establishments with compliance assistance under the Small Business Regulatory Flexibility Act (SBRFA). However, all

FSIS regulated meat and poultry establishments may be able to apply the recommendations in this guidance. It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective HACCP systems. Although large establishments can benefit from the guidance that FSIS provides, focusing the guidance on the needs of small and very small establishments provides them with information that may be otherwise unavailable to them because of cost. For example, FSIS included growth limits for *Staphylococcus aureus* published in an ICMSF book chapter. Establishments can reference this guideline for support for the development of critical limits based on these values instead of having to purchase the costly textbook. FSIS also included an inexpensive way for establishment\u2019s to make their own wet bulb in

Attachment 3 courtesy of University of Wisconsin-Madison Center for Meat Process Validation.

2. Validation Comment: One commenter recommended FSIS postpone the release of the finalized guidance document until the finalized HACCP systems validation guidance document is released to ensure the documents are cohesive and complete. Response: This Compliance Guideline articulates how industry can meet FSIS requirements regarding jerky processing as well as FSIS recommendations to help produce a safe product based on the scientific information available in the literature. The primary focus of this guidance document is on the first element of validation: scientific support. This element includes the process of identifying scientific support documents that closely match the establishment\u2019s actual process along with identification of the critical operational parameters from the scientific support relevant to the establishment\u2019s process. FSIS is currently enforcing this element of the initial validation requirement (9 CFR 417.4(a)(1)). In addition, FSIS does not wish to delay finalizing this document because it reflects the most up-to-date science and understanding of jerky processing and addresses key issues FSIS has identified through FSAs and response to outbreak investigations. FSIS is sharing this information in a timely manner in order to help establishments produce a safe product. Comment: One commenter expressed concern with the following \u201cKey Question\u201d in the guidance document: \u201cCan an establishment\u2019s process use a different level of a critical operational parameter (for example, a higher concentration of an antimicrobial or a higher processing temperature) than what was used in the support document?\u201d. The commenter provided an example of shelf-stable jerky that has a water activity of 0.85 or less. In the example, some processors may reduce the water activity lower than 0.85 for quality issues or an extended shelf life. The commenter expressed concern that establishments would have to provide a justification for the lower water activity level chosen.\",\"34 Response: FSIS has found through FSAs that establishments use levels of critical operational parameters that are different from those in their scientific support without any consideration as to whether this will result in the same efficacy demonstrated in the scientific support. The Agency is recommending that establishments provide a scientific justification as to why the same efficacy would be achieved with a different level of a critical operational parameter. In the example provided by the commenter, an establishment could provide the justification, with reference to applicable scientific support, that pathogen growth decreases as water activity decreases, supporting that if 0.85 is adequate to preclude growth, then a lower water activity would also preclude growth of pathogenic microorganisms. Such a justification would be adequate and could be maintained in the establishment\u2019s decision-making documents as scientific support for the process

used. Comment: One commenter indicated that the guidance document is not specific enough in explaining how closely scientific support must match an establishment's process, species, or products. In addition, the commenter stated that inspection program personnel would find noncompliance with the validation regulations simply because the supporting document does not match the establishment's production precisely. Response: FSIS is not prescriptive in terms of how closely the scientific support should match the actual process. Rather, FSIS recommends that the critical operational parameters used in the scientific support be consistent with those used in the establishment's process and is providing establishments the flexibility to use different levels as long as a scientific justification is provided. FSIS inspection program personnel (IPP) verify establishment validation when performing the Hazard Analysis Verification (HAV) task. Instructions for performing the HAV task are provided in FSIS Directive 5000.6 Performance of the Hazard Analysis Verification (HAV) Task and in the HAV section of the Inspection Methods training. FSIS will issue additional instructions to its field personnel for them to verify that establishments meet all validation requirements once the FSIS HACCP Systems Validation Guidance is finalized. Comment: One commenter stated that the type of equipment used in the process should not be considered a critical operational parameter. Response: FSIS has found through FSAs that establishments use different types of equipment than that used in the scientific support without any consideration as to whether this change will result in the same efficacy demonstrated in the scientific support. The type of equipment, such as a smokehouse, could influence the ability to implement other critical operational parameters such as humidity. FSIS is recommending that establishments consider the type of equipment as a critical operational parameter so that establishments take into account whether changes in equipment affect the implementation of other critical operational parameters. This consideration should be a part of the initial set-up of the system and would not need to be done on an on-going basis unless changes to the equipment are made.

3. Step-by-step guide for jerky processing", "35

Comment: Two commenters stated that Steps 2 (Marination) and 3 (Interventions) in the 2007 and 2012 versions of the guidance are not commonly used steps in the industry. Response: FSIS recognizes that not all processes may include the same steps listed in the step-by-step guide. FSIS included steps such as intervention in the guidance because some heating processes may not deliver an adequate lethality and, thus, may require an additional intervention step to ensure product safety. To more accurately reflect commonly used processing steps, FSIS has included the surface preparation step (now Step 4) in the guidance, which is a commonly used step in which strips are heated using a low temperature heat step to make the surface tacky, thus aiding in smoke adherence and improving product texture.

Comment: Two commenters stated that steps 5 (drying) and 6 (post-drying heat step) in the 2007 and 2012 versions of the guidance should be combined because they are often performed as single step by processors. Response: Although the steps may be combined, in a processing schedule, for example, these steps are listed separately for purposes of the guidance document to provide information to establishments on the use of a post-drying heat step for processes that do not result in an adequate reduction of *Salmonella* through the initial heating process. Adding a post-drying heat step has the potential to reduce *Salmonella* levels by approximately  $2\text{-log}_{10}$ s from the level of reduction achieved during initial heat step.

4. Lethality treatment

Comment: One commenter questioned the recommendation that the lethality treatment of meat jerk should

achieve at least a 5.0-log10 reduction of *Salmonella* spp. when there is no USDA\FSIS performance standard specifically for this product. Response: Jerky producers (and all producers of RTE product) are required to control the food safety hazards in their products (9 CFR 417.4(a)) and document that their HACCP systems work according to 9 CFR 417.5(a). For RTE products, this requirement means that, among other controls, the establishment needs to achieve lethality of pathogens (e.g., *Salmonella*) in the product. In the FSIS *Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products, FSIS recommends that processors achieve a 5log10 reduction of *Salmonella* in such meat products as jerky to produce a product safe for consumption. This recommendation is based on expected levels of *Salmonella* in raw products. The compliance guideline also provides alternative forms of lethality that establishments may use. Establishments producing a RTE product must provide adequate scientific support that the process for the RTE product will not result in an adulterated product. In addition, FSIS tests ready-to-eat product for *Salmonella* (as well as *Listeria monocytogenes*) to verify that establishments are addressing the pathogen.

5. Highly pathogenic avian influenza Comment: Two commenters disagreed with the following statement: \u201clf highly pathogenic avian influenza (HPAI) virus H5N1 is identified as a hazard reasonably likely\,"36 to occur, cured and smoked poultry should be cooked to at least 158\u00b0F or a time and temperature combination that achieves a 7-log reduction of *Salmonella*.\u201d The commenters stated that if this statement is included in this guidance document, establishments will now have to reassess all their HACCP plans if inspection personnel interpret it as a requirement. Response: This statement has appeared in previous versions of the jerky compliance guidance document. The Agency has not required establishments to reassess their HACCP plans for highly pathogenic avian influenza and does not intend to do so at this time. This information has been included as guidance in the event that an establishment identifies HPAI virus H5N1 as a hazard reasonably likely to occur.

6. Humidity Comment: One commenter disagreed with the following statement: \u201cOne way for an establishment to know that the product has not dried out before a lethal timetemperature combination is attained is to measure the water activity of the product after the lethality treatment but before drying.\u201d The commenter stated that this is not necessary if the humidity requirements are achieved. The commenter also said the guideline should clearly state that lethality should be achieved prior to drying the product to achieve desired quality and water activity for shelf stability. Response: FSIS has added the following clarifying information: \u201cAlthough this information may provide useful information to an establishment, such data are not needed if an establishment is following procedures to achieve the relative humidity in the scientific support.\u201d

Comment: One commenter disagreed with statements in the guidance document that establishments should monitor humidity throughout the entire lethality treatment. The commenter stated that establishments could conduct some sort of 90-day validation of their thermal processing schedules to achieve confidence that humidity was properly addressed. Response: As stated on page 13, FSIS recommends that establishments monitor relative humidity using wet and dry bulb thermometers or a humidity sensor with every lot or batch of product although FSIS does not require this monitoring frequency. It is the responsibility of the establishment to support its monitoring procedures and frequencies. However, inadequate or inaccurate recordkeeping (e.g., data entry error or unclear monitoring records) has contributed to jerky product recalls,

particularly when such records were associated with a lack of information regarding the implementation of all of the critical operational parameters for each batch or lot produced.

Comment: One commenter recommended that FSIS remove the following statement related to Appendix A: \u201clf an establishment cannot apply these humidity options for equal to or more than one hour, then the humidity of the oven should be maintained at 90% or above throughout the lethality treatment.\u201d Response: The option in Appendix A that allows for humidity levels less than 90% is as follows:

\u201cHeating roasts of any size to a minimum internal temperature of 145 \u00b0F (62.8 \u00b0C) in an oven maintained at any temperature if the relative humidity of the", "37 oven is maintained either by continuously introducing steam for 50 percent of the cooking time or by use of a sealed oven for over 50 percent of the cooking time, or if the relative humidity of the oven is maintained at 90 percent or above for at least 25 percent of the total cooking time, but in no case less than 1 hour.\u201d The final clause \u201cbut in no case less than 1 hour\u201d means that the humidity options of continuously introducing steam or sealing the oven should be applied for at least 1 hour. FSIS recognizes that jerky is a small mass product that often has total cooking times of less than 1 hour. Appendix A, and that the additional humidity options were originally designed for large mass products with longer cooking times. In cases where these humidity options can not be applied for at least 1 hour, the establishment should apply at least 90% humidity throughout the cooking time (even if the cooking time is less than 1 hour) in order to use Appendix A as scientific support and to ensure product reaches a lethal temperature and does not dry out before lethality is achieved.

Establishments have flexibility to use other scientific support if they are unable to meet the critical operational parameters. FSIS clarified this issue in the guidance. Comment: FSIS received one question through askFSIS inquiring whether reference to the cooking time in the humidity options in Appendix A refers to the entire cooking time (including come up time) or just the time during which the temperature in Appendix A is achieved and maintained (e.g., 145\u00b0F for 4 minutes). Response: As stated on page 7, the cooking time (also referred to as the lethality treatment) includes the time when the thermal processing begins (e.g., the product is placed in the heated oven) until the time the product reaches the desired lethality time-temperature combination from Appendix A. Therefore, if an establishment is applying humidity by continuously introducing steam for 50% of the cooking time, but in no case less than 1 hour, 50% of the cooking time should be calculated based on the total cooking time, not just the time during which the temperature in Appendix A is achieved and maintained. If humidity is not applied early in the process, evaporating water will absorb the heat and a lethal temperature will not be achieved. Comment: One commenter disagreed with the statement:

\u201cEstablishments using the option to continuously inject steam should also have a procedure or mechanism in place to ensure that steam is being continuously injected\u2026.\u201d The commenter indicated that smokehouses do not operate this way, and that if a program is set for 40% relative humidity, the smokehouse may spray water on the heating element to achieve this 40% relative humidity. If the smokehouse reads that the house has, for example, 50% relative humidity, it will stop spraying water on the heating elements and the dampers will fluctuate to achieve the desired 40% relative humidity in the smokehouse.

Response: FSIS recognizes that steam may be turned on and off throughout the cooking time when the target humidity is reached and has included this approach in the guideline. Some of the supporting documentation that can be used to demonstrate that steam is being

\u201ccontinuously introduced\u201d is illustrated in Attachment 4. 7. Ambient vs. smokehouse temperatures Comment: One commenter requested further explanation of the effects of ambient temperature on the smokehouse or oven temperatures. The commenter also", "38 requested that FSIS acknowledge that smokehouses\ovens cannot be completely sealed. Response: FSIS has provided additional information on page 12 regarding the role relative humidity in the ambient air plays on the relative humidity in the smokehouse or oven. FSIS has also provided clarification on page 21 that, even when a tight seal is obtained, some loss of humidity is the form of minor smoke or vapors may be seen. 8. Reference to International Commission on Microbiological Specifications in Foods (ICMSF) (1996) Microorganisms in Foods 5 Comment: Two commenters expressed concern that establishments will use the ICMSF book chapter in place of Appendix A. Response: The only reference to the ICMSF book made in this guidance document is provided as support for finished water activity limits in order to support product shelf-stability. It would not be acceptable for an establishment to cite the water activity critical limits or the ICSMF book chapter as support for a lethality or drying process because meeting a specific water activity level does not support that a 5-log<sub>10</sub> reduction is achieved. In general, establishments should not use finished product water activity levels alone as support that a product is RTE. The reason is that low water activity alone, without a further heat treatment, would not necessarily result in adequate reduction of *Salmonella* because the pathogen is known to be resistant to drying. This issue has been clarified and addressed in this guidance on page 15. Comment: One commenter stated that FSIS should not provide specific guidance on water activity values that can be used to support shelf-stability by an establishment within the guidance. The commenter indicated if FSIS provides one specific number in any guidance document, industry or FSIS may consider the guidance a requirement. Response: FSIS has found through askFSIS questions and FSAs that establishments are not maintaining adequate scientific support that products are shelfstable. Therefore, water activity values are provided as guidance to provide small and very small establishments with compliance assistance under SBRFA. However, establishments have flexibility in terms of selecting and supporting the critical limits of their process and are not required to use the limits provided. FSIS has made clear that this document is guidance and is not establishing new requirements (see page 2) Comment: One commenter requested a rationale for the guidance provided on water activity limits to support shelf-stability for products packaged under aerobic and anaerobic conditions because the limits are different than those in the ICMSF book chapter. The commenter also pointed out that the citation for the ICMSF book chapter referenced the wrong page. Response: The water activity limits of 0.85 under aerobic conditions and 0.91 under anaerobic conditions provided in this document are based on the definition of shelf-stability in the guidance on page 15 and the growth limit of *Staphylococcus aureus* in the ICMSF Book chapter (Page 304 Table B). The definition of shelf-stability in the guidance is stated as the \u201ccondition achieved when meat and poultry products can be", "39 stored under ambient temperature and humidity conditions; if the package integrity is maintained during storage, shipping, and display at retail and in the home; and the product will not spoil or become unsafe throughout the manufacturer\u2019s specified shelflife. \u201c Under this definition, no growth of pathogenic organisms occurs. According to the ICMSF book chapter, the limit of growth for *Staphylococcus aureus* is 0.83 under aerobic conditions and 0.90 under anaerobic conditions. However, as noted in the footnote of the book, this criterion

is based on optimal conditions. FSIS recognizes that most jerky type products have other intrinsic factors such as sodium nitrite, indigenous microflora, and salt concentration that would also act as barriers to *Staphylococcus aureus* growth. By considering these factors, FSIS has recommended an upper limit of 0.85 under aerobic conditions or 0.91 under anaerobic conditions. This rationale is now provided in the guidance document. The guidance document also now clarifies that these factors may be used to consider a product stable provided the establishment takes steps to prevent mold growth on the finished product. Finally, FSIS revised the reference to include the page number of the specific table containing these values.

Comment: One commenter expressed concern that the ICMSF book chapter used as the reference for the limits of growth of *Staphylococcus aureus* under aerobic and anaerobic conditions does not contain microbiological data supporting the limits. Response: FSIS considers information found in textbooks and other scientific texts as acceptable scientific support because this type of scientific data goes through a process of evaluation involving qualified individuals within the relevant field. Often textbooks and other scientific texts contain a summary of information based on other peer-reviewed published research, as is the case with the ICMSF book. In the case of the water activity values provided in this guidance, establishments can refer to the guidance and are not required to provide a copy of the ICMSF book chapter or the original research referred to in the book because this guidance document contains the critical operational parameter (water activity).", "This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process. 40

Attachment 2: Time, temperature, and humidity combinations reported in the literature for beef jerky that achieve at least a 5-log<sub>10</sub> reduction in *Salmonella* and *E. coli* O157:H7. Unless noted, finished product water levels were \u2264 0.85. Reference Product Marinated (Yes\No) Smoke Added (Yes\No) Oven Temperature (\u00b0F) Time (min) Humidity (%) Log10 Reduction

Salmonella *E. coli* O157:H7 Buege et al. (2006a) 3 Whole muscle beef jerky Yes \u2013 pH 5.3 No Type 1-A\* Stage 1 \u2013 145 170 Stage 2 \u2013 Choose either: dry bulb at 170 and wet bulb at 125 OR dry bulb at 170 and wet bulb at 130\2020 OR dry bulb at 170 and wet bulb at 135\2020 OR dry bulb at 170 and wet bulb at 140\2020 Stage 3- Dry at 170 dry bulb 15 15 at least 60 at least 60 at least 30 at least 10 to targeted doneness 27 32 37 43 6.5 6.9 7.0 6.9 6.9 7.1 7.1 7.1 3 Buege, D.R., Searls, G., and Ingham, S.C. 2006. Lethality of commercial whole-muscle beef jerky manufacturing processes against *Salmonella* Serovars and *Escherichia coli* O157:H7. Also see the following website for a more detailed, user-friendly critical limit summary document:

[http://www.meathaccp.wisc.edu/validation/assets/CLSummary\\_WMJerkyJune2013.pdf.](http://www.meathaccp.wisc.edu/validation/assets/CLSummary_WMJerkyJune2013.pdf.)," This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process. 41 Reference Product Marinated (Yes\No) Smoke Added (Yes\No) Oven Temperature (\u00b0F) Time (min) Humidity (%) Log10 Reduction Salmonella *E. coli* O157:H7 Buege et al. (2006a) Whole muscle beef jerky Yes \u2013 pH 5.3 No Type 1-B\*\u2020 Stage 1 \u2013 145 Then choose either: Stage 2 \u2013 dry bulb at 150 THEN dry bulb at 150 and wet bulb at 130; THEN dry bulb at 150 OR Stage 2- dry bulb at 190 THEN dry bulb at 190 and wet bulb at 130; THEN dry bulb at 190 15 15 60 to targeted doneness 15 60 to targeted doneness 56 19 6.8 7.1 7.0 7.3 Yes \u2013 pH 5.3 No Type 2\*\*\u2020 145 170 15 to targeted doneness 27-

31(start)\*\*\* 17-21(end) 6.3 6.0","This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process. 42 Reference Product Marinated (Yes\No) Smoke Added (Yes\No) Oven Temperature (\u00b0F) Time (min) Humidity (%) Log10 Reduction Salmonella E. coli O157:H7 Buege et al. (2006a) Whole muscle beef jerky Yes \u2013 pH 5.3 No Type 3\*\*\u2020 145 170 90 to targeted doneness 41(start)\*\*\* 21(end) 5.5 5.6 Yes \u2013 pH 5.3 No Type 5\*\* 180 to targeted doneness 29(start)\*\*\*\* 15(end) 5.1 5.6 \*Type 1-A and Type 1-B processes with a higher dry bulb temperature in Stage 1, a higher wet bulb temperature or longer time in Stage 2, or a higher dry bulb temperature in Stage 3, as long as other parts of the process are not changed, can also be considered validated because they should have greater lethality. \*\*Processes reaching higher dry bulb temperatures in either stage can also be considered validated because they would have greater lethality. \*\*\*Humidity values are from Table 3 in Buege et al. (2006a). \*\*\*\*Humidity values are from Table 5 in Buege et al. (2006a). \u2020Finished product water activity level was > 0.85 (if an establishment wants to support the product is shelf-stable using 0.85 as a criteria, it should consider further drying the product). Oven: Pans of water were placed on the lowest rack in the smokehouse, and a low fan speed was used. Humidity (steam or water) was introduced in Type 1-A and 1-B processes. Study did not indicate whether dampers were open or closed.", "This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process. 43 \*\*Processes reaching higher dry bulb temperatures in either stage can also be considered validated because they would have greater lethality. \*\*\*Humidity values are from Table 3 in Buege et al. (2006a). \u2020Finished product water activity level was > 0.85 (if an establishment wants to support the product is shelf-stable using 0.85 as a criteria, it should consider further drying the product). Oven: Pans of water were placed on the lowest rack in the smokehouse, and a low fan speed was used. Humidity (steam or water) was introduced in Type 1-A and 1-B processes. Study did not indicate whether dampers were open or closed. Reference Product Marinated (Yes\No) Smoke Added (Yes\No) Oven Temperature (\u00b0F) Time (min) Humidity (%) Log10 Reduction Salmonella E. coli O157:H7 Buege et al. (2006a) Whole muscle beef jerky Yes \u2013 pH 5.3 No Type 7\*\*\u2020 120 130 140 170 60 60 60 60 43\*\*\* 15 6.0 5.6", "This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process. 44 \*Oven temperatures are average of continuous readings taken every 30s after CUT. \u2020Finished product water activity level was > 0.85 (if an establishment wants to support the product is shelf-stable using 0.85 as a criteria, it should consider further drying the product). Oven: Dampers were completely open. 4 Porto-Fett, A.C.S., Call, J.E., and Luchansky, J.B. 2008. Validation of a commercial process for inactivation of Escherichia coli O157:H7, Salmonella Typhimurium, and Listeria monocytogenes on the surface of whole muscle beef jerky. Journal of Food Protection. 71(5): 918-926. Reference Product Marinated (Yes\No) Smoke Added (Yes\No) Oven\Product Temperature (\u00b0F)\* Time (hours) Humidity (%) (Start\End) Log10 Reduction (cfu\strip) Salmonella E. coli O157:H7 Porto-Fett et al. (2008)4 Whole muscle beef jerky Yes \u2013 ~pH 5.5 Yes 178 1.5 63.4 21.9 \u22657 \u22657\u2020 Whole muscle beef jerky No Yes 178 1.5 63.4 21.9 \u22657 \u22657\u2020 Whole muscle beef jerky Yes \u2013 ~pH 5.5 Yes 178.3 2.5 63.8 21.5 \u22657

\u22657 Whole muscle beef jerky No Yes 178.3 2.5 63.8 21.5 \u22657 \u22657\u2020 Whole muscle beef jerky Yes \u2013 ~pH 5.5 Yes 178.5 3.5 62.3 19.2 \u22657 \u22657 No Yes 178.5 3.5 62.3 19.2 \u22657 \u22657", "This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process. 45 \*Humidity levels were calculated from actual dry and wet bulb temperatures reported in Getty et al. (2006):

[http://www.fsis.usda.gov/wps/wcm/connect/35151cb4-1603-4164-b71f-bfea44e487e8/C12\\_New\\_Technology\\_FY2004\\_Final\\_Report.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/35151cb4-1603-4164-b71f-bfea44e487e8/C12_New_Technology_FY2004_Final_Report.pdf?MOD=AJPERES). Although the report states that humidity remained at less than 10% throughout the entire smokehouse cycle, humidity levels calculated from dry and wet bulb temperatures in the report were higher, as indicated in the table. This was verified through personal communication with the author [April 2011]. Oven: Automated dampers and steam injection. 5 Harper, N.M., Roberts, M.N., Getty, K.J.K., Boyle, E.A.E., Fung, D.Y.C., Higgins, J.J. 2009. Evaluation of two thermal processing schedules at low relative humidity for elimination of Escherichia coli O157:H7 and Salmonella Serovars in chopped and formed beef jerky. Journal of Food Protection. 72: 2476-2482. 6 Getty, K.J.K., Boyle, E.A.E., Roberts, M.N., Lonneker, S.M. 2006. Jerky Validation for Small and Very Small meat and Poultry Businesses: Final Report. Available at:

[http://www.fsis.usda.gov/wps/wcm/connect/35151cb4-1603-4164-b71f-bfea44e487e8/C-12\\_New\\_Technology\\_FY2004\\_Final\\_Report.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/35151cb4-1603-4164-b71f-bfea44e487e8/C-12_New_Technology_FY2004_Final_Report.pdf?MOD=AJPERES). Accessed 17 August 2013. Reference Product Marinated (Yes\No) Smoke Added (Yes\No) Oven Temperature (\u00b0F) Time (min) Humidity (%)\* Log10 Reduction Salmonella E. coli O157:H7 Harper et al. (2009),5 Getty et al. (2006)6 Chopped and formed beef jerky No No (smoke flavor was added) Stage 0 \u2013 Stage 1 \u2013 132 Stage 2 \u2013 132 Stage 3 \u2013 132 Stage 4 \u2013 172 Stage 5 \u2013 172 Stage 6 \u2013 172 Stage 7 \u2013 172 Stage 8 \u2013 172 Stage 9 \u2013 172 Stage 10 \u2013 172 Stage 11 \u2013 172 Stage 12 \u2013 172 14 16 14 16 14 16 14 16 14 16 14 5 h 32.6 52 14.5 22 22 22 22 22 22 22 22 22 7.1 7.1", "This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process. 46 \*A spice rub mix was used. Two types of spice mixes (Colorado and BBQ) were used in the study. Results for one type of spice mix (Colorado) are reported here. Variability in lethality was found due to spice mix type. See Borowski et al. (2009a) for details on the spice mixes used including pH and aw values and results for products prepared with the BBQ spice mix. \*\*%RH values are approximate based on an average of the range of actual dry and wet bulb temperatures provided in the article. RH values reported as ND were not determined. NOTE: All processes reported here used a commercial oven-smokehouse. Oven: Dampers were open for processes without smoke added. 7 Borowski, A.G., Ingham, S.C., Ingham, B.H. 2009. Validation of ground-and-formed beef jerky processes using commercial lactic acid bacteria starter cultures as pathogen surrogates. Journal of Food Protection. 72(6): 1234-1247. Reference Product Marinated (Yes\No) Smoke Added (Yes\No) Oven Temperature (\u00b0F) Time (min) Humidity (%)\*\* Log10 Reduction Salmonella E. coli O157:H7 Borowski et al. (2009a)7 Groundand-formed beef jerky No\* No No No Type 2-A 170 130 170 30 120 90 57 22 28 7.4 7.4 Groundand-formed beef jerky No\* No No No Type 3-A 170 170 170 30 15 130 7 23 ND 6.1 6.8 Groundand-formed beef jerky No\* No No Type 4-A 135 185 90 150 67 9 7.8 8.1", "This Attachment is not considered adequate support on its own because it does not provide the

details of each study an establishment needs to determine if the study is representative of the actual process. 47 \*\*A spice rub mix was used. Two types of spice mixes (Colorado and BBQ) were used in the study. Results for one type of spice mix (Colorado) are reported here. Variability in lethality was found due to spice mix type. See Borowski et al. (2009a) for details on the spice mixes used including pH and aw values and results for products prepared with the BBQ spice mix. \*\*%RH values are approximate based on an average of the range of actual dry and wet bulb temperatures provided in the article. RH values reported as ND were not determined. NOTE: All processes reported here used a commercial oven-smokehouse. Oven: Dampers were open until smoke was added at which point dampers were closed. 8 Smoke added after 30 min. 9 Smoke discontinued after 90 min. Reference Product Marinated (Yes\No) Smoke Added (Yes\No) Temperature (\u00b0F) Time (min) Humidity (%)\*\* Log10 Reduction Salmonella E. coli O157:H7 Borowski et al. (2009a) Groundandformed beef jerky No\* Yes Yes Yes Type 2-B 170 130 170 30 120 90 32 ND ND 7.2 7.4 Groundandformed beef jerky No\* No No Yes Type 3-B 170 170 170 30 15 130 7 39 ND 7.3 7.4 Groundandformed beef jerky No\* Yes8 Yes9 Type 4-B 135 185 90 150 68 ND 7.5 7.5","This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process. 48 NOTE: The process reported here used a commercial oven-smokehouse. Oven: No humidity control. Study did not indicate whether dampers were open or not. 10 Harrison, M. A., R. K. Singh, J. A. Harrison and N. Singh. 2006. Antimicrobial intervention and process validation in beef jerky processing. Final Report. Available at:

[http://www.fsis.usda.gov/wps/wcm/connect/8dd0f238-08d7-4ca0-a31a-77fa3ca8acf6/C-17\\_New\\_Technology\\_FY2004\\_Final\\_Report.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/8dd0f238-08d7-4ca0-a31a-77fa3ca8acf6/C-17_New_Technology_FY2004_Final_Report.pdf?MOD=AJPERES). Accessed 17 August 2013. Reference Product Marinated (Yes\No) Smoke Added (Yes\No) Oven Temperature (\u00b0F) Time (hours) Humidity (%) Log10 Reduction Salmonella E. coli O157:H7 Harrison et al. (2006)10 Beef jerky strips Yes No 143.6 8-9 33 >6 >6","49 Attachment 3: Making Your Own Wet Bulb Thermometer (Reprinted with permission) By G. Burnham, S.C. Ingham and B.H. Ingham University of Wisconsin-Madison Center for Meat Process Validation If you are smoking or drying meat, there are several parameters to monitor which will help you control your process: dry bulb temperature, wet bulb temperature, and relative humidity. Research at the University of Wisconsin Center for Meat Process Validation has shown that monitoring wet bulb temperature is even more important (and much easier!) than monitoring product temperature during your process. Since wet bulb temperature is critical to process monitoring, this document describes how to easily, and perhaps inexpensively, construct a wet bulb thermometer. Dry bulb temperature, usually referred to as air temperature, is the smokehouse\oven property that is most commonly measured by jerky-makers. When people refer to the temperature (heat content) of the air, they are normally referring to the dry bulb temperature. It is called \"dry bulb\" because the air temperature is indicated by a thermometer that is not moistened and will not be affected by evaporative cooling. Wet bulb temperature is the temperature indicated by a moistened thermometer bulb exposed to air. A wet bulb thermometer measures the extent of cooling that happens as moisture dries from a surface (evaporative cooling). The wet bulb temperature is always lower than the dry bulb temperature except when there is 100% relative humidity. Because evaporative cooling occurs on the surface of thin jerky strips, the wet bulb temperature is more accurate measurement of

product temperature. We developed a wet bulb thermometer (WBT) which is easy to assemble and economical for a meat processor to use. To begin assembling a wet bulb thermometer, you will need to determine what type of temperature measuring device you will use. You will need to use a temperature recorder with a \u201ctip reading\u201d probe\u201c/wire\u201d/stem. Either an instant read or a data-logging temperature measuring device will work; both are pictured in image 1. A - 3 styles of \u2018instant read\u2019 temp- A B 1 erature measuring device B - a data logger-style of temp- erature measuring device In each case, the \u2018tip reading\u2019 probe\u201c/wire is circled. Instant read temperature recorders. (A) An instant read temperature Recorder will offer immediate feedback, with the temperature displayed on the front of the unit. However, data may not be recorded with this type of unit; the processor must record the data periodically. See page 51 for more information on ordering instant-read temperature recorders.", "50 A data logger-style temperature recorder. (B) This type of device keeps track of, or \u2018logs\u2019 temperature over a period of time. An inexpensive data logger usually does not offer immediate readout of data. A processor must connect the data logger to a computer to view the temperature data. A data logger does, however, offer a continuous record of temperature history which can be important for HACCP documentation. See page 51 for information on ordering a standard data logger. Once you have your temperature recorder, you will need to choose material to serve as the \u201cwick\u201d to cover the tip probe. Water evaporating from the wick will reduce the temperature recorded, giving an indication of evaporative cooling. The wick should be made from an absorbent material, preferably cotton. It should also be constructed of two phases: a loose, absorbent interior, and an exterior that is of an absorbent tighter meshing material. The exterior keeps the inner absorbent material around the sensing portion of the temperature probe and prevents the sensing portion of the recorder from being exposed to direct ambient conditions. You may wish to purchase wicks commercially, such as from an online supplier

(<http://www.wickstore.com/wetbulbwick.html>), or a good substitute is a round cotton bootlace (image 2). See page 51 for more information on supplies for a wet bulb thermometer. There are several simple steps to setting up a wet bulb thermometer. 1. Gather materials. You will need a vessel for holding water which must either be refilled during processing, or must be sufficiently large to hold enough water (allowing for evaporation) to keep the water level close to the temperature probe. Choosing a vessel with a small diameter opening will reduce evaporation. Once a water vessel has been chosen, simply fill it with water. You will also need a temperature measuring device and material to serve as a wick. In image 3, the bottom of a soda bottle 2 and a glass beaker are pictured as vessels. 3 Both an instant read and a data logger are shown for measuring temperature and pieces of brown cotton shoelace serve as the wick. 2. Assemble the wet bulb thermometer. Cut a portion of the wicking material (it should be long enough to reach the bottom of the water vessel and than some). Connect the sensing portion of your temperature recorder to the wick by inserting the probe\u201c/wire\u201d/stem into the center of the wick (image 2). Secure the end of the wick to the probe\u201c/wire\u201d/stem using tape. 4 Place the wick in the water-containing vessel. Make sure the wick is completely", "51 saturated with water, then position the wick-covered sensing portion of your temperature recorder so that it is completely exposed to ambient conditions, yet as close as possible to the water source (image 4). This will ensure adequate wicking of the water to the sensing portion of the temperature recorder. If exposure to ambient conditions is too great, such as when the wick is too long or

the recorder too far from the water surface, the wick may dry out, and evaporative cooling will not be recorded. 3. Place the wet bulb thermometer inside the chamber. If you are using an instant reading temperature measuring device to make process adjustments, place the wet bulb thermometer for easy access and readability, such as near a door or window (image 5). If immediate feedback is not a consideration (image 6), place the device where the ambient conditions of your process are least likely to give you optimum conditions 5 - hence a \u201cworst case\u201d reading. Position the wet bulb thermometer in a flow of air (such as in a stream of incoming air), but away from fans which will cause excessive evaporation and drying of the wick. 4. Record wet bulb temperature. Establish a regular schedule of recording or down-loading wet bulb temperature. Check water level in the vessel periodically, and also check the position of the wick. The portion of the wick above the water must remain moist for accurate temperature measurement. The wet bulb temperature can be used to adjust your process conditions, as needed. Supplies for Making a Wet Bulb Thermometer\* Instant Read Temperature Recorders Fisher Scientific (800-766-7000) \u2022 Part 15-078-38; price \$131.49 plus shipping \u2022 Part 15-077-14; price \$111.15 plus shipping Data Logger-Type Temperature Recorders Dickson Company (800-323-2448) \u2022 Part SM325 (LCD Display Temperature Data Logger w/\ 2 K-thermocouple probes); price \$399 plus shipping \u2022 Also order software to download information to computer (\$79) Wick Material \u2022 Round cotton bootlace (pictured in this document) - available at many general stores \u2022 Wet-bulb wick (\$50-\$60 per spool <http://www.wickstore.com/wetbulbwick.html>) 6","52 \u2022 Wet-bulb sock: Alkar, part #50040; price \$127.00 for bundle of 100 (608-592-4865) \*The items and suppliers listed here are suggestions only, based on price and availability. The mention of particular suppliers is not meant to exclude others from consideration. For more information contact: Steve Ingham, Extension Food Safety Specialist (608) 265-4801, scingham@wisc.edu May, 2006 The University of Wisconsin-Madison Center for Meat Process Validation provides science-based HACCP support to small meat processors in meeting state and federal mandates for safe food processing and handling. For more information on the Center contact Dr. Steve Ingham, 1605 Linden Drive, UW-Madison, Madison, WI 53706 (608) 265-4801 Email: scingham@wisc.edu", "Cooking Program and Recorder Chart Courtesy of: Dr. Jeff J. Sindelar; Meat Science & Muscle Biology Lab, University of Wisconsin-Madison & Robert Hanson; HansonTech, LLC 53 Attachment 4: Example Time-Temperature Recorder Chart to Support Option to Continuously Inject Steam The chart on the next page illustrates and supports that steam is being continuously introduced into the smokehouse for at least 50% of the cooking time but in no case for less than one hour per Appendix A. The smokehouse schedule is provided for reference below. As can be seen on the recorder chart, during the cooking time (that is the first hour of the process), the wet bulb rises while humidity (in the form of steam) is continuously injected. The process eventually achieves and maintains a wet bulb of 150oF, which at a dry bulb temperature of 170oF equates to a relative humidity of 59%. The process targets an internal product temperature of 145oF for 4 minutes per Appendix A. Cooking program for beef jerky Stage Type Time Dry Bulb Wet Bulb Dampers Notes 1 Cook 60 min 170oF 150oF Closed Humidity continuously injected 2 Dry 120 min 150 --- Closed 3 Dry 80 min (to aw) 150 --- Open In addition to supporting that steam is being continuously introduced, the chart provides a good illustration of why wet bulb temperature is a better indicator of product internal temperature than dry bulb temperature. As can be seen on the chart, the product

internal temperature (shown by the yellow line), follows the wet bulb temperature (shown by the blue line) more closely than the dry bulb temperature (shown by the dark red line) during the lethality treatment. Towards the end of the process, the product internal temperature breaks above the wet bulb temperature and rises towards the dry bulb temperature as a result of diminishing evaporative cooling of the jerky that occurs because the product is drying out (i.e., moisture has been lost) (Buege et al., 2006a).", "Cooking Program and Recorder Chart Courtesy of: Dr. Jeff J. Sindelar; Meat Science & Muscle Biology Lab, University of Wisconsin-Madison & Robert Hanson; HansonTech, LLC 54 Temperature profile for beef jerky process during cooking and drying Sliced whole muscle beef jerky, 0.125\" thick 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 0 1 2 3 4 5 time (hr) Temperature (F) DryBulb Temperature WetBulb Temperature Jerky Temperature Stage 1. Wet-surface lethality step. Steam is continuously injected from the beginning of the process to achieve and maintain a wet bulb of 150oF. Stage 2. Jerky dried with sealed intake\exhaust dampers. Wet bulb temperature slowly decreases from 140 to 130oF. Evaporative cooling causes the jerky temperature to closely follow the wet-bulb temperature. Stage 3. Intake and exhaust dampers are opened and wet bulb temperature drops. Drying accelerates and jerky temperature breaks above the wet bulb temperature."], {"file\_name": "FSIS\_GD\_2014\_0011", "title": "Compliance Guidelines for Shiga toxin Escherichia coli (STEC) Organisms Sampled and Tested Labeling Claims for Boneless Beef Manufacturing Trimmings (\u201cBeef Trim\u201d)", "num": "FSIS-GD-2014-0011", "id": "0181dd3bec74885e8af19d08695d33ffb28cf30e8a799ff24e82fb8351d50a00", "corp\_us": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Compliance-Guide-Ecoli-Tested-Claims.pdf", "type": "pdf", "n\_pages": 8, "word\_count": 2829, "text\_by\_page": ["Compliance Guidelines for Shiga toxin Escherichia coli (STEC) Organisms Sampled and Tested Labeling Claims for Boneless Beef Manufacturing Trimmings (\u201cBeef Trim\u201d) August 2014 I. Purpose of the Labeling Guidance This document provides guidance on the use of labels bearing an FSIS sketch approved Shiga toxin-producing Escherichia coli (STEC) sampled and tested claim on beef trim. Such special labeling claims are voluntary. An establishment may use such claims when it demonstrates that they are truthful and not misleading (9 CFR 317.8(a)). FSIS must approve such claims before the establishment may use them on labels (9 CFR 412.1). The labeling guidance provided in this document applies to beef slaughter\fabrication establishments, although it\u2019s likely to be most useful to those that manufacture 50,000 pounds or more of trimmings daily and conduct lot by lot testing. II. Background On October 14, 2008, FSIS issued draft guidance entitled \u201cLabel Policy Guidance for N-60 Testing Claims for Boneless Beef Manufacturing Trimmings (\u201cTrim\u201d) Concerning E. coli O157:H7,\u201d and requested comments on the document. FSIS also held a public meeting to discuss the guidance and other topics concerning E. coli O157:H7. A second version of this document, published in May 2012, was revised in response to the comments on the draft guidance. The current version was updated to reflect the Agency\u2019s recent policy developments regarding non-O157 STEC. Since FSIS issued this compliance guideline for comments in May 2012, FSIS began testing beef manufacturing trimmings for six non-O157 STEC (O26, O45, O103, O111, O121, and O145) in addition to E. coli O157:H7. FSIS also declared these six non-O157 STEC adulterants in raw, non-intact beef products and product components."]}]

(<http://www.fsis.usda.gov/wps/wcm/connect/6aa26172-2d27-4534-99d48c528b285fd2/2010-0023.pdf?MOD=AJPERES>). Additionally, FSIS updated the Compliance Guideline for E. coli O157:H7 Sampled-and-Tested Claims for Boneless Beef Manufacturing Trim to recognize that establishments may want to submit a request for a labeling claim stating that product has been tested for the six additional STEC adulterants. FSIS clarified that it would need to see the same type of information to approve sampled and tested claims for the other adulterant STEC as it would need to see for sampled and tested claims concerning E. coli O157:H7. FSIS has developed the following guidance for establishments that wish to use a label claim asserting that beef trim has been sampled, tested, and found negative for E. coli O157:H7, adulterant non-O157 STEC or a general claim for all STEC. This label claim is intended to provide receiving establishments with information regarding the sampling and testing of beef trim for STEC organisms conducted by supplier establishments. FSIS may approve claims of this type if supported by adequate information.", "Compliance Guidelines for Shiga toxin Escherichia coli (STEC) Organisms Sampled and Tested Labeling Claims for Boneless Beef Manufacturing Trimmings (\u201cBeef Trim\u201d) 2 A label claim that beef trim comes from a production lot that has been sampled, tested, and found to be negative for STEC will be helpful for receiving establishments because Certificates of Analysis (COAs), which also provide sampling and testing information, frequently do not properly transfer with beef trim product through the distribution chain. This guidance document addresses label claims that are not intended to be displayed to consumers. FSIS may approve STEC sampled and tested claims on trim that goes to retail stores, for example to a retailer who purchases the trim for grinding. However, FSIS will not approve such a label claim for display to consumers because it may be misleading to consumers by suggesting that the end product is free of the pathogens or may not need to be cooked thoroughly. A negative test for STEC does not guarantee that all of the beef trim from the sampled production lot is free of the pathogens. Such assurance cannot be provided by sampling and testing. Rather, sampling and testing for STEC is intended to provide evidence regarding the effectiveness of Hazard Analysis and Critical Control Points (HACCP) measures related to the prevention, elimination, and reduction of the pathogens. A sampled and tested claim is meaningless \u2013 and therefore misleading \u2013 if the establishment asserting the claim has not incorporated into its HACCP system measures designed to control for STEC, and if the sampling and testing methodologies used are not designed to verify the effectiveness of those measures. Therefore, for FSIS to determine that a label claim that beef trim has been sampled, tested, and found negative for STEC is truthful and not misleading, the establishment requesting to make the claim would need to submit evidence demonstrating that its HACCP measures related to STEC are effective in reducing the pathogens to non-detectable levels, and that the results of the establishment\u2019s sampling and testing demonstrate that those HACCP measures are effective. To demonstrate that a labeling claim would be truthful and not misleading, FSIS would accept documentation showing that an establishment uses the FSIS sampling and testing methods or equivalent methods. The FSIS sampling method for beef trim is described in FSIS Directive 10,010.1. Additionally, relevant sampling program guidance, including a discussion of High Event Period criteria, is provided in the document \u201cCompliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers.\u201d The method of analysis should be equivalent to that of the current method that the FSIS laboratories use as

cited in the Microbiological Laboratory Guidebook (MLG). A list of STEC testing methods that have been validated by recognized international organizations can be found at the following link: Foodborne Pathogen Test Kits Validated by Independent Organizations .","Compliance Guidelines for Shiga toxin Escherichia coli (STEC) Organisms Sampled and Tested Labeling Claims for Boneless Beef Manufacturing Trimmings (\u201cBeef Trim\u201d) 3 STEC testing methods that have not yet been validated by these organizations but have received FSIS Letters of No Objection can be found at the following link: STEC No Objection Letters While these sources of information indicate that the methodology has been validated for use in some context, it is important to confirm that the method of choice is fit for the intended purpose of the analysis and provides useful information for the food safety program used by the establishment. It is important for establishments to ensure that their private laboratory complies with the specific method that was validated, including the enrichment broth, incubation conditions, and test portion used to ensure that the pathogen screening test is effective. Private laboratories should have documented quality control programs that ensure the integrity of testing results. The establishment and laboratory should demonstrate confidence in test results and not re-sample or re-test pathogen-positive and non-compliant products. The sections below describe the types of information that FSIS would expect to see on labels that bear STEC sampled and tested claims to prevent the labels from being false or misleading. They also describe the specific types of documentation that interested persons would need to submit to FSIS to obtain sketch approval for the use of such claims. Labels that include such special claims need to be submitted in accordance with 9 CFR \u00a7 412.2 for evaluation and sketch approval by the Labeling and Program Delivery Staff (LPDS) before use. FSIS inspection program personnel (IPP) periodically will verify that the establishments that make such claims are performing the sampling and testing that are described in the supporting documentation. FSIS intends to provide instructions to IPP for verifying that product meets these claims in establishments that use such labeling claims. FSIS intends to issue these instructions before it approves such claims.

III. Information to Appear on a Label Bearing a Sampled and Tested Claim

A sampled and tested label claim should include all applicable features required by 9 CFR 317.2. FSIS likely would find that a sampled and tested claim for beef trim is not misleading if it is supported by the following information

1. A statement that the product in the labeled container is comprised of only beef trim derived from a production lot that has been sampled, tested and found negative for STEC;
2. A statement specifying that the sample collection method used was either the FSIS method or an equivalent method;
3. A statement specifying that the testing method used was either the FSIS method or an equivalent method;","Compliance Guidelines for Shiga toxin Escherichia coli (STEC) Organisms Sampled and Tested Labeling Claims for Boneless Beef Manufacturing Trimmings (\u201cBeef Trim\u201d) 4
4. A statement that sampling and testing was conducted independently from FSIS testing;
5. A statement identifying the production lot from which the sampled and tested trim was derived (e.g., lot identification number or lot code);
6. If the production lot identified by the sampled and tested claim was created by combining product from two or more source production lots of trim (for example to create a particular formulation of lean to fat content), a statement that (a) explains this fact; (b) explains whether all source lots of trim bear STEC sampled and tested labels; and (c) explains whether the lot of trim identified by the sampled and tested label was sampled and tested in its final formulation;
7. If the labeled product

(whether the label is applied to a container, a box, etc.) contains beef trim from a split lot (i.e., the labeled product contains only a portion of the production lot identified by the label or only a portion of any source production lot used to create the identified production lot), a statement that the labeled product contains part of a split lot; and 8. A statement of limited use indicating that the label may not be displayed at retail. The following are examples of labeling claims that would be deemed acceptable under various circumstances, provided the establishment submits adequate documentation to support the claim. Other wording also may be appropriate.

1. Beef trim from a production lot independently sampled and tested negative for E. Coli O157:H7 using FSIS sampling and testing methods. Production lot No. 12345. This label may not be displayed at retail.
2. Beef trim from a production lot independently sampled and tested negative for STEC using FSIS-equivalent sampling and testing methods. Derived from production lot No. 12345. Part of a split lot. This label may not be displayed at retail.
3. Beef trim from a production lot independently sampled and tested negative for STEC using FSIS sampling and testing methods. Production lot No. 12345. Contains product from multiple source lots. Source lots not labeled as sampled and tested. Lot No. 12345 was", "Compliance Guidelines for Shiga toxin Escherichia coli (STEC) Organisms Sampled and Tested Labeling Claims for Boneless Beef Manufacturing Trimmings (\u201cBeef Trim\u201d) 5 sampled and tested. This label may not be displayed at retail.
4. Beef trim from a production lot independently sampled and tested negative for STEC using FSIS sampling and testing methods. Production lot No. 12345. Contains product from multiple source lots. Source lots labeled as sampled and tested negative. Lot No. 12345 not sampled and tested negative. This label may not be displayed at retail.
5. Beef trim from a production lot independently sampled and tested negative for E. coli O157:H7 using FSIS sampling and testing methods. Derived from production lot No. 12345. Part of a split lot. Contains product from multiple source lots. Source lots and Lot No. 12345 sampled and tested negative. This label may not be displayed at retail.

IV. Documentation to be Included with the Label Submittal In order to ensure that a claim stating beef trim has been sampled, tested, and found negative for STEC is not misleading, an establishment should submit information that would allow FSIS to determine that the sampling results verify the effectiveness of the establishment\u2019s HACCP system in controlling the pathogen. The list that follows describes the types of documentation, all of which needs to be submitted to LPDS with the label application, which would enable FSIS to make this determination.

1. Documentation demonstrating that lots of beef trim used to produce the product labeled with a sampled and tested claim originated from carcasses slaughtered at an official establishment using at least one validated intervention for STEC at a Critical Control Point (CCP) in the slaughter establishment\u2019s HACCP plan;
2. Documentation demonstrating on-going communication (e.g. communication SOP, email records, phone logs) between establishments that use or commingle products that bear STEC sampled and tested claims and establishments that produced those products to ensure any changes to the HACCP plan are made known;
3. Documentation demonstrating that the sample collection method used is the same as or equivalent to the FSIS sample collection method described in FSIS Directive 10,010.1, and that the sampling is incorporated into the establishment\u2019s HACCP plan;" "Compliance Guidelines for Shiga toxin Escherichia coli (STEC) Organisms Sampled and Tested Labeling Claims for Boneless Beef Manufacturing Trimmings (\u201cBeef Trim\u201d) 6
4. Documentation demonstrating that the testing method used is the same as or equivalent to the

FSIS testing method described in the FSIS Microbiology Laboratory Guidebook, and that the testing is incorporated into the establishment's HACCP plan. This documentation should provide assurance that the testing method protocol has been appropriately validated, is fit for the intended purpose of the analysis, and provides useful information for the food safety program. The establishment also should maintain documentation that ensures that the private laboratory complies with the specific method protocol that was validated, including the enrichment broth, incubation conditions, and test portions used to ensure that the pathogen screening test is effective, and that the laboratory has a documented quality program that ensures the integrity of the testing result; 5. Documentation demonstrating that if any sample tests positive or presumptive positive for STEC, the production lot represented by that sample is diverted from raw ground beef operations (e.g., the positive production lots are diverted to cooking or other full lethality treatment that will destroy the pathogen) and demonstrating how the establishment will ensure that such production lots have received an appropriate disposition either at an official establishment, landfill operation, or renderer; Note: If product screens positive for STEC and is not confirmed to be negative, FSIS considers the product to be positive for the pathogen. 6. Documentation demonstrating that there is no re-sampling (collecting another sample) of any production lots that test positive or presumptive positive for STEC; 7. When either multiple operations within one establishment, or multiple establishments, are involved in creating the materials that will constitute a single production lot of sampled and tested trim, documentation that provides: a. An explanation of how and when all involved operations or establishments communicate information pertaining to sanitary dressing performance and trim testing results; b. An explanation of how that documentation will be made available to FSIS personnel for review at each establishment;" "Compliance Guidelines for Shiga toxin Escherichia coli (STEC) Organisms Sampled and Tested Labeling Claims for Boneless Beef Manufacturing Trimmings (\u201cBeef Trim\u201d) 7 c. An explanation of how the communicated information is used to investigate and adjust the HACCP system to ensure that the system is adequate to control STEC; and d. A discussion of how the combination of materials from separate operations or establishments may affect the microbiological independence of production lots; 8. Documentation demonstrating that the establishment maintains a written protocol describing the criteria used to distinguish an acceptable number of sporadic positives from a trend towards a systemic failure to control for STEC (i.e., high event period). These criteria should justify how the establishment discerns whether one production lot is microbiologically independent of another when the same source material is used to produce individual production lots. (Same source material is trim produced from one or more carcasses slaughtered and dressed consecutively or intermittently within a defined period of time (e.g., shift).) The protocol also should describe the decision-making criteria for product disposition when the establishment experiences a high event period; and 9. A description of how the establishment will use the FSIS approved sampled and tested label to identify the specific production lot tested (e.g., lot code or lot identification number). V. Procedures for Submitting Labels for Approval Establishments interested in utilizing an STEC sampled and tested labeling claim on their beef trim products need to submit label applications in accordance with the information provided on the FSIS Label Application Guidance web page. Questions about this guidance may be submitted to the Labeling and Program Delivery Staff (LPDS) through askFSIS or by telephone at 1-800-233-3935. When submitting a question, use

the Submit a Question tab, and enter the following information in the fields provided: Subject Field: Enter STEC Labeling Claims Question Field: Enter question with as much detail as possible. Product Field: Select Labeling from the drop-down menu. Category Field: Select Labeling Regulations, Policies and Claims \u2013 Special Claims from the drop-down menu. Policy Arena: Select Domestic (U.S.) Only from the drop-down menu. 1 Additional guidance on designing high event period criteria is provided in the document \u201cCompliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers.\u201d", "Compliance Guidelines for Shiga toxin Escherichia coli (STEC) Organisms Sampled and Tested Labeling Claims for Boneless Beef Manufacturing Trimmings (\u201cBeef Trim\u201d) 8 When all fields are complete, press Continue."}, {"file\_name": "FSIS\_GD\_2014\_0012", "title": "Pre-Harvest Management Controls and Intervention Options for Reducing Shiga Toxin-Producing Escherichia coli Shedding in Cattle: An Overview of Current Research", "num": "FSIS-GD-2014-0012", "id": "f98bfef5f372a97bfe9a511ebdd98c3608be2290e2843703ae83c9b8d8e33728", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Reducing-Ecoli-Shedding-in-Cattle.pdf", "type": "pdf", "n\_pages": 32, "word\_count": 11213, "text\_by\_page": ["August 2014 This document provides an overview of the current status of pre-harvest control and intervention strategies discussed in scientific literature to reduce shedding of Shiga Toxin-Producing Escherichia coli in cattle. The document covers the application, state of the findings, and links Pre-Harvest Management Controls and Intervention Options for Reducing Shiga Toxin-Producing Escherichia coli Shedding in Cattle: An Overview of Current Research", "2 Pre-harvest Management Controls and Intervention Options for Reducing Shiga Toxin-Producing Escherichia coli Shedding in Cattle: An Overview of Current Research Table of Contents I. Introduction and Background", "Discussion", "II. Exposure Reduction Strategies", "6 a. Pre-Harvest Cattle Management Controls", "b. Management Practices and Transportation", "i. Clean and Dry Bedding", "ii. Sanitation Practices on Farms and Feedlots", "iii. Housing", "iv. Transportation", "III. Exclusion Reduction Strategies", "\u2026.", "10 a. Cattle Water and Feed Management", "b. Cattle Drinking Water Treatments", "c. Cattle Feed Types and Feeding Strategies", "d. Water and Food Additives", "IV. Direct Anti-Pathogen Strategies", ".\u2026.", "20 a. Cattle Hide Washing", "b. Bacteriophages", "c. Competitive Exclusion", "d. Siderophore Receptor and Porin Protein Vaccines", "e. Bacterial Extract Vaccines", "V. Conclusion", "\u2026.", "26 VI. Appendices", "a. Appendix 1: What are Shiga Toxin-Producing Escherichia coli"]}]



contaminated with STEC, Salmonella, and other pathogens. The meeting", "4 featured presentations on the latest research and included three break-out sessions to address the following questions: 1. What factors influence the shedding of Salmonella and E. coli O157:H7 and other STEC (e.g., age of cattle, stress conditions)? 2. What effective and practical mitigations are available to reduce the pathogen load in general, and Salmonella and STEC specifically, in cattle before slaughter? 3. How can producers, processors, and government work together to promote adoption of pre-harvest food safety mitigations? Meeting participants sought clarification of what super shedders are, and how they would be identified during production. They felt strongly that the United States should build upon successful mitigations used in foreign countries, allow the market to drive the value of any particular mitigation technology including vaccines, and streamline the regulatory approval process. They recommended also that there be sustained discussions among federal, industry, and academic partners to identify and put into practice pre-harvest mitigations for reducing foodborne hazards in beef. The meeting agenda, transcript, and participant\u2019s response to the questions can be found on the FSIS web site at:

<http://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/past-meetings/past-meetings2011>. As discussed, this document provides innovative ways to control pathogens in beef at preharvest and pre-harvest pathogen control strategies for animals presented for slaughter. The application, state of the findings, and links to additional scientific references are provided for the strategies discussed. Food Safety Hazards Federally inspected establishments are required to conduct a hazard analysis as part of their Hazard Analysis and Critical Control Point (HACCP) system. The hazard analysis is required to include food safety hazards that can occur before, during, or after entry into the establishment (9 CFR 417.2). Fecal shedding in cattle is a hazard that occurs at pre-harvest and can continue in the holding pens at the establishment. This fecal shedding may result in contamination of the hides, and the contamination can subsequently be transferred to the carcass during carcass dressing. Establishments may address this hazard by incorporating purchase specifications, other programs, or agreements as part of their HACCP plans or prerequisite programs to require that their suppliers implement certain pre-harvest management controls. These programs, designed to support decisions in the hazard analysis, are part of the HACCP system. Pre-harvest Management Practices and Interventions FSIS recommends that slaughter establishments receive their cattle from beef producers that implement one or more documented pre-harvest management practices to reduce fecal shedding. FSIS encourages pre-harvest interventions as the first control steps in an integrated beef products safety system.", "5 This document describes several pre-harvest interventions and management practices and the state of the findings about these practices. Research on pre-harvest interventions for STEC is ongoing. Most of the research has focused on E. coli O157:H7 but has potential for reducing other strains of STEC. Therefore, this document focuses primarily on research conducted for E. coli O157:H7. Pre-harvest interventions that eliminate fecal shedding have yet to be discovered; however, current research suggests that at least two pre-harvest interventions, certain probiotics, and vaccines, have the potential to be effective in reducing fecal shedding in cattle. FSIS encourages slaughter establishments to share this information with their suppliers and consider its use in designing their food safety systems. FSIS will continue to monitor this type of research and update this document as needed. Veal FSIS test results show that the percent positive for STECs

from trimmings produced from veal appears to be higher than from trimmings produced from other cattle slaughter classes since the Agency began testing the six additional STECs in June 2012. In January 2013, FSIS consulted the National Advisory Committee on Meat and Poultry Inspection about the higher numbers seen in veal operations. The committee recommended that the Agency confer with ARS or other research providers to conduct research into pre-harvest risk factors associated with STEC in veal slaughter. The committee also recommended that the Agency promote research into the development of industry best management practices. The committee concluded with the following statement that is being considered by the Agency: Recognizing that pre-harvest practices can impact potential pathogen contamination, the Agency should conduct a series of stakeholder meetings to facilitate knowledge sharing and capturing to more fully fill the data gap that exists for this specific class of beef. The committee encourages the agency to investigate and develop recommendations for pre-harvest interventions and . . . ensure discussions with interested stakeholder meetings on this topic. Further, the committee recognizes potential differences between the subgroups bob veal and formula fed veal within the veal class and recommends the agency focus its efforts at the stakeholder meetings on this topic with intent to capture both optimum in-plant sanitary dressing procedures and pre-harvest best practices.

([http://www.fsis.usda.gov/wps/wcm/connect/1937a01a-7478-4d5d-9d4816b237f19a1e/NACMPI\\_Transcript\\_Subcmt1\\_011613.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/1937a01a-7478-4d5d-9d4816b237f19a1e/NACMPI_Transcript_Subcmt1_011613.pdf?MOD=AJPERES)) Background Information on STEC Shedding in Cattle E. coli O157:H7 is a food safety hazard well documented in scientific research. Appendix 1, \u201cWhat is Shiga toxin-producing E. coli?\u201d and Appendix 2 , \u201cEcological and Epidemiological Characteristics of E. coli O157:H7,\u201d provide general information regarding the pathogen. Appendix 3 is a quick reference table that summarizes the pre-harvest management options and interventions presented in this document." As suggested in some scientific literature, pre-harvest practices and interventions are grouped into three categories in this document: (1) exposure reduction strategies (environmental management), (2) exclusion strategies (treatments such as dietary and vaccination modifications), and (3) direct anti-pathogen strategies (certain types of treatments such as bacteriophages). Request for comments This document is a revision of a previous guidance document. As such, it is not subject to the Office of Management and Budget\u2019s (OMB) \u201cFinal Bulletin for Agency Good Guidance Practices\u201d (GGP). More information can be found on the FSIS web site:

<http://www.fsis.usda.gov/wps/portal/footer/policies-and-links/significant-guidancedocuments>. However, FSIS is seeking comments on this document as part of its efforts to continuously assess and improve the effectiveness of policy documents. The comments will be considered for future revisions of this document. FSIS requests that all interested persons submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. Comments may be submitted by either of the following methods: (1) Online submission at regulations.gov: This web site provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the instructions for submitting comments. (2) Mail, including floppy disks or CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, 8-163A, Washington, DC 20250-3700.

All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title Pre-Harvest Management Controls and Intervention Options for Reducing Shiga Toxin-Producing Escherichia coli Shedding in Cattle: An Overview of Current Research, August 2014. Comments received in response to this document will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>. Key Point: Sound management practices, including proper sanitation measures and pest control, can reduce levels of E. coli O157:H7 and other pathogens in the cattle\u2019s environment.","7 II. EXPOSURE REDUCTION STRATEGIES The goal of exposure reduction strategies is to reduce the frequency of exposure of cattle to contaminated sources in the environment, thereby reducing the prevalence of STEC in live animals. Pre-Harvest Cattle Management Controls Pre-harvest cattle management controls and interventions are emerging as an option that offers great opportunity to improve food safety. The beef industry is investigating production practices that reduce food safety risks. The beef industry has invested heavily in processing interventions to address E. coli O157:H7 in raw beef products. Despite these measures, E. coli O157:H7 remains a food safety hazard in our food supply. The following are the basic recommended principles of cattle management. 1. Clean water; 2. Clean feed; 3. Clean environment that is appropriately drained; 4. Separate housing of calves and heifers or reduced animal density; and 5. Biosecurity\u2014wildlife exclusion to the extent possible. FSIS supports the principles of good pre-harvest management control because they provide the foundation for the processing interventions and sanitary dressing procedures used to control E. coli O157:H7 contamination in raw beef. References: Subcommittee on Pre-harvest. 2013. Production Best Practices (PBP) to Aid in the Control of Foodborne Pathogens in Groups of Cattle. BIFSCO.

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<http://digitalcommons.unl.edu/vetscidiss/10>. Management Practices and Transportation (1) Clean and Dry Bedding Clean and dry bedding may help prevent heavy soiling of the animal\u2019s brisket area. Keeping the brisket clean helps control contamination during

slaughter. The brisket area is the site that contacts hands and knives when the initial cut is made at the start of the hide removal process during sanitary dressing procedures. A clean brisket may help control hide contamination and transmission of E. coli O157:H7 within the herd. (2) Sanitation Practices on Farms and Feedlots The maintenance of clean clothes and equipment by farm and feedlot personnel can reduce the opportunities to transmit E. coli O157:H7 between herds or between cattle on the same farm or feed lot. However, it does not reduce E. coli O157:H7 shedding in cattle. Exclusion of animals other than livestock from access to cattle feed and water is a best practice. Insects, rodents, and other animals such as sheep and deer are known to be carriers of E. coli O157:H7. Pest management may reduce reservoirs of non-bovine sources of E. coli O157:H7 and reduce sources of contamination to water sources, feed, hides, and housing. (3) Housing Separate Housing of Calves and Heifers \u2013 Some research indicates that calves excrete E. coli O157:H7 more frequently and in greater numbers than adult animals. Separating calves from adults shows some effect in reducing prevalence and shedding of E. coli O157:H7 in calves. Housing calves away from other livestock may provide a mechanism to reduce E. coli O157:H7 in a dairy operation. However, separating calves is not practical in beef cow- Management Practices and Transportation (1) Clean and Dry Bedding (2) Sanitation Practices on Farms and Feedlots (3) Housing (4) Transportation", "9 calf operations. Off-site heifer raising is another option to reduce exposure of older cattle to the calves, but there may be biosecurity risks with bringing heifers back onto a farm. Animal Density \u2013 A recent study reported a significantly greater E. coli O157:H7 prevalence in feedlot cattle housed at high density of cattle per area compared to cattle housed at a low density of cattle per area. (4) Transportation Cross contamination among animals from different farms during transportation to the slaughter facility and at lairage (holding pens) can be an important source of hide contamination. Therefore, appropriate controls should be in place to minimize hide contamination. Recent research showed that loading areas and dust generated during loading can increase pathogen loads on the animals before and after shipping. Stress may play a role in the ability of E. coli O157:H7 to colonize the gastrointestinal tract and in E. coli O157:H7 fecal shedding. Stressful events, such as the stress associated with transportation, may be a factor in increased fecal shedding in cattle. However, one study suggested that the feedlot pen has a greater effect on hide contamination at the slaughter plant than transportation factors including temperaturehumidity index, loading density, and duration of transport. References: \u2022 Ahmad, A, T.G. Nagaraja, L. Zurek. 2007. Transmission of Escherichia coli O157:H7 to cattle by house flies. Prev. Vet. Med. 80:74-81. \u2022 Carr, M. Executive Director, Beef Safety Research and M. Rossman, Director, Beef Safety Research \u2013 NCBA, Issues Update. Special report: Beef safety research focuses on pre-harvest opportunities. May/June 2007. pp. 23-25. [www.beefresearch.org/CMDocs/BeefResearch/Safety\\_Issues\\_Update/Special\\_Report\\_Beef\\_Safety.pdf](http://www.beefresearch.org/CMDocs/BeefResearch/Safety_Issues_Update/Special_Report_Beef_Safety.pdf). \u2022 Cray, W.C., and H.W. Moon. 1995. Experimental infection of calves and adult cattle with Escherichia coli O157:H7. Appl. Environ. Microbiol. 61:1586\u20131590. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC167413/pdf/611586.pdf>. \u2022 Hancock, D.D., T.E. Besser, D.H. Rice, E.D. Ebel, D.E. Herriott, L.V. Carpenter. 1998. Multiple sources of Escherichia coli O157 in feedlots and dairy farms in the Northwestern USA. Prev. Vet. Med. 35:11-19. \u2022 Hegde, N.V., M.L. Cook, D.R. Wolfgang, B.C. Love, C.C. Maddox, B.M. Jayarao. 2005. Dissemination of Salmonella enterica subsp. enterica Serovar Typhimurium var.

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EXCLUSION REDUCTION STRATEGIES The goal of exclusion reduction strategies is to modify or change the microhabitat of the gastrointestinal tract of cattle so STEC will not be established or will be displaced by bacteria less harmful to humans. Cattle Water and Feed Management (1) Cattle Drinking Water Treatments Application: Research suggests that there is a correlation between cattle that drink contaminated water and *E. coli* O157:H7 shedding. Researchers are studying the application of chlorination, electrolyzed water, and ozonation as water treatments to improve and maintain drinking water quality. Chlorine is an FDA approved and commercially available water treatment used to disinfect cattle drinking water and to reduce the transmission of pathogens including *E. coli* O157:H7. Beef producers that use chlorine must maintain the required chlorine levels throughout the day in order to disinfect trough water effectively. Electrolyzed water and ozonation are also water treatment methods; however, specialized equipment is required to apply these interventions to drinking water sources. In addition, researchers have not tested electrolyzed water under field conditions. Findings: Adding chlorine to water at 2-5 PPM significantly reduces total *E. coli* concentrations. However, the effectiveness of the chlorine is diminished if organic material, such as manure, is present in the water. Under field conditions, treating livestock drinking water with chlorine has been shown to have a negligible effect on the prevalence of *E. coli* O157:H7. Chlorine water treatment may be more practical to implement than electrolyzed water and ozonation; however, its effect on *E. coli* O157:H7 shedding is inconclusive. References: \u2022 Besser, T.E., J.T. LeJeune, D.H. Rice, J. Berg, R.P. Stilborn, K. Kaya, W. Bae, and D.D. Hancock. 2005. Increasing prevalence of *Campylobacter jejuni* in feedlot cattle through the feeding period. *Appl. Environ. Microbiol.* 71:5752\u20135758.

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S. Tkalcic, M.P. Doyle, B.G. Harmon, C.A. Brown, and P. Zhao. 2003. Pathogenicity of enterohemorrhagic Escherichia coli in neonatal calves and evaluation of fecal shedding by treatment with probiotic Escherichia coli. J. Food Prot. 66:924\u2013930. (2) Cattle Feed Types and Feeding Strategies A. Feed Types Application: Research indicates that the type of feed, fasting, and feed additives can affect E. coli O157:H7 shedding in cattle. Researchers have studied the effects of feeding hay, grain, distillers grains, and forage on E. coli O157:H7 shedding in cattle. Findings: A significant amount of research has been conducted, but there is no conclusive evidence that feeding cattle forage is consistently effective at reducing pathogens under field conditions. Grains such as barley and distillers grains have been shown to increase E. coli O157:H7 shedding in cattle. Studies have shown that even the form of corn fed to cattle can affect E. coli O157:H7 shedding. Cattle fed steam-flaked corn shed more E. coli O157:H7 than those fed dry-rolled corn because of the passage of more starch to the hindgut where it is fermented to produce volatile fatty acids that kill E. coli O157:H7. Calves fed on grain-based diets shed more E. coli O157:H7 than those fed on a forage diet. While E. coli O157:H7 populations tend to be lower in cattle fed forage, pathogens are still found in cattle fed forage. Although some have claimed that grass-fed cattle have fewer pathogens than grain-fed cattle, researchers have found no significant food safety differences in grass-fed cattle versus corn-fed cattle. References: \u2022 Allison, M.J., I.M. Robinson, R.W. Dougherty, and J.A. Bucklin. 1975. Grain overload in cattle and sheep: changes in microbial populations in the cecum and rumen. Am. J. Vet. Res. 36:181\u2013185. Feed Types and Feeding Strategies: Research supports that cattle on grain-based diets shed higher levels of generic E. coli in their feces than cattle on a high-forage diet. However, there is no conclusive evidence that feeding cattle forage is consistently effective at reducing pathogens under field conditions.", "12 \u2022 Buchko, S.J., R.A. Holley, W.O. Olson, V.P.J. Gannon, D.M. Veira. 2000. The effect of fasting and diet on fecal shedding of Escherichia coli O157:H7 by cattle. Can. J. Anim. Sci. 80:741\u2013744. \u2022 Callaway T.R., M.A. Carr, T.S. Edrington, R.C. Anderson, D.J. Nisbet. 2008. Diet, E. coli O157:H7 and cattle: A review after 10 years. Issues Mol. Biol. 11:67-80.  
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[www.journalofanimalscience.org/content/89/9/2829.full.pdf](http://www.journalofanimalscience.org/content/89/9/2829.full.pdf). (3) Antibiotic Feed Additives Application: Antibiotics such as ionophores, neomycin sulfate, tetracycline, and oxytetracycline are used in cattle feed for various purposes. Antibiotics have been suggested as a means to reduce E. coli O157:H7 shedding in cattle. Ionophores are commercially available and routinely added to feed to increase feed efficiency in feedlot", "18 cattle. Some studies suggest that they may also reduce fecal shedding. Ionophores are not used in human medicine, so use of ionophores in cattle is not viewed as a concern with regard to development of antimicrobial resistant pathogens. Other antibiotics that are used in cattle feed for disease prevention, such as neomycin, oxytetracycline, and chlortetracycline, have uses in human medicine. Thus, their use in cattle to reduce E. coli O157:H7 shedding is controversial because of the risk associated with antimicrobial resistance and human health. Findings: Most of the research does not indicate that neomycin sulphate, tetracycline, and oxytetracycline are effective at reducing of E. coli O157:H7 shedding in cattle. Some researchers consider neomycin a good candidate for use as a pre-harvest E. coli O157:H7 management control in feedlot cattle. Some studies suggest that ionophores reduce E. coli O157:H7 shedding in certain circumstances. References: \u2022 Elder, R., J. Keen, T. Wittum, T.R. Callaway, T.S. Edrington, R.C. Anderson, J. Nisbet. 2002. Intervention to reduce fecal shedding of enterohemorrhagic Escherichia coli O157:H7 in naturally infected cattle using neomycin sulfate. *Am. Soc. Anim. Sci./Am. Dairy Sci. Assoc. Joint Meet. Quebec*: 602. \u2022 LeJeune, J.T. and A.N. Wetzel. 2007. Preharvest control of Escherichia coli O157 in cattle. *J. Anim. Sci.* 85:E73 \u2013 E80.

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E. coli O157:H7 shedding in cattle. Studies show that probiotics administered under the right conditions and using the correct methods are effective feed supplements for farm animals." "19 However, not all strains of Lactobacillus acidophilus effectively reduce the shedding of E. coli O157:H7 when used in a Lactobacillus-based direct-fed microbial. References: \u2022  
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IV. DIRECT ANTI-PATHOGEN STRATEGIES

The goal of direct anti-pathogen strategies is to target and kill the STEC.

(1) Cattle Hide Washing Application:

Hide washes are a very effective method to remove visible debris from hides as well as reducing the pathogen load on cattle hides in the live animal before slaughter or immediately after slaughter. It does not have any effect in reducing E. coli O157:H7 fecal shedding in cattle.

Findings:

A Beef Checkoff funded study of hide washing systems resulted in the development of Trichloromelamine \u2013 a non-toxic, biodegradable hide wash intervention that reduces foodborne pathogens on beef cattle hides by 50 percent.

Key Point:

Hide washes significantly reduce the bacterial load on cattle hides entering the plant for slaughter."

"In a study published in 2012, researchers at the United States Department of Agriculture\u2019s Agricultural Research Service (ARS), tested hypobromous acid (HOBr) as an antimicrobial treatment on hides at two concentrations, 220 and 500 ppm. At 220 ppm, HOBr reduced the prevalence of E. coli O157:H7 on hides from 25.3 to 10.1%. At 500 ppm, HOBr reduced the prevalence of E. coli O157:H7 on hides from 21.2 to 10.1%. Salmonella and aerobic plate counts, total coliform counts, and generic E. coli counts were also reduced. This study suggests that adoption of HOBr as a hide wash will reduce spoilage bacteria and pathogen prevalence, resulting in lower risk of carcass contamination.

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(2) Bacteriophages Applications: Bacteriophages are FDA approved for use in or on live cattle as a treatment or for control of E. coli O157:H7 shedding in cattle. Bacteriophages (phages) are viruses that kill bacteria. A subset of bacteriophages can reduce bacterial loads in and on cattle and on the carcasses post-harvest. In 2006, FSIS issued a no-objection letter for the use of bacteriophages on the hides of cattle in holding pens before slaughter to control E. coli O157:H7 and Salmonella. Beef slaughterers may also use them on hides of cattle before skinning. In February 2012, FSIS issued a no-objection letter for the use of an E. coli O157:H7 bacteriophage on the hides of cattle within lairage or holding pens, restraining areas, stunning areas, and stations immediately before hide removal. Shortly thereafter, in April 2012, FSIS issued a letter of no-objection for use of a STEC targeted bacteriophage cocktail that is effective for E. coli serogroups O157, O26, O45, O103, and O145 applied in the same manner as the one for E. coli O157:H7. "22 Killing pathogens on hides before removal is an effective way of reducing carcass contamination. Spraying or washing hides with bacteriophages is being used more widely at pre-harvest as more companies develop a marketing strategy for pre-harvest applications of their products. Finalyse\u00ae is a commercially available bacteriophage cocktail sprayed on cattle before their entering the establishment to reduce the load of E. coli. Findings:

A 2006 study suggests that the bacteriophage CEV1 shows promise as a component in a treatment for reduction of E. coli O157:H7 levels in food animals. Reducing E. coli O157:H7 in cattle by bacteriophage treatment is possible, but efforts to clear E. coli O157:H7 from cattle consistently with phage therapy may be unrealistic. The commercial application of this pre-harvest intervention to aid in the control of E. coli O157:H7 in cattle may be a few years in the future.

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number of doses necessary to ensure maximum effectiveness in reducing E. coli O157:H7 in cattle when using SRP vaccines. The vaccine is commonly administered in three doses. Feedlot practices in the U.S. do not easily accommodate a three-dose vaccination treatment. The same 2012 study cited in the paragraph above indicates effectiveness of a two-dose regimen in reducing fecal prevalence of E. coli O157:H7 in high shedding cattle reared in a commercial feedlot in the summer on a finishing diet with 25% distiller's grains. References: \u2022 Cull, C.A., Z.D. Paddock, T.G. Nagaraja, N.M. Bello, A.H. Babcock, D.G. Renter. 2012. Efficacy of a vaccine and a direct-fed microbial against fecal shedding of Escherichia coli O157:H7 in a randomized pen-level field trial of commercial feedlot cattle. Vaccine 30(43):6210-6215. <http://www.sciencedirect.com/science/article/pii/S0264410X12008328>. \u2022 Snedeker, K.G., M. Campbell, J.M. Sargeant. 2012. A Systematic review of Vaccinations to Reduce the Shedding of Escherichia coli in the Faeces of Domestic Ruminants. Zoonoses and Public Health 59(2):126-138. \u2022 Thornton A.B., D.U. Thomson, G.H. Loneragan, J.T. Fox, D.T. Burkhardt, D.A. Emery, T.G. Nagaraja. 2009. Effects of a siderophore receptor and porin proteins-based vaccination on fecal shedding of Escherichia coli O157:H7 in experimentally inoculated cattle. J Food Prot. 2:866-869. (5) Bacterial Extract Vaccines Application: Econiche\u2122 is a bacterial extract vaccine. To make the vaccine, the bacteria are grown, and key proteins that cause the bacteria to attach to the intestines of cattle are extracted. Vaccinated cattle produce antibodies that affect the attachment proteins in the bacteria, preventing the bacteria from attaching and reproducing. Bioniche Life Sciences, Inc., of Belleville, Ontario, Canada, received full licensing approval for the use of Econiche\u2122 from the Canadian Food Inspection Agency in October 2008. In Pre-harvest Agreements Establishments are required to conduct a hazard analysis that includes food safety hazards that can occur before, during, or after entry into the establishment (9 CFR 417.2). Fecal shedding in cattle is a hazard that occurs at pre-harvest, before entry into the establishment. Establishments may address this hazard by incorporating purchase specifications or other programs or agreements as part of their HACCP plans or prerequisite programs to require that their suppliers implement certain pre-harvest management controls.", "25 December 2011, the Australian Quarantine and Inspection Service granted an import permit for the vaccine, a required first step in gaining full approval of the vaccine. In August 2012, the United Kingdom approved the importation of the vaccine to be used under conditions of a Special Treatment Certificate. Econiche\u2122 is not licensed in the United States. Econiche\u2122 is a three-dose vaccine, but it has also been tested as a two-dose vaccine. U.S. feedlot practices do not easily accommodate a three-dose vaccination treatment. Studies suggest that the efficacy of the vaccine is dose-dependent. Findings: Several published articles support the efficacy of Econiche\u2122. One study found that vaccinating feedlot cattle three times at three-week intervals against Type III secretory proteins of E. coli O157:H7 reduced the probability of fecal shedding of the E. coli O157:H7 by 59%. References: \u2022 Allen, K.J., 2011, R. Dragon, B.B. Finlay, A.A. Potter, D.J. Aper. 2011. Vaccination with type III secreted proteins leads to decreased shedding in calves after experimental infection with Escherichia coli O157. Can. J. of Vet. Res. 75:98-105).

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O157:H7 vaccine dose-effect in feedlot cattle. *Foodborne Pathog. Dis.* 6:879-84. \u2022 Moxley, R.A., D.R. Smith, K. Hansen, M.K. Luebbe, G.E. Erickson, T.J. Klopfenstein, D. Rogan. 2008 Vaccination for *Escherichia coli* O157:H7 in Feedlot Cattle. Animal Science Department, Nebraska Beef Cattle Reports, University of Nebraska - Lincoln Year 2008, pp. 102-104. [E. coli O157:H7 shedding and contamination in cattle. \*Vet. Immun. and Immunopath.\* 128\(1-3\):334. \u2022 Smith, D.R., R.A. Moxley, T.J. Klopfenstein, E.G. Erickson. 2009. A randomized longitudinal trial to test the effect of regional vaccination within a cattle feedyard on \*E. coli\* O157:H7 rectal colonization, fecal shedding and hide contamination. \*Foodborne Pathog. and Dis.\* 6\(7\):885-892. \u2022 Smith, D.R., R.A. Moxley, R.E. Peterson, T.J. Klopfenstein, G.E. Erickson, G. Bretschneider, E.M. Berberov, S. Clowser. 2009. A Two-Dose Regimen of a Vaccine Against Type III Secreted Proteins Reduced \*Escherichia coli\* O157:H7 Colonization of the Terminal Rectum in Beef Cattle in Commercial Feedlots. \*Foodborne Pathog. and Dis.\* 6:155-161. \u2022 Van Donkersgoed, J., D. Hancock, D. Rogan, A.A. Potter. 2005. \*Escherichia coli\* O157:H7 vaccine field trial in 9 feedlots in Alberta and Saskatchewan. \*Can. Vet. J.\* 46:724\u2013728. <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1180423/pdf/cvj46pg724.pdf. \u2022 Wileman, B.W., D.U. Thomson, K.C. Olson, J.R. Jaeger, L.A. Pacheco, J Bolte, D.T. Burkhardt, D.A. Emery, D. Straub. 2011. <i>Escherichia coli O157:H7 shedding in vaccinated beef calves born to cows vaccinated prepartum with \*Escherichia coli\* O157:H7 SRP vaccine. 10:1599\u20131604. V. CONCLUSION Several strategies to reduce fecal shedding of STEC in beef cattle production have been discussed above. Other resources are also available including the beef industry\u2013s](http://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1037&context=animalscinbcr&sid=1&referer=http%3A%2Fwww.bing.com%2Fsearch%3Fq%3DVaccination%2Bfor%2BEscherichia%2Bcoli%2BO157%253AH7%2Bin%2BFeedlot%2BCattle.%2BAnimal%2BScience%2BDepartment%252C%2BNebraska%2BBeef%2BCattle%2BReports%26qs%3Dn%26form%3DQ%26pq%3Dvaccination%2Bfor%2Bescherichia%2Bcoli%2Bo157%253Ah7%2Bin%2Bfeedlot%2Bcattle.%2Banimal%2Bscience%2Bdepartment%252C%2Bnebraska%2Bbeef%2Bcattle%2Breports%26sc%3D0-0%26sp%3D1%26sk%3D#search=%22Vaccination%20Escherichia%20coli%20O157%3AH7%20Feedlot%20Cattle.%20Animal%20Science%20Department%2C%20Nebraska%20Beef%20Cattle%20Report%22. \u2022 Potter, A.A., S. Klashinsky, Y. Li, E. Frey, H. Townsend, D. Rogan, G. Erickson, S. Hinkley, T. Klopfenstein, R. A. Moxley, D. R. Smith, B.B. Finlay. 2004. Decreased shedding of <i>Escherichia coli</i> O157:H7 by cattle following vaccination with type III secreted proteins. <i>Vaccine</i> 22:362\u2013369. \u2022 Peterson, R.E., D.R. Smith, R.A. Moxley, T.J. Klopfenstein, S. Kinkley, G.E. Erickson. 2005: Vaccination for <i>Escherichia coli</i> O157:H7 in market ready feedlot cattle, pp. 61\u201363. Nebraska Beef Report, University of Nebraska, Lincoln. <a href=)

guidance on production best practices (<http://www.bifasco.org/CMDocs/BIFSCO/Production%20Best%20Practices.pdf>) and cattle ecology and management options (<http://afabjournal.com/articles/current-and-near-marketintervention-strategies-for-reducing-shiga-toxin-producing-escherichia-coli-stec-shedding-in-cattle/>) produced in collaboration with ARS and academia. It is generally recognized that a multi-hurdle approach involving application of preventive measures at both pre-harvest and post-harvest should be more effective at reducing the chance of contamination at harvest. The Agency encourages pre-harvest interventions as the first control steps in an integrated food safety system. Multi-hurdle Approach Food producers recognize that applying pre-harvest interventions with post harvest technologies for a \u201cmulti-hurdle\u201d approach is the most effective way to minimize contamination of foods.

[http://www.ars.usda.gov/research/publications/publications.htm?seq\\_no\\_115=227290](http://www.ars.usda.gov/research/publications/publications.htm?seq_no_115=227290)," 27 FSIS acknowledges that several gaps exist in preharvest food safety research and knowledge. The Agency provides guidance and support to other government agencies that conduct research, academia, and industry to encourage them to conduct priority food safety research. FSIS research priorities are posted on FSIS\u2019 website at <http://www.fsis.usda.gov/wps/portal/fsis/topics/science/food-safety-research-priorities>. With appropriate data, further assessments and modeling of the relationships among fecal prevalence and concentration, hide contamination, and subsequent carcass contamination can be made to further define risks and benefits of STEC interventions on contamination of beef. \u201cThe purpose of the pre-harvest hurdle would simply be to control the prevalence to such a level that the in-plant hurdles would not be overwhelmed.\u201d Dr. Guy Loneragan, Texas Tech Professor, &The E. coli Issue", "28 Appendix 1: What are Shiga Toxin-Producing Escherichia coli (STEC)? STECs are associated with cattle and disease in humans. Escherichia coli (E. coli) bacteria live in the intestines of healthy cattle and have a symbiotic relationship with the cattle, an association where the E. coli derives benefit, and cattle are not harmed. Several strains of E. coli have evolved from being mildly pathogenic in humans to being highly pathogenic and capable of causing death when they infect humans. Symptoms of infection vary from person to person but often involve severe gastroenteritis, bloody diarrhea, vomiting, and mild fever if present. STEC can cause hemorrhagic colitis and hemolytic uremic syndrome in humans, especially in children, the elderly, and those in weakened immune states. Hemorrhagic colitis and hemolytic uremic syndrome are more commonly associated with infections resulting from E. coli O157:H7. Since 1994 when FSIS declared E. coli O157:H7 to be an adulterant in ground beef, it has been the E. coli strain of primary interest to FSIS because of its (1) presence on the hide and in the gut of cattle presented for slaughter; (2) its presence as a contaminant in raw beef component used to make ground beef; and (3) low infectious dose capable of causing severe human disease and death associated with consumption of undercooked non-intact beef products such as ground beef, which is the most frequently implicated source of E. coli O157:H7 outbreaks in the United States. However, the Centers for Disease Control and Prevention identified six additional strains of STEC (O26, O45, O103, O111, O121, and O145) that are pathogenic. These strains have been found on the hide, in the gut, and in the feces of cattle at levels comparable to those for E. coli O157:H7. In September 2011, FSIS declared these six additional strains as adulterants in beef. Since 1994, the beef industry has invested time, effort, and research on post-harvest interventions, focusing its efforts on

effective sanitary dressing practices (e.g., skinning and evisceration), treating beef carcasses with chemical or physical interventions during slaughter and dressing operations, and using sanitary practices during fabrication of trim and ground beef products to minimize cross contamination of ground beef product lots. These post-harvest in-plant efforts have reduced E. coli O157:H7 contamination on carcasses that may occur during carcass dressing. However, several studies have highlighted the importance of the E. coli O157:H7 load on feedlot cattle entering slaughter establishments as a critical factor for determining the level of E. coli O157:H7 contamination on dressed carcasses and eventually in ground beef. These studies suggest that if the E. coli O157:H7 \u2013 as well as non-O157 STEC \u2013 load on cattle entering the slaughter establishments is reduced, there would be a corresponding reduction in E. coli O157:H7 on carcasses and in ground beef. NOTE: In addition to STEC, cattle are reservoirs of several food borne pathogens including Campylobacter spp., Cryptosporidium spp., Listeria spp. and Salmonella and of several emerging human diseases, such as Helicobacterium pylori and Mycobacterium avium subspecies paratuberculosis.", "29 Appendix 2: Ecology and Epidemiology of E. coli O157:H7 Distribution: 1. The bacteria are found sporadically in the gut of individual animals but are not associated with clinical disease in animals; 2. Widespread in animals and commonly found in cattle; 3. High numbers of these bacteria are found in the colon and rectum of cattle 4. Survives in many different environments remaining viable in water, soil, and manure for several months; and 5. Can be found in a variety of species including humans. Prevalence (percentage of the population affected): 1. Higher during warm months; 2. Higher in calves than mature cattle; and 3. Higher prevalence in animals after gut bacteria have been affected by feed changes, antimicrobial dosing, or transportation stress.", "30 Appendix 3: Summary Table of Pre-harvest Management Controls and Intervention Options for Control of E. coli O157:H7 Shedding in Cattle A. Water and Feed Treatment Application 1. Water Treatments Chlorination at 2 \u2013 5 ppm is an effective and inexpensive means of reducing total E. coli counts in drinking water. The presence of organic matter reduces its effectiveness. It can be difficult to maintain adequate chlorine levels for it to be consistently effective. Electrolyzed water has been shown to be effective in killing E. coli O157:H7 under experimental conditions; it has not been tested under field conditions. Special equipment is required. Ozonation is an FDA approved process for disinfecting drinking water. Special equipment is required. 2. Feed Types and Feed Strategies Fasting of cattle before slaughter can reduce fecal output and reduce fecal soiling in the environment and on the hide. Some studies have shown an increase in E. coli O157:H7 shedding in fasting cattle. Grain vs. forage diets: In general, research supports that cattle on grain-based diets appear to shed higher levels of generic E. coli in their feces than cattle on forage diets but the effect of forage diets on fecal shedding of E. coli O157:H7 is inconclusive. Hay: Abrupt feeding of hay to cattle on a grain based diet can prevent colonization of E. coli O157:H7 in the intestines, but this may have detrimental effects on performance. Some studies have shown an increase in shedding in cattle fed poor quality forage. B. Water and Feed Additives Treatment Application 1. Antibiotics Some individual antibiotics have been shown to be effective in reducing fecal shedding of E. coli O157:H7 Development of antibiotic resistance to some antibiotics may have a negative impact on human health. Producer compliance with withdrawal times is required to prevent antibiotic residues in", "31 cattle presented for slaughter. 2. Probiotics Research supports the efficacy of some combinations of probiotic bacteria strains. There is no systemic absorption and no concerns of drug residues

with their use. They must be administered correctly to be effective. 3. Colicin-producing E. coli strains Use of colicin-producing E. coli strains, in feed or as direct fed products may be effective in reducing fecal shedding of E. coli O157:H7. However, colicins are not easily produced and are expensive. 4. Seaweed Extract (Tasco \u2013 14) When used as a feed supplement for two weeks before slaughter, it results in fewer naturally occurring E. coli O157:H7 in the feces and on the hides of cattle. However, some researchers indicate that data are insufficient to recommend that it can be used alone to control STEC. 5. Ractopamine Preliminary studies have demonstrated a decrease in fecal shedding of E. coli O157:H7 and Salmonella in cattle. This is an FDA approved feed supplement for use to improve cattle quality and performance. Currently not FDA approved for reducing fecal shedding. C. Live Animal Treatments Treatment

Application 1. Bacteriophage Bacteriophages are FDA approved for use in or on live cattle as a treatment or for control of E. coli O157:H7 shedding in cattle. As recently as April 2012, FSIS issued a letter of no objection for use of a Shiga toxinproducing E. coli targeted bacteriophage cocktail effective for E. coli serogroups O157, 026, 045, 0103, and 0145 for use on the hides of cattle within lairage or holding pens, restraining areas, stunning areas, and stations immediately before hide removal. 2. Competitive Exclusion (CE) Can be an effective means to interfere with the ability of E. coli O157:H7 to adhere to the intestinal lining and populate the gut. Several products are under research and development. 3. Vaccines Studies of two types of vaccines have demonstrated that vaccines can be effective in reducing colonization and adherence of E. coli O157:H7 in the intestinal tract and", "32 reduce fecal shedding in vaccinated cattle. The efficacy and safety of the vaccines are still being validated. D.

Management Practices and Transportation Treatment Application 1. Clean and Dry Bedding May help prevent heavy soiling of the brisket area of cattle, decreasing the potential for contamination during carcass dressing. Inconclusive evidence as to whether it reduces transmission of E. coli O157:H7 within the herd. 2. Sanitation Practices on Farms and Feedlots Maintaining good hygiene practices among farm and feedlot workers and sanitation of equipment and premises may prevent cross contamination between and within cattle herds. 3. Pest Management Control of insect, bird, rodent and other pest populations may reduce reservoirs of nonbovine sources of E. coli O157:H7 and reduce sources of contamination to water, feed, housing, and hides. 4. Maintain Closed Herds Maintaining cattle in closed herds reduces social stress and eliminates cross contamination between herds. Reducing stress may help to reduce fecal shedding of E. coli O157:H7. 5. Transportation Cross contamination between animals from different farms or feedlots during transportation to the slaughter plant and at lairage can be an important source of hide contamination. Stress of handling and transportation may affect fecal shedding of E. coli O157:H7 in individual cattle."]}, {"file\_name": "FSIS\_GD\_2014\_0013", "title": "Compliance Guideline for Training Establishment Carcass Sorters in the New Poultry Inspection System (NPIS)", "num": "FSIS-GD-2014-

0013", "id": "19516d1cefef8ad9c87345ab97d485f6270e931f3ce1722162bc3764f0d24459", "corp\_us": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/compliance-guide-NPIS.pdf", "type": "pdf", "n\_pages": 54, "word\_count": 15410, "text\_by\_page": ["1 Compliance Guideline for Training Establishment Carcass Sorters in the New Poultry Inspection System (NPIS) Food Safety and Inspection Service U.S. Department of Agriculture September

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..... 42 I. PURPOSE This compliance guideline would help poultry slaughter establishments train their employees to conduct the carcass and associated viscera sorting activities that are required under the New Poultry Inspection System (NPIS). II. BACKGROUND The Food Safety and Inspection Service (FSIS) published a final rule <a href="http://www.fsis.usda.gov/wps/wcm/connect/00ffa106-f373-437a-9cf36417f289bfc2/2011-0012F.pdf?MOD=AJPERES">http://www.fsis.usda.gov/wps/wcm/connect/00ffa106-f373-437a-9cf36417f289bfc2/2011-0012F.pdf?MOD=AJPERES</a> ; to establish a new inspection system called the NPIS. Under the NPIS establishment personnel are required to sort carcasses and remove unacceptable carcasses and parts before the birds are presented to the FSIS online carcass inspector. FSIS believes that training of establishment sorters is vitally important to ensure that they are able to properly perform their duties under the NPIS. Therefore, FSIS has developed guidance documents to assist establishments in the training of their carcass sorters. This guidance is based on the training that FSIS provides to its online inspection personnel, who are responsible for sorting carcasses under the existing inspection systems. The Agency is	

posting this guidance material on the FSIS Web site:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/complianceguides-index>

and announcing the availability of such materials through the FSIS Constituent Update. This Compliance Guideline articulates how establishments can meet FSIS expectations regarding sorting activities under the NPIS. It is important to note that this Guidance represents FSIS\u2019s current thinking on this topic and should be considered useable as of this issuance. Request for Comments: FSIS is seeking comments on this guidance document. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. FSIS will update these guidelines in response to any comments that it receives and as needed to reflect the most current information available to FSIS and stakeholders. The comment period will be 60 days. Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Mail, including CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue, SW, Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.","4

Instructions: All items submitted by mail or electronic mail must include the Agency name, FSIS,

and document title: FSIS Compliance Guideline for Training Establishment Carcass Sorters in the New Poultry Inspection System (NPIS). Comments received will be made available for public inspection and posted without change, including any personal information, to

<http://www.regulations.gov> . III. GUIDANCE FOR SORTER TRAINING PROGRAMS A. Training Program Elements This compliance guideline recommends training elements and post-mortem inspection standards that FSIS has found effective in training FSIS online inspectors to identify carcasses and parts exhibiting condemnable conditions that are unwholesome and unfit for human food. Poultry slaughter establishments can use the information in this guideline to train establishment employees that would conduct sorting activities under the NPIS. As stated previously this compliance guideline is based on FSIS training materials for its online inspectors which are available at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/regional-onsite-training>; These training materials can be a valuable resource for additional details and background, such as providing a module for familiarizing employees with the steps in the slaughter process. Training objectives, workshops and evaluation tests are also provided in the training. Proper training is important to establishment sorters\u2019 ability to make accurate decisions on how to address carcasses exhibiting condemnable conditions.

Under the NPIS, if sorters do not make these decisions correctly, FSIS inspection personnel are required to take actions such as stopping the production line to remove contaminated carcasses, issuing non-compliance records, and directing the establishment to reduce the line speed to ensure that the establishment is able to maintain process control, and that the online carcass inspector is able to conduct a carcass by carcass inspection. A single training method or program may not be applicable to all establishments. Individual establishments should design training programs consistent with the operational conditions in the establishment. FSIS recommends that each establishment develop a standardized training program for its sorters to

enable them to properly identify and dispose of carcasses and parts exhibiting condemnable conditions to ensure that carcasses and parts are not used as human food. FSIS recommends the following types of training as effective elements of a sorter training program:

- \u2022 Classroom or offline training is a lecture type presentation that provides essential information for sorters to be able to:
  - o recognize and name common parts of poultry carcasses and organs;
  - o recognize and name common conditions affecting poultry carcasses and viscera;
  - o differentiate among normal, localized, and generalized conditions affecting poultry carcasses and viscera;
  - o determine the disposition of each carcass and viscera and take appropriate actions to ensure removal and disposal of unwholesome and unfit carcasses, parts, or viscera to ensure they can not be used as human food; and
  - o take appropriate recording actions.
- NOTE: An exam or self-assessment for trainees may be helpful to measure and quantify understanding and comprehension of training.
- \u2022 Wet lab is an offline training activity that provides trainees with practical application of what they have learned in classroom training. Features include:
  - o using real examples of carcasses and parts both normal and abnormal;
  - o performing hands on practice prior to beginning normal duties online to identify carcass conditions and make dispositions;
  - o acting on carcass disposition made; and
  - o recording actions.
- \u2022 On the job training is to practice what has been learned in lecture including:
  - o performing sorting at production rates;
  - o identifying carcass, parts, and viscera dispositions;
  - o receiving real time feedback from supervisors; and
  - o taking appropriate actions as determined necessary.
- \u2022 Follow up sessions (called correlations) are to reinforce previous learning. Features include:
  - o conducting these sessions at a set regular frequency,
  - o discussing regularly standardized procedures to make decisions to identify and properly dispose of carcasses on a continuous basis at production rates; and
  - o describing reasons for making dispositions and appropriate actions.
- \u2022 Continuous monitoring of individual employee performance to maintain skill level If questions related to dispositions arise establishment management may contact the FSIS public health veterinarian (PHV) or send questions to askFSIS. (<http://askfsis.custhelp.com/>);

"6 B. Carcass Disposition and Sorting Procedures

The purpose of carcass sorting is to separate carcasses, parts and viscera that are unwholesome and unfit for human food from those that are fit for human food. When carcasses and parts exhibiting condemnable conditions are identified, they would be properly disposed to ensure they are not used as human food. Through observation and occasional touching of the carcass and viscera, sorters make decisions called dispositions of each carcass, part, or viscera. Dispositions are based on the stage of the disease and to what degree, if any, the bird is recovering from the disease at the time the bird is slaughtered. If a disease process or injury exists in the live bird, the disease will stop progressing at the time of slaughter, but the visible changes (lesions) in the bird caused by the illness or injury will remain. The more severely affected a bird is, the more likely the whole carcass is unwholesome. Under the NPIS, the establishment sorter would make a decision about the wholesomeness and fitness of each carcass and viscera and properly dispose of unwholesome carcasses, parts and viscera to ensure they are not used as human food.

- \u2022 If the carcass and viscera appear wholesome, they would be allowed to continue down the line to the FSIS carcass inspector located at the end of the line.
- \u2022 If the carcass is wholesome except for localized conditions that can be removed, those portions of the carcass exhibiting condemnable conditions would be removed and disposed of properly. The rest of the carcass is wholesome and would proceed down line to

the FSIS online carcass inspector. \u2022 Localized conditions means one or more conditions exist in the carcass or viscera, but each condition affects only one particular part and does not relate to the other parts of the carcass or viscera. The localized portions of carcasses, parts, and viscera are unwholesome and unfit and actions may be taken to trim, salvage or reprocess locally affected carcasses either on the line or off the line. The affected tissues that are unwholesome would be removed and disposed of properly as described above. \u2022 Generalized conditions include conditions that have affected the carcass to the extent that much of the carcass is affected and cannot be trimmed or salvaged. Carcasses and viscera affected with generalized disease conditions are unwholesome and unfit for human food and should be disposed of properly. (In some cases, the viscera may be saved for human food.) \u2022 Generalized conditions also include those conditions that make the entire carcass and viscera unwholesome, and the carcass and viscera must be properly disposed to ensure that they are not used as human food. \u2022 Finally, generalized conditions also include disease conditions that produce systemic change in birds. Those carcasses and viscera show certain obvious changes (see section V. A. Septicemia and Toxemia) that affect the whole", "7 carcass. Carcasses showing systemic change may also exhibit a localized condition. In either case any carcasses showing systemic change would require proper disposal of the entire carcass and viscera to ensure they are not used as human food. \u2022 If the carcasses exhibit conditions that are questionable and require further review, then the carcasses could be placed on a holding rack for further review by establishment supervisors or team leaders. This compliance guideline includes an appendix to be used as resources to assist establishments in the training of sorters. Appendix: Anatomy of Poultry is provided for establishment sorters to recognize common parts of the poultry carcass, skeleton, and digestive tract. Image Descriptions are provided in the text of this guide to describe the conditions of carcasses and parts shown in each image. The descriptions are under each image and a list of the descriptions is also located at the end of this document. FSIS has found that using standardized procedures and thought processes result in effective and accurate sorting on a continuous basis. A single sorting procedure or thought process may not be applicable to all establishments. FSIS recommends that sorters on a moving line use standardized procedures to enable them to make accurate dispositions on a continuous basis.

IV. NORMAL CARCASSES, PARTS, AND VISCERA

A. General Features

Knowing how normal carcasses, parts, and viscera appear is necessary to accurately identify carcasses, parts, or viscera that are abnormal. Diseases and other abnormalities produce visible changes to poultry carcasses. Poultry carcasses that are normal can look different from each other because of their age, breed, diet and the slaughter practices of the establishment. Normal young chickens and turkeys will have healthy skin, firm muscles, and fat in the flaps, the gizzard and around the heart. There may be some slight color changes to the skin of the drumstick and thigh and sometimes in the fat inside their bodies. The best way to learn what is normal is to look at birds under the direction of establishment supervisors or lead team members. Normal carcasses, parts, and viscera are not affected with disease or other conditions. If the carcass is wholesome and normal without any localized or generalized disease or other conditions, it would be allowed to continue down the line to the FSIS online carcass inspector. The following images show normal carcasses.", "8 10-1822 This is a well-nourished young chicken with ample body fat and no obvious blemishes. The body is plump. The general form of the wings and hips is round. The skin appears uniform in color, moist, and thick. The

underlying muscle tissue is barely visible through the skin. 07-0877 This is a well-nourished young chicken with ample body fat and minimal blemishes. The body is plump. The general form of the wings and hips is round. The skin appears uniform in color, moist, and thick. The underlying muscle tissue is barely visible through the skin. The yellow color is due to yellow plant pigments in the feed. 10-1846 This is an adequately nourished young chicken with adequate body fat and minimal blemishes. The body is slender. The general form of the wings and sternum is angular. The skin appears uniform in color, moist, and thin. The underlying muscle tissue is visible through the skin. 10-1320 This is a well-nourished young turkey with ample body fat and minimal blemishes. The body is plump. The general form of 10-1324 This is a well-nourished young turkey with ample body fat and minimal blemishes. The body is plump. The general form 10-1318 This is an adequately nourished young turkey with adequate body fat and minimal blemishes. The body is slender. The general form ", "9 the wings and hips is round. The skin appears uniform in color, moist, and thick. The underlying muscle tissue is barely visible through the skin. of the wings and hips is round. The skin appears uniform in color, moist, and thick. The underlying muscle tissue is barely visible through the skin. of the wings and sternum is angular. The skin appears uniform in color, moist, and thin. The underlying muscle tissue is visible through the skin. B. Normal Skin 06-0316 The skin of this young chicken appears uniform in color, moist, and thick. Feather follicles appear uniform in size and arranged in rows with approximately equal space between follicles. The minor quality defects \u2013 feather remnant and scratches \u2013 do not make the skin unsafe or unfit for human food. 10-0403 The skin of this young chicken appears uniform in color, moist, and thick. Feather follicles appear uniform in size and arranged in rows with approximately equal space between follicles. The minor quality defects \u2013 feather remnants and red blemishes \u2013 do not make the skin unsafe or unfit for human food. 10-1161 The skin of this young chicken appears uniform in color, moist, and thick. Feather follicles appear uniform in size and arranged in rows with approximately equal space between follicles. The minor quality defects \u2013 red blemishes \u2013 do not make the skin unsafe or unfit for human food.", "10 10-1465 This is a well-nourished young chicken with ample body fat and no obvious blemishes. The skin appears uniform in color, moist, and thick. Feather follicles appear uniform in size and arranged in rows with approximately equal space between follicles. 10-1532 The skin of this young turkey appears uniform in color, moist, and thick. Feather follicles appear uniform in size and arranged in rows with approximately equal space between follicles. The minor quality defects \u2013 surface blemishes \u2013 do not make the skin unsafe or unfit for human food. 10-1606 The skin of this young turkey appears uniform in color, moist, and thick. Feather follicles appear uniform in size and arranged in rows with approximately equal space between follicles. The minor quality defects \u2013 retained cuticle and feather remnant \u2013 do not make the skin unsafe or unfit for human food. C. Normal air sacs 10-2223 The normal thoracic and abdominal air sacs in this young turkey appear thin, pliable, and somewhat 10-1044 The normal thoracic air sac in this young chicken appears thin, pliable, and somewhat transparent. 10-1046 The normal thoracic air sac in this young chicken appears thin, pliable, and somewhat transparent.", "11 transparent. The minor quality defect \u2013 lung \u2013 does not make the carcass unsafe or unfit for human food. D. Normal Liver 10-1807 This normal liver in a young chicken appears reddishpurple with lights spots and blotches. The general outline is a smooth, unbroken curve. The texture of a normal liver is firm. The normal fat attached to the gizzard

appears uniformly white and completely opaque. 06-0228 This normal liver in a young turkey appears brown with light spots and blotches. The general outline is a smooth, unbroken curve. The texture of a normal liver is firm. 09-0690 These normal livers from two young turkeys appear reddish-brown with lights spots and blotches. The general outline is a smooth, unbroken curve. The dry appearance of the liver on the left is a post mortem artifact. The texture of a normal liver is firm. E. Normal Heart", "12 07-0159 This normal heart in a young chicken appears reddish-tan with uniformly white fat where the arteries and veins attach. The surface color appears uniform. The general outline is a smooth, unbroken curve except where the arteries and veins attach. 03-0732 This normal heart in a young turkey appears red with uniformly white fat where the arteries and veins attach. The surface exhibits spots and blotches. The general outline is a smooth, unbroken curve except where the arteries and veins attach. 09-0691 These two normal hearts from two young turkeys appear red with uniformly white fat where the arteries and veins attach. The surface exhibits spots and blotches. The general outline is a smooth, unbroken curve except where the arteries and veins attach. F. Normal Spleen 07-0242 These normal spleens from young chickens are round to oval. Their color varies from red to tan. The surface color appears uniform or exhibits spots and blotches. 09-0693 These normal spleens from young turkeys are round to oval. Their color varies from red to tan. The surface color appears uniform or exhibits spots and blotches.", "13 G. Normal Joints, Tendons, and Bone Marrow 10-1232 This normal joint surface and tendon in a young turkey are white. The surface is shiny. 10-0236 This normal joint surface and tendon in a young chicken are white. The surface is shiny. 09-0794 This normal bone marrow from a young turkey appears uniformly red with a fine texture. V. GENERALIZED CONDITIONS REQUIRING WHOLE BIRD DISPOSAL A.

Septicemia\Toxemia Septicemia\toxemia (Sep\Tox) is caused by disease-producing bacteria and their toxins in the blood which produce systemic change in the bird. Systemic change affects the body as a whole, rather than localized portions of it. The systemic changes found in Sep\Tox are the result of the bird\u2019s organ systems not working properly. Cells weaken allowing blood to leak out of vessels (hemorrhage) into the viscera organs (liver, spleen, kidneys) and muscles of the bird. Other changes cause drying out (dehydration) of the skin and muscle wasting. Sep\Tox carcasses are usually dark in color with dark reddish viscera, especially the gizzard and heart fat. Other fat may also have an abnormal color ranging from pale to brownish red. The kidneys, liver, and spleen may appear swollen. Inside the cavity of the carcass small amounts of fluid mixed with blood may be found. In both eviscerated (opened to remove the guts) and non-eviscerated carcasses, the skin and muscle will appear dark or blue and have a dried appearance (dehydrated). The carcasses may also show muscle breakdown or wasting which gives a shrunken appearance especially to the breast muscles. The keel bone may be seen sticking out from beneath the skin of the breast muscles. If a carcass shows systemic change (Sep\Tox), as described above, it is unwholesome and must be disposed of properly to ensure the carcass and its viscera are not used as human food. However, not every carcass affected with Sep\Tox will show all of these signs.", "14 If carcasses are affected with any other condition or disease and also shows signs of systemic change (Sep\tox), the carcass and its viscera must be disposed of properly to ensure they are not used as human food. What to Look For: \u2022 carcass appears dark red, pale, or blue in color; \u2022 severe drying out of the skin and muscle may be observed; \u2022 liver, kidneys, and spleen are swollen and congested (filled up) with blood; \u2022 carcass has generalized muscle wasting. Do not

dispose of carcasses if: \u2022 only dark skin or meat is observed, and the rest of the carcass is normal; \u2022 the birds are only small birds and have good fat color and healthy looking skin and meat (flesh); and \u2022 the carcass appears only slightly dehydrated (the skin looks a little dry). 10-1901 This young chicken evidences adequate body fat and normal skin. The uniformly dark muscle tissue is suggestive of an extreme loss of body fluids, which is consistent with a generalized disease condition. 04-0536 This young chicken evidences necrosis and hemorrhage in the liver and spleen. The liver appears reddish-brown. The general outline is a smooth, unbroken curve. The linear white areas are soft and suggestive of dead tissue. The dark red areas in the liver and dark purple spleen are characteristic of hemorrhage. The parallel orientation of the white and dark red tissue in the liver is 07-0564 This young chicken evidences hemorrhage in the heart. The general outline is a smooth, unbroken curve except where the arteries and veins attach. The dark red surface blotches are characteristic with hemorrhage, which is consistent with a generalized disease condition.", "15 suggestive of swelling caused by the liver pressing against the ribs. Necrosis and hemorrhage are consistent with a generalized disease condition. 10-2017 This young chicken evidences necrosis in the liver. The liver appears red. A significant portion of the liver is pink. Exudates are visible on the surface. The general outline is a smooth, unbroken curve. Necrosis with exudates is consistent with a generalized disease condition. The yellow color of the fat is due to yellow plant pigments in the feed. 09-0625 This young turkey evidences necrosis in the liver. The liver appears red. The general outline is a smooth, unbroken curve. The linear white areas are soft and suggestive of dead tissue. The parallel orientation of the white tissue is suggestive of swelling caused by the liver pressing against the ribs. Necrosis is consistent with a generalized disease condition. 09-0921 This young chicken evidences necrosis in the liver and hemorrhage in the spleen. The liver is soft with white blotches suggestive of dead tissue. The general outline is a smooth, unbroken curve. The dark purple and soft spleen is characteristic of hemorrhage. The heart appears normal. Necrosis and hemorrhage are consistent with a generalized disease condition.", "16 07-0851 This young chicken evidences adequate body fat and normal skin. The enlarged joint at the end of the drumstick is suggestive of inflammation. The uniformly dark muscle tissue is suggestive of extreme loss of body fluids. Inflammation with loss of body fluids are compatible with wasting, which is a generalized disease condition. 10-1950 This young chicken evidences inadequate body fat and normal skin. The prominent keel bone and uniformly dark muscle tissue are compatible with wasting, which is consistent with a generalized disease condition. 10-1257 This young turkey evidences inadequate body fat and normal skin. The prominent thighbone and uniformly dark muscle tissue are compatible with wasting, which is consistent with a generalized disease condition. 10-1352 This young turkey evidences inadequate body fat and normal skin. The linear, red blemishes in the skin are veins filled with blood. The prominent thighbone and uniformly dark muscle tissue 10-0866 The fat attached to the gizzard of this young turkey appears thin, pink, and transparent. This is compatible with wasting, which is a generalized disease 10-0706 The heart of this young turkey appears wet, and offwhite. The fat, normally visible where the arteries and veins attach, is gone. The general outline is no longer a smooth, unbroken curve.", "17 are compatible with wasting, which is consistent with a generalized disease condition. condition. This is compatible with wasting, which is a generalized disease condition. B. Cadaver A cadaver is a generalized condition that causes the carcass and viscera to be unwholesome and unfit for human food. Cadavers are any birds that did not bleed

out properly due to a poor or missed cut of the neck veins before the bird entered the scalding tank. The heat of the scalding tank causes blood left in the carcass to expand into the skin blood vessels, giving the skin of the carcass and neck a cherry red to purple color. The blood also accumulates in the dependent (lower) regions, such as the necks, wings, and upper breast area. Some cadavers may appear red all over; others will appear red only in the lower regions of the carcass. The blood vessels in the viscera will appear enlarged and the liver may appear burgundy colored. The entire carcass and viscera of cadavers are unwholesome and must be disposed of properly to ensure that they are not used as human food. What to Look For: \u2022 cherry red to purple color of whole carcass or the lower regions of the carcass; \u2022 sometimes, just the neck will appear cherry red or purple color; \u2022 may be no cut on the neck, or may be only partially cut; and \u2022 blood vessels in the viscera may appear engorged (filled up with blood). NOTE: Free blood found in the body cavity and on the viscera (not inside the blood vessels) may be caused by improper stunning. Those carcasses are not cadavers. A thorough examination of the carcass may be necessary to make this determination.

05-0899 These are two adequately fleshed young chickens with ample body fat, normal skin, and minimal blemishes. The carcass on the right has normal skin color. The skin over the breast, thigh, and drumstick on the carcass on the left is dark red. The red skin discoloration of the otherwise normal carcass is consistent with a bird that was still breathing when it entered the scald tank. fleshed young turkey with ample body fat and normal skin. The skin over the entire carcass is dark red. The red skin discoloration of the otherwise normal carcass is consistent with a bird that was still breathing when it entered the scald tank. this young chicken is dark red. A visible cut across the cervical vessels is absent. The red skin discoloration and absence of a cervical cut are consistent with a cadaver - a bird that was still breathing when it entered the scald tank. Cadavers are unfit for human food. C. Dead on Arrival (DOA) DOAs are birds that have died by means other than slaughter and are not allowed to be brought into the establishment. However, if DOAs are mistakenly hung on the line, they are to be removed as quickly as possible from the slaughter or evisceration line. Dead on arrival carcasses will have red to purple color and will be cool or cold to the touch. Also, the bird may have a floppy neck. The carcasses may also feel stiff and may have a foul (bad smelling) odor. DOAs are unwholesome and to be disposed of properly to ensure they are not used as human food. What to Look For: \u2022 red to purple color; \u2022 cool or cold to the touch; \u2022 may have a floppy neck; \u2022 feel stiff; or \u2022 may smell bad.

06-0298 This is an adequately fleshed", "19 young chicken with ample body fat, normal skin, and minimal blemishes. The overall dark appearance evidences dehydration. The prominent dark red discoloration of one side of the carcass is suggestive of blood setting in the carcass. Depending on the ambient temperature and time since death, the carcass might be cool and\or stiff. The overall condition is consistent with a bird that was dead on arrival. D. Leukosis

Leukosis is a tumor-causing (neoplastic) viral infection of young chickens. The tumors are seldom seen now because of the vaccination of all birds. The tumors are often small, round, well-defined white to tan nodules in the liver, spleen, or kidney. In the liver or other organs the tumors may appear as white specks. When the skin is affected, the tumors appear in the feather follicle as bumps that are round, small, and whitish to light yellow in color. Leukosis can appear in just the viscera or just in the skin of the carcass; but any carcass affected with only one (or more) of the leukosis tumors in the skin or the viscera are unwholesome; both the

carcass and its viscera must be disposed of properly to ensure they are not used as human food. What to Look For: \u2022 One or more tumors in the visceral organs or the skin. \u2022 Tumors appear white to tan, small, round, and well-defined. \u2022 Carcasses with one or more of these tumors are unwholesome, and the entire carcass and viscera must be disposed of properly as described above.", "20 09-0910 This young chicken has round, white nodules, with smooth borders, throughout the liver and spleen. The heart appears normal. Such nodules are compatible with the avian leukosis complex, which is a generalized tumor condition requiring disposal of carcass and viscera. 09-0904 This young chicken has round, white nodules, with smooth borders, throughout the liver and spleen. The heart appears normal. Such nodules are compatible with the avian leukosis complex, which is a generalized tumor condition requiring disposal of carcass and viscera . 09-0834 This young chicken has round, white nodules, with smooth borders, throughout the liver and spleen. The heart appears normal. Such nodules are compatible with the avian leukosis complex, which is a generalized tumor condition requiring disposal of carcass and viscera . 07-0885 The skin of a young chicken with a round, white to tan nodule greater than one millimeter in greatest dimension, with smooth borders, centered on a 07-0194 The skin of a young chicken with a round, white to tan nodule greater than one millimeter in greatest dimension, with smooth borders, centered on a feather follicle. Such a ", "21 feather follicle. Such a nodule is compatible with the avian leukosis complex, which is a generalized tumor condition requiring disposal of carcass and viscera. nodule is compatible with the avian leukosis complex, which is a generalized tumor condition requiring disposal of carcass and viscera.

**VI. LOCALIZED DISEASE OR OTHER CONDITIONS AFFECTING POULTRY**

**CARCASSES**

A. Contamination During slaughter operations, visible fecal material from the digestive tract is the main way that disease-causing bacteria can be spread to the portions of the carcass that are edible (fit to be eaten by humans). Bacteria that can cause human illness are found in the digestive tract and on the skin of birds when the birds come to slaughter. To prevent fecal material from spreading to edible portions of the carcasses, special care must be taken during handling and sanitary dressing procedures. For these reasons FSIS inspectors enforce a zero tolerance standard for visible fecal material on carcasses before the chiller. FSIS also requires that the establishment put into place effective sanitary dressing procedures throughout its slaughter process to prevent contamination of carcasses and parts. Carcasses that are accidentally contaminated with fecal (or digestive tract) material during slaughter can be reconditioned, if they are reprocessed in a sanitary manner to remove all visible contamination by either online or offline reprocessing procedures. Note: Carcasses that are excessively contaminated are unwholesome and must be disposed of properly to ensure they are not used as human food. What to Look For: \u2022 Feces identification o Color is yellow to green, brown or white, o semi-solid to a paste in consistency, and o may or may not have plant material. \u2022 Ingesta identification o Color varies with the diet, o Solid or granular consistency and sometimes has digestive fluids and o Identifiable plant material.", "22 10-0174 Digestive tract content is present on the exposed muscle tissue of a young chicken. Digestive tract contents that require removal from carcass and viscera 10-0192 Digestive tract content is present on the skin and exposed muscle tissue of a young chicken. Digestive tract contents that require removal from carcass and viscera 10-0399 Feces is present on the skin of a young chicken. Color is green, has a semi-solid to paste consistency and does not have plant material. Feces requires removal from carcass and viscera.", "23 B. Keratoacanthoma and Other Tumors

Keratoacanthoma and other tumors is referring to tumors other than the leukosis tumors that were previously discussed. The most common tumor in young chickens is a keratoacanthoma, which is a tumor of the skin that looks like a miniature crater or ulcer. This tumor can range from one small tumor to many large tumors that overlap or join together (coalesce). If the carcass has so many of these tumors that they coalesce, then the entire carcass and its viscera are unwholesome and must be disposed of properly to ensure they are not used as human food. If there are only a few, smaller tumors, then the tumors can be trimmed and disposed of properly as described above. After the tumors are trimmed, the rest of the carcass can proceed down the line to the FSIS online inspector. What to Look For: \u2022 Single tumors or several small tumors that are localized and can be trimmed; \u2022 Many tumors that are intermediate to large in size and coalesce are unwholesome, and the carcass are unwholesome and must be disposed of properly as described above. 10-1080 This is an adequately fleshed young chicken. Several round, crater-shaped masses extend throughout the skin. Such masses are compatible with localized tumors and require trimming. 09-0879 This is an adequately fleshed young chicken with coalescing, multiple, round, crater-shaped masses extending throughout the skin. Coalescing tumors require disposal of the entire carcass. There are many other types of tumors that occur occasionally in young poultry. If one tumor is very large in size and disrupts normal body functions, for example, taking up too much space in the body then the entire carcass and viscera are unwholesome and must be disposed of properly to ensure they are not used as human food. If there is, "24 more than one tumor of the same kind, which indicates that the tumor has spread (metastasized) then the carcass and its viscera are unwholesome and must be disposed of properly. Localized tumors can be trimmed (if just on the carcass) or all of viscera disposed of properly (if just on the viscera). What to Look For: \u2022 If one very large tumor or more than one tumor of the same type, then dispose of carcass and viscera properly to ensure they are not used as human food. \u2022 If the tumor is not very large and has not spread then trim tumor if on the carcass, or dispose of viscera only if located on the viscera. 05-1045 This is an adequately fleshed young chicken with a solitary mass extending out from the skin. Such a mass is compatible with a localized tumor and requires trimming. 09-0579 This is an adequately fleshed young chicken. Multiple, round, white masses extend out of the skin. Such masses are compatible with localized tumors and require trimming. 10-1100 This is a well-fleshed young chicken. Multiple, black masses are present in the skin. Such masses are compatible with localized tumors and require trimming. 09-0275 03-0681 10-0151", "25 This is an adequately fleshed young chicken. A round, white mass extends out of the kidney. Such a mass is compatible with a localized tumor and requires trimming. This is an adequately nourished young chicken with a quality defect \u2022 retained lung. A round, red mass compatible with a localized tumor extends out of the kidney and requires trimming. This is a well-fleshed young chicken. A single, firm mass is present under the skin of the thigh. Such a mass is compatible with a localized tumor and requires trimming. 09-0842 Multiple masses filled with blood are visible in the liver of this young chicken. A large ruptured mass is visible in the center of the liver. Such masses are compatible with localized tumors and require trimming. 10-1039 This is a well-fleshed young chicken. A solitary mass is present in the skin. Such a mass is compatible with a localized tumor and requires trimming. 10-0923 Multiple black masses are visible in the liver and lung of this young chicken. Such masses are compatible with localized tumors and requires trimming. C. Airsacculitis In addition to lungs, birds have balloon-like

\u201cair sacs\u201d throughout the inside of their chest and belly (abdomen). (See Figure 2. In the Appendix.) The air sacs move the air in and out allowing the bird to breathe. When the carcasses are opened to pull out the viscera, the air sacs are torn apart, so they do not appear as balloons when being sorted. There are 6 pairs of air sacs in chickens and 5 pairs in turkeys. Normal air sacs appear very clear with thin membranes or linings. Normal air sacs are not very noticeable. Airsacculitis is an inflammation of the air sacs that occurs when the bird is fighting off a respiratory tract infection or disease. The signs of inflammation that can be observed are a red color, swelling, and increased production of fluid. In the early (acute) stages of the disease, the air sacs can have a slight, cloudy appearance with a small amount of watery fluid, and only the air sacs are affected. If the disease has been going on for awhile (chronic), then the air sacs may appear thickened and have large amounts of", "26 thick, white to cream-color fluid (exudate). The fluid may also have a cheesy- pus-like appearance. Other organs, such as the liver, lungs, and heart may also show these signs. In carcasses affected with airsacculitis, all of the diseased tissues and fluids may be removed either by online or by offline salvage (vacuum or cut-up) procedures. The kidneys also must be removed and disposed of properly. If disease has spread from the air sacs to the bones of the shoulder joint, all affected tissues must be removed and disposed. After removal of affected tissues online or offline, the carcasses can go down the line to the FSIS online carcass inspector. Carcasses with airsacculitis and signs of systemic change (Sep\Tox) are to be disposed of properly to ensure they are not used as human food. Additionally, carcasses that are extensively affected with air sac such that the inner surfaces of the carcass cannot be observed or the carcass cannot be salvaged are to be disposed of properly as described above. What to Look For: \u2022 If a carcass has early stages of airsacculitis with slightly cloudy air sacs and a small amount of fluid, then the affected tissues and kidneys should be removed. \u2022 If a carcass has thickened air sacs: large amounts of white to cream-colored fluid; or dry, yellow, cheesy pus, and the visceral organs are affected, then the affected tissues, viscera, and kidneys should be removed. \u2022 If airsacculitis has spread from the air sacs to the bones in the shoulder joint, then the affected tissues must be removed and disposed of properly. \u2022 If carcasses have airsacculitis and signs of systemic change (Sep\Tox) then the entire carcass and viscera are unwholesome and must be removed for proper disposal. \u2022 If carcasses are extensively affected with airsacculitis such that the inside of the carcass cannot be observed, or the carcass cannot be salvaged, then the entire carcass and viscera must be disposed of properly as described above. , 10-1052 10-1051 10-1054", "27 The thoracic air sac of this young chicken contains exudates, which evidence inflammation of the air sac and adjacent tissue. Inflamed tissue is unfit for human food. The abdominal air sac of this young chicken contains exudates, which evidence inflammation of the air sac and adjacent tissue. Inflamed tissue is unfit for human food. The abdominal air sac and sac around the heart of this young chicken contain exudates, which evidence inflammation. The general outline of the liver is not a smooth, unbroken curve, which is suggestive of fibrosis. Inflamed tissue is unfit for human food. 10-2218 The abdominal air sac of this young turkey contains exudates, which evidence inflammation of the air sac and adjacent tissue. Inflamed tissue is unfit for human food. 10-1424 The abdominal air sac of this young turkey contains exudates, which evidence inflammation of the air sac and adjacent tissue. Inflamed tissue is unfit for human food. 10-1074 The abdominal air sac of this young chicken contains exudates, which evidence inflammation of the air sac and adjacent tissue. Inflamed tissue is unfit for

human food. D. Inflammatory Process Inflammatory Process (IP) is a term to describe inflammation in or under the skin caused by bacteria. Most often the bacteria enter through breaks in the skin caused by birds pecking one another. Usually IP appears as yellow, scabbed areas between the skin and the underlying tissues. IP may also appear as a yellow cheesy material or dried brownish flakes under the skin. In severe cases the skin will have a burnt waffle appearance. IP can occur anywhere on the bird but is most often seen around the vent, abdominal fat flaps, or side of the bird. These localized areas of infection generally can be trimmed to remove affected tissues. IP can also spread under the skin to breast muscles, and for this reason, these carcasses should be thoroughly examined to ensure that all affected portions are removed. If most of the carcass is affected by IP, then the entire carcass and viscera are unwholesome and must be disposed of properly to ensure they are not used as human food." "28 If the carcass affected with IP also has signs of systemic change (Sep\Tox), then the entire carcass and viscera are unwholesome and must be disposed of properly as described above. What to Look For: \u2022 Localized IP: look for areas of yellow, cheesy material found in the vent area, side of the carcass, or abdominal flaps. These areas must be trimmed to remove the unwholesome tissues. \u2022 Generalized IP: if the areas of yellow, cheesy material has travelled down to the breast, and most of the carcass is affected or the carcass shows signs of systemic change, then the entire carcass and viscera must be disposed of properly as described above. 06-0305 This is a well-nourished young chicken with ample body fat and no obvious blemishes. A well-defined area across the back is dark yellow to brown. Such a discoloration is compatible with inflammation. Tissue affected by inflammation is unfit for human food. 06-0338 This is a well-nourished young chicken with ample body fat and no obvious blemishes. A well-defined area on the vent flap is dark yellow to brown. Such a discoloration is compatible with inflammation. Tissue affected by inflammation is unfit for human food. 03-0679 The connective tissue below the skin of this young chicken contains localized exudates. The skin appears normal. Exudates evidence inflammation and inflamed tissue is unfit for human food." "29 10-1544 This is an adequately fleshed young turkey with quality defects \u2013 surface blemishes. Feather follicles appear uniform in size and arranged in rows with approximately equal space between follicles. The scabs and open sores with red margins are consistent with inflammation 10-1502 The skin of this young turkey over the drumstick appears thick, wet, and yellow. The appearance of the skin is consistent with exudates and inflammation. 10-1490 This is a well-nourished young turkey with ample body fat and no obvious blemishes. The majority of the skin appears uniform in color, moist, and thick. Feather follicles appear uniform in size and arranged in rows with approximately equal space between follicles. The thick, wet, yellow appearance of the skin over the breast is consistent with exudates and inflammation. E. Turkey Osteomyelitis Complex Turkey Osteomyelitis Complex (TOC) affects the cartilage of bones and surrounding tissues and joints. The cause is unknown. Any bone may have TOC, but most often the knee, shoulder or hip joints are affected. The swollen joints and soft tissues may be affected mildly or more severely. A green fringed liver may indicate TOC or some other condition. Additionally, carcasses affected with TOC may not have a green liver. For each flock, special examinations are conducted by cutting into the joints to determine whether the flock is affected with TOC. If the flock is affected with TOC, then sorters should identify the carcasses and viscera with swollen joints or green livers for the establishment to perform additional procedures to remove the unwholesome tissue. All

affected tissues must be removed from TOC carcasses. If it is not possible to do so, or if the carcass is showing signs of systemic change (Sep\Tox), the entire carcass and associated viscera are to be disposed of properly to ensure they are not used as human food.", "30 What to Look For: \u2022 Green fringed livers or swollen joints, especially the knee, hip, or shoulder, may indicate TOC, but it also may indicate other conditions. Carcasses are to be identified for further examination. \u2022 Enlarged livers, soft livers with smooth surfaces, or green streaked livers may all be signs of TOC. \u2022 Carcasses with green livers or swollen joints and with signs of systemic change are unwholesome and the carcasses and viscera must be disposed of properly. 03-0739 The bone marrow cavity of this young turkey appears white with an open area of tan fluid. This appearance is suggestive of necrosis and exudates, which is consistent with inflammation. 10-2234 This fibrotic liver in a young turkey contains excess bile. The liver appears purple with white spots and blotches. The general outline is not a smooth, unbroken curve. The texture of a fibrotic liver is firm. The fibrosis and excess bile does make the liver unfit for human food. 10-2256 This fibrotic liver in a young turkey contains excess bile. The liver appears purple with white spots and blotches. The general outline is not a smooth, unbroken curve. The texture of a fibrotic liver is firm. The fibrosis and excess bile does make the liver unfit for human food. The fat attached to the gizzard appears thin, pink, and transparent, which is suggestive of a wasting condition. F. Synovitis Synovitis is inflammation of the tissues around a joint. The hock joint is most often affected. Synovitis is caused by either physical injury or infection. The joints appear swollen and may have a red or yellow appearance and contain extra visible fluid. The fluid can range from a clear watery fluid to a severe pus-like fluid that is yellowish in", "31 color and creamy or flaky. The tendons may also be swollen. The affected legs are unwholesome and must be removed from the carcass and disposed of properly. A carcass with synovitis is wholesome unless it also shows systemic changes. If there is no systemic change, then all affected synovial tissues should be removed. 03-0893 The soft tissue around the joint in this young chicken is swollen. The skin appears wet and yellow. This appearance is suggestive of inflammation in the tendons and skin. 09-0811 The drumstick from this young turkey has a prominent swelling under the skin. Such swelling is consistent with the presence of exudates in the underlying tendons. Inflamed tissue is unfit for human food. 10-1203 A prominent greenish swelling is visible next to the kidney in this young chicken. The swelling and discoloration are consistent with the presence of exudates in the hip joint. Inflamed tissue is unfit for human food. 10-1342 The upper drumstick from this young turkey is normal. The lower drumstick has a 10-1383 This is an adequately nourished young turkey with minimal quality defects \u2013 retained cuticle and surface", "32 prominent swelling of the joint and the skin is thick and yellow. Such swelling and discoloration is consistent with the presence of exudates in the underlying tendons and skin. Inflamed tissue is unfit for human food. blemishes. A prominent swelling is visible over the thighbone. Such swelling is consistent with the presence of exudates in the underlying tendons. Inflamed tissue is unfit for human food. G. Mutilation Mutilated means the carcass is torn apart shredded or damaged by the slaughter processing equipment. Any part or organ that is mutilated and can be trimmed from the carcass is unwholesome and must be disposed of properly to ensure that it is not used as human food. If the entire carcass is affected, then the carcass is unwholesome and would be disposed of properly as described above. The viscera is wholesome and could be saved for edible product. What to Look For: \u2022 If the entire carcass is affected, then it is unwholesome and must be

disposed properly as described above; but the viscera is wholesome. \u2022 If part of the carcass is affected, then the affected tissues are unwholesome and must be trimmed and disposed of properly as described above. 10-0127 The skin and muscle tissue on this young turkey is mutilated. Mutilated tissue is contaminated and unfit for 10-1254 The muscle tissue on this young turkey is mutilated. Mutilated tissue is contaminated and unfit for", "33 human food. human food. H. Overscald Often overscald carcasses are found after the picking line breaks down, and the carcasses are held in the scalding tank too long. When both the top breast muscle and deep breast muscle have a cooked, white, dry texture, the carcasses are unwholesome and unfit for human food and should be disposed of properly along with its associated viscera to ensure they are not used as human food. Sometimes only the top layer of breast muscle appears white. This hard scald will likely show whitening only of the top layer of breast muscle. The hard scalded carcasses should not be disposed for overscald but should be trimmed to remove any affected tissue, and the viscera if it appears to be cooked. What to Look For: \u2022 If both top and deep breast muscles are white and appear cooked: then dispose properly as described above of the entire carcass and viscera. \u2022 If only the top layer of breast muscle is whitened: it may be trimmed. I. Ascites Ascites is an abnormal condition that is caused by the heart being overworked. As a result a clear to amber colored fluid collects inside the bird\u2019s body cavity (chest and abdomen). The fluid may also be found in the sac around the heart and the liver may appear swollen. It occurs in young chickens because of growing very fast. The fluid in the body of the carcass should be removed if the inside of the cavity cannot be viewed. If the carcass shows only signs of ascites, then the viscera is unwholesome and must be disposed of properly. The carcass can go down the line to the FSIS online inspector. If the carcass shows signs of ascites and systemic change (Sep\Tox) or any other disease condition, the entire carcass and viscera are unwholesome and must be disposed of properly to ensure the carcass and viscera are not used as human food.", "34 10-1862 A clear, watery fluid is visible in the body cavity of young chicken. Such fluid retention is compatible with ascites. 03-0869 Normal kidneys in a young chicken with blood tinged gelatinous fluid in the body cavity. Such fluid is compatible with ascites. 10-0977 A clear, watery fluid is visible inside the capsule surrounding the heart of young chicken. Such fluid retention is compatible with ascites. J. Breast Atrophy This condition has several names, including green atrophy, green breast, and green muscle degeneration. Atrophy means \u201cwasting away or to decrease in size.\u201d The deep breast muscle on either one or both sides of the keel bone is affected. The condition is found mostly in broad breasted hen turkeys older than five months. The breast (on one or both sides) will appear wasted away as if it has shrunken away from the keel bone. The change in the muscle could look like a small depression or dip, or it could look very extreme or obvious. The deep muscle will be greenish in color, and it will feel hard with a wood-like texture. The breast muscle is unwholesome and must be removed and disposed of properly. K. Turkey Leg Edema Turkey Leg Edema occurs mostly in heavy hen turkeys (older than 25 weeks) from August to October. The thigh may appear very white. The thigh will feel slick on the outside, and gas bubbles may be felt under the skin. Turkey leg edema is an inflammation of the leg. The affected leg is unwholesome and is to be disposed of properly. If there are signs of systemic change in the carcass, then the carcass and viscera are unwholesome and must be disposed of properly to ensure they are not used as human food. L. Bruises A bruise comes from physical trauma or damage to blood vessels and the leakage of blood into the surrounding

tissue. The color of a bruise varies from red to green to black depending on the age of the bruise. Bruises that affect most or all of the whole carcass or carcasses showing signs of systemic change are unwholesome and must be disposed of properly. If bruises are localized, they may be removed by trimming. NOTE: If sorters find increased numbers or clusters of severely bruised carcasses at the sorting station, this finding may be an indication that there has been a breakdown in the establishment's good commercial practices. Appropriate establishment personnel should be notified of the findings.

10-0210 This is a well-nourished young chicken with ample body fat and minimal blemishes. A well-defined area across the breast and wing is dark red. Such a discoloration is compatible with a bruise. Tissue affected by a bruise is unfit for human food.

07-0263 This is a well-nourished young chicken with ample body fat and minimal blemishes. A well-defined area across the breast is dark red. Such a discoloration is compatible with a bruise. Tissue affected by a bruise is unfit for human food.

10-1625 The skin of the hip in this young turkey is dark red. Such a discoloration is compatible with a bruise. Tissue affected by a bruise is unfit for human food.

","36 09-0661 The skin of this young chicken is normal with quality defects retained feathers. A well-defined area across the back of the wing is dark red. Such a discoloration is compatible with a bruise. Tissue affected by a bruise is unfit for human food.

10-0440 The skin of the drumstick in this young chicken is dark red. Such a discoloration is compatible with a bruise. Tissue affected by a bruise is unfit for human food.

10-0443 The skin of the drumstick in this young chicken is dark red to green. Such a discoloration is compatible with a bruise. Tissue affected by a bruise is unfit for human food.

M. Parts Disposition Generally, when carcasses are affected with localized disease or other conditions, the affected carcass, part or viscera is unwholesome and must be disposed of properly to ensure that they are not used as human food. If the unwholesome portions or parts can be effectively removed, the remainder of the carcass is wholesome. The following are some examples of some organs or parts that are unwholesome and must be removed and disposed of properly, but the rest of carcass is wholesome. Dispose properly to ensure the livers with the following unwholesome conditions are not to be used as human food:

\u2022 Fatty degeneration: Have visible, well defined light spots. (Livers with a uniform yellowish color throughout the liver are the result of diet and are wholesome.)

\u2022 Scar tissue due to disease (cirrhosis)

\u2022 Extensive small hemorrhages

\u2022 Inflammation (redness, swelling)

\u2022 Abscess

\u2022 Contamination from bile

\u2022 Green or other discoloration

\u2022 Granuloma

\u2022 One Leukosis tumor (also dispose of carcass and all viscera)

\u2022 One non-leukosis tumor

\u2022 Areas of necrosis (cells are dead because of death or injury)",

","37 03-0673 This normal liver in a young chicken contains excess fat. The liver appears tan with spots and blotches. The general outline is a smooth, unbroken curve. The texture of a fatty liver is soft. The excess fat does not make the liver unsafe or unfit for human food.

07-0296 This normal liver in a young chicken contains excess fat. The liver appears tan with spots and blotches. The general outline is a smooth, unbroken curve. The texture of a fatty liver is soft. The excess fat does not make the liver unsafe or unfit for human food.

10-0885 This normal liver in a young chicken contains excess fat. The liver appears tan with spots and blotches. The general outline is a smooth, unbroken curve. The texture of a fatty liver is soft. The excess fat does not make the liver unsafe or unfit for human food.

10-0929 This inflamed liver in a young chicken is fibrotic. The liver appears reddish-brown with spots and blotches. The general outline is not a smooth, unbroken curve. The texture of an inflamed, fibrotic liver is firm

to hard. 10-0884 This inflamed liver in a young chicken is fibrotic and enlarged. The liver appears uniformly tan. The general outline is a smooth, unbroken curve. The texture of an enlarged, inflamed, 10-0821 This inflamed liver in a young turkey is fibrotic and enlarged. The liver appears uniformly tan. The general outline is a smooth, unbroken curve. The texture of an enlarged, inflamed, fibrotic liver is hard. The", "38 The fibrosis makes the liver unfit for human food. fibrotic liver is hard. The fibrosis makes the liver unfit for human food. fibrosis makes the liver unfit for human food. 03-0667 This inflamed liver in a young chicken contains small granuloma throughout. The liver appears tan with spots and blotches. The general outline is a smooth, unbroken curve. The texture of an inflamed liver is soft to firm. The granuloma make the liver unfit for human food. 10-0907 This inflamed liver in a young chicken contains small granuloma throughout. The liver appears purple with spots and blotches. The general outline is a smooth, unbroken curve. The texture of an inflamed liver is soft to firm. The granuloma make the liver unfit for human food. The slight green tinge is suggestive of bile retention. 10-0835 This inflamed liver in a young turkey contains large granuloma throughout. The liver appears purple with spots and blotches. The general outline is not a smooth, unbroken curve. The texture of an inflamed liver is soft to firm. The granuloma make the liver unfit for human food. The slight green tinge is suggestive of bile retention. 10-0779", "39 This normal liver in a young turkey contains excess bile. The liver appears purple with green spots and blotches. The general outline is a smooth, unbroken curve. The texture of a normal liver is firm. The excess bile does make the liver unfit for human food. Kidneys are unwholesome and unfit and must be removed when: \u2022 from carcasses affected with airsacculitis in the abdominal area; \u2022 the liver is unwholesome because of disease; \u2022 the viscera is unwholesome; or \u2022 the kidneys are swollen. 09-0491 The kidneys in this young chicken are uniformly enlarged and pale in color. The uniform enlargement and color change are compatible with a growth disturbance and significant fibrosis. Tissue affected by disturbances of growth and significant fibrosis are unfit for human food. Salpingitis: the oviduct tubes are swollen and filled with firm cheesy fluid (normally the tubes are not seen, but when infected they are visible). All affected tissues are", "40 unwholesome and must be removed and disposed of properly. If the carcass shows signs of systemic change (Sep\Tox) then the carcass and viscera is unwholesome and must be disposed of properly. 06-0257 The oviduct of this young chicken contains white exudates. The oviduct is inflamed and unfit for human food. 09-0935 The oviduct of this young chicken contains white exudates. The oviduct is inflamed and unfit for human food. 10-0694 The oviduct of this young turkey contains white exudates. The oviduct is inflamed and unfit for human food. Pericarditis: the sac around the heart is swollen, cloudy, or filled with fluid. All affected tissues are unwholesome and must be removed and disposed of properly. If the carcass shows signs of systemic change (Sep\Tox) then the carcass and viscera is unwholesome and must be disposed of properly. 10-0988 This inflamed heart in a young chicken evidences the presence of exudates in the sac around the heart and on 10-0992 This inflamed heart in a young chicken evidences the presence of exudates on the 10-0987 This inflamed heart in a young chicken evidences the presence of exudates in the sac around the heart and on", "41 the surface of the heart. The presence of exudates makes the heart unfit for human food. surface of the heart. The presence of exudates makes the heart unfit for human food. surface of the heart. The presence of exudates makes the heart unfit for human food.", "42 Appendix: ANATOMY OF POULTRY Anatomy refers to the parts of a poultry bird or carcass. Outside

(External) Anatomy Figure 1. Outside Anatomy shows the parts of a chicken carcass after the feathers are removed and before the carcass is opened to remove the viscera (guts). The comb and wattles are on the head of poultry and are largely for looks. They vary in size and color based on type and breed, and whether they are females or males. Snoods and whiskers (beards) are external structures only found in turkeys.","43 Feathers cover almost the entire surface of the bird. They grow from follicles, which are organized into groups or zones and are called feather tracts (see shaded areas of Figure 1. The skin of chickens is thinner and more delicate than that of animals. In addition, the color of the skin depends on the type or breed of poultry, age, and diet. The skin may also be affected by the scalders used to loosen feathers. The neck attaches the head to the body. The wings are the \u201carms\u201d of the bird. The thigh is the upper leg and the drumstick is the lower leg. Meat from both of them is commonly called \u201cdark meat.\u201d The breast (\u201cwhite meat\u201d) is located in the front of the bird and contains large muscles. The hock joint is between the lower leg and the paw. The paws are the feet of the bird. The preen or oil gland is an important gland and is located near the tip of the tail. When poultry are preening, they take oil from this gland and apply it to their feathers. Inside (Internal) Anatomy The trachea or windpipe is the structure that carries air into the bird. Air passes through the trachea and into the air sacs. These structures are very thin, colorless membranes that when filled with air look like tiny balloons inside the body. The air sacs come in pairs, and the number of pairs is 5 in chickens and 4 in turkeys. The air sacs are round sacs that also have tiny finger like projections that go into certain bones and are shown in Figure 2. Air Sacs.","44 The digestive tract of the bird are shown in Figure 3. Digestive Tract of Fowl. The digestive tract of the chicken begins with the mouth or beak, which does not contain lips or teeth. The mouth is connected to the esophagus, also called the gzzle or gullet, which connects with the Crop (or craw) where feed is stored. After the crop is the stomach of birds. This stomach is called the true stomach (or proventriculus) and digests proteins. Next is the gizzard or the ventriculus. Its function is to grind the food. Often in healthy birds, there are large amounts of fat around the gizzard. The small and then large intestines come next and end at the cloaca. The cloaca opens to outside of the bird in an area called the vent. There is also a small sac on the side of the cloaca","45 called the rosebud. The rosebud is seen when the equipment cutting around the vent accidentally cuts into it. Birds that are healthy and well nourished usually have large amounts of fat throughout their tissues. The areas storing the fat are the abdominal or belly area, the vent flaps, and the gizzard and the heart. The normal liver has two lobes and each lobe is drained by a bile duct. One duct is larger and makes the gall bladder. The color of the liver depends on the fat content or bile content. Poultry do not contain a urinary bladder, but they do have two kidneys, one on each side and are set into the back bone of the bird. Ureters carry urinary waste from the kidneys to the cloaca where it leaves the bird. Bones: The bones of chickens are shown in Figure 4. Skeleton of domestic fowl.","46 The vertebral column (spine) is made up of many small bones and is divided into several parts: the neck, chest, lower back or pelvic and the tail. The neck has a bone called a wishbone or pulley bone. The bone has two branches and an air sac lies between the two branches. The shoulder blade is a bone that lies on top of each side of the rib cage. The shoulder blade with a bone from the wings and the coracoid bone makes up the shoulder joint. There are several bones in the wing. The bones at the very end of the wing are called the wing tip, and it is often broken during the slaughter process. The knee joint is made of the thigh bone

and the drumstick. The upper leg of the chicken is the thigh bone just as in animals. The drumstick is the lower leg, again just as in animals. The next bone down from the drumstick is the shank bone. The hock joint is formed from the drumstick and the shank. The hock joint is normally opened up for sorting. The shank joins the paws (or toes). The keel or breast bone is a single large bone on the bottom surface of the bird." , "47 Image Descriptions 03-0667: This inflamed liver in a young chicken contains small granuloma throughout. The liver appears tan with spots and blotches. The general outline is a smooth, unbroken curve. The texture of an inflamed liver is soft to firm. The granuloma make the liver unfit for human food. 03-0673: This normal liver in a young chicken contains excess fat. The liver appears tan with spots and blotches. The general outline is a smooth, unbroken curve. The texture of a fatty liver is soft. The excess fat does not make the liver unsafe or unfit for human food. 03-0679: The connective tissue below the skin of this young chicken contains localized exudates. The skin appears normal. Exudates evidence inflammation and inflamed tissue is unfit for human food. 03-0681: This is an adequately nourished young chicken with a quality defect \u2013 retained lung. A round, red mass compatible with a localized tumor extends out of the kidney and requires trimming. 03-0715: The skin over the neck on this young chicken is dark red. A visible cut across the cervical vessels is absent. The red skin discoloration and absence of a cervical cut are consistent with a cadaver - a bird that was still breathing when it entered the scald tank. Cadavers are unfit for human food. 03-0732: This normal heart in a young turkey appears red with uniformly white fat where the arteries and veins attach. The surface exhibits spots and blotches. The general outline is a smooth, unbroken curve except where the arteries and veins attach. 03-0739: The bone marrow cavity of this young turkey appears white with an open area of tan fluid. This appearance is suggestive of necrosis and exudates, which is consistent with inflammation. 03-0869: Normal kidneys in a young chicken with blood tinged gelatinous fluid in the body cavity. Such fluid is compatible with ascites. 03-0893: The soft tissue around the joint in this young chicken is swollen. The skin appears wet and yellow. This appearance is suggestive of inflammation in the tendons and skin. 04-0536: This young chicken evidences necrosis and hemorrhage in the liver and spleen. The liver appears reddish-brown. The general outline is a smooth, unbroken curve. The linear white areas are soft and suggestive of dead tissue. The dark red areas in the liver and dark purple spleen are characteristic of hemorrhage. The parallel orientation of the white and dark red tissue in the liver is suggestive of swelling caused by the liver pressing against the ribs. Necrosis and hemorrhage are consistent with a generalized disease condition. 05-0899: These are two adequately fleshed young chickens with ample body fat, normal skin, and minimal blemishes. The carcass on the right has normal skin color. The skin over the breast, thigh, and drumstick on the carcass on the left is dark red. The red skin discoloration of the otherwise normal carcass is consistent with a bird that was still breathing when it entered the scald tank. 05-1045: This is an adequately fleshed young chicken with a solitary mass extending out from the skin. Such a mass is compatible with a localized tumor and requires trimming. 06-0228: This normal liver in a young turkey appears brown with light spots and blotches. The general outline is a smooth, unbroken curve. The texture of a normal liver is firm." , "48 06-0257: The oviduct of this young chicken contains white exudates. The oviduct is inflamed and unfit for human food. 06-0298: This is an adequately fleshed young chicken with ample body fat, normal skin, and minimal blemishes. The overall dark appearance evidences dehydration. The prominent dark red discoloration of one side of the carcass is suggestive of

blood setting in the carcass. Depending on the ambient temperature and time since death, the carcass might be cool and\or stiff. The overall condition is consistent with a bird that was dead on arrival. 06-0305: This is a well-nourished young chicken with ample body fat and no obvious blemishes. A well-defined area across the back is dark yellow to brown. Such a discoloration is compatible with inflammation. Tissue affected by inflammation is unfit for human food. 06-0316: The skin of this young chicken appears uniform in color, moist, and thick. Feather follicles appear uniform in size and arranged in rows with approximately equal space between follicles. The minor quality defects \u2013 feather remnant and scratches \u2013 do not make the skin unsafe or unfit for human food. 06-0338: This is a well-nourished young chicken with ample body fat and no obvious blemishes. A well-defined area on the vent flap is dark yellow to brown. Such a discoloration is compatible with inflammation. Tissue affected by inflammation is unfit for human food. 07-0159: This normal heart in a young chicken appears reddish-tan with uniformly white fat where the arteries and veins attach. The surface color appears uniform. The general outline is a smooth, unbroken curve except where the arteries and veins attach. 07-0194: The skin of a young chicken with a round, white to tan nodule greater than one millimeter in greatest dimension, with smooth borders, centered on a feather follicle. Such a nodule is compatible with the avian leukosis complex, which is a generalized tumor condition requiring disposal of carcass and viscera. 07-0242: These normal spleens from young chickens are round to oval. Their color varies from red to tan. The surface color appears uniform or exhibits spots and blotches. 07-0263: This is a well-nourished young chicken with ample body fat and minimal blemishes. A well-defined area across the breast is dark red. Such a discoloration is compatible with a bruise. Tissue affected by a bruise is unfit for human food. 07-0296: This normal liver in a young chicken contains excess fat. The liver appears tan with spots and blotches. The general outline is a smooth, unbroken curve. The texture of a fatty liver is soft. The excess fat does not make the liver unsafe or unfit for human food. 07-0564: This young chicken evidences hemorrhage in the heart. The general outline is a smooth, unbroken curve except where the arteries and veins attach. The dark red surface blotches are characteristic with hemorrhage, which is consistent with a generalized disease condition. 07-0851: This young chicken evidences adequate body fat and normal skin. The enlarged joint at the end of the drumstick is suggestive of inflammation. The uniformly dark muscle tissue is suggestive of extreme loss of body fluids. Inflammation with loss of body fluids are compatible with wasting, which is a generalized disease condition. 07-0877: This is a well-nourished young chicken with ample body fat and minimal blemishes. The body is plump. The general form of the wings and hips is round. The skin appears uniform in color, moist, and thick. The underlying muscle tissue is barely visible through the skin. The yellow color is due to yellow plant pigments in the feed." 49 07-0885: The skin of a young chicken with a round, white to tan nodule greater than one millimeter in greatest dimension, with smooth borders, centered on a feather follicle. Such a nodule is compatible with the avian leukosis complex, which is a generalized tumor condition requiring disposal of carcass and viscera. 09-0275: This is an adequately fleshed young chicken. A round, white mass extends out of the kidney. Such a mass is compatible with a localized tumor and requires trimming. 09-0491: The kidneys in this young chicken are uniformly enlarged and pale in color. The uniform enlargement and color change are compatible with a growth disturbance and significant fibrosis. Tissue affected by disturbances of growth and significant fibrosis are unfit for human food. 09-0579: This is an

adequately fleshed young chicken. Multiple, round, white masses extend out of the skin. Such masses are compatible with localized tumors and require trimming. 09-0625: This young turkey evidences necrosis in the liver. The liver appears red. The general outline is a smooth, unbroken curve. The linear white areas are soft and suggestive of dead tissue. The parallel orientation of the white tissue is suggestive of swelling caused by the liver pressing against the ribs. Necrosis is consistent with a generalized disease condition. 09-0661: The skin of this young chicken is normal with quality defects \u2013 retained feathers. A well-defined area across the back of the wing is dark red. Such a discoloration is compatible with a bruise. Tissue affected by a bruise is unfit for human food. 09-0690: These normal livers from two young turkeys appear reddish-brown with light spots and blotches. The general outline is a smooth, unbroken curve. The dry appearance of the liver on the left is a post mortem artifact. The texture of a normal liver is firm. 09-0691: These two normal hearts from two young turkeys appear red with uniformly white fat where the arteries and veins attach. The surface exhibits spots and blotches. The general outline is a smooth, unbroken curve except where the arteries and veins attach. 09-0693: These normal spleens from young turkeys are round to oval. Their color varies from red to tan. The surface color appears uniform or exhibits spots and blotches. 09-0794: This normal bone marrow from a young turkey appears uniformly red with a fine texture. 09-0811: The drumstick from this young turkey has a prominent swelling under the skin. Such swelling is consistent with the presence of exudates in the underlying tendons. Inflamed tissue is unfit for human food. 09-0834: This young chicken has round, white nodules, with smooth borders, throughout the liver and spleen. The heart appears normal. Such nodules are compatible with the avian leukosis complex, which is a generalized tumor condition requiring disposal of carcass and viscera. 09-0842: Multiple masses filled with blood are visible in the liver of this young chicken. A large ruptured mass is visible in the center of the liver. Such masses are compatible with localized tumors and requires trimming.. 09-0879: This is an adequately fleshed young chicken with coalescing, multiple, round, crater-shaped masses extending throughout the skin. Coalescing tumors require disposal of the entire carcass 09-0904: This young chicken has round, white nodules, with smooth borders, throughout the liver and spleen. The heart appears normal. Such nodules are compatible with the avian", "50 leukosis complex, which is a generalized tumor condition requiring disposal of carcass and viscera. 09-0910: This young chicken has round, white nodules, with smooth borders, throughout the liver and spleen. The heart appears normal. Such nodules are compatible with the avian leukosis complex, which is a generalized tumor condition requiring disposal of carcass and viscera. 09-0921: This young chicken evidences necrosis in the liver and hemorrhage in the spleen. The liver is soft with white blotches suggestive of dead tissue. The general outline is a smooth, unbroken curve. The dark purple and soft spleen is characteristic of hemorrhage. The heart appears normal. Necrosis and hemorrhage are consistent with a generalized disease condition. 09-0935: The oviduct of this young chicken contains white exudates. The oviduct is inflamed and unfit for human food. 10-0127: The skin and muscle tissue on this young turkey is mutilated. Mutilated tissue is contaminated and unfit for human food. 10-0151: This is a well-fleshed young chicken. A single, firm mass is present under the skin of the thigh. Such a mass is compatible with a localized tumor and requires trimming 10-0174: Digestive tract content is present on the exposed muscle tissue of a young chicken. Digestive tract contents require removal from the carcass and viscera. 10-0192: Digestive tract content is present on the skin and exposed muscle tissue of a

young chicken. Digestive tract contents require removal from the carcass and viscera. 10-0210: This is a well-nourished young chicken with ample body fat and minimal blemishes. A well-defined area across the breast and wing is dark red. Such a discoloration is compatible with a bruise. Tissue affected by a bruise is unfit for human food. 10-0236: This normal joint surface and tendon in a young chicken are white. The surface is shiny. 10-0399: Feces is present on the skin of a young chicken. Color is green, has a semi-solid to paste consistency and does not have plant material. Feces requires removal from carcass and viscera. 10-0403: The skin of this young chicken appears uniform in color, moist, and thick. Feather follicles appear uniform in size and arranged in rows with approximately equal space between follicles. The minor quality defects \u2013 feather remnants and red blemishes \u2013 do not make the skin unsafe or unfit for human food. 10-0440: The skin of the drumstick in this young chicken is dark red. Such a discoloration is compatible with a bruise. Tissue affected by a bruise is unfit for human food. 10-0443: The skin of the drumstick in this young chicken is dark red to green. Such a discoloration is compatible with a bruise. Tissue affected by a bruise is unfit for human food. 10-0694: The oviduct of this young turkey contains white exudates. The oviduct is inflamed and unfit for human food. 10-0706: The heart of this young turkey appears wet, and off-white. The fat, normally visible where the arteries and veins attach, is gone. The general outline is no longer a smooth, unbroken curve. This is compatible with wasting, which is a generalized disease condition. 10-0779: This normal liver in a young turkey contains excess bile. The liver appears purple with green spots and blotches. The general outline is a smooth, unbroken curve. The texture of a normal liver is firm. The excess bile does make the liver unfit for human food.", "51 10-0821: This inflamed liver in a young turkey is fibrotic and enlarged. The liver appears uniformly tan. The general outline is a smooth, unbroken curve. The texture of an enlarged, inflamed, fibrotic liver is hard. The fibrosis makes the liver unfit for human food. 10-0835: This inflamed liver in a young turkey contains large granuloma throughout. The liver appears purple with spots and blotches. The general outline is not a smooth, unbroken curve. The texture of an inflamed liver is soft to firm. The granuloma make the liver unfit for human food. The slight green tinge is suggestive of bile retention. 10-0866: The fat attached to the gizzard of this young turkey appears thin, pink, and transparent. This is compatible with wasting, which is a generalized disease condition. 10-0884: This inflamed liver in a young chicken is fibrotic and enlarged. The liver appears uniformly tan. The general outline is a smooth, unbroken curve. The texture of an enlarged, inflamed, fibrotic liver is hard. The fibrosis makes the liver unfit for human food. 10-0885: This normal liver in a young chicken contains excess fat. The liver appears tan with spots and blotches. The general outline is a smooth, unbroken curve. The texture of a fatty liver is soft. The excess fat does not make the liver unsafe or unfit for human food. 10-0907: This inflamed liver in a young chicken contains small granuloma throughout. The liver appears purple with spots and blotches. The general outline is a smooth, unbroken curve. The texture of an inflamed liver is soft to firm. The granuloma make the liver unfit for human food. The slight green tinge is suggestive of bile retention. 10-0923: Multiple black masses are visible in the liver and lung of this young chicken. Such masses are compatible with localized tumors and require trimming. 10-0929: This inflamed liver in a young chicken is fibrotic. The liver appears reddish-brown with spots and blotches. The general outline is not a smooth, unbroken curve. The texture of an inflamed, fibrotic liver is firm to hard. The fibrosis makes the liver unfit for human food. 10-0977: A clear, watery fluid is visible inside the

capsule surrounding the heart of young chicken. Such fluid retention is compatible with ascites. 10-0987: This inflamed heart in a young chicken evidences the presence of exudates in the sac around the heart and on the surface of the heart. The presence of exudates makes the heart unfit for human food. 10-0988: This inflamed heart in a young chicken evidences the presence of exudates in the sac around the heart and on the surface of the heart. The presence of exudates makes the heart unfit for human food. 10-0992: This inflamed heart in a young chicken evidences the presence of exudates on the surface of the heart. The presence of exudates makes the heart unfit for human food. 10-1039: This is a well-fleshed young chicken. A solitary mass is present in the skin. Such a mass is compatible with a localized tumor and require trimming. 10-1044: The normal thoracic air sac in this young chicken appears thin, pliable, and somewhat transparent. The minor quality defect \u2013 lung \u2013 does not make the carcass unsafe or unfit for human food. 10-1046: The normal thoracic air sac in this young chicken appears thin, pliable, and somewhat transparent. 10-1051: The abdominal air sac of this young chicken contains exudates, which evidence inflammation of the air sac and adjacent tissue. Inflamed tissue is unfit for human food.", "52 10-1052: The thoracic air sac of this young chicken contains exudates, which evidence inflammation of the air sac and adjacent tissue. Inflamed tissue is unfit for human food. 10-1054: The abdominal air sac and sac around the heart of this young chicken contain exudates, which evidence inflammation. The general outline of the liver is not a smooth, unbroken curve, which is suggestive of fibrosis. Inflamed tissue is unfit for human food. 10-1074: The abdominal air sac of this young chicken contains exudates, which evidence inflammation of the air sac and adjacent tissue. Inflamed tissue is unfit for human food. 10-1080: This is an adequately fleshed young chicken. Several , round, crater-shaped masses extend throughout the skin. Such masses are compatible with localized tumors and require trimming. 10-1100: This is a well-fleshed young chicken. Multiple, black masses are present in the skin. Such masses are compatible with localized tumors and require trimming. 10-1161: The skin of this young chicken appears uniform in color, moist, and thick. Feather follicles appear uniform in size and arranged in rows with approximately equal space between follicles. The minor quality defects \u2013 red blemishes \u2013 do not make the skin unsafe or unfit for human food. 10-1203: A prominent greenish swelling is visible next to the kidney in this young chicken. The swelling and discoloration are consistent with the presence of exudates in the hip joint. Inflamed tissue is unfit for human food. 10-1232: This normal joint surface and tendon in a young turkey are white. The surface is shiny. 10-1254: The muscle tissue on this young turkey is mutilated. Mutilated tissue is contaminated and unfit for human food. 10-1257: This young turkey evidences inadequate body fat and normal skin. The prominent thighbone and uniformly dark muscle tissue are compatible with wasting, which is consistent with a generalized disease condition. 10-1318: This is an adequately nourished young turkey with adequate body fat and minimal blemishes. The body is slender. The general form of the wings and sternum is angular. The skin appears uniform in color, moist, and thin. The underlying muscle tissue is visible through the skin. 10-1320: This is a well-nourished young turkey with ample body fat and minimal blemishes. The body is plump. The general form of the wings and hips is round. The skin appears uniform in color, moist, and thick. The underlying muscle tissue is barely visible through the skin. 10-1324: This is a well-nourished young turkey with ample body fat and minimal blemishes. The body is plump. The general form of the wings and hips is round. The skin appears uniform in color, moist, and thick. The underlying muscle

tissue is barely visible through the skin. 10-1342: The upper drumstick from this young turkey is normal. The lower drumstick has a prominent swelling of the joint and the skin is thick and yellow. Such swelling and discoloration is consistent with the presence of exudates in the underlying tendons and skin. Inflamed tissue is unfit for human food. 10-1352: This young turkey evidences inadequate body fat and normal skin. The linear, red blemishes in the skin are veins filled with blood. The prominent thighbone and uniformly dark muscle tissue are compatible with wasting, which is consistent with a generalized disease condition." "53 10-1383: This is an adequately nourished young turkey with minimal quality defects \u2013 retained cuticle and surface blemishes. A prominent swelling is visible over the thighbone. Such swelling is consistent with the presence of exudates in the underlying tendons. Inflamed tissue is unfit for human food. 10-1424: The abdominal air sac of this young turkey contains exudates, which evidence inflammation of the air sac and adjacent tissue. Inflamed tissue is unfit for human food. 10-1465: This is a well-nourished young chicken with ample body fat and no obvious blemishes. The skin appears uniform in color, moist, and thick. Feather follicles appear uniform in size and arranged in rows with approximately equal space between follicles. 10-1490: This is a well-nourished young turkey with ample body fat and no obvious blemishes. The majority of the skin appears uniform in color, moist, and thick. Feather follicles appear uniform in size and arranged in rows with approximately equal space between follicles. The thick, wet, yellow appearance of the skin over the breast is consistent with exudates and inflammation. 10-1502: The skin of this young turkey over the drumstick appears thick, wet, and yellow. The appearance of the skin is consistent with exudates and inflammation. 10-1532: The skin of this young turkey appears uniform in color, moist, and thick. Feather follicles appear uniform in size and arranged in rows with approximately equal space between follicles. The minor quality defects \u2013 surface blemishes \u2013 do not make the skin unsafe or unfit for human food. 10-1544: This is an adequately fleshed young turkey with quality defects \u2013 surface blemishes. Feather follicles appear uniform in size and arranged in rows with approximately equal space between follicles. The scabs and open sores with red margins are consistent with inflammation. 10-1568: This is an adequately fleshed young turkey with ample body fat and normal skin. The skin over the entire carcass is dark red. The red skin discoloration of the otherwise normal carcass is consistent with a bird that was still breathing when it entered the scald tank. 10-1606: The skin of this young turkey appears uniform in color, moist, and thick. Feather follicles appear uniform in size and arranged in rows with approximately equal space between follicles. The minor quality defects \u2013 retained cuticle and feather remnant \u2013 do not make the skin unsafe or unfit for human food. 10-1625: The skin of the hip in this young turkey is dark red. Such a discoloration is compatible with a bruise. Tissue affected by a bruise is unfit for human food. 10-1807: This normal liver in a young chicken appears reddish-purple with lights spots and blotches. The general outline is a smooth, unbroken curve. The texture of a normal liver is firm. The normal fat attached to the gizzard appears uniformly white and completely opaque. 10-1822: This is a well-nourished young chicken with ample body fat and no obvious blemishes. The body is plump. The general form of the wings and hips is round. The skin appears uniform in color, moist, and thick. The underlying muscle tissue is barely visible through the skin. 10-1846: This is an adequately nourished young chicken with adequate body fat and minimal blemishes. The body is slender. The general form of the wings and sternum is angular. The skin appears uniform in color, moist, and thin. The underlying muscle



Analysis and Critical Control Point (HACCP) plan or Sanitation Standard Operating Procedures (Sanitation SOP) or other prerequisite programs. The Agency is posting this guidance material on the FSIS Web site: <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guidesindex> and announcing its availability through the FSIS Constituent Update. This Compliance Guideline articulates how establishments can meet chilling requirements. It is important to note that this Guidance represents FSIS\u2019s current thinking on this topic and should be considered useable as of this issuance. Request for Comments FSIS is seeking comments on this guidance document. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. FSIS will update these guidelines in response to any comments that it receives and as needed to reflect the most current information available to FSIS and stakeholders. The comment period will be 60 days.", "2 FSIS Compliance Guide: Modernization of Poultry Slaughter Inspection: Chilling Requirements 2014 Comments may be submitted by either of the following methods: Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Mail, including CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue, SW, Mailstop 3782, Room 8-163A, Washington, DC 20250-3700. Instructions: All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title: FSIS Compliance Guideline for Chilling Requirements. Comments received will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>. ", "3 FSIS Compliance Guide: Modernization of Poultry Slaughter Inspection: Chilling Requirements 2014 New Regulations Effective October 20, 2014 9 CFR 381.66 (b) (1) (i). Each official poultry slaughter establishment must ensure that all poultry carcasses, parts, and giblets are chilled immediately after slaughter operations so that there is no outgrowth of pathogens, unless such poultry is to be frozen or cooked immediately at the official establishment. 9 CFR 381.66(b) (1) (ii). Previously chilled poultry carcasses and major portions must be kept chilled so that there is no outgrowth of the pathogens, unless such poultry is to be packed and frozen immediately at the official establishment. 9 CFR 381.66(b) (2). After product has been chilled, the establishment must prevent the outgrowth of pathogens on the product as long as the product remains at the establishment. 9 CFR 381.66 (b) (3).The establishment must develop, implement, and maintain written procedures for chilling that address, at a minimum, the potential for pathogen outgrowth, the conditions affecting carcass chilling, and when its chilling process is completed. The establishment must incorporate these procedures into its HACCP plan, or sanitation SOP, or other prerequisite program. 9 CFR 381.66 (e) Air chilling is the method of chilling raw poultry carcasses and parts predominately with air. An antimicrobial intervention may be applied with water at the beginning of the chilling process, provided that its use does not result in any net pickup of water or moisture during the chilling process. The initial antimicrobial intervention may result in some temperature reduction of the product, provided that the majority of temperature removal is accomplished exclusively by chilled air.", "4 FSIS Compliance Guide: Modernization of Poultry Slaughter Inspection: Chilling Requirements 2014 Former Regulatory Provisions That Have Been Removed That May be

Followed to Meet New Requirements Establishments can meet the new chilling requirements by implementing the former regulatory time and temperature provisions that the final rule on modernization of poultry inspection removed from 9 CFR 381.66 (b). Below are the former regulatory provisions that an establishment can continue to implement to meet the regulatory requirements. FSIS considers these provisions to be \u201csafe harbors\u201d that will meet the new regulatory requirements. Under the new regulations, establishments producing RTC poultry that choose to use the former regulations must incorporate these procedures into their HACCP system (HACCP plan or Sanitation SOP or other prerequisite programs). These procedures will prevent the outgrowth of pathogens. As under any other procedures in a HACCP plan, Sanitation SOP, or other prerequisite program that is addressing pathogens, they will also need to continue to monitor those operating parameters and maintain documentation showing that they are following these procedures. Former provisions that FSIS considers to be safe harbors: A. All poultry that is slaughtered and eviscerated in the official establishment shall be chilled immediately after processing so that the internal temperature of poultry carcasses and major portions weighing under 4 pounds was reduced to 40 \u00b0F or below within 4 hours of processing; carcasses weighing 4 to 8 pounds, within 6 hours of processing; and those weighing over 8 pounds, within 8 hours of processing unless such poultry is to be frozen or cooked immediately at the official establishment. Once chilled, poultry to be packaged and shipped is to be stored at 40 \u00b0F or less. B. During further processing and packaging operations, the internal temperature of the poultry carcass may rise to 55 \u00b0F, provided that immediately after packaging, the poultry is chilled to 40 \u00b0F or placed in a freezer. Any poultry held at the establishment in packaged form longer than 24 hours should be held in a room at a temperature of 36 \u00b0F or lower. These times and temperatures ensure no bacterial outgrowth occurs before the package leaves the establishment. C. Only ice produced from potable water may be used for ice and water chilling, except that water and ice used for chilling may be reused in accordance with 9 CFR 416.2(g). Major portions of poultry carcasses (as defined in 9 CFR 381.170(b) (22) may be chilled in water and ice. The ice must also be handled and stored in a sanitary manner. D. Poultry chilling equipment must be operated in a manner consistent with meeting the applicable pathogen reduction performance standards for raw poultry products as set forth in 9 CFR 381.94 and the provisions of the establishment\u2019s HACCP plan.","5 FSIS Compliance Guide: Modernization of Poultry Slaughter Inspection: Chilling Requirements 2014 E. Previously chilled poultry carcasses and major portions must be maintained constantly at 40\u00b0 F or below until removed from vats or tanks for immediate packaging. Such products may be removed from the vats or tanks prior to being cooled to 40\u00b0 F or below, for freezing or cooling in the official establishment. Such products must not be packed until after they have chilled to 40\u00b0 F or below, except when the packaging will be followed immediately by freezing at the official establishment. F. Giblets should be chilled to 40\u00b0 F or lower within two hours of the time that they are removed from the inedible viscera, except that when the giblets are cooled with the carcass from which they were drawn, the giblets should be subject to the same time and temperatures for carcasses above in paragraphs A and B. Any of the acceptable methods of chilling the poultry carcass may be followed in cooling giblets. G. Poultry washing, chilling and draining practices and procedures must be such as will minimize water absorption and retention at time of packing. The establishment must provide scales, weights, identification devices and other

supplies necessary to conduct water tests. H. In air chilled, ready-to-cook poultry, the internal temperature of the carcasses shall be reduced to 40°F or less within 16 hours. Alternative Chilling Procedures Granted under Salmonella Initiative Program (SIP) waiver(s) Under the Modernization of Poultry Slaughter final rule, establishments will no longer need waivers of the regulatory provisions of 9 CFR 381.66 to use alternative approaches for chilling poultry.

Establishments that were granted SIP waivers from the time and temperature regulations can use the alternative chilling procedures to meet the new regulatory requirements. FSIS considers the alternative procedures approved under SIP waivers to be validated to prevent outgrowth of pathogens. The establishments producing RTC poultry that choose to use alternative operating parameters granted under SIP must incorporate these scientifically validated procedures into their HACCP system (HACCP plan or Sanitation SOP or other prerequisite programs). They will also need to continue to monitor those operating parameters. Below are examples of common alternative procedures implemented by establishments that participated in SIP. Because these alternative procedures have been validated under the SIP program, any establishment producing RTC poultry may choose to implement the alternative procedures and incorporate these scientifically validated procedures into their HACCP system (HACCP plan or Sanitation SOP or other prerequisite programs). These procedures will address the outgrowth of pathogens and no further scientific validation is needed. However, as with any procedure in a HACCP plan, Sanitation SOP, or other prerequisite program that addresses pathogens, establishments will need to document that they have executed these validated procedures to operate as intended within their establishment.", "6 FSIS Compliance Guide: Modernization of Poultry Slaughter Inspection: Chilling Requirements 2014 \u2022 Alternative procedures to chill young chicken carcasses immediately after processing so that the internal temperature is reduced to 44°F or below in six hours at the chiller exit. Under these alternative procedures, the internal temperature may rise to a maximum of 55°F during further processing provided that immediately after packaging the poultry is placed under refrigeration that promptly lowers the internal temperature to 44°F or less, and that temperature is maintained until shipping. Under these procedures, poultry held in packaged form in excess of 24 hours may be held in a room at a temperature of 40°F or less and poultry to be shipped from the establishment in packaged form needs to be maintained and shipped at 44°F internal temperature or less. \u2022 Procedures for time and temperature as the critical limit (CL) in the critical control point (CCP) to chill young chicken carcasses immediately after processing so that the internal temperature is reduced to 45°F or below in 16 hours. Under this alternative procedure, after chilling, the internal temperature may rise to a maximum of 60°F during further processing provided that immediately after packaging the poultry is placed under refrigeration that promptly lowers the internal temperature to 45°F or less until shipping. Under this procedure, poultry held in packaged form in excess of 24 hours needs to be held in a room at a temperature of 36°F, or less. \u2022 Procedures to maintain previously chilled young chicken carcasses and major portions so that the internal temperature is 44°F or below until removed from vats and tanks for immediate packaging. Such products may be removed from the vats or tanks prior to being cooled to 44°F or below for freezing or cooling in the official establishment. Under this alternative procedure, such products may not be packaged until after they have been chilled to 44°F or below, except when the packaging will be followed immediately by freezing at the official

establishment. \u2022 Procedures to chill giblets, major portions, paws, and parts to 44\u00b0F or less within 4 hours from the time they are removed from the inedible viscera."],{"file\_name":"FSIS\_GD\_2015\_0001","title":"Letter to Foreign Governments","num":"FSIS-GD-2015-0001","id":"60d5bcff3e9d342806310ea28e8399e581e720617cf67d34f4f5aaa3d5ad275c","corp\_us":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/import/Import-Rule-Letter-to-Foreign-Gov.pdf","type":"pdf","n\_pages":20,"word\_count":4916,"text\_by\_page":["USDA iiiiiii United States Department of Agriculture Food Safety and Inspection Service 1400 Independence Avenue, SW. Washington, D.C. 20250 TO: See Distribution SUBJECT: Final Rule-Electronic Import Inspection Application, Certification of Imported Products, Foreign Establishments; Amendments to PHIS, Other Import Inspection Regulations The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) recently modified the meat, poultry, and egg products import regulations to allow foreign countries to certify shipments electronically, eliminating the need to issue a paper certificate. FSIS also modified its requirements for official inspection certificates to provide more flexibility to countries eligible to export products to the United States. Further, FSIS changed the annual certification of foreign establishments, and it clarified the U.S. prior notification requirements and the actions that FSIS will take when product for import is not presented for reinspection (FTP). On September 18, 2014, FSIS announced these changes in a final rule in the U.S. Federal Register (Docket No. FSIS-2009-0022; Electronic Import Inspection Application and Certification of Imported Products and Foreign Establishments: Public Health Information System and Import Inspection Regulations), and it notified the World Trade Organization of the rule as well (SPS\NV\USA\2484\Add.I). The final rule was effective on November 18, 2014; however, to ensure that foreign countries have sufficient time to adjust to the new requirements for certifying foreign establishments and additional product information on foreign inspection certificates, FSIS will allow countries to continue using existing inspection certificates until March 18, 2015. Foreign Establishment Certificates: FSIS will continue to require each eligible country's competent authority to submit annual certification of eligible establishments. FSIS sent a letter to each competent authority on December 16, 2014, requesting this certification; however, the December 16letter did not include the updated requirements that are contained in the final rule and discussed in Attachment 1 of this letter. Attachment 1 describes the changes designed to minimize the burden on foreign governments by reducing the information required for countries currently exporting to the United States that are not changing the previous year's annual establishment certification. Attachment 1 also includes the requirements for countries eligible to export to the United States that are changing the previous year's certification, or providing an initial certification. An Equal Opportunity Provider and Employer","Foreign Inspection Certificates: FSIS requires each eligible country's competent authority to certify shipments of product to the United States (9 CFR 327.4 (a) and (b), 381.197, and 590.915). After November 18, 2014, when foreign governments certify shipments electronically, FSIS no longer requires a paper copy of the certificate. You can find requirements for paper-based and electronic foreign inspection certificates in Attachment 2. Furthermore, FSIS has deleted certain requirements for the certification statements on foreign inspection certificates to provide foreign countries with

more flexibility. For paper-based foreign inspection certificates, the competent authority must certify that any product described on any official certificate is in compliance with requirements equivalent to U.S. domestic requirements. Foreign countries have the option to continue using the current certification statements or can certify to the applicable regulatory requirements (e.g. \u00a7327.2 (meat or meat products) or \u00a7381.196 (poultry or poultry products) or 590.910 (egg products)). Foreign governments can refer to the Codex Alimentarius generic model official certificate as a guideline for organizing the required data elements on an official certificate. The certificate guideline (CAC/GL 38-2001) can be found on the Codex Alimentarius Web site at: <http://www.codexalimentarius.org/standards/list-of-standards>. Questions about foreign inspection certificates should be submitted to FSIS at

InternationalEquivalence@fsis.usda.gov. Application for Import Inspection and Prior Notification: For foreign countries' awareness, FSIS also amended its regulations (9 CFR 327.5, 381.198, and 590.920) for the Import Inspection Application (FSIS Form 9540-1). These changes apply only to U.S. importers or brokers but could affect certified shipments destined for export to the United States if U.S. importers\brokers do not meet the requirements. U.S. importers and brokers have the option of submitting the application electronically through U.S. Customs and Border Protection's (CBP) Automated Commercial Environment (ACE) utilizing the Partner Government Agency (PGA) Message Set or on paper. FSIS will expand the PGA Message Set to include all ports, as well as all interested importers and brokers. For importers or brokers that electronically file entries with CBP using the PGA Message Set, this entry will replace the paper inspection application. U.S. importers or brokers that do not file the full PGA Message Set data must continue to submit paper applications to FSIS at the official import inspection establishment or other PSIS-approved location designated on the import inspection application. FSIS will enter the additional required FSIS data into the Public Health Information System (PHIS) Import Component by using information from the paper Import Inspection Application. An Equal Opportunity Provider and Employer","The final rule requires U.S. importers or brokers to submit electronic or paper import inspection applications to FSIS in advance of the shipment's arrival, but no later than when the initial entry is filed with CBP. If the U.S. importer or broker files the PGA Message Set with their Customs entry, this requirement is met. If the U.S. importer or broker is using the paper applications, this must be provided to FSIS in advance of the shipment's arrival at the official import inspection establishment (or other FSIS approved location designated on the import inspection application), and no later than when the entry is made with CBP. If the application has not been received prior to the shipment's arrival, FSIS will notify the establishment management of the violation, and that future shipments that do not meet the prior notification requirement may be refused entry. The objective of the prior notification requirement is to ensure that there is notice and data entry in PHIS is performed well before the shipment arrives at the official import inspection establishment. Importers and brokers that do not utilize PGA Message Set are to transition from the current FSIS Form 9540-1 to the revised Import Inspection Application (FSIS Form 9540-1) no later than March 18, 2015. Failure to Present (FTP): Imported meat, poultry, and egg products that have entered commerce without FSIS import reinspection violate the Federal Meat Inspection Act (21 U.S.C. 601-695); the Poultry Products Inspection Act (21 U.S.C. 451--472); or the Egg Products Inspection Act (21 U.S.C. 1031-1056), as well as the implementing regulations for each Act (9 CFR 327.6; 381.199; 590.925). It is the U.S. importer's responsibility to present the imported

product to FSIS, but there could be negative impact on the exporting company if the product enters commerce illegally (e.g., FSIS may request the importer of record conduct a voluntary recall of product in commerce). To help prevent future FTPs, FSIS will provide FTP notifications to the foreign competent authority. The foreign competent authority may then notify the exporter, as appropriate, to help ensure that future shipments will be presented to FSIS. An Equal Opportunity Provider and Employer", "While these regulatory changes provide for efficiencies at the port-of-entry, please be aware that FSIS will continue to require all shipments of meat, poultry, and egg products exported to the United States to be certified by the foreign country's competent authority and presented for reinspection at the designated FSIS official import inspection establishment or alternative inspection location authorized by FSIS. FSIS also will continue to perform verification activities at the designated official import inspection establishment on these imported products, prior to release into commerce. FSIS intends to work with foreign governments, industry, and all interested stakeholders in implementing these changes. In particular, we believe that progressing toward a more electronic environment will benefit the Agency, industry, and most of all, the public health. If you have questions, please contact Mike Kelley at Mike.Kelley@fsis.usda.gov or (713) 718-3322.

Incerel Daniel L. Engeljohn, PhD Assistant Administrator Office of Policy and Program Development An Equal Opportunity Provider and Employer", "Attachment 1: Foreign Establishment Certificate Requirements 1) Countries currently exporting to the United States that are making no changes to the previous year's annual establishment certification should submit the foreign establishment's name and control number (e.g. the establishment number assigned by the foreign inspection agency). The foreign official's title and signature is required for paper-copy submissions. FSIS does not require the foreign official's title and signature for foreign governments that electronically transmit foreign establishment certifications. 2) For countries providing an initial certification or countries currently exporting to the United States that are adding new establishments or listing any establishment for which information from last year's certificate has changed, the following information should be submitted for the new or changed establishments: \u2022 foreign establishment's name address, and control number; \u2022 foreign official's title, signature, and date (paper certificates only); \u2022 type of operations conducted at the foreign establishment (e.g., slaughter, processing, storage, exporting warehouse); \u2022 the establishment's eligibility status (e.g., new or relisted (if previously de listed) and, \u2022 for slaughter and processing establishments only, the species and type of products produced, such as the process category. The process categories include raw non-intact; raw -intact; thermally processed -commercially sterile; not heat treated -shelf stable; heat treated -shelf stable; fully cooked -not shelf stable; heat treated but not fully cooked -not shelf stable; and, products with secondary inhibitors -not shelf stable, and egg products.", "Attachment 2: Foreign Inspection Certificate Requirements 1) For paper-based foreign inspection certificates, FSIS requires the following information, in English, for all meat, poultry, and egg products: \u2022 date, name, and title of the official authorized to issue inspection certificates for products imported into the United States; \u2022 the official seal of the foreign government responsible for the inspection of the product; \u2022 foreign country of export and the producing foreign establishment number; \u2022 species used to produce the product and the source country and foreign establishment number, if the source materials originate from a country other than the exporting country; \u2022 product's description,

including the process category, the product category, and the product group (see Attachment 3); \u2022 name and address of the exporter or consignor; \u2022 name and address of the importer or consignee; \u2022 number of units (pieces or containers) and the shipping or identification mark on the units; \u2022 net weight of each lot, \u2022 production dates or codes used when country or establishment was ineligible. When production codes are used on product from establishments that have been delisted or relisted the codes must be translated into dates on the inspection certificate, and \u2022 any additional information needed by FSIS to determine whether the product is eligible to be imported into the United States., 2) For electronic foreign inspection certification, FSIS requires the same information listed above for paper-based certificates, except the name and title of the official authorized to issue inspection certificates for products imported into the United States.", "Attachment 3: Product Categorization FSIS has developed this document to assist with accurate identification of the meat, poultry, and egg products certified for export to the United States. Process Category: There are nine (9) process categories identified in 9CFR 417 .2(b ). Of the nine (9) listed, Slaughter is considered an internal process that occurs in establishments where the animals or birds are slaughtered. This category is not used for imported products. An additional process category that is not contained in 9CFR 417 .2(b ) is Egg Products. Note that FSIS has recently renamed two process categories: Raw Product-Ground and Raw ProductNot Ground are now referred to as Raw Product-Non-Intact and Raw Product-Intact, respectively. However, use of either terminology will be acceptable to FSIS. Note that official foreign inspection certificates should reflect the process category name, rather than the obsolete coding previously used by FSIS (e.g. 03B, 03C, etc.). These codes have been included in the table as some countries previously certified the process categories on the inspection certificates with this coding. Raw Product-Non-Intact: This process category applies to establishments that further process by using processing steps such as grinding, comminuting, injecting product with solutions, or mechanical tenderization by needling, cubing, pounding devices or other means of creating non-intact product. Examples of finished products in this category include raw products reconstructed into formed entrees, mechanically separated species and advanced meat recovery product. If the establishment produces bench trim or pieces of meat produced from non-intact meat, then the bench trim or pieces are also considered non-intact. Raw Product-Intact: FSIS considers raw products to be intact unless they have undergone any of the processes associated with the Raw Product-Non-Intact process category. Thermally Processed - Commercially Sterile: This process category applies to establishments that use a thermal processing step. Thermally processed, commercially sterile finished products are products in cans or flexible containers such as pouches, or semi-rigid, as in lunch bowls. Thermally processed, commercially sterile products are addressed in Subpart G, 318.300-311 for meat food products, and Subpart X, 381.300 to 311, for poultry products. Not Heat Treated-Shelf Stable: This process category applies to establishments that further process by curing, drying, or fermenting processing step as the sole means by which product achieves food safety. Establishments in this process category may apply a low-level heat treatment as long as the heat treatment is not used as means to achieve food safety. The finished products produced under this Process Categories are shelf stable. FSIS does not require shelf stable products to be frozen or refrigerated for food safety purposes. Heat Treated-Shelf Stable: This process category applies to establishments that further process by using a heat treatment processing

step to achieve food safety in combination with curing, drying, or fermenting processing step to achieve food safety. The finished products produced under this process category are shelf stable. FSIS does not require shelf stable products to be frozen or refrigerated for food safety purposes. If the establishment produces using the processing steps applicable under this process category,"and the product is not shelf stable, then establishment is producing product under the process category Fully Cooked-Not Shelf Stable. Fully Cooked-Not Shelf Stable: This process category applies to establishments that further process products by using primarily a full lethality heat process step (e.g. cooking) to achieve food safety. The finished products that establishments produce under this process category are not shelf stable. FSIS requires the products to be frozen or refrigerated for food safety purposes. These products also meet the definition of Ready to Eat (RTE) as defined in 9 CFR 430.1. Heat Treated but Not Fully Cooked-Not Shelf Stable: This process category applies to an establishment that further processes products that are (1) not ready-to-eat products (NRTE) or (2) raw otherwise processed products that are refrigerated or frozen throughout the product's shelf life. Meat and poultry products are produced using a heat process that meets one of the following criteria: a. The heat processing step is not adequate to achieve food safety. Products may be partially cooked or heated to set batter on a raw product. b. The heat processing step applied to meat or poultry component was adequate to achieve food safety, however product is further processed, assembled, or packaged so that cooked meat or poultry products contacts non-ready to-eat product ingredients. In this case, the final product is in a form that is not edible without additional preparing to achieve food safety. An example of this product is pot pie product that contains cooked chicken and raw dough. NOTE: This category may also include products that receive a full lethality treatment but there is no standard of identity defining them as fully cooked (e.g., hotdogs or barbecue) or a common or usual name that consumers understand to refer to RTE product (e.g., pates). Products with Secondary Inhibitors-Not Shelf Stable: This process category applies to establishments that further process by using a curing processing step or a processing step using other ingredients that inhibit bacterial growth. These products are generally refrigerated or frozen throughout the product's shelf life. Depending on the process and ingredients, these products may or may not meet the definition of RTE as defined in 9 CFR 430.1. Eggs\ /Egg Products: This process category applies to dried, pasteurized and unpasteurized egg products. Product Category (with Applicable Species) The Product Categories are shown in the PSIS Product Categorization table with the appropriate species indicated for each. The Species designations PSIS is using for PHIS are: for Meat: Beef, Veal, Pork, Lamb, Mutton, and Goat; for Poultry: Chicken, Turkey, Duck, Goose, Guinea, and Squab, including for Ratites: Emu, Ostrich, and Rhea; for Eggs: Chicken, Turkey, Duck, Goose and Guinea; and for Egg Products: Chicken, Turkey, Duck, Goose, and Guinea. For each product, the certification must indicate which species is predominant in the product to assure the appropriate regulations are applied to the product when applicable. Product Group. The product group defines the product down to a level that PSIS can program appropriate types of inspections (TOI) for examinations and laboratory sampling. Regulatory references are added where applicable for clarification. While these appear to be self-explanatory, for Raw Product-Intact, Cuts are cuts of meat (e.g., steaks, chops, etc.) that are below the Primal and Subprimal level."The following table displays the process categories and the types of finished products that can be present in a process category. Finished Product Types by Process Category

Raw Product NRTE Product RTE Products Thermally Processed Product Slaughter \u2022 Raw - Non Intact (Raw Ground) \u2022 Raw-Intact (Raw Not Ground) \u2022 Thermally Processed-Commercially Sterile \u2022 Not Heat-Treated -Shelf Stable \u2022 \u2022 Heat Treated -Shelf Stable \u2022 \u2022 Fully Cooked-Not Shelf Stable \u2022 Heat Treated but Not Fully CookedNot Shelf Stable \u2022 Product with Secondary Inhibitors-Not Shelf Stable \u2022 \u2022 \u2022 Eggs\Egg Products Not Applicable Ready to Eat applies to any product intended for human consumption without further preparation steps. Note: Products that appear fully cooked or are customarily consumed without further preparation, but the label does not include cooking instructions, are by default considered RTE. RTE fully cooked means that the products have been sufficiently cooked so that they are safe to eat as they are, with no further preparation required by the consumer. Note: Many of these products are customarily eaten hot, and heating instructions may be included on the label. Some frozen RTE products require reheating for palatability. These frozen products are still safe to eat without this further preparation by the consumer and are therefore still considered RTE. Some examples include: fully cooked hams, cooked beef, roast beef, pastrami, corned beef, hot dogs, meat loaves, meat and poultry salads, sliced luncheon meats, baked chicken, frozen entrees, and poultry rolls. Fresh or frozen entrees with fully cooked meat or poultry portions combined with fully cooked sauces, vegetables, pasta, or other ingredients are RTE products. These products are designed to be re-heated by the consumer, and may include instructions for re-heating. Not Ready to Eat applies to products with cooking instructions or labeled with statements on the principal display panel such as \"Cook Thoroughly, Cook and Serve, Not Ready to Eat, or For Safety and Quality-follow these cooking instructions.\" These products are considered NRTE. Certain NRTE products are required to bear safe handling instructions (SHI).,"Some NRTE finished products are heat treated but are not fully cooked. These NRTE products should have sufficient labeling information to inform the consumer that the product must be cooked for safety. This information may be contained within the product name on the principal display panel, and may contain cooking instructions that refer to cooking the product for safety rather than heating the product for best quality. The product often times may bear a safe handling instruction. Some NRTE finished products are prepared with both meat\poultry components that have received a lethality treatment in combination with non-meat\poultry components that need to receive a lethality treatment. These multi-component products, e.g., meals, dinners, and entrees, have labeling features which are conspicuous so that intended users are fully aware that the product must be cooked for safety. The principle display panel on the label defines these products, e.g., \"Cook and Serve, \"Must be thoroughly cooked,\" \"Cook before eating\", and the product should include cooking instructions when required. Processors should refer to <http://www.fsis.usda.gov/wps/wcmfcontent/ebb99ef17-40f9-4528-ac0f0b733ld871d6/ResourceI.pdf?MOD=AJPERES> for guidance on the labeling of NRTE products. ...","Raw Product-Non-Intact [HACCP] Process Category [Finished] Product Category Species Product Group Raw Product\u00ad Non-1 ntact Raw ground, comminuted, or otherwise non-intact beef Beef, Veal - Ground Beef [\u00a7319.1S(a)] -Hamburger [\u00a7319.15(b)] -Beef Patty Product [\u00a7319 .15(c)] -Formed Steaks [\u00a7319 .1S(d)] -Sausage [\u00a7319.142; 319.143] -Advanced Meat Recovery Product (AMR) -Finely Textured Beef -Non-1 nta ct Cuts -\u00b7 -Trimmings from Non-1 ntact -Bench Trim from Non-1 ntact -Other Non-Intact -Low Temperature Rendered Product -Partially Defatted Chopped Beef (PDCB) -Partially Defatted Beef Fatty Tissue

(PDBFT)[\u00a7319.1S(a)] Raw ground, comminuted, or otherwise non-intact pork Pork - Ground Product -Sausage (\u00a7319.141; 319.143; 319.144; 319.145] -Other Non-Intact (includes PDPFT [\u00a7319.29]) -Adva need Meat Recovery Product (AMR) -Mechanically Separated [\u00a7319.5] Raw ground, comminuted, or otherwise non-intact meatother: Goat, Lamb, Mutton -Ground Product -Sausage -Other Non-Intact -Adva need Meat Recovery Product (AMR) -Mechanically Separated [\u00a7319.5] Raw ground, comminuted, or otherwise non-intact chicken Chicken -Ground Product -Sausage -Other non-intact -Mechanically Separated [\u00a7381.173] Raw ground, comminuted, or otherwise non-intact turkey Turkey - Ground Product -Sausage -Other non-intact -Mechanically Separated [\u00a7381.173] Raw ground, comminuted, or otherwise non-intact poultryother: Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea -Ground Product -Sausage -Other non-intact -Mechanically Separated [\u00a7381.173]", "Raw Product-Intact [HACCP] Process Category [Finished] Product Category Species Product Group Raw Product Intact Raw Intact Beef Beef, Veal -Carcass (including halves or quarters) -Primals and Subprimals -Cuts -Bnls. Mfg. Trimmings -Head Meat Raw Intact Beef (can't) Beef, Veal -Cheek Meat -Weasand Meat -Heart Meat -Edible Offal -Other Intact Raw Intact Pork Pork -Carcass (including halves or quarters) -Primals and Subprimals -Cuts -Bnls. Mfg. Trimmings -Edible Offal -Other Intact Raw Intact Meat-Other Goat, Lamb, Mutton -Carcass (including halves or quarters) -Primals and Subprimals -Cuts -Bnls. Mfg. Trimmings - Edible Offal -Other Intact Raw Intact Chicken Chicken -Whole Bird -Poultry Parts (including necks\feet& giblets) -Boneless and\or Skinless Parts -Bnls. Mfg. Trimmings Raw Intact Turkey Turkey -Whole Bird -Poultry Parts (incl udi ng necks\feet & giblets) -Boneless and\or Skinless Parts -Bnls . Mfg. Trimmings Raw Intact Poultry-Other Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea -Whole Bird -Poultry Parts (incl udi ng necks\feet & giblets) -Boneless and\or Skinless Parts -Bnls. Mfg. Trimmings", "II p . II S \u00b71 Therma ty rocessed -commerc1a 1y ten e [HACCP] Process Category [Finished] Product Category Species Product Group Thermally Processed- Commercially Sterile Thermally ProcessedCommercially Sterile Beef, Veal, Pork, Goat, Lamb, Mutton -Sausage [\u00a7319.140; 319.180; 319.181] Pork -Ham (includes: Shoulders, Picnics, Butts and Loins [\u00a7319.104]; Chopped Ham, Pressed Ham, Spiced Ham, etc. [\u00a7319.105]) All meat or poultry -Soups -Corned (Species) -Other Chicken, Turkey, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea -Sausage", "Not Heat Treated-Shelf Stable [HACCP] Process [Finished] Product Species Category Category Not Heat TreatedNot Ready-To-Eat (NRTE) Beef, Veal, Pork, Shelf Stable Otherwise Processed Meat Goat, Lamb, Mutton Not Ready-To-Eat (NRTE) Chicken, Turkey, Otherwise Processed Poultry Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea Ready-To-Eat (RTE) Acidified\ Beef, Veal, Pork, Fermented Meat (w\o cooking) Goat, Lamb, Mutton Ready-To-Eat (RTE) Acidified\ Chicken, Turkey, Fermented Poultry (w\o Duck, Goose, cooking) Guinea, Squab, Emu, Ostrich, Rhea Ready-To-Eat (RTE) Dried Meat Beef, Vea l, Pork, Goat, Lamb, Mutton Ready-To-Eat (RTE) Dried Meat Pork Ready-To-Eat {RTE} Dried Chicken, Turkey, Poultry Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea Ready-To-Eat (RTE) Salt Cured Beef, Vea l, Pork, Meat Goat, Lamb, Mutton Ready-To-Eat (RTE) Salt Cured Chicken, Turkey, Poultry Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea Product Group -Rendered Fats, Oils -Bacon -Meals\ Dinners\ Entrees -Sandwiches\ Filled Rolls\ Wraps -Sauces -Pies\ Pot Pies -Smoked Parts -Soups -Other -Rendered Fats, Oils -Bacon \u2022Mea ls\ Di nners\ Entrees -Sandwiches\ Filled Rolls\ Wraps -Sauces -Pies\ Pot Pies \u00b7 Smoked Parts -Soups -Other -Sausage\Sa lami -Not 51 iced -Sausage\Salami -Sliced -Other -Not 51

iced -Other -51 iced -Sausage\Salami -Not Sliced -Sausage\Salami -Sliced -Other-Not 51 iced -Other -Sliced -Jerky -Other, Sliced (Except Ham) -Other, Not 51 iced (Except Ham) -Ham, 51 iced -Ham, Not 51 iced (Ham includes: Shoulders, Picnics, Butts and Loins [\u00a7319.104]; Chopped Ham, Pressed Ham, Spiced Ham, etc. [\u00a7319.105]) -Jerky -Other, Sliced -Other, Not 51 iced -Not 51 iced -Sliced -Not Sliced -Sliced", "Heat Treated -Shelf Stable [HACCP] Process [Finished] Product Species Product Group Category Category Heat TreatedNot Ready-To-Eat (NRTE) Beef, Veal, Pork, -Rendered Fats, Oils Shelf Stable Otherwise Processed Meat Goat, Lamb, Mutton -Bacon -Meals\Dinners\Entrees -Sandwiches\Filled Rolls\ Wraps -Sauces -Pies\PotPies -Smoked Parts -Soups -Other Not Ready-To-Eat (NRTE) Chicken, Turkey, -Rendered Fats, Oils Otherwise Processed Poultry Duck, Goose, -Bacon Guinea, Squab, Emu, -Meat\Is\Dinners\Entrees Ostrich, Rhea -Sandwiches\Filled Rolls\Wraps -Sauces -Pies\Pot Pies -Smoked Parts -Soups -Other Ready-To-Eat (RTE) Acidified\ Beef, Veal, Pork, -Sausage\Salami -Not Sliced Fermented Meat (w/o cooking) Goat, Lamb, Mutton -Sausage\Salami -Sliced -Other-Not Sliced -Other-Sliced Ready-To-Eat (RTE) Acidified\ Chicken, Turkey, -Sausage\Salami -Not Sliced Fermented Poultry (w/o Duck, Goose, -Sausage\Salami -Sliced cooking) Guinea, Squab, Emu, -Other-Not Sliced Ostrich, Rhea -Other-Sliced Ready-To-Eat (RTE) Dried Meat Beef, Veal, Pork, -Jerky Goat, Lamb, Mutton -Other, Sliced (Except Ham) -Other, Not Sliced (Except Ham) Ready-To-Eat (RTE) Dried Meat Pork -Ham, Sliced -Ham, Not Sliced (Ham includes: Shoulders, Picnics, Butts and Loins [\u00a7319.104]; Chopped Ham, Pressed Ham, Spiced Ham, etc. [\u00a7319.105]) Ready-To-Eat (RTE) Dried Chicken, Turkey, -Jerky Poultry Duck, Goose, -Other, Sliced Guinea, Squab, Emu, -Other, Not Sliced Ostrich, Rhea Ready-To-Eat (RTE) Salt Cured Beef, Veal, Pork, -Not Sliced Meat Goat, Lamb, Mutton -SI iced Ready-To-Eat (RTE) Salt Cured Chicken, Turkey, -Not Sliced Poultry Duck, Goose, -SI iced Guinea, Squab, Emu, Ostrich, Rhea", "Fully Cooked-Not Shelf Stable with subsequent exposure to the environment (post-lethality exposure) [HACCP] Process [Finished] Product Species Product Group Category Category Fully Cooked-Not Ready-To-Eat (RTE) Fully Beef, Veal, Pork, -Hot Dog Products (including applicable sausages) Shelf Stable Cooked Meat Goat, Lamb, Mutton [\u00a7319.180; 319.181] -Sausage products [\u00a7319.140] -Sausage\Spread\Pate -Meat+ Non-meat Component -Diced\Shredded -Nuggets -Parts -Other, Sliced (Except Ham) -Other, Not Sliced (Except Ham) -Patties (Except Ham) Ready-To-Eat (RTE) Fully Cooked Meat Pork -Ham, Sliced -Ham, Not Sliced (Ham includes: Shoulders, Picnics, Butts and Loins [\u00a7319.104]; Chopped Ham, Pressed Ham, Spiced Ham, etc. [\u00a7319.105]) -Ham Patties [\u00a7319.105(d)] Ready-To-Eat(RTE) Fully Cooked Poultry Chicken, Turkey, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea -Hot Dog Products -Sausage\Spread\Pate -Poultry+ Non-poultry component -Sausage Products -Diced\Shredded -Patties\Nuggets -Parts -Other, sliced -Other, not sliced", "Fully Cooked-Not Shelf Stable without subsequent exposure to the environment (no post-lethality exposure) [HACCP] Process Category [Finished] Product Category Species Product Group Fully Cooked -Not Shelf Stable (con't) Ready-To-Eat (RTE) Fully Cooked Meat (w/o subsequent exposure to the environment) Beef, Veal, Pork, Goat, Lamb, Mutton -Hot Dog Products (including applicable sausages) [\u00a7319.180; 319.181] -Sausage products [\u00a7319.140] -Sausage\Spread\Pate -Meat+ Non-meat Component -Diced\Shredded -Nuggets -Parts -Other, Sliced (Except Ham) -Other, Not Sliced (Except Ham) -Patties (Except Ham) Ready-To-Eat (RTE) Fully Cooked Meat Pork -Ham, Sliced Cooked Meat (w/o subsequent -Ham, Not SI iced exposure to the environment) (Ham includes: Shoulders, Picnics, Butts and Loins [\u00a7319.104]; Chopped

Ham, Pressed Ham, Spiced Ham, etc. [\u00a7319.105] -Ham Patties [\u00a7319.105(d)] Ready-To-Eat (RTE) Fully Cooked Poultry (w/o subsequent exposure to the environment) Chicken, Turkey, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea -Hot Dog Products -Sandwiches\Spread\Pate -Poultry+ Non-poultry component -Sausage Products -Diced\Shredded -Patties\Nuggets -Parts ... -Other, sliced -Other, not sliced", "Heat Treated but Not Fully Cooked-Not Shelf Stable [HACCP] Process Category [Finished] Product Category Species Product Group HeatTreated but Not Fully CookedNot Shelf Stable Not Ready-To-Eat {NRTE} Otherwise Processed Meat Beef, Veal, Pork, Goat, Lamb, Mutton -Rendered Fats, Oils -Bacon -Meals\Entrees\Sandwiches\Filled Rolls\Wraps -Sauces -Pies\Pot Pies -Smoked Parts -Soups -Other -Sausage products [\u00a7319.140] Not Ready-To-Eat {NRTE} Chicken, Turkey, -Rendered Fats, Oils Otherwise Processed Poultry Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea -Bacon -Meals\Entrees\Sandwiches\Filled Rolls\Wraps -Sauces -Pies\Pot Pies -Smoked Parts -Soups -Sausages -Other", "Products with Secondary Inhibitors-Not Shelf Stable [Finished] Product Category [HACCP] Process Category Products with Secondary Inhibitors-Not Shelf Stable Species Product Group Not Ready-To-Eat (NRTE) Otherwise Processed Meat Beef, Veal, Pork, Goat, Lamb, Mutton -Rendered Fats, Oils -Bacon -Meals\Entrees\Sandwiches\Filled Rolls\Wraps -Sauces -Pies\Pot Pies -Smoked Parts -Soups -Other -Rendered Fats, Oils -Bacon -Meals\Entrees\Sandwiches\Filled Rolls\Wraps -Sauces -Pies\Pot Pies -Smoked Parts -Soups -Other -Not Sliced -Sliced Not Ready-To-Eat (NRTE) Otherwise Processed Poultry Chicken, Turkey, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea Ready-To-Eat(RTE) Salt Cured Meat Beef, Veal, Pork, Goat, Lamb, Mutton Ready-To-Eat (RTE) Salt Cured Poultry Chicken, Turkey, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea -Not Sliced -Sliced", "Eggs\Egg Products [HACCP] Process [Finished] Product Species Category Category Egg Products Chicken, Turkey, Duck, Goose, Guinea Eggs\Egg Products Product Group -Pasteurized (Frozen or Liquid) \u00b7 Whole egg (with or without added ingredients) \u00b7 Egg whites (with or without added ingredients) \u00b7 Vol k (with or without added ingredients) \u00b7 Egg Products (blends of whole egg, egg whites and\or yolks) (with or without added ingredients) -Pasteurized (Tanker\Large Totes) \u00b7 Whole egg (with or without added ingredients) \u00b7 Egg whites (with or without added ingredients) \u00b7 Yolk (with or without added ingredients) \u00b7 Egg Products (blends of whole egg, egg whites and\or yolks) (with or without added ingredients) -Unpasteurized (Frozen or Liquid) \u00b7 Whole egg (with or without added ingredients) \u00b7 Egg whites (with or without added ingredients) \u00b7 Vol k (with or without added ingredients) \u00b7 Egg Products (blends of whole egg, egg whites and\or yolks) (with or without added ingredients) -Unpasteurized (Tanker\Large Totes) \u00b7 Whole egg (with or without added ingredients) \u00b7 Egg whites (with or without added ingredients) \u00b7 Yolk (with or without added ingredients) \u00b7 Egg Products (blends of whole egg, egg whites and\or yolks) (with or without added ingredients) -Dried \u00b7 Whole egg (with or without added ingredients) \u00b7 Egg whites (with or without added ingredients) \u00b7 Vol k (with or without added ingredients) \u00b7 Egg Products (blends of whole egg, egg whites and\or yolks) (with or without added ingredients)"]}, {"file\_name": "FSIS\_GD\_2015\_0002", "title": "Letter to Importers and Customs Brokers", "num": "FSIS-GD-2015-0002", "id": "943eee922018933edac1738d72a8e8d2f4417c2434d0ba2d24dea86f4091a929", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-"}]

guidelines","url":"<https://www.fsis.usda.gov/sites/default/files/import/Import-Rule-Letter-to-Brokers.pdf>","type":"pdf","n\_pages":19,"word\_count":4852,"text\_by\_page":["USDA United States Department of Agriculture Food Safety and Inspection Service 1400 Independence Avenue, SW. Washington, D.C. 20250 Dear Importer or Customs Broker: The United States Department of Agriculture's (USDA) Food Safety and Inspection Service (PSIS) is the public health regulatory agency responsible for ensuring that domestic and imported meat, poultry, and processed egg products are safe, wholesome, and correctly labeled and packaged, based on the statutory authority of the Federal Meat Inspection Act (FMIA); the Poultry Products Inspection Act (PPIA); and the Egg Products Inspection Act (EPIA). All shipments of meat, poultry, and egg products exported to the United States, which are certified by the foreign country's competent authority, must be presented for reinspection at an PSIS official import inspection establishment, or alternative inspection location authorized by PSIS. FSIS has published a final rule that, effective November 18, 2014, changed FSIS' meat, poultry, and egg products import regulations to eliminate the requirement for a paper copy of the import application for import inspection (FSIS Form 9540-1), clarify that the prior notification timeframe for import inspection applications must be submitted when entry is filed with U.S. Customs and Border Protection (CBP) and change the specific product information that will assist FSIS in designating reinspection assignments and enforcement strategies for shipments that fail to present (FTP) to FSIS for reinspection. Additional clarification for each of these changes is provided below. Public Health Information System (PHIS) Import Component and the Automated Commercial Environment (ACE) On February 19, 2014, President Obama signed an Executive Order streamlining the import and export process for America's businesses. Executive Order 13659 requires the completion and government-wide utilization of the International Trade Data System (ITDS) by December 2016. When fully implemented, ITDS will allow businesses to submit the data required by CBP and its Partner Government Agencies (PGAs) to import or export cargo through the Automated Commercial Environment (ACE), or "Single Window." CBP is working to complete and deploy core trade processing capabilities in ACE by December 2016, and as part of this transition, a mandatory time line has been established requiring trade users to begin filing electronic data to ACE. Starting on November 1, 2015, importers or brokers must submit electronic cargo release and entry summary data-including any data within PGAs' jurisdiction-to CBP through ACE. An Equal Opportunity Provider and Employer,"The FSIS PHIS import component, which launched in 2012, automates and streamlines the import inspection application processes by electronically linking with CBP's ACE. The current PHIS-ACE interface accommodates a limited amount of data transfer, transmitting the entry and entry summary data collected by CBP. Importers and Customs brokers filing entry with CBP submit the additional PSIS-specific data on the paper import inspection application (FSIS Form 9540-1 ). Ultimately, the Single-Window system will enable U.S. importers and Customs brokers to enter FSIS import inspection application data directly into ACE through the Automated Broker Interface (ABI) as part of the CBP entry process, thereby eliminating the need to file a separate paper application with FSIS. To incorporate the PSIS-specific data elements as part of the PHIS-ACE interface and give importers or brokers the option of submitting import applications electronically, FSIS implemented a PGA Message Set pilot in April 2014, initially involving two Customs brokers and three ports of entry. The PGA Message Set populates additional PSIS-specific data elements in the PHIS import component for

importers and brokers filing entry with CBP, which expedites data entry and shipment clearance. Since the publication of FSIS' final rule, the PGA Message Set eliminates the need to file a separate paper application (FSIS Form 9540-1) with FSIS. FSIS will expand the pilot to include all ports, as well as all interested importers and brokers by November 2015. FSIS will soon provide information on upcoming stakeholder events that will give importers and brokers an overview of the FSIS PGA Message Set and outline the next steps for the industry. Import Inspection Application and Prior Notification FSIS' meat, poultry, and egg products import regulations require importers to apply for the inspection of imported product. In the final rule, FSIS clarified the timeframe for when applicants must submit import inspection applications; required the import inspection application (FSIS Form 9540-1) for egg products; and required additional information, such as production dates, when a country, foreign establishment, or specific product has been delisted or relisted as eligible for export. This information will help FSIS to verify that the relevant product was produced in the foreign establishment during an eligible timeframe. The final rule clarifies that applicants must submit import inspection applications to FSIS in advance of the shipment's arrival, but no later than when the initial entry is filed with CBP (prior notification). As noted above, the PHIS import component interfaces with CBP's ACE system and has the capability to receive the data needed to complete the import inspection application. Applicants that file their Customs entry with the PGA Message Set will meet the prior notification requirement. Applicants using paper applications must provide the paper application to FSIS in advance of the shipment's arrival at the official import inspection establishment or other PSIS-approved location designated on the import inspection application, and no later than when the entry is made An Equal Opportunity Provider and Employer", "with CBP. FSIS inspection program personnel will enter the additional required FSIS data into the PHIS import component by using information from the paper import inspection application. If FSIS has not received the application prior to the shipment's arrival, FSIS will notify the establishment management of the violation and that future shipments that do not meet the prior notification requirement will likely be refused entry. In addition, if the shipment is not rejected and FSIS proceeds with reinspection, the importer may experience delays in the import inspection process as a result of the delayed receipt of the application and subsequent data entry into PHIS. Importers and brokers that do not utilize PGA Message Set are to transition from the current FSIS Form 9540-1 to the revised import inspection application (FSIS Form 95401) no later than March 18, 2015. The revised FSIS Form 9540-1 ([http://www.fsis.usda.gov/wps/wcm/connect/a8eead0d-23c3-428e-937f\u00ad](http://www.fsis.usda.gov/wps/wcm/connect/a8eead0d-23c3-428e-937f/u00ad) a8a0Sb09edbb/FSIS~9540-1-Import-Inspection-Application.pdf?MOD=AJPERES) that is completed by the importer or broker must be correct. The revised import inspection application requires the production date(s) when a country, foreign establishment, or specific product has been de listed or relisted as eligible for export. If product codes are used in place of production dates, these codes must be translated into dates (mm\dd\yyyy) on the inspection certificate. Attachment 1 summarizes the options and requirements to apply for import inspection and Attachment 2 provides information on FSIS product categorization for meat, poultry, and egg products certified for export to the United States. Failure to Present (FTP) Imported meat, poultry, and egg product that has entered commerce without FSIS import reinspection violates the FMIA; the PPIA; or the EPIA, as well as the implementing regulations for each Act (9 CFR 327.6; 381.199; 590.925). The importer of record is responsible for any product identified as FTP

and when a product has been identified as a FTP, FSIS will request, through CBP, a redelivery of the shipment and appropriate CBP penalties. As part of the Single Window initiative, FSIS is working with CBP to automate the redelivery process by December 2016, which will streamline enforcement of CBP redelivery requirements and meet the goals of Executive Order 13659. Customs has full authority to assess penalties and liquidated damages claims and to seize merchandise for violations of Customs or other laws enforced by the Customs Service. For more information about CBP redelivery requirements and penalties, please contact CBP's Office of Regulations and Rulings (<http://www.cbp.gov/contact/internationaltrade-contacts>). FSIS may also request that the importer of record recall FTP product, if the shipment cannot be redelivered. Imported meat, poultry and egg products are considered "in-commerce" when they are off-loaded at a location other than the official import inspection establishment or other FSIS approved location designated on the import inspection application. If imported product bypasses FSIS reinspection, FSIS considers such product to be in-commerce and a FTP. The FTP product -whether the shipment is intact or partial -will no longer be eligible for reinspection. Product still in the original shipping containers may either be destroyed or returned to the country of An Equal Opportunity Provider and Employer", "origin. If any imported product identified as FTP has been removed from the original cartons or further processed, FSIS will initiate a regulatory control action to deal with the product, including any further processed product that contains the FTP product, to ensure appropriate disposition (i.e., destruction). Under this final rule, FSIS will continue to require all shipments of meat, poultry, and egg products exported to the United States to be certified by the foreign country's competent authority and presented for reinspection at the designated FSIS official import inspection establishment, or alternative inspection location authorized by FSIS. FSIS also will continue to perform verification activities at the designated official import inspection establishment on these imported products, prior to release into commerce. FSIS intends to work with foreign governments, industry, and all interested stakeholders in implementing these changes. In particular, we believe it is important for importers and brokers to begin adopting and participating in the electronic import processes described in this letter, which will help ensure that FSIS meets the goals and deadlines of Executive Order 13659. We believe this transition to a more electronic environment will benefit industry, FSIS, and most of all, the public health. FSIS strongly encourages importers and brokers to work together closely in meeting FSIS import requirements. If you have questions, please contact Mike Kelley at [Mike.Kelley@fsis.usda.gov](mailto:Mike.Kelley@fsis.usda.gov) or (713) 718-3322. Daniel L. Engeljohn, PhD Assistant Administrator Office of Policy and Program Development Enclosure An Equal Opportunity Provider and Employer", "Attachment 1: Options and Requirements for \u00b7 [Import Inspection Application Mode of CBP Entry Foreign Inspection Certificate Type Paper Foreign Inspection Certificate required? Paper 9540-1 required? Prior notification met? ACE\Automated Commercial System (ACS) Entry Paper Yes Yes Yes, if paper 9540-1 received no later than when entry filed with CBP ACE\ACS Entry Electronic Certification (eCert) No Yes Yes, if paper 9540-1 \u00b7 received no later than when entry , led with CBP ACEwithPGA Message Set Paper Yes No Yes ACEwithPGA Message Set eCert No No Yes", "Attachment 2: FSIS Product Categorization FSIS has developed this document to assist with accurate identification of the meat, poultry, and egg products certified for export to the United States. Process Category: There are nine (9) process categories identified in 9CFR 417.2(b). Of the nine (9) listed, Slaughter is considered an internal

process that occurs in establishments where the animals or birds are slaughtered. This category is not used for imported products. An additional process category that is not contained in 9CFR 417 .2(b) is Egg Products. Note that FSIS has recently renamed two process categories: Raw Product-Ground and Raw Product-Not Ground are now referred to as Raw Product-Non-Intact and Raw Product-Intact, respectively. However, use of either terminology will be acceptable to FSIS. Note that official foreign inspection certificates should reflect the process category name, rather than the obsolete coding previously used by FSIS (e.g. 03B, 03C, etc.). These codes have been included in the table as some countries previously certified the process categories on the inspection certificates with this coding.

**Raw Product-Non-Intact:** This process category applies to establishments that further process by using processing steps such as grinding, comminuting, injecting product with solutions, or mechanical tenderization by needling, cubing, pounding devices or other means of creating non-intact product. Examples of finished products in this category include raw products reconstructed into formed entrees, mechanically separated species and advanced meat recovery product. If the establishment produces bench trim or pieces of meat produced from non-intact meat, then the bench trim or pieces are also considered non-intact.

**Raw Product-Intact:** FSIS considers raw products to be intact unless they have undergone any of the processes associated with the Raw Product-Non-Intact process category.

**Thermally Processed -Commercially Sterile:** This process category applies to establishments that use a thermal processing step. Thermally processed, commercially sterile finished products are products in cans or flexible containers such as pouches, or semi-rigid, as in lunch bowls. Thermally processed, commercially sterile products are addressed in Subpart G, 318.300-311 for meat food products, and Subpart X, 381.300 to 311, for poultry products.

**Not Heat Treated-Shelf Stable:** This process category applies to establishments that further process by curing, drying, or fermenting processing step as the sole means by which product achieves food safety. Establishments in this process category may apply a low-level heat treatment as long as the heat treatment is not used as means to achieve food safety. The finished products produced under this Process Categories are shelf stable. FSIS does not require shelf stable products to be frozen or refrigerated for food safety purposes.

**Heat Treated -Shelf Stable:** This process category applies to establishments that further process by using a heat treatment processing step to achieve food safety in combination with curing, drying, or fermenting processing step to achieve food safety. The finished products produced under this process category are shelf stable. FSIS does not require shelf stable products to be frozen or refrigerated for food safety purposes. If the establishment produces using the processing steps applicable under this process category and the product is not shelf stable, then establishment is producing product under the process category Fully Cooked-Not Shelf Stable.

**Fully Cooked-Not Shelf Stable:** This process category applies to establishments that further process products by using primarily a full lethality heat process step (e.g. cooking) to achieve food safety. The finished products that establishments produce under this process category are not shelf stable. FSIS requires the products to be frozen or refrigerated for food safety purposes. These products also meet the definition of Ready to Eat (RTE) as defined in 9 CFR 430.1."

**"Heat Treated but Not Fully Cooked-Not Shelf Stable:** This process category applies to an establishment that further processes products that are (1) not ready-to-eat products (NRTE) or (2) raw otherwise processed products that are refrigerated or frozen throughout the product's shelf life. Meat and poultry products are produced using a heat process that meets one of the following

criteria: a. The heat processing step is not adequate to achieve food safety. Products may be partially cooked or heated to set batter on a raw product. b. The heat processing step applied to meat or poultry component was adequate to achieve food safety, however product is further processed, assembled, or packaged so that cooked meat or poultry products contacts nonready to-eat product ingredients. In this case, the final product is in a form that is not edible without additional preparing to achieve food safety. An example of this product is pot pie product that contains cooked chicken and raw dough. NOTE: This category may also include products that receive a full lethality treatment but there is no standard of identity defining them as fully cooked (e.g., hotdogs or barbecue) or a common or usual name that consumers understand to refer to RTE product (e.g., pates). Products with Secondary Inhibitors-Not Shelf Stable: This process category applies to establishments that further process by using a curing processing step or a processing step using other ingredients that inhibit bacterial growth. These products are generally refrigerated or frozen throughout the product's shelf life. Depending on the process and ingredients, these products may or may not meet the definition of RTE as defined in 9 CFR 430.1. Eggs\|Egg Products: This process category applies to dried, pasteurized and unpasteurized egg products. Product Category (with Applicable Species) The Product Categories are shown in the FSIS Product Categorization table with the appropriate species indicated for each. The Species designations FSIS is using for PHIS are: for Meat: Beef, Veal, Pork, Lamb, Mutton, and Goat; for Poultry: Chicken, Turkey, Duck, Goose, Guinea, and Squab, including for Ratites: Emu, Ostrich, and Rhea; for Eggs: Chicken, Turkey, Duck, Goose and Guinea; and for Egg Products: Chicken, Turkey, Duck, Goose, and Guinea. For each product, the certification must indicate which species is predominant in the product to assure the appropriate regulations are applied to the product when applicable. Product Group. The product group defines the product down to a level that FSIS can program appropriate types of inspections (TOI) for examinations and laboratory sampling. Regulatory references are added where applicable for clarification. While these appear to be self-explanatory, for Raw Product-Intact, Cuts are cuts of meat (e.g., steaks, chops, etc.) that are below the Primal and Subprimal level.", "The following table displays the process categories and the types of finished products that can be present in a process category. Finished Product Types by Process Category

Process Categories	Finished Products
Raw Product NRTE Product	RTE Products
Thermally Processed Product	Slaughter \u2022 Raw - Non Intact (Raw Ground) \u2022 Raw-Intact (Raw Not Ground) \u2022 Thermally Processed - Commercially Sterile \u2022 Not Heat-Treated-Shelf Stable \u2022 \u2022 Heat Treated -Shelf Stable \u2022 \u2022 Fully Cooked-Not Shelf Stable \u2022 Heat Treated but Not Fully CookedNot Shelf Stable \u2022 Product with Secondary Inhibitors-Not Shelf Stable \u2022 \u2022 Eggs\ Egg Products
Not Applicable Ready to Eat	applies to any product intended for human consumption without further preparation steps. Note: Products that appear fully cooked or are customarily consumed without further preparation, but the label does not include cooking instructions, are by default considered RTE. RTE fully cooked means that the products have been sufficiently cooked so that they are safe to eat as they are, with no further preparation required by the consumer. Note: Many of these products are customarily eaten hot, and heating instructions may be included on the label. Some frozen RTE products require reheating for palatability. These frozen products are still safe to eat without this further preparation by the consumer and are therefore still considered RTE. Some examples include: fully cooked hams, cooked beef, roast beef, pastrami, corned beef, hot dogs, meat loaves, meat

and poultry salads, sliced luncheon meats, baked chicken, frozen entrees, and poultry rolls. Fresh or frozen entrees with fully cooked meat or poultry portions combined with fully cooked sauces, vegetables, pasta, or other ingredients are RTE products. These products are designed to be re-heated by the consumer, and may include instructions for re-heating." "Not Ready to Eat applies to products with cooking instructions or labeled with statements on the principal display panel such as \"Cook Thoroughly, Cook and Serve, Not Ready to Eat, or For Safety and Quality-follow these cooking instructions.\" These products are considered NRTE. Certain NRTE products are required to bear safe handling instructions (SHI). Some NRTE finished products are heat treated but are not fully cooked. These NRTE products should have sufficient labeling information to inform the consumer that the product must be cooked for safety. This information may be contained within the product name on the principal display panel, and may contain cooking instructions that refer to cooking the product for safety rather than heating the product for best quality. The product often times may bear a safe handling instruction. Some NRTE finished products are prepared with both meat\poultry components that have received a lethality treatment in combination with non-meat\poultry components that need to receive a lethality treatment. These multicomponent products, e.g., meals, dinners, and entrees, have labeling features which are conspicuous so that intended users are fully aware that the product must be cooked for safety. The principle display panel on the label defines these products, e.g., \"Cook and Serve, \"Must be thoroughly cooked,\" \"Cook before eating\", and the product should include cooking instructions when required. Processors should refer to [http://www.fsis.usda.gov/wps/wcm/connect/ebb99e\\_17-40f9-4528-ac0f0b7331d871d6/Resource I.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/ebb99e_17-40f9-4528-ac0f0b7331d871d6/Resource I.pdf?MOD=AJPERES) for guidance on the labeling of NRTE products." "Raw Product-Non-Intact [HACCP] Process Category [Finished] Product Category Species Product Group Raw Product\u00ad Non-1 ntact Raw ground, comminuted, or otherwise non-intact beef Beef, Veal -Ground Beef [\u00a7319.15(a)] -Hamburger [\u00a7319.15(b)] -Beef Patty Product (\u00a7319.15(c)] -Formed Steaks [\u00a7319 .15(d)] -Sausage [\u00a7319 .142; 319.143] -Adva need Meat Recovery Product (AMR) -Finely Textured Beef -Non-1 nta ct Cuts -Trimmings from Non-1 ntact -Bench Trim from Non-Intact -Other Non-1 nta ct -Low Temperature Rendered Product -Partially Defatted Chopped Beef (PDCB) -Partially Defatted Beef Fatty Tissue (PDBFT)[\u00a7319 .15(a )] Raw ground, comminuted, or Pork -Ground Product otherwise non-intact pork -Sausage [\u00a7319 .141; 319.143; 319.144; 319.145] -Other Non-Intact (includes PDPFT (\u00a7319.29)] -Adva need Meat Recovery Product (AMR) -Mechanically Separated [\u00a7319.5] Raw ground, comminuted, or otherwise non-intact meatother: Goat, Lamb, Mutton -Ground Product -Sausage -Other Non-1 ntact -Adva need Meat Recovery Product (AMR) -Mechanically Separated [\u00a7319.5] Raw ground, comminuted, or Chicken -Ground Product otherwise non-intact chicken -Sa usage -Other non-intact -Mechanically Separated [\u00a7381.173] Raw ground, comminuted, or Turkey -Ground Product otherwise non-intact turkey -Sausage -Other non-intact -Mechanically Separated [\u00a7381.173] Raw ground, comminuted, or otherwise non-intact poultryother: Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea -Ground Product -Sausage -Other non-intact -Mechanically Separated [\u00a7381 .173]" "Raw Product -Intact [HACCP] Process Category [Finished] Product Category Species Product Group Raw ProductIntact Raw Intact Beef Beef, Veal -Carcass (including halves or quarters) -Primals and Subprimals -Cuts -Bnls. Mfg. Trimmings -Head Meat Raw Intact Beef (can't) Beef, Veal -Cheek Meat -Weasand Meat -Heart Meat -Edible Offal -

Other Intact Raw Intact Pork Pork -Carcass (including halves or quarters) -Primals and Subprimals -Cuts -Bnls. Mfg. Trimmings -Edible Offal -Other Intact Raw Intact Meat-Other Goat, Lamb, Mutton -Carcass (including halves or quarters) -Prima ls and Subprimals -Cuts -Bn ls. Mfg. Trimmings -Edible Offa I -Other Intact Raw Intact Chicken Chicken -Whole Bird -Poultry Parts (including necks\feet& giblets) -Boneless and\or Skinless Parts -Bnls. Mfg. Trimmings Raw Intact Turkey Turkey -Whole Bird -Poultry Parts (including necks\feet& giblets) -Boneless and\or Skinless Parts -Bn ls. Mfg. Trimmings", "[HACCP] Process Category ThermaJl y processed [Finished] Product Species Category c . II St \"I ommercta ty en e Product Group Thermally Processed- Commercially Steri l e Thermally ProcessedCommercially Sterile Beef, Veal, Pork, Goat, Lamb, Mutton -Sausage [\u00a7319.140; 319.180; 319.181] Pork -Ham (includes: Shoulders, Picnics, Butts and Loins [\u00a7319.104]; Chopped Ham, Pressed Ham, Spiced Ham, etc. [\u00a7319.105]) All meat or poultry -Soups -Corned (Species) -Other Chicken, Turkey, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea -Sausage", "Not Heat Treated-Shelf Stable [HACCP] Process [Finished] Product Species Product Group Category Category Not Heat TreatedNot Ready-To-Eat (NRTE) Beef, Veal, Pork, -Rendered Fats, Oils Shelf Stable Otherwise Processed Meat Goat, Lamb, Mutton -Bacon -Mea ls\V/Dinners\V/Entrees -Sa ndwi ches\V/Fi ll ed Rolls\V/Wraps -Sauces -Pies\V/Pot Pies -Smoked Parts -Soups -Other Not Ready-To-Eat (NRTE) Chicken, Turkey, -Rendered Fats, Oils Otherwise Processed Poultry Duck, Goose, -Bacon Guinea, Squab, Emu, -Meals\V/Dinners\V/Entrees Ostrich, Rhea -Sa ndwi ches\V/Fi ll ed Rolls\V/Wraps - Sauces -Pies\V/PotPies -Smoked Parts -Soups -Other Ready-To-Eat (RTE) Acidified\V Beef, Veal, Pork, -Sausage\V/Salami -Not Sliced Fermented Meat (w\o cooking) Goat, Lamb, Mutton - Sausage\V/Salami -Sliced -Other-Not Sliced -Other -Sliced Ready-To-Eat (RTE) Acidified\V Chicken, Turkey, -Sausage\V/Salami -Not Sliced Fermented Poultry (w\o Duck, Goose, -Sausage\V/Salami -Sliced cooking) Guinea, Squab, Emu, -Other-Not Sliced Ostrich, Rhea -Other -51 iced Ready-To-Eat (RTE) Dried Meat Beef, Veal, Pork, -Jerky Goat, Lamb, Mutton -Other, Sliced (Except Ham) - Other, Not Sliced (Except Ham) Ready-To-Eat (RTE) Dried Meat Pork -Ham, Sliced -Ham, Not Sliced (Ham includes: Shoulders, Picnics, Butts and Loins [\u00a7319.104]; Chopped Ham, Pressed Ham, Spiced Ham, etc. [\u00a7319.105]) Ready-To-Eat (RTE) Dried Chicken, Turkey, - Jerky Poultry Duck, Goose, -Other, 51 iced Guinea, Squab, Emu, \u00b7Other, Not Sliced Ostrich, Rhea Ready-To-Eat (RTE) Salt Cured Beef, Vea l, Pork, -Not 51 iced Meat Goat, Lamb, Mutton -Sliced Ready-To-Eat (RTE) Salt Cured Chicken, Turkey, -Not Sliced Poultry Duck, Goose, -Sliced Guinea, Squab, Emu, Ostrich, Rhea", "Heat Treated -Shelf Stable [HACCP] Process Category [Finished] Product Category Species Product Group Heat Treated \u00ad Shelf Stable Not Ready-To-Eat (NRTE) Otherwise Processed Meat Beef, Veal, Pork, Goat, Lamb, Mutton - Rendered Fats, Oi ls -Bacon -Mea ls\V/Dinners\V/Entrees -Sa ndwi ches\V/Fi ll ed Rolls\V/Wraps - Sauces -Pies\V/Pot Pies -Smoked Parts -Soups -Other Not Ready-To-Eat (NRTE) Otherwise Processed Poultry Chicken, Turkey, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea -Rendered Fats, Oils -Bacon -Mea ls\V/Dinners\V/Entrees -Sa ndwi ches\V/Fi ll ed Rolls\V/Wraps -Sauces -Pies\V/PotPies -Smoked Parts -Soups -Other Ready-To-Eat (RTE) Acidified\V Fermented Meat (w\o cooking) Beef, Veal, Pork, Goat, Lamb, Mutton -Sausage\V/Salami -Not Sliced - Sausage\V/Salami -Sliced -Other-Not Sliced -Other-51 iced Ready-To-Eat (RTE) Acidified\V Fermented Poultry (w\o cooking) Chicken, Turkey, Duck, Goose, Guinea, Squab, Emu, Ostrich,

Rhea -Sausage\Salami -Not Sliced -Sausage\Salami -Sliced -Other-Not Sliced -Other-Sliced Ready-To-Eat (RTE) Dried Meat Beef, Veal, Pork, Goat, Lamb, Mutton -Jerky -Other, Sliced {Except Ham} -Other, Not 51 iced {Except Ham} Ready-To-Eat (RTE) Dried Meat Pork -Ham, Sliced -Ham, Not Sliced (Ham includes: Shoulders, Picnics, Butts and Loins [\u00a7319.104]; Chopped Ham, Pressed Ham, Spiced Ham, etc. [\u00a7319.105]) Ready-To-Eat (RTE) Dried Poultry Chicken, Turkey, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea -Jerky -Other, 51 iced -Other, Not Sliced Ready-To-Eat (RTE) Salt Cured Meat Beef, Veal, Pork, Goat, Lamb, Mutton -Not 51 iced -51 iced Ready-To-Eat (RTE) Salt Cured Poultry Chicken, Turkey, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea -Not Sliced -Sliced", "Fully Cooked-Not Shelf Stable with subsequent exposure to the environment (post-lethality exposure [\u00b7e]) [HACCP] Process Category Fully Cooked-Not Shelf Stable [Finished] Product Category Ready-To-Eat (RTE) Fully Cooked Meat Ready-To-Eat (RTE) Fully Cooked Meat Ready-To-Eat (RTE) Fully Cooked Poultry Species Product Group Beef, Veal, Pork, -Hot Dog Products (including applicable sausages) Goat, Lamb, Mutton [\u00a7319.180; 319.181] -Sausage products [\u00a7319.140] -Sa l ad\Spread\Pate -Meat+ Non-meat Component -Diced\Shredded -Nuggets -Parts -Other, 51 iced (Except Ham) -Other, Not 51 iced (Except Ham) -Patties (Except Ham) Pork -Ham, 51 iced -Ham, Not Sliced (Ham includes: Shoulders, Picnics, Butts and Loins [\u00a7319.104]; Chopped Ham, Pressed Ham, Spiced Ham, etc. [\u00a7319.105]) -Ham Patties [\u00a7319.105(d)] Chicken, Turkey, -Hot Dog Products Duck, Goose, -Sa l ad\Spread\Pate Guinea, Squab, Emu, -Poultry+ Non-poultry component Ostrich, Rhea -Sausage Products -Diced\Shredded -Patties\Nuggets -Parts -Other, sliced -Other, not sliced", "Fully Cooked-Not Shelf Stable without subsequent exposure to the environment (without post-lethality exposure) [HACCP] Process Category [Finished] Product Category Species Product Group Fully Cooked-Not Shelf Stable (can't) Ready-To-Eat (RTE) Fully Cooked Meat (w/o subsequent exposure to the environment) Beef, Veal, Pork, Goat, Lamb, Mutton -Hot Dog Products (including applicable sausages) [\u00a7319.180; 319.181] -Sausage products [\u00a7319.140] -Sa l ad\Spread\Pate -Meat+ Non-meat Component -Diced\Shredded -Nuggets -Parts -Other, 51 iced (Except Ham) -Other, Not 51 iced (Except Ham) -Patties (Except Ham) Ready-To-Eat(RTE) Fully Pork -Ham, 51 iced Cooked Meat (w/o subsequent -Ham, Not 51 iced exposure to the environment) (Ham includes : Shoulders, Picnics, Butts and Loins [\u00a7319.104]; Chopped Ham, Pressed Ham, Spiced Ham, etc. [\u00a7319.105]) -Ham Patties [\u00a7319.105(d)] Ready-To-Eat (RTE) Fully Cooked Poultry (w/o subsequent exposure to the environment) Chicken, Turkey, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea -Hot Dog Products -Sa l ad\Spread\Pate -Poultry+ Non-poultry component -Sa usage Products -Diced\Shredded -Patties\Nuggets -Parts -Other, sliced -Other, not sliced", "Heat Treated but Not Fully Cooked-Not Shelf Stable [HACCP] Process Category [Finished] Product Category Species Product Group HeatTreated but Not Fully CookedNot Shelf Stable Not Ready-To-Eat (NRTE) Otherwise Processed Meat Beef, Veal, Pork, Goat, Lamb, Mutton -Rendered Fats, Oils -Bacon -Meals\Dinners\Entrees -Sandwiches\Filled Rolls\Wraps -Sauces -Pies\Pot Pies -Smoked Parts -Soups -Other -Sausage products [\u00a7319.140] Not Ready-To-Eat (NRTE) Chicken, Turkey, -Rendered Fats, Oils Otherwise Processed Poultry Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea -Bacon -Meals\Dinners\Entrees -Sandwiches\Filled Rolls\Wraps -Sauces -Pies\Pot Pies -Smoked Parts -Soups -Sausages -Other", "Products with Secondary Inhibitors-Not Shelf Stable [HACCP] Process Category Products with Secondary Inhibitors-Not Shelf Stable [Finished]

Product Category Not Ready-To-Eat (NRTE) Otherwise Processed Meat Species Product Group Beef, Veal, Pork, Goat, Lamb, Mutton -Rendered Fats, Oils -Bacon -Meals\\\Dinners\\Entrees - Sandwiches\\Filled Rolls\\Wraps -Sauces -Pies\\Pot Pies -Smoked Parts -Soups -Other - Rendered Fats, Oils -Bacon -Meals\\Dinners\\Entrees -Sandwiches\\Filled Rolls\\ Wraps - Sauces -Pies\\Pot Pies -Smoked Parts -Soups -Other -Not Sliced -51 iced Not Ready-To-Eat (NRTE) Otherwise Processed Poultry Chicken, Turkey, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea Ready-To-Eat (RTE) Salt Cured Meat Beef, Veal, Pork, Goat, Lamb, Mutton Ready-To-Eat (RTE) Salt Cured Poultry Chicken, Turkey, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea -Not Sliced -51 iced","Eggs\\Egg Products [HACCP] Process Category [Finished] Product Category Species Product Group Eggs\\Egg Products Egg Products Chicken, Turkey, Duck, Goose, Guinea -Pasteurized (Frozen or Liquid) \u00b7 Whole egg (with or without added ingredients) \u00b7 Egg whites (with or without added ingredients) \u00b7 Yolk (with or without added ingredients) \u00b7 Egg Products (blends of whole egg, egg whites and\\or yolks) (with or without added ingredients) -Pasteurized (Tanker\\Large Totes) \u00b7 Whole egg (with or without added ingredients) \u00b7 Egg whites (with or without added ingredients) \u00b7 Vol k (with or without added ingredients) \u00b7 Egg Products (blends of whole egg, egg whites and\\or yolks) (with or without added ingredients) -Unpasteurized (Frozen or Liquid) \u00b7 Whole egg (with or without added ingredients) \u00b7 Egg whites (with or without added ingredients) \u00b7 Yolk (with or without added ingredients) \u00b7 Egg Products (blends of whole egg, egg whites and\\or yolks) (with or without added ingredients) -Unpasteurized (Tanker\\Large Totes) \u00b7 Whole egg (with or without added ingredients) \u00b7 Egg whites (with or without added ingredients) \u00b7 Yolk (with or without added ingredients) \u00b7 Egg Products (blends of whole egg, egg whites and\\or yolks) (with or without added ingredients) -Dried \u00b7 Whole egg (with or without added ingredients) \u00b7 Egg whites (with or without added ingredients) \u00b7 Yolk (with or without added ingredients) \u00b7 Egg Products (blends of whole egg, egg whites and\\or yolks) (with or without added ingredients)"]}, {"file\_name": "FSIS\_GD\_2015\_0003", "title": "\u201cAt Least Equal To\u201d Data System Guidance for State Cooperative Meat and Poultry Inspection (MPI) Programs Electing Not to Use Public Health Information System (PHIS)", "num": "FSIS-GD-2015-0003", "id": "2e3302e2635f22e308c259f4e00577cb1ac7b81c71d28b8e38ea12f0ab90e1d4", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/amendment-state-cip.pdf", "type": "pdf", "n\_pages": 29, "word\_count": 12521, "text\_by\_page": ["January 8, 2015 \u201cAt Least Equal To\u201d Data System Guidance for State Cooperative Meat and Poultry Inspection (MPI) Programs Electing Not to Use Public Health Information System (PHIS) Table of Contents I. Purpose II. Background III. Elements of an \u201cAt Least Equal To\u201d Data System 1. Daily inspection verification activities at operating establishments 2. State MPI program HACCP verification testing 3. State MPI program in-depth food safety reviews 4. State MPI program administrative enforcement actions IV. References and Attachments 1", "January 8, 2015 I. PURPOSE To provide guidance to State Cooperative Meat and Poultry Inspection (MPI) programs electing to use a data system other than FSIS\u2019s Public Health Information System (PHIS) for meeting the \u201cat least equal to\u201d data system essentials. II. BACKGROUND The Federal Meat Inspection Act (FMIA) (21 USC 661) and the Poultry Products Inspection Act (PPIA) (21 USC 454) provide for FSIS to cooperate with State agencies in

developing and administering their own Meat and Poultry Inspection Programs. Individual State MPI programs are required to operate in a manner and with authorities that are at least equal to the antemortem and post-mortem inspection, reinspection, sanitation, recordkeeping, and enforcement provisions as provided for in the FMIA and PPIA. Therefore, State MPI programs are required to develop a data system with characteristics that can produce inspection and recordkeeping outcomes at least equal to FSIS's procedures. FSIS maintains PHIS as its data system. PHIS functions as an integrated data collection and analysis system that verifies the effectiveness and efficiency of Agency inspection. FSIS relies heavily on data to promote proactive decisions affecting food safety and public health and has strengthened both its data collection and analysis activities to ensure valid, timely data is collected, carefully analyzed, and continually reported. FSIS ensures that data collected through PHIS is fully available and organized so that the analysis of data from FSIS's regulatory verification and compliance and enforcement activities, sampling, and other sources of data provide the Agency with evidence that shows whether or not the Agency's approach is working. To determine the success of the strategies used to combat threats to food safety and defense, FSIS employs data analysis as a management verification measure that helps ensure that the program components are effective in meeting the Agency's public health goals and objectives. FSIS recognizes that an integrated infrastructure with high quality data and feedback interaction is essential to a data-driven approach to inspection. A data-driven approach to inspection requires quality data collection methods, ongoing data analysis to refine analytical decisionmaking tools, and performance measures to assess the impact of policies and programs. PHIS is designed to consolidate and integrate the Agency's critical functions of inspection, surveillance, auditing, enforcement, scheduling, modeling, and analysis to provide better public health protection. It also reduces delays in FSIS decision-making by providing feedback loops that utilize the data input by the inspection staff and laboratory test results to drive automated scheduling functions, reporting functions, and alerting of events. PHIS uses the Task Library to develop the Task List for each establishment. Each task arrives on the inspection program personnel's (IPP) Task List with a due date and a frequency for performing the task. The inspectors then have the ability to place assigned tasks onto their personal Task Calendars and to schedule them for completion. PHIS gives IPP the flexibility to schedule tasks. As tasks are completed, IPP record their findings of compliance and non-compliance in PHIS. FSIS uses PHIS data to schedule follow-up tasks and additional lab sampling as required. There are feedback loops in PHIS that produce information vital to all levels of FSIS. Information and revised schedules are fed back to field personnel. Headquarters and District management generate reports to keep apprised of critical information for decision-making. Alerts and notifications are issued to Headquarters and IPP as events occur. The automated "January 8, 2015 feedback mechanisms are designed to reduce delays where action is required, through a system of specific input points. Alerts are issued when specific events requiring immediate attention occur. An alert consists of a trigger and a notification function. The trigger is a program that automatically scans the data for a specific event, and upon finding it, issues the notification. The notification can take the form of an email sent by PHIS, a message on the user's PHIS dashboard, or both. Examples of key events that would trigger an alert are: a large number of inspection activities not completed at an establishment, high rates of noncompliance in an

establishment, and a positive adulterant pathogen test result at an establishment (e.g., Escherichia coli (E. coli) O157:H7 in raw ground beef, Shiga toxin-producing Escherichia coli (STEC) in beef manufacturing trimmings, or Listeria monocytogenes (Lm)\Salmonella in ready-to-eat (RTE) products). The alert text gives directions to IPP by pointing them to the appropriate regulations and directives needed for the response. Reports are produced by PHIS that include aggregated data representing a period of time rather than a single specific event. Reports may be produced on demand and viewed online or offline. Reports allow users to access data and can be set up to flag irregular data so that users can investigate further and take corrective action. PHIS has a wide range of reporting capabilities and can produce a variety of reports. An example of a generated report is the monthly report of non-compliances by District. Reports are used at all levels of FSIS to manage the processes, to identify areas needing corrective actions, and to communicate progress towards goals.

III. ELEMENTS OF AN \u201cAT LEAST EQUAL TO\u201d DATA SYSTEM

To be \u201cat least equal to\u201d FSIS\u2019s system, the State MPI data system needs to:

- \u2022 Collect, analyze, and respond to establishment and State MPI program data
- \u2022 Monitor data streams to determine establishment performance, and
- \u2022 Respond, near real-time, to establishments that may pose a risk to public health

Also to be \u201cat least equal to,\u201d the State MPI data system needs to collect data from the following four activities:

1. Daily inspection verification activities at operating establishments
2. State MPI program HACCP verification testing
3. State MPI program in-depth food safety reviews
4. State MPI program administrative enforcement actions

Set out below are guidance and recommendations for State MPI programs on their data systems if they choose not to participate in PHIS. State MPI programs should monitor data collected from the four activities listed above. The data collected should be compared to different data sets (e.g., data of multiple circuits, data of multiple establishments, and data from previous months) and analyzed to determine whether the State MPI program is meeting program goals and objectives. State MPI programs should take appropriate actions, based on the analysis, when goals and objectives are not being met.

1. Daily inspection verification activities at operating establishments

Data Collection

State MPI programs should collect establishment demographics (profiles). These profiles should include critical up-to-date information about the establishment\u2019s size, products 3", "January 8, 2015 produced, production volume, recall history, non-compliance history, and food defense plans. HACCP information for the establishment should be available in the profile and include summary information, processing categories, food safety hazards, critical control points, and prerequisite programs. A State MPI program should ensure IPP verify that establishments\u2019 profile information is accurate and current at set intervals (e.g., at least every thirty days or whenever HACCP plans change).

NOTE: The FSIS PHIS Inspection Task Catalog is provided as an attachment to this guidance. This Task Catalog is subject to change, but it sets out the PHIS tasks available based on establishment profile information.

Data Analysis

The State MPI program\u2019s data system should contain public health-based decision criteria to identify establishments requiring more frequent inspection activities (e.g., increased directed food safety verification tasks). The State MPI program\u2019s data system should include a mechanism to react to inspection results. Examples of events or trends that would trigger the State MPI program to react to inspection results may include, but are not limited to:

- \u2022 A large number of inspection activities not completed in an establishment
- \u2022 High rates of non-compliance in an establishment

\u2022 A positive pathogen test result in an establishment (e.g., E. coli O157:H7 in raw ground beef or Lm in RTE products) \u2022 Infrequent establishment profile updates (e.g., HACCP plan changes failed to be identified or documented) \u2022 Tasks are not being performed at frequencies sufficient to ensure public health The State MPI programs should ensure data quality and accuracy (i.e., a system identifying outdated establishment profile information, unperformed tasks). 2. State MPI program HACCP verification testing Data Collection The State MPI programs should maintain a system for tracking pathogen and residue testing results. Data Analysis The State MPI program\u2019s verification testing system should contain public health-based decision criteria to identify establishments requiring more frequent inspection activities (e.g., increased directed sampling due to positive sampling results or concerns with establishment\u2019s production process). The system should include a mechanism to react to sampling results. Examples of events that would trigger the program to react to sampling results may include but are not limited to: \u2022 A large number of sampling activities not completed in an establishment \u2022 A large number of laboratory discards \u2022 Positive sampling results in an establishment for adulterant pathogens (e.g., E. coli O157:H7 in raw ground beef, STEC in beef manufacturing trimmings, or Lm/Salmonella in RTE products) 4", "January 8, 2015 \u2022 Violative residues \u2022 Identifying long term processes that may have exceeded their schedule (e.g., a Salmonella sample set that has not been finished) 3. State MPI program in-depth food safety reviews State MPI programs should have procedures (e.g., Food Safety Assessments (FSA)) in place to verify that an establishment\u2019s food safety systems are effective and producing wholesome unadulterated product. Data Collection A system should track routine and \u201cfor cause\u201d in-depth food safety reviews. Data Analysis The State MPI program\u2019s data system should include a mechanism to react to sampling and inspection results that could lead to a \u201cfor cause\u201d in-depth food safety system review. Examples of events that may trigger the State MPI program to conduct a \u201cfor cause\u201d in-depth food safety system review may include, but are not limited to: \u2022 Establishments not in compliance with specific laws and regulations \u2022 A positive for STECs in raw ground beef or raw ground beef components \u2022 A positive Lm or Salmonella in RTE products or a positive Lm food contact surface sample \u2022 A Class I recall or a food safety-related enforcement action (e.g., Notice of Intended Enforcement) that is not the result of an in-depth food safety system review \u2022 Establishments that fail Salmonella or Campylobacter performance standards \u2022 An establishment that is the supplier of product that tested positive for STECs in raw beef products \u2022 Human illness linked to product from a State-regulated establishment \u2022 An establishment that has a high level of public health-related Non-compliance Records (NR) 4. State MPI program administrative enforcement action State MPI programs should have procedures in place to initiate enforcement actions, as needed, to ensure food safety compliance. Data Collection The State MPI programs should maintain a system to collect data and facts to support administrative enforcement actions and to track the results of actions taken (e.g., NRs, in-depth food safety system reviews, intensified verification testing (IVT), suspensions, and recall information). Data Analysis The State MPI program\u2019s data system should include a mechanism to react to the data collected that support administrative enforcement actions. Examples of events that may trigger the State MPI program to take administrative enforcement actions may include, but are not limited to: \u2022 Positive STECs in raw ground beef or raw ground beef components

5","January 8, 2015 \u2022 Positive Lm, Salmonella, or E. coli O157:H7 in RTE products or a positive Lm food contact surface sample \u2022 An establishment which is the supplier of product that tested positive for STECs in raw beef products \u2022 Human illness linked to State-regulated product from an establishment (possible recall) \u2022 Establishments not in compliance with specific State laws and regulations An explanation of the data system and supporting documents are to be included in the annual State Self-Assessment that is submitted to the Federal State Audit Branch by November 15. IV. References and Attachments FSIS Public Health Information System Reference Information: FSIS Strategic Data Analysis Plan for Domestic Inspection [http://www.fsis.usda.gov/wps/wcm/connect/84fa563e-0f5c-4df5-8e0499a04e9ce102/2010\\_Strategic\\_Data\\_Analysis\\_Plan.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/84fa563e-0f5c-4df5-8e0499a04e9ce102/2010_Strategic_Data_Analysis_Plan.pdf?MOD=AJPERES) Data-Driven Inspection for Processing and Slaughter Establishments  
[http://www.fsis.usda.gov/wps/wcm/connect/fcaeabab-b89e-4bd4-b990c697f34a797f/2010\\_Public\\_Health\\_Decision\\_Criteria\\_Report.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/fcaeabab-b89e-4bd4-b990c697f34a797f/2010_Public_Health_Decision_Criteria_Report.pdf?MOD=AJPERES) Public Health Regulation List, Fiscal Year 2015  
<http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/fsis-data-analysisand-reporting/data-reporting/public-health-regulations> 6","January 8, 2015 Attachment FSIS PHIS Inspection Task Catalog Priority 1: Emergency Directed Procedures Priority 2: All Verification and Follow up Sampling for. E. coli O157:H7 in beef products, Listeria monocytogenes in ready-to-eat products, 01A, 01B, 01C Procedures Priority 3: Salmonella Verification and All Other Sampling, 06D, 03A, 03J Procedures Priority 4: 03B, 03C, 03G, 03H, Procedures Priority 5: 03D, 03E, 03F, 03I, 06B Procedures Priority 6: 04, 06A, 08\* Procedures Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification 01A01 Priority 2: Basic SSOP Compliance Checks Development of SSOP 416.12(a) 416.12(b) 416.12(c) 416.12(d) Implementation of SSOP 416.13(a) 416.13(b) 416.13(c) 416.14 Corrective Actions 416.15(a) 416.15(b) Record Requirements 416.16(a) 416.16(b) 416.16(c) Written Sanitation SOP Verify written SSOP describes procedures the establishment conducts daily to prevent direct contamination or adulteration of product. Verify pre-operational procedures are identified. Verify pre-operational procedures address the cleaning of food contact surfaces of facilities, equipment, and utensils. Verify the frequency of the SSOP is stated. Verify employees responsible for implementation are identified. Verify identified records, on a daily basis, document implementation and monitoring of SSOP and any corrective action. Verify the individual with overall authority on-site, or a higher level official, signed and dated the SSOP upon initial implementation and any modification. 01B01 Priority 2: Pre-Op SSOP Record Review Development of SSOP 416.12(a) 416.12(b) 416.12(c) 416.12(d) Implementation of SSOP 416.13(a) 416.13(b) 416.13(c) 416.14 Corrective Actions 416.15(a) 416.15(b) Record Requirements Pre-operational Sanitation SOP verification by review of establishment records Verify written SSOP describes procedures the establishment conducts daily to prevent direct contamination or adulteration of product. Verify pre-operational procedures are identified. Pre-operational procedures address the cleaning of food contact surfaces of facilities, equipment, and utensils. Verify when SSOP or procedures specified therein may have failed to prevent direct product contamination or adulteration, the establishment took appropriate disposition of products that may be contaminated, restore sanitary conditions, and prevent recurrence of direct product contamination or adulteration. Verify the establishment routinely evaluates the effectiveness of SSOP procedures, and revises

procedures when necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel. Verify daily records document-implementation of pre-operational procedures, and monitoring of pre-operational procedures; corrective actions taken (if any). Verify records are initialed and dated by employee identified in SSOP as responsible for implementing and monitoring specific procedures.

7", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification 416.16(a) 416.16(b) FSIS Directive 5000.1 Part 3, Par. III Verify the establishment has implemented controls to ensure data integrity for part 416-required records maintained on computers (if any). Verify Part 416-required records are retained for at least six months; on-site for at least 48 hours, and available within 24 hours of request if stored off site.

01B02 Priority 2: Pre-Op SSOP Review and Observation Development of SSOP 416.12(a) 416.12(b) 416.12(c) 416.12(d) Implementation of SSOP 416.13(a) 416.13(b) 416.13(c) 416.14 Corrective Actions 416.15(a) 416.15(b) Record Requirements 416.16(a) 416.16(b) 416.16(c) 310.22 310.22(a) 310.22(b) 310.22(c) 310.22(d)(1) 310.22(d)(2) 310.22(d)(3) 310.22(d)(4) 416.2-416.5 FSIS Directive 5000.1 Part 3, Par. III Review the establishment's SSOP and become familiar with the procedures Verify the establishment conducts pre-operational procedures before beginning operations, and monitors daily implementation procedures. Verify pre-operational procedures are sufficient to prevent direct contamination or adulteration of products. Verify when SSOP or procedures specified therein may have failed to prevent direct product contamination or adulteration, the establishment took appropriate corrective actions including procedures to ensure appropriate disposition of products that may be contaminated, restore sanitary conditions, and prevent recurrence of direct product contamination or adulteration. Verify daily records document implementation of pre-operational procedures and monitoring of pre-operational procedures; corrective actions taken (if any).

01C01 Priority 2: Operational SSOP Record Review 9 CFR 310.22 310.22(a) 310.22(b) 310.22(c) 310.22(d)(1) 310.22(d)(2) 310.22(d)(3) 310.22(d)(4) 430.4 Verify operational SSOP records, Verify the establishment conducts procedures during operations at frequencies specified in SSOP and monitors daily implementation of procedures conducted during operations. Verify procedures conducted during operations are sufficient to prevent the adulteration of products. Verify when SSOP or procedures specified there may have failed to prevent direct product contamination or adulteration, the establishment took appropriate corrective actions, including procedures to ensure appropriate disposition of products that may be contaminated, restore sanitary conditions, and prevent recurrence of direct product contamination or adulteration.

8", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification 430.4(a) 430.4(b)(1) 430.4(b)(2) 430.4(b)(3) 430.4(c)(2) 430.4(c)(3) 430.4(c)(4) 430.4(c)(5) 430.4(c)(6) 430.4(c)(7) 430.4(d) 430.4(e) FSIS Directive 5000.1 Part 3, Par. III Verify the establishment routinely evaluates the effectiveness of SSOP procedures, and revises procedures when necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel. Verify daily records document implementation of operational procedures, and monitoring of operational procedures; corrective actions taken (if any). Verify records are initialed and dated by employee identified in SSOP as responsible for implementing and monitoring specific procedures. Verify the establishment has implemented controls to ensure data integrity for part 416-required records maintained on computers (if any). Verify Part 416-required records are retained for at least six

months; on-site for at least 48 hours, and available within 24 hours of request if stored off site.

01C02 Priority 2: Operational SSOP Review and Observation 9 CFR Development of SSOP  
416.12(a) 416.12(b) 416.12(c) 416.12(d) Implementation of SSOP 416.13(a) 416.13(b) 416.13(c)  
416.14 Corrective Actions 416.15(a) 416.15(b) Record Requirements 416.16(a) 416.16(b)  
416.16(c) 430.4 430.4(a) 430.4(b)(1) 430.4(b)(2) 430.4(b)(3) 430.4(c)(2) 430.4(c)(3) 430.4(c)(4)  
430.4(c)(5) 430.4(c)(6) 430.4(c)(7) 430.4(d) Verification of the establishment's operational  
SSOP, Verify the establishment conducts procedures during operations at frequencies specified  
in the SSOP and monitors daily implementation of procedures conducted during operations.  
Verify procedures conducted during operations are sufficient to prevent direct contamination  
or adulteration of products. Verify when SSOPs or procedures specified therein failed to  
prevent direct product contamination or adulteration, the establishment took appropriate  
corrective actions including procedures to ensure appropriate disposition of products that may  
be contaminated, restore sanitary conditions, and prevent recurrence of direct product  
contamination or adulteration. Verify daily records document implementation procedures,  
conducted during operations and monitoring of procedures conducted during operations;  
corrective actions taken (if any). Verify daily records are maintained which document the  
implementation and monitoring of operational activities, as well as initiation of corrective  
actions. The records are authenticated by the date and the initials of responsible establishment  
employee. 9", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive  
Inspection Task Description and Verification 430.4(e) FSIS Directive 5000.1 Part 3, Par. III  
11,100.3 01D01 Priority 2: SPS Verification 9 CFR Part 416.1 \u2013 416.6 FSIS Directive 5000.1  
Part 3, Par. III Verification of the sanitation performance standards 01D02 Beef Sanitary  
Dressing 9 CFR Part 416.1 \u2013 416.6 FSIS Directives 5000.1 Part 3, Par. III 6410.1 Verify  
Sanitary Dressing in Livestock Slaughter Establishments 01D03 Poultry Sanitary Dressing 9 CFR  
Part 416.1 \u2013 416.6 FSIS Directives 5000.1 Part 3, Par. III 6410.3 Verification of sanitary  
dressing in poultry slaughter 01D04 SPS Verification (V) 9 CFR Part 416.1 \u2013 416.6 FSIS  
Directive 5000.1 Part 3, Par. III Verification of sanitation performance standards in voluntary  
facilities 01E01 Priority 2: Generic E. coli Verification 9 CFR Part 310.25 and 381.94 FSIS  
Directive 5000.1 Part 3, Par. III Verify the establishment's generic E. coli program. 03A02 Priority  
3: Hazard Analysis Verification 9 CFR Part 417 \u00a7304.3(c) or \u00a7318.22(c) FSIS Directive  
5000.1 Part 3, Par. II Hazard Analysis Verification for all HACCP categories, Basic Compliance  
Checks Verify the establishment has conducted a hazard analysis. The hazard analysis includes  
food safety hazards reasonably likely to occur, a flow chart, and identifies intended use or  
consumers of the finished products. Verify if one or more food safety hazards are reasonably  
likely to occur, establishment has a written HACCP plan for each product (process). Verify the  
establishment has conducted validation analysis activities, and records include multiple results  
that verify monitoring of CCPs and conformance with critical limits and after each deviation  
from a critical limit (if any), subsequent results support adequacy of corrective actions in  
achieving control. Verify the establishment reassesses the hazard analysis if, after hazard  
analysis revealed no food safety hazard reasonably likely to occur, there was a change that  
could reasonably affect whether a food safety hazard exists. Verify before producing a new  
product for distribution, the establishment has conducted hazard analysis and has an applicable  
HACCP plan. If in distribution for more than 90 days, HACCP plan has been validated. Verify if  
the HACCP plan covers more than one product; all products are within one of 10", "January 8,

2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification nine specified processing categories. Verify the HACCP plans lists food safety hazards identified in hazard analysis (exception: thermally processed\commercially sterile products produced in accordance with part 318, subpart G, or part 381, subpart X); lists CCPs for each food safety hazard; lists critical limits to be met at each CCP; lists procedures to be used to monitor each CCP and frequency with which performed; identifies corrective actions to be followed in response to a deviation from a critical limit at a critical control point; lists verification procedures and frequency with which performed. Verify the record keeping system documents monitoring of CCPs, and include records with actual values and observations. Verify the responsible establishment official signed and dated the HACCP plan upon initial acceptance, and at least annually thereafter. If the HACCP plan is modified, responsible establishment official signed and dated. 03A03 Priority 3: Directed Hazard Analysis Verification 9 CFR Part 417 FSIS Directive 5000.1 Part 3, Par. III Directed HAV procedure is initiated if a public health based threshold has been exceeded (e.g., positive pathogen test results, trend of food safety NCs, or other information that requires follow-up). 03A04 Priority 3: Review of Establishment Data 9 CFR Part 417 FSIS Directive 5000.1 Part 3, Par. III Weekly review of establishment data per Directive 5000.2 03B02 Priority 4: Raw Non-Intact HACCP 9 CFR Part 417, \u00a7304.3(c) or \u00a7318.22(c) and \u00a7310.25(b) or \u00a7381.94(b) FSIS Directive 5000.1 Part 3, Par. III HACCP verification for raw non-intact products Raw Ground Verify the establishment is monitoring CCPs to ensure compliance to ensure compliance with critical limits. Verify records documenting monitoring include actual values. Verify the establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. Verify the HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedures in their plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed. Verify the establishment reassessed the plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan. If plan reassessment revealed a HACCP plan no longer meets \u00a7417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed plan assessment or modification meets the training 11", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification requirements. Verify each record entry is made when the specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Verify prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective actions including proper disposition of product. Raw Ground Verify the establishment is monitoring CCPs to

ensure compliance with critical limits. Records documenting monitoring include actual values. Verify the establishment is performing verification activities. Verify records documenting verification activities include calibration of processmonitoring instruments, and actions taken in response to a deviation from a critical limit. Verify if establishment has substituted an alternative sampling frequency for E.coli that the alternative is an integral part of HACCP verification procedures. Verify the HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedures in the HACCP plan. Verify records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performs a review to determine acceptability of affected product, and when necessary, action to ensure adulterated product is not distributed. Verify the establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plant; if HACCP plan reassessment revealed that a HACCP plan no longer meets \u00a7417.2(c) requirements the establishment modified the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements. Verify establishment records document the decision making associated with the selection and development of CCP\u2019s and critical limits, and support the monitoring and verification procedures and frequency; document slaughter product a shipment of product, product code, product name or other identifier. Verify each record entry is made at the time the specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made the entry. The establishment has implemented controls to ensure data integrity for plan records maintained on computers (if any). Verify \u00a7417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least six months, and are available within 24 hours of request if stored off site. 12", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification 03C02 Priority 4: Raw Intact HACCP 9 CFR Part 417, \u00a77304.3(c) or \u00a77318.22(c) and \u00a77310.25(b) or \u00a77381.94(b) FSIS Directive 5000.1 Part 3, Par. III Verify all 5 HACCP regulatory requirements at all CCPs for specific production, Verify the establishment is monitoring CCP\u2019s to ensure compliance with critical limits. Records documenting monitoring include actual values. Verify the establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. Verify if establishment has substituted an alternative sampling frequency for E.coli, the alternative is an integral part of HACCP verification procedures. Verify the HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedures in the HACCP plan. Verify records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation

not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performs a review to determine acceptability of affected product, and when necessary, action to ensure adulterated product is not distributed. Verify the establishment reassessed the plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan. Verify if plan reassessment revealed a HACCP plan no longer meets \u00a77417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed plan assessment or modification meets the training requirements. Establishment records document the decision making associated with the selection and development of CCP\u2019s and critical limits, and support the monitoring and verification procedures and frequency; document slaughter of product, shipment of product, product code, product name, or other identifier. Verify each record entry is made at the time the specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Verify the establishment has implemented controls to ensure data integrity for plan records maintained on computers. Verify \u00a77417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least six months, and are available within 24 hours of request if stored off site. 03D02 Priority 5: Thermally Processed Commercially Sterile HACCP 9 CFR Part 417, \u00a77304.3(c) or \u00a77318.22(c) and \u00a77310.25(b) or \u00a77381.94(b) FSIS Directive 5000.1 Part 3, Par. III Verification of the 318.300, Subpart G, 381.300, Subpart X; Canning and Canned Products regulatory requirements and HACCP regulatory requirements. Thermally Processed\Commercially Sterile Verify the establishment is monitoring CCP\u2019s to ensure compliance with critical limits. Records documenting monitoring include actual values. Verify the establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. Verify if establishment has substituted an alternative sampling frequency for E.coli, the alternative is an integral part of HACCP verification procedures. 13", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification Verify the HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan. Verify records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product at least until the establishment performs a review to determine acceptability of affected product, and when necessary, take action to ensure adulterated product is not distributed. Verify the establishment reassessed the plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan. If plan reassessment revealed a HACCP plan no longer meets \u00a77417.2(c) requirements, the establishment modified the

HACCP plan. Individual who performed plan assessment or modification meets the training requirements. Verify establishment records document the decision making associated with the selection and development of CCPs and critical limits, and support the monitoring and verification procedures and frequency; document slaughter product a shipment of product, product code, product name or other identifier. Verify each record entry is made when the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Verify the establishment has implemented controls to ensure data integrity for plant records maintained on computers. Verify \u00a7417.5(a)(3) requires HACCP records be maintained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelfstable product; on site for at least six months, and are made available to inspection program personnel within 24 hours of request if stored off site.

Thermally Processed\Commercially Sterile Verify the establishment is monitoring CCPs to ensure compliance with critical limits. Records documenting monitoring include actual values. Verify the establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. Verify the HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan. Verify records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product at least until the establishment performs a review to determine acceptability of affected product, and when necessary, take action to ensure adulterated product is not distributed. Verify the establishment reassessed the plan if a deviation not covered by a corrective 14", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification action occurred, or another unforeseen hazard arose; if a raw meat or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan. If plan reassessment revealed a HACCP plan no longer meets \u00a7417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed plan assessment or modification meets the training requirements. Verify each record entry is made when the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Verify prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s) including proper disposition of product. 03E02 Priority 5: Not Heat Treated-Shelf Stable HACCP 9 CFR Part 417, \u00a77304.3(c) or \u00a77318.22(c) and \u00a77310.25(b) or \u00a77381.94(b) FSIS Directive 5000.1 Part 3, Par. III Verification of HACCP regulatory requirements through the use of review and observation and recordkeeping components. Not Heat Treated-Shelf Stable Verify the establishment is monitoring CCPs to ensure compliance with critical limits. Records documenting monitoring include actual values. Verify the establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a

deviation from a critical limit. Verify if establishment has substituted an alternative sampling frequency for E.coli, the alternative is an integral part of HACCP verification procedures. Verify the HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedures in the HACCP plan. Verify records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product at least until the establishment performs a review to determine acceptability of affected product, and when necessary, take action to ensure adulterated product is not distributed. Verify the establishment reassessed the plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan. If plan reassessment revealed a HACCP plan no longer meets \u00a7417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed plan assessment or modification meets the training requirements. Verify establishment records document the decision making associated with the selection and development of CCPs and critical limits, and support the monitoring and verification procedures and frequency; document slaughter product a shipment of product, product code, product name or other identifier. Verify each record entry is made when the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. 15","January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification Verify the establishment has implemented controls to ensure data integrity for plant records maintained on computers. Verify \u00a7417.5(a)(3) requires HACCP records be maintained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelfstable product; on site for at least six months, and are made available to inspection program personnel within 24 hours of request if stored off site. Not Heat Treated-Shelf Stable Verify the establishment is monitoring CCPs to ensure compliance with critical limits. Records documenting monitoring include actual values. Verify the establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. Verify if establishment has substituted an alternative sampling frequency for E.coli, the alternative is an integral part of HACCP verification procedures. Verify the HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedures in the HACCP plan. Verify records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product at least until the establishment performs a review to determine acceptability of affected product, and when necessary, take action to ensure adulterated product is not distributed. Verify the establishment reassessed the plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat or raw poultry product tested positive for Salmonella at a rate exceeding

performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan. If plan reassessment revealed a HACCP plan no longer meets \u00a77417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed plan assessment or modification meets the training requirements. Verify each record entry is made when the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Verify prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product. 03F02 Priority 5: Heat Treated-Shelf Stable HACCP 9 CFR Part 417, \u00a77304.3(c) or \u00a77318.22(c) and \u00a77310.25(b) or \u00a77381.94(b) FSIS Directive 5000.1 Part 3, Par. III Verification of all five HACCP regulatory requirements through the review and observation and recordkeeping components. Heat Treated-Shelf Stable Verify the establishment is monitoring CCPs to ensure compliance with critical limits. Records documenting monitoring include actual values. Verify the establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. Verify if establishment has substituted an alternative sampling frequency for E.coli, the 16", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification alternative is an integral part of HACCP verification procedures. Verify the HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedures in the HACCP plan. Verify records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product at least until the establishment performs a review to determine acceptability of affected product, and when necessary, take action to ensure adulterated product is not distributed. Verify the establishment reassessed the plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan. If plan reassessment revealed a HACCP plan no longer meets \u00a77417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed plan assessment or modification meets the training requirements. Verify establishment records document the decision making associated with the selection and development of CCPs and critical limits, and support the monitoring and verification procedures and frequency; document slaughter product a shipment of product, product code, product name or other identifier. Verify each record entry is made when the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Verify the establishment has implemented controls to ensure data integrity for plant records maintained on computers. Verify \u00a77417.5(a)(3) requires HACCP records be maintained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelfstable product; on site for at least six months, and are made available to inspection program personnel within 24

hours of request if stored off site. Heat Treated-Shelf Stable Verify the establishment is monitoring CCPs to ensure compliance to ensure compliance with critical limits. Records documenting monitoring include actual values. Verify the establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. Verify the HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedures in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed. Verify the establishment reassessed the plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat or raw poultry 17", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan. Verify if plan reassessment revealed a HACCP plan no longer meets \u00a7417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed plan assessment or modification meets the training requirements. Verify the establishment has implemented controls to ensure data integrity for plan records maintained on computers. Verify prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective actions including proper disposition of product. 03G02 Priority 4: Fully Cooked-Not Shelf Stable HACCP 9 CFR Part 417, \u00a7304.3(c) or \u00a7318.22(c), and \u00a7310.25(b) or \u00a7381.94(b) FSIS Directive 5000.1 Part 3, Par. III Verification of all 5 HACCP regulatory requirements through review and observation and recordkeeping components. Fully Cooked-Not Shelf Stable Verify the establishment is monitoring CCPs to ensure compliance with critical limits. Records documenting monitoring include actual values. Verify the establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. Verify if establishment has substituted an alternative sampling frequency for E.coli, the alternative is an integral part of HACCP verification procedures. Verify the HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedures in the HACCP plan. Verify records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product at least until the establishment performs a review to determine acceptability of affected product, and when necessary, take action to ensure adulterated product is not distributed. Verify establishment records document the decision making associated with the selection and development of CCPs and critical limits, and support the

monitoring and verification procedures and frequency; document slaughter product a shipment of product, product code, product name or other identifier. Verify each record entry is made when the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Verify the establishment has implemented controls to ensure data integrity for plant records maintained on computers. Verify \u00a7417.5(a)(3) requires HACCP records be maintained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelfstable product; on site for at least six months, and are made available to inspection program personnel within 24 hours of request if stored off site. Verify the HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedures in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence and prevent distribution 18", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed. Verify the establishment reassessed the plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan. Verify if plan reassessment revealed a HACCP plan no longer meets \u00a7417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed plan assessment or modification meets the training requirements. Verify the establishment has implemented controls to ensure data integrity for plan records maintained on computers. Verify prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s) including proper disposition of product. 03H02 Priority 4: Heat Treated-Not Fully Cooked-Not Shelf Stable HACCP 9 CFR Part 417, \u00a7304.3(c) or \u00a7318.22(c) and \u00a7310.25(b) or \u00a7381.94(b) FSIS Directive 5000.1 Part 3, Par. III Verification of all 5 HACCP regulatory requirements through use of review\observation and recordkeeping components Heat Treated but Not Fully Cooked-Not Shelf Stable Verify the establishment is monitoring CCPs to ensure compliance with critical limits. Records documenting monitoring include actual values. Verify the establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. Verify if establishment has substituted an alternative sampling frequency for E.coli, the alternative is an integral part of HACCP verification procedures. Verify the HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan. Verify records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product at

least until the establishment performs a review to determine acceptability of affected product, and when necessary, take action to ensure adulterated product is not distributed. Verify the establishment reassessed the plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan. Verify establishment records document the decision making associated with the selection and development of CCPs and critical limits, and support the monitoring and verification procedures and frequency; document slaughter product a shipment of 19", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg/Directive Inspection Task Description and Verification product, product code, product name or other identifier. Verify each record entry is made when the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Verify the establishment has implemented controls to ensure data integrity for plant records maintained on computers. Verify \u00a7417.5(a)(3) requires HACCP records be maintained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelfstable product; on site for at least six months, and are made available to inspection program personnel within 24 hours of request if stored off site. Verify the HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedures in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed. Verify the establishment reassessed the plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan. Verify if plan reassessment revealed a HACCP plan no longer meets \u00a7417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed plan assessment or modification meets the training requirements. Verify the establishment has implemented controls to ensure data integrity for plan records maintained on computers. Verify prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective actions including proper disposition of product. 03I02 Priority 5: Secondary Inhibitors-Not Shelf Stable HACCP 9 CFR Part 417 \u00a7304.3(c) or \u00a7318.22(c) \u00a7310.25(b) or \u00a7381.94(b) FSIS Directive 5000.1 Part 3, Par. III Verification of all 5 HACCP regulatory requirements through the use of review\observation and recordkeeping components. Product With Secondary Inhibitors-Not Shelf Stable Verify the establishment is monitoring CCPs to ensure compliance with critical limits. Records documenting monitoring include actual values. Verify the establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. Verify if establishment has substituted an alternative

sampling frequency for E.coli, the alternative is an integral part of HACCP verification procedures. Verify records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product at least until the establishment performs a review to determine 20", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification acceptability of affected product, and when necessary, take action to ensure adulterated product is not distributed. Verify the establishment reassessed the plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan. If plan reassessment revealed a HACCP plan no longer meets \u00a7417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed plan assessment or modification meets the training requirements. Verify establishment records document the decision making associated with the selection and development of CCPs and critical limits, and support the monitoring and verification procedures and frequency; document slaughter product a shipment of product, product code, product name or other identifier. Verify each record entry is made when the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Verify the establishment has implemented controls to ensure data integrity for plant records maintained on computers. Verify \u00a7417.5(a)(3) requires HACCP records be maintained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelfstable product; on site for at least six months, and are made available to inspection program personnel within 24 hours of request if stored off site. Verify the HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedures in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed. Verify the establishment reassessed the plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan. Verify if plan reassessment revealed a HACCP plan no longer meets \u00a7417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed plan assessment or modification meets the training requirements. Verify the establishment has implemented controls to ensure data integrity for plan records maintained on computers. Verify prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s) including proper disposition of product. 03J02 Priority 3: Slaughter HACCP Verification of all 5

HACCP regulatory requirements through the review\observation and recordkeeping components. 21","January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification 9 CFR Part 417 \u00a7304.3(c) or \u00a7318.22(c) \u00a7310.25(b) or \u00a7381.94(b) FSIS Directive 5000.1 Part 3, Par. III Slaughter Verify the establishment is monitoring CCPs to ensure compliance with critical limits. Records documenting monitoring include actual values. Verify the establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit. Verify if establishment has substituted an alternative sampling frequency for E.coli, the alternative is an integral part of HACCP verification procedures. Verify the HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan. Verify records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product at least until the establishment performs a review to determine acceptability of affected product, and when necessary, take action to ensure adulterated product is not distributed. Verify the establishment reassessed the plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat or raw poultry product tested positive for Salmonella at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan. If plan reassessment revealed a HACCP plan no longer meets \u00a7417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed plan assessment or modification meets the training requirements. Verify establishment records document the decision making associated with the selection and development of CCPs and critical limits, and support the monitoring and verification procedures and frequency; document slaughter product a shipment of product, product code, product name or other identifier. Verify each record entry is made when the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry. Verify the establishment has implemented controls to ensure data integrity for plant records maintained on computers. Verify \u00a7417.5(a)(3) requires HACCP records be maintained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelfstable product; on site for at least six months, and are made available to inspection program personnel within 24 hours of request if stored off site. Verify each record entry is made at the time when the event occurs, and includes date and time and is signed or initialed by the employee who made entry. Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product. 03J03 Priority 3: Livestock Zero Tolerance Verification Verification of zero tolerance for feces, milk, ingesta on livestock carcasses Verify the adequacy of the establishment\u2019s procedures to ensure that carcasses are not contaminated with fecal material, ingesta, or milk by the post-mortem rail inspection 22","January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification 9 CFR 307.2(g) and (m), \u00a7310.3, \u00a7310.17a,

\u00a7310.18a, \u00a7318.4b, \u00a7381.65e and \u00a7381.76(b)(iv) FSIS Directives 5000.1 and 6420.2 station, and that head, cheek, and weasand meat are not contaminated with fecal material, ingesta, or milk at the completion of the harvesting process 03J04 Priority 3: Poultry Zero Tolerance Verification 9 CFR 307.2(g) and (m), \u00a7310.3, \u00a7310.17a, \u00a7310.18a, \u00a7318.4b, \u00a7381.65e and \u00a7381.76(b)(iv) FSIS Directives 5000.1 and 6420.2 Verification of zero tolerance for feces on poultry carcasses entering chilling system Verify that the establishment\u2019s process is producing carcasses free of visible fecal material 04A01 Priority 6: Percent Yield\Shrink 9 CFR 319.107 \u00a7319.80 \u00a7319.81 \u00a7319.100 \u00a7319.101 \u00a7319.102 \u00a7319.103 \u00a7319.106 \u00a7424.21 (c) FSIS Directive 7620.3 \u201cProcessing Inspectors\u2019 Calculations Handbook\u201d Chapters 11, 12, & 13; % gain, %shrink & %yield Verification of certain products that have a specified %Yield\Shrink as part of their Standard of Identity are met and not misbranded. Select an appropriate product and Verify compliance with regulatory requirements by reviewing establishment records and labels, calculating the % yield or shrink, and comparing the result with the appropriate regulatory requirement. In addition, Verify compliance by weighing a sample of product before and after the appropriate step in the process calculating the % yield or shrink, and comparing the result with the appropriate regulatory requirement. 04A02 Priority 6: X Percent (%) Solution 9 CFR \u00a7319.104\* \u00a7319.105\* \u00a7381.129 \u00a7381.169 \u00a7317.2 (c) \u00a7317.8 \*NOTE: Applies only to sections of 319.104 and 319.105 covering X% labeled products. FSIS Directives 7620.3 Chapter 10 Verification of products that contain Percent (%) Added Solution meets regulatory standards and are not misbranded. \*NOTE: Applies only to X% Labeled Products Select an appropriate product and Verify compliance with X% labeling requirements by reviewing establishment records and labels, calculating the % added solution and comparing the results with the X% labeling declaration. In addition, inspection program personnel are to Verify compliance by weighing a sample of product before and after the appropriate step in the process (i.e., pumping, curing, drying, etc.), calculating the % added solution, and comparing the result with the X% labeling declaration. 23", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification Labeling Policy Book FLD Policy Memos 42 44A 57A 59 66C 84A 04A03 Priority 6: MSS; MSP; PDBFT; PDPFT; PDCB; PDCP; AMRS 9 CFR 318.24 \u00a7319.5 \u00a7319.15(e) \u00a7319.29 \u00a7381.173 FSIS Directives 7160.1 7160.2 7160.3 Revision 1 Verification of Mechanically Separated, Partially Defatted, and Advanced Meat Recovery Products meet regulatory requirements. Select an appropriate product and Verify compliance by reviewing establishment records and labels, or by observing the preparation of products, and comparing the findings to the standards listed in the regulations. In addition, inspection program personnel are to take samples as directed. To Verify compliance, inspection program personnel should: -check product identification, condition, temperature, and holding time\temperature. -examine bones (for example, two intact portions of bones) before and after the meat recovery systems in order to observe condition and conformation. -review establishment laboratory results and compare findings with the appropriate regulatory standard -take samples as directed. 04A04 Priority 6: Batter Breading 9 CFR 319.880 \u00a7381.166 FSIS Directive 7620.3 Chapter 14 Directive 7220.1 Labeling Policy Book FLD Policy Memo 089 Verification of batter and breading of applicable products meets regulatory requirements and product is not misbranded. Select an appropriate product, Verify

compliance with the batter and breading regulatory requirements by reviewing establishment records to calculate final % batter\breading, and comparing the findings to the standards listed in the regulations. In addition, inspection program personnel are to: Verify compliance by performing batter and breading pickup tests on one or more subgroups (according to the plant\u2019s QC programs) or batches of the product. 04A05 Priority 6: Livestock Finished Product Standards Verification of Livestock products are wholesome and not adulterated. 04A06 Priority 6: Poultry Finished Product Standards Verification of poultry products are produced in a safe, wholesome manner and not misbranded. 04B01 Priority 6: Labeling - Product Standards 9 CFR 319.15 \u00a7319.140 \u00a7319.141 \u00a7319.142 \u00a7319.143 \u00a7319.144 \u00a7319.145 \u00a7319.160 \u00a7319.180 \u00a7319.181 \u00a7319.182 \u00a7319.260 \u00a7319.261 \u00a7319.280 \u00a7319.281 \u00a7319.300 \u00a7319.301 \u00a7319.302 \u00a7319.303 \u00a7319.304 \u00a7319.305 \u00a7319.306 Verification of Product Labeling Standards Select an appropriate product and Verify compliance by reviewing establishment records and labels; or observe the preparation of products and compare the findings to the appropriate regulatory standards. Verify some regulatory requirements, by performing calculations to determine specified components, such as % fat, or % water.

24", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification \u00a7319.307 \u00a7319.308 \u00a7319.309 \u00a7319.310 FSIS Directives 7620.3 7220.1 04B02 Priority 6: Child Nutrition\Grade Labeling\ Declared Count\Vignette A 9 CFR 317.2, \u00a7317.8 and \u00a7381.116 FSIS Directives 6810.1 and 7222.1 Verification of Child Nutrition Labeling Select product and Verify that the product\u2019s label is correct and a label approval is on file 04B03 Priority 6: Labeling - Net Weights 9 CFR 317.18, \u00a7317.19 \u00a7317.20, \u00a7317.21, \u00a7317.22, \u00a7381.121a, \u00a7381.121b, \u00a7381.121c, \u00a7381.121d, and \u00a7381.121e NBS Handbook 133 NIST Handbook 44 Verification of Net Weights Select an appropriate retail-sized product and Verify net weight regulatory requirements by reviewing establishment records and conducting net weight\drained weight, scale calibration, or tare weight checks. Follow the QC program requirements after evaluating the program to ensure that following the program results in compliance with net weight regulatory requirements. \* FSIS has determined inspectors are to use NBS handbook 133 and NIST Handbook 44 as the definitive references for determinations of net weight compliance. 04B04 Priority 6: General Labeling 9 CFR Part 316 Part317 Part 318 Part 319 \u00a7319.6 \u00a7327.10(d) \u00a7327.26 Part 381 \u00a7381.174 \u00a7424.21 \u00a7441.10 FSIS Directives 7120.1, 7620.3, 6700.1, 7235.1 and 7270.1 Verification of General Labeling Requirements Verify that: 1) the label contains all required information; 2)the ingredients statement is accurate, (i.e., that all ingredients are listed in descending order of predominance); 3) the label declares any proteinaceous substances\* used in the ingredients statement; 4) the establishment used restricted ingredients as per regulatory requirements; 5) the label is used on appropriate product; and a label approval is on file. Verify the establishment meets the regulatory requirements for pre-stamping of imported product. When verifying restricted ingredient requirements or ingredient statement compliance, inspection program personnel are to observe the establishment formulating product and compare to the approved label. \* NOTE: Proteinaceous substances can cause adverse reactions (i.e., allergic and nonallergic) in certain individuals, and therefore, such substances are of a food safety concern if not clearly declared in the ingredients statement. 04C02 Priority 6: Livestock

Humane Handling 9 CFR 313, \u00a7318.2, \u00a7318.5, \u00a7318.6, \u00a7500.1, Verification of compliance with the following categories: \uf0fc adequate measures for inclement weather \uf0fc truck unloading \uf0fc water and feed availability \uf0fc handling during ante-mortem inspection \uf0fc handling of suspect and disabled animals 25", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification \u00a7500.2, and \u00a7500.3 FSIS Directive 6900.1 and 6900.2 \uf0fc electric prod\alternative object use \uf0fc observations for slips and falls \uf0fc stunning effectiveness \uf0fc check for conscious animals on the rail \uf0fc check for sensibility NOTE: Humane handling is not, never has been, and never will be a HACCP issue. Livestock Product Examination Verify these regulatory requirements by reviewing establishment records or observing plant performance of activities. Examine product to determine whether it is economically adulterated or misbranded- (\u00a7318.2(b). 04C05 Priority 6: Poultry Good Commercial Practices 9 CFR 381.76, \u00a7381.78, \u00a7381.91(b), \u00a7381.84, \u00a7381.86, \u00a7381.145, \u00a7381.1, and \u00a7381.65(b) Verification of Poultry Product Examination Verify compliance by performing: - pre-chill FPS testing - post-chill FPS testing - reinspection of carcasses, giblets - inspection of returned products - inspection of rework products - condition inspection of products in establishment - observation of slaughter practices 05A03 Salmonella Verification Sampling 9CFR 310.25(b), \u00a7318.9 and \u00a7381.94(b) FSIS Directive 10,210.1 Verification of Directed requests to collect Salmonella verification samples Salmonella Testing and Criteria Collect, process, and mail the sample as directed to determine compliance with the 5000.1 regulatory standards. 05A04 Microbiological Sampling Verification of Directed collection of microbiological samples 05B01 Economic Verification Sampling 9CFR 301.2, \u00a7318.9 \u00a7381.1, and \u00a7381.146 FSIS Directives 10,210.1 Amendments 1, 3 and 5 7355.1 Revision 2 10,240.3 10,520.1 Revision 1 Verification of Directed sampling for economic wholesomeness issues Misbranding\economic adulteration sampling, directed and unscheduled sampling Economic Testing and Criteria Randomly selected as applicable: Randomly select an appropriate product for verification. To verify compliance, inspection program personnel are to select and process samples and mail to the designated laboratory as scheduled, or when there is reason to believe that product does not comply with regulatory requirements. Food Safety\Public Health Directed Sampling Economic Testing and Criteria verify compliance by collecting, processing and mailing samples (bacon, species testing, Escherichia coli 0157:H7, Salmonella, Listeria, advanced meat recovery products, mechanically-separated species, etc.) to the designated laboratory, upon request from computer-generated instructions, or upon instructions from the Frontline Supervisor or District Office, or Washington Headquarters. 05C01 Directed Residue Sampling Verification of Task for directed residue sampling for NRP Residue Sampling 26", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification 9CFR 310.21, \u00a7381.9 \u00a7381.80, and \u00a7381.346 FSIS Directives 7355.1 10,210.1 10,220.1 Residue Sampling and Criteria Collect random samples of poultry and livestock as requested for monitoring, and surveillance samples (KIS), or submit diagnostic samples as necessary Prepare sample and mail designated laboratory. Perform in-plant residue testing on livestock as required. 06B01 Priority 5: Custom Exempt 9CFR 303.1, \u00a7316.6, \u00a7317.6, \u00a7320.1, \u00a7381.10 \u00a7381.14, \u00a7381.15 and \u00a7381.175 FSIS Directive 5930.1 Verify that custom exempt operations in official establishments meet regulatory

requirements and do not impact inspected products or operations. . Custom Exempt\Retail Exempt Verify the establishment is conducting custom-exempt\retail-exempt operations in accordance with all applicable regulatory requirements including time\space separation and adequate procedures to assure that product does not bear the mark of inspection. . Actions are taken by the establishment or FSIS determines that the standards have not been met. This includes actions to ensure that misbranded\mislabelled products do not enter commerce.

06B02 Priority 5: Retail Exempt Verify that retail exempt operations do not interfere with inspected products\operations 06D02 Priority 3: Other Inspection Requirements 9CFR 307.2, \u00a7308.3 \u00a7308.8, \u00a7310.1, \u00a7310.3 \u00a7381.36, \u00a7381.76, \u00a7416.15, \u00a7416.17(c)&(d), \u00a7381 and Subpart H \u00a7381.50(a)(f) \u00a7381.91 FSIS Directives 5000.1, 5220.1 Rev.1, 5930.1, and 7640.1 Verify other inspection requirements Facilities and Equipment Verify plant facilities (including lighting, ventilation, and plumbing) and equipment meet regulatory requirements and therefore do not pose a public health hazard or result in product contamination. Verify welfare areas and lockers are clean. Verify outside premises are clean and orderly. Verify actions are taken by the establishment or FSIS determines that the standards have not been met. This includes actions to ensure that misbranded\mislabelled products do not enter commerce. Other Requirements Verify inspection and Reprocessing Stations meet the criteria set forth in regulations to ensure they are adequate for the purpose and do not pose a public health hazard. Verify that line speeds do not exceed regulatory limits. Verify that efficient inspection can be performed on carcasses and parts Verify actions are taken by the establishment or FSIS determines that the standards have not been met. This includes actions to ensure that misbranded\mislabelled products do not enter commerce. 07B01 Update Establishment Profile Review and update establishment profile to reflect current establishment operations. 07C01 Meeting with Establishment Management FSIS Directive 5420.6 Meet with establishment management for food defense surveys 08A11 Priority 6: 2011 Food Defense Survey Record performance of 2011 Food defense survey (note only some establishments in PHIS at this point) 27", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification 08S14 Priority 6: Food Defense - Water Systems FSIS Directive 5420.6 Verify establishment measures to protect water systems (a) observe the security of the establishment\u2019s water systems, especially well water, ice storage facilities, and water reuse systems; (b) pay special attention to water used to prepare injection solutions and water and ice used in emulsification (for the production of deli meats and hot dogs); (c) to a lesser extent, check water used to prepare surfactant, antimicrobial agent sprays, and chill tank recharge. Suggested Activities: Determine whether the establishment: controls access to private wells; appropriately secures potable water lines or storage tanks; appropriately secures ice storage facilities. 08S15 Priority 6: Food Defense \u2013 Processing Manufacturing FSIS Directive 5420.6 Verify food defense for processing and manufacturing areas (a) observe production processes (e.g., raw product handling, processing, and packaging of final product) in which exposed products are being handled for indications of attempts to introduce contaminants into the product; (b) observe, in particular, operations where the establishment mixes bulk products (e.g., process monitoring by establishment personnel at balance tanks, grinding\emulsification of meat and poultry products, solution injection in preparation areas); (c) observe whether the establishment has procedures in place to prevent deliberate contamination (e.g., camera surveillance, closed

systems, or restricted access of personnel to sensitive production areas). Suggested Activities: Check a production process (e.g., ground beef production area) for evidence of possible intentional product contamination. Check to determine whether the establishment has implemented a system to restrict access to sensitive processing areas where bulk products are mixed or processed (e.g., camera surveillance, color-coded uniforms, identification badges, sign-out sheets). Check calibration of equipment (if any) used to dispense restricted ingredients.

08S16 Priority 6: Food Defense - Storage Areas FSIS Directive 5420.6 Verify access\tampering in storage areas. (a) observe products in cold and dry storage areas for evidence of tampering; (b) pay special attention to bulk product ingredients that will undergo mixing, such as combo bins of meat trim and poultry parts used for grinding or emulsification; (c) check dry ingredients, including spices, breading materials, and those used in injection solution preparations, for indication of tampering; (d) observe the use and storage of any hazardous materials in the establishment; (e) verify whether entry into such storage areas is controlled, and that usage logs are maintained and current; (f) pay special attention to cleaning materials, particularly those used in clean-in-place systems; (g) pay special attention to areas where bulk products are mixed (e.g., storage silos); and (h) verify the control of laboratory reagents and cultures.

Suggested Activities: Verify that the establishment has implemented: access control procedures to dry ingredient areas; access control procedures to raw product storage areas; access control procedures to finished product storage areas; control procedures for access and use of hazardous chemicals; and 28", "January 8, 2015 Inspection Task Code, Priority Task Name, Reg\Directive Inspection Task Description and Verification observation procedures of all products in storage for evidence of tampering.

08S17 Priority 6: Food Defense - Shipping and Receiving FSIS Directive 5420.6 Verify food defense in shipping and receiving areas (a) observe loading dock areas and vehicular traffic in and out of the establishment; (b) report immediately all unattended deliveries on loading docks and unmarked vehicles parked on the premises to establishment management; (c) verify that the establishment secures, when possible, dry and cold products stored in on-site trailers and parks the trailers in a restricted access area of the facility; (d) verify that the facility security staff routinely check the trailers\u2019 physical integrity (e.g., locks, seals, and general condition); and (e) pay special attention to storage silos, combo bins of meat trim, and dry ingredients.

Suggested Activities: Check to determine whether the establishment has procedures in place to restrict or control access to the loading dock area and verify that the establishment has implemented these access control procedures. Observe incoming raw materials to verify that the establishment checks deliveries against shipping documents. Pay special attention to tanker trucks, dry ingredients, combo bins of fresh meat trim or poultry parts, and boxes of frozen trim that the establishment will ship for further processing.

08S19 Priority 6: Food Defense - Processing; Manufacturing FSIS Directive 5420.6 Food defense verification in processing and manufacturing areas for ID warehouses

08S20 Priority 6: Food Defense - Storage Areas FSIS Directive 5420.6 Verify food defense in storage areas in ID warehouses.

08S21 Priority 6: Food Defense - Shipping and Receiving (V) FSIS Directive 5420.6 Verify food defense for shipping and receiving in ID warehouses.

29"]}, {"file\_name": "FSIS\_GD\_2015\_0005", "title": "Labeling and Establishment Responsibilities", "num": "FSIS-GD-2015-0005", "id": "095e5ae3b4031d373f335582be76b7eed0daddea2b783a8f01130e532c7e6133", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-"}]

guidelines","url":"<https://www.fsis.usda.gov/sites/default/files/import/Responsibilities.pdf>","type":"pdf","n\_pages":1,"word\_count":274,"text\_by\_page":["Updated January 21, 2015 Labeling and Establishment Responsibilities The Labeling and Program Delivery Staff (LPDS) grants temporary and sketch approvals of labels. Before submitting label applications for approval, establishments should ensure that the print is legible and that all required features (i.e., inspection legend, ingredients statement, handling statement, product name, signature line, and safe handling instructions, net weight, and nutrition facts, when required) are present and in compliance with requirements. The generic approval labeling regulations (9 CFR 412.2) provide for use of final labeling without further authorization from FSIS. It is the establishment's responsibility to prepare final labeling in accordance with applicable regulations\policies, and to create and maintain records of all final labeling. Establishment Responsibility \u2022 Create a record of final labeling for labeling previously approved as a sketch by LPDS. Final labeling includes modifications made by LPDS during evaluation. \u2022 Create a record of final labeling that has been generically approved. \u2022 Create a record of final labeling when changes are made to a label that do not require LPDS reapproval (changes that do not affect any special statements or claims and are in compliance with all regulations; adding additional products to a blanket label approval) \u2022 Update labeling records with temporary approvals where regulatory deviations occur that have received temporary approval from LPDS. \u2022 Maintain labeling records and provide them for FSIS inspectors upon request. Label Record Each label record consists of: \u2022 The actual product's label \u2022 The product formulation \u2022 Processing procedure \u2022 All documentation required to demonstrate the label\u2019s compliance with regulatory requirements, including sketch or temporary approvals if appropriate. For additional information, please contact LPDS at (301) 504-0878."]}, {"file\_name": "FSIS\_GD\_2015\_0006", "title": "Prior Notification and Failure to Present: Compliance Guidance for Importing Meat, Poultry and Egg Products to the United States", "num": "FSIS-GD-2015-0006", "id": "83ca372c7def62c7b31861d9573d790e12266b735cce6be6158303c08f3a38c0", "corpus": "fsis\_guidelines", "source\_page\_url": "<https://www.fsis.usda.gov/policy/fsis-guidelines>", "url": "<https://www.fsis.usda.gov/sites/default/files/import/failure-to-present.pdf>", "type": "pdf", "n\_pages": 5, "word\_count": 1998, "text\_by\_page": ["Prior Notification and Failure to Present: Compliance Guidance for Importing Meat, Poultry and Egg Products to the United States This guidance is designed to help importers of record (IOR), U.S. Customs brokers, and Official Import Inspection Establishment management understand and comply with the Food Safety and Inspection Service\u2019s (FSIS) import inspection regulations for meat, poultry, and egg products on prior notification and explains regulatory actions taken when products fail to present for FSIS reinspection, known as \u201cFailure to Present\u201d (FTP). Background: Final Rule and Statutory Authority FSIS published a final rule, effective November 18, 2014, that amends the meat, poultry, and egg products import regulations to provide for the Agency\u2019s Public Health Information System (PHIS) Import Component. The final rule also clarifies prior notification requirements and the definition of FTP for imported product, among other changes. The regulatory changes in this rule are based on the statutory authority of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601\u2013695); the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451\u2013470); and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031\u20131056). This guidance discusses and clarifies FSIS"]}]

prior notification and FTP requirements as described in the final rule. Definitions For the purposes of this guidance, electronic applications are applications for import inspection that are submitted through the Partner Government Agency (PGA) Message Set, which facilitates the transfer of required FSIS-specific data from the U.S. Customs and Border Protection (CBP) Automated Commercial Environment (ACE) into FSIS Public Health Information System (PHIS). Paper applications are FSIS Form 9540-1, Import Inspection Application. Applying for import inspection electronically (i.e. PGA Message Set) eliminates the need to file a separate paper application with FSIS. Prior Notification of Imported Product The final rule clarifies that the applicant (importer of record or designated agent) must apply for the inspection of imported product as far as possible in advance of the anticipated arrival of each consignment, but no later than when entry is filed with CBP (9 CFR 327.5(b), 381.198(b), and 590.920(b)). The objective of the prior notification requirement is to enhance FSIS ability to identify shipments that are not presented for inspection, as well as to ensure that there is notice and data entry in PHIS is performed well before the shipment arrives at the official import inspection establishment, thus avoiding delays in the re-inspection of the shipment by FSIS at the official import inspection establishment. It is important to emphasize that applicants automatically meet the prior notice requirement by filing Customs entry with the PGA Message Set (i.e., an electronic application). Applicants using paper applications will meet the prior notice requirement if the application is provided to FSIS at the official import inspection establishment (or other FSIS approved location designated on the import inspection", "application) as early as possible, but no later than when entry is filed with CBP). Of note, FSIS has revised the import inspection application (FSIS Form 9540-1) to include egg products and additional required information, such as production dates, and whether and when a country, foreign establishment, or specific product has been delisted or relisted as eligible for export. This information will help FSIS to verify that the relevant product was produced in the foreign establishment during an eligible timeframe. FSIS announced in the final rule that importers and brokers that do not use the PGA Message Set are to transition from the current FSIS Form 9540-1 (Import Inspection Application and Report) to the revised FSIS Form 9540-1 (Import Inspection Application) no later than March 18, 2015. The revised FSIS Form 9540-1 completed by the importer or broker must be correct. Table 1: Options and Requirements for Import Inspection Application Mode of CBP Entry Foreign Inspection Certificate Type Paper Foreign Inspection Certificate required? Paper 9540-1 required? Prior notification met? ACE\Automated Commercial System (ACS) Entry Paper Yes Yes Yes, if paper 9540-1 received no later than when entry filed with CBP ACE\ACS Entry Electronic certification (eCert) No Yes Yes, if paper 9540-1 received no later than when entry filed with CBP ACE with PGA Message Set Paper Yes No Yes ACE with PGA Message Set eCert No No Yes Failure to Present (FTP) Shipments Imported meat, poultry, and egg product that has entered commerce without FSIS import reinspection violates the FMIA, the PPIA, or the EPIA, as well as the implementing regulations for each Act (9 CFR 327.6; 381.199; 590.925). The importer of record is responsible for any product identified as FTP. FSIS will likely request that importers of record recall FTP product. Imported meat, poultry, and egg products are considered \u201cin-commerce\u201d when they are off-loaded at a location other than the official import inspection establishment or other FSIS approved location designated on the import inspection application. The FTP product is no longer eligible for reinspection. Product still in the original shipping container may

either be destroyed or returned to the country of origin. When a product has been identified as a FTP, FSIS will request, through CBP, a redelivery of the shipment and appropriate CBP penalties. As part of the Single Window initiative, FSIS is working with CBP to automate the redelivery process by December 2016, which will streamline enforcement of CBP redelivery requirements and meet the goals of Executive Order 13659. Customs has full authority to assess penalties and liquidated damages claims and to seize merchandise for violations of Customs or other laws enforced by the Customs Service. For more information about CBP redelivery requirements and penalties, please", "contact CBP\u2019s Office of Regulations and Rulings (<http://www.cbp.gov/contact/international-tradecontacts>). If any imported product identified as FTP has been removed from the original cartons or further processed, FSIS will initiate a regulatory control action on the product, including any further processed product that contains the FTP product, to ensure appropriate disposition (i.e., destruction). Prior Notification Q&As 1. What action will FSIS take if a shipment is presented for reinspection and FSIS did not receive the paper import inspection application in advance of the shipment\u2019s arrival at the official import inspection establishment? Answer: FSIS inspection program personnel will first check the PHIS Import Component to determine whether the IOR made entry with CBP using the PGA message set. If the IOR submitted the entry using the PGA message set, FSIS will proceed with the reinspection. If the IOR did not submit the entry using the PGA message set, FSIS inspection program personnel will identify the shipment in PHIS as a \u201cPrior Notification Violation.\u201d In addition, FSIS personnel will notify the IOR through the official import inspection establishment management of the violation, and that if violations continue, future shipments that do not meet the prior notification requirement will likely be refused entry. FSIS inspection program personnel will document the discussion with establishment management in a Memorandum of Interview (MOI) and then proceed with reinspection unless otherwise directed by FSIS management. If the shipment is not rejected, and FSIS proceeds with reinspection, the importer may experience unnecessary delays in the import inspection process if it does not meet this requirement. For prior notification violations, FSIS will consider using outreach (e.g., education and communication) with the IOR to ensure that prior notice requirements are understood. 2. Will there be allowances for legitimate, mitigating circumstances, e.g., when ACE is not operational? Answer: Under the final rule, the applicant is required to submit an Import Inspection Application in advance of the shipment\u2019s arrival, but no later than when the entry is filed with CBP (9 CFR 327.5, 381.198, 590.920). FSIS is committed to working through any ACE-to-PHIS Import Component data transfer problems to avoid any delays in completing reinspection. 3. How will prior notification apply to those who apply for import inspection electronically via the PGA Message Set? Answer: Applying for FSIS import inspection electronically via the PGA Message Set will fulfill the prior notification requirement. 4. How will prior notification apply to those who apply for import inspection with a paper-based application? Answer: For those importers or brokers using the paper-based import inspection application (FSIS Form 9540-1), FSIS must receive the paper application as far as possible in advance of the anticipated arrival of the consignment at the official import inspection establishment (or other FSIS approved location", "designated on the import inspection application), but no later than when the entry is filed with CBP (9 CFR 327.5(b), 381.198(b), and 590.920(b)). 5. How can I learn more about participating in the PGA Message Set? What kind of software or other upgrades do I need? Answer: More information can be

found in CBP\u2019s Federal Register Notice on the PGA Message Set. Regarding technical requirements, please consult CBP\u2019s website on ACE Automated Broker Interface (ABI) and CBP and Trade Automated Interface Requirements (CATAIR). FSIS will expand its PGA Message Set pilot to include all ports, as well as all interested importers and brokers by November 2015). Failure to Present (FTP) Q&As 6. How does FSIS define \u201cin-commerce\u201d for purposes of imported product that has bypassed reinspection and entered commerce? Answer: Imported meat, poultry, and egg products are considered \u201cin-commerce\u201d when they are offloaded at a location other than the official import inspection establishment or other FSIS approved location designated on the import inspection application. If the FTP product shipment is in-commerce, the imported product, or any product produced from the ineligible product, is subject to regulatory control action (i.e., FSIS would retain or detain the product if it is not returned to the importer of record), and FSIS may request that the importer of record recall the product. 7. Is transporting and storing imported product at a U.S. warehouse prior to reinspection considered a FTP? Answer: Yes. FSIS does not permit storing of imported meat, poultry, or egg products in a warehouse or other facility prior to reinspection unless the warehouse or facility has the same physical address as the official import inspection establishment (or other FSIS-approved location designated on the import inspection application), and it is physically connected to the establishment. Official import inspection establishment managers can notify FSIS import inspection personnel of the shipment\u2019s arrival to such a warehouse or facility, so that the status of the shipment can be changed to \u201cOn Premises\u201d in the PHIS Import Component so as not to be identified as FTP. 8. Will FSIS alert importers\agents to potential FTP product problems as soon as they are discovered? Answer: Yes. FSIS inspection program personnel are instructed in FSIS Directive 9900.1 to notify the applicant electronically (e-mail) through the PHIS Import Component when a shipment has not arrived at the official import inspection establishment or other FSIS-approved location designated on the import inspection application by the Estimated Date of Arrival (EDA) recorded on the import inspection application. When prompted, PHIS will automatically send the e-mail to the applicant e-mail address entered on the Import Inspection Application, which is completed by the IOR or his agent. FSIS will communicate and work with import inspection establishment management to track and control potential FTPs.", "9. Can FTP products be re-exported or removed from the U.S? Answer: If the product is still in its original containers it may be removed from the United States and returned to the country of origin as part of the disposition process with FSIS. However, FSIS cannot issue an FSIS export certificate for imported product subject to a FTP violation. Reference Links Federal Register Final Rule on Electronic Import Inspection Application: Electronic Import Inspection Application and Certification of Imported Products and Foreign Establishments; Amendments To Facilitate the Public Health Information System (PHIS) and Other Changes to Import Inspection Regulations (Sep 19, 2014) FSIS Federal Register Notice on PGA Message Set Pilot Program: Electronic Filing of Import Inspection Applications for Meat, Poultry, and Egg Products: Availability of Draft Compliance Guide and PGA Message Set Pilot Program (Mar 29, 2013) Electronic Import Inspection Application (FSIS Form 9540-1) Guideline: Data Samples and Guidelines for Using the PGA Message Set for Electronic Completion of the U.S. Department of Agriculture, Food Safety Inspection Service Application for Import Inspection (Aug 2013) PHIS Import Component: Public Health Information System (PHIS)-Import Component Home Page askFSIS:

[http://askfsis.custhelp.com"\]}, {"file\\_name": "FSIS\\_GD\\_2015\\_0011", "title": "FSIS Compliance Guideline: HACCP Systems Validation", "num": "FSIS-GD-2015-0011", "id": "7a5b8939444ae9ee09b1104ea3b78d9e902126b7f57f4a0e635d0fdd8fb16b00", "corpus": "fsis\\_guidelines", "source\\_page\\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/HACCP\\_Systems-Validation.pdf", "type": "pdf", "n\\_pages": 68, "word\\_count": 22245, "text\\_by\\_page": \["This guidance document is designed to help very small meat and poultry establishments meet the initial validation requirements in 9 CFR 417.4. In particular, the guidance covers: \u2022 The difference between initial validation and ongoing verification; \u2022 How to identify scientific support relevant to their process; \u2022 What are critical operational parameters and how to identify them in the scientific or technical support; \u2022 How to demonstrate that the critical operational parameters are being met during initial validation \(i.e., through the collection of in-plant validation data\); and \u2022 How an existing establishment can incorporate this guidance into their HACCP system. FSIS Compliance Guideline HACCP Systems Validation April 2015 i", "This Compliance Guideline follows the procedures for guidance documents in the Office of Management and Budget\u2019s \(OMB\) \u201cFinal Bulletin for Agency Good Guidance Practices\u201d \(GGP\). More information can be found on the Food Safety and Inspection Service \(FSIS\) Web page. This guidance has been revised in response to public comment. A summary of the comments received and responses to those comments can be found at <http://www.fsis.usda.gov/wps/wcm/connect/3ba826ec-6e79-4f17-85fc29200f4e8d05/2009-0019-2015.pdf?MOD=AJPERES>. It is important to note that this Guideline represents FSIS\u2019s current thinking on this topic and should be considered usable as of this issuance. Purpose The purpose of this guidance document is to aid small and very small establishments in meeting the initial validation requirements in 9 CFR 417.4. This document provides guidance to assist establishments in meeting FSIS regulations. Guidance represents best practice recommendations by FSIS, based on the best scientific and practical considerations, and does not represent requirements that must be met. Establishments may choose to adopt different procedures than those outlined in the guideline, but they would need to support why those procedures are effective. Is this version of the guideline final? Yes, this version of the guideline, dated April, 2015 is final. FSIS will update this guideline as necessary should new information become available, although comments will no longer be accepted through regulations.gov on this guideline. What if I still have questions after I read this guideline? If the desired information cannot be found within the Compliance Guideline, FSIS recommends that users search the publicly posted Questions & Answers \(Q&As\) in the AskFSIS database or submit questions through AskFSIS. Documenting these questions helps FSIS improve and refine present and future versions of the Compliance Guideline and associated issuances. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided: Subject Field: Enter HACCP Systems Validation Guideline Question Field: Enter question with as much detail as possible. Product Field: Select General Inspection Policy from the drop-down menu. Category Field: Select Sampling from the drop-down menu. Policy Arena: Select Domestic \(U.S.\) Only from the drop-down menu. ii", "When all fields are complete, press Continue. Table of Contents Purpose .....ii Is this version of the guideline final? .....ii What if I still have](http://askfsis.custhelp.com)

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.....	64 iii","Who is this guidance designed for? This guideline is focused on small and very small establishments in support of the Small Business Administration\u2019s initiative to provide small and very small establishments with compliance assistance under the Small Business Regulatory Flexibility Act (SBRFA). However, all FSIS regulated meat and poultry establishments may be able to apply the recommendations in this guideline. It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective HACCP systems. Although large establishments can benefit from the guidance that FSIS provides, focusing the guidance on the needs of small and very small establishments provides them with information that may be otherwise unavailable to them.
	Why did FSIS develop this guidance document? FSIS has determined from its HACCP verification activities that many establishments have not properly validated their systems. In particular, establishments have not conducted adequate activities during the initial validation period to translate all the required critical operating parameters from the scientific or technical support into their processes and gather in-plant validation data demonstrating the HACCP plan is functioning as intended. In addition, Agency enforcement actions have identified instances in which inadequate validation has led to the production of adulterated product and in some cases even illnesses. Specific examples of when inadequate validation has led to the production

of adulterated product and in some cases illnesses are provided in Appendix 1. Based on the findings from FSIS data analyses and outbreak investigations summarized in Appendix 1, FSIS recommends that establishments use this guidance document to ensure that their HACCP systems are properly validated. While most establishments have assembled the scientific or technical support for the judgments made in designing their HACCP systems, which is the first element of initial validation, many establishments have not gathered the necessary in-plant validation data demonstrating that the HACCP system is functioning as intended. FSIS has also found establishments have not: HACCP System Design Issues \u2022 Identified scientific support that properly relates to the establishments\u2019 current processes; or \u2022 Identified the critical operating parameters in the scientific support necessary for the intervention to function as intended. Agency enforcement actions have identified instances in which inadequate validation has led to the production of adulterated product and in some cases even illnesses 1","HACCP System Execution Issues \u2022 Translated those critical operating parameters into their HACCP systems; or \u2022 Documented that they have validated their HACCP systems under actual in-plant conditions. By ensuring that the HACCP system is designed and executed properly, an establishment can reduce the likelihood for product contamination and illnesses in the future. Initial validation of any HACCP system must include scientific or technical support related to the establishment\u2019s process supporting the design of the HACCP system along with some practical in-plant validation data reflecting an establishment\u2019s actual early experience in executing the HACCP system. Validation must demonstrate not only that the HACCP system is theoretically sound (design), but also that the establishment can implement it and make it work (execution). What concepts and skills will small and very small establishments learn from this guidance? Small and very small establishments that utilize this guidance will learn: \u2022 The difference between initial validation and ongoing verification; \u2022 How to identify scientific or technical support relevant to their processes; \u2022 What are critical operational parameters and how to identify them in the scientific and technical support; and \u2022 How to demonstrate that the critical operational parameters are being met during initial validation (i.e., through in-plant validation data). Establishments that understand these topics should have the tools needed to successfully validate their HACCP systems. What is the history of validation in the context of the HACCP regulations? On July 25, 1996, FSIS published a final rule on Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems (PR\HACCP) (61 FR 38806). The PR\HACCP rule requires that meat and poultry establishments under Federal inspection take responsibility for, among other things, reducing the contamination of meat and poultry products with disease-causing (pathogenic) bacteria by implementing a system, known as HACCP, of preventative controls designed to improve the safety of their FSIS stated in the HACCP Final Rule that validation data for any HACCP system must include practical data or information reflecting an establishment\u2019s actual experience in implementing the HACCP system 2","products. An establishment must have an effective HACCP system to comply with regulatory requirements and prevent adulteration of product. The HACCP requirements that establishments must meet are set out in 9 CFR Part 417. These requirements are based on the seven HACCP principles recommended by the National Advisory Committee on Microbiological Criteria for Food (NACMCF) in 1992. One of the principles identified by the NACMCF was \u201cVerification\u201d describing that HACCP systems should be systematically verified. In

the NACMCF explanation of the verification principle, which FSIS follows, an establishment is responsible for the following three processes encompassing the verification principle: \u2022 Validation, \u2022 Verification, and \u2022 Reassessment NOTE: This guidance document speaks only to the initial validation component of the verification HACCP principle. The recommendations in the verification principle form the basis for the requirements in 9 CFR 417.4. This section requires that every establishment validate the HACCP plan\u2019s adequacy in controlling the food safety hazards identified in the hazard analysis, verify that the plan is being effectively implemented on an ongoing basis, and reassess the plan at least annually, or when an unforeseen hazard or change occurs, or whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Although the HACCP regulations were implemented over 15 years ago, FSIS has found through Food Safety Assessments (FSAs) that establishments have not complied with the initial validation requirement. In particular, establishments have not collected the necessary in-plant validation data demonstrating that the HACCP system is functioning as intended. Therefore, FSIS determined that additional validation guidance for HACCP systems is needed. Key definition HACCP is a scientific system for process control that has long been used in food production to prevent problems by applying controls at points in a food production process where hazards could be controlled, reduced, or eliminated. The HACCP system is defined as the HACCP plan in operation, including the HACCP plan itself. The HACCP plan in operation includes the hazard analysis, any supporting documentation including prerequisite programs supporting decisions in the hazard analysis, and all HACCP records. Key Requirement 9 CFR 417.4(a)(1) requires \u201cupon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP\u2019s, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.\u201d 3", "What is HACCP System Validation? Validation is the process of demonstrating that the HACCP system as designed can adequately control potential hazards to produce a safe, unadulterated product. Validation encompasses activities designed to determine whether the entire HACCP system is functioning as intended. Validation of a HACCP system involves two separate elements 1) design and 2) execution. Under 9 CFR 417.4(a)(1) establishments are required to assemble two types of supporting documentation to demonstrate these elements are met: 1. The scientific or technical support for the HACCP system design (design) - that is the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards; and 2. The in-plant validation data (execution) - that is the in-plant observations, measurements, microbiological test results, or other information demonstrating the control measures in the HACCP system can perform as expected within a particular establishment to achieve the intended food safety objective. Under 9 CFR 417.5(a)(1) and 9 CFR 417.5(a)(2), these supporting documents must be kept for the life of the plan. The two elements will be discussed in detail throughout this document. In summary, to validate the HACCP system, establishments should:

4 Element 1: Scientific or Technical Support (Design)

\u2022Gather scientific or technical support (e.g., published processing guidelines, journal articles, challenge studies, etc.) for its HACCP system that:

- \u2022Closely matches the actual process; and
- \u2022Shows that the establishment's process prevents, reduces, or eliminates the hazard identified in the hazard analysis; and
- \u2022Identifies the critical operational parameters from the scientific support relevant to the establishment's process

Element 2: Inplant Validation Data (Execution)

- \u2022Implements critical operational parameters in the actual production process consistent with the parameters in the scientific or technical support;
- \u2022Identifies at least one product from each HACCP category to gather in-plant validation data;
- \u2022Collects in-plant data demonstrating the effectiveness of the implementation of the critical operational parameters for at least one product from each HACCP category; and
- \u2022Analyzes the data to determine whether the critical operational parameters are being implemented effectively.

"What is the definition of a HACCP System, and do prerequisite programs have to be validated? Validation of the HACCP system involves validation of the critical control points in the HACCP plan, as well as of any interventions or processes used to support decisions in the hazard analysis. The regulations provide that \"[v]alidation \u2026 encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities\" (9 CFR 417.4(a)(1)). Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). Said differently, when an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis (Element 1 of validation) and must collect in-plant validation data to support that the programs are implemented as designed (Element 2). For this reason, the HACCP system rather than the HACCP plan only is discussed throughout the rest of this document.

**KEY QUESTION** Question: Are establishments required to collect in-plant microbiological data to comply with the initial validation requirements? Answer: FSIS encourages establishments to gather in-plant microbiological data as part of in-plant validation data but does not require that they do so, provided that the establishment has adequate scientific or technical support (the first element of validation), is following the parameters in the scientific or technical support, and can demonstrate that it can meet the critical parameters during operation through in-plant validation data (the second element of validation). A discussion of scientific and technical support can be found beginning on page 6 and a discussion of in-plant data can be found beginning on page 20.

5", "What is the first element of HACCP Systems Validation? The first element of HACCP systems validation is the scientific or technical support that demonstrates that the HACCP system is theoretically sound. To meet the first element of validation, establishments should:

- \u2022 Gather scientific or technical support (e.g., published processing guidelines, journal articles, challenge studies, etc.) for its HACCP system that:
  - o Closely matches the actual process; and
  - o Shows that the establishment's process prevents, reduces, or eliminates the hazard identified in the

hazard analysis; and \u2022 Identify the critical operational parameters from the scientific or technical support relevant to the establishment\u2019s process. The scientific or technical support should reflect current thinking and not be outdated. In order to identify scientific or technical support that closely matches the actual process, establishments should understand the major types of scientific and technical support documents. What are the major types of scientific and technical support documents used to satisfy the design element of HACCP Systems Validation? There are several types of documents that can be used as scientific and technical support. These include:

1. Published processing guidelines that achieve a stated reduction of a pathogen are examples of scientific support. The time-temperature guidelines in Appendix A of the final rule \u201cPerformance Standards for the Production of Certain Meat and Poultry Products\u201d (64 FR 746-748) is an example of a guideline that addresses process lethality. The guidelines in Appendix B, Compliance Guidelines for Cooling HeatTreated Meat and Poultry Products (Stabilization), address product stabilization to meet the requirements of 9 CFR 318.17(a)(2), 9 CFR 318.23(c)(1), and 9 CFR 381.150(a)(2). Published processing guidelines are not limited to those published by FSIS. Published guidelines from other agencies, trade organizations, or universities can also be used as scientific support. Extension publications may also be cited as scientific support; however, extension publications often reference the original journal articles that were used to develop the support. In those cases, establishments should have the original journal articles on-file referenced in the extension publication because the extension publications often do not include all of the critical operational parameters that establishments would need to implement. Establishments need information on all the critical operational parameters in order to determine whether the process in the publication matches their actual process.
2. Peer-reviewed scientific or technical data or information that describe a process, and the results of the process can provide adequate scientific or technical support. This type of support could include journal articles, graduate student theses, or information found in a textbook. All of these types of scientific data go through a process of evaluation involving qualified individuals within the relevant field. In addition to describing the microbiological results of the process, the data may also describe the role intrinsic and extrinsic product factors play on the growth of microorganisms. For example, a textbook may contain data on the growth limits of certain pathogens based on a food product\u2019s water activity and pH. For journal articles, the study should relate closely to the establishment\u2019s process with regards to species, product characteristics, and equipment (to the extent that the use of different equipment would result in an inability to achieve the critical parameters of the study). The establishment should use the critical operational parameters cited in the journal article that achieve the required or expected lethality or stabilization if the establishment does not intend to perform additional research to validate its process. In addition, for biological hazards, the scientific article should contain microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis. A lack of microbial data in the scientific support could raise questions concerning whether the process design has been adequately validated. NOTE: Most scholarly journals use a process of peer review before publishing an article. As part of the review, scholars with expertise in the topic addressed by the draft article critically assess the article. Peer-reviewed journals only publish articles that have passed through a review process. The review process helps ensure that published articles

contain solid research work. If an establishment uses scientific or technical data that is not peer-reviewed, the establishment may be subject to additional scrutiny by Agency personnel performing verification activities. 3. Expert advice from processing authorities may also be used as scientific or technical support. Such expert advice may include reference to established scientific principles as well as reference to peer-reviewed scientific data. Expert advice from processing authorities should not rely on expert opinion alone. The scientific principles and data should relate to the establishment's product and process as well as the hazard identified in the hazard analysis. One example of how expert advice may be used is a processing authority's justification for why a different level of a critical operational parameter from the one studied in the scientific support should be used. Key definitions Intrinsic factors are those inherent parameters of a food that affect the growth of microorganisms. Examples of intrinsic factors include, among other things, pH, moisture content, water activity, and nutrient content. Extrinsic factors are those parameters that are external to the food that affect the growth of microorganisms. Examples of extrinsic factors include, among other things, temperature of storage, time of storage, and relative humidity.

"not impact the effectiveness of an intervention. As part of the justification, in addition to their own expert opinion, the processing authority should cite one or more peer-reviewed scientific data sets or documents that provide a science-based rationale for why the different level of the critical operational parameter should be at least equally as effective from the one in the scientific support. Another example of how expert advice from a processing authority may be used is as support for a scheduled process to produce a commercially sterile product. Prior to the processing of canned product for distribution in commerce, an establishment must have a process schedule for each canned meat or poultry product to be packed by the establishment. The process schedule used by an establishment is developed or determined by a processing authority. Any changes that may adversely affect the adequacy of the process must also be evaluated by a processing authority and that process schedule amended accordingly. When developing the process schedule, the processing authority should take into account established scientific principles as well as peer-reviewed scientific data in order to establish a thermal process that will specify the amount of time at a specific temperature necessary to ensure the destruction of *Clostridium botulinum* and spoilage organisms that may be present.

4. A challenge or inoculated pack study that is designed to determine the lethality or stabilization of a process also is an example of scientific support. These studies are performed in a laboratory or pilot plant by a processing authority or expert and sometimes can be accessed through the internet. The documentation on file should specify the level of pathogen reduction, elimination, or growth control (e.g., for stabilization); describe the process, including all critical parameters affecting the reduction or elimination; and give the source of the documentation. Such studies are often not published in peer-reviewed journal articles but should contain the same level of detail as is provided for peer-reviewed studies. Challenge studies should be based on a sound statistical design (i.e., a statistical design that ensures confidence in the data) and should also employ positive and negative controls. The statistical design should include the number of samples collected at each time interval and the number of study replicates needed to ensure the validity of the study. There are quantitative methods for assessing the statistical quality of a study (e.g., power analysis). As recommended by the National Advisory Committee on Microbiological Criteria of Foods (NACMCF), the number of samples to be analyzed initially and at each time interval

during processing or storage should be at least two; however, NACMCF recommends analysis of three or more samples. According to NACMCF, replicates should also be conducted. Replicates should be independent trials using different lots of product and inoculum to account for variations in product, inoculum, and other factors. When the number of samples analyzed at each time interval is only two, it is better for the study to be repeated (replicated) more than two times. In studies with three or more samples tested at each time interval, two replicates are usually adequate. NOTE: For more information on conducting challenge studies, please review the article, "Parameters for Determining Inoculated Pack/Challenge Study Protocols," published by the National Advisory Committee on Microbiological Criteria for Foods in the Journal of Food Protection in 2010. For more information on the use of positive and negative controls in challenge studies as well as general guidance on how to select a microbiological testing laboratory please review FSIS' 2019 Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory.

5. Pathogen modeling programs are computer-based software that, based on such factors as growth, lethality, and survival in culture broth and food products, estimate the growth or decline of foodborne microbes in food samples in production. Examples of uses of pathogen modeling programs include those to support the development of custom cooling schedules; to support product safety following heating, cooling, and storage deviations; and to support the use level of antimicrobial agents. Establishments may use the results of modeling programs as scientific support provided that the establishment inputs accurate values into the modeling program, and that the modeling program has been validated for the product in question. Validation data for the model is often provided along with the modeling program or can be obtained by contacting the model developer. The modeling program chosen should also be specific for the pathogen identified in the hazard analysis. If the modeling program has not been validated for the product in question, the establishment should provide additional scientific support for its use. Such additional support could include in-plant data showing routine levels of pathogens in the product, or documentation addressing the production of the raw materials and the product's intended use. Establishments should have the modeling results on-file for review and should have documentation supporting the values entered into the model (e.g., time-temperature profile data, pH, salt concentration).

6. Data gathered by the establishment in-plant can also be used to validate a process as part of a research study or other study. This data gathering can be done if the establishment could not implement the process as documented in the literature within its processing environment. Examples of this approach could be if an establishment is introducing a new technology not established in the literature or applying a standard technology in an unusual way (e.g., modifying critical operational parameters from the literature). In these cases the establishment should gather scientific support and in-plant validation data for its HACCP system under commercial operating conditions. For example, microbiological data may show that a steam vacuum process is achieving a certain level of reduction for the specified microorganism. If the establishment is modifying the critical operational parameters of the steam vacuum process then the documentation gathered in-plant used to show that the HACCP system is valid as designed should contain information from all the tests performed, such as temperature of steam, time of exposure, and microbiological results of swab tests, and information that makes clear whether the testing was performed on a routine or specified schedule. When collecting data in-plant, the

establishment should develop a sampling plan in advance of data collection to ensure that the data collected are adequate to make statistical determinations about effectiveness. 9", "In-plant data could also be collected as technical support for an establishment\u2019s HACCP system design. For example, an establishment may identify foreign material as a hazard in ground product because of the wooden pallets it uses, and how the product is loaded to be dumped into a hopper. The establishment could determine that the foreign material hazard is not reasonably likely to occur because of a prerequisite program that includes steps the establishment takes to ensure that pieces of the pallet do not break off and fall into the grinder to contaminate the product. The establishment could collect in-plant data to demonstrate the effectiveness of these technical procedures for preventing the hazard from occurring in its process. Large corporations with multiple establishments often conduct studies in one establishment to gain scientific information to validate an intervention\u2019s design and then extend the use of the intervention to other establishments within the corporate umbrella. For the establishment at which the data were gathered, FSIS would consider the data to be data gathered in-house, and thus the data would meet both parts of validation (design and execution). However, for the establishments to which use of the intervention was extended, the data would meet only the first element of validation. To meet the second element of validation, the corporation would still need to demonstrate that the intervention will function as intended in each of those establishments by gathering data on the critical operating parameters\u2019 execution in those additional establishments. So, for biological hazards, microbial data collected at one establishment could be used to support effectiveness of the intervention or process (i.e., the first element of validation) at other establishments within the corporation that use the same procedures.

7. Regulatory performance standards, as defined in the Code of Federal Regulations, that outline specific prescribed procedures such as time\temperature combinations, product storage conditions, or product reconditioning procedures. The poultry chilling requirements defined in 9 CFR 381.66 or the trichinae requirements in 9 CFR 318.10 would be examples of instances where the regulations clearly define the performance standard for a processing step and can be used to support the HACCP system design.

8. Best practice guidelines are another example of scientific or technical support. These guidelines generally contain a list of procedures or a set of principles that have been identified by experts as having a scientific or technical basis for preventing a hazard from occurring when implemented. For example, the Beef Industry Food Safety Council (BIFSCO) has developed a document that contains Best Practices for Beef Slaughter. This document may be used as scientific support that an establishment\u2019s sanitary dressing program prevents contamination with NOTE: FSIS does not advocate the introduction of pathogens in the plant environment.

10", "microbiological hazards such as STEC and ensures that the interventions the establishment has in place achieve their intended effect. What are some examples of incomplete scientific or technical support? The following are examples of incomplete scientific or technical support for validation:

- \u2022 Documentation that specifies the log reduction achieved by the process but that does not include information about critical parameters, such as pH, critical to achieving that reduction. That information should be included in order for the process to be considered validated.
- \u2022 Having a validated process on file but not following the process described.
- \u2022 Validating a process for a specific log reduction of a pathogen in a product other than meat and poultry. This validation data alone would not be sufficient

scientific support. For example, a process that achieves a 5-log reduction of E. coli O157:H7 in apple cider would not be sufficient scientific support for the reduction of E. coli O157:H7 in a beef product process. \u2022 Implementing an intervention based on scientific or technical support that did not contain data supporting the process\u2019s effectiveness. For example, implementing a lactic acid intervention in a prerequisite program to support E. coli O157:H7 as a hazard not reasonably likely to occur but maintaining scientific support with microbiological data for Salmonella. NOTE: Ensuring that the scientific support contains microbiological data for the hazard listed in the hazard analysis is particularly important for slaughter processes where interventions have different efficacy depending on the species of product and the pathogen. In other cases, such as for lethality processes, Salmonella may be used as an indicator of lethality for other pathogens. \u2022 Documentation in the form of a No Objection Letter or FSIS Directive 7120.1 without additional scientific or technical support that provides information on the levels of all of the critical operational parameters used, and without support that demonstrates the effectiveness of the new ingredient or technology against the specific hazards identified in the hazard analysis. Examples of such necessary scientific and technical support are included on pages 6 through 11 of this document. This additional support is needed because the No Objection Letter and FSIS Directive 7120.1 Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products do not contain efficacy data or data on all of the critical operational parameters. \u2022 Expert opinion from a processing authority stating the growth limit of a pathogen without any reference to established scientific principles or peer-reviewed data. 11", "How can an establishment identify whether the scientific or technical support closely matches the process, product, and hazard analysis? In all cases, the scientific or technical support should identify: \u2022 The product studied (including formulation and intrinsic factors) \u2022 The hazard (biological, physical, or chemical), \u2022 The expected level of hazard reduction or prevention to be achieved, \u2022 All critical operational parameters or conditions necessary, \u2022 The processing steps that will achieve the specified reduction or prevention, and \u2022 How these processing steps can be monitored. The establishment should evaluate this information to determine whether it\u2019s scientific or technical support is sufficiently related to the process, product, and hazard identified in the hazard analysis. The scientific or technical support should be complete and available for FSIS review, so that FSIS personnel can also determine whether the support is sufficiently related to the actual process. Failure to take these steps would raise questions about whether the HACCP system has been adequately designed and validated. How can an establishment identify scientific support that adequately addresses the expected level of hazard reduction or prevention to be achieved for biological hazards? The type of scientific support (e.g., published processing guideline, peer-reviewed data or information, pathogen modeling program results) and the type of data or information contained in the support will differ depending on the product, biological hazards identified in the hazard analysis, and the intervention strategy the establishment designs to reduce, eliminate, or prevent the hazards. Some of these considerations for identifying scientific support for intervention strategies used to address hazards in RTE and raw products are outlined below. Scientific Support for RTE Products Establishments producing meat or poultry products that are RTE must support that potential hazards have been addressed in the product according to 9 CFR 417.2(a)(1). The Listeria Rule (9 CFR 430.1) defines RTE products as meat or poultry products that are edible without additional

preparation to achieve food safety. To support that products are RTE, among other steps, establishments need to achieve lethality of pathogens in the product. To support decisions in the hazard analysis related to lethality of pathogens RTE products, establishments must provide scientific support that specifies the expected level of pathogen reduction achieved by the intervention strategy for the product being produced. For example, establishments producing RTE semi-dry fermented products must provide scientific support that the fermentation and drying steps achieve a specific level of pathogen reduction. In the *Salmonella Compliance 12*,"*Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products*, FSIS recommends that these processes achieve at least a 5.0-log<sub>10</sub> reduction on of *Salmonella* spp. Without data demonstrating a specific log reduction is achieved, it would be difficult for an establishment to support that a product is RTE. The scientific support for RTE products should be sufficiently related to the process, product, and hazard identified in the hazard analysis. For thermal lethality treatments (i.e., cooking), establishments can use scientific support that demonstrates reduction in one pathogen to support that another pathogen would also be reduced. For example, although establishments may identify several biological hazards (i.e., *Salmonella*, *Listeria monocytogenes* (Lm), and *E. coli* O157:H7) that are addressed by a lethality treatment, *Salmonella* is generally considered the reference organism for lethality for most RTE meat and poultry products because: (1) It is prevalent in raw poultry, beef, and pork; (2) it causes a high incidence of foodborne illness; and (3) foodborne illness associated with *Salmonella* is severe (66 FR 12593). In addition, FSIS recommends that establishments use *Salmonella* as an indicator of lethality because it tends to be more heat resistant than other pathogens. Therefore, if an establishment's scientific support demonstrates that its lethality treatment achieves sufficient reduction in *Salmonella*, it does not need to provide additional support that adequate reduction in other pathogens such as Lm or *E. coli* O157:H7 is achieved. For these reasons, establishments should not use pathogens other than *Salmonella* as indicators of lethality unless they can provide support that the pathogen studied displays similar resistance to the process that destroys the bacteria (e.g., heat, acid, or drying). For example, establishments should not use scientific support demonstrating reductions in Lm from a lethality treatment to support that similar reductions in *Salmonella* would be achieved without support that Lm is at least equally as resistant as *Salmonella* under the conditions being studied. Non-pathogenic indicator organisms may be used and will be discussed in a later section. KEY QUESTION Question: Can an establishment use Appendix A, which was designed to address *Salmonella*, to support other pathogens such as *E. coli* O157:H7 or *Listeria monocytogenes* are controlled? Answer: Yes, an establishment can cite Appendix A as support that *E. coli* O157:H7 and *Listeria monocytogenes* are controlled as a result of a thermal process. Although Appendix A was developed based on experiments measuring the efficacy of thermal processes on *Salmonella*, *Salmonella* can be used as an indicator of lethality for other pathogens such as *E. coli* O157:H7 and *Listeria monocytogenes*. 13","*Scientific Support for Raw Products Under 9 CFR 417.2(a)(1)*, establishments producing raw meat or poultry products must support that potential hazards have been addressed in the product. For the production of raw products, the scientific support should contain microbiological data specifying the expected level of pathogen control or prevention achieved by the intervention strategy so that the establishment can determine whether the intervention is adequate for its product and process. Using documentation that does not contain

microbiological data on the specific level of reduction achieved could represent a vulnerability in an establishment's HACCP system design. For example, an establishment that identifies Salmonella as a hazard reasonably likely to occur in its poultry slaughter process because it has historically occurred would have a vulnerability in its process if it relies on scientific support that contains the number of samples that test positive for Salmonella before and after the application of an intervention. Using this type of data would represent a vulnerability because it would not provide information on the specific log reduction achieved. Without this information, the establishment would be unable to determine whether the intervention would reduce Salmonella in its process to acceptable levels. The scientific support for raw meat and poultry products should also be sufficiently related to the process, product, and hazard identified in the hazard analysis. It is particularly important that the scientific support for intervention strategies used in the production of raw products include microbiological data that specifies the expected level of pathogen reduction for the same hazard identified in the hazard analysis. For example, in slaughter establishments, interventions such as lactic acid and peroxyacetic acid (PAA) have been found to perform differently for different pathogens (e.g., Salmonella and E. coli O157:H7) and different species (e.g., poultry vs. beef). Therefore, it would be important for a beef slaughter establishment that references a lactic acid intervention applied to beef carcasses as a control for E. coli O157:H7 in its hazard analysis during slaughter and dressing to provide support that a specific log reduction in E. coli O157:H7 is achieved when the lactic acid is applied to beef carcasses. One exception when the scientific support may not need to address the specific pathogen listed in the hazard analysis for raw products is for intervention strategies designed to control or prevent non-O157 shiga-toxin producing Escherichia coli (STEC). At this time, FSIS is not aware of any controls specific to non-O157 STEC. Interventions validated to control E. coli O157:H7 should be effective in controlling non-O157 STEC when properly implemented as described in the establishment's scientific support. Can establishments use scientific support containing microbiological data from indicator or surrogate organisms? In general, establishments should not rely on scientific support containing data only from indicator or surrogate organisms unless there is sufficient data to establish a relationship between the presence or level of a pathogen or toxin and the indicator organism. When selecting the appropriate surrogate organism, the establishment 14", "should consider the process that destroys the bacteria (e.g, heat, acid, drying). For example, a surrogate organism that is at least as heat resistant as the pathogen of concern should be used if the process primarily relies on thermal destruction (i.e., heat). If the primary pathogen reduction mechanism is fermentation, then a surrogate should be at least as acid resistant as the pathogen of concern. The surrogate chosen in each of these situations may not be the same. Data demonstrating a relationship between the presence or level of a pathogen or toxin and the indicator organism can be collected from studies using indicator organisms that parallel the data in a challenge study performed with the inoculated pathogen. This data could be collected by performing the study with the indicator and pathogen as part of a single study or separately in two studies performed under similar conditions. If similar and consistent reduction or control can be established, then control of the indicator organisms can be reliably used to indicate expected pathogen control in actual application. An example of when similar and consistent reduction in an indicator or surrogate organism and a pathogen have been found is research that was done by the University of Wisconsin with ground-and-

formed jerky that found that two *Pediococcus* strains (Saga 200 and Biosource) have similar heat-resistance to *Salmonella* and can be used in validation studies (Borowski et al., 2009) for jerky lethality processes. In addition, FSIS has identified four surrogate organisms that have been shown to respond similarly to *E. coli* O157:H7 during cooking (see the following askFSIS Q&A1 for more information) for use in validation studies designed to demonstrate a reduction in *E. coli* O157:H7. At this time, however, FSIS is not aware of supporting documentation demonstrating a strong correlation to support the use of generic *E. coli* testing in lieu of testing for *E. coli* O157:H7 or non-O157 STEC. How can an establishment identify scientific or technical support that adequately addresses the expected level of hazard reduction or prevention to be achieved for physical and chemical hazards? For physical and chemical hazards, establishments will often use technical support to demonstrate that particular process control measures can adequately address specific hazards. As with biological hazards, the scientific or technical support should closely match the product, process, and hazard. For example, if the establishment uses detection equipment to identify foreign material such as metal in a particular product, it should have technical support on-file that demonstrates that the equipment can in fact detect the targeted materials (e.g., metal of a defined size and type) in the product. The same is true for chemical hazards. For example, an establishment that uses a lactic acid intervention during a beef slaughter process may identify a chemical hazard from [http://askfsis.custhelp.com/app/answers/detail/a\\_id/1392/kw/surrogate/session/L3RpbWUvMTMyNzUyMTY0Ni9zaWQvVFR6c3cyUGs%3D15](http://askfsis.custhelp.com/app/answers/detail/a_id/1392/kw/surrogate/session/L3RpbWUvMTMyNzUyMTY0Ni9zaWQvVFR6c3cyUGs%3D15), "excessive levels of lactic acid. The establishment may support that the hazard is not reasonably likely to occur based on instructions from the manufacturer on mixing the lactic acid with water to achieve a concentration that is safe and suitable in accordance with FSIS Directive 7120.1. In this case, the manufacturer's instructions or conditions of use are often provided as technical support that demonstrates the use of the chemical is controlled. How can an establishment identify scientific support for prerequisite programs? As previously discussed on page 5, when an establishment determines that a hazard is not reasonably likely to occur because the implementation of a prerequisite program prevents the hazard from occurring, that prerequisite program becomes part of the HACCP system. Therefore, prerequisite programs designed to support decisions in the hazard analysis (e.g. Sanitation Standard Operating Procedures [Sanitation SOPs], written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, antimicrobial interventions) must be validated to ensure that the overall system can operate effectively. Although prerequisite programs within HACCP systems are often designed as multiple hurdles of control, establishments should be able to provide scientific or technical support that each hurdle or combination of hurdles provides the necessary level of prevention for the identified hazards. For some prerequisite programs that are implemented at a discrete point or step in the process, such as those for antimicrobial interventions, the guidance provided on the previous pages for identifying scientific support for the expected level of reduction necessary to prevent the hazard can be applied. When using an antimicrobial intervention as a prerequisite program, establishments should identify scientific support that matches the product, process, and hazard and that contains microbiological data specifying the expected level of pathogen reduction necessary to prevent the hazard from occurring. For other prerequisite programs that are implemented across multiple points or steps in the process, such as those for allergen control or programs

that incorporate written sanitary dressing procedures, establishments may rely on scientific or technical support that contain best practices regarding the implementation of such programs. For example, the Beef Industry Food Safety Council (BIFSCO) has developed a document that contains Best Practices for Beef Slaughter. FSIS has identified, through both scientific literature review and best practice guidance created by industry, the points in the slaughter process where carcasses are most vulnerable to contamination and has included these steps in FSIS Directive 6410.1 Verifying Sanitary Dressing and Process Control Procedures by Off-line Inspection Program Personnel (IPP) in Slaughter Operations of Cattle of Any Age. These documents may be used as scientific support that an establishment's sanitary dressing program prevents contamination with microbiological hazards such as STEC and ensures that the interventions the establishment has in place achieve their intended effect. See Appendix 4 page 55 for an example of scientific support and in-plant data that could be collected to validate Sanitation SOPs, page 56 for an example of scientific support and in-plant data that could be collected to validate a temperature control prerequisite program, and page 57 for an example of scientific support and in-plant data that could be collected to validate a sanitary dressing program. What are the critical operational parameters of a process, and how does an establishment identify them in its scientific support? Critical operational parameters are the specific conditions that the intervention must operate under in order for it to be effective. For an establishment to validate an intervention, it should first identify the critical operational parameters within its process that it needs to implement and monitor. These critical operational parameters are identified in documents gathered as part of Element 1 of validation and often include but are not limited to: Time pH Temperature Contact Time Concentration Product Coverage Humidity Spatial Configuration Dwell Time Pressure Water Activity Equipment Settings or calibration To be effective, the process procedures should be consistent with the critical operational parameters in the scientific support. For example, if the scientific support listed a particular critical operational parameter such as the concentration of an antimicrobial, that same concentration should be used in the process. In some cases, establishments may be able to support using different levels of a critical operational parameter than that used in the support. For example, an establishment may be able to provide a justification for why using a higher lethality temperature than that used in the scientific support would result in the same level of pathogen reduction. When different levels of a critical operational parameter than those in the support document are used, establishments should consider developing a decision-making document that explains the scientific rationale for why the different level would not affect the efficacy of the intervention or process. See Appendix 2 for an example. This scientific rationale could be provided by a processing authority or other expert provided there is reference to established scientific principles or peer-reviewed scientific data and does not rely on expert opinion alone. Developing a decision-making document and explaining the rationale for use of a critical operational parameter different from the one in the scientific support is important because changing a critical operational parameter can impact the intended result in unexpected ways. For example, antimicrobials have been determined to be safe and suitable up to specific concentrations at specific pH levels as listed in FSIS Directive 7120.1 and 9 CFR 424.21(c)). Although the Directive and regulation provide maximum allowable concentrations for

antimicrobials, the establishment needs to determine the 17", "optimum concentration for its process based on the critical operational parameters in its scientific support (e.g., journal articles, challenge studies). The concentration chosen by an establishment is often the concentration at which maximum efficacy is observed. A synergistic or an additive effect may be observed when combinations of antimicrobials are used. Above the optimum concentration, although still within the allowable range, the chemical or antimicrobial efficacy decreases because the cells\membrane of the microorganism are saturated with the compound, and further inactivation of the bacteria is not observed. In other words, more of an antimicrobial is not always better. An establishment may be able support using a higher concentration of an antimicrobial in its process than that used in the scientific support but within the allowable range, provided that it evaluates whether changes to the concentration would affect the efficacy of the intervention or process, and that there is scientific support for its decisions. To identify the critical operational parameters when evaluating the scientific support, there are several questions one can ask. For example: \u2022 What parameters were measured in the research? \u2022 Where in the process or on the product were the measurements taken? o Is the establishment taking measurements in these locations? \u2022 What parameters, if any, were held constant across experimental conditions? \u2022 What parameters, if any, were varied or changed in the research? o When these parameters were changed, did the effectiveness of the intervention change as well? o If so, are these parameters that you have considered in your process? \u2022 Did the authors provide some guidelines as to the limitations of the research or any cautions against applying the findings outside of the scope of the study? o For example, were there some parameters that were controlled in the laboratory that differ in-plant that you should be aware of? o If so, have you considered if those apply to your process? If the scientific support does not document the measurement of a critical operational parameter, the establishment should evaluate whether this parameter really needs to be met or measured, or whether additional support is needed for the level of that parameter in the actual process. For example, humidity is a critical operational parameter in the cooking or heating of many ready-to-eat meat and poultry products. For the production of some of these products, however, humidity does not need to be met or measured. For example, as addressed in the Appendix A Guidance on Relative Humidity and Time\Temperature for Cooking\Heating and Applicability to Production of Other Ready-to-eat Meat and Poultry Products, humidity does not need to be met or measured when a product is cooked in a sealed, moisture impermeable bag. Establishments producing such cook-in-bag products may develop a decision-making document and cite the Appendix A Guidance on relative humidity as support for why humidity does not need to be met or measured in the process. What is important in this case is that the establishment considers the parameters that are relevant for their product and process 18", "and does not assume that just because the parameter was not measured in the scientific support it is not important. For prerequisite programs that are implemented across multiple points or steps in the process, such as those for allergen control or programs that incorporate written sanitary dressing procedures, establishments may rely on scientific or technical support that contains best practices regarding the implementation of such programs. When relying on these types of scientific or technical support, establishments may consider the recommended procedures that should be incorporated into the written prerequisite program as critical operational parameters. These procedures would be considered critical operational parameters

because these steps need to be implemented and monitored in order to ensure that the program is effectively preventing a hazard from occurring. See Appendix 3 for additional guidance as to how to identify critical operational parameters from the scientific support. Appendix 4 contains examples of critical operational parameters that have been identified for different types of processes and scientific support. Examples of the types of in-plant documentation expected are also provided. Key Point: An establishment that gathers scientific support for its processes (and properly identifies the critical operational parameters in the support) as described above would meet the threshold indicated in the HACCP Systems Final Rule (61 FR 38806) for the first element of initial validation in designing a valid HACCP system. The establishment's processes would be considered by FSIS to be based on or supported with documented scientific evidence. These processes would not need any additional scientific support as part of the initial validation process. However, as stated in the HACCP Systems Final Rule (61 FR 38826), an establishment introducing a new technology not established in the literature or applying a standard technology in an unusual way (e.g., modifying critical operational parameters from the literature) should gather scientific support and in-plant validation data for its new or modified HACCP system under commercial operating conditions. The effort to develop such information may require that the establishment conduct, or have conducted for it, scientific studies either in a laboratory setting, pilot plant, or in-plant. An establishment that lacks experience with a technology should also gather scientific support and in-plant validation data with the exception of when the effectiveness of the new technology has already been studied, but the establishment lacks experience implementing the technology. In this case, the effort to develop such information may focus more on the collection of in-plant validation data (discussed further in the next section). 19", "What is the second element of HACCP Systems Validation? The second element of HACCP systems validation is initial in-plant validation which may include in-plant observations, measurements, microbiological test results, or other information demonstrating that the control measures, as written into a HACCP system, can be executed within a particular establishment to achieve the process's intended result (61 FR 38806, 38826 (July 25, 1996)). FSIS stated in the HACCP Final Rule that validation data for any HACCP system must include practical data or information reflecting an establishment's actual experience in implementing the HACCP system. The validation must demonstrate not only that the HACCP system is theoretically sound in its design (Element 1), but also that the KEY QUESTION Question: Can an establishment's process use a different level of a critical operational parameter (for example, a higher concentration of an antimicrobial or a higher processing temperature) than what was used in the scientific or technical support? Answer: Generally, establishments should use the same critical operational parameters as those in the scientific or technical support. However, some minor differences are acceptable. For example, Table 1 of the Tompkin paper can be used to support a storage temperature CCP for raw meat of 45°F even though it cites 44.6°F as minimum growth temperature for Salmonella. This rounding is suitable because the growth rate of Salmonella at 45°F is not significantly different from its growth rate at 44.6°F. Furthermore, when temperatures are converted from Celsius to Fahrenheit, as in Table 1 of the Tompkin paper, numbers are often converted as fractions, which establishments may round to whole numbers because of practical measurement limitations of equipment in establishments. On the other hand, rounding may not be suitable for other critical operational parameters such as water

activity and pH because minor changes in the values can have a significant impact on pathogen growth. In some circumstances, establishments may be able to support using critical operational parameters (e.g., higher concentrations of antimicrobials or higher thermal processing temperatures) that are different from those in the scientific or technical support. In these cases, establishments should provide justification supporting that the levels chosen are at least as effective as those in the scientific or technical support. This justification is needed because higher levels of a critical operational parameter may not always be equally effective. For example, antimicrobial agents may only be effective within a range of concentration after which point efficacy may decrease. Similarly, higher processing temperatures may result in the surface of the product drying out before adequate lethality is achieved. In addition to ensuring that the levels chosen are at least equally as effective, establishments should ensure the levels are also safe and suitable (FSIS Directive 7120.1 Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products and 9 CFR 424.21(c)). 20", "establishment can execute it as designed to reach the desired effect (Element 2). To meet the second element of validation, establishments should: \u2022 Implement the critical operational parameters in the actual production process consistent with the parameters in the scientific support; \u2022 Identify at least one product from each HACCP category for which to gather inplant validation data; \u2022 Collect in-plant data demonstrating the effectiveness of the implementation of the critical operational parameters for at least one product from each HACCP category; and \u2022 Analyze the data to determine whether the critical operational parameters are being implemented effectively. Once the critical operational parameters are identified, how should they be implemented in the actual process? Once the critical operational parameters are identified, an establishment should implement the critical operational parameters in the actual process consistent with the scientific support. If an establishment is using the scientific support as support for the development of a CCP and its critical limits (9 CFR 417.5(a)(2)) to prevent, reduce, or eliminate a hazard identified as RLTO, the establishment should incorporate all of the critical operational parameters into the critical limits of the CCP. An establishment may determine, however, based on its decision making, that some of the parameters can be monitored on an ongoing basis as part of a prerequisite program. An establishment may also determine that it only needs to ensure some of the critical operational parameters are implemented consistent with the support during the initial validation period (e.g., spatial configuration, equipment type to the extent that it affects other parameters, or ingredient formulation provided it does not change). These parameters should be included in a decision-making document, but they do not need to be monitored after the 90 days of initial validation unless there is a change. If an establishment is using the scientific support as support for a decision that a hazard is not reasonably likely to occur (9 CFR 417.5(a)(1) because the implementation of a prerequisite program prevents conditions that make the potential hazard likely, then all of the critical operational parameters should be incorporated into the prerequisite program. An establishment may also determine that it only needs to ensure some of the critical operational parameters are implemented consistent with the support during the initial validation period (e.g., spatial configuration, equipment type to the extent that it affects other parameters, or ingredient formulation provided it does not change). 21", "What types of data should establishments collect during the initial inplant validation period? Often establishments incorporate interventions into their processes to reduce the level of certain

pathogens and use published scientific articles as scientific support for the design of the interventions (see above discussion of the first part of validation). Establishments may implement those interventions consistent with the scientific support or make modifications to the critical operating parameters that could affect the efficacy of the intervention. To implement an intervention consistent with the scientific support means that changes among the critical operational parameters used in the scientific support and those used in the actual process will not affect the efficacy of the intervention or treatment. Depending on how an establishment implements the critical operational parameters for an intervention and the type of support used, different data should be collected during the initial in-plant validation period. These two scenarios are described below:

**Scenario 1** - In cases where the establishment's process is implemented consistent with the critical operational parameters described in the scientific support, and when the scientific support used contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, to meet the second element of validation, the establishment should:

- \uf0fc Identify the critical operating parameters in the scientific support, AND
- \uf0fc Implement those critical operational parameters in the establishment's production process consistent with the scientific support, AND
- \uf0fc Collect in-plant data that demonstrates that the critical operating parameters are being met (e.g., data on quantifiable characteristics of the critical operational parameters such as pressure, temperature, and concentration).

Thus, if an establishment implements the actual process consistent with the critical operational parameters in the scientific support, the establishment should collect in-plant data demonstrating that the critical operational parameters can all be met, and no in-plant microbiological data would be needed. For example, if the scientific support for a carcass wash intervention includes critical parameters of water pressure at the nozzle, water temperature at the point of contact with the carcass, whole carcass coverage, and a water\carcass contact time, then the establishment should measure and gather data on whether those parameters are being achieved. The water temperature measured in a holding tank or at the nozzle may not be the actual water temperature at point of contact with a carcass, so it is crucial to design measurement procedures appropriately.

**Scenario 2** - In cases where the establishment's process is not implemented in a manner that is consistent with the critical operational parameters described in the 22", "scientific support without justification, or when the scientific support used does not contain microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, to meet the second element of validation the establishment should:

- \uf0fc Identify the critical operating parameters in the actual process (either because they were modified from the scientific support without justification, or the scientific support does not contain microbiological data), AND
- \uf0fc Collect in-plant microbiological data that demonstrates the intervention's effectiveness under actual in-plant conditions or identify scientific support with microbiological data demonstrating the effectiveness of those critical operational parameters, \uf0fc AND
- \uf0fc Collect in-plant data that demonstrates that the modified critical operating parameters are being met.

Thus, if an establishment implements different critical operational parameters in the process from the scientific support, or if the scientific support does not contain microbiological data, then the establishment should collect in-plant data demonstrating the critical operational parameters

that it has implemented can all be met AND collect in-plant microbiological validation data or identify scientific support with microbiological data for the effectiveness of those implemented critical operational parameters. The establishment should develop the appropriate in-plant data during the initial 90 days of implementing a new HACCP system, or whenever a new or modified food safety hazard control is introduced into an existing HACCP system (e.g., as implemented after a HACCP plan reassessment). During these 90 calendar days, as described in the HACCP Final Rule, an establishment gathers the necessary in-plant data to demonstrate that the critical operating parameters are being achieved. In essence, the establishment would repeatedly test the adequacy of the process steps in the HACCP system to establish that the HACCP system meets the designed parameters and achieves the intended results. These in-plant data become part of the validation scientific support along with the scientific support used to design the HACCP system. See the section below on records for more information. Failure to take these steps would raise questions as to whether the HACCP system has been adequately validated. In addition to collecting the in-plant data described, it is critical that the establishment analyze the data to whether the critical operational parameters are being implemented effectively. This analysis should include a review of the records generated by the HACCP system during the initial validation period. Establishments may need to work with a statistician to conduct more in-depth statistical analyses of the in-plant data collected. For example, an establishment may need to work with a statistician to determine whether the in-plant validation data supports that it is implementing the critical operational parameters consistent with the scientific support. 23", "An establishment may also need to conduct more in-depth analysis if it implements critical operational parameters that are different from the process in the scientific support, and, as a result, it would need to collect in-plant microbiological data. For what types of processes and products should establishments collect in-plant validation data? Establishments should maintain scientific support for all processes and products; however, establishments should collect in-plant data for at least one product from each HACCP process category at that establishment. Depending on the HACCP category and products, establishments should consider collecting in-plant data for more than one product within each category. The object is to collect in-plant data for a wide variety of different products and worst case scenarios. Establishments should collect in-plant data for all CCPs and prerequisite programs used to support decisions in the hazard analysis for at least one product from each HACCP category at that establishment. Establishments should use food science principles in their decision making when deciding which product types within a HACCP category should be used to gather in-plant data. In addition, establishments should use decision-making documents to describe how the HACCP team decided on the product or product types that would be used during initial validation. Similarities and differences in species, process, intrinsic factors, product public health risk, and food safety hazards should be considered. Some examples of food science principles that could be used to decide which product within a HACCP category should be used to gather in-plant data include: \u2022 Fat content: Fat level in meat has been documented to influence bacterial heat resistance (Juneja et al., 2001). As the fat level increases, bacterial heat resistance increases. Therefore, higher fat content meat or poultry products require greater time or temperatures to achieve equal lethality compared with lower fat content products. o How this criterion could be used: If an establishment produces several fully cooked poultry products, the establishment should gather data for the product

with the highest fat content. Similarly, if an establishment produces several ground poultry products, and some of the products are made from skin-on thigh meat while others are made with boneless, skinless thigh meat, the establishment should collect in-plant validation data for the ground product made from the skin-on thigh meat because of the additional fat from the skin.

\u2022 Size and shape of the food: The size and shape of food affects heat penetration, heating rate, and heating uniformity. Irregularly shaped products, for example, are subjected to non-uniform heating because of differences in product thickness. In addition, in thicker products, more time will be needed for the heat to penetrate to the center of the product.

- o How this criterion could be used: If an establishment produces several fully cooked deli meat products of various thicknesses, the establishment should gather data on the thickest product because heat penetration is critical.

\u2022 Number and type of processing steps or ingredients: Certain processing steps, such as slicing of ready-to-eat product, are known to be potential sources of cross-contamination. In addition, some ingredients such as spices are known to introduce contamination (biological, chemical, or physical). Therefore, establishments should consider whether some products within a HACCP category undergo additional processing steps or contain additional ingredients that may introduce contamination and should collect in-plant validation data for that product.

- o How this criterion could be used: If an establishment fabricates beef manufacturing trimmings and uses the trimmings to produce ground beef and patties, the establishment should collect in-plant validation data for the patty process because the patty forming process introduces an additional step that could provide an opportunity for contamination.

\u2022 Product species: Studies have shown that there is a difference in bacterial resistance in products from different types of species. Therefore, establishments should consider collecting data separately for each species slaughtered or processed within a HACCP category.

- o How this criterion could be used: If an establishment slaughters hogs and cattle under one HACCP category, in-plant data should be gathered for both species because the slaughter process and the hazards associated with each are substantially different.

\u2022 Public health risk: Establishments should take past outbreaks into account when selecting a product to collect in-plant data for within a HACCP category.

- o How this criterion could be used: If an establishment produces several types of fully cooked ready-to-eat products, and one of the products is Lebanon bologna, data should be gathered for the Lebanon bologna because it was associated with an illness outbreak. In some cases, an establishment may produce products that are all of equal risk. In those cases, FSIS recommends that establishments select the product with the highest production volume because that product would have the greatest public exposure.
- o How this criterion could be used: If an establishment makes several types of fully cooked sausages and the only difference among these products are ingredients such as pimentos or pickles that are used as flavorings and that do not affect food safety, an establishment should gather data on the product produced in the highest volume. Finally, in other cases establishments may consider selecting more than one product from a HACCP category.

\u2022 For example: If an establishment processes both hot dogs and RTE whole turkey breast that is sliced, both products should be validated because their processes are substantially different, and both have been found to represent an increased risk of listeriosis illness to the consumer. How long does an establishment have to complete initial validation (Elements 1 and 2)? During the process of conducting a hazard analysis and developing a HACCP plan, establishments gather supporting documentation in the

form of scientific or technical support for the HACCP system design (Element 1). New establishments must conduct a hazard analysis (9 CFR 417.2) and develop and validate a HACCP plan (9 CFR 417.4) before being granted Federal inspection as required by 9 CFR 304.3(b) and 381.22(b). Additionally, establishments must conduct a hazard analysis and develop a HACCP plan (9 CFR 417.2) before producing a new product for distribution in commerce as required by 9 CFR 304.3(c) and 381.22(c). Consistent with these requirements, establishments should gather scientific or technical support for a modified HACCP plan before implementation, if the results of a reassessment indicate new or additional support is needed (e.g., if significant changes to an intervention are made or a new intervention is added). Establishments can begin gathering their support by conducting reviews of the available scientific literature, published processing guidelines, and regulatory performance standards to determine whether scientific documentation already exists matching their actual product and process. After the hazard analysis has been conducted, and the HACCP plan has been developed, establishments gather in-plant validation data proving that the HACCP system can perform as expected (Element 2). New establishments are issued a conditional grant of inspection for a period up to 90 days during which they must complete the initial validation as required in 9 CFR 304.3(b) and 381.22(b) (Element 2). Additionally, 9 CFR 304.3(c) and 381.22(c) require establishments producing a new product to complete the initial validation of the new HACCP plan during a period not to exceed 90 days after the date the new product is produced for distribution in commerce. Consistent with these requirements, initial validation should encompass the first 90 calendar days of an establishment's processing experience with a modified HACCP plan, if the results of a reassessment indicate in-plant validation data should be collected (e.g., if significant changes to an intervention are made or a new intervention is added). For large establishments, 90 calendar days equates to approximately 60 production days. FSIS recognizes that many small and very small establishments do not operate daily. Therefore, FSIS recommends a minimum level of records from 13 production days within those initial 90 calendar days should be used to initially validate a small or very small establishment's HACCP system. FSIS also recognizes that there are some establishments that produce products so infrequently that they would not be able to gather records from 13 production days within those 90 initial calendar days. If the establishment infrequently produces several products that are each part of a separate HACCP category, there is inherent risk with the processes if the establishment does not have experience in producing them. Therefore, to determine whether the system is "properly designed and executed, even though the regulations provide 90 days for initial validation, an establishment needing more than 90 days can ask the District Office, in writing, for additional time to collect at least 13 production days of records when it first starts operating, or when it begins producing new product, or for a modified HACCP plan if the results of a reassessment indicate additional support is needed. In the request, an establishment should indicate why more than 90 days are needed to collect the in-plant validation data, and how it plans to gather at least 13 production days worth of in-plant validation data within the next 30 calendar days. The request will then be evaluated on a case by case basis. The establishment should consider focusing validation activities on the product produced most frequently within each HACCP category. In addition, the establishment may consider evaluating data collected for products across multiple HACCP categories to determine whether the data together can support its ability to meet critical operational parameters. As

previously discussed, if an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the inplant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. However, if an establishment implements different critical operational parameters in the process from the scientific support, or the scientific support identified does not contain microbiological data, then the establishment should collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological validation data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameters. Establishments can continue producing and shipping product into commerce during the 90 day initial validation period with the exception of establishments that are gathering inplant microbiological data to support that a product is RTE. For example, if an establishment producing a RTE product is implementing a lethality process using different critical operational parameters (e.g., time, temperature, or relative humidity) from its scientific support, the establishment could commission a challenge study to demonstrate the effectiveness of the alternate parameters during the 90 day initial validation period. During this time, the establishment could not ship the RTE product into commerce because it does not have the necessary scientific support to demonstrate that all potential hazards have been addressed and that the product would meet the definition of RTE in 9 CFR 430.1 (that it is in a form that is edible without additional preparation to achieve food safety). If an establishment has questions as to whether complete scientific support is needed for its products before the products can be shipped into commerce, then it can submit a question through askFSIS at <http://askfsis.custhelp.com/> following the guidance on page ii of this document. 27", "What types of records are validation documents, and how long should an establishment keep them? The scientific support (design) and in-plant (execution) validation data support the decisions made in the hazard analysis and the adequacy of the process to control those hazards. Therefore, these supporting documents must be kept for the life of the plan to meet the requirements of 9 CFR 417.5(a)(1) & (2). NOTE: Establishments using existing HACCP systems developed before the issuance of this document that do not have the documents from their initial validation on file will need to gather the necessary data. Appendix 5 contains further guidance for establishments that no longer have the in-plant validation data. KEY QUESTION Question: If an establishment has not utilized a process for a year or more, is the process still validated? Answer: Most likely, no. An establishment would need to perform a reassessment in order to determine whether changes have occurred that could affect the hazard analysis or alter the HACCP plan. If the reassessment led to modifications in the HACCP system, then the establishment would need to gather additional in-plant validation data. Meat and poultry establishments must document each reassessment and the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment (9 CFR 417.4(a)(3)). For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination. Key Requirement The scientific or technical support for the design

and initial in-plant execution validation documents must be kept on file as part of 9 CFR 417.5(a)(1) & (2) supporting documentation records. 28", "What is the difference between initial validation and on-going verification, and what happens after the initial validation period is over? Many agree that validation should be a distinct function from verification (see, e.g., Scott and Stevenson, 2006). During the 90 calendar days of initial validation following completion of the hazard analysis and development of the HACCP system, establishments check the validity or adequacy of the HACCP system. Establishments are to conduct validation activities during their initial experience with a new HACCP system. Establishments are required to complete the initial validation of the new HACCP plan in accordance with 9 CFR 417.4 during a period not to exceed 90 calendar days after the date the new process is used to produce product for distribution in commerce. During these 90 calendar days, an establishment gathers data from its monitoring and on-going verification activities at an increased frequency compared to the frequency listed in the HACCP plan and gathers additional data to demonstrate that the process is being executed effectively. During this period an establishment should be reviewing these data and making modifications to its system as necessary. NOTE: Establishments may determine that modifications are needed to an intervention during the initial validation period either because the design did not result in the intended effect or because the establishment could not execute the intervention as designed. Such modifications are part of the initial validation process. However, establishments that make major modifications multiple times throughout the initial validation period and as a result do not generate sufficient records that support the KEY QUESTION Question: If an establishment moves physical locations, will it have to repeat the in-plant documentation element of its initial validation? Answer: Most likely yes, as a result of the establishment\u2019s reassessment. Much like with large corporations with multiple establishments, the establishment will be able to transfer the scientific support from one location to another (meeting the first element of validation - design) but will most likely need to gather in-plant data to support the second element of validation (execution). There are often differences from location to location that may affect whether the critical operational parameters in the scientific or technical support can be implemented properly in the new establishment. For example, the same type of spray cabinet made by different manufacturers may have different flow rates for the intervention spray delivery that would require changes to other critical operational parameters in order to achieve equivalent application. The same may be true for the effect of employees or the size or shape of the physical location on the critical operational parameters. 29", "design and execution of the intervention used in the hazard analysis may not be able to support that the HACCP system is adequate. Following the 90 calendar day period of initial validation, an establishment uses its findings during the initial validation period to fully implement its system and solidify its monitoring and on-going verification procedures and frequencies. The establishment then continues on a daily basis to perform monitoring and verification activities to ensure that the HACCP system continues to be implemented properly. Establishments are required to support both the monitoring and verification procedures selected and the frequency of those procedures as part of 9 CFR 417.5(a)(2). Data gathered during initial validation, during which critical operational parameters are monitored at an intense frequency, is one source of information that can be used to support monitoring and verification procedures and frequencies (see examples in Appendix 4). Importantly, not all critical operational parameters

that are measured during initial validation are monitored on an ongoing basis after the initial validation period is over. For example, some parameters, such as spatial configuration or ingredient formulation, may not change over time and therefore do not need to be monitored. In addition, ongoing verification may include activities that were not performed as part of initial validation because the purposes of these two processes differ. The purpose of validation is to demonstrate that the HACCP system as designed can adequately control identified hazards to produce a safe, unadulterated product, while the purpose of ongoing verification is to support that the HACCP system is functioning as intended on an ongoing basis. Although it may be adequate to measure the critical operational parameters during initial validation to ensure that the HACCP system as designed can be executed, doing so does not negate the need for ongoing verification activities, such as testing for appropriate pathogens or other microorganisms, to support that the HACCP system is working as intended on an ongoing basis. In addition to continuing ongoing verification following the completion of the initial validation period, it is also important to recognize the role of reassessment in the process. At every reassessment, establishments should reassess the hazard analysis taking into account information on any foodborne illnesses associated with the products to determine whether all relevant hazards have been considered. In addition, establishments should ask: \u201cls my HACCP system adequate to control the identified food safety hazards?\u201d Annually and whenever changes occur that affect the hazard analysis, the establishment should review records generated over the course of the previous year, or during the period the change occurred, that reflect how the HACCP system is performing as a whole, and analyze them to determine whether food safety goals are being met. This review should include records of the monitoring of critical limits and parameters of prerequisite programs to ensure that the critical operational parameters in the scientific support continue to be met and any records from ongoing verification 30", "activities, such as microbiological testing, to ensure identified food safety hazards are being controlled. If the establishment determines at the end of the reassessment that the HACCP system is effective and functioning as intended, the establishment can continue on with the same system and the same monitoring and verification procedures and frequencies. If the establishment determines at the end of the reassessment that either its HACCP system was not set up correctly, is not being implemented consistently, or is no longer effective, the establishment should make changes to its HACCP system (e.g., add another intervention) and then would, in most cases, be required to validate any changes to its HACCP system. In some cases, however, changes that result from reassessment would not require validation. For example, an establishment that reassesses its HACCP system following a change in supplier of a raw material may find that the change does not require validation because the composition of the raw material and its microbiological profile are not significantly different from the material provided by the previous supplier. In other cases, changes that result from the reassessment would not require additional scientific support but would require additional in-plant validation data. For example, an establishment may find through reassessment that the design of an intervention was adequate, but that the employees were not implementing it correctly. In that case, the establishment would only need to collect in-plant validation data demonstrating the intervention could be implemented appropriately. Finally, depending on the change, the establishment will likely only need to validate that the change is functioning as intended and not assess the entire HACCP system. For example, an establishment may change the thickness

of a raw patty product and determine that it only needs to validate that the cooking instructions still achieve the desired endpoint temperature and does not need to validate the entire HACCP system. NOTE: Official establishments are to make a record of each reassessment required by 9 CFR 417.4(a)(3)(i). The regulations require establishments to document the reasons for any changes to the HACCP plan based on the reassessment or the reasons for not changing the HACCP plan based on the reassessment. For annual reassessments, according to the regulation, if an official establishment determines that it does not need to make changes to its HACCP plan, it is not required to document the reasons for not changing the HACCP plan. While the establishment is validating any changes it made to its HACCP system, the establishment continues to implement other parts of its HACCP system, such as any on-going verification activities, including testing that is done as part of its existing system. In other words, when an establishment makes changes to its existing HACCP If the establishment determines at the end of the reassessment that the HACCP system is effective and functioning as intended, the establishment can consider continuing on with the same system and the same monitoring and verification procedures and frequencies. 31", "system and is validating those changes, this validation does not occur in a vacuum. While microbiological testing is not required specifically as part of initial validation, other HACCP principles, such as on-going verification activities, continue to apply, including verification testing that is done to support that the HACCP system addresses identified hazards on an on-going basis. The following chart illustrates some of the key differences between initial validation and ongoing verification and shows the sequence of these key steps.

Initial Validation \u2022Frequency: \u2022Once over a period of the first 90 days of new or revised HACCP system \u2022Purpose: \u2022To ensure the HACCP system as designed functions as intended \u2022Process: \u2022Repeatedly test all critical operational parameters to show the establishment can implement them, and that they are effective at controlling the identified hazards

Ongoing Verification \u2022Frequency \u2022Ongoing following completion of initial validation (i.e., day 91) and onward

\u2022Purpose: \u2022To ensure the HACCP system is functioning as intended on an ongoing basis \u2022Process: \u2022Conducting ongoing verification activities including calibration, direct observation, and review of records as well as other independent checks such as testing

Reassessment \u2022Frequency \u2022Annually and whenever changes occur that affect the hazard analysis or HACCP plan \u2022Purpose: \u2022To determine whether the HACCP system as designed and executed is still adequate \u2022Process: \u2022Review of records generated from ongoing verification to ensure that the HACCP system as designed and executed is still adequate (i.e., through test results and monitoring of critical operational parameters) If reassessment results in no changes If reassessment results in changes to the HACCP system 32", "An example of the dynamic process illustrated earlier for a ground beef establishment is shown below. In this example, the establishment has decided to add an antimicrobial intervention to trimmings prior to grinding. Please note that the example only shows one part of the entire HACCP system.

Initial Validation \u2022During the first 90 days the establishment: \u2022Identified the scientific or technical support. \u2022Carpenter et al. 2011. Meat Sci: 88. \u2022Identified the critical operational parameters of the intervention \u2022Concentration: 2% lactic acid \u2022Dwell time: 20s \u2022Pressure: 20 psi

\u2022Temperature: 55\u00b0C \u2022Equipment: CHAD cabinet \u2022Complete coverage \u2022Demonstrated the critical operational parameters were met \u2022Trim Spray Cabinet

Worksheet was used to record critical operational parameters Ongoing Verification \u2022 On day 91 and onward the establishment chose to monitor the critical operational parameters as part of a CCP. \u2022 The establishment conducted ongoing verification activities related to the parameters being monitored including calibration, direct observation, and review of records. In addition the establishment, taking into account volume, chose to conduct ongoing verification testing of E. coli O157:H7 in trim on a quarterly basis. The establishment collected samples of trim after allowing the antimicrobial appropriate drip time and increased the frequency of testing during the high prevalence months. Reassessment \u2022 At the yearly reassessment the establishment evaluated the records generated during ongoing verification for the past year. Since there were no positives and the critical operational parameters of the intervention were consistently met, the establishment determined that the HACCP system is working as intended and will continue with conducting ongoing verification at the current frequency.

Reassessment resulted in no changes 33", "HACCP Initial Validation Self-Assessment Does my HACCP system: 1. Contain supporting documents for each CCP or prerequisite program that is used to support decisions in my hazard analysis? 2. Contain supporting documents that relate sufficiently to my product/process? 3. Identify the critical operating parameters based on the supporting documents used as scientific or technical support? 4. Contain critical operating parameters that are aligned with the referenced supporting document? 5. Contain critical operating parameters that support rather than contradict the selected critical operating parameter if multiple supporting references are used? 6. Contain in-plant validation data from 90 calendar days (see pages 26-27 for expectations regarding the equivalent number of production days) documenting the critical operating parameters are implemented for at least one product within each HACCP category? 7. Contain HACCP system in-plant validation data for at least one product within each HACCP category that was reviewed and found acceptable by the HACCP team to support that the process is validated by the HACCP team or other group responsible for food safety? 8. Contain additional research data demonstrating the effectiveness of the process in instances where the critical operational parameters from the support were not followed? For each HACCP category, identify at least one product from the category for which collect inplant demonstration data and complete a validation worksheet for such product containing the following information. Examples can be found in Appendix 4.

Product: Name the HACCP plan type or product category. Hazard: Name the hazard of concern. This should be the same content that is in the hazard analysis. Process: Name the processing step or prerequisite program that addresses the hazard. Critical Operating Parameters: Refers to the critical limits or other parameters cited in the scientific or technical support necessary for effective execution of the process step or program. Validation: Scientific or Technical Support - State the scientific or technical support document references and page numbers where the critical operating parameters are described. In-plant Validation Data - State the name of the monitoring documents or other records where observations were collected including the time frame. 34", "References FSIS. 1996. Pathogen Reduction; Hazard Analysis Critical Control Point (HACCP) Systems: Final Rule. 9 CFR Part 304 et al., Federal Register 61(144), 38805-38989. Juneja, V.K., Eblen, B.S., Marks, H.M. 2001. Modeling non-linear survival curves to calculate thermal inactivation of Salmonella in poultry of different fat levels. International Journal of Food Microbiology. 70: 37-51. NACMCF. 1998. Hazard Analysis and critical control point principles and application guidelines. J. Food Prot. 61:762-775. Scott, V.N., Stevenson, K.E., and

Gombas, D.E. 2006. Verification procedures. Pp. 91-98. In Scott, V.N., and Stevenson, K.E. (ed.), HACCP - A Systematic Approach to Food Safety, 4th ed. The Food Products Association, Washington, D.C. Web links Food Safety Inspection Service (FSIS) \u2013 HACCP Validation Webpage: <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/resourcesand-information/haccp-validation> Compliance Assistance: <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance> State HACCP Contacts & Coordinators: <http://www.fsis.usda.gov/wps/portal/informational/contactus/state-haccp-contacts-andcoordinators> Ohio State University, Meat Science Extension \u2013 <http://meatsci.osu.edu/home> University of Wisconsin, Center for Meat Process Validation \u2013 [www.meathaccp.wisc.edu](http://www.meathaccp.wisc.edu) Penn State University, Food Science \u2013 <http://foodsafety.psu.edu/extension-people.html> HACCP Alliance - <http://www.haccpalliance.org/sub/index.html> 35", "Appendix 1: Examples of Food Safety Problems Linked to Inadequate Validation Below are some specific examples where FSIS has found that inadequate validation has led to adulterated product and in some cases illness outbreaks. 2012 \u2013 Veal E. coli O157:H7 and adulterant non-O157 STEC Positives from FSIS Testing FSIS test results show that the percent positive for E. coli O157:H7 and adulterant nonO157 STEC from ground beef and raw ground beef components produced from veal appear to be higher than ground beef and raw ground beef components produced from other cattle slaughter classes. Following up on these results, FSIS conducted a review of Food Safety Assessments (FSAs) and onsite visits to veal slaughter establishments to identify concerns unique to veal slaughter. FSIS found that veal slaughter establishments, in applying their antimicrobial interventions, failed to achieve carcass coverage because of the practice of suspending carcasses from the rail system with both hind limbs on a single hook. Because of this practice, antimicrobial or hot water interventions, such as sprays, did not reach all parts of the carcasses. Carcass coverage \u2013ensuring that the entire carcass surface is treated -- is a critical operational parameter that is necessary for the intervention to operate effectively and as intended. As a result of the incomplete carcass coverage, interventions were likely less effective than intended, and this ineffectiveness may have contributed to the production of products contaminated with E. coli O157:H7. In addition, during on-site visits to beef fabrication establishments, FSIS found that beef fabrication establishments, in applying their antimicrobial intervention, had also failed to achieve product coverage because establishments stacked products and folded longer pieces, particularly loins. These actions prevented antimicrobial sprays from reaching all product surfaces. Additionally, establishment personnel did not adjust the conveyor belt timing, properly design spray applications, or ensure that product was singlestacked and lying flat so that all product surfaces received the antimicrobial spray. Validation Take-away: Had establishments translated this critical operational parameter \u2013 product coverage \u2013 into their HACCP system (either through a pre-requisite program, CCP, or during the initial set-up of their system) the contamination of raw beef products with E. coli O157:H7 and other STEC may have been prevented. 2011 \u2013 Lebanon Bologna E. coli O157:H7 Illness Outbreak In March 2011, there was a foodborne illness outbreak of E. coli O157:H7 associated with Lebanon bologna. The establishment that produced the product recalled it. An FSIS investigation into the processing of the product revealed that the establishment relied on scientific support that did not match the actual commercial process

used. In the scientific support, to represent a commercial process for Lebanon bologna, raw 36", "Lebanon bologna mix was compacted in 27 millimeter diameter impermeable sealed glass tubes that were immersed in a well-controlled water bath. However, in the actual process at the establishment, raw Lebanon bologna mix was compacted in 52 to 119 mm diameter permeable casings that were placed in a large smokehouse fitted with a single source of heat and humidity that was not well-controlled. The difference in the diameter and type of casing material likely led to a lower reduction in foodborne pathogens of concern in the actual process than what was demonstrated in the support. If the diameter of the establishment's product is larger than that of the product used in the support, it is possible that the product core will take longer to reach the desired temperature and pH. Taking a longer time than expected to reach the desired temperature and pH may lead to a lower level of pathogen reduction. Critical operational parameters such as the product diameter and type of casing material can also affect the amount of moisture exchange between the product and the environment and can play a role in the effectiveness of the fermentation. For these reasons, it is important that the support used by the establishment is representative of the establishment's actual process so that the results can be repeatable. Validation Take-away: Had the establishment ensured that its actual process matched its scientific support during the initial design of its system, the establishment could have addressed actual relative humidity and the time it took the actual product to reach the desired temperature and pH compared to that in the support, preventing product contamination and illnesses.

2007 \u2013 Chicken Pot Pie Salmonella Illness Outbreak and 2011 \u2013 Turkey Burger Salmonella Illness Outbreak In October 2007, a number of varieties of frozen pot pies were linked to an outbreak of salmonellosis. The establishment that produced the product recalled it. The pot pies contained pre-cooked poultry products but raw vegetables and dough. Testing of two of the pies taken from case patient homes found that the filling of the pot pies tested positive for Salmonella. An investigation revealed that the likely cause of illnesses was that consumers were not cooking the products in the microwave to a lethality temperature. Specifically, the investigation revealed that the instructions may have been confusing because different parts of the package recommended different preparation times. In addition, microwave time varied by wattage; however, most case patients interviewed did not know the wattage of their microwave. Other patients reported not following the microwave directions, including not following the rest time and microwaving more than one pie at a time. Therefore, one of the primary conclusions of the investigation was that the cooking instructions for such products should be validated to account for variability in microwave wattage and common misconceptions among consumers regarding the nature of not-ready-to-eat foods (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5747a3.htm>). 37", "Between late December of 2010 and March of 2011, an outbreak of Salmonella Hadar linked to turkey burgers sickened 12 people, three of whom were hospitalized. Investigators were not able to determine consumption of turkey burgers for all casepatients. However, FSIS determined that at least three of the case-patients in three states specifically reported eating turkey burgers produced at the same establishment the week before their illness began. Samples of ground turkey burgers were collected by public health agencies from the homes of two case-patients who tested positive for the outbreak strain of Salmonella Hadar. Both turkey burger samples were positive for the outbreak strain. As a result of these findings, the establishment that

produced the product recalled 54,960 pounds of potentially contaminated product ([http://www.cdc.gov/salmonella/hadar0411/040411/index.html?s\\_cid=ccu041111\\_016](http://www.cdc.gov/salmonella/hadar0411/040411/index.html?s_cid=ccu041111_016)). In a post-outbreak investigation, FSIS found that the cooking instructions for the turkey burger were not sufficient to guarantee that a safe end-point temperature would be reached so that pathogens would be killed in the cooking process. Validation Take-away: Had the establishments validated the cooking instructions on the pot pies and turkey burgers to ensure they would achieve the desired end-point temperature under actual consumer cooking conditions; these illnesses may have been prevented.

38", "Appendix 2: Example Decision-making Document The following is an example of a decision-making document that could be used by a beef jerky processing establishment to justify using modified levels of critical operational parameters. In this case, the establishment has identified scientific support for its process; however, it has modified the critical operational parameters (length of cooking time and dry-bulb temperature during drying) in the actual process from those used in the scientific support. A rationale is provided for why the modified critical operational parameters should also be considered validated.

XYZ Meat Company - October 5, 2012 Beef Jerky Decision-Making Documentation Process Step: Cooking and Drying Process Step Overview: This process step includes the cooking and drying of beef jerky using a modified Type 1A process from Buege et al (2006). Scientific Support: \u2022 Critical limit summary for shelf stability of beef jerky and related products:[http://www.meathaccp.wisc.edu/validation/assets/CLSummary\\_WMJerkyleJune2013.pdf](http://www.meathaccp.wisc.edu/validation/assets/CLSummary_WMJerkyleJune2013.pdf). \u2022 Buege, D.R., Searls, G., and Ingham, S.C. 2006. Lethality of commercial wholemuscle beef jerky manufacturing processes against Salmonella Serovars and Escherichia coli O157:H7. J. Food Prot: 69(9): 2091-2099. Cooking and Drying Critical Operational Parameters: Stage 1 \u2013 170\u00b0F for 30 minutes. Stage 2 \u2013 Dry-bulb at 170\u00b0F and wet-bulb at 125\u00b0F for at least 90\* minutes Stage 3 - Dry at 175\u00b0F\* dry-bulb to doneness \*Rationale for Modified Critical Operational Parameters (those with an \*): The length of Stage 2 and the dry bulb temperature during Stage 3 were increased from what was studied in Buege et al. In Buege et al. the length of Stage 2 with a wet bulb of 125\u00b0F was 60 minutes, while the dry bulb temperature during Stage 3 was 170\u00b0F. As stated in the critical limit summary that goes along with the article: Type 1-A processes with a higher wet-bulb temperature or longer time in Stage 2, or a higher dry-bulb temperature in Stage 3, can also be considered validated as long as other parts of the process are not changed. So, these changes can also be considered validated.

39", "Appendix 3: Guidance to Identify Critical Operational Parameters from Scientific or Technical Support If a journal article from the scientific literature is used as the scientific support, it is important to understand how to read it and to identify the critical operational parameters used in the study. Researchers may measure a number of parameters during the scientific study; however, not all of these parameters are critical to the efficacy of the intervention studied. The establishment should document and explain any differences in its production process relative to any of the studies it used as scientific support. Critical operational parameters are those parameters of an intervention that must be met in order for the intervention to operate effectively and as intended. Typically critical parameters, identified in scientific documents gathered as part of Element 1 of validation, may include but are not limited to:

- \u2022 Time \u2022 Temperature \u2022 Concentration \u2022 Humidity \u2022 Dwell Time \u2022 Water Activity \u2022 pH \u2022 Contact Time \u2022 Product Coverage \u2022 Spatial Configuration \u2022 Pressure \u2022

**Equipment Settings or Calibration** The following discussion provides an overview of the sections of a journal article along with questions one can ask while reading each section to help identify the critical operating parameters in the scientific support.

**Organization of Journal Articles** In most scientific journals, scientific papers follow a standard format. Papers are divided into several sections, and each section serves a specific purpose. Common sections include the:

- \u2022 Abstract
- \u2022 Introduction
- \u2022 Materials & Methods
- \u2022 Results
- \u2022 Discussion
- \u2022 Conclusion

**Abstract** The paper begins with a short summary or abstract. Generally, the abstract gives a brief background to the topic, describes concisely the major findings of the paper, and relates these findings to the field of study.

**Introduction** This section presents the background necessary for the reader to understand why the findings of the paper are an advance on the knowledge in the field of study. Typically, the introduction:

- First, describes the accepted state of knowledge in a specialized field.
- Then, focuses more specifically on a particular aspect, usually describing a finding or a set of findings that led to the work described in the paper (i.e. objective or rationale).

**Materials & Methods** In some journals, this section is the last one but not in most food science-related journals. Its purpose is to describe the materials used in the experiments and the methods by which the experiments were carried out. When reading the abstract, first consider and review what you know about the topic. Discuss the study within the HACCP Team and gain an understanding of how you can apply the study in your HACCP decision making.

Questions to ask when reading the Materials & Methods:

- What food products did the researchers study?
- How similar are the products to the ones you are processing?
- If a product's characteristics were provided (i.e., % salt, fat, moisture, etc.), how similar are they to your product?
- What hazards did the researchers study? Are they the same hazards you have identified in your hazard analysis?
- Or did they study surrogates or indicator organisms only?
- Can you identify which operational parameters were measured? For example:
  - pH of the product;
  - Temperature of the product or carcass;
  - Temperature of the laboratory and/or processing facility;
  - Pressure or temperature at which that wash or antimicrobial was applied;
  - Length of time intervention was applied for.
- Where in the process or on the product were the measurements taken?
- Is your establishment taking measurements in these locations?
- What parameters, if any, were held constant across experimental conditions?
- What parameters, if any, were varied or changed in the research? Although some parameters may or may not have been experimentally manipulated, they are all important and their impact on the effectiveness on the intervention should be considered.

Note that some measured parameters in a study are not related to the efficacy of interventions and are not, therefore, critical operational parameters.

**Results** This section describes the experiments and documents the experiment outcomes.

**Discussion** In some journals the Results & Discussion section may be combined. When the discussion section is a stand-alone section it usually serves several purposes:

- Analyzing and interpreting the data in the results section.
- Explaining how the findings relate to other findings in the field of study.
- Explaining how the findings contribute to knowledge or correct errors of previous work.
- Sometimes provides guidance on appropriate applications of the research.

**Conclusion** This section summarizes key findings.

Often includes implications of research for broader field.

\u2022 May highlight limitations of the study. Figures & Tables \u2022 Contain the data described in the paper. \u2022 Give details of a particular experiment or experiments conducted. \u2022 The \u201cmeat\u201d of the article. Questions to ask when reading the Discussion: \u2022 Did the authors provide some guidelines as to the limitations of the research or any cautions against applying the findings outside of the scope of the study? o For example, were there some parameters that were controlled in the laboratory that differ in-plant that you should be aware of? o If so, have you considered if those apply to your process? 42", "For Illustration Purposes Only Appendix 4: Validation Worksheet Examples The following pages include validation worksheet examples that can be used to help an establishment understand the types of scientific support and in-plant documentation that are needed to comply with the validation requirements. Please note that these are only examples. Each establishment will have to identify scientific support that closely matches its process and identify and implement the critical operational parameters in the support. Depending on the support chosen, different critical operational parameters may be identified. In addition, mention of trademarks or commercial names does not constitute endorsement by USDA. 43", "For Illustration Purposes Only Product Hazard Process Critical Operational Parameters2 Validation Scientific or Technical Support In-Plant Validation Data Poultry Carcass Biological - Salmonella Final Chiller Dilution of 15% peracetic acid\10% hydrogen peroxide mixture (PAHP) to a final concentration of 85 ppm peracetic acid in chiller; exposure in chiller for 20 minutes; pH = 4.5; complete carcass coverage Bauermeister, L.J., J.W.J. Bowers, J.C. Townsend, and S.R. McKee. 2008. Validating the Efficacy of Peracetic Acid Mixture as an Antimicrobial in Poultry Chillers. J. Food Prot. 71(6): 11191122. Food and Drug Administration Environmental Decision Memo for Food Contact Notification No. 000323: April 10, 2003 FSIS Directive 7120.1 Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products In plant monitoring records for 90 day period recorded on Final Chiller Monitoring Check Sheet (including PAHP concentration, estimation of exposure time, pH, and carcass coverage); Trial report showing consistent operational parameters and microbial analysis, if possible, for 90 days. 2 Refers to the critical limit or other parameter cited in the scientific support necessary for effective execution of the intervention. 44", "For Illustration Purposes Only Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Poultry Carcass Biological Salmonella Spraying of carcasses with peroxyacetic acid prior to chiller 25-230 ppm of peracetic acid (PAA). Pressure or flow rate, pH, contact time, and complete carcass coverage specified in challenge study. Challenge study from \u201cXYZ\u201d laboratory demonstrating a 1 log reduction Salmonella on poultry carcasses after spraying with PAA using critical operational parameters specified. Food and Drug Administration Environmental Decision Memo for Food Contact Notification No. 000323: April 10, 2003. FSIS No Objection Letter for Use of PAA spray, June 12, 2007 on file with company \u201cABC\u201d. FSIS Directive 7120.1 In plant monitoring records for 90 day period confirm that antimicrobial solution was applied consistent with the critical operational parameters (pressure, pH, contact time, and carcass coverage)in the study. 45", "For Illustration Purposes Only Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Poultry parts intended for grinding and ground poultry (including mechanically separated poultry) Biological Salmonella Acidified sodium chlorite applied to poultry parts as a dip prior to grinding and applied to ground poultry. 1200 ppm

acidified sodium chlorite in combination with any GRAS acid at a level sufficient to achieve a pH of 2.5 in accordance with 21 CFR 173.325 and scientific support (Note: The pH depends on the application, see 21 CFR 173.325) Contact time of dip and complete coverage. Chemical manufacturer's pamphlet demonstrating a 1-log<sub>10</sub> reduction Salmonella on poultry parts following acidified sodium chlorite dip using critical operational parameters specified. 21 CFR 173.325 for poultry parts and acceptability determination for ground poultry. FSIS Directive 7120.1 In plant monitoring records for 90 day period that indicate the antimicrobial was applied to the poultry parts prior to grinding and the mechanically separated poultry prior to mixing according to the appropriate concentration and pH and that indicate contact time and complete coverage were achieved according to scientific support. 46", "For Illustration Purposes Only Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Ground Poultry Patties Biological Salmonella Validated cooking instructions for consumers Time and temperature combinations specific to various cooking methods (skillet on electric stove, skillet on gas stove, gas grill, charcoal grill), diameter and thickness of patties produced, formulation of patties produced (80% lean patties vs. 95% lean patties), and state of patties during cooking (frozen and thawed). Food Safety Inspection Service. 1999. Appendix A of the Compliance Guidelines for meeting Lethality Performance Standards for Certain Meat and Poultry Products. Available at: <http://www.fsis.usda.gov/wps/wcm/connect/212e40b3b59d-43aa-882ee5431ea7035f/95033Fa.pdf?MOD=AJPERES>. Cooking trials on-file supporting the timetemperature combination selected from Appendix A can be achieved using various cooking instructions provided on the label. Cooking trials should be for the thickest and largest diameter patties produced as these will need the greatest time to achieve the desired endpoint temperature. In plant monitoring records for 90 day period that demonstrate establishment produces products that are of the thickness, diameter, fat level, and state for which the instructions are validated. 47", "For Illustration Purposes Only Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Hog Carcass Biological Salmonella Hot Lactic Acid Spray Cabinet A least a 2% Lactic acid solution at 131°F (55°C) for more than 60 seconds and 13-23 psi. Complete carcass coverage. Van Netten. P., D.A.A. Mossel, and J. Huis In't Veld. 1995 Lactic acid decontamination of fresh pork carcasses: a pilot plant study. Int. J. Food Micro. 5: 1-9. Dormedy, E.S., M.M. Brashears, C.N. Cutter, and D.E. Burson. 2000 Validation of acid washes as critical control points in hazard analysis and critical control point systems. J. Food Prot. 63:1676-1680. FSIS Directive 7120.1 In plant monitoring records for 90 day period recorded on Spray Cabinet Monitoring Check Sheet (including parameters for water temperature, and water pressure), records of lactic acid concentration and Trial Reports run under specified critical parameters demonstrating complete coverage of carcass with spray and temperature of the spray at the carcass. Hog Carcass Biological Salmonella Scalding Scalding in water at 145°F (62°C) for 5 minutes. Complete carcass coverage. Gill, C.O. and J. Bryant. 1993. The presence of Escherichia coli, Salmonella, and Campylobacter in pig carcass dehairing equipment. Food Microbiol. 10: 337-344. Bolton, D.J., R.A. Pearce, J.J. Sheridan, D.A. McDowell, and I.S. Blair. 2003. Decontamination of pork carcasses during scalding and the prevention of Salmonella crosscontamination. J Appl Microbiol. 94: 1036-1042. In plant monitoring records for 90 day period recorded on Scalding Tank Monitoring Check Sheet (including reading for temperature of water and transit time). 48", "For Illustration Purposes

Only Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Beef Carcass Biological E. coli O157:H7, non-O157 STEC Hot Carcass Wash or Carcass Thermal Treatment Hot Carcass Wash: Water Temp over 180°F, Pressure over 13 psi. Complete carcass coverage. Contact time: 10 or more seconds. Carcass Thermal Treatment: Ambient steam temp sufficient to achieve 160°F at the surface in five key anatomical locations. K.R. Davey, M.G. Smith. 1989 A laboratory evaluation of a novel hot water cabinet for the decontamination of sides of beef. Int J Food Sci Tech. 24: 305-316.

Dorsa, W.J., C.N. Cutter, G.R. Sirgusa, M. Koohmaraie. 1996. Microbial Decontamination of Beef and Sheep carcasses by Steam, Hot water Spray Washes, and a Steam-vacuum Sanitizer. J. Food Prot. 59: 127-135. AMI Lethality model, demonstrating lethality at 160°F at carcass surface. Nutsch, A.L., R.K. Phebus, M.J. Riemann, J.S. Kotrola, R.C. Wilson, J.E. Boyer, and T.L. Brown. 1998. Steam pasteurization of commercially slaughtered beef carcasses: evaluation of bacterial populations at five anatomical locations. J. Food Prot. 61:571-577. Nutsch, A.L., R.K. Phebus, M.J. Riemann, D.E. Schafer, J.E. Boyer, R.C. Wilson, J.D. Leising, C.L. Kastner. 1997. Evaluation of a Steam Pasteurization Process in a Commercial Beef Facility. J. Food Prot. 60:485-492. In plant monitoring records for 90 day period documenting critical parameters and trial Reports run under specified critical parameters demonstrating complete coverage of carcass with spray and temperature of the spray at the carcass. In plant monitoring records for 90 day period of plant temperature mapping. 49", "For Illustration Purposes Only Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Beef carcass Biological E. coli O157:H7, Salmonella Typhimurium Lactic Acid Spray 2% lactic acid applied within 12 inches of carcass surface and entire carcass covered using a stainless steel spray tank fitted with a pressure gauge and air compressor. Each side of beef should be sprayed for at least 1 minute and sprayed from top to bottom and sufficient lactic acid is applied such that some of it drips off. Note: The entire carcass is sprayed with lactic acid following washing each side of beef from top to bottom for at least 2 minutes with hot water and allowing a 5 minute drip time after the hot water wash. Antimicrobial Spray Treatments for Red Meat Carcasses Processed in Very Small Meat Establishments. Pennsylvania State University. 2005. [http://www.meatpath CCP.wisc.edu/valid ation/assets/vacid\\_spray\\_intervention\\_booklet\\_from\\_Penn\\_State\\_2005.pdf](http://www.meatpath CCP.wisc.edu/valid ation/assets/vacid_spray_intervention_booklet_from_Penn_State_2005.pdf). FSIS Directive 7120.1 In plant monitoring records for 90 day period recorded on Hot Water and Drip Time Monitoring Check Sheet (including parameters for the time the carcass is sprayed with hot water, carcass coverage, method application (from top to bottom and spray nozzle within 12 inches of carcass), and drip time. Records of lactic acid concentration. Trial Reports run under specified lactic acid critical parameters demonstrating complete carcass coverage, sufficient amount (lactic acid drips off carcass), contact time, method of application (spray nozzle within 12 inches of carcass and from top to bottom). 50", "For Illustration Purposes Only Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Beef carcass Biological -E. coli O157:H7 Lactic Acid Spray Lactic Acid >2%; Pressure 40 psi (CHAD spray cabinet), Dwell time: minimum of 10 seconds Lactic Acid Temperature: 104°F at point of delivery. Complete carcass coverage. Design of the spray cabinet includes an oscillating (90 rpm) nozzle-header arrangement composed of four spray nozzles. Gastillo, A, L.M. Lucia, K.J. Goodson, J.W. Savell, G.R. Acuff. 1998. Comparison of Water Washing, Trimming, and combined Hot Water and Lactic Acid Treatment for Reducing Bacteria

of Fecal Origin on Beef Carcasses. J. Food Prot. 61: 823-828. Hardin, M.D., Acuff, G.R., Lucia, L.M., Oman, J.S., Savell, J.W. 1995. Comparison of Methods for Decontamination from Beef Carcass Surfaces. J. Food Prot. 58: 368-374. Delmore, R.J., J.N. Sofos, G.R. Schmidt, K.E. Belk, W.R. Lloyd, G.C. Smith. 2000. Interventions to Reduce Microbiological Contamination of Beef Variety Meats. J. Food Prot. 63: 44-50. FSIS Directive 7120.1 In plant monitoring records for 90 day period recorded on Pre-evisceration cabinet worksheet that monitored lactic acid percent, dwell time of the carcass in the cabinet, pressure, carcass coverage and lactic acid temperature at point of delivery. 51","For Illustration Purposes Only Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Raw Ground Beef or Beef Trim for use in Raw Ground Beef Biological -E. coli O157:H7 Prerequisite Program: Supplier Programs Supplier program to demonstrate a pathogen intervention strategy, including a testing protocol and notification of test results. Documentation from the supplier assuring that the supplier employs validated interventions addressing E. coli O157:H7, certificates of analysis or web based information that conveys same information, records of ongoing communication with supplier and verification data to support the achievement of the first two conditions. Beef Industry Food Safety Council. 2009. Best Practices for Raw Ground Beef Products. In plant records for 90 day period that show plant employees obtain and review purchase specifications for adequacy at receiving for each lot and any additional verification testing results or web based information on incoming product lots. 52","For Illustration Purposes Only Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Raw Ground Beef or Beef Trim for use in Raw Ground Beef Biological \u2013 E. coli O157:H7 Trimmings prior to Grinding Acetic acid (2%); OR Lactic acid (2%) sprayed on trim for 20s at 20psi and 55\u00b0C using a custom- made stainless steel washing apparatus (CHAD spray cabinet). Complete coverage of trimmings. Carpenter, C.E., Smith, J.V., and Broadbent, J.R. 2011. Efficacy of washing meat surfaces with 2% levulinic, acetic, or lactic acid for pathogen decontamination and residual growth inhibition. Meat Sci. 88:256-260. FSIS Directive 7120.1 In plant monitoring records for 90 day period recorded on Trim Spray Cabinet Worksheet demonstrating that the antimicrobial is applied per concentration, pressure, dwell time, and temperature in the article during 90 day period. Records demonstrating that complete coverage of trimmings is consistently achieved. 53","For Illustration Purposes Only \*This example is for the Type 1-A process. Note that Type 1-A processes with a higher dry-bulb temperature in Stage 1, a higher wet-bulb temperature or longer time in Stage 2, or a higher dry-bulb temperature in Stage 3, as long as the oven reaches the minimum temperature as outlined in Stage 1. Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Beef Jerky Biological \u2013 E. coli O157:H7, Salmonella, Listeria monocytogenes Cooking and Drying (For the Type 1-A Process) Stage 1\* \u2013 170\u00b0F (oven must reach 145\u00b0F within 10 minutes and 170\u00b0F within 25 minutes. Stage 2 \u2013 Choose either: Dry-bulb at 170\u00b0F and wetbulb at 125F for at least 60 minutes; OR Dry-bulb at 170\u00b0F and wet-bulb at 130\u00b0F for at least 60 minutes; OR Dry-bulb at 170\u00b0F and wet-bulb at 135\u00b0F for at least 30 minutes; OR Dry-bulb at 170\u00b0F and wet-bulb at 140\u00b0F for at least 10 minutes. Stage 3- Dry at 170\u00b0F drybulb to doneness Relative humidity during wet-bulb temperature spike at Stage 2, water activity of the product at the end of wet-bulb temperature spike, and total drying time. Critical limit summary for shelf stability of beef

jerky and related products: [http://www.meathaccp.wisc.edu/validation/assets/CLSummary\\_WMJ\\_2013.pdf](http://www.meathaccp.wisc.edu/validation/assets/CLSummary_WMJ_2013.pdf). Buege, D.R., Searls, G., and Ingham, S.C. 2006. Lethality of commercial wholemuscle beef jerky manufacturing processes against Salmonella Serovars and Escherichia coli O157:H7. J. Food Prot: 69(9): 2091-2099. In plant monitoring records for 90 day period demonstrating Time and dry-bulb and wet bulb temperature data. Use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor to measure relative humidity during wet-bulb temperature spike and compare test results with relative humidity results in Table 2 of article. Test beef jerky product for water activity at the end of wet-bulb temperature spike and compare test results with water activity results in Table 2 of article. 54", "For Illustration Purposes Only \*NOTE: Establishments may also collect environmental swab samples on different processing dates and at different times during the 90-day initial validation period to potentially find hard-to-control areas and niches within the establishment. Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Postlethality exposed ready-toeat meats Biological Listeria monocytogenes Prerequisite program \u2013 SSOPs Listeria control program for food contact surfaces. Sanitary design of equipment and sanitary zone concept. Frequency for collecting samples and number of samples that should be collected per line. Joint Industry Task Force on Control of Microbial Pathogens in Ready-to-Eat Meat and Poultry Products. 1999. Interim Guidelines: Microbial Control During Production of Readyto-Eat Meat and Poultry Products, Controlling the Incident of Microbial Pathogens. Sanitary Design Assessment Fact Sheet <http://www.sanitarydesign.org/pdf/Sanitary%20Design%20Fact%20Sheet.pdf>. Tompkin, R.B. 2004. Environmental Sampling \u2013 A tool to verify the effectiveness of preventative hygiene measures. Mitt Lebens Hyg. 95:45-51. Tompkin, R.B. 2002. Control of Listeria monocytogenes in the food processing environment. J Food Prot. 65: 709-725. FSIS. 2012. Compliance Guidelines to Control Listeria monocytogenes in Post-lethality Exposed Ready-to-eat Meat and Poultry Products. [http://www.fsis.usda.gov/wps/wcm/connect/d3373299-50e6-47d6-a577e74a1e549fde/Controlling\\_LM\\_RTE\\_guideline\\_0912.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/d3373299-50e6-47d6-a577e74a1e549fde/Controlling_LM_RTE_guideline_0912.pdf?MOD=AJPERES). In plant records for 90 day period mapping food contact surface swab results for Listeria spp. collected on different processing dates and at different times and locations a 90-day period to potentially find hard-tocontrol areas in the plant and to support ongoing verification testing frequency after the initial validation period\*. Assessment of sanitary design of equipment in the post-lethality environment using the AMI Sanitary Equipment Design worksheet and changes to Listeria control program based on assessment. Identification of all possible food contact surfaces. 55", "For Illustration Purposes Only Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Postlethality exposed ready-toeat meats Biological Listeria monocytogenes Storage Time and Temperature GMP\u2019s Storage temperature \u2264 50\u00b0F. Product remains in storage \u2264 24 hours. Tompkin Paper. Table 2. [http://www.meathaccp.wisc.edu/Model\\_Haccp\\_Plans/assets/raw\\_ground/TompkinPaper.pdf](http://www.meathaccp.wisc.edu/Model_Haccp_Plans/assets/raw_ground/TompkinPaper.pdf). In plant records for 90 day period demonstrating ambient air temperature does not exceed 50\u00b0F and that product is not held during storage at that temperature for more than 24 hours. 56", "For Illustration Purposes Only Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Raw beef products (e.g., beef carcasses, beef manufacturing trimmings) Biological -STEC Sanitary dressing

procedures prerequisite program (same question as above) Employee procedures associated with each station as defined in the written sanitary dressing program ( e.g., specific steps employees take at each station to prevent contamination during hide removal, evisceration, etc.) BIFSCO. 2009. Best Practices for Slaughter. <http://www.bifSCO.org/CMDocs/BIFSCO/Best%20Practices/BestPracticeslaught%20Sept%202009.pdf> FSIS. 2002. Guidance for Minimizing the Risk of Escherichia coli O157:H7 and Salmonella in Beef Slaughter Operations. FSIS. 2012. Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers. [http://www.fsis.usda.gov/wps/wcm/connect/e0f06d97-90264e1ea0c21ac60b836fa6/Compliance\\_Guide\\_Est\\_Sampling\\_STEC\\_0512.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/e0f06d97-90264e1ea0c21ac60b836fa6/Compliance_Guide_Est_Sampling_STEC_0512.pdf?MOD=AJPERES) In plant records for 90 day period demonstrating employees consistently perform the sanitary dressing procedures as written. Review of additional records generated during the 90 day period as part of the HACCP system that support that the procedures are effective (e.g., carcass audits, generic E. coli test results, and any other microbial test results). 57", "For Illustration Purposes Only \*NOTE: Reduction of L<sub>m</sub> was found to be less for smoked turkey deli meat with skin-on using these time\temperature parameters than smoked turkey deli meat without skin, although the log reduction was > 1 log. For products subject to 9 CFR 430, the post-lethality treatment should be designed to achieve at least a 1-log lethality of L<sub>m</sub> before the product leaves the establishment. Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Postlethality exposed ready-to-eat smoked turkey deli meat with skin on\* Biological -Listeria monocytogenes Hot water Pasteurization Hot water temperature at 195\u00b0F; product submerged for at least 6 minutes. Muriana, P.M., Quimby, W., Davidson, C.A., Grooms, J. 2002. Postpackage pasteurization of ready-to-eat deli meats by submersion heating for reduction of Listeria monocytogenes. J. Food Prot. 65(6): 963-969. In plant monitoring records for 90 day period demonstrating time and temperature can be consistently achieved. In plant monitoring records for 90 day period in which temperature of water is mapped and measured at increased frequencies to support monitoring procedures and frequencies. 58", "For Illustration Purposes Only \*NOTE: The limit for degree-hours will depend on the highest chamber temperature. Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Semi-dry sausage Biological Staphylococcus aureus Fermentation Ferment product to a pH<5.3 within fewer than 1000 degreehours\*. Shrink to an MPR of 3.1:1 or less (which equates to <11% product shrink) and achieve a pH of 5.0 or less to be considered a shelf stable dry or semi-dry fermented sausage. American Meat Institute. 1995. Interim Good Manufacturing Practices for Fermented Dry and Semi-Dry Products. Degree Hour Calculation - Degree-hours to reach a pH of 5.3 or less for a process when the highest chamber temperature is between 90 and 100\u00b0F = 1000 degree-hours or less. FSIS Food Standards and Labeling Policy Book and Ingham et al. 2005. Fate of Staphylococcus aureus on VacuumPackaged Ready-to-Eat Meat Products Stored at 21\u00b0C. Journal of Food Protection. 68:1911-1915. In plant monitoring records for 90 day period demonstrating Degree Hour Calculation per GMP conducted and demonstrating Degreehours are < 1000. For example on 10/24/99: Establishment process = (95\u00b0F-60\u00b0F) multiplied by 12 = 420 degree hours to a pH of 4.9, well within the guidelines for control of Staphylococcus aureus. In plant monitoring records for 90 day period indicating pH is \u2264 5.3 for the Degree Hours

Calculation and  $\text{MPR} \leq 3.1:1$  or less for shelf stability. 59", "For Illustration Purposes Only Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Roast Beef (uncured) Biological -C. perfringens and C. botulinum Stabilization Chilling should begin within 90 minutes after the cooking cycle is completed. All product should be chilled from  $120^{\circ}\text{F}$  to  $55^{\circ}\text{F}$  in no more than 6 hours. Chilling should then continue until the product reaches  $40^{\circ}\text{F}$ . Chilling between  $120^{\circ}\text{F}$  to  $80^{\circ}\text{F}$  should take no more than 1 hour. pH = 6.2, salt concentration = 3% Appendix B: Compliance Guidelines for Cooling HeatTreated Meat and Poultry Products (Stabilization) available at: [http://www.fsis.usda.gov/wps/wcm/connect/a3165415-09ef4b7f-8123-93bea41a7688/95033F\\_Appendix\\_B.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/a3165415-09ef4b7f-8123-93bea41a7688/95033F_Appendix_B.pdf?MOD=AJPERES) Results (including screen shots of the predicted growth) from the ComBase Perfringens Predictor model demonstrating no more than 1 log growth C. perfringens is achieved using the establishment's custom stabilization schedule and intrinsic factors. Perfringens Predictor User Manual ([http://modelling.combase.cc/HelpPerPredictor/Perfringens\\_Predictor\\_Manual.pdf](http://modelling.combase.cc/HelpPerPredictor/Perfringens_Predictor_Manual.pdf)) supporting that the model has been validated for cured and uncured meat and poultry products. In plant monitoring records for 90 day period showing each batch of product cooled from  $120^{\circ}\text{F}$  to  $55^{\circ}\text{F}$  in no more than 6 hours, and that all batches reached  $40^{\circ}\text{F}$ . In plant monitoring records for 90 day period demonstrating product chilling for each batch produced was between  $120^{\circ}\text{F}$  to  $80^{\circ}\text{F}$  in less than 1 hour. Product testing results for pH at 6.2 and salt concentration at 3 %. 60", "For Illustration Purposes Only Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Semi-dry Sausage (Lebanon Bologna) Biological Salmonella, E. coli O157:H7 Fermentation and intermediate heating step Diameter:115 mm  $\text{b1}$  23 mm Starter culture: Pediococcus, Lactobacillus, and Micrococcus spp. Casing: Cellulose Smokehouse Schedule: Stage 1: Come-up to  $80^{\circ}\text{F}$   $\text{t1}$  5 hours Hold at  $80^{\circ}\text{F}$   $\text{t2}$  8 hours Relative humidity  $\text{RH}_1$  88  $\text{b1}$  2% Stage 2: Come-up to  $100^{\circ}\text{F}$   $\text{t3}$  4 hours Hold at  $100^{\circ}\text{F}$   $\text{t4}$  25 hours Relative humidity  $\text{RH}_2$  80  $\text{b1}$  2% Stage 3: Come-up to  $110^{\circ}\text{F}$   $\text{t5}$  2 hours Hold at  $110^{\circ}\text{F}$   $\text{t6}$  24 hours Relative humidity  $\text{RH}_3$  80  $\text{b1}$  2% During the last 2 hours at  $110^{\circ}\text{F}$  hickory smoke applied Product Composition: pH = 4.39 aw = 0.94 % salt = 4.77 % fat = 10.43 Getty, K.J.K, Phebus, R.K, Marsden, J.L., Schwenke, J.R., and Kastner, C.L. 1999. Control of Escherichia coli O157:H7 in Large (115 mm) and Intermediate (90 mm) Diameter Lebanonstyle Bologna. J of Food Sci. 64(6): 1100-1107. In plant monitoring records for 90 day period recording time and dry-bulb and wet bulb temperature data. Use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor to measure relative humidity during wetbulb temperature spike and compare test results with relative humidity results in article. Cold-spot determination in smokehouse to support monitoring procedures and frequencies. Records assessing variability in sausage diameter. Records supporting product composition data. Decision-making document showing that starter culture and casing used in actual process are the same as those used in support documents. 61", "For Illustration Purposes Only Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Fully Cooked Not Shelf Stable Poultry Fillets Biological Salmonella Impingement Oven Cooking D62  $\text{b1}$   $\text{t1}$  145  $\text{b1}$  -values for chicken with between 2 and 6.3% fat (D62  $\text{b1}$   $\text{t1}$  145  $\text{b1}$  = 1.14 min). Cook to internal

temp of  $145^{\circ}\text{F}$ , hold for 8 minutes. Product formulation: salt and phosphate concentration (%) and in-going sodium nitrite level (ppm); pH of the product. Thickness of the fillets; arrangement of fillets on the belt; conveyor belt speed; and air flow rate. Wet-bulb and dry-bulb temperature. American Meat Institute Process Lethality Spreadsheet. Available at <http://www.amif.org/process-lethality/>. Juneja, V.J., B.S. Eblen, and H.M. Marks. 2001. Modeling non-linear survival curves to calculate thermal inactivation of *Salmonella* in poultry of different fat levels, *Int J Food Microbiol.* 70: 37-51. Documentation supporting that the D- and z-values of the product are comparable to the values used in the AMI spreadsheet. Factors that can impact D- and zvalues include the salt and phosphate concentration (%), the in-going sodium nitrite level (ppm), the pH of the product, and the fat level. In plant monitoring records generated during 90 day period demonstrating that process can achieve time and temperature. Records documenting that variability in thickness of the fillets; arrangement of fillets on the conveyor belt; conveyor belt speed; and the air flow rate used in the process will consistently meet time and temperature parameters. Records supporting that the % fat of product is consistently between 2 and 6.3%. Records generated during 90 days demonstrating the dry-bulb and wet-bulb temperatures meet those in the scientific support. 62", "For Illustration Purposes Only Product Hazard Process Critical Operational Parameters Validation Scientific or Technical Support In-Plant Validation Data Fully Cooked Roast Beef Biological *Salmonella*, *E. coli* O157:H7 Product Cooking Internal temperature of  $130^{\circ}\text{F}$  for a minimum of 112 minutes. Relative humidity >90% for at least 25% of the cooking time and in no case less than one hour. Food Safety Inspection Service. 1999. Appendix A of the Compliance Guidelines for meeting Lethality Performance Standards for Certain Meat and Poultry Products. Available at: <http://www.fsis.usda.gov/wps/wcm/connect/212e40b3-b59d-43aa-882ee5431ea7035f/95033Fa.pdf?MOD=AJPERES>. Doyle, M.P., and J.L. Schoeni. 1984. Survival and growth characteristics of *Escherichia coli* associated with hemorrhagic colitis. *Appl. Environ. Microbiol.* 48:855-856. In plant monitoring records for 90 day period indicating a minimum internal temperature of  $130^{\circ}\text{F}$  for 112 minutes is achieved. In plant monitoring records for 90 day period demonstrating use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor to measure relative humidity during cooking. Records should indicate that humidity can be maintained >90% for at least 25% of the cooking time and in no case less than one hour by use of steam injection for 90 days. 63", "Appendix 5: Guidance for Establishments that No Longer Have the In-Plant Validation Data FSIS realizes that some establishments may not have kept their initial in-plant validation data from when HACCP was originally implemented. These documents for example would generally include 90 days of production records and any additional data gathered to demonstrate the establishment is able to effectively execute the critical operating parameters of their system as described below. Those establishments that have not kept the records will be allowed the time to assemble their in-plant validation data. For large establishments, FSIS will wait until January 4, 2016 before including verification that establishments have complied with the second element of validation (inplant validation data) as part of its inspection activities. Thus, large establishments will have six months to gather all necessary in-plant validation documents. Small and very small establishments will have until April 4, 2016 gather all necessary inplant validation data before FSIS will verify and enforce the second element of validation (in-plant validation data). Such documents may include HACCP records that are already generated as part of the monitoring of

critical limits or parameters of prerequisite programs. Examples of documents that can be used by existing establishments that no longer have in-plant validation data include: \u2022 HACCP records collected during 90 days when the current HACCP system is in operation. \u2022 Decision-making documents related to CCPs and critical operational parameters data gathering methods. \u2022 Records associated with initial equipment set up or calibration that contain data on additional critical operational parameters that did not become CCPs to support that the parameters were met during the initial set-up. \u2022 Any establishment sampling results for the product and process of interest. Establishments should review such in-plant validation data already being collected to ensure that they continue to support that the critical operational parameters identified in the scientific documentation are being met. If these documents do not address all of the critical operational parameters identified in the scientific or technical support, then additional data may need to be generated to demonstrate that those parameters can be properly implemented. Establishments may also wish to use the HACCP Initial Validation Self-assessment provided on Page 34 as a check to ensure that the HACCP system was designed correctly the first time.

64", "<http://askfsis.custhelp.com/> FSIS\USDA www.fsis.usda.gov 2015 65"]}, {"file\_name": "FSIS\_GD\_2015\_0013", "title": "FSIS Compliance Guideline: Modernization of Poultry Slaughter Inspection - Microbiological Sampling of Raw Poultry", "num": "FSIS-GD-2015-0013", "id": "8e53bb33f8b96dd334e0ca4d5b45844bc4cecda268ba9d71452fab642eec8171", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Microbiological-Testing-Raw-Poultry.pdf", "type": "pdf", "n\_pages": 26, "word\_count": 8312, "text\_by\_page": ["This guidance document is designed to help small and very small poultry establishments in meeting the sampling and analysis requirements under the final rule to modernize poultry slaughter inspection. This guidance is designed to assist establishments as they: \u2022 Develop a microbiological sampling plan; \u2022 Utilize microbial testing results to monitor their ability to maintain process control; and \u2022 Make decisions on process control throughout the poultry slaughter process."], "Table of Contents": "FSIS Compliance Guideline: Modernization of Poultry Slaughter Inspection Microbiological Sampling of Raw Poultry June 2015 1", "Table of Contents": "What is the purpose of this Compliance Guideline? 3 How can I comment on this Compliance Guideline? 3 Requirements for written procedures and microbiological sampling 5 Statistical process control and indicator organisms 9 Written microbiological sampling program 11 Random selection of carcasses 12 Pre-sampling preparation and aseptic technique 13 Sample analysis 14 Microbiological testing method 15 Recordkeeping 16 Charting and interpreting test results 17 Actions in response to test results 20 Finished Product Standards (FPS) Waivers 21 Sampling Frequency Waivers (9 CFR 381.65(g)(2)(i)) 22 References 23 Appendix - Microbiological Sampling Program Self-Assessment Checklist 25 2", "Table of Contents": "This Compliance Guideline follows the procedures for guidance documents in the Office of Management and Budget\u2019s (OMB) \u201cFinal Bulletin for Agency Good Guidance Practices\u201d (GGP). More information can be found on the Food Safety and Inspection Service (FSIS) Web page: <http://www.fsis.usda.gov/wps/portal/footer/policies-and-links/significant-guidancedocuments> This is the first edition of the Compliance Guideline: Modernization of Poultry Slaughter Inspection - Microbiological Testing of Raw Poultry. Future editions will continue to reflect feedback received from all stakeholders."}]

represents FSIS\u2019s current thinking on this topic and should be considered usable as of this issuance. Therefore, FSIS encourages establishments slaughtering or producing raw poultry products to incorporate information in this guideline in their decision making process. A final version of this guidance will be issued in response to public comments. The information in this compliance guideline is provided as guidance to assist poultry slaughter establishments, and is not legally binding from a regulatory perspective. What is the purpose of this Compliance Guideline? The purpose of this guidance document is to help small and very small poultry slaughter establishments comply with the new microbiological sampling and analysis requirements that apply to all official poultry slaughter establishments, except for establishments that slaughter ratites (79 FR 49566). Establishments may also find the references listed at the end of this document useful for further resources as well as background on technical concepts. Note that establishments can also seek guidance from University Extension Service specialists within the state that the establishment is located on how to design sampling plans, how to collect samples, and how to test raw poultry products. How can I comment on this Compliance Guideline? FSIS is seeking comments on this guidance document as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days and the document will be updated in response to the comments received.

Comments may be submitted by either of the following methods:

- 3", "Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to regulations.gov and follow the online instructions at that site for submitting comments.
- Mail, including CD-ROMs, and hand - or courier-delivered submittals: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, OPPD, RIMD, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, Room 8-163A, Washington, DC 20250-3700. All items submitted by mail or electronic mail must include the Agency name and docket number FSIS\u2019s ability to maintain process control for prevention of contamination with enteric pathogens (e.g., *Salmonella* and *Campylobacter*) and fecal material. Under the new rule, establishments must incorporate their written procedures, including their microbiological sampling plans, into their Hazard Analysis and Critical Control Points (HACCP) plans or Sanitation Standard Operating Procedures (Sanitation SOP) or other prerequisite program. Because this sampling and analysis is part of the procedures to prevent contamination by enteric pathogens and fecal material, the establishment needs to be able to support that the results relate to prevention of enteric pathogens and contamination by fecal material throughout the slaughter and dressing operation. The new recordkeeping and sampling

requirements in 9 CFR 381.65(g) are applicable to poultry establishments that slaughter poultry under any of the exemptions based on religious dietary laws in 9 CFR 381.11 through 9 CFR 381.14 (Confucian, Buddhist, Islamic, or Kosher). Establishments that slaughter multiple classes of poultry, other than ratites, may test the type of poultry slaughtered in the greatest number to meet the requirements in 9 CFR 381.65(g). However, these establishments are required to have written procedures to prevent enteric pathogen and fecal contamination throughout slaughter and dressing process to address all species slaughtered at the establishment.

Establishments that slaughter poultry other than ratites are responsible for determining which microbial organisms will be most effective in monitoring process control for enteric pathogens and fecal contamination and in supporting their sampling plan. Establishments are required to have a supportable sampling plan, including sampling frequency, microbes for which there will be analysis, and, where appropriate and practical, acceptable microbiological levels. FSIS recommends that establishments conduct baseline sampling periods during which they map the various points in the slaughter operation that could impact microbial and fecal contamination. This baseline sampling and mapping should occur at some regular, defined interval (e.g., seasonally or annually). Such sampling can be used to determine the frequency of testing and set the microbiological levels that are needed to ensure that the food safety system is in control. The regulations prescribe the minimum requirements for the location and frequency of sampling, based on establishment size and production volume. The microbial testing program may include indicator organisms, enteric pathogens, or both collectively to 5", "meet the minimum sampling frequency requirements. Establishments may combine these sampling data into one sampling program and make process control decisions based on a collective analysis of these data. As FSIS stated in the final rule, \u201cFSIS considers the microbial characteristics of poultry carcasses at pre-chill to be a valuable source of data about how well an establishment is minimizing contamination with enteric pathogens and fecal material on live birds coming to slaughter and on carcasses throughout the evisceration and dressing process. FSIS considers the microbial characteristics of poultry carcasses post-chill to be a valuable source of data about how well an establishment is minimizing contamination during chilling and the overall effectiveness of any antimicrobial interventions the establishment has chosen to apply throughout its process. Because most establishments apply one or more antimicrobial interventions between the pre- and post-chill sampling points to help control microbiological hazards, FSIS would expect that a reduction in microbiological contamination between these two points to be an indication of the effectiveness of those controls.\u201d (79 FR 49602). Therefore, with an exception for very small and very low volume (VLV) establishments operating under the Traditional Inspection System, poultry slaughter establishments are required to collect samples for microbial analysis at the pre-chill and post-chill locations to monitor for process control. Establishments may integrate existing sampling programs, such as programs that were part of the Salmonella Initiative Program (SIP), to develop one comprehensive sampling program. Such a program could include microbiological sampling from process mapping or other programs that met requirements in previous generic E. coli requirements. This program could be acceptable provided that the total number of samples collected and analyzed at pre-chill and post chill is at least equal to the minimum number of samples required in the regulation. These programs could also include sampling of more than one microbe. The written plan should describe how the establishment

intends to analyze the data and to make process control determinations. Although an establishment is not required to routinely test for enteric pathogens (e.g., *Salmonella* and *Campylobacter*), it should maintain data on file to support why the indicator organism it has selected to monitor process control is representative of process control for enteric pathogens, and that it is reaffirming this relationship on a recurring basis (e.g., at least once per quarter). There are no identified index organisms that directly reflect the presence or absence of enteric pathogens in poultry (e.g., *Salmonella* and *Campylobacter*). Therefore, FSIS recommends that an establishment test for enteric pathogens at least intermittently and compare its results against the presence or absence of other non-pathogenic organisms (i.e., the indicator organisms the establishment is using) to assess whether it is maintaining process control. An establishment's program for preventing contamination of carcasses and parts by enteric pathogens and fecal material needs to address all edible products, including whole carcasses, reprocessed carcasses, and parts, produced during the slaughter process. The establishment must include in its design the frequency and location of sampling within its process and which microorganisms to test for to demonstrate process control in preventing contamination of carcasses and parts by enteric pathogens and fecal material. FSIS has defined very small establishments operating under Traditional Inspection and VLV establishments operating under Traditional Inspection below. These establishments must collect samples for microbial organisms at the post-chill point in the process. In addition, VLV establishments must collect and analyze samples at least once during each week of operation starting June 1 of every year. If, after consecutively collecting 13 weekly samples, a VLV establishment can demonstrate that it is effectively maintaining process control, it may modify its sampling plan. For example, after collecting 13 weekly samples, a VLV establishment could collect samples less frequently, such as once a month, and use visual observation and documentation at control points to monitor process control. In this case, the establishment would need to document the changes and maintain documentation showing that the changes allow the establishment to continue to effectively monitor process control. Additionally, the establishment should identify in a written document conditions that would indicate that there is a failure in its process that requires a return to the higher level of sampling until the source is identified and effectively corrected. All other establishments are required to collect and analyze a pair of samples - one sample at pre-chill and one sample at post-chill - at the following minimum frequency: Chickens: once per 22,000 carcasses but at a minimum of once during each week of operation; and turkeys, ducks, geese, guineas, and squabs: once per 3,000 carcasses but at a minimum once each week of operation. Table 1. Establishment Size, Sampling Frequency and Sampling Location Requirements Establishment size Defined as Minimum sampling location Minimum sampling event frequency Very low volume (VLV) Slaughter no more than 440,000 chickens, 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas, or 60,000 squabs annually A sample at post-chill per sampling event At least once during each week of operation, starting June 1 of every year. If, after consecutively collecting 13 weekly samples and upon demonstrating effective process control, the sampling plan may be modified. Very small (VS) Fewer than 10 employees or annual sales of less than \$2.5 million. A sample at post-chill per sampling event Chickens: once per 22,000 carcasses, but at a minimum of once during each week of operation. Turkeys, ducks, geese, guineas, and squabs: once per 3,000 carcasses 7", "Small 10 \u2013 499 employees unless annual sales total less than \$2.5 million A sample at

pre-chill and a sample at post-chill locations per sampling event but at a minimum once each week of operation. Large 500 or more employees The effective date of these requirements for establishments was as follows: \u2022 Large establishments: November 19, 2014; \u2022 Small establishments: December 19, 2014; and \u2022 VS and VLV establishments: February 17, 2015. To provide additional clarification to help establishments meet these sampling requirements, FSIS is providing information concerning how to determine the necessary number of samples on an annual basis. An establishment (other than a VLV slaughter establishment that needs to sample at the minimum frequency specified above) can determine the total number of samples that it would need to collect on a given production day based on its annual production volume over the previous calendar year divided by the total number of production days within the same calendar year. The establishment would then determine the distribution of total number of samples over the total number of production days. An establishment should consider seasonal increases in production over the calendar year when allocating how many sampling events need to take place on any given production day or production period. For example, many turkey slaughter establishments traditionally experience a seasonal increase in slaughter production volume during the later months of the year. To support their sampling frequency, establishments need to consider this seasonal increase in slaughter volume. Establishments may determine that they need to increase the number of samples collected on production days during this period as compared to other times of the year. This increase would provide increased assurance that testing data will be sufficient to inform the establishment of its process control during these periods of higher production volume. These determinations are required to be in decision making documents that support the establishment\u2019s sampling frequency. An establishment may choose to sample parts (e.g., wings, legs) rather than carcasses to meet the requirements under 9 CFR 381.65(g)(2). If an establishment chooses to do so, the establishment is required to maintain data that demonstrates that its process is preventing contamination of carcasses and parts by enteric pathogens and fecal material throughout the entire slaughter process. The establishment is also required to maintain data that demonstrates that the sampling of parts at pre-chill and post-chill is representative of results that would be observed with sampling of whole carcasses at pre-chill and post-chill locations. The establishment should verify this association at some frequency (e.g., annually). 8", "Statistical Process Control and Indicator Organisms Statistical process control provides a powerful mechanism for establishments to monitor and interpret the data collected for ongoing HACCP verification. Statistical process control can provide establishments with an early warning that their process may not be functioning as designed. This warning can allow establishments to take corrective actions or make other process modifications to bring their process back into control without actually failing the individual establishment-identified pre-determined performance criteria. Statistical process control can also provide establishments with reasonable assurance that their HACCP system is functioning as designed, and that they are likely to meet applicable establishment-identified performance criteria. A number of methods and approaches are available for establishments to follow. Establishments should consider available guidance and develop a statistically valid approach for interpreting sample results (Saini et al. 2011; De Vries and Reneau 2010). In cases where an establishment does not have the resources or capacity to conduct baseline sampling that would be used to develop and implement their own statistical control limits or procedures,

establishments can utilize the results from FSIS nationwide poultry surveys, provided in Tables 2 (chicken) and 3 (turkey). As the establishment continues to collect its own data, FSIS recommends that the establishment consider these data to modify their statistical process control parameters to be more useful within their own establishment. The results in Tables 2 and 3 come from nationwide surveys conducted between 2007 and 2012<sup>1</sup>. During these surveys, FSIS collected samples from multiple points during processing; both chicken and turkey carcasses at rehang; and post chill. In these studies, FSIS sampled chicken by rinsing the carcass with 400 mL of solution and turkeys by swabbing two 50 cm<sup>2</sup> areas on the carcass. The tables show the median enumeration values for four common indicator bacteria: generic E. coli, APC, Enterobacteriaceae, and total coliforms. The median indicates that 50% of the samples in the FSIS surveys had enumeration values below the ones in the table, and 50% had values above the ones in the table.

Table 2 - Indicator Organism Median Values for Chickens Median (CFU\mL) Generic E. coli APC Enterobacteriaceae Total Coliform Carcass \u2013 Rehang 540 28,000 1,600 940 Carcass \u2013 Post Chill 20 260 20 20 1 FSIS Young Chicken Survey; FSIS Young Turkey Survey. 9", "Table 3 - Indicator Organism Median Values for Turkeys Median (CFU\mL) Generic E. coli APC Enterobacteriaceae Total Coliform Carcass \u2013 Rehang 22 1,800 50 40 Carcass \u2013 Post Chill <1.2 18 <1.2 <1.2 If an establishment uses the data from these tables, it is important that its sampling methodology (i.e., amount of solution to rinse the chicken carcass) be comparable to the FSIS method. When establishments compare their sample results to the ones in the table, a sample value that is higher than the corresponding one listed in the table indicates that the establishment may not be maintaining process control and may be less likely to meet the applicable performance criteria. Sample values lower than the one listed in the table indicate that the establishment is maintaining process control unless there is evidence that there are other problems in the establishment\u2019s procedures or production environment, such as evidence that the establishment\u2019s product has been associated with illnesses. When illnesses are associated with a particular establishment, achievement of a lower frequency of contamination, along with a lower level of contamination, has been demonstrated to be essential in reducing or eliminating illness from the establishment\u2019s products and protecting public health. Very small and VLV slaughter establishments operating under Traditional Inspection can choose to continue to conduct generic E. coli testing at post-chill to meet these requirements. FSIS considers the requirements under the former regulations for generic E. coli testing of poultry to be a scientifically validated \u201csafe harbor\u201d for monitoring process control specifically for fecal contamination. However, an establishment may choose to perform additional testing to monitor for process control of enteric pathogens to meet the new regulatory requirements. Former provisions that FSIS considers to be safe harbors:

- A. Each very small or VLV establishments that slaughters poultry under Traditional Inspection may test for Escherichia coli Biotype I (also referred to as generic E. coli) at the post-chill point in the process.
- B. To collect the sample, the establishment should collect a whole bird from the end of the chilling process. If this is impracticable, the whole bird can be taken from the end of the slaughter line. The sample is collected by rinsing the whole carcass in an amount of buffer appropriate for that type of bird. Samples from turkeys may also be collected by sponging the carcass on the back and thigh.

10", "C. Laboratories analyzing the samples should use any quantitative method for analysis of generic E. coli that is validated by a recognized independent testing body and based on the results of a

collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index. D. An establishment is operating within the criteria when the most recent E. coli test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken as in Table 4 below. For classes of poultry that do not have established M and m values, an establishment can use Statistical Process Control to determine its upper and lower control limits: Table 4 \u2013 Upper and Lower Limits for Generic E. coli testing in Chickens Type of poultry Lower limit of marginal range (m) Upper limit of marginal range (M) Number of Samples tested (n) Maximum number permitted in the Marginal range Chickens 100 cfu/ml 1,000 cfu/ml 13 3 Written microbiological sampling program The following elements should be included in the written sampling program: 1. A description of the sample collection procedures, including how random sampling is achieved, how the sample is taken, and how samples are handled to ensure sample integrity; and the name or title of the establishment employees designated to collect the samples for testing. 2. Information on the analytical method used to analyze the samples and identify the laboratory performing the analysis. The method used should be validated by a recognized independent testing body. 3. The microbiological organisms (i.e., *Salmonella*, *Campylobacter*, or indicator organisms, such as aerobic plate count (APC), total coliform, *Enterobacteriaceae*, and generic E. coli) that it will test for to monitor the effectiveness of its process control procedures. 11", "4. The locations within the process where samples are collected. Establishments, except for very small establishments or VLV establishments operating under Traditional Inspection, must collect samples at pre-chill and post-chill points in their process (9 CFR 381.65(g)(1)). Very small establishments or VLV establishments operating under Traditional Inspection must collect samples at post -chill point in their process. 5. The frequency of sample collection (9 CFR 381.65(g)(2)) (See Table 1). 6. Scientific and technical documentation to support the design of the sampling program. Further information on scientific and technical documentation can be found in the FSIS Compliance Guideline: HACCP Systems Validation, May 2013. The Appendix on page 25 contains a self-assessment checklist that highlights the key elements that an establishment should address as part of their written microbiological sampling program. Random selection of carcasses Samples should be collected randomly at the frequency determined by the establishment as part of its sampling plan. At a minimum, the establishment must collect samples at the frequency specified under 9 CFR 381.65(g)(2). If more than one shift is operating at the establishment, the sample can be taken on any shift provided there are samples collected from all shifts randomly over time, and there are not notable differences in the outcome. Different methods of selecting the specific carcass for sampling could be used, but the method used should include the use of random numbers to ensure that testing data are not biased. Examples of methods include random number tables, calculator or computer-generated random numbers, or drawing cards. The carcass that is sampled should be selected at random from all eligible carcasses and should include reconditioned, trimmed and reprocessed whole carcasses as well as \u201cmajor portions\u201d since these carcasses can be a significant source of redistribution of contamination prior to chilling. If there are multiple lines or chillers, randomly select the line or chiller for sample collection for that interval. Each line or chiller should have an Definitions Pre-

chill: a point in the slaughter process between and including rehang and just prior to the carcass entering the chiller. Allow appropriate drip time after interventions before collecting sample.

Post-chill: a point in the slaughter process after the carcass exits the chiller and after all slaughter interventions are completed, which is the same point in the process that FSIS collects samples for *Salmonella* and *Campylobacter* verification testing. If water immersion chilling is used, allow appropriate drip time before collecting the sample. 12", "equal chance of being selected at each sampling interval within the relevant time frame (based on the sampling frequency for the establishment). Carcasses should be selected at the identified points in the process (pre- and post- chill). At the post-chill site, samples should be collected after the final wash and the application of any final antimicrobial interventions. A drip time of at least 60 seconds should be observed before sample collection to prevent excessive antimicrobial carryover in the collected sample. A longer drip time prior to sample collection may better ensure that the technical effect of the antimicrobial treatment is neutralized. Establishments should seek guidance from the manufacturer of the antimicrobial treatment as to the optimal drip time and process to counter adverse outcomes of the treatment. Pre-sampling preparation and aseptic technique Extraneous organisms from hands, clothing, sampling equipment, or the processing environment may contaminate samples and lead to erroneous analytical results.

Aseptic sampling techniques should be followed to ensure accurate results that are representative of the product and process. Before beginning sample collection, it is important to assemble sampling supplies, such as sterile gloves, sterile sampling solutions, and sanitizing solution. Sterile sampling solutions, such as Butterfield's phosphate diluent (BPD) or buffered peptone water (BPW), should be stored according to the manufacturer\u2019s instruction at room temperature; however, at least the day before sample collection, check such solutions for cloudiness and do not use solutions that are cloudy or turbid or that contain particulate matter. An area should be designated as a staging site for preparing the sampling supplies. A sanitizable surface, such as a stainless steel table or wheeled cart, can be used. A small plastic tote may also be useful for transporting sampling supplies to sample collection sites. Sterile gloves should be used when handling carcasses or sterile sampling equipment (e.g., sampling sponge) during the sample collection process. Care should be taken to prevent contamination of the external surface of the gloves prior to or during the sample collection process. Step-by step instructions on aseptic gloving are included as an attachment to this document (Attachment 1).

13", "Examples of non-destructive sample collection techniques that an establishment may choose to use to collect samples are included as attachments to this document. The methods describe a nondestructive sponge technique for sample collection from turkeys and a whole bird rinse technique for sample collection from chickens (Attachments 2 and 3). Sample analysis To obtain the most accurate results, samples should be analyzed as soon after collection as possible. If samples must be transported to an off-site laboratory, they should be refrigerated and then shipped refrigerated, on the same day they were collected, via an overnight delivery or courier service to the laboratory. NOTE: *Campylobacter* is particularly sensitive to freezing conditions. Thus, frozen samples may significantly underestimate whether this pathogen was present in the unfrozen sample. Multiple samples collected on the same day can be shipped together to the laboratory in the sample shipping container. A sample should arrive at the laboratory and be analyzed no later than the day after it is collected. If sample collection, pick-up or shipment, and laboratory analysis cannot be carried out within this timeframe, the

carcass or product selected for sampling should be held under refrigeration until the process can be accomplished in the appropriate span of time. The same principle applies for samples that are analyzed in-plant: If a carcass cannot be sampled and the sample analyzed by the day after it is collected, the carcass should be held under refrigeration until this is possible. Rinsate from a collected sample should not be held for an extended period of time. It should be either analyzed in-plant the same day as it is collected or by the following day or immediately shipped for overnight delivery to the laboratory that will conduct the analysis. Rinsate, sponge, or product samples should be held at refrigerated temperature, not frozen, and shipped cold to the laboratory in an insulated shipping container with frozen gel packs. FSIS recommends that multiple samples collected on the same day be analyzed individually and not composited into one sample. However, an establishment may consider compositing samples collected from the same Key Question Question: How soon after the samples are collected should they be analyzed to ensure the accuracy of the test results? Answer: To obtain the most accurate results, samples should be analyzed as soon after collection as possible. If samples must be transported to an off-site laboratory, they should be refrigerated and then shipped refrigerated, on the same day they were collected, via an overnight delivery or courier service to the laboratory. A sample should arrive at the laboratory and be analyzed no later than the day after it is collected. 14", "day and at the same point in the process as an option if a quantitative test is used. To help establishments meet regulatory requirements, FSIS is clarifying that establishments may composite samples. Additional information may be required to support compositing of pre-chill samples. If an establishment composites samples, it will need to demonstrate that it has collected sufficient data at various points throughout the pre-chill process over time in order to understand process variations that may be present at the various points in pre-chill where contamination may be redistributed. If the establishment has information to support that minimal variation exists within its pre-chill process then an establishment may elect to composite its pre-chill samples over a production day. However, the compositing of pre-chill and post-chill samples together would not be considered an acceptable practice. If an establishment uses a microbiological test that enumerates an organism, each of the individually composited samples would contribute to the final result. Therefore if the results are normalized (e.g., CFU/g) then these values can be applied to each of the individual samples with the understanding that these results are the average value among all of the composited samples. Microbiological Testing Method The establishment should ensure that microbiological testing meets its food safety needs. An establishment needs to determine whether sample analysis will be performed by an outside laboratory or in its own microbiological testing laboratory onsite (if available). Because of the costs and the logistics involved with maintaining an onsite microbiological testing laboratory, establishments may choose to have samples analyzed by an outside laboratory. FSIS has available the compliance guideline, Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory. This guidance document should be particularly useful to very small establishments when they are selecting a commercial or private laboratory to analyze establishment microbiological samples. Establishments should clearly communicate their needs to the testing laboratory and direct them to any necessary testing protocols or other guidance, including this document, on the FSIS Web site. Establishments that select a laboratory that does not apply appropriate testing methods or effective Quality Control\Quality Assurance

(QC\QA) practices may not receive reliable or useful testing results. FSIS has also made available a list of Foodborne Pathogen Test Kits Validated by Independent Organizations for the detection of relevant foodborne pathogens (i.e., *Salmonella*, *Campylobacter*, *E. coli* O157:H7, and *Listeria* spp. including *L. 15*,"*monocytogenes*). These lists are intended to be informational and are not an endorsement or approval of any particular method, regardless of its inclusion in the list. To prevent cross contamination, FSIS recommends that a microbiological testing laboratory be segregated from manufacturing areas and that access to the laboratory space be limited. If the establishment will be performing testing for pathogens onsite, then they should have the following additional safeguards in place to ensure food safety and security: \u2022 Follow requirements for Biosafety Level II laboratory operation as outlined in Biosafety in Microbiological and Biomedical Laboratories (BMBL) available at:

<http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf>; \u2022 Restrict access to the laboratory to trained staff; and \u2022 Ensure the laboratory is operating under the supervision of a qualified microbiologist or equivalent. NOTE: Establishments can (and often do) analyze samples for non-pathogenic organisms such as generic *E. coli* and aerobic plate counts (APC) on-site. The test method used should be validated for the target organisms and for the sample matrix being analyzed to ensure accuracy of the results. It should also be a method validated by a recognized independent body, such as the Association of Official Analytical Chemists (AOAC). Recordkeeping Upon implementation of the sampling program, the establishment must maintain records sufficient to document the implementation and monitoring of sample collection. Records should include the testing procedures, including support for the adequacy of the testing frequency, and the test results and information such as the: \u2022 Time, date, and location of the sample collection. \u2022 Sample collector\u2019s name. \u2022 Name or description of the product or sample source. \u2022 Lot information and producer. All entries should be dated and initialed by the sample collector immediately upon completion of the entry. If an outside laboratory is used for testing, then these records should also include information such as date the sample was shipped to the laboratory for analysis. The outside laboratory should document the: \u2022 Date received; 16"," \u2022 Condition of the sample upon receipt, including sample temperature, if applicable; \u2022 Date the analysis was started and completed; and the \u2022 Analytical result. Test results should also be recorded and linked to the sample collection records by a sample number, form number, or some other unique identifier. These records should be maintained in a way that ensures the integrity of the data. These records can be maintained in an electronic format, provided there are measures in place to ensure the security of the information. These records should be readily accessible for review by the establishment and FSIS inspection program personnel upon request. Charting and Interpreting Test Results Specific techniques of statistical process control include the use of a control chart, which plots data over time but also displays an upper control limit for specific measurements and a centerline, above and below which there is an equal number of sample results (the centerline is in effect an average). A sample result above the upper control limit would indicate the likely presence of a special cause of variation that should be addressed. Results within control limits indicate simply that the process is in control. Control charts are used to (1) analyze and understand variables that affect the process, (2) determine process capabilities, and (3) monitor effects of the variables on the difference between target and actual performance. In most situations more than one type of

control chart would be applicable. Detailed information on the use of control charts can be found in texts on statistical process control, under the topic \u201ccontrol charts\u201d. The following control charts are hypothetical examples of using quantitative microbiological test results, collected over time, to verify the effectiveness of a food safety system (Buchanan).

17","0.0 0.2 0.4 0.6 0.8 1.0 1.2 1.4 1.6 1.8 0 5 10 15 20 25 Log (cfu\/ml) Sample Number Chart 1

- System under control 0.0 0.2 0.4 0.6 0.8 1.0 1.2 1.4 1.6 1.8 0 5 10 15 20 25 Log (cfu\/ml)

Sample Number Chart 2 - Lack of control due to excess variability 0.0 0.2 0.4 0.6 0.8 1.0 1.2 1.4

1.6 1.8 0 5 10 15 20 25 Log (cfu\/ml) Sample Number Chart 3 - Loss of control due to gradual

process failure Chart 1 depicts a pattern of test results that would be seen in a well-controlled system. In a well-controlled system, the majority of test results will be clustered around a central value. It is important to note that even in a well-controlled system; there is some frequency of isolated results above the acceptable level. Chart 2 depicts a loss of process

control due to excess variability. This is reflected in both an increased number of results above the maximum acceptable level and an increase in the scatter of points below the maximum acceptable level. This chart suggests either a loss of control at a critical control point or the existence of another critical control point that had not been identified and controlled. Chart 3 -

depicts a situation where a component of the process is losing its effectiveness over time. This loss of control is apparent by the upward trend in the data points toward the maximum acceptable level. Maximum acceptable level Maximum acceptable level Maximum acceptable

level 18","The test results should be charted and evaluated in a \u201cmoving window\u201d format. For establishments other than very small and VLV establishments operating under the Traditional Inspection System, the test results for both pre-chill and post-chill samples should be plotted and evaluated in a series over time. The results should be evaluated to determine the effectiveness of process control measures in reducing microbiological levels between these two points. The test result chart should be updated within the next business day following the reporting of test results by the testing laboratory. Every time a new test result is recorded, the oldest test in the series is dropped from the moving window. For example, an establishment may choose to evaluate their test results in a moving window of 13 tests. The establishment would use this series of 13 tests to evaluate their process control over the period of time represented by the series of 13 tests. The 0.0 0.2 0.4 0.6 0.8 1.0 1.2 1.4 1.6 1.8 0 5 10 15 20 25 Log (cfu\/ml) Sample Number Chart 4 - Loss of control due to abrupt process failure 0.0 0.2 0.4

0.6 0.8 1.0 1.2 1.4 1.6 1.8 0 5 10 15 20 25 Log (cfu\/ml) Sample Number Chart 5 -Loss of control due to reoccurring transitory process failure Chart 4 depicts a catastrophic loss of process

control. This pattern of test results would be encountered in a situation such as an abrupt failure of a key piece of equipment, such as an antimicrobial wash cabinet. Chart 5 depicts conditions where there is the existence of an intermittent but reoccurring problem within the process. Note the distinct periodicity of the test results over time. An example of a situation where this pattern may be observed is the dripping of condensation onto product as it travels down a conveyor belt Maximum acceptable level Maximum acceptable level 19","control chart would be updated with each new test result reported, adding the new test result and removing the oldest test result on the chart. Microbiological testing provides a measure of the extent of control at the step being evaluated and all preceding steps. By performing microbiological analyses at several points within a process, it is relatively easy to identify the segment of the process where control has been lost. In addition, while it is not required, end-product testing

can provide an integrated measure of the performance of the entire process. Actions in Response to Test Results As part of its process control procedures, an establishment should define the actions it will take if the test results obtained through its sampling are above the limits it has set. The establishment should delineate what its actions will be, who will take each action, how the outcome of these actions will be documented, and how it will be verified. FSIS has made available the FSIS Compliance Guidelines for the Control of Salmonella and Campylobacter in Raw Poultry. The guidelines summarize known control points for Salmonella and Campylobacter in the pre- and post-harvest production process. Establishments should use this compliance guide to improve management practices, to ensure effective sanitary dressing procedures and to assist in investigating when there is a loss of process control. When an establishment makes changes at the appropriate locations, process control should improve. As a result, establishments should produce raw poultry products that have less contamination with pathogens, including Salmonella and Campylobacter. Generally, those interventions to reduce or prevent Salmonella will likewise reduce or prevent Campylobacter. If the establishment determines that the trends in its test results indicate a loss of process control, the establishment should take action to investigate the cause. An establishment should consider how the different parts of its food safety system work together and how they affect the entire food safety system. To do this, establishments should evaluate its process control procedures and sanitary dressing practices to determine whether a root cause can be identified and take steps to correct the problem. This determination should include a review of its process monitoring records as well as evaluation of the process during normal operations. The establishment should consider any implementation problems or changes in its practices, such as sanitary dressing procedures, including but not limited to: \u2022 Procedures for routine cleaning and sanitizing of equipment, including hand tools that are used to remove contamination or to make cuts into the carcass; 20", "\u2022 The design, configuration, and calibration of equipment to ensure proper function within operational parameters to prevent the contact between carcasses and parts and prevent contamination of carcasses during operation; \u2022 Employee hygiene practices, ensuring that employees frequently wash hands and aprons that come in contact with carcasses; and \u2022 The implementation of antimicrobial or mechanical intervention treatments, such as carcass washes, sprays, dips, drenches, or brushes, in accordance with the limits selected by the establishment, including effective application to ensure coverage of the entire carcass. Following its investigation, the establishment should respond appropriately to its findings through the use of decontamination procedures and antimicrobial intervention treatments as necessary to address any contamination that may have occurred on the carcasses and parts. The establishment should also take steps to initiate any necessary equipment repair or recalibration and employee training when identified. Finished Product Standards (FPS) Waivers On July 13, 2011, FSIS announced the Salmonella Initiative Program (SIP) as a voluntary program to provide incentives to establishments to maintain consistent process control to minimize Salmonella levels and to conduct microbial testing to demonstrate that they are maintaining process control (76 FR 41186). In return, establishments received one or more waivers of certain provisions of the regulations, such as those on use of alternative Finished Product Standards (FPS) procedures (9 CFR 381.76). These waivers were authorized under 9 CFR 381.3(b), which provides that the FSIS Administrator may, in specific classes of cases, waive any provisions of the poultry inspection

regulations for limited periods in order to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements, provided that such waivers are not in conflict with the purposes or provisions of the Poultry Products Inspection Act (PPIA). FSIS has granted waivers to establishments with respect to testing and other provisions in the FPS regulations, so that establishments could collect data and assess whether this other data would facilitate definite improvements. 21", "The final rule to modernize poultry slaughter inspection (79 FR 49566) amended the poultry regulations to establish an additional inspection system, called the New Poultry Inspection System (NPIS), for young chicken and turkey slaughter establishments. Under the final rule, NPIS does not replace the Streamlined Inspection System (SIS), New Line Speed Inspection System (NELS), and New Turkey Inspection System (NTIS). For establishments that choose to operate under NPIS, the final rule replaces FPS with a requirement that establishments maintain records to document that poultry products resulting from its slaughter operation meet the definition of ready-to-cook (RTC) poultry (9 CFR 381.1). Thus, all FPS waivers will be terminated by operation of the final rule. The purpose of the waivers was to gather the information on how non-food safety defects should be handled. The Agency\u2019s decision on this matter, to go the ready-to-cook standard in NPIS, was based on the information obtained under these waivers. Therefore, the reason for granting the waiver has been fulfilled. The effect of the termination of the waiver will depend on what an establishment elected to do on February 23, 2015 (the opt-in date). Establishments that are operating under FPS waivers and that would like to continue to use their alternative FPS procedures will need to convert to the NPIS. Establishments that notify FSIS of their intent to operate under NPIS may continue to operate under the waiver from FPS requirements until they start operating under NPIS. If establishments choose to operate under SIS, NELS, or NTIS inspection systems (which require complying with FPS), their FPS waiver ends on February 23, 2015. FSIS will give 30 days written notice of the termination of that waiver. Otherwise, establishments will need to submit a request for a new waiver from FPS requirements under SIS, NELS, or NTIS with information on how the waiver would provide new information that would facilitate definite improvements (9 CFR 381.3(b)). FSIS expects that it will be difficult for establishments to meet requirements necessary to obtain a waiver now that NPIS is available. Sampling Frequency Waivers (9 CFR 381.65(g)(2)(i)) The Agency will consider granting waivers of provisions of the 9 CFR 381.65(g)(2)(i) requirements that specify sampling frequency for establishments, except for VLV establishments, to reduce the frequency of sampling below the minimum frequency of once per 22,000 chickens and once per 3,000 turkeys. VLV establishments will not need to request a waiver since the regulations (9 CFR 381.65(g)(ii)) provide for VLV 22", "establishments to reduce their sampling frequency if they are able to demonstrate process control after 13 consecutive samples are collected. These waivers of sampling frequency will be considered provided that the establishment 1) has collected and analyzed data in compliance with 9 CFR 381.65(g)(2)(i) over a minimum of six months (including before or after the effective date of the regulation) to demonstrate consistent process control over time; 2) provides the alternative procedures for reduced sampling frequency that it intends to follow; and 3) provides evidence that its alternative sampling program, along with other control procedures in its plan for preventing contamination by fecal materials or pathogens, will be at least as effective as the required sampling frequency to demonstrate process control. Such establishments may request a waiver of regulations

under the Salmonella Initiative Program (SIP) (76 FR 41186) as described above. FSIS will not grant waivers to 9 CFR 381.65(g)(2)(i) for a testing frequency that is less than the SIP data testing frequencies [i.e., daily Salmonella testing post-chill (one per line per shift) and weekly matched pair at re-hang and post-chill sampling for Salmonella, Campylobacter, and indicator organism] To obtain additional information, send an email to SIP.Mailbox@FSIS.USDA.gov.

**Submitting Monthly SIP Microbial Data:** Establishments operating under a waiver of regulations granted under SIP are required to continue to collect and analyze samples according to the SIP frequency and location; record and evaluate test results; take and document corrective actions, if any; and submit monthly test results on the data sheet provided by FSIS to the SIPMailbox@FSIS.USDA.gov.

**References**

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24", "Appendix - Microbiological Sampling Program Self-Assessment Checklist 1. Written microbiological sampling program a. Sample Collection \uf071 Procedure for random selection of carcasses for sampling \uf071 Location within process where samples are collected. \uf071 Pre-chill \uf071 Rehang \uf071 Other \uf071 Post-chill \uf071 Frequency of sample collection \uf071 Aseptic technique for gloving and sample collection \uf071 Description of sample collection procedure \uf071 Carcass rinse \uf071 Sponge sampling \uf071 Designated employee to collect the sample \uf071 Date and time collected b. Sample Handling and Shipping \uf071 Proper sample handling and packaging to ensure sample integrity \uf071 Sample identification \uf071 Held under refrigeration\not frozen \uf071 Packed in an insulated shipping container with cold packs \uf071 Shipped to the testing laboratory on same day as collected \uf071 Name of person or service (e.g., FedEx or courier service) transporting the sample \uf071 Chain-of-custody documentation when samples transported from the establishment to an off-site laboratory (e.g., by a delivery service such as FedEx or courier) \uf071 Holding time met (time from collection to analysis) c. Testing method and Test Results Reporting \uf071 Description of the testing method used by laboratory \uf071 Microbiological test results report received from testing laboratory \uf071 Results reported in appropriate units of measure \uf071 Test results recorded on a control chart (moving window format) \uf071 Interpretation of results based on defined process control criteria \uf071 Acceptable \uf071 Unacceptable \uf071 Actions taken in response to test results and trends in results over time 25", "2. Testing Laboratory a. Establishments should refer to the FSIS

Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory for guidance on selecting a microbiological testing laboratory. The checklist provided in the guidance is intended to assist establishments to determine whether a microbiological laboratory is capable of producing accurate and reliable results. Some of the general criteria to consider in selecting a testing laboratory include: \uf071 Personnel \uf071 Facilities \uf071 Equipment \uf071 Operations \uf071 Analytical methods b. Laboratory Testing Method FSIS has made available a list of Foodborne Pathogen Test Kits Validated by Independent Organizations for the detection of relevant foodborne pathogens (i.e., *Salmonella*, *Campylobacter*, *E. coli* O157:H7, and *Listeria* spp. including *L. monocytogenes*). This list is intended to be informational and is not an endorsement or approval of any particular method, regardless of its inclusion in the list. Some of the general criteria to consider when selecting a method include: \uf071 Sample size analyzed \uf071 Microorganism tested for (e.g., *Salmonella*, APC, generic *E. coli*) \uf071 Analytical method used (e.g., AOAC, NordVal) \uf071 Date test was received at the laboratory \uf071 Date analysis was started \uf071 Date analysis was completed \uf071 Analytical results recorded and reported to establishment \uf071 Corrective actions related to test results, such as laboratory error, unacceptable sample temperature upon arrival 26"]}, {"file\_name": "FSIS\_GD\_2015\_0014", "title": "Best Practices Guidance for Controlling Listeria monocytogenes (Lm) in Retail Delicatessens", "num": "FSIS-GD-2015-0014", "id": "1372a9b12fc150c61be373334ed0cf02b1e26f926cf3e1b57580131e8dcffa05", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-03/Controlling-LM-Delicatessens.pdf", "type": "pdf", "n\_pages": 21, "word\_count": 7069, "text\_by\_page": ["FSIS Best Practices Guidance for Controlling Listeria monocytogenes (Lm) in Retail Delicatessens June 2015 This guidance document provides specific actions that retailers can take in the delicatessen (deli) area to decrease the potential for *Listeria monocytogenes* (Lm) growth or cross-contamination. In particular, the guidance covers: \u2022 Actions identified by the Interagency Retail Lm Risk Assessment (see page 3) that can decrease the predicted risk of listeriosis from deli products; \u2022 Information from the U.S. Food and Drug Administration (FDA) Food Code, scientific literature, other guidance documents, and lessons learned from meat and poultry establishments that retailers can use to control Lm; \u2022 Steps retailers can take to help ensure that deli products are maintained under sanitary conditions that do not allow Lm adulteration of the product; and \u2022 A self-assessment tool that retailers can use to determine what practices they are currently using and what new practices to adopt to control Lm.", "Table of Contents Purpose 1 Introduction 1 Regulation of Meat and Poultry Products at Retail The Interagency Retail Lm Risk Assessment Findings 2 3 How to Use this Guidance 6 Product Handling 7 Cleaning and Sanitizing 9 Facility and Equipment Controls 11 Employee Practices 12 Deli Self-Assessment Tool References and Resources 14 15 ii", "Purpose This guidance document provides specific recommendations for actions that retailers can take in the delicatessen (deli) area to control *Listeria monocytogenes* (Lm) contamination of ready-to-eat (RTE) meat and poultry products. These materials highlight recommendations that are based on an evaluation of retail conditions and practices in the Interagency Risk Assessment-Listeria monocytogenes in Retail Delicatessens (Interagency Retail Lm Risk Assessment). In

addition, FSIS has included information from the Food and Drug Administration (FDA) Food Code, scientific literature, other guidance documents, and lessons learned from Food Safety and Inspection Service (FSIS) verification sampling and review of sanitation programs for Lm in meat and poultry processing establishments. This version of the guidance document replaces the previous version of the document which was issued and announced in the Federal Register (79 FR 22082; April 21, 2014). FSIS updated this guidance based on comments received during the public comment period, which closed on June 20, 2014. FSIS made the following changes in response to comments:

- \u2022 Clarified that food processing equipment should be disassembled during cleaning and sanitizing.
- \u2022 Added a recommendation that retailers scrub surfaces during cleaning to prevent biofilm formation.
- \u2022 Clarified that retailers should rotate (change) sanitizers to help prevent Lm from establishing niches in the environment and forming biofilms.

Although comments will no longer be accepted through regulations.gov on this guidance document, FSIS will update this document as necessary, should new information become available.

**Introduction**

Lm is a bacterium that is found in moist environments, soil, and decaying vegetation and can persist along the food continuum. Transfer of the bacteria from the environment (e.g., deli cases, slicers, and utensils), employees, or raw food products is a particular hazard of concern in RTE foods, including meat and poultry products. Listeriosis is a serious infection usually caused by eating food contaminated with Lm. Controlling Lm has long been an objective of the public health community. The Centers for Disease Control and Prevention (CDC) estimates that infection with Lm causes about 1,600 illnesses, 1,500 hospitalizations, and 260 deaths in the United States each year. Listeriosis is rare, but its fatality rate is very high (about 16 percent, compared with 0.5 percent for either *Salmonella* or *E. coli* O157:H7) (Scallan et. al., 2011). It primarily affects older adults, pregnant women, newborns, and adults with weakened immune systems. Lm can survive and grow at cool temperatures (as low as 34\u00b0F/1\u00b0C). Because of its growth and survival characteristics, Lm is usually persistent in the environment and is commonly referred to. The CDC estimates that Lm causes a high level of deaths compared to other foodborne pathogens. Deli products have been shown to be a major contributor to these illnesses. Retailers can help decrease the risk of illness by controlling Lm contamination in the deli. Lm is a harborage organism (i.e., it can form niches and grow to high numbers in the environment; niches provide an ideal place for Lm to establish and multiply). It can cross-contaminate food contact surfaces and foods. Improper sanitation, product handling, and employee practices can lead to the transfer of Lm to RTE meat and poultry products at retail causing them to become adulterated (see Regulation of Meat and Poultry Products at Retail below). RTE meat and poultry products do not require cooking prior to being consumed and are often held at refrigerated temperatures. Once contaminated with Lm, RTE food products may provide an ideal environment for this harmful bacterium to grow. A variety of retail surveys of deli meats and a number of risk assessments of Lm in deli-sliced versus pre-packaged deli meats have analyzed the risk of listeriosis associated with deli prepared meat and poultry products. The FSIS Comparative Risk Assessment for Lm in Ready-to-eat Meat and Poultry Deli Meats (May 2010) estimated that of listeriosis illnesses attributed to deli meat, 83% are associated with deli meat sliced and packaged at retail (Endrikat et al. 2010). Safe food handling practices, thorough cleaning and sanitation procedures, maintenance of the facility and equipment, and good employee practices are key components that may prevent or reduce the likelihood of RTE foods

becoming contaminated in retail delis. Regulation of Meat and Poultry Products at Retail FSIS shares jurisdiction with FDA and with State, local, and tribal authorities for meat and poultry products at retail. FDA makes recommendations regarding retail practices through the FDA Food Code. The Food Code is used by the State and local agencies as a model to establish regulations, ordinances, and actionable policies that can be enforced in their jurisdictions. Operators of retail establishments are required to comply with the conditions of the permit or license under which they operate. The Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) apply to meat and poultry products produced in federally inspected establishments and other entities producing or handling meat and poultry, including at retail. Although retail firms are generally exempt from FSIS inspection, retailers are required to maintain sanitary conditions and otherwise not produce adulterated or misbranded product (21 U.S.C. 623(d) and 464(e); 9 CFR 303.1(f) and 381.10(d)(4)). The types of operations that are traditionally and usually conducted at retail stores can be found in 9 CFR 303.1(d)(1) and 9 CFR 381.10(d)(1). FSIS provides instructions to its personnel for surveillance activities at retail in FSIS Directive 8010.1. The purpose of in-commerce surveillance is to ensure that FSIS-regulated meat and poultry products distributed in commerce are: \u2022 Safe, wholesome, and not adulterated; \u2022 Correctly marked, labeled, and packaged; \u2022 Secure from intentional acts of contamination, and \u2022 Legally imported and properly exported. When performing in-commerce surveillance, FSIS verifies that: 1. Meat and poultry are wholesome and not adulterated; 2. Sanitary conditions are such that meat and poultry will not become contaminated with filth or rendered injurious to health; 3. Hazard controls are adequate to prevent meat and poultry from becoming adulterated; 4. Meat or poultry not intended for use as human food are properly denatured or otherwise made inedible as prescribed by Federal regulations; and 5. All records are kept and maintained in a manner that fully and correctly discloses all transactions involved in the business activity that is subject to the provisions of the FMIA and PPIA. This guidance does not replace the FDA Food Code, State, tribal or local, or FSIS regulations. This document can be used along with the 2013 FDA Food Code to help retailers ensure that meat and poultry products are not prepared or sliced under insanitary conditions in the retail deli area, which can lead to Lm contamination and outgrowth of the organism on the product. The Interagency Retail Lm Risk Assessment Findings The Interagency Retail Lm Risk Assessment was jointly developed by FSIS and FDA, and in consultation with the CDC, to help guide food safety efforts to minimize the public health burden of listeriosis in the U.S. The risk assessment was conducted to better understand how retail practices (e.g., temperature control, sanitation, worker behavior) influence the public health risk of listeriosis associated with eating deli products (e.g., meats, cheeses, and salads) sliced or prepared in retail. It also examines how effective various interventions are in limiting the survival, growth, or crosscontamination of Lm. The risk assessment is based on observations of: \u2022 Deli employees' work routines; \u2022 Concentrations of Lm on incoming products and in the deli environment; \u2022 Studies on the ability of Lm to spread in retail delis, such as from a slicer to food; and \u2022 An existing dose-response model. The study was designed to apply to a range of deli establishments, from small independent operations to the deli departments in large supermarkets. The risk assessment also reinforces the importance of FDA's Food Code recommendations to operators of retail delis. State, local, and tribal jurisdictions can do their part to reduce listeriosis by enforcing all relevant provisions of the 2013 FDA Food Code as part

of their own food safety requirements. The risk assessment found that certain practices are needed to effectively prevent crosscontamination and limit Lm growth in RTE foods handled or prepared in retail delicatessens, including: No single action or practice will control Lm contamination of retail foods. Instead there are many steps that retail deli operators and their suppliers can take to help reduce the risk of listeriosis. 3", "\u2022 Proper storage, \u2022 Adequate sanitation, and \u2022 Effective employee practices. NOTE: This guidance document includes key findings from the Interagency Retail Lm Risk Assessment and provides an overall summary of the data for typical retail deli settings. More detailed information regarding the findings is in the Retail Lm Risk Assessment Report. 4", "Key Findings The following are key findings of the Interagency Retail Lm Risk Assessment for typical retail deli settings. \u2022 Storage Temperature. If all refrigerated RTE foods are stored at 41\u00b0F (5\u00b0C) or below, as the 2013 FDA Food Code (3-501.16(A)(2)) recommends, approximately 9% of predicted listeriosis cases caused by contaminated deli products prepared or sliced in the retail deli could be prevented. \u2022 Growth Inhibitors. If all deli products that support Lm growth were reformulated to include growth inhibitors, approximately 96% of predicted listeriosis illnesses caused by RTE products prepared or sliced in the retail deli could be prevented. While this finding is significant, the actual benefit may be smaller in part because the concentration of the growth inhibitor used may not be sufficient to be effective throughout the shelf life of a food or may not be used in high enough concentrations because the inhibitors can adversely affect the flavor of the product. \u2022 Control Cross-Contamination. The predicted risk of listeriosis dramatically increases in retail delis as a result of cross-contamination. In particular, slicers are key sources of crosscontamination in retail delis. Eliminating all points of cross-contamination in the deli (including slicers) would decrease the predicted risk of illness from the consumption of RTE products prepared or sliced in the retail deli by approximately 34%. Cross-contamination is particularly difficult to control completely; however, the risk assessment shows that proper product handling, cleaning, sanitizing, and glove use help prevent cross-contamination. \u2022 Control Contamination at its Source. Increased levels of Lm from incoming products and the environment (including potential niches), directly increases the predicted risk of illness. Therefore, elimination of environmental niches in the deli area will reduce the predicted risk of listeriosis from the consumption of RTE products prepared or sliced in the retail deli. Additionally, if levels of Lm on RTE foods (including foods that do not support the growth of Lm) that the retail deli receives from processing establishments were reduced by half, approximately 22% of the predicted listeriosis illnesses caused by contaminated deli products could be prevented. This finding suggests that continued efforts to prevent low levels of Lm contamination during processing, even on products that do not support growth of the pathogen, reduces the predicted risk from these products and other RTE foods that can be subsequently cross-contaminated in the retail delis. \u2022 Continue Sanitation. Sanitation practices that eliminate Lm from deli food-contact surfaces reduce the predicted risk of illness. Cleaning and sanitizing food-contact surfaces reduces the predicted Lm levels in the deli area. Employees not wearing gloves while serving customers increases the predicted risk of listeriosis from the consumption of RTE products prepared or sliced in the retail deli by approximately 5%. 5", "How to Use this Guidance This guidance provides practical recommendations that retailers can use to control Lm contamination and outgrowth in the deli area based on the findings of the Interagency Retail Lm Risk Assessment, available scientific knowledge, the 2013 FDA Food

Code, as well as lessons learned from controlling Lm in meat and poultry processing establishments. Retailers can use this best-practices guidance to help ensure that RTE meat and poultry products in the deli area are handled under sanitary conditions and are not adulterated as defined in the FMIA and PPIA. While these practices are designed to control Lm specifically, they also may help control other food borne pathogens that may be introduced into the retail deli environment and other facilities where consumers take possession of food. The best practices are divided into four sections: (1) product and product handling, (2) cleaning and sanitizing, (3) facility and equipment controls, and (4) employee practices. Practices identified by the risk assessment that can significantly decrease the predicted risk of foodborne illness are highlighted in each section. The other practices that are based on scientific knowledge or lessons learned also will help retailers increase Listeria control in the deli area. For example, although floors and drains were not considered as a source of crosscontamination according to the Interagency Retail Lm Risk Assessment, FSIS data has shown that floors, drains, and items like floor mats tend to be harborage points in FSIS establishments. Providing this information can assist retailers in controlling Lm in the deli area. A selfassessment tool, starting on page 14 of this guidance, is provided for deli operators to help them identify the best practices they are using and to assess whether they need to adopt others. By following the best practices in the guidance and the 2013 FDA Food Code, retailers can help ensure that RTE products are not adulterated with Lm, and that the potential for listeriosis is decreased. NOTE: Retailers should be aware that the recommendations in this guidance, especially those based on the 2013 Food Code may be requirements in State, local, or tribal regulations. Questions on this guidance may be submitted through AskFSIS. 6", "Product Handling The Interagency Retail Lm Risk Assessment found that using practices that prevent bacterial growth in the product substantially reduced the predicted risk of listeriosis. In addition, while the risk assessment showed that the risk from incoming Lm-contaminated products that do not support growth is low, it also showed that these products can cross-contaminate RTE products that support growth, and when they do, the risk increases substantially. The formulation of RTE products with antimicrobial agents prevents growth of Lm in RTE foods both at retail and during consumer home storage, leading to an overall reduction in the predicted risk of listeriosis. The 2013 FDA Food Code (3501.16(A)(2)) recommends keeping RTE products at or below 41\u00b0F (5\u00b0C), which slows the growth of Lm in the deli and decreases the predicted risk for listeriosis. Other scientific studies also have shown that preventing product contamination reduces the risk of foodborne illness. Therefore, it is important for retailers to adopt practices that protect RTE product from contamination with Lm and to use strategies to prevent or limit the growth of Lm in deli products. Below are a few such strategies. \u2022 Use products formulated with antimicrobial agents (e.g., acetic acid, sodium diacetate, lactic acid, citric acid) when possible, to eliminate or prevent the growth of Lm in RTE products. In some cases, the addition of antimicrobial agents may not be possible because of the adverse effect on the flavor of the products. Retailers can read the ingredients statements on the labels to see whether the products in the deli have antimicrobial agents and can contact their suppliers to determine whether products formulated with antimicrobial agents are available. NOTE: As stated previously, the Interagency Retail Lm Risk Assessment estimated that if antimicrobial agents are used in all products in the deli, the predicted risk of listeriosis from the consumption of RTE products sliced or prepared in retail departments could be decreased by approximately 96%.

Things to Consider at Retail \uf0fc Are the deli products being sold formulated with antimicrobial agents? \uf0fc Is RTE product properly identified and labeled? \uf0fc Are RTE products identified with the date the package is opened? \uf0fc Is RTE product discarded if it is past the recommended discard date? \uf0fc Is there a process to routinely remove RTE products that are not suitable for sale from the retail case? \uf0fc Are RTE meat and poultry products promptly refrigerated after use? \uf0fc Are RTE products prepared and stored adjacent to raw product? \uf0fc Is the retail deli case maintained at 41\u00b0F (5\u00b0C) or below to prevent pathogen growth? \uf0fc Is RTE product covered, wrapped, or otherwise protected after opening? \uf0fc Are RTE products placed on the same contact surfaces as other RTE product, e.g., cheese, vegetables, seafood? 7", "\u2022 Use products that have been treated to reduce pathogens (e.g., through high pressure processing (HPP)). This information can be determined from certificates of analysis (COA), letters of guarantee (LOG), or other information from suppliers. Separate products that support growth from products that do not support growth (when possible) to help prevent cross contamination. NOTE: As stated previously, the Interagency Retail Lm Risk Assessment found that if current levels of Lm in RTE foods (e.g., meats, cheeses, and salads) received by the retail deli were reduced by half, the predicted risk of listeriosis from the consumption of RTE products sliced or prepared in retail deli departments could be decreased by approximately 22%. \u2022 Monitor the shelf life of an RTE product that is opened, prepared, and held in a retail setting for more than 24 hours. To monitor shelf life of the opened product, retailers should date-mark the product (e.g., clearly mark it with the date of opening and the discard date) as recommended by the 2013 FDA Food Code (3-501.17). Products also should be properly identified and labeled. RTE products that are past their shelf life should be discarded. \u2022 Do not pre-slice products in the morning, after cleaning. Retailers should slice the product at the time it is requested by consumers. NOTE: The Interagency Retail Lm Risk Assessment found that pre-slicing the product increases the predicted risk of listeriosis from the consumption of RTE products sliced or prepared in retail deli departments by approximately 6%. \u2022 Remove products that are filthy, putrid, decomposed, slimy, rancid, or in off-condition, which are considered adulterated, from the deli area as soon as possible. Thoroughly clean and sanitize areas that were contacted by the affected product to prevent any cross-contamination. \u2022 Promptly return RTE products to refrigerated units, after slicing, to prevent pathogen growth. Maintain refrigeration units at or below 41\u00b0F (5\u00b0C) to slow the growth of Lm, as recommended by the 2013 FDA Food Code (3-501.16(A)(2)). RTE products should be covered, wrapped, or otherwise protected to prevent cross-contamination when not in use. NOTE: The Interagency Retail Lm Risk Assessment found that storing the products at or below 41\u00b0F (5\u00b0C) decreases the predicted risk of listeriosis from the consumption of RTE products sliced or prepared in retail deli departments by approximately 9%. \u2022 Store and handle RTE products in separate areas from raw products. RTE products that are prepared, held, or stored near raw products can become contaminated (e.g., because of aerosolization or dripping). The 2013 FDA Food Code (3-302.11(A)(1)) recommends that retailers separate RTE foods from raw foods. If storage space is limited, wrap the products and store RTE products above raw products. When wrapping, unwrapping, and slicing products, take care to prevent cross-contamination from the outer wrapper, other products, and unclean surfaces and utensils. Raw 8", "products (e.g., chicken used for frying or rotisserie) prepared in the same area as RTE products can increase

the potential for cross-contamination. \u2022 Clean and sanitize surfaces between RTE items when using the same equipment to cut, slice, or otherwise reduce the size of large RTE products (e.g., ham, seafood, and vegetables). \u2022 Ensure that grinders, dicers, or other equipment are maintained in sanitary condition when preparing deli salads. Cleaning and Sanitizing The Interagency Retail Lm Risk Assessment found that following the sanitation practices in the 2013 FDA Food Code aid in controlling Lm on deli area food contact surfaces and reduces the predicted risk of listeriosis. The 2013 FDA Food Code (4-602.11(C)) recommends cleaning equipment and utensils at least every 4 hours. Below are some key issues to consider when cleaning and sanitizing. \u2022 Develop written sanitation procedures that describe how utensils and equipment (e.g., slicers) will be cleaned and sanitized prior to use. Ensure employees are familiar with and follow these procedures to reduce the risk of contaminating RTE products with Lm. Insanitary conditions (e.g., flies, rodent droppings, mold, or dirty surfaces) should not be present in retail areas. Retailers should document the actions they perform to ensure that sanitation procedures are performed on a regular basis. NOTE: The Interagency Retail Lm Risk Assessment found that the predicted risk of listeriosis from the consumption of RTE products sliced or prepared in retail deli departments increases by approximately 41% if wiping, washing, and sanitizing activities are not performed. \u2022 Clean and sanitize utensils and equipment used to handle, prepare, and store RTE products frequently (e.g., at least every 4 hours as recommended by the 2013 FDA Food Code (4-602.11 (C)) to maintain sanitary conditions throughout the day. Things to Consider at Retail \uf0fc Are sanitation procedures documented? \uf0fc Are RTE product contact surfaces cleaned and sanitized prior to use? \uf0fc Are routine cleaning and sanitation procedures performed in areas where RTE products are handled, stored, and sold? \uf0fc Is RTE equipment disassembled before cleaning and sanitizing? \uf0fc Are surfaces scrubbed during cleaning to prevent biofilm formation? \uf0fc Are sanitizers used at the recommended concentrations? \uf0fc Are sanitizers rotated on a periodic basis? \uf0fc Are cleaning cloths rinsed or soaked in sanitizer between uses? \uf0fc Are only low-pressure water sources (hoses) used during cleaning to prevent splashing? 9", "Clean and sanitize items that employees routinely handle, such as on/off switches, slicer handles, display cases, cooler handles, and similar surfaces. NOTE: As stated previously, the Interagency Retail Lm Risk Assessment found that slicers are sources of Lm cross-contamination to RTE foods. Control of Lm crosscontamination at all points (including slicers) during retail preparation and handling of RTE foods will reduce the predicted risk of listeriosis from the consumption of RTE products sliced or prepared in retail deli departments by approximately 34%. \u2022 Disassemble RTE food-processing equipment when cleaning and sanitizing equipment as recommended by the Food Code to ensure that hard to reach areas where Lm can hide are addressed. For more information, see the FDA poster: Keep Commercial Deli Slicers Safe. \u2022 Scrub surfaces during cleaning to prevent biofilms from occurring. Biofilms are thin layers of microorganisms that adhere to product contact surfaces. Lm and other bacteria can adapt to the environment over time and form biofilms. Biofilms are difficult to remove, and they may protect Lm from the effects of sanitizers. \u2022 Follow the manufacturer\u2019s recommendations for sanitizer strength and application to ensure it is effective. Many sanitizers, when used as recommended, are effective against Lm, including those containing quaternary ammonia compounds, chlorine solutions, and organic acids. Generally, increasing the sanitizer strength above the recommended levels will not increase the

efficacy of the sanitizer and may result in harmful levels of the sanitizer in foods. \u2022 Rotate (change) sanitizers as needed to provide more effective bacterial control. Alternating sanitizers (e.g., quaternary ammonia and bleach) may help prevent Lm from establishing niches in the environment and forming biofilms. For example, retailers can use quaternary ammonia on the week days and bleach on the weekends when rotating sanitizers. \u2022 Develop a procedure to sanitize cleaning aids or have single-use items that are discarded after use. Cleaning cloths, brushes, sponges, mops, and similar cleaning aids can become contaminated with bacteria and then can spread the bacteria to every surface they contact. Therefore, they should be cleaned of visible material and soaked in clean sanitizer between uses. Retailers should monitor sanitizer strength and change the sanitizer as needed so that food particles do not overwhelm the effectiveness of the sanitizer. \u2022 Use low water pressure when cleaning in the deli areas. Splashing and overspray from high-pressure hoses can aerosolize microorganisms and distribute them into the air and onto nearby surfaces. \u2022 Use separate sinks for hand washing and cleaning product or equipment (as recommended by the 2013 Food Code (2-301.15 and 4-501.16)). Hand washing can cause the sink to be contaminated with Lm and other pathogens, which can be spread to any other items cleaned in the sink. 10", "\u2022 Eliminate or remove unnecessary items (e.g., supplies and equipment) from the deli area. Organize supplies and equipment to facilitate thorough cleaning. Facility and Equipment Controls As stated on page 4, the Interagency Retail Lm Risk Assessment found that increasing the level of Lm and the potential of cross-contamination increases the predicted risk of listeriosis. The 2013 FDA Food Code (6-101.11(A)(1)) recommends that floors, walls, and ceilings be smooth, durable, and easily cleanable. Facilities, equipment, and utensils should not contribute to product adulteration or contamination. Here are some areas to check and some insanitary issues to avoid. \u2022 Do not allow conditions in the retail facility that could cause the product to become adulterated. These conditions could include condensation dripping on exposed product, construction dust on product or food contact surfaces, or broken equipment which could harbor Lm. \u2022 Ensure that walls, floors, drains, and overhead structures in the RTE deli and cooler areas are smooth, durable, easily cleanable, and in good repair. Rubber floor mats and other items used on the floor may be harborage sites for Lm. Clean them as often as necessary to ensure that sanitary conditions are maintained. \u2022 Do not perform construction (e.g., replacing floors, walls, or ceilings) when exposed RTE product is present in the deli. Lm can be harbored behind the walls and carried by dust. Therefore, the product and equipment should be protected during construction, and the deli area should be cleaned and sanitized after construction and before use. \u2022 Maintain tables, slicers, and other food contact surfaces so that they are easily cleanable. Rough surfaces created by welds, cracks, and other defects can be difficult to clean and can create areas where bacteria can hide. Replace worn, missing, or degraded seals or gaskets because they may become contaminated with Lm. \u2022 Clean overhead structures as often as necessary to keep them free of condensation and ensure that sanitary conditions are maintained. Overhead items (e.g., cracked light fixtures) can be Lm harborage points. Condensation on overhead structures can lead to contamination of food or food preparation surfaces. \u2022 Keep water from pooling on the floor or other surfaces within the deli area. Doing so will reduce the likelihood that splashes could contaminate food products or food contact surfaces. Standing water can serve as a vehicle for Lm and other pathogens. Things to Consider at Retail \uf0fc Is the facility structure in good

repair to prevent contamination or adulteration of products in the deli area? \uf0fc Is the equipment nonporous and free of cracks, pits, and rough welds? \uf0fc Is the overhead structure in the deli area free of condensation? \uf0fc Is the deli area free of standing water on floors or product contact surfaces? 11", "Employee Practices As mentioned previously, the Interagency Retail Lm Risk Assessment found that wearing gloves while serving customers reduces the predicted risk of listeriosis. The 2013 FDA Food Code also recommends that employees wear gloves or use other suitable utensils to handle RTE foods and includes recommendations for training, hand washing, employee health and hygiene, and limiting public access in deli areas to prevent product contamination (references below). Good employee hygiene practices are critical to prevent cross-contamination and the spread of Lm and other pathogens. Lm can be present on, and spread by, equipment, materials, foods, and people. Here are a few employee practices retailers can use to minimize cross-contamination. \u2022 Ensure that employees wear gloves or use suitable utensils when handling RTE products, as recommended by the 2013 FDA Food Code (3-301.11(B)). Provide disposable gloves so that employees wear and change gloves, as needed, to prevent the contamination of food. NOTE: The Interagency Retail Lm Risk Assessment found that employees not wearing gloves increases the predicted risk of listeriosis from the consumption of RTE products sliced or prepared in the retail deli department by approximately 5%. \u2022 Train employees in sanitation practices and safe food handling procedures. Ensure that the manager has knowledge of food safety practices and procedures, as recommended by the 2013 FDA Food Code (2-102.11), and that employees have been properly trained in hygienic practices. \u2022 Provide adequate facilities, including soap and running water, for employees to wash their hands. As recommended by the 2013 FDA Food Code (2-301.14), employees should wash hands prior to gloving, when switching between handling raw and RTE foods, after engaging in other activities that may contaminate the hands (e.g., handling money or potentially dirty or contaminated surfaces), or using the restroom. \u2022 Implement a policy to ensure that ill employees do not work with open food items, including RTE foods. For example, written procedures should include removing workers from the deli when they are ill with respiratory or diarrheal diseases, as recommended by the 2013 FDA Food Code (2-201.11). Things to Consider at Retail \uf0fc Are there procedures to prevent ill employees from working in the food preparation area? \uf0fc Do employees wash hands prior to handling exposed RTE product? \uf0fc Do employees wear disposable gloves when handling exposed RTE product? \uf0fc If employees wear disposable gloves, do they change them, as necessary, to prevent crosscontamination (e.g., after handling raw product or money) when handling RTE product? \uf0fc Is foot traffic limited in RTE food product handling areas? 12", "\u2022 Limit employee traffic in the deli area and develop traffic-flow plans for product, employees, and other items to prevent contamination by consumers and employees. The plans should minimize exposure of open RTE foods to raw foods, exterior packaging, and other possibly contaminated materials, such as boxes, trash, and chemicals. Designing facilities and controlling traffic in the deli area to restrict movement of people and material reduces the chance of cross-contamination. Non-deli workers should not handle exposed RTE products. \u2022 Develop practices to prevent outer clothing from spreading contamination. Ensure that employees change their aprons or outer clothing, such as frocks or smocks, when the clothing is soiled with food or dirt particles that could transfer to food or food contact surfaces. Employees should not hold exposed RTE food products against their aprons or other clothing. Employees

should not wear this outer clothing into restrooms, in break areas, or outside the deli area.

13", "Deli Self-Assessment Tool Retailers should use this tool to determine whether they have adopted the appropriate procedures to control L<sub>m</sub>, or whether they should adopt new procedures. The preferred answer (based on the information in the guidance) is indicated with an asterisk. Having a \u201cno\u201d answer does not necessarily indicate lack of control. If retailers find that they are not meeting the recommendations in this guidance, they should consider changing practices to better control L<sub>m</sub> in the deli area.

Product\ Product Handling:

RTE Deli Area YES NO N\A

1. Is any visibly adulterated product present in the area (e.g., filthy, putrid, decomposed, slimy, rancid, off-condition)? \u25a1 \u25a1\* \u25a1
2. Are RTE meat or poultry products refrigerated promptly after use? \u25a1\* \u25a1 \u25a1
3. Is RTE product prepared, held, or stored near or adjacent to raw product in the deli case and elsewhere in the deli area? \u25a1 \u25a1\* \u25a1
4. Is the RTE product date-marked when opened? \u25a1\* \u25a1 \u25a1
5. Is there any RTE product in the deli case that is outside of the date-marked period? \u25a1 \u25a1\* \u25a1
6. Are the deli cases and other refrigerated units maintained at or below 41\u00b0F (5\u00b0C)? \u25a1\* \u25a1 \u25a1
7. Is opened RTE product covered, wrapped, or otherwise protected to prevent cross-contamination when not in use in the deli case and elsewhere in the deli area? \u25a1\* \u25a1 \u25a1
8. Is RTE product stored in the deli case properly identified and labeled? \u25a1\* \u25a1 \u25a1
9. Do you use deli products formulated with antimicrobial agents? \u25a1\* \u25a1 \u25a1
10. Are RTE product contact surfaces cleaned and sanitized prior to using the surface for another product to avoid cross-contamination of products? \u25a1\* \u25a1 \u25a1
11. If you prepare deli salads, are there controls in place to ensure that grinders, dicers, or other equipment are maintained in sanitary condition? \u25a1\* \u25a1 \u25a1

Cleaning\Sanitizing:

RTE Deli Area YES NO N\A

  12. Are insanitary conditions (e.g., flies, rodent droppings, mold, or dirty surfaces) present in areas where meat and poultry products are prepared, packed, or held? \u25a1 \u25a1\* \u25a1
  13. Do you use sanitizers at the proper concentration? \u25a1\* \u25a1 \u25a1
  14. Do you clean and sanitize the RTE equipment (including slicers) at least every 4 hours? \u25a1\* \u25a1
  15. Do you disassemble RTE equipment (including slicers) during cleaning and sanitizing? \u25a1\* \u25a1 \u25a1
  16. Do you scrub surfaces during cleaning to prevent biofilms? \u25a1\* \u25a1 \u25a1
  17. Do you soak or rinse cleaning cloths in sanitizer between uses? \u25a1\* \u25a1 \u25a1
  - 14", "18. Are sanitizer types (e.g., quaternary ammonium, chlorine- based, or iodophores) rotated periodically? \u25a1\* \u25a1 \u25a1
  19. Do you clean the RTE area with a high pressure hose (e.g., with enough pressure to cause splashing)? \u25a1 \u25a1\* \u25a1
  20. Are there separate sinks for hand washing and other uses? \u25a1\* \u25a1 \u25a1
  21. Do you have material (e.g., pallets, milk cartons, cardboard boxes, or push carts) in the deli area that makes cleaning difficult? \u25a1 \u25a1\* \u25a1

Facility:

RTE Deli Area YES NO N\A

    22. Are there facility conditions (e.g., condensation dripping on exposed product, construction dust on product, or broken equipment) that could cause the product to become adulterated? \u25a1 \u25a1\* \u25a1
    23. Is there condensation on overhead structures or over the RTE product? \u25a1 \u25a1\* \u25a1
    24. Is there standing water on surfaces, including the floor? \u25a1 \u25a1\* \u25a1
    25. Are product contact surfaces in good condition (e.g., non-porous surfaces, free from cracks, pits, and rough welds)? \u25a1\* \u25a1 \u25a1
    26. Are slicers and mixers in good condition (e.g., free of cracks, broken, missing or unattached parts; seals and gaskets not worn, degraded, or missing)? \u25a1\* \u25a1 \u25a1
    27. Are the walls,

floors, and ceilings sanitary and in good repair? \u25a1\* \u25a1 \u25a1 Employee Practices: RTE Deli Area YES NO N/A 28. Are visibly ill employees working in food preparation areas where product could become contaminated (e.g., by coughing or sneezing)? \u25a1 \u25a1\* \u25a1 29. Do employees work without washing hands prior to handling exposed RTE product? \u25a1 \u25a1\* \u25a1 30. Do employees wear disposable gloves when handling exposed RTE product that will not be cooked? \u25a1\* \u25a1 \u25a1 31. If employees wear gloves, do they change them as necessary to avoid cross-contamination of RTE product? \u25a1\* \u25a1 \u25a1 32. Do employees change outer clothing (e.g., frocks, aprons, or smocks) as often as necessary to avoid contamination of RTE product? \u25a1\* \u25a1 \u25a1 33. Is foot traffic limited to necessary employees in areas where RTE product is handled? \u25a1\* \u25a1 \u25a1

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*Listeria monocytogenes* (Lm) Lm is a bacteria found in moist environments, soil, and decaying vegetation. It causes the foodborne illness, listeriosis. Transfer of Lm from the environment, equipment, employees, or raw food is a particular hazard of concern in retail delis. It can cross-contaminate food contact surfaces and foods. Improper sanitation, product handling, and employee practices can lead to the transfer of Lm to RTE meat and poultry products at retail. Lm forms biofilms (thin layers of microorganisms that stick to product contact surfaces) that are difficult to remove from equipment and other surfaces. Listeriosis Serious infection can result from eating food contaminated with Lm. Infection is rare, but could result in a high fatality rate (16% compared to 0.5% for *Salmonella* or *E. coli* O157:H7). It affects everyone, with older adults, pregnant women and fetuses, newborns, children, and adults with weakened immune systems being at higher risk. Flu-like symptoms can begin a few days after consuming contaminated products. However, invasive listeriosis, which can affect the central nervous system and may cause stillbirth or result in death, can begin up to 2 months after eating food contaminated with Lm. There are an estimated 1,600 illnesses, 1,500 hospitalizations, and 260

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deaths in the U.S. each year. Product Handling It is important to adopt practices that protect RTE product from contamination with Lm (see bullets below on ways to prevent or limit the growth of Lm in deli products). \u2022 Use products that contain antimicrobial agents or have received other treatments to eliminate or prevent the growth of Lm in RTE products. \u2022 Monitor and limit the shelf life of an RTE product that is opened, prepared, and held in a retail setting for more than 24 hours. \u2022 Do not pre-slice products - product should be sliced at the time it is requested by consumers. \u2022 Remove products that are filthy, putrid, decomposed, slimy, rancid, or in off-condition from the deli area as soon as possible and thoroughly clean and sanitize areas that were contacted by such product to prevent any cross-contamination. \u2022 Promptly return RTE products to refrigerated units (at or below 41\u00b0F), after slicing, to slow pathogen growth. \u2022 Store and handle RTE products in separate areas from raw products. RTE products that are prepared, held, or stored near raw products can become contaminated (e.g., because of aerosolization or dripping). A number of food safety practices are needed to control Lm contamination of retail foods. Cleaning and Sanitizing \u2022 Develop written sanitation procedures that describe how utensils and equipment (e.g., slicers) will be cleaned and sanitized prior to use. \u2022 Clean and sanitize utensils and equipment used to handle, prepare, and store RTE products frequently (e.g., at least every 4 hours). \u2022 Disassemble RTE food-processing equipment when cleaning and sanitizing to ensure that hard to reach areas where Lm can hide are addressed. \u2022 Scrub surfaces during cleaning to prevent biofilms from occurring. \u2022 Follow the manufacturer's recommendations for sanitizer strength and application, including exposure time, to ensure it is effective. \u2022 Consider rotating sanitizers to provide more effective bacterial control. \u2022 Develop a procedure to sanitize cleaning aids (e.g., cloths and scrub brushes) or have singleuse items that are discarded after use. \u2022 Use low water pressure when cleaning in the deli areas to minimize splashing and overspray. \u2022 Use separate sinks for hand washing and cleaning product or equipment. \u2022 Eliminate or remove unnecessary items (e.g., supplies and equipment) from the deli area.", "Employee Practices \u2022 Train employees in sanitation practices and safe food handling procedures. \u2022 Ensure that employees wear gloves and change them as needed to prevent crosscontamination of RTE products. \u2022 Provide adequate facilities, including soap and running water, and post instructions for employees to wash their hands. \u2022 Implement a policy to ensure that ill employees do not work with open food items, including RTE foods. \u2022 Limit employee traffic in the deli area and develop traffic-flow plans for product, employees, and other items to prevent contamination by consumers and employees. \u2022 Develop practices to prevent outer clothing from spreading contamination, such as wearing disposable aprons. For more information and a checklist of practices for your deli, go to FSIS Best Practices Guidance for Controlling Listeria monocytogenes (Lm) in Retail Delicatessens at [http://www.fsis.usda.gov/wps/wcm/connect/29d512\\_58-0651-469b-99b8-e986baee8a54/Controlling-LMDelicatessens.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/29d512_58-0651-469b-99b8-e986baee8a54/Controlling-LMDelicatessens.pdf?MOD=AJPERES) See the FDA Food Code, 2013, at: <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm374275.htm> Additional information on Listeria is at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/listeria-Facility-and-Equipment-Controls> \u2022 Do not allow conditions in the retail facility that could cause the product to become contaminated. \u2022 Ensure that walls, floors, drains, and overhead

structures in the RTE deli and cooler areas are smooth, durable, easily cleanable, and in good repair. \u2022 Do not perform construction (e.g., replacing floors, walls, or ceilings) when exposed RTE product is present in the deli. Thoroughly clean\ sanitize the equipment and facilities after construction and before handling product. \u2022 Maintain tables, slicers, and other food contact surfaces so that they are easily cleanable. \u2022 Clean overhead structures as often as necessary to keep them free of condensation and ensure that sanitary conditions are maintained. \u2022 Keep water from pooling on the floor or other surfaces within the deli area. \u2022 Clean and sanitize surfaces between different types of RTE items (for example ham, seafood, and vegetables) when using the same equipment. \u2022 Ensure that grinders, dicers, scoops, or other equipment are maintained in sanitary condition. \u2022 Maintain product cases and storage at or below 41\u00b0F to slow Lm growth. USDA is an equal opportunity provider and employer. United States Department of Agriculture Food Safety and Inspection Service Guidance for Controlling Listeria monocytogenes (Lm) in Retail Delicatessens Best practice tips for deli operators The information in this brochure is taken from FSIS Best Practices Guidance for Controlling Listeria monocytogenes (Lm) in Retail Delicatessens. These are suggestions and not requirements. Retailers should be aware that the recommendations in this guidance, especially those based on the 2013 Food Code may be requirements in State, local, or tribal regulations."}],{"file\_name":"FSIS\_GD\_2015\_0016","title":"Label Submission and Approval System (LSAS): User Guide for Industry Users","num":"FSIS-GD-2015-0016","id":"156786ad74c3a4d44cf0fbc4227adae3430359efe214fe4c007d72e2e1517bb9","corpus":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/import/LSAS-Industry-User-Guide-063015.pdf","type":"pdf","n\_pages":182,"word\_count":45089,"text\_by\_page":["USDA United States Department of Agriculture USER GUIDE FOR INDUSTRY USERS V1.25 SEP 6, 2019 Label Submission and Approval System (LSAS) Application Version: 2.12.0","Label Submission and Approval System (LSAS) Industry User Guide Contact Information For assistance relating to the Label Submission and Approval System (LSAS) USDA Food Safety and Inspection Service Labeling and Program Delivery Staff Food Safety Inspection Service Phone: 301-504-0878 Email: lsas@usda.gov September 09, 2019 i","Label Submission and Approval System (LSAS) Industry User Guide Table of Contents 1 INTRODUCTION

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Introduction Primary Business Function The Label Submission and Approval System (LSAS) is a	
web-based software application that integrates and implements an electronic label application	
process for establishments to submit label applications. LSAS allows LPDS personnel to view,	
evaluate, and adjudicate all electronically submitted Label Application Packages (LAPs) and	
Appeal Packages (APs) efficiently and accurately. Industry users will be able to check on the	
status of their application via their web browser without calling LPDS. Also, the submitter can	
utilize the Generic Label Advisor to determine whether an application can be generically	
approved. Industry users that will be accessing LSAS include establishments, expeditors, label	
consultants, and small businesses. To use LSAS, all users are required to have an	
eAuthentication (eAuth) user ID and password. Users of LSAS will be required to have a USDA	
Level 2 eAuthentication account to access the system. USDA eAuth is the system used by USDA	
agencies to enable FSIS staff, customers, and contractors to obtain accounts that will allow	
them to access USDA web applications and services via the Internet. Purpose and Scope This	
document describes the features and capabilities of the United States Department of	
Agriculture\u2019s (USDA) Food Safety and Inspection Service (FSIS) Office of the Labeling and	
Program Delivery Staff (LPDS) Label Submission and Approval System (LSAS). The LSAS User	
Guide for Industry Users provides detailed, role-based step-by-step instructions for performing	
all industry tasks within LSAS. Personnel who use LSAS are highly trained and experienced in	
their jobs, and as such, this resource does not provide instruction on job requirements other	
than those directly involving entering data and working directly with LSAS. This document does	
provide detailed instructions on the use of LSAS. Audience The LSAS User Guide for Industry	

Users is designed for all food safety industry members who support the USDA FSIS staff in the management of food safety. Users include preparers, plant managers, agents, and label consultants. September 09, 2019 1 Chapter 1 \u2013 Introduction", "Label Submission and Approval System (LSAS) Industry User Guide Organization of the User Manual This guide is separated into sections that describe the major available functionalities and their necessary requirements for system use. A general description of each section is listed in Table 1-1. Table 1-1: User Guide Section Overviews Section Name Contents A high-level brief overview of the system, general information, and conventions used in this user guide 1 Introduction 2 System Capabilities A brief overview of the system and its capabilities. This section describes the purpose of the application and provides an overview of the system\u2019s capabilities, functions, and operation 3 System Requirements, Login, and User Profile Login instructions and a general overview of the home page 4 User Interface General introduction of the LSAS user interface 5 Menus and Functions General description and instructions on using common functionalities in LSAS 6 Generic Label Advisor (GLA) A description and instruction for using the Generic Label Advisor (GLA) 7 Submit a Label Application A description of the submission process 8 Edit a Draft Application Steps for editing an existing label application 9 View & Download Adjudicated Applications Steps to view and download a label application that has been adjudicated by LPDS 10 Handle a Returned Label Application Steps to manage a label application that was returned by LPDS 11 Manage an Appeal Steps to create and manage an appeal for a previously adjudicated label application 12 Search for Label Applications A description of the LSAS search functionalities 13 Import an Application via XML Format Steps to create a label application using the Import XML function Appendix A Glossary of Common Terms Glossary of LSAS common terms Appendix B Instructions for preparation of FSIS Form 7234 Instructions for preparation of FSIS Form 7234 Appendix C Instructions for preparation of FSIS Form 8822-4 Instructions for preparation of FSIS Form 8822-4 (Appeal form) Appendix D LSAS Tips Tips for using the LSAS system. These tips also appear in the Announcements pool on the dashboard. Appendix E LSAS Links URL links for FSIS labeling, Title 9, and other general links Appendix F FAQs Frequently asked questions regarding the LSAS application and their answers. September 09, 2019 2 Chapter 1 \u2013 Introduction", "Label Submission and Approval System (LSAS) Industry User Guide Document Conventions The following conventions are used in this guide: Convention Examples Bold and Italic text indicates the main navigation menus and their associated menu options. \u2022 From the Label Applications menu, select the Search option. \u2022 From the Administration menu, select the Ingredients option. Italic text indicates pool names, screen names, and screen section names. \u2022 LSAS displays the label application in the Appeals pool. \u2022 LSAS displays the Label Application Search screen. \u2022 LSAS displays the agent\u2019s name, address, and contact information in the Agent Information section of the Submission Information screen. Bold text indicates links and buttons. \u2022 Click the Save and Continue button. \u2022 Click the Home link. \u2022 Click the Submit button. Font enclosed in quotes indicates text for you to type verbatim or the specific value you should select. \u2022 Enter \u201cACME Foods\u201d in the textbox. \u2022 Select \u201cView\u201d from the Available Actions drop-down. Notes, Tips, and Warnings Notes provide additional clarification or explanation. NOTE: Note text appears between two blue lines. Tips provide ideas or hints that help you through a data entry form or process. TIP: Tip text appears between two yellow lines. Warnings represent a potential problem or a serious

issue. The information in warnings will help you prevent the loss or damage of data, processes, software, or hardware. WARNING: Warning text appears between two red lines.

September 09, 2019 3 Chapter 1 \u2013 Introduction", "Label Submission and Approval System (LSAS) Industry User Guide Recommendations \u2022 Avoid using your browser's buttons to navigate within LSAS. It is recommended that you use LSAS\u2019s buttons to navigate between screens.

\u2022 Save your work periodically. Safeguards, put in place by USDA, close applications and log you out of them after a period of inactivity. \u2022 LSAS makes use of messaging and comments fields for communications between LPDS and external industry users. Acronyms and Abbreviations This section provides a glossary of acronyms that may be used in this user guide.

Table 1-2: Acronym List

Acronym	Definition
AMS	Agriculture Marketing Service
AP	Appeal
CFR	Code Of Federal Regulations
CN	Child Nutrition
CSI	Consumer Safety Inspector
DU	Distribution Unit
EC	Extraordinary Circumstances
FSIS	Food Safety Inspection Service
GLA	Generic Label Advisor
HACCP	Hazard Analysis & Critical Control Points
IIC	Inspector In Charge
LAP	Label Application Package
LPDD	Labeling and Program Delivery Division (former division name)
LPDS	Labeling and Program Delivery Staff
LSAS	Label Submission and Approval System
OCIO	Office of the Chief Information Officer
OPPD	Office of Policy and Program Development
OPEER	Office of Program Evaluation, Enforcement and Review
PHIS	Public Health Information System
USDA	United States Department of Agriculture
XML	Extensible Markup Language

September 09, 2019 4 Chapter 1 \u2013 Introduction", "Label Submission and Approval System (LSAS) Industry User Guide Notes Throughout this guide, there will be many label application examples used. The author has gone through great effort to minimize the possibility of using branded names, establishment numbers, approval numbers, and any other relevant FSIS Label Application Form 7234 information. If such match should occur, then it was purely coincidental.

September 09, 2019 5 Chapter 1 \u2013 Introduction", "Label Submission and Approval System (LSAS) Industry User Guide 2 System Capabilities The USDA FSIS LPDS develops and provides labeling guidance, policies, and inspection methods, and it administers programs to protect consumers from misbranded and economically adulterated meat, poultry, and egg products to ensure that all labels are truthful and not misleading. Labeling includes all forms of product identification, health-related claims, net weight, species identification, and nutrition. LSAS is a web-based software application that integrates and implements an electronic label application process for establishments to submit label applications and appeals. Through LSAS, LPDS personnel will view, evaluate, and adjudicate all electronically submitted LAPs and APs efficiently and accurately. An adjudicated LAP\u2019s results and status will appear on the user\u2019s home page. Using LSAS, LPDS will be able to process label applications more efficiently. The required functionalities for this system include submitting label applications via the web, querying for a label application\u2019s status and information, downloading LAPs and supporting documents to a portable format, and exporting search results to a spreadsheet of submitted LAPs. The LSAS application serves as a searchable database when seeking information about products or establishments. Label information includes product identification, special claims, processes, geographical origin claims, guarantees, net weight, ingredient list, species identification, and nutritional information. LSAS provides a central tracking system for establishments and LPDS leadership. To a certain extent, LSAS replaces almost all paper-and email-based processes. Purpose The LSAS application provides the following benefits: \u2022 Establishments can submit applications and supporting materials via



and irrevocable. You may not rely on any statements or informal policies purporting to provide you with any expectation of privacy regarding communications on this system, whether oral or written, by your supervisor or any other official, except USDA's Chief Information Officer. \*\*

Your progress through these steps will be displayed on the left side navigation menu .. Click Next to continue. Click Cancel to exit the wizard. All modifications will be canceled. Label Submission and Approval System (LSAS) Industry User Guide FSIS Enrollment Request Wizard: Click Next Figure 3-4: FSIS Enrollment Request Wizard (Step 1) September 09, 2019 13 Chapter 3 \u2013 System Requirements, Login, & User Profile", "Uninstall Software Management of Agreements: Food Safety and Inspection Service J. Doe Welcome Account Type Primary Role My Preferences My Comments Summary J. Doe Enrollment welcome [ Account Type Primary Role My Preferences My Comments Summary Home Help Contact Us Logout eAuth The FSIS Enrollment Request Wizard Step 2] Select Your Account Type Select your account type. Account Type: LSAS Submitter Description: --Select - Domestic Non FSIS Federal,1 Employee corporate Brokers And Traders M#MIHI IIMSFM Circular@M he FSIS Enrollment Request Wizard (Step 2), or Select You'll Account Type S@l@ct your account type, \* Account Type: Industrial, SA\_S\_S\_\u00b7u\_b\_m\_it er \_\_\_\_\_ -E) - e if you are an industry user (including Decription: Select LSAS Submitter for your Account Type if you are an industry user (including EII4WIHM Mi@IFE G-i:LSAS Label Submission and Approval System (LSAS) Industry User Guide Account Type: Select \u2013LSAS Submitter\u201d from the drop-down. Figure 3-5: FSIS Enrollment Request Wizard (Step 2) Click Next. September 09, 2019 14 Chapter 3 \u2013 System Requirements, Login, & User Profile", "li.lf'l,led't , Oc:p Im o A fla.i! 1:110 Food Safety and Inspection Service Home Help Contact Us Logout eAuth The FSIS Enrollment Request Wizard (Step 3 of 3) J. Doe iHt s ...t,z..rd helps you prep\u2022rc \u2022nd submit your enrollment 1\"4;Question. Enrollment LSAS User Orientation \u00b7011 Wetco1ne Account Type C y, click Finish below to complete your LSAS enrollment. You will be redirected to LSAS to create your Profile information. LSAS Information: MWM Label Submission and Approval System (LSAS) Industry User Guide LSAS User Orientation: Click Finish to Complete Your Enrollment Figure 3-6: FSIS Enrollment Request Wizard (Step 3) September 09, 2019 15 Chapter 3 \u2013 System Requirements, Login, & User Profile", "IJSDA United States Department of Agriculture \u2013 Food Safety and Inspection Service LSAS Label Submission and Approval System Home Contact Us Exit LSAS Logout I Submitter Welcome You do not yet have any profiles associated with your account. To continue, you may either create a new profile, or request access to an existing profile. Home I USDA Internet I USDA Intranet I FSIS Internet I FSIS Intranet I FOIA I Accessibility Statement I Privacy Policy I Non-Discrimination Statement I Information Quality I USA.gov I White House Version: 2.0 Label Submission and Approval System (LSAS) Industry User Guide Welcome to LSAS: Set Up Your Profile in LSAS as a Submitter Figure 3-7: LSAS Welcome Screen \u2013 Create New User Profile Please refer to the Create a New Profile section on page 20. For assistance or questions concerning the LSAS enrollment process, you may email the administrator at LSAS@fsis.usda.gov or call 301-504-0837. Log In After Enrollment is Complete The user must provide an eAuth User ID and password, and then click the Login button. After the user is authenticated by eAuth and authorized by FSIS Security, the user is directed to the LSAS application. LSAS retrieves a list of LSAS-specific roles and permissions from FSIS. For each user login, LSAS is provided with the user's roles, permissions, and privileges and caches this information. LSAS also performs concurrency checks to make sure that two users are not editing an application simultaneously or attempting to modify an application's status simultaneously. LSAS will not allow users to access or modify label applications that belong to profiles to which they have no access permission. September 09, 2019 16 Chapter 3 \u2013

System Requirements, Login, & User Profile", "USDA I.Ollc,o~-\u2022OI~\_=-:= Food Safety and  
I11spec1011 Service LSAS -----Hoin\_e\_ : ! Submller vi Dashboard Us~r. 011..J.Willi;Ims,  
Allnounccomflnu: (S11t>mitlerl Label Submission and Approval System (LSAS) Industry User  
Guide Log Out of LSAS Close LSAS by clicking the \u2018X\u2019 button ( ) on your browser  
window or by clicking the Logout button on LSAS\u2019s home page. September 09, 2019 17  
Chapter 3 \u2013 System Requirements, Login, & User Profile", "Label Submission and Approval  
System (LSAS) Industry User Guide Automatic Session Termination WARNING: LSAS will  
terminate a user session after 30 minutes of inactivity. This is a security function provided by  
LSAS. Two minutes prior to the 30-minute deadline, LSAS will display a warning message (Figure  
3-8). The warning message includes a timer that shows a real-time countdown (in minutes and  
seconds) until session termination. When this message appears, the user can choose either to  
continue using the application or to log out. Figure 3-8: Session Timeout Warning If the  
countdown completes before the user chooses either to continue or to log out, LSAS will close  
the warning message and display the Session Timed Out screen (Figure 3-9). Session Timeout  
Warning Your session will expire due to inactivity in: 39 seconds Click "Continue" to keep  
working, or "Log Out" if you are finished. Con Log Out Session Timed out A Toe application  
has timed out. You must Close\Exit the browser. Close Browser Figure 3-9: Session Timed Out  
If the user clicks the Close Browser button, LSAS will close the browser and end the  
user\u2019s LSAS session. NOTE: The Close Browser button will not function in Firefox. If you  
are using Firefox, you must close the browser using the icon located at the top right of the  
browser window: September 09, 2019 18 Chapter 3 \u2013 System Requirements, Login, &  
User Profile", "Select a Profile Please select a profile from the list below. You may also request  
access to a different profile, or create a new profile. If you have any other LSAS browser  
windows or tabs open with a different profile selected, PLEASE CLOSE 11-IEM. Those windows  
or tabs will NO LONGER BE VALID after selecting a new profile. LSAS Training 1 LSAS Training 2  
LSAS Training 3 LSAS Training 4 Submit Label Submission and Approval System (LSAS) Industry  
User Guide LSAS User Profiles Once a user is granted access to LSAS, LSAS requests the user to  
select his or her Profile. Figure 3-10 illustrates the Select a Profile screen. Profiles can be  
created by the user. All that is required is a name for the organization or establishment.  
Organizational profiles are essentially label application containers. A user will always be logged  
in under a particular profile, and any label applications he or she submits while logged in under  
that profile belong to that profile. It is possible to have more than one profile. As a general rule,  
a single profile should not be used for multiple establishments that are for different  
organizations. A new profile should be created for each establishment. However, a single  
profile can have multiple establishments, but this should be limited to cases in which all of the  
establishments fall under the same parent organization. In order to continue to the LSAS home  
page, you must select a profile from the list. Select the desired profile, and then click the  
Submit button. Next, confirm your selection. Figure 3-10: Select a Profile Screen After selecting  
a profile, LSAS displays the LSAS home page, aka the Dashboard screen. This is the user  
interface from which you will initiate your day-to-day activities in LSAS. September 09, 2019 19  
Chapter 3 \u2013 System Requirements, Login, & User Profile", "USDA Ikl~ Sl!tis DepArlrnilll ol  
Agl'k:Ultur!! = Food Safety and Inspection Service LSAS Label Subml11ion and Approval System  
Home Contact Us !Logout !Submitter Welcome You do not yet have any profiles associated with  
your account. Create a new profile to continue. Home | USDA Internet | USDA Intranet | FSIS

Inlemet | FSIS Intranet | FOIA | Accessibility statement | Privacy Policy | No Discrimination statement | Information Quality | USAgov | White House USDA ..-... 0.,,-\u2022 ....-.

FOOC,~&t'd~S.MC>t Select a Profile Version: 2.11.0-0AT04 The Create link appears within the statement at the top of the screen '1HI+ HIHII | IKOfilli fr-MI'IM [ biilow:.. 'l'iou IQ'il illM rlQUTH INHI: [it I Mili.l\"tNl'I ~ \u2022. o.r LSAS l'l'JOU'hft'lp .UTJOfi4!r'5.il.ltm:nwt\u2022r~-Qi'Ul\u2022cpE1wttftii!it!..-4f'1'nli;\u00abClftl\u2022bl\u25a0i;:t\u25a0d,Pr.~. Th9M..tnffqlf\"lwlt'-Ql,,ONQliR:9 VMIO~r 1-tl\u2022~ng-1 n.-\u25a0 pn;tftl1, The create link ==-c-----\"-----..... appears within the l.:iiUTl\""!IVlg1 ~~~=: statement at the top IU.,ST-4 of the screen. \_l\_ l\_ l\_l\_iQIII t~ lt+rftECE, Srcrt1 Label Submission and Approval System (LSAS) Industry User Guide Create a New Profile If there are no user profiles to choose, then LSAS will prompt you to create a new profile. This usually occurs only the first time you log into LSAS. Then, each subsequent time you log into LSAS you will have a profile to select. 1. Access the Create a Profile screen using one of the following methods: \u2022 From the Welcome screen, click the create link. \u2022 From the Select a Profile screen, click the create link. \u2022 From the home page (Dashboard screen), select the Create new Profile menu option from the dropdown list on the left-hand side of the home page. September 09, 2019 20 Chapter 3 \u2023 System Requirements, Login, & User Profile","I Submitter User: 01\u2713.WJllams,(Submille r) ~ole: Submitter Proli le: Plurmrs,e -Boon B'ilille Switch profiles \"' Create new Pr,ofile menu option ReQuest access tAanag e users -t.tanage Sharing >---,- Manage Eslablist1men1s L IU1'1 ... &earch Cte ,e Generic L,a el A.dv~or tn(lorl Applie41i:in\$ SmtLJS Check . ApplICBJtlon \" I I 111 Chec1k II Label Submission and Approval System (LSAS) Industry User Guide September 09, 2019 21 Chapter 3 \u2023 System Requirements, Login, & User Profile","Create Profile Profile Name\u2022:: \u2022 Required Fields Submit Label Submission and Approval System (LSAS) Industry User Guide LSAS displays the Create Profile screen (Figure 3-11). Figure 3-11: Create Profile Screen All that is required to create a profile is to enter a name for the organization or establishment. 2. Enter the name of the organization (e.g., company or establishment name) or other identifiable name, in the Profile Name field. It is recommended to create a generic name that includes the company or establishment name you represent with a suffix that is identifiable to you, instead of a given name; e.g., Jane Doe. All profile names will be listed and visible to the public for selection to request access to a profile (see next section topic). 3. Click the Submit button. 4. Click the Confirm button to submit and save the profile name. LSAS confirms the creation of the new profile by displaying a Submission Successful message. You are prompted to click the created profile\u2019s dashboard link to continue to your home page. The first time you access the home page under a newly created profile, all pools on the dashboard will be empty. September 09, 2019 22 Chapter 3 \u2023 System Requirements, Login, & User Profile","USDA .....-\u2022....-' F--. .... ~ s...LSAS !INI :lubftl1\u2022kin 6MI ~fil\"WII :lrlbiffl Sel&ct a Profile l'fHI+ HIH[ 1,.-affli fl\"\\Nli'lhil CbillD'IIlt. 'l',au~ illM tAlllll\\,~D\u2022 \u2022 ata.l'ft'l'jf!f'Gftiil, o.r~ \u2022 MW PMtfiL w~\u2022-\u2022nr\u2022 ... \u2022u.a.\u2022\u2022-\u2022-\u2022.~\u2022\"\" The request ac,c,e.ss \"JIKIHlftrtr.l,....Qf~lfiQ!!.'QlffQlifli9 YMl0111.11r , ... ~ I Submitter ~-----+link appears within u,113 T-1 ~}:!;: the statement at the UI,i,STrMV,;4 top of the screen. Us er: O 1-JI. 'Nill I ams,(Su bmltter) Ro'le: Sutm11Har SINtch profiles Create new i:irolile l:lif~IH~r-111 \u2022 ~ Request access menu option t.i, anag e Users Manage Sharing ..\_\_ Manage Establishments Latlel .Ap plications ..

Searoti Create Generic Label Ad isor Import Appkations >- Status Check ..... Application t l 11 Che<lk l Label Submission and Approval System (LSAS) Industry User Guide Request Access to a Different Profile A submitted entity, such as an expeditor or corporation, can create as many user profiles as necessary to represent the various user groups within its establishment(s). An organization\u2019s main contact person or corporate administrator will typically create all necessary user profiles for the organization. The same person will also assign the user profiles to the appropriate establishments (subsidiaries) associated with the parent corporation. NOTE: Every LSAS user must have an LSAS user profile before he can log on to the application. A user will not be able to request access to another user profile unless he already has an existing profile, because he must log on and use the Request Profile Access function within LSAS.

1. Access the Request Profile Access screen using one of the following methods:

- \u2022 From the Select a Profile screen, click the request access link.
- \u2022 From the home page (Dashboard screen), select the Request access menu option from the dropdown list on the left-hand side of the home page.

September 09, 2019 23 Chapter 3 \u2013 System Requirements, Login, & User Profile", "Request Profile Access Please select the profiles you would like to request access to from the list below. You will have the opportunity to request access to other profiles at any time.

001 Pilgrim's Pride (Cheri Schneider) 02 Prime Label Consultants A 03 Prime Label Consultants \u25a0 080051 Trimmed Pork Cushion Butterfly 09270 1I2X Frozen Pill.la 100% Beef Pattie 100% Berkshire Pork 132Farm 19292H Submit Label Submission and Approval System (LSAS) Industry User Guide LSAS displays the Request Profile Access screen (Figure 3-12).

Figure 3-12: Request Profile Access Screen 2. Select (highlight) the profile and then click the Submit button.

3. Click the Confirm button to accept your selection. LSAS displays the Submission Successful screen. When you request access to a profile, you will not have immediate access to it until the profile owner grants approval. The owner will approve or deny the request through the Manage Users function accessed from the Profile menu. The profile owner can grant approval as an administrator or associate. Once approved, you will see the new profile, but only after your next login. Once your request has been approved, your profile will become available on the Select a Profile screen, as shown in Figure 3-10.

September 09, 2019 24 Chapter 3 \u2013 System Requirements, Login, & User Profile", "I Submitter vi User: 01-J.Williams,(Submitter) n.,\_1.,\_. f\"l..L \u00b7 Switoh profiles Ore ate new 13rofile Request access . .... . Manage Sharing Manage Establishments Label Applications \u2022 Search Or,eate Generic Labeil Advisor Imp\u25a1 rt Ap;plicatio n>S Status Check . Apptication # 11 Check l Label Submission and Approval System (LSAS) Industry User Guide Profile Users, Sharing, and Establishments On the home page, the user has additional options to manage users, sharing, and establishments, as illustrated in Figure 3-13.

Figure 3-13: User's Profile Options The Manage Users option is especially valuable when an establishment wants to delegate additional resources for submitting or managing a label application. An establishment\u2019s first LSAS user will generally be the initial contact person. This person will likely be the administrator of any profiles associated with the establishment. It will be the establishment\u2019s responsibility to manage all users associated with that establishment, independently of LPDS. Through LSAS\u2019s profile management function, the establishment\u2019s newly assigned administrator can easily add\assign other establishment resources as LSAS users. These users will be assigned an LSAS role as associates within the establishment. Additionally, in the situation where the establishment farms out its label application process, the

establishment's administrator, using LSAS's profile tool, can create user profiles for agents/expeditors. Then, the establishment can share certain label applications with a designated agent/expeditor. Also, its LSAS privileges may have limited functionality. The Manage Sharing option allows a user to share his applications with another user. As mentioned in the preceding paragraph, an establishment can share specific applications with its agent once the agent has permission to access LSAS. The Manage Establishments option allows a user to add establishments to his profile. For example, a major corporation will have multiple subsidiaries, so there will be a need to create a separate profile for each of the subsidiaries. This option provides the establishment a way to include its establishment numbers and allows LSAS to easily associate a user with his establishment's number and address. The establishment number and address is a required field in the Form 7234. LSAS provides a tool to import establishment information directly from PHIS. September 09, 2019 25 Chapter 3 \u2013 System Requirements, Login, & User Profile", "Profile Users Profile access requests are pref\bO(ed wilh a \u00b7+\u00b7 character and shown in green and at the top of the list below. + ~I P\_e\_n\_d\_in~g \_\_\_\_ v~I AbouTaleb, Heather Ayesha Email unavailable + ~I P\_e\_n\_d\_in~g \_\_\_\_ v~I Abramczyk, Mary Email unavailable Administrator Williams, Jennifer Email unavailable submit Prome Users Profile access requesis are prefixed wilh a "+" character and shown in green and at the lop of the fist below. + \u2022 . Abm.rTaleb, Heather Ayesha Email unavailable -Administrator + Denied Abramczyk, Mary Email unavailable Pending Administra or Wimams, Jennifer Email unavailable ..... ,..... ..

..... I Submit I Label Submission and Approval System (LSAS) Industry User Guide Manage Users A user can request access to a specific user profile. The requestor uses the Request Access function to ask for access privileges to a LAP. If a user has requested access, his username will appear on the Profile Users screen (Figure 3-14) of the user who currently has access to the profile (the requestee). The requestee will then have the option to approve or deny the request. Using the Manage Users option, the user receiving the request (the requestee) will approve or deny the request. Figure 3-14 shows the Profile Users screen with profile access requests from two other Submitter users. These new requests will appear in green text with a status of \u201cPending\u201d until the requestee either approves or denies the request. Figure 3-14: Profile Users Screen If approved, the requestor can be assigned as an Administrator or Associate. Associate An associate is an LSAS user assigned by his organization's administrator to perform label submission tasks, including checking label status and viewing LAPs. Administrator An administrator is the main contact person representing a company or establishment. The main role of the administrator is to grant access to LSAS to users within his organization, in addition to all of the associate's tasks. Select the appropriate value (Associate, Administrator, or Denied) using the drop-down list associated with each request for access: Figure 3-15: Profile Users Screen \u2013 Select \u201cAssociate\u201d Option September 09, 2019 26 Chapter 3 \u2013 System Requirements, Login, & User Profile", "Label Submission and Approval System (LSAS) Industry User Guide What to Do If a User Is Leaving or Has Already Left an Establishment If you are leaving an establishment or firm, send an email notification to the LSAS Administrator: lsas@fsis.usda.gov. Specify whether you are leaving your current position permanently; or, if you will be employed as a Submitter for the new establishment or firm. At a minimum, provide your name, establishment name and number,

user profile name (located on the upper left of the main LSAS screen in the left navigation menu), phone number, and if applicable and known the name of the person who will assume responsibility for the establishment's label applications in LSAS. The LSAS Administrator will set your account accordingly. To deactivate your LSAS account, send an email or letter (dated and signed on official letterhead) to the LSAS Administrator, providing the following information: 1. First Name, Last Name (as registered with eAuth) 2. Profile name(s) as established in LSAS (located on the left navigation panel of your dashboard) 3. Establishment Name and Number 4. Reason for deactivation 5. Effective Date 6. Contact information (phone and email address) To request access to another user's profile for a user who is no longer with the establishment or firm, send an email or letter (dated and signed on official letterhead) to the LSAS Administrator providing the following Information: 1. First and last name of the previous user (original submitter) whose profile you need to access 2. The previous user's User Profile name(s) as established in LSAS 3. Confirmation that the previous user account should be deactivated 4. The reason(s) the previous user's account should be deactivated 5. A listing of the previous user's application/approval number(s), product names, and establishment number(s) 6. Your first and last name 7. The relationship you hold with the previous user 8. Your User Profile name as established in LSAS (located on the left navigation panel of your dashboard) 9. Contact information for all parties involved (phone and email address) Letters may be mailed via UPS or FedEx to: Attention: Lynn G. Yoder USDA, FSIS, OPPD, LPDS Labeling Distribution Unit Patriots Plaza III, 9-171A 355 E. Street, SW Washington, DC 20024-3221 September 09, 2019 27 Chapter 3 System Requirements, Login, & User Profile", "Label Submission and Approval System (LSAS) Industry User Guide Contact the LSAS Administrator: Email: lsas@fsis.usda.gov Phone: (301) 504-0878 Note: Your eAuth password is unique to you as an individual. Do NOT share it with others. September 09, 2019 28 Chapter 3 System Requirements, Login, & User Profile", "I submitted User ID: 01-J.Williams,(Submitter) Role-: Submitter Profile: Plumrose -Booneville -----Switch profiles Create new profile Request access Manage users Manage Sharing L r.tanage !Establishments Se<111'011 Craellle Generic LI!betAdvbi;iir lmPQrt Applic!!(iQn~ ...\_.\_\_ Switr:h pmfil,es menu option status Check .... Ai.>pli~iiQn I: 11 ! clu:ck II I Submitter v I User: 01.J.Williams,(Submitter) Role: Sullrnitt.er Pru 11e: PIIUmrose -Boo11e'o'i11e I SWikh pro 1les. I S11bn iii: I ,..-----+-- Submit button Label Appl catoris Searefl o~ate Gen rie IL.al:Itl M \u00b7 or ~Ort AppiioallIns. status Che ct; p[ic;ation = Label Submission and Approval System (LSAS) Industry User Guide Switch Profiles If you have access to multiple profiles, then you can switch between them. If you want to switch from one profile to another, then you must save your work before moving on to the other profile. Otherwise, you will lose your updates in your current profile. Follow the steps below to switch profiles: 1. Select the Switch profiles menu option from the left-hand drop-down menu. 2. Click the Submit button that appears below the menu. LSAS displays the Select a Profile screen (Figure 3-10). September 09, 2019 29 Chapter 3 System Requirements, Login, & User Profile", "I Submitter User: 01-J.Williams,(Submitter) Role: Submitter Profile: Plumrose -Booneville .... . Create new profile Request access -Manaae Users Manaae Sharina I - L Manage Establishments .. Search Orea.le Generic La.t>el Advisa r Imp\u25a1 rt Applica.tio ns Status Check .. I Applicatio11 # I I I Check I --- Profile Associations Would you like to associate a new 1pmfile? There are currently no associated profiles. Label Submission and Approval System (LSAS) Industry User Guide 3. Select a profile from the list and

then click the Submit button. 4. Click the Confirm button to accept your selection. LSAS displays the Submission Successful screen. Manage Sharing LSAS allows the current user to associate label applications with another user. Select the Manage Sharing option from the Switch profiles drop-down menu (Figure 3-16), then click the Submit button. Figure 3-16: Manage Sharing Menu Option LSAS opens the Profile Associations screen (Figure 3-17). Currently, there are no associated profiles shown. Figure 3-17: Profile Associations Screen September 09, 2019 30 Chapter 3 \u2013 System Requirements, Login, & User Profile", "Add Profile Association a)ael a.P1>lications be1onoiM to 11\is profile-may be inefivic,h.1a 11 sna e<1 br users or !his i!)i'OIue with 1heser:, o an,y assodaled llllItiles. You ma;; add a ne\u00b7 profile 11sin4,1 lhe fllim tiel~. D LSAS Training Profile 1 D A.lsoas 'I ,exisdng lalle apptlcations D D A.lso ass!g n access to I ,exisdng la!J4!11 apptlca.tlons 0 LSAS TralnIn Pro e J D A.lso ass! n access to I ,e,xisdng l:mel apptlca.tlons 0 LSAS TralnIn Profile 4 D A.lso as n access to I \u2022ltXisdng 11 apptlcations . ubmit ~ LSAS Trninin!J Profile 1 ~ Also as.st!Jn acoess to all \u2022ex.fistin!I label applications \u25a1 LSAS Trninin!I Profile 2 D Also as.st!Jn acoes.s to all ,e.x.fistin!J label applications \u25a1 LSAS Trninin!J Profile 3 D Also as.si!Jn acoess to all \u2022ex.iistin!I label applications \u25a1 LSASTrninin!I Profile4 D Also as.st!Jn acoes.s to all ,e.x.fistin!J label applications Submit Label Submission and Approval System (LSAS) Industry User Guide Click the Add button on the Profile Associations screen to open a list of all profiles created within the establishment. LSAS will display the Add Profile Association screen (Figure 3-18). The Add Profile Association screen displays the list of available profiles with which the user can be associated. Figure 3-18: Add Profile Association Screen The user selects the checkbox for each desired profile. There is also the option to assign all existing applications to a requested profile. To complete the Sharing function, click the Submit button and then the Confirm button.

September 09, 2019 31 Chapter 3 \u2013 System Requirements, Login, & User Profile", "Add Profile Associations Confirmation ,...-S bmission1 Successful Your selected profile associa~ions have been served. Label appltcations may now be shared wi h the newly assoc ia ed profiles. Profile Associations WouTd you l'ike to as.sodate a new profil'e? ~ Selected profiles will have all current aooess to label applications under this profile revoked. , Additionally, label applications under this profile will no longer be eligible for sharing with the selected profile,s. \u25a1 LSAS lirainin,g ProfiTc 1 Submit Label Submission and Approval System (LSAS) Industry User Guide LSAS will display a Submission Successful message that states the selected profile association(s) have been saved and LAPs can now be shared with the newly associated profile(s). If the user then selects the Manage Sharing option from the drop-down list on the Dashboard, the Profile Associations screen will display the newly associated profile. September 09, 2019 32 Chapter 3 \u2013 System Requirements, Login, & User Profile", "I Submitter User: 01-J.Williams,(Submitter) Role: Submitter Profile: Plumrose -Booneville S11vitch profiles Oreate new profile Request access ~ Manage Users ~ M,:m;;i,n! ~h;;ir,inn \u2022 l.: Manage Establishments I ..... II Search Or,eate Gen eric Lab:el Adlvis\u25a1 r Imp\u25a1 rt Ap;p,licati\u25a1 ns Status Che ck ..... Ap,pl'i'catton # I I Check I Label Submission and Approval System (LSAS) Industry User Guide Manage Establishments LSAS allows users to add, update, or remove establishment data. An establishment can add other establishments, e.g. subsidiaries, to LSAS independently of LPDS. Hence, an establishment can have full control of its users\u2019 access to LSAS. The Manage Establishments functionality can be accessed via the left-hand drop-down menu on the home page (Figure 3-19). Figure 3-19: Manage

Establishments Menu Option September 09, 2019 33 Chapter 3 \u2013 System Requirements, Login, & User Profile", "Label Submission and Approval System (LSAS) Industry User Guide Add an Establishment If you select the Manage Establishments menu option (Figure 3-19), LSAS will display the Establishments screen (Figure 3-20). The establishments in this screen are listed in alphabetical order by Establishment Name. Establishment Names that begin with numbers will appear at the top of the list. NOTE: The Establishments screen can also be accessed during the creation of a new label application by clicking the Add Establishment button on the Establishment Information screen. NOTE: The Establishments screen will be blank the first time the user logs in to LSAS (no establishments will be listed). Figure 3-20: Establishments Screen The Establishments screen provides separate functions to add either a domestic or a non-domestic establishment. 1. Click the Add Domestic or Add Non-Domestic button, as appropriate, to open the Add Establishment screen (Figure 3-21). Establishments Would you like to add a new establishment? Add Domestic | Add Non-Domestic | 333 Meat Corporation 528 Update Remove 701 Foods, Inc. M34814+P34814 Update Remove Global Egg Corporation 691 Update Remove Hayters Turkey Products Inc. 85 Update Remove Marshall Egg Products Company G1612+V1612 Update Remove Quality Beef Company M5070+P5070 Update Remove Stanbroke Beef Pty Ltd. 203 Update Remove Turkey Valley Farms LLC P7669 Update Remove Add Establishment | Add I:stabli.!ihment from PHIS (Click on rbe above button ro yet Esta'bfishme.net data from PHISI Figure 3-21: Add Establishment Screen 2. Click the Add Establishment from PHIS button. September 09, 2019 34 Chapter 3 \u2013 System Requirements, Login, & User Profile", "Search Establishment Search by Establishment Name or by Establishment Number. If searching by Establishment Number, enter only the numeric value; do not enter alpha characters. Establishment Name Establishment Number Search Search Establishment Search by Establishment Name or by Establishment Number. If searching by Establishment Number, enter only the numeric value; do not enter alpha characters.

Establishment Name Establishment Number Search Label Submission and Approval System (LSAS) Industry User Guide LSAS will display the Search Establishment screen (Figure 3-22). Figure 3-22: Search Establishment Screen 3. Type in either the establishment name or the establishment number. NOTE: For the Establishment Number field, enter only the number without the accompanying letter designation. Only one number is allowed for each search. You can enter partial names in the Establishment Name field. Example: Search for all establishments that contain the word \u201cEgg\u201d in the Establishment Name: September 09, 2019 35 Chapter 3 \u2013 System Requirements, Login, & User Profile", "Search Establishment Search by Establishment Name or by Establishment Number. If searching by Establishment Number, enter only the numeric value; do not enter alpha characters. Establishment Name IEgg | Establishment Number | \u2022 \u25a0\u2022 \u25a0

..... \u25a0 \u25a0\u2022 \u25a0\u2022 \u25a0..... I Search | Select Establishment

Establishment Name Number City State Select Papetti's Hygrade Egg Products Inc. G1028 Elizabeth | New Jersey Select Shanghai Egg Rolls Co. M19212+P19212 Beckley | West Virginia Select Reggio's Pizza, Inc. M18349+P18349 Chicago | 111inois Select Establishment

Establishment Name Number City St.ate Select Papetti's Hygrade Egg Products Inc. G1028 Elizabeth | New Jersey Select Shanghai Egg Rolls Co. M19212+P19212 Beckley | West Virginia Select Reggio's Pizza, Inc. M 18349+P18349 Chicago | Illinois Select Heggies Pizza, LLC

M15816+P15816 Milaca I Minnesota . Lincoln Poultry & Egg Co P5585 Select \\"li Select Gammon Brothers Poultry & Eggs P8216 Label Submission and Approval System (LSAS) Industry User Guide 4. Click the Search button. LSAS will display the matching establishment(s) in a table format at the bottom of the screen (Figure 3-23). Figure 3-23: Search Establishment Screen \u2013 Results NOTE: If PHIS is currently unavailable, the Add Establishment screen will display a notification message indicating that LSAS failed to establish a connection. Please wait and try again later. 5. From the results table, locate the establishment that you would like to add to your User Profile and click on its associated Select link. September 09, 2019 36 Chapter 3 \u2013 System Requirements, Login, & User Profile", "Add Establishment Add IEstablishment from PHIS (Click on the above button to get Establishment data from PHIS) Establishment Name\u2022 Lincoln Poultry & Egg Co Establishment Number\u2022 IP5585 Address\u2022 State\u2022 1-Please Select- ZipCode \u2022 Phone\u2022 (Ex: for 202-111-3333, enter 2021113333 and for 1-800-256-5678 enter 18002565678), ~ Required Fields Submit Label Submission and Approval System (LSAS) Industry User Guide LSAS will display the Add Establishment screen. The establishment information from PHIS will be autopopulated into the Add Establishment screen fields in LSAS. In the example used here, the establishment did not have any address information in PHIS, and so these fields appear blank on the screen in LSAS (Figure 3-24). Figure 3-24: Add Establishment Screen \u2013 Auto Populated With PHIS Data If the establishment information from PHIS is incorrect, notify your District Office. The Establishment Name and Establishment Number fields will be populated with read-only data. You cannot edit or delete this information. You can, however, edit the remaining contact and address information fields. NOTE: It is strongly recommended that you do not edit the pre-populated information from PHIS unless it is absolutely necessary. PHIS is the official system of record for establishment information and therefore, the information that is pulled from PHIS into LSAS should be the correct, most current information. 6. Ensure that all required fields have data. For example, PHIS does not auto-populate phone information for establishment records. You must enter this information manually. September 09, 2019 37 Chapter 3 \u2013 System Requirements, Login, & User Profile", "Add Establishment Confirmation Submission Successful You have created a new establishment under this profile. Any new or resubmitted applications submitted under this profile may now be associated with this establishment. Label Submission and Approval System (LSAS) Industry User Guide 7. Click the Submit button. 8. Click the Confirm button. LSAS will display the Add Establishment Confirmation screen which indicates that the new establishment record was successfully created. September 09, 2019 38 Chapter 3 \u2013 System Requirements, Login, & User Profile", "Establishments Would you like to add a new establishment? Add Domestic Add Non-Domestic I 333 Meat Corporation 528 701 Foods, Inc. M34814+P34814 Global Egg Corporation 691 Update Establishment I Add Establishment from PHIS I (Click on the above button to get Establishment data from PHIS) Establishment Name \u2022 Global Egg Corporation Establishment Number\u2022 691 Address\u2022 I 1234 Winding Way City\u2022 !Toronto Country\u2022 I CANADA Postal Code \u2022 IM8Y 2D2 Update Update \u2022 I Update Phone \u2022 (Ex: for 202-111-3333, enter 2021113333 and for 1-800-256-5678 enter 18002565678) 11234567890 1 Submit Remove Remove Remove Label Submission and Approval System (LSAS) Industry User Guide Update an Establishment Follow the process description in this section to update the establishment information for an establishment that is already associated with your User Profile. Select the

Manage Establishments menu option (Figure 3-19). LSAS will display the Establishments screen. From the Establishments screen, click the Update button for an existing establishment. LSAS will display the Update Establishment screen for the selected establishment (Figure 3-25).

Figure 3-25: Update Establishment Screen The Update Establishment screen has all the same features and requirements as the Add Establishment screen for new establishments. Please refer to the Add an Establishment section on page 34 for descriptions of the available fields and functions.

September 09, 2019 39 Chapter 3 \u2013 System Requirements, Login, & User Profile", "Establishments Would you like to add a new establishment? Add Domestic Add Non-Domestic | 333 Meat Corporation 701 Foods, Inc. Global Egg Corporation Remove Establishment Establishment Name: Global Egg Corporation Establishment Number: 691 Phone: 1234567890 Address: 1234 Winding Way Toronto M8Y 202 CANADA 528 Update M34814+P34814 Update 691 Update Submit Remove Remove --\u25a0~| Remove Label Submission and Approval System (LSAS) Industry User Guide Remove an Establishment From the Establishments screen, you can remove an establishment from your User Profile. The establishment information will still exist in PHIS for other label applications, if needed. You can delete an establishment only if the establishment is not associated with a label application, even if the application is only a draft that has not yet been submitted to LPDS. Exception: If you discard a draft application, then you can delete the establishment associated with the discarded draft (as long as the establishment is not associated with any other label applications). 1. Click the Remove button that is associated with the establishment you wish to delete. LSAS will display the Remove Establishment screen for the selected establishment: Figure 3-26: Remove Establishment Screen 2. Click the Submit button. LSAS will prompt you to confirm the removal.

September 09, 2019 40 Chapter 3 \u2013 System Requirements, Login, & User Profile", "Removal Confirmation Submission Successful You have removed an eXjsbng establishment from this profile. New applications will no longer be able to refer to it as an establishment. Existing applications are unaffected. Remove Establishment The selected establishment record cannot be deleted because it is associated with one or more label applications. !Establishment Name: Global Egg Corporation !Establishment Number: 691 Phone: 1234567890 Address: 1234 Winding Way Toronto M8Y 202 CANADA Label Submission and Approval System (LSAS) Industry User Guide 3. Click the Confirm button. LSAS will display the Removal Confirmation screen. This screen indicates the establishment was successfully removed. NOTE: If you attempt to remove an establishment that is associated with a label application, LSAS will prevent you from deleting the establishment and display an error message. Identify an Establishment as Temporary Refer to the Temporary Establishments section on page 132 for details on how to mark an establishment as Temporary.

September 09, 2019 41 Chapter 3 \u2013 System Requirements, Login, & User Profile", "1 3 5 6 7 USDA un,..., sia1e, a \u2022 ..., , ..... z Food Safety and Inspection Service , , , , , , , , ~! ---t 2 | Submitter User: Smith, John Role: Submitter Profile: LSAS Training | Switch profiles Label Applications Search Create Generic Label Advisor Import Applications Status Check Application# | II Check | Dashboard Announcements Headline Web Submissions Status Update Important Update Regarding Label Backlog, Generic Label Approval, and Expedited Review Request Criteria Updated User Guide for Industry Users now available LSAS TIP 4 (updated) -My application was returned to me. Where do I find the reason(s) it was returned? LSAS TIP 8 (updated) -Extraordinary Circumstances LSAS TIP 6 (updated) -I received a Sketch Modified label. Where do I find the explanation of the

modifications that were made? LSAS TIP 1 (updated) -What is a temporary establishment? When should I utilize this function? LSAS TIP 11 -Egg Product Labels and Exotic Species LSAS TIP 10-Label Documentation LSAS TIP 9 -Formula Information Application Messages No label applications available. Drafts No label applications available. Appeals No label applications available. Submitted Applications No label applications available. Adjudicated Applications No label applications available. Returns and Rescinded Applications No label applications available. Home Contact Us Logout -4 ----8 Creation Created Date By 2\13\2017 YODER, I View I LYNN 6\14\2016 YODER, I View I LYNN 8\27\2015 YODER, I View I LYNN 9 7\30\2015 YODER, [ View I LYNN 9\29\2014 YODER, [ View I LYNN 9\29\2014 YODER, [ View I LYNN 9\29\2014 YODER, I View I LYNN 9\24\2014 YODER, I View I LYNN 8\5\2014 YODER, I View I LYNN 5\20\2013 YODER, I View I LYNN View AH 1 0--~ome I USDA Internet I USDA Intranet I FSIS Internet I FSIS Intranet I FOIA I Accessibility Statement I Privacy Policy I Non-Discrimination Statement I Information Quality I USA.gov] White House ~ Version: 2.10.0-QA T04 Label Submission and Approval System (LSAS) Industry User Guide 4 User Interface This section provides information on LSAS\u2019s graphical user interface (GUI). It is based on USDA\u2019s standard GUI requirements and should look familiar to industry users. The LSAS GUI utilizes the standard layout illustrated in Figure 4-1. It incorporates many features that are standard across most LSAS screens. Several of these features are standard on all USDA websites and enhance the intuitiveness and usability of LSAS. Figure 4-1: LSAS User Interface Table 4-1 on the next page describes the LSAS GUI features, as numbered in Figure 4-1 above. September 09, 2019 42 Chapter 4 \u2013 User Interface", "Label Submission and Approval System (LSAS) Industry User Guide Table 4-1: LSAS User Interface Elements Item Name Notes 1 Banner With the exception of the LSAS logo, this banner appears on all USDA web pages. 2 LSAS logo Appears on all screens within LSAS 3 Role Displays the user\u2019s current role; Certain users may be assigned multiple roles and can select a role by using the drop-down list. 4 Navigation bar Navigation Bar Options: \u2022 Home: Navigates to the home page (Dashboard screen) \u2022 Contact Us: Provides point of contact information for the LSAS administration team and a messaging interface \u2022 Logout: Logs the user out of the eAuth Security portal; In order for the user to access LSAS again, the user will need to log back into eAuth. 5 Profile information Identifies the currently logged-in user\u2019s name, role, and profile. Switch Profiles menu: Allows a user to change his role, share applications, and manage establishments. 6 Label Applications menu Appears on the left-hand panel of many LSAS screens; menu options depend upon user role. 7 Status Check menu Allows the user to enter the Application Number for a specific label application in order to locate and access the application quickly. 8 Header \ Screen title Appears on every LSAS screen; describes the functionality in the content area. 9 Content area Central to all LSAS screens, this area of the screen provides the functionality needed to enable the user to perform a task within LSAS. 10 Quick links Appears at the bottom of every screen; displays links to additional resources; displays the current application version. September 09, 2019 43 Chapter 4 \u2013 User Interface", "Label Applications ..... Search Orea.te Generic La.MI Adivis\u25a1 r Imp\u25a1 rt Ap;p'.licati\u25a1 n,s Status Che ck .... Ap;p[icaticm # I 11 Check I Label Applications -&~s~e~ \u2022 A,ppHcatto n # I 11 Check Label Applications 4 S.ea.rch Criea.te Generic La.be! Adivis\u25a1 r Im,p\u25a1 rt A.~licati\u25a1 n,s Status Che ck ... Label Submission and Approval System (LSAS) Industry User Guide The Label Applications and Status Check Menus The Label Applications menu is the primary tool to access

the LSAS functionality. It is customized based on the user's role; the user sees only those navigation links that are appropriate to the user's role. Note: The Label Applications and Status Check menus are expanded by default. You can click the arrow to collapse the menus, if desired. Example: The Label Applications and Status Check menus are expanded by default to show their menu options: The user can click the \u201cUp arrow\u201d ( ) to collapse these menus, if desired. The user collapsed the Label Applications menu: The user collapsed the Status Check menu: September 09, 2019 44 Chapter 4 \u2013 User Interface", "Label Submission and Approval System (LSAS) Industry User Guide Site Map Figure 4-2 graphically depicts screen navigation within LSAS. LSAS Site Map Navigation Menu Headers Check Application Status Label Application Tasks Create LAP Search LAP Generic Label Advisor HOME Contact US Logout Dashboard Pools (Role Dependent) Manage LAP Messages Manage Message Administrator Tasks (Role Dependent) Announcements Rev. 05 Import Applications Figure 4-2: Site Map September 09, 2019 45 Chapter 4 \u2013 User Interface", "Oashooa1cl - ~\" ..... ...\_...\_ ---c-~-\u2022 -t~, lolMIWAI'R T~i --\u00b7~---. ... [ vi... <CDC ,\_ MbBMI.M o,m ----\u00b7 LOilb,t-.. \u2022 ... IIIIO HiJH,UJI ..,\_., .. .... .. ....,,. o,,,\_...\_. ;. --~-\u00b7 '\"\\" -\u00b7 -- i... \u2022 \u00b7IID1tm1 ~\u25a0ill1 ..,\_ - N-<.TrS.le<:L J~~JIDi} IID..Y. oldjodi.-d \"wb---- L\*il~~ I ..,... . ~ 11.i 1111\"'1 1..\_,..., ili.l',l7,'Jt)!! ,I ~-~1 ~ mai. -\u00b7 ~.,\_, - , ... \_.,\_ , .... -.. ,,,.,.... 11~IEI'N .... IHIJ ..... un~u 0.-t.-\u00b7 llb!I A\_.io -.,\_ -Lail~ \u2022 ..,. --SII:MQ'il~ -.,\_ - \u00b7\u00b7 ~.,~ - Label Submission and Approval System (LSAS) Industry User Guide Home Page The LSAS home page, aka the Dashboard screen, provides a point of entry to LSAS. The home page is customized so each user sees information that is relevant to the user's role and responsibilities. The home page consists of profile management, a tasks menu, and pools. For a submitter, the pools are Announcements, Application Messages, Drafts, Submitted Applications, Adjudicated Applications, Returns and Rescinded Applications, and Appeals. Dashboard Pools Depending on the user's role, the Dashboard screen will display specific pools from which the user can access label applications. Some pools are common for all user roles, such as the Announcements and Application Messages pools. Figure 4-3 illustrates a typical Submitter's Dashboard screen pools. Figure 4-3: LSAS Dashboard September 09, 2019 46 Chapter 4 \u2013 User Interface", "Announcements HemHine Creation Cmated By I Da1e Web Submissions Status Update 8/5/2014 04-L.Y o cle r, I View I (Administrator) LSAS TIP 1 o -Label Documentation 8/5/2014 04-L.Y o cle r, I View I (Administrator) LSAS TIP 9 - Formula Information 5/20/2013 04-L.Y o cle r, I View I (Administrator) Webinar Presentations 4/17/2013 04-L.Y o cle r, I View I (Administrator) LSAS TIP 8 -Extraordinary Circumstances 4/17/2013 04-L.Y o cle r, I View I (Administrator) LSAS TIP 7 -Appeal 317/2013 04-L.Y o cle r, I View I (Administrator) LSAS TIP 6 -I received a Sketch Modified label. Where do I find 9/20/2012 04-L.Y o cle r, I View I the explanation of the modifications that were made? (Administrator) LSAS TIP 3-How to Print An Adjudicated Label with Annotations 9/20/2012 04-L.Y o cle r, I View I (Stamps, Modifications, etc.) (Administrator) LSAS TIP 2-Label Image Resolution 9/20/2012 04-L.Y o cle r, I View I (Ac:lm in i strato r) LSAS TIP 1 -How To Avoid Selecting A Temporary 9/20/2012 04-L.Y o cle r, I View I Establishment: LSAS\_Temp## (Administrator) ViewAll Label Submission and Approval System (LSAS) Industry User Guide Announcements LSAS management can post\broadcast general notifications (e.g., system maintenance) which are then displayed in the Announcements pool. This pool is visible to all users, regardless of their user role in LSAS. Figure 4-4: Announcements Pool September 09,

2019 47 Chapter 4 \u2013 User Interface", "Application Messages Application Product Name Creation Created By Message # Date Crispy This submission is for a new label for a brand new product We 91047407 Breaded 611012016 01-J.Williams, will most likely be changing, the label soon, though\_ We submitted I View I Chicken (Submitter) this as \"Sketch\" but we are not sure if it should have been sent as Nuggets \"Temporary\"? Please let us know. Thank you! This LAP is being returned because the text entered for the 09-J.Canavan, \"Processing Procedures\u00b7 section included the wrong, type of info. 91047401 Turkey 619\|/2016 (Sr.Techical (The Submitter entered ingredient information rather than I View I Tetrazinni Staff) processing information.) Please correct and resubmitthe application. Label Submission and Approval System (LSAS) Industry User Guide Application Messages Using LSAS Messages, LPDS technical staff can communicate with industry users regarding any issues for a particular label application. The Application Messages pool on the Dashboard screen will display the most recently created message for each of your label applications (Figure 4-5). This pool is visible to all users, regardless of their user role in LSAS. LPDS will see and respond to any messages you create for your label applications. Figure 4-5: Application Messages Pool For submitters, the Application Messages pool displays the following types of records: \u2022 Messages: The most recent message for a label application will appear in the pool. If a label application has multiple associated messages, only the latest message for the label application will appear in the pool. Messages that were created more than 15 days ago will not appear in the Application Messages pool on the dashboard; however, they can still be viewed on the Messages screen that is accessed via the Available Actions menu, as discussed in the Messages section on page 83. \u2022 Vet EC comments: If an EC application has been vetted by an EC Gatekeeper, any comment that the EC Gatekeeper entered will appear in the pool. If you click the View button for an application in the Application Messages pool (Figure 4-5), LSAS will display all of that application\u2019s messages in a new window. For example, if the user clicks the View button for the second message shown in the image above, LSAS will display the Label Application Message screen for the associated label application (see Figure 4-6 on the next page); this screen shows all the messages that currently exist for the label application. September 09, 2019 48 Chapter 4 \u2013 User Interface", "Label Application Message label Aipplic.moa Samma:ry Appli.callon N--Umbtrl BIIIIIDt: 91047401 Nsame DI Product: SUbmil!tl:1!3): Cammi stal:tlls: CIIffllll Slaws. Stt etr. Subml9sloo Type: Appeal Status: , ess g-e Turkey Telrazinni ACIAE Fooos ill! mlllional \u2022 us SW R.eltuned Q6\|u2022f, WHEELER, (TedInlc:al Sta at & '9J'.WUi 3:31:43 P , Web Und rAppt Tlhis LAP i~ JJe ng relvm~d be<:3ij~e \u00b7 e text ernere~ r11r 1he ~e~sln,g ?ioC'!!(lur(!).~\u00b7 e~on inclu!J~d 1he-'i'fflllll In)e gl n!Q, (Tlhe Sul)mU1.er entered rnegre\\;!ien1 l11lorm31ii;;n r,!!her an p~ce~~lru;i dnro~on.) Pl~a~e corre~ and resv~mil e applca on, i>uhlished To Put.1isl'I To Inttmal Use~ MCI Sul'.lmi ~r Application Product Orealiorn CteaiMB: M~saoe # Name, [b!e Tnls LAP I\$ bting fllllmed IH!aUH ll'lt tioo tnltred for III.ti \\"PrOctiHinQ 91047401 Tort: 6.IW2016 09-J.Ganava.n, Pmcelllt.s\" Hetion illd1111 d \u00b7u1u1 wro11,11 trlle 01 inro. (Tile Sullfljbr uilered Telra2iMI (Sr.TedInlcal Sta Ingrelitnt in'lormaliM ra1111e1 ll'an ~ssing inl'Mmlllon:J P'lease corred and !~SUI! 'Int aPPI:caUon. 91047401 Turtey 61912016 !)1-J,Wll~ams, we are s.eeking wffill'l)rary appr0\\'3I ror olJ!r rema \u00b7ng labels until new labels are Te .az!Mi (Sullm :ter) made. LPIOS':s ear1i~t response woul! be mu(ft appreote<ll (Page 1 ol 1) Re~urn to Da bo11rd Label Submission and Approval System (LSAS) Industry User Guide Figure 4-6: Label Application Message Screen On this screen,

you can view the messages that exist for the label application. If you wish to create a new message or delete a message that you created, use the Available Actions \u201cMessages\u201d action to access a different screen where you can create or delete messages. This screen is discussed in detail in the Messages section on page 83. September 09, 2019 49 Chapter 4 \u2013 User Interface", "(Page 1 of 2) Next Enter Piag,e No: ~-~I B Retl!! rn to Dash hoa rid I Label Submission and Approval System (LSAS) Industry User Guide Application Messages \u2013 View All The \u201cView All\u201d screen for the Application Messages pool is accessed by clicking the View All link at the bottom of the pool on the dashboard screen. Messages on the View All screen are grouped into sets of 100 messages per page. The \u201cView All\u201d screen for the Application Messages pool includes the following paging elements: \u2022 Page number of the currently displayed page (read only) \u2022 Total number of pages (read only) \u2022 Input field (numeric): The user can enter a specific, desired page of messages. \u2022 Go button: When clicked, LSAS will display the specified page. NOTE: These paging options will appear on the View All screen only if there are more than 100 messages. Messages that were created more than 15 days ago will not appear in the View All screen for the Application Messages pool; however, they can still be viewed on the Messages screen that is accessed via the Available Actions menu, as discussed in the Messages section on page 83. September 09, 2019 50 Chapter 4 \u2013 User Interface", "Drafts Application # Product Name Product Type Status Last Modified Date , -I - 91093438 Sweet & Tangy Texas BBQ Meat Draft 12\6\2018 Select 91093384 Macaroni Casserole with Ham & Bacon Meat Draft 12\5\2018 Select I 91093426 Corn Chowder with Ham Meat Withdrawn 12\5\2018 Select I~ f---I 91093427 Family Size Vegetable Beef Stew Meat Withdrawn 12\5\2018 Select ~ I 91093377 Spaghetti with Meatballs in Traditional Sauce Meat Withdrawn 12\3\2018 Select ~ 91093378 Hearty Turkey Noodle Soup Poultry Withdrawn 12\3\2018 Select I =====,----- 191093379 Tasty Chicken Noodle Soup Poultry Withdrawn 12\3\2018 Select I ~ 91093380 Meatball Hero Sub Sandwich Meat Draft 11\27\2018 Select I .----1 91092324 Thanksgiving Turkey & Dressing Dinner 32 OZ Poultry Draft 11\13\2018 Select I =====,----- 191092238 Cheesy Ham & Egg Breakfast Scramble Egg Withdrawn 11\13\2018 Select I Label Submission and Approval System (LSAS) Industry User Guide Drafts The Drafts pool lists the following applications: \u2022 Applications that have been created, but which have not yet been submitted to LPDS for evaluation; These applications may be in a partially completed state pending further information. \u2022 Applications that have been withdrawn Figure 4-7: Drafts Pool Inactive draft applications (never submitted to LPDS) will be deleted after 30 days. LSAS will send a warning notification email on the 25th day indicating, \u201cThe system has not detected any activity in the draft <application number>, and it will be removed after five days.\u201d Exception: LSAS will not send a notification for any deleted draft label application that has neither a Firm nor an Agent email address indicated. Nevertheless, LSAS will delete the inactive draft application. If a submitter wishes to keep the inactive draft application from being deleted because he intends to submit it at a later time, then he must update the draft label application. September 09, 2019 51 Chapter 4 \u2013 User Interface", "Submitted Applications Application Product Name Product Status Last Modified Last Modified By # Type Date - 91023874 Meatballs in Tomato Basil Sauce Meat Pending 411\2015 04-L Yoder, (Administrator) Select -- 91023982 Chicken Parmesan Poultry Received 3\30\2015 01-J.Williams, (Submitter) Select 91023863 Hearth Favorites Chicken Pot Pie Poultry Pending

3\27\2015 0 6-M WHEEL ER, (Technician Select Staff) 91023967 Jameson's Hearty Beef Stew Meat Pending 3\16\2015 04-L Yoder, (Administrator) Select -- 91023977 Turkey and Cheese Pita Pockets Poultry Received 3\3\2015 01-J. Williams, (Submitter) Select 91023975 Egg & Cheese Breakfast Croissant Egg Received 2\12\2015 01-J. Williams, (Submitter) Select 91023964 Chicken Pot Pie Poultry Pending 1\27\2015 02-G. Holcomb, (AMS Select Adjudicator) 91023879 Heartland's All-Beef Frankfurters Meat Received 11\20\2014 01-J. Williams, (Submitter) Select 91023877 Hearty Beef Stew Meat Pending 11\19\2014 04-L Yoder, (Administrator) Select 91023873 Dee-Lite Zesty Chicken Cheese & Poultry Pending 11\17\2014 04-L Yoder, (Administrator) Select Spinach Bites ~ -~ -- View All Adjudicated Applications Application Product Name Product Status Last Modified By # Type Date 91023777 Master's Chicken Marsala Poultry Sketch 312712015 04-L Yoder, (Administrator) Select 91023978 Just Like Mom's Chicken Pot Poultry Temporary 31612015 04-L Yoder, (Administrator) Select Pie 91023966 Tender Turkey Medallions Poultry Sketch 1129\2015 04-L Yoder, (Administrator) Select 91023875 Savory Chicken and Rice Poultry Sketch 11\19\2014 04-L Yoder, (Administrator) Select 91023778 Tex-Mex Chili Supreme Meat Sketch 1016\2014 09\J. Canavan, (Sr Technical Select Staff) 91009824 Lower Sodium Ham Water Meat Sketch 7118\2013 05-S. JONES, (EC Gatekeeper) I Select I Added 91009875 Ham Water Added Meat Temporary 71812013 09\J. Canavan, (Sr Technical I Select I Staff) 91009808 Turkey Breast Poultry Sketch 71112013 HARRINGTON, TAWANA I Select I 91009786 Cooked Ham Water Added Meat Sketch 7\112013 09-J. Canavan, (Sr Technical I Select I Staff) 91009783 Country Ham Biscuits Meat Sketch 71112013 09-J. Canavan, (Sr. Technical I Select I Staff) View All Label Submission and Approval System (LSAS) Industry User Guide Submitted Applications The Submitted Applications pool includes applications that were submitted and which have not yet been reviewed and adjudicated by LPDS. This pool contains both first-time submissions and resubmissions. Figure 4-8: Submitted Applications Pool Adjudicated Applications The Adjudicated Applications pool includes applications that have been reviewed and adjudicated (approved) by LPDS. Figure 4-9: Adjudicated Applications Pool September 09, 2019 52 Chapter 4 \u2013 User Interface", "Returns and Rescinded Applications Application# Product Name Product Type Status Last Modified Date Last Modified By 91023876 Corned Beef Hash Meat Returned 1111912014 04-L Yoder, (Administrator) Select 91023741 Beef Brisket Meat Returned 1111912014 06-M. WHE.E.LE.R, (Technical Staff) Select 91023745 Spinach & Feta Quiche Egg Returned 8\26\2014 04-L Yoder, (Administrator) Select 91023742 Tomato and Onion Quiche Egg Returned 8\26\2014 04-L Yoder, (Administrator) Select 91023728 Mini Cheeseburger Sliders Meat Returned 8\25\2014 06-M. WHE.E.LE.R, (Technical Staff) Select 91023686 Sirloin Beef Tips in Gravy Meat Returned 8\21\2014 06-M. WHE.E.LE.R, (Technical Staff) Select View All Appeals Application # Product Name Product Type Application Status Appeal Status Last Modified Date 91047401 Turkey Tetrazinn I Poultry I Returned I Under Appeal 16\10\2016 Label Submission and Approval System (LSAS) Industry User Guide Returns and Rescinded Applications The Returns and Rescinded Applications pool includes: \u2022 Returns: Applications that LPDS returned to the submitter for additional information or correction. A returned application can be resubmitted once the submitter adds the requested information or performs the requested corrections. \u2022 Rescinded applications: Applications that were previously adjudicated (approved) by LPDS, and for which LPDS subsequently revoked the approval Figure 4-10: Returns and Rescinded Applications Pool Appeals The Appeals pool

includes appeals for applications that were previously adjudicated (approved) or rejected by LPDS. Figure 4-11: Appeals Pool UI Label Description Application # The application number Product Name The name of the product Product Type Meat, Poultry, Egg, etc. Application Status Displays the Application Status of the label application associated with the appeal. Appeal Status Displays the Appeal Adjudication Status. \u2022 If LPDS has received, but not yet adjudicated the appeal, the value will be \u201cUnder Appeal\u201d \u2022 If LPDS has adjudicated the appeal, the value will be either \u201cAppeal Approved\u201d or \u201cAppeal Denied\u201d Last Modified Date Displays either the appeal adjudication date or the submission date (whichever occurred most recently). \u2022 If LPDS has received, but not yet adjudicated the appeal, then this is the submission date. \u2022 If LPDS has adjudicated the appeal, then this is the adjudication date. September 09, 2019 53 Chapter 4 \u2013 User Interface", "Submitted Applications Application Product Name Product Status last \u2022odified last Modified By '11 Type Date 91023874 I,leatballs in Tomato Basil Sa1.1ce Meat Pending 41112015 04-L Yoder, (Mministrator) [ Select ] 91023982 Chleken Parmesan Poultry Received 313012015 01-J.Williams., (SubmlUer) I Select 91023863 Heartli Favorites Chiclctln Pol Piil' Poultry Pending 312712015 06-MWHEE:LER. (TelliInical Select staff) 91023'967 Jameson\u00b7s Hearty Beel Stew Meat Pemting 3\1612015 04-L Yooer, (Mmlnstrator) Select 91023977 Turkey and Ch,ees,e Pila. Pockets Poultry Received 3\312015 01.J.Williams, (SubmiHer) select 91023975 Eg9 & Cheese Breakfast. Croissant Eg11 Received 211212015 01-J}Williams, (SubmiUer) elect 91023'964 CllOken Pot Pie Poultry PeMing 112712015 02-GJ-totoomll, (N-JS Select AQ.iu di ca tor) 91023879 Heartland's AJI-BeefFrankfTTJrters Meat Received 11120\2014 01-J.Williams., (SubmlUer) Select 9W23877 Hearty Beer stew Meat PeMing 1111912014 04-LYooer, (Mministrator) select 91023873 Dee\u2022Ule Zesfy Chicken Cheese & Poultry Pendng 1111712014 04-L Yoder. {Administrator} Select Spinact1 Bites ~ Submitted Applications Application Product Name Product Status last P.1od ifled ast Modif1ed By # Ty,pe Date 91023874 Meatballs in Tomato :Basil Sauce Meat Pending 4\112015 04-L Yoeler, (Administrator) Select 91023982 C!hlcicen Parmesan Poullly Receil'eel 313012015 01-J.Williams, (Submitter) Select 91023853 Hearlli Favorites Chieken Pol Pie Poultr; Pending 312712015 06-M.WHEELER. Select (Technical staff) 91023967 Jameson's Hearfy Be,efstew Meat Pendin11 311612015 04\u2022L Yoder, (Administrator} Select 910239'77 Turkey anel Cheese Pila PoC:llets Poullry Received 313f2015 01.J.Williarns, (Submitter) Select 910239\u00b775 Egg & Oheese Brea111as1 croissant Egg ReceiveCI 2\1212015 01-J.Williams, (Submitter) [select J 91023964 Ohicllen Pot Pie Poullry Pending 112712015 02-G.Holcomll, (AMS Select ADJUdicator) 91023879 HeartJ;and's All-Beel Frankfurters Meat Receil'ed 1~120\2014 01-J.Williams, (Submitter) Select 91023877 Hearty Beef Stew Meat Pending 11119\2014 04-L Yoder, (Administrator) Select 91023873 Dee-Lite Zesty Chicken Cheese & PoUltr; Pending 1111712014 04-L YOCler, (Actminisllator) Select Spinach Brtes 91023645 F~eMI)\\"s Fnect Cnic~en Poultr; ReceiveCI 8181201<1 01-J.Williams, (Submitter) Select 91023642 Bentte)fs Breal



All Label Submission and Approval System (LSAS) Industry User Guide 5 Menus and Functions

View Home Page and Dashboard The LSAS home page, aka the Dashboard screen, provides a point of entry to LSAS. The dashboard takes up most of the screen and is customized so that each user sees information that is relevant to the user's role and assignments. The left-hand navigation panel provides access to user-specific features and functions. Regardless of user role, the Dashboard screen will always include the following pools:

Announcements Application Messages Figure 5-1 is a typical dashboard as seen by a user with the Submitter role. Other typical pools appearing on the dashboard for a Submitter are Drafts, Submitted Applications, Adjudicated Applications, and other pools, as previously described.

September 09, 2019 57 Chapter 5 "Menus and Functions", "Drafts Application Product Name Product Status Last Modified Type Date 91032752 Chris Test Alignment-4 Poultry Oran 9130\2015 .1-I Select I\_91032751 Chris Test Alignment-3 Poultry Oran 9130\2015 LI Select I\_91032750 Chris TestAlignment(As Poultry Draft 9130\2015 I Select I Submiller)-2 91032749 Chris Tes!Alignment(As Poultry Oran 9130\2015 I Select I Submitter) 91032747 Cyrano's Famous Beef & Onion Meat Oran 9\2912015 I Select I Ptua 91032746 C)Tano's Famous Meat Lover's Meat Oran 9\29\2015 I Select I Pizza 91032583 VRTest005--15 Poultry Withdrawn 511512015 I Select I View All Submitted Applications Application# Product Name 91032745 Cassie's Chicken Parmesan I Select I 91032743 testing nonEC app grouping I Select I 91032744 test EC application Poultry Recei11ed 9\25\2015 J Select L 91032741 test EC grouping Meat Pending 9\22\2015 I Select I I Select I I Select I 91032733 EC9\18 Poultry Recei11ed 9117\2015 I Select I 91032735 non EC Meat Recei11ed 9117\2015 d Select I 91032730 test temp app Poultry Pending 9115\2015 d Select I 91032729 testEC9\11 Meat Recei11ed 9115\2015 d Select I View All Adjudicated Applications Application # Product Name Product Type Status Last Modifed Date 91032742 test EC sorting9\23 Poultry Sketch Modified 9\24\2015 I Select I 91032737 Buddy's All-Beef Hotdogs Meat Sketch Modified 9117\2015 I Select I 91032715 teslinr;i 123456 Poultry Sketch 9\3\2015 I Select I 91032716 christesID90315 Poultry Temporary 9\3\2015 I Select I 91032714 layered file Meat Sketch 9\2\2015 I Select I- 91032682 test inspector Poultry Sketch 7130\2015 I Select TI 91032606 ec app7-20 Meat Sketch 7\20\2015 I Select I 91032603 New Gen Chicken Com Dog E,o Sketch 7117\2015 I Select I 91032593 Purple 2 RESUBMISSION Poultry Sketch 6123\2015 I Select I j 91032594 Purple 3 Poultry Sketch 6122\2015 I Select I View All Returns and Rescinded Applications Application Product Name Product Status LastModifed \u2022 Type Date 91032736 Turkey& Swiss Pita Pockets Poultry Returned 9117\2015 I Select I 91032684 inspecotr tyson45102 Meat Returned 7130\2015 -kl Select I\_91032642 temp3 Poultry Returned 7129\2015 I Select I 91032613 reg app Meat Returned 7\21\2015 I select I 91032609 EC\11721 Poultry Returned 7\21\2015 I select I 91032587 Lynn VR2 Meat Returned 6130\2015 I Select I 91032590 testdownload annotation for Poultry Returned 6\25\2015 I Select I submitter 91032595 Purple 4-RESUBMISSION Poultry Returned 6\23\2015 I select I 91032582 VRTeslC05-15 Poultry Returned 5115\2015 I select I VieWAll Appeals No label applications .wailable Home I USDA Internet I USDA Intranet I FSIS Internet I FSIS Intranet I FOIA I Accessibility Statement I Privacy Policy I Non-Discrimination Statement I Information Quality I USA gov I ~ Version: 2.6.0 Label Submission and Approval System (LSAS) Industry User Guide Figure 5-1: Typical LSAS Dashboard for Submitter The Submitter can navigate LSAS using the navigation menus or directly via the pools. Typical tasks include

searching for, selecting, and viewing applications from the available pools. The left navigation panel includes menu options for the Search and Status Check functions. More importantly, the Create menu option is the tool that the submitter will utilize to create and submit an application in LSAS for evaluation and adjudication. See Chapter 7, Submit a Label Application, for the label application submission process.

September 09, 2019 58 Chapter 5 \u2013 Menus and Functions", "Application Messages Application Product Name Creation Created By Message # Date 91047407 | Crispy Breaded Chicken Nuggets 17\|/2016 | 09-J.Canavan, (Sr.Technical Staff) | Please contact FSIS regarding this label application. 11 View | Label Application Message Label Awticalion Summary ApI)liC3~0il NumMr J Ba\u00ab,ode:91047407 Name-or Produ Crispy Elreadei:I Ohid:en Nuggets Submilled Ely; AC! E Food~ Inlilmational \u2022 US SW Cu\u00abent Slarus: Siattxitl Mo<li eel cu rentSlarus Set By. 06-I,IJM-1EELER. (T@Oln ear Stal1').at712612016 2:14:25 PM Submission TypE!: Web Ma nnge mls ap,pllcatfon Ptaase eo:ntad FSIS regarding 1111s la Mt app,Ilca~on. Ptl'.blisII d TO F'ubllsh To Intllma.I users ancl Su11mllt111 91047407 91047407 P,roduct Name CriiiPI' Blea-dad Chleken Nuggets CdSP)' B'lea!led cn1c1:en Nuggets (Page 1 of O ~eturn to I);shbo--, rd CttlliOll Dale 6110\|/2016 G.9.J.Cmavan, (Sr.TectiniCil1 Stall) 01.J.W41 ams. (SUBminer) T'lis su bmissIon ts 1or a n!!'w 1a11e1 ro, a brand Mv,1 procrut we '1!,ill most llkllll' b;fl cnanglng Ille lallel SOO'I, ougn. We SU bmitl~CI In s as \u00b7s~etcnbu1 we-are not su1e i!i!Shour<1 nave beeri sent as ,em,porar)\"?flease lel oo 1:now. Tnant you! Label Submission and Approval System (LSAS) Industry User Guide Application Messages View a Message\|/Announcement 1. Click the View button for an application in the Application Messages pool. 2. The Label Application Message screen displays all the messages that are associated with the selected application (Figure 5-2).

Figure 5-2: Label Application Message Screen

Label application message details include summary information for the label application, including the application\u2019s current status.

3. If a response to the message is desired, click the Manage this application button. For additional information, see the Messages section on page 83.

4. Click the Home link in the navigation bar to return to the Dashboard screen.

September 09, 2019 59 Chapter 5 \u2013 Menus and Functions", "Application Messages Application Product Creation Created By Reviewer Message # Name Date | I am denying the adjudication decision of \"Sketch Modified\" made by Gail Smith 91079069 Whtte Bean 9\|/1112017 05-WHITE, because there was no indication that the I View | Turkey Chili (Administrator) reviewer made any modifications to the values that the Submitter provided for the I original submission. - Turkey 08-S.JONES, Your EC request has been approved. Thank I View | 91079068 9\|/1112017 you! -S. Jones (LSAS LPDS EC Lasagna (EC Gatekeeper) Gatekeeper) Steak & Egg This label application was adjudicated as 91079008 Breakfast 9\|/1112017 1 05-Abadir , 05-WHITE, \"Temporary\" because you indicated you only I View | Burri1o (Administrator) (Administrator) had 5,000 labels left and would only be using the remaining latJels for the next 30 days. We need to submit another similar label Turkey & Bechtold, 105-Abadi r , application that only has one slight change to I View | 91079067 Stuffing, 9\|/11\|/2017 Christina (Administrator) the label. Can we attach it to this current Family Size application so that they stay associated within L the LSAS system? ---~---

Application Messages Application Messages Application Product Creation Created By Reviewer Message # Name Date | I am denying the adjudication decision of \"Sketch Modified\" made by Gail Smith 91079069 Whtte Bean 9\|/11(2017 05-WHITE, because there was no indication that the I View | Turkey Chili (Administrator) reviewer made any modifications to the values that the

Submitter provided for the original submission. Turkey 08-S.JONES, Your EC request has been approved. Thank I View I 91079068 Lasagna 9\11(2017 (EC Gatekeeper) you! -S. Jones (LSAS LPDS EC Gatekeeper) Steak & Egg This label application was adjudicated as 91079008 Breakfast 9\1112017 1 05-Abadir , 05-WHITE, \"Temporary\" because you indicated you only I View I Burrito (Administrator) (Administrator) had 5,000 labels left and would only be using the remaining labels for the next 30 days. We need to submit another similar label Turkey & Bechtold, 105-Abadir , application that only has one slight change to I View I 91079067 Stuffing, 9\1112017 Christina (Administrator) the label. Can we attach it to this current Family Size application so that they stay associated within the LSAS system? (Page 1 of 1) Return to Dashboard Label Submission and Approval System (LSAS) Industry User Guide View All Messages The Applications Messages pool (as with the other pools on the Dashboard) can only display an abbreviated list. The View All option allows you to display the complete list of messages. 1. Click the View All link for the Application Messages pool. LSAS displays the Application Messages screen (Figure 5-3). Figure 5-3: Application Messages Screen -View All Results 2. Click the Return to Dashboard button to return to the Dashboard screen. Please also refer to the following section for more information on managing messages: Messages, page 83 September 09, 2019 60 Chapter 5 \u2013 Menus and Functions", "Submitted Applications Al)pliel Oil ti PFO<IUCt rtame Produl T'fil)e s s L t .. O<hi'led Oate st Modi By 91018293, PDF' fe,st:)12 !eGJ Rei;eL\u00a5ec1 4f21'i2Q,14 01-J.Williams, (Subrnille1I 91018299 f&s1EGapp\_~ Poolrly Ret!t\u00a5ec1 4121'2014 01 \u2022,I.Wlllaams, (Sllbmill!) 91(118298 eca~p\_4 Pooltry Receveel 4\2112014 01.J. ill;ams, (&fbnll! n 3] ----- Manage Application LabelApplication Summary-----; Application Number I Barco de: 91047604 Name of Product: Submitted By: Current Status: Current Status Set By: Submission Type: Available Actions: View Create Appeal Download Messages Manage Access Summary Chicken Alfredo Dinner, 16 02ACME International Foods Temporary 04-L.Yodler, (Administrator) at 7126\2016 11 :59:12 AM Web Select Label Submission and Approval System (LSAS) Industry User Guide Select a Label Application The pools on the Dashboard screen are the primary tools that the submitter will use to access all label applications, whether they are drafts, returns, appeals, or resubmissions. All label applications are sorted by date. The LAPs with the oldest submission dates will be sorted to the top of the pool lists. In this section, as an example, we will pull a LAP from a pool. 1. Click the Select button for a label application in a pool. Figure 5-4: Select a Label Application from a Pool The Manage Application screen opens (Figure 5-5). This screen provides summary information about the application, including its current status. 2. Click the Available Actions drop-down arrow ( ) to select an action. The available actions will be rolespecific. 3. Select \u201cView\u201d from the Available Actions drop-down list to perform actions needed to review the label\u2019s Form 7234. Figure 5-5: Manage Application Screen \u2013 Available Actions Drop-down Options September 09, 2019 61 Chapter 5 \u2013 Menus and Functions", "I Sullmller User: 01-j.Williams,(Sut11nlter) Role: Sutimiller F'rrolil e: Pl umros e -Boo nevi I le I Switct, profiles vi II Submit I Label Applications Se1rdl I Cre<11te G~rn~ric La'b~! Admcr Import Appcalions Slab.is Clledc Application ~ I II Che<:k I Label Application Search Note: Ali datesearches are Inclusive of the specified dates. Establishment Number Application Status Any Draft Extension ofTemporary Pending Received Rescinded Returned Sketch Sketch Modified Temporary Earliest Submission Date Latest Submission Date Earliest Status Date Latest Status Date Earliest Expiration Date Latest

Expiration Date Approval Number vi . . . Label Submission and Approval System (LSAS) Industry User Guide Search for a LAP or AP 1. If the navigation panel is not displayed, click the Home link in the menu bar. 2. Select the Search menu option on the left navigation panel. LSAS displays the Label Application Search screen (Figure 5-6). Figure 5-6: Label Application Search Screen 3. On the Label Application Search screen, enter your criteria in one or more of the fields. The search fields available on the Label Application Search screen include the following fields. Refer to the Glossary in Appendix A for a description of the search fields. September 09, 2019 62 Chapter 5 \u2013 Menus and Functions", "Label Submission and Approval System (LSAS) Industry User Guide Date Fields \u2022 Earliest Submission Date ; Latest Submission Date \u2022 Earliest Status Date ; Latest Status Date \u2022 Earliest Expiration Date ; Latest Expiration Date \u2022 Earliest Appeal Adjudication Date ; Latest Appeal Adjudication Date Textbox Fields Textbox fields allow a maximum of 30 characters. \u2022 Establishment Number \u2022 Approval Number \u2022 Name of Product \u2022 Name and Address of Firm Users can enter the percent symbol (%) as a wildcard in textbox fields to perform searches on partial text strings. Some examples of wildcard searches in the Name of Product field include: \u2022 %hot dog -All label names ending in \u201chot dog\u201d will be found. \u2022 hot dog% -All label names beginning with \u201chot dog\u201d will be found. \u2022 %hot%dog% -All label names that contain the words \u201chot\u201d and \u201cdog\u201d will be found. \u2022 hot dog -Only label names with the exact name of \u201chot dog\u201d will be found. Drop-down List Fields Drop-down list fields allow you to select a single value from a list. Click the downward facing arrow to the right of the field label name to display the complete list, then click the desired value. \u2022 Appeal Status \u2022 Resubmission Listbox Fields Listbox fields allow you to select one or multiple values simultaneously. To select multiple values, press and hold down the Ctrl key while you click on each of the desired values. \u2022 Application Status \u2022 Approval Request Type \u2022 Type of Product September 09, 2019 63 Chapter 5 \u2013 Menus and Functions", "Label Application Search Results (1 of 1) Sea\00b7rcn ag.ain EST. = t.11~ ~ + P2646 EST. = :Pe '\\" Pe..tirq l'eooirq Sketcl Status Date OI\1612015 10\2ll.ml 4 0:9117\2014 02\09\2ll5 Yes 10i2912ll I 4 No 08\19121114 Yes 08\20\2012 08\1612012 Yes EST. = Temporary 07\03.l28 2 ~12 No Records: 5 Label Application Search Results EST. 20722 07J01812013 Name of Prod'uct Ja =-0.n\00b7s Hearty 8-92\ Ste-N Retest 1247S Beel Ste'N All-Beef Hot Dcgs ROAST BEEF Corna! Beef 07J08J\2013 tkat ~\_at IJieat .Approval R,e,g;u.est I:il!!t Sl.etc Sketcl Sketcl IJieat Sketcl IJ>e.at Temporary 11112ll 3 Yes ,1ea1 Items per p,agl": ~ Status Date 10t151W13 Acme F\\"\\5 I nt:rnatio.~'l-1200 Co.rpor~t: Ellsd, S it: Y\00bb-A, Re-to, Virginia, :W1~1. UNI1'ED STATES, @005551212, IKntS.e M'.eats- 888 West 22nd Street, , Little Rocle, Arkar>SaS, I&D!!!, UNITED STA1'ES, :!-01C<140878, JO:h Ham Cormpa. y1st Line AM.ress, , Tyler, Texas, 40TTI, UNITED STATES, 3793221239, 100 p;IL1m.rose Drive, , &or.evilk!:!, I.ltsSiss-\Ppi, 33829, UNITED STATES,(M1)7202615, PI <>:: USA, loc.- 100 :Phrrue:se DriYe, , Boor.eviine, ikltsSiss:ippi, 33829, UNITED STA1'ES, (M1) 7202615, Label Submission and Approval System (LSAS) Industry User Guide 4. Click the Search button. LSAS displays the Label Application Search Results screen (Figure 5-7) which lists all the label applications that met the search criteria. Figure 5-7: Label Application Search Results Screen Open a Label Application From the Search Results List From the resulting list of LAPs, locate the LAP that you want to edit or to view. Click the application\u2019s associated App# link from the leftmost column to open the Manage Application screen. Continue to the Manage Application

Actions section on page 67 for complete details on the Manage Application screen. September 09, 2019 64 Chapter 5 \u2013 Menus and Functions","USDA

UnlodSllotHDopnr\_,lolAgl1cullure -= Food Safety and Inspection Service LSAS L1bel Submlnlon and Approval Sy\u2022l\u2022m Dashboard Use~ 01-J\_Wimams. Announcements (Submitter) Role: Submitter Headline Creation created By P,ome; Plumrose -8oone-111e Date Web Submissions Slarus Updae 815\2014 04-LYOCler, I View I I Switch ,profiles vi (\u2013dmlnf-str;alor) I Submit I LSAS TIP 10 -L3bell Documentati(ln 81512014 04-LYocler, I View I (Mministfator) Label Applications LSAS nP 9-Fo1m1.11a 1nlormation !ir.?Of.1013 04--LYOCler, I view I (MmlnlstJator) seartn CIMlt Webinar Presentations 4'1712013 04-LYocler, I View I G1!!n111ric LI!lbel Advisor (Mmini,s!rialor) txins 04--L YOCl, I View I LSAS TIP 8 -Emaort1nar, Circumstanoes 4{17\2013 (I\\(Imlnisll'at.ol') status Chee!.. Appliealion , LSAS TIP 7 -Appeall 3\712013 04-LYoCl, I View I I 11 ChEck I (\u2013dmini.stJalor) LSAS TIP 6-1 received a Skelch IAodified label. Wllere do I find 91'20\2012 04-LYocler. I View I tne e,p1ana~on or the moeliflcations trtat were made? (A(lminiStl3IOI') Status Che ct .... A,pp'licatfcm # .\_I 91\_ae\_39\_84 \_ \_\_\_,I IL.-.\u00a2.~--~--~-.JI Label Application Status Check Labe:11 A1ppl'tca1iion Smnmary-----\u00ad Application Number\ Barcoe: 91023,984 Name of the Product: Tasty Turkey Tenders Submitted By: Ou rre nt Status: Ou rre nt Status Set By: Submission Type: Acme Foods International Pending 04--L.Yodler, ,(Administrator) at4J31201512:46:13 PM Web Manage thi,s applirati:on Label Submission and Approval System (LSAS) Industry User Guide Use the \u2018Status Check\u2019 Function to Open a Specific LAP If you know the application number of the label application you wish to view, you can use the Status Check function to open the application directly, rather than having to search for it in the dashboard pools. In order to use this feature, simply type the application number into the textbox, then click the Check button. LSAS will display the Label Application Status Check screen for the selected label application (Figure 5-8): Figure 5-8: Label Application Status Check Screen September 09, 2019 65 Chapter 5 \u2013 Menus and Functions","Label Application Status Check LabellAppl'ication Summary-----1 Application Number I Barcoe: Name of Product: Submitted By: Current Status: Current Status Set By: Submission Type: 91047604 Ohicken Alfredo Dinner, 16 oz. AOME International Foods Pending 04-L.Yoder, (Administrator) at 712612016 1135:48 AM Web The application cannot be accessed until it has been adjudicated by LPDS. Please contact your LSAS Administrator only if you need to make additional edits to the application or if the application needs to be withdrawn Label Submission and Approval System (LSAS) Industry User Guide Pending Applications When a label application is submitted to LPDS via LSAS, the submission is originally assigned a status of \u201cReceived\u201d. LPDS will change the status from \u201cReceived\u201d to \u201cPending\u201d in order to evaluate the application. After you submit an application, you can open it via LSAS to view its details up until the point that LPDS changes the status to \u201cPending\u201d. LSAS prevents the Submitter from opening or viewing a label application that is currently in Pending status, and the label application will continue to be inaccessible to the Submitter until it has been adjudicated by LPDS. If a Submitter tries to access the Manage Application screen for an application that LPDS has already changed from Received to Pending, then LSAS will display a message (Figure 5-9) that indicates the application cannot be accessed until it has been adjudicated by LPDS, and to please contact the LSAS Administrator only if you need to make additional edits to the application or if the application needs to be withdrawn.



document in the viewer. September 09, 2019 68 Chapter 5 \u2013 Menus and Functions", "1 2 3 4 5 6 7 8 9 BJ Label Submission and Approval System (LSAS) Industry User Guide 4. Click the Save button to save any changes To return to the Manage Application screen, click the Exit Viewer button (4). Print, Zoom, Pan, and Rotate Operations The print icon enables you to print. To zoom in or out or to pan right or left in the document, click the appropriate icon. 1 Print 2 Zoom Out 3 Zoom In 4 View Image Full Size 5 Zoom in to the selected rectangle 6 Pan on drag 7 Rotate the selected image 90 degrees counter-clockwise 8 Rotate the selected image 90 degrees clockwise 9 Rotate the selected image 180 degrees (flip the image vertically) Edit Select the \u201cEdit\u201d option to open a text editor for the 7234 label application information and make additions, deletions, changes, or corrections as appropriate. NOTE: The Edit option will appear in the Available Actions drop-down only if the application is either in \u201cDraft\u201d status (the application has not yet been submitted) or in \u201cReturned\u201d status (the application was returned to the submitter by FSIS). All changes can be saved when the Save button is selected. Once in the editor, the submitter can quickly navigate to the desired information or screen by using the Go to drop-down list (Figure 5-12). 1. Click the down arrow ( ) on the Go to drop-down list. The list opens displaying ten screens to select. Scroll to the desired screen and select\highlight the desired screen. 2. Click the Go button ( ). LSAS will display the selected screen. Make the appropriate changes and save them using the Save button at the bottom of the screen. September 09, 2019 69 Chapter 5 \u2013 Menus and Functions", "LSAS Label Submission and Approval ,System Home. Contact Us Logout Goto: Special Claims Information Label Documentation Display Panel Information ,--t- io\_n\_u\_n\_les:s -. it-d-is\_.p\_ISi\_ys\_. a.-va-l i\_d\_O\_M\_B\_c:o---<n Formular Information \_ ing the time for reviewing instructions, s Processing Information Approval Information ,----- --< Submission Information 7234 Summary mbsfor and\" Label Submission and Approval System (LSAS) Industry User Guide Figure 5-12: Go To Drop-down List 3. To return to the Manage Application screen, click the Exit Editor button at the bottom of the screen. September 09, 2019 70 Chapter 5 \u2013 Menus and Functions", "----- Man age AppHcation Label Applicattm1 Sumrny-----I Application umbert Bare ode: 91079050 ame of Produc : Turkey Po Pie Submitted By: ACME Foods International Curren Stat ,s: etumed C rren Status Set By: Submiss,ion ype: ornea, We dy at 10[2312017 11 :00:56 AM !Neb A.vanable Actiio,ns: Edit Create Appeal Download Messages Manage Access Summary Select Label Submission and Approval System (LSAS) Industry User Guide Create Appeal This function allows the submitter to appeal an LPDS decision. The submitter may appeal a Sketch Modified label application. Normally, a returned label application is resubmitted. You can create an appeal for a label application only if LPDS has adjudicated the application to one of the following statuses: \u201cSketch Modified,\u201d \u201cReturn,\u201d \u201cTemporary,\u201d or \u201cExtension of Temporary.\u201d An appeal cannot be created for a label application that LPDS adjudicated as \u201cSketch.\u201d The \u201cCreate Appeal\u201d action does not appear in the Available Actions drop-down list if you have already used up all of the appeal requests (Appeal Levels 1, 2, and 3) for the selected label application. You can create an appeal for a returned application only if the application includes the same, unedited data as the original submission. If LPDS returns a label application, and then you edit the returned application, you will not be able to create an appeal for the edited application. If you edit a returned application, you can resubmit the application with the

updated information, but you cannot create an appeal. Once submitted, the appeal is evaluated by an Appeals Handler, a senior level LPDS personnel member. Each appeal will be reviewed to determine whether the reason submitted by the submitter is valid. The Appeal Handler has the option to approve the appeal. Alternatively, the handler can reject the appeal and send the label application back to the submitter. The submitter, upon reviewing the new decision, has the option to reappeal this decision. When a subsequent appeal is submitted, it is escalated to a higher priority\level and will be reviewed by a higher authority in LPDS. If an appealed LAP is approved, then LPDS will change the status to \u201cApproved\u201d. LPDS\u2019s decision will appear in the submitter\u2019s Dashboard. September 09, 2019 71 Chapter 5 \u2013 Menus and Functions", "Returns and Rescinded Applications Application# Product Name Product Type Status Last Modified Date 91079050 | Turkey Pot Pie | Pooled | Returned | 10/23/2017 11:00:56 AM | Manage Application Label Application Summary-----< Application Number | Bare Code: 91079050 | Name of Product: Turkey Pot Pie | Submitted By: ACME Foods International | Current Status: Returned | Current Status Set By: Honey, Wendy | Submission Type: Web | Manage this Application Label Submission and Approval System (LSAS) Industry User Guide The steps in the remainder of this section illustrate an example of the creation of an appeal for a returned application. 1. From the Returns and Rescinded Applications pool, select the returned application that you wish to appeal. 2. LSAS will display the Manage Application screen for the selected application. 3. Select the \u201cCreate Appeal\u201d option from the Available Actions drop-down list. September 09, 2019 72 Chapter 5 \u2013 Menus and Functions",-----Appeals | Label Application Adjudication A=rding to the Paperwork. Reduction in cost of 1 >It is, an agency may not obtain information or respond to a person if required to do so. a collection of information unless it is necessary to carry out a function. The valid control number for this information collection is (583-0002). The final estimate is 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Label Application Summary-----< Application Number | Bare Code: 91079050 | Name of Product: Turney Pot Pie | Submitted By: ACME Foods International | Current Status: Returned | Current Status Set By: Honey, Wendy | Submission Type: Web | Manage this Application Label Application Information-----, Product Name: Turkey Pot Pie -----Establishment Number/Foreign Country: 358 Application Number/Barcode: 91079D50 Label Submission and Approval System (LSAS) Industry User Guide LSAS will display the Appeal Label Application Adjudication screen. September 09, 2019 73 Chapter 5 \u2013 Menus and Functions", "-Label Application Information-----; Product Name: Turkey Pot Pie -----Establishment Number/Foreign Country: 358 Application Number/Barcode: 910179050 - S1.1submitter Information-----1 Firm Name: ACME Foods International Contact Name: Umberto Eco Address: 1222 Farmers Way City: Reston State: Virginia Country: UNITED STATES Zip Code: 20191 Phone: 888.7776666 Fax: Email: u.eco@acmefoods.com Company Reason(s) for Requesting Label Reconsideration\u2013 Label Submission and Approval System (LSAS) Industry User Guide 4. Review the information in the following sections: \u2022

Label Application Information \u2022 Submitter Information 5. In the Company Reason(s) for Requesting Label Reconsideration textbox, enter a description of why you believe LPDS\u2019s decision was incorrect and should be re-evaluated. September 09, 2019 74 Chapter 5 \u2013 Menus and Functions","[ Rev;ewe,\u2022s Ream ro, rnsopproval o, Mod;ficio, s uppo rti D ng ocurnen ts Previously Uploaded Files File Name -Label Image.jpg Organic Certification.doc Ingredient List.doc Nutrition Data \u2022 Detailed.doc - Approval Type Req11estel!\" 0 Sk,etch 0 Temporary Upload Date -4/16/2017 B 26 33 AM 4/16/2017 B 30 34 AM 4/16/2017 B 30 34 AM 4/17/2017 10:43:13 AM -- Do not upload files that contain layers, comments, bookmarks, or hidden text, or which are password-protected. Files that are created in Adobe Illustrator--or similar imaging applications--must be flattened before being uploaded to LSAS. Select a file to upload\\" 11 Browse ... 111 Upload I - Label Submission and Approval System (LSAS) Industry User Guide 6. Skip the Reviewer's Reason for Disapproval or Modification. This is a read-only field. Only LPDS can enter data in this field. 7. Select a value for the Approval Type Requested field. This is a required field. 8. In the Supporting Documents section, upload all of the files and supporting documentation related to the appeal. LSAS displays all documents that were uploaded for all previous submissions of the label application and all previous appeals (if any) in the Previously Uploaded Files list which appears at the top of the Supporting Documents section. The filenames and dates of these previously uploaded files are displayed for reference purposes only. September 09, 2019 75 Chapter 5 \u2013 Menus and Functions","Previously Uploaded Fiiles File Name 'Upload Date Label Image.jpg 4/26/2017 8:26:33 AM Organic Certification\_doc 4/26/2017 8:36:34 AM Ingredient LisLdoc 4/26/2017 8:36:34 AM Nutrition Data -Detailed\_doc 4/27/2017 10:43:13 AM Do not upload files that contain layers, comments, bookmarks, or hiidaen, text, or which are password-protected. Files that are created in Adobe Illustralor--or similar imaging applicalions--must be flattened before being uploaded to LSAS. Select a file to upload' Browse... 111 Upload Uploaded Files Document File Name 'Upload Date Size \u25a1 I Apoeal Requestdocx 15/5/2017 11:02:16 AM 113 KB Remove Selected Label Submission and Approval System (LSAS) Industry User Guide Click the Browse button to locate a file that you wish to attach to the current appeal, then click the Upload button to upload the file to LSAS. All files that you upload for the current appeal will appear in the Uploaded Files list. If you uploaded a file in error, you can remove it from the appeal by selecting its associated checkbox and then clicking the Remove Selected button. You can only remove files that were uploaded for the current appeal; you cannot remove any files that were uploaded for a previous submission or a prior appeal of the label application. 9. After you have selected the desired values and uploaded all necessary documents, click the Submit button. 10. Click the Confirm button. September 09, 2019 76 Chapter 5 \u2013 Menus and Functions","Submitted Applications Application# 91047598 91047597 91047596 91047595 91047407 91047418 91047406 91047405 91047404 91047403 Product Name Product Type Status, Last Modified Date Seasoned Organic Turkey Burgers Poultry Received 7/120/2016 Chicken & Vegetables Stir Fry Mix Poultry Received 7/2012/2016 Breaded Chicken Breast Cutlets Poultry Received 7/120/2016 Cheesy Chicken Pot Pie Poultry Received 7/2012/2016 Crispy Breaded Chicken Nuggets Poultry Pending 6/23/2016 Turkey Pot Pie -Reduced Sodium Poultry Received 6/13/2016 Barbeque Chic~en Wings Poultry Received 6/110/2016 Turkey Dots for Tots Poultry Received 6/9/2016 Tempting Turkey Torteliini Poultry Received 6/19/2016 Spicy Turkey Meatballs Poultry Received 6/9/2016 Manage Application Label Appl'icati:on

Summary-----, Application Number I Barco de: 91047403 Name of Product: Spicy Turkey Meatballs Submitted By: Current Status: Outstanding Status Set By: Submission Type: Available Actions: I view ACME Foods International -US SW Received 01-J.Williams, (Submitter) at 6/9/2016 3:38:09 PM Web Select Select Select Select Select Select Select Select Select I I.., Select 1..., View All Label Submission and Approval System (LSAS) Industry User Guide Withdraw This function allows the Submitter to withdraw a label application. NOTE: The Withdraw function is not available to the Submitter if the LAP\2019s status is \u201cPending\u201d; an application can be withdrawn only if it is in \u201cReceived\u201d status. Perform the following steps to withdraw an application: 1. Locate the label application in the Submitted Applications pool. 2. Click the application\2019s associated Select button. LSAS will display the Manage Application screen for the selected application. September 09, 2019 77 Chapter 5 \u2013 Menus and Functions", "Available Actions: ---.withdraw Download I lessages I anage ccess Summary Withdraw Application -Label Application Summary----- 1 Application Number I Barcode: 91047403 Name of Product: Submitted By: Current Status: Current Status Set By: Submission Type: Spicy Turkey Meatballs ACME Foods International -US SW Received 01-J.Williams, [Submitter] at 6/9/2016 3:38:09 PM Web Manage this application Are you sure you wish to Withdraw this application? If you submit this application at a later time, it will be considered new in the queue and will fall accordingly by last modified date. Label Submission and Approval System (LSAS) Industry User Guide 3. Select \u201cWithdraw\u201d from the Available Actions drop-down list. 4. Click the Select button. LSAS will display the Withdraw Application screen (Figure 5-13). The Withdraw Application screen displays a message asking the user to confirm the withdrawal action. The message notifies the user that withdrawn applications lose their position in LPDS\2019s review queue; if a withdrawn application is submitted at a later time, then it will be treated as a brand new application and placed at the bottom of the review queue. Figure 5-13: Withdraw Application Screen 5. Click the Yes button to proceed with the withdrawal. September 09, 2019 78 Chapter 5 \u2013 Menus and Functions", "Label Submission and Approval System (LSAS) Industry User Guide The Withdraw Application screen displays a Status Change Comment textbox. 6. Enter a comment in the Status Change Comment field. A comment is required. 7. Click the Submit button. The bottom of the Withdraw Application screen displays a message indicating that you must confirm the action to complete the withdrawal. Withdraw Application Label Application Summary-----, Application Number I Barco de: 91047403 Name of Product: Submitted By: Current Status: Outstanding Status Set By: Submission Type: Spicy Turkey Meatballs ACME Foods International -US SW Received 01-J.Williams, (Submitter) at 6/9/2016 3:38:09 PM Web Manage this application Status Change Comment\* Submit ~ Required Field Please review your data\selections and click \"Confirm\" to submit this form and save any changes. Confirm 8. Click the Confirm button. September 09, 2019 79 Chapter 5 \u2013 Menus and Functions", "Withdrawal Confirmation Label Application Sm1111mrnry----- -----, Application Number I Barcode: 91047403 Name of Product: Submitted By: Current Status: Outstanding Status Set By: Submission Type: Spicy Turkey Meatballs ACME Foods International -US SW Withdrawn 01-J.Williams, (Submitter) at 7/26/2016 2:00:13 PM Web Manage this application Submission Successful The label application has been withdrawn. Label Submission and Approval System (LSAS) Industry User Guide LSAS displays the Withdrawal Confirmation screen. The withdrawn LAP will appear in the submitter\2019s

Drafts pool and be sorted to the top of the list. September 09, 2019 80 Chapter 5 \u2013 Menus and Functions", "Label Application Documents Label Application Summary Application Number\ Barcodle: 91090170 Name of Product: HEARTY BEEF STEW Submitted By: Acme Foods International Curre11t Status: Retumed Curre11t Status Set By MALLON, MELIINDA at 6\29'\2018 10:51 :40 AM Submissiion Type Web Appeal Status: Under Appeal Manage this application Select Documents to Download If you selled more tjhan one document, they will be oombined into one PDF for the download. D Select All Documents D Form7234.pdf D Appeal Request.PDF \u25a1 Form8822.PDF \u25a1 MY PRODUCT LABEL !IMAGE.PDF D Organic Claim.PDF D Include Annotations ? Download Label Submission and Approval System (LSAS) Industry User Guide Download The \u201cDownload\u201d option allows the submitter to select one or more uploaded documents, convert them into a single PDF, and open the PDF for review. Select the \u201cDownload\u201d option from the Available Actions drop-down to display the Label Application Documents screen (Figure 5-14). Figure 5-14: Label Application Documents Screen \u2013 Select Documents to Download September 09, 2019 81 Chapter 5 \u2013 Menus and Functions", "Select Documents to Download If you sellect more than one document, they will be oombined into one PDF for the download. D Select All Documents D Form7.234.pdf D Appeal Request.PDF 0 Form8822.PDF \u25a1 MY PRODUCT LABEL IMAGE.PDF D Organic Claim.PDF D Include Annotations ? Download Label Submission and Approval System (LSAS) Industry User Guide The Select Documents to Download section of this screen lists all of the files that are associated with the label application. Screen Element Description Select All Documents checkbox Select this checkbox if you would like to select all of the documents associated with the label application. This option will automatically select all the checkboxes except for the Include Annotations? checkbox. Include Annotations? checkbox Select this checkbox if you would like to include LPDS\u2019s annotations in the downloaded PDF. Download button Click this button to generate the PDF and display a prompt from which you can choose to either open or save the file. Download Sort Order Download sort order should be: 7234 Form, Label image and supporting document(s). If Appeal then download sort order should be: 7234 Form, Label image, supporting document(s) from original, Appeal Form, Supporting Documents for Appeal. September 09, 2019 82 Chapter 5 \u2013 Menus and Functions", "Messages la'bel Application Summaiyl Appffcatiom Nm:riber J BaroodE!: Q10l'QD!!' Ma e of Prodir.t: !!Jlli!ey & St 1mg, Family Size, Sllllilmited By: ACME Fo:::ds Imter1113tiomal C1.merat Stat!!ls: Tem,porary Cl!lrremit Stat!!ls Set By: 05-Abatirr \u2022 {Admi is rater) at 11 \u25a1 \u00b7 J 11 :.37:21 AM SI!!!ilm\ \u00b7issio Type: 'IJVelil 1a nage ~is application Would y,au like fo ,create a new message? I OIr,eate I D Select Al MessaW!'S Delete Al Selected MeSJSages \u25a1 lihank 1fO u,r axing the sta!Us o i t Js ~pplicatio to be 'Temporary\. ihis is w - 1 ,..le meant to do ..lit t original submissio 0.Jet!~::l By: E.e,:hID ChM!In!! <Un Bf1fflDU E=u tsh o - . mtl .~r:S. ~m::l 8ul:!mlt!~r PDS recei \u00b7 \_ 'fO r mes~;: and revie .\_ t '= label ~plicatiiora. IPDS believes tmis. applicatiom slilotilld ila.,.e ileem sllJilmited as ai \'Te parall', '\u00b7 a;iplic.If rat er t a \"Ske clh\" applicaliorn. \\i\\le ha11e appro11ed the .applica'.ion as \u00b7 emporary'. ea,;;e call PDS if 1his wa.s your i 1entio :Jel!~::l B:Y: 10:;-A'.b^t , m -stmtnr] on Bf11f2DU i::: tsh -o . !!I .ser:S. ~ aut:mm~r \u25a1 Pieaise review t is ~p'licaf ASAP l:ecause we are almost o of - \_ ,..\_ wm he s111bmitfimg a me\\'I label applf:c3tfam as soam a.s !he current labels run o \_ Ti you! 0.Jel!~::l B:Y: E.e,:hID C\\.hr1sHn!! <Dn Bf1fflD17 ~ tsh -o ':5mtl .~r:S. u.i::l 8ul:!mlt!~r Label Submission and Approval System (LSAS) Industry User Guide Messages The

submitter can publish messages to or review messages from LPDS for assistance on a LAP. Select \u201cMessages\u201d from the Available Actions drop-down to display the Messages screen (Figure 5-15) for the selected application. Figure 5-15: Messages Screen The Messages screen displays messages in the order they were created, from the most recent to the oldest. Note: This screen is slightly different from the Messages screen that is accessed from the dashboard. If accessed from the dashboard, you can only view messages, and, if desired, delete the most recently created message for the label application. In contrast, the Messages screen accessed from the Available Actions allows you to delete any message you created for the label application, as well as create new messages. September 09, 2019 83 Chapter 5 \u2013 Menus and Functions", "Messages la'bel .Api;>lica1io\u00b7 S1.1mmaiy Appffcatia11 N!!rriber I Baroode: II1Urn05f M3 e of ProdIIICl: T!IIJi!:ey & St -ITIQ. Family S:iz.e\u2022 SIIIIlmitteil B,:,-: ACME foods l11te1111=11itmal C1.memt St3tl!ls: em;porary Clirreml St3tlils Set By: 05-Abadir \u2022 {Admimis ratar'J at 1112\u25a1 J 11 :37:21 AM SI!!ilm\u00b7issio Type: '!JVeb 1anage tihis a:pp1ication Would y,au lit\_e fo ,create a new message? Oir,eate D Select All Messa~s De1ete Al Selected Me=ages \u25a1 Thank yo for -IXing the sta.1us oi t \u00b7; ~pf=tio to be eniporary". This is w -h'1e meant to do „,it t \_ original submi;s\"to \u25a1 yo r rne5S5'!1,'= and revie, \_ t -label s5,pplicatio!. PDS believe-s tmis-application slriol!!ld lla .... e ileem s~illiliittd as a \"S'ke ::lii\" appliralion. liVe ha~e appro!ledl e .applica'ion as\u00b7 empo.r.;. e call your\u00b7 lento . m \u2022 stn,b!r] an Bf1112Df1 8ul:!mffl~r P,85!5e review t i; .;pp!catio: ASAP lb=use "-= are ~!most o of -'tels .;. -wTII ile s~i11:riitt1TtQ a me,,, label applrcati:am as scam a,; !he current labels run o 1i you! C ChrtsHn~ an Bf11I2DU Label Submission and Approval System (LSAS) Industry User Guide Create a Message To create a message, click the Create button. September 09, 2019 84 Chapter 5 \u2013 Menus and Functions", "Create Message Label Application, Smnmary-----1 Application umber I Barcode: 91079067 Name of Product Turkey & S uffing, Family Size Submitted By: ACME Foods Internatiornal Gu rrent Status: Temporary Current Status Set By: 105-Abadir, (Administrator) at 9111'201711:37:21 AM Submissiorn Type: Web Manage this application Message Submit Label Submission and Approval System (LSAS) Industry User Guide LSAS will display the Create Message screen (Figure 5-16). Figure 5-16: Create Message Screen 1. Enter your message in the textbox provided. 2. Click the Submit button. LSAS will prompt you to confirm the creation of the new message. 3. Click the Confirm button. LSAS will display the Message Submission Confirmation screen which indicates that the message was successfully created. Because this is the most recently created message for the label application, it will appear in the Messages pool on the dashboard. September 09, 2019 85 Chapter 5 \u2013 Menus and Functions", "Messages la'bel Ap?)cation Summa!" Appl[catia11 Nm:ribet I Barood!!: II1OJIID!!J M3 e of Prod!!I:t: IIJli!:ey & Stllfi:111Q, Family S:Iz.e, SIIIIJmitted B,:,: ACME f,c,:.ds. Imtermo11al Currerat Status: Temporary Currerat Status S:et By: 05-Abadir \u2022 {Admi is rater) at .1112\u25a1 7 11 :37:21 AM SI!!Jmis.sio Type: '!Neb 1a nage ~is application Would y,ou like-fo ,create a new me,ssage? I Oi-,eate I D Select All MessaW!S De1ete Al Selected MeSJSGes \u25a1 lihank 1f0 Eor ax\ing the status o t Js ~pplicatio to be \"Temporary\". This is I'I' -1 ,..re meant to do ..lii t \_ original submisslio \_ PDS rec,ei'la 1f0 messs;g;;: and revie \_ t --e label .a;pplication. IPDS believes tliis. appli::atiDra slito1.11d lla.'o'e ileeJil sIIJilmited as a 'Te parall'j\u00b7 licatn rat r l a \"Slee clh\" applicaliora. 1i'Ve ha1te approl.IEd e .appicalion as\u00b7 emporar{. e call PDS if this w.s.s your i tentio C.rea~::I By: 10:i-Ail~~ , m -stnlblr] on

Bf11f2DU' u tsh 'io . m,1 .~r:S. en aut:cmm:r \u25a1 Pil8aise review I \u00b7s .a;pp'licaf ASAP !Bcause we are almos,t o of -\"bels a wlll ile sllJilmitfillQ a lill!\"I label appll:c3tia11 as soa11 ~s the current labels run o \_ 1i you! :reei~::I By: E-e,:hID O.hrtsl:tn~ <Dn Bf1ffID17 E=u tsh o -. m,1 .~r:S. cntl aut:cmlt!:r Label Submission and Approval System (LSAS) Industry User Guide Delete a Message To delete a message, select its associated checkbox and then click the Delete All Selected Messages button. If desired, you can select multiple checkboxes and delete all the selected messages simultaneously. If you would like to delete all of the messages associated with a label application, select the checkbox beside the \u201cSelect All Messages\u201d option and then click the Delete All Selected Messages button. Note: Submitters will see checkboxes only for the messages that they created. Submitters will not see checkboxes for any messages that LPDS created; Submitters cannot select or delete messages that were created by LPDS users. LSAS will prompt you to confirm the deletion. Click Submit and then Confirm to complete the deletion. September 09, 2019 86 Chapter 5 \u2013 Menus and Functions", "Manage Application Label Appl'tcatron Summary-----; Application Number 1 Barco die: 91047604 Name of Product: Submitted By: Ou rre nt Status: Current Status Set By: Submission Type: Available Actions: -----View Oreate Appeal Download Messages Manage Access Summary Ohicken Alfredo Dinner, 16 oz\_ AOME International Foods Temporary 04-L.Yoder, (Administrator) at 712612016 1159:12 AM Web Select Label Application Access LabelAppfication Summary-----~1 Application Number 1 Barco die: 91047604 Name of Product: Submitted By: Current Status: Ohicken Alfredo Dinner, 16 oz. AOME International Foods Temporary Current Status Set By Submission Type: 04-L.Yodler, (Administrator) at 712612016 11 :59:12 AM Web Manage this .application Would you lrike to aScsign another profile access to this labell appl:ication? Assign There are no profiles with which this label application is currently shared. Label Submission and Approval System (LSAS) Industry User Guide Manage Access This function allows the current submitter to assign a LAP to another profile. 1. On the Manage Application screen, select \u201cManage Access\u201d from the Available Actions drop-down. LSAS will display the Label Application Access screen for the label application (Figure 5-17). Figure 5-17: Label Application Access Screen \u2013 From the \u2018Manage Access\u2019 Available Action If the label application is currently shared with other user profiles, then those profiles will be listed on the Label Application Access screen. The user can select one or more of the profiles, and then click the Assign button, in order to share the label application with them. September 09, 2019 87 Chapter 5 \u2013 Menus and Functions", "Label Submission and Approval System (LSAS) Industry User Guide If there are no user profiles to select, then the current user will utilize the Manage Sharing function in the Profile area of the Dashboard screen. I sUJbmitter vi User: 01-J.Williams,(Submitter) Role: Submitter Profile: ACME International Foods US. SW Division ~1 Switch profiles vi I Submit I Switch profiles Oreate new profile Req1.1est access Manage Users Manage Sharing Manage Establishments September 09, 2019 88 Chapter 5 \u2013 Menus and Functions", "Application For Approval of Labels, Marking or Device Label Application Summary Application Number\ Barcode: 12345678 Application Status: Sketch Submission Date: 12\5\2018 Submission Type: WEB Label Application Adjudication Information Approval Number: 12345678 Adjudication Date: 12\512018 Approval Status: Sketch Adjudicated By: Bond, James Label Submission and Approval System (LSAS) Industry User Guide Summary The Summary option allows the submitter to view the 7234 application information, including

supporting documentation, messages, and comments. This view displays all the label information entered by the submitter, whereas only a portion of the information appears on the Form 7234. Figure 5-18: Application For Approval of Labels, Marking or Device Screen (aka \u201cSummary screen\u201d) The information on this screen is organized into sections as follows:

Label Application Summary \u2022 Application Number \u2022 Barcode \u2022 Application Status \u2022 Submission Date \u2022 Submission Type (WEB, MAIL, FAX, COURIER, or EXPRESS)

Label Application Adjudication Information

NOTE: This section will be displayed on the screen only if the label application has been adjudicated. It will not appear for applications that are have a status of Draft, Received, or Pending.

\u2022 Approval Number \u2022 Adjudication Date \u2022 Approval Status \u2022 Adjudicated By September 09, 2019

89 Chapter 5 \u2013 Menus and Functions", "Establishment Information

Included Establishment Establishment Number Establishment Name I 479 X>rZ Meat Corporation I Product Information

Name of Product: Vegetable Beef Soup HACCP Process Category: 03B: Raw Product -ground

Include a 'USDA-AMS Child Nutrition Program CN-Logo': No CN Identification Number Assigned:

Type of Product: Meat Establishment Type International Voluntary Review of a Submission which can be generically approved: No Organization Detail 88 Ashley Boulevard Toronto M1V 1V3 CANADA Extraordinary Circumstances: Yes. I certify this label meets the FSIS extraordinary circumstances requirements EC GateKeeper Vetting Decision: Approved EC GateKeeper's comments: Vet EC decision is 'Confirm' I Label Submission and Approval System (LSAS) Industry User Guide Establishment Information \u2022 Establishment Number \u2022 Establishment Name \u2022 Establishment Type \u2022 Organization Detail (Establishment address) Product Information \u2022 Name of Product \u2022 HACCP Process Category \u2022 Include a 'USDA-AMS Child Nutrition Program CN-Logo' (Yes\No) o CN Identification Number Assigned (This will be blank if no CN number was provided.) \u2022 Type of Product \u2022 Voluntary Review of a Submission which can be generically approved (Yes\No) \u2022 Extraordinary Circumstances: (Yes\No) certification -label meets FSIS\u2019s EC requirements \u2022 Special Claims Information September 09, 2019

90 Chapter 5 \u2013 Menus and Functions", "Special Claims Information Label Documentation Information Document Name Documentation Type Upload Date Uploaded by Size MY PRODUCT LABEL IMAGE.PDF Label Image\u2022 12\512018 10:59:53 AM KENT, CLARK 71 KB Extraordinary Circumstance Claim.PDF Extraordinary Circumstances\u2022 12\512018 10:59:54 AM KENT, CLARK 13 KB Principal Display Panel Information Area of Principal Display Panel: 8.0000 (sq Inches) Total available labeling space for entire package: 20.0000 (sq Inches)

Label Submission and Approval System (LSAS) Industry User Guide Special Claims Information \u2022 Special Claims Information (This section will be blank if the Submitter did not include any Special Claims.) Label Documentation Information \u2022 Document Name \u2022 Documentation Type \u2022 Upload Date \u2022 Uploaded by \u2022 Size Principal Display Panel Information \u2022 Area of Principal Display Panel \u2022 Total available labeling space for entire package September 09, 2019

91 Chapter 5 \u2013 Menus and Functions", "Formula Information Unit Type: Percent Added Ingredients Ingredient Name Percentage WATER 40 BEEF ]20 POTATOES 15 CARROTS 10 CELERY I 10 ONION 5 Calculated Total: 100% Processing Information Processing Procedures All ingredients are prepared in the same commercial-size stainless steel containers in large batches. Product is fully cooked, then portioned and vacuum-sealed in plastic packaging. The portioned product is individually boxed using lightly waxed, heavy card stock paper to protect the product, retain

freshness. Waxed paper also improves integrity of box in wet conditions. Product is frozen and stored on premises until delivery \ sale. Label Submission and Approval System (LSAS) Industry User Guide Formula Information \u2022 Unit Type (Percent or Weight) \u2022 Added Ingredients table: o Ingredient Name o Percentage or Weight (depending on Submitter\u2019s selection for the Unit Type \u2022 Calculated Total (For ingredient formulas that use percentages, this value must be 100% in order to submit the label application.) Processing Information \u2022 Processing Procedures September 09, 2019 92 Chapter 5 \u2013 Menus and Functions","Approval Information Type of Approval requested: Sketch Previously Approved Label Information Prior Approval Number: Approval Date: Number of Labels on Hand: Number of Days Requested: Submission Information Firm Name: XYZ Corporation Contact Name: Clark Kent Address: 333 Aubergine Road Suite 5A City: Austin State: Texas ZipCode: 12345 Country: UNITED STATES Phone: 8885551111 Fax: Email: c.kent@xyzfoods.org This is not a submission by an Agent. II Label Submission and Approval System (LSAS) Industry User Guide Approval Information \u2022 Type of Approval requested: (Sketch, Sketch Modified, Temporary, Extension of Temporary) If Temporary: \u2022 Conditions for Temporary Applications \u2022 Reason why the label application is submitted for Temporary Approval \u2022 (Yes\No) certification -user followed instructions for a Temporary Application request. \u2022 Previously Approved Label Information: Prior Approval Number, Approval Date \u2022 Number of Labels on Hand \u2022 Number of Days Requested Submission Information \u2022 Firm Name \u2022 Contact Name \u2022 Address, City, State, Zip Code, Country \u2022 Phone, Fax, Email \u2022 Submission by an Agent (Yes\No) September 09, 2019 93 Chapter 5 \u2013 Menus and Functions","Label Application Versions Previous Versions Version Date 121512018 Label Application Comments Created By: Bond, James Application Status: Sketch Comment: Adjudication decision -Changing Returned to Sketch

\u2022 M\_a\_n\_a\_g\_e\_t\_lh\_i\_s\_a\_p\_p\_li\_c\_a\_,t\_i\_o\_n\_~II Download Summary Version by I External 12\5\2018112418AM Label Submission and Approval System (LSAS) Industry User Guide Label Application Versions \u2022 Previous Versions table: o Version Date o Version by Label Application Comments If the label has been adjudicated, the submitter can view any comments entered by the LPDS. Each comment will include the following data: \u2022 Created By \u2022 Date and time the comment was created \u2022 Application Status \u2022 Comment Buttons: Manage this application Return to the Manage Application screen. Download Summary Download a PDF version of the information that is displayed on this screen. Note: The PDF obtained from this Summary screen is not the same as the one obtained via the Download screen, which includes the actual label image, form, and supporting documentation. See the Download section on page 81 for details. September 09, 2019 94 Chapter 5 \u2013 Menus and Functions","I Submitter vJ User: 01-J.Williams,(Submitter) Role: Submitter Profile: Plumrose - Booneville J Switch profiles vi I Submit I Label Applications ... - Search Create I Generic Label Advisor I ~ I Import App6cations - Status Check ... -Application # 11 11 Check I Label Submission and Approval System (LSAS) Industry User Guide 6 Generic Label Advisor Prior to creating a label application, an establishment may want to check whether the label can be generically approved. Effective January 6, 2014, FSIS regulation 9 CFR 412.2 streamlined the label approval process and allowed establishments more flexibility. The generic approval category was expanded so that establishments could use certain labeling without prior FSIS approval. LSAS has incorporated the regulations into a wizard, the Generic Label Advisor, to allow the

submitter to determine if a label can be generically approved. The following conditions prohibit a label application from being considered for generic approval:

- \u2022 The product was produced under a religious exemption.
- \u2022 The label is for export only with deviations from domestic requirements.
- \u2022 The label is for temporary approval.
- \u2022 The label bears a special statement or claim that was not previously approved.
- \u2022 Product Type is \\"Egg\\Other\\".
- \u2022 The Product Type is an exotic species under voluntary inspection.

NOTE: The Product Type \u201cEgg\\Other\u201d includes exotic species. If the Generic Label Advisor (GLA) determines that a label can be generically approved, LSAS will generate a certificate for the establishment to file with its labeling records. If the wizard determines that the label cannot be generically approved, it will display a message stating so. The wizard will also display a Go To Label Application button that you can click to open the LSAS label application screens for the normal submission process.

1. To start the GLA, click the Generic Label Advisor menu option in the left navigation panel.

Figure 6-1: Generic Label Advisor

September 09, 2019 95 Chapter 6 \u2013 Generic Label Advisor", "LSAS : Generic Label Advisor

You are here: Home \Wizard for Ge~erically Approved Labels

Labels must display all the mandatory features as required in 9 CFR Part 317.2 and 9 CFR Part 381 SubPart N a~d not be false or misleading.

1 . 1:s this label for a meat (which includes siluriformes and catfish), pou!Jy, or egg product\others? \u2022 Meat 0 Poultry 0 Egg Product\Others | Next | | Cancel | 1 .. !ls this label 'for a meat, poultry, or eg,g pmductJoth\u2022ers? -Egg Product\others Sorry. No egg, exotic species, non-amenable, voluntary reimbursable products can be generically approved 1 ... !ls thi!s l'.a'be:l1 for a 1m eat, 1pouUry., or ,egg 1prod ucf.i\\oth,ers? -Meat 2. Does the label fall under one or more of the following categories? \u25a1 i~ Produoed under a religious eX!emption \u25a1 fil Labels fior ,eJ<iport only with d-evraUons from ,domesUc r,eq,u\u00b7r,ements \u25a1 f~ Labels fior tern porary approval! \u25a1 i,v~ Bears special sta1em ents or c!atrns \u25a1 v~ None ofth,e above Label Submission and Approval System (LSAS) Industry User Guide 2. LSAS displays a series of questions. Based on the submitter\u2019s responses, LSAS may display additional questions to obtain more details.

NOTE: The opening window of the wizard includes a link to the regulations, 9 CFR Part 317.2 and 9 CFR Part 381, SubPart N, for reference. Throughout the wizard, the user will find links to specific regulations for easy access. The first question in the wizard asks whether the label is for meat, poultry, or egg\other (Figure 6-2). Figure 6-2: Generic Label Advisor Wizard \u2013 Question 1 3. Select the appropriate product type, then click the Next button.

\u2022 If your answer to Question 1 was \u201cEgg Product\Others\u201d then LSAS will display a message indicating that you cannot submit the application for generic review.

\u2022 If your answer to Question 1 was \u201cMeat\u201d or \u201cPoultry\u201d then the wizard will proceed to ask Question 2 to determine whether the label falls under one or more categories (Figure 6-3).

Figure 6-3: Generic Label Advisor Wizard \u2013 Question 2 \u2022 For categories i, ii, iii, and iv, you can select one category, none, or multiple.

\u2022 If you select \u201cv) None of the above\u201d then you cannot select any other category.

September 09, 2019 96 Chapter 6 \u2013 Generic Label Advisor", "2. Does the llabel fall under one or more of the foUowfn,g categories? -v) None of the above Based on your responses, your new label is in a category that allows for a generically approved label. Please provide us the Product Name and Establishment Number (or Temporary Establishment number) before creating a generically approved labeling completion record.

NOTE: It is the establishmenfs responsibility to prepare final labeling in

accordance with applicable regulations\policies, and to create and maintain records of final labeling, otherwise known as generic. For further information, access the Labeling, and Establishment Responsibilities on FSIS public site. LSAS : Generic Label Advisor You are here Home\Wizard for Generically Approved Labels Labels must display all the mandatory features as required in 9 CFR Part 317.2 and 9 CFR Part 381 SubPart N and not be false or mislead[ng\_ 1. Is this label for a meat (which includes siluriformes and catfish), poultry, or egg product\others? -Meat 2. Does the label fall under one or more of the following categories? -ii) Labels for export only with deviations from domestic requirements Based on your response, you need to submit for label approval through the Labeling and Program Delivery Staff. !Previous | Create Label Application | Cancel | 2.. Does, the label t:a'll under one or 1more of the following categories? -i) Produced Under a religious exemption Based on your response, you need to submit for label approval through the Labeling and Program Delivery Staff. Label Submission and Approval System (LSAS) Industry User Guide 4. Select the appropriate category or categories, then click the Next button. Based on your answer to Question 2, the wizard will respond accordingly: \u2022 If \u201cv) None of the above\u201d was selected, then the wizard will display a confirmation message indicating that you can submit the application for generic review. The wizard will display an Additional Information section for you to enter the required information for the label application. Proceed to Step 7. \u2022 If category i, ii, and\or iii was selected, then the wizard will display the screen below indicating that you will need to submit for label approval through the labeling and program delivery staff NOTE: If you select category iv in addition to category i, ii, and\or iii, then this same message will be displayed. \u2022 If \u201cBears special statements or claims\u201d was selected, and no other category was selected, then the wizard proceeds to ask the next question (Question 3) to determine whether the label was previously approved with that statement or claim (Figure 6-4). September 09, 2019 97 Chapter 6 \u2013 Generic Label Advisor", "1 .. Is this label for meat, poultry, or egg products? -Meat 2 .. Does the label fall under one or more of the following categories? -iv) Bears special statements or claims .. Was the label previously approved with the special statement or claim? 0 Yes Q No 3 .. Was the label previously approved with the special statement or claim? -No Based on your response, you need to submit for label approval through the Labeling and Program Delivery Staff. 4. Are you making a change related to the previously approved special statement or claim {e.g., making a formulation change to a product labeled with no preservatives\") or adding a new special statement or claim? 0 Yes Q No 4. Are you changing a statement or claim to the previous label? -Yes Based on your response, you need to submit for label approval through the Labeling and Program Delivery Staff. Label Submission and Approval System (LSAS) Industry User Guide Figure 6-4: Generic Label Advisor Wizard \u2013 Question 3 5. Select \u201cYes\u201d or \u201cNo\u201d as appropriate, then click the Next button. Based on your answer to Question 3, the wizard will respond accordingly: \u2022 If \u201cNo\u201d was selected, then the wizard will display a confirmation message indicating that you can submit the application for generic review. The wizard will display an Additional Information section for you to enter the required information for the label application. Proceed to Step 7. \u2022 If \u201cYes\u201d

was selected, then the wizard proceeds to ask the next question (Question 4) to determine whether you are making a change related to the previously approved special statement or claim. Figure 6-5: Generic Label Advisor Wizard \u2013 Question 4 6. Select \u201cYes\u201d or \u201cNo\u201d as appropriate, then click the Next button. Based on your answer to Question 4, the wizard will respond accordingly: \u2022 If \u201cYes\u201d was selected, then the wizard will display a message indicating that you cannot submit the application for generic review, and that you must submit the application for the normal LPDS review process.

September 09, 2019 98 Chapter 6 \u2013 Generic Label Advisor", "Addit:onal Inforrnatio111----- Product Name\u2022: Esfablishne111t Num1ber": Esfablishm,e111t Name\u2022: Esfablishme111 Address\u2022: Country\u2022 I UNITED STATES Cify": State\u2022: I-Please Select-- ZipCode\*: Cont:ac,t Nam,e\u2022: NOTE: Include botll fiirstname and lastname Telephone Number": NOTE: Do not incl11de dashes, enter only digits Submit I I c,mc:el Generic Label App li cation Confirmation P1rea.se down'l 10ml your ,g,en,elitca'ltv a,pprov,ed !la'bell oonfililiuti:on oertificate., Dowl'.III,oad Geirt-fica,te Label Submission and Approval System (LSAS) Industry User Guide \u2022 If \u201cNo\u201d was selected, then the wizard will display a confirmation message indicating that you can submit the application for generic review. The wizard will display an Additional Information section for you to enter the required information for the label application. Proceed to Step 7. 7. Enter the information for each of the fields in the Additional Information section (Figure 6-6). All fields in this section are required. Figure 6-6: Generic Label Advisor Wizard \u2013 Additional Information Section 8. Click the Submit button. LSAS displays the Generic Label Application Confirmation screen (Figure 6-7). A certificate number is generated and displayed in the confirmation message. 9. To obtain the certificate, click the Download Certificate button. Figure 6-7: GLA Confirmation Message September 09, 2019 99 Chapter 6 \u2013 Generic Label Advisor", "LSAS US DA United States Departmernt of Agricul1ture -Food Safety and Inspection Service Label Su'bmi1ssion and A\_pprnval System Certificate of Compliance for Generically Apprn,\u2022ed Labels Date Issued: Certific.ate ID Number: E-stablisment 1Number: Establishment ,Name : Esiabl ishmen1 Address: Contact. Name and Phone: Plrodu<>t Name: 25-Sep-2'1I 15 8685 4!455P Heritage Fam,; of Virgi\"ia QDOO Farmland Road amsonburg, Virginii> 201 n UNITED STATES John ()a,,is, 800-565-1212 Farmers Pride Tui:ikey Medallions For wfurm;tion on i,o,,liug Oll<i esrabilisbm.ent recspomwility \""1d what 11.e!!ds to \"\"\"illc!nded iiD the labeling reco,d, refer m the website address: http:f\www. lsis.usda.govfwps\porlallfsisfiopicsJregu laiory-com p liance.lla beli,g.llabelin g-prccedures\labe~ngand-e-stabllshme,nt-responjs.ibilities\labeling- es:ta.lbl'.ishm en -responisibElii!ies Discbim:,r. 'Thi!>CertifimteofCot:np]iaoo, fuo' Generic Apprm.-edu,beJ is being isruedoosed on cheinfoonarionpimed ii';,\u2022 me II50las mnlhful amd. xrurare. 'IIIs remfu:me \"\"\"\"\"\" bt' m::L\\rled as SUj!!pOlting doomr,em:tion i'1 your !aile!ing ,ecord. Ilir.\u1\u2022er, this ,cenmcace sbll!!:Id DDtben!liedup<111solely:liOD officiol !!IDOIS\""1El!Oibi:ndillgdocml!a!rby me Food.Sofe<yaadlnspeaion S=ire(FSIIS) c,fm,, U.:S. DepoJ:t,nEJt of Agriru]tu,,, (!USDA), L,,be!mg :md Pro,g,am Dem-ery St!ff (IPDS) if ii,Jse\"" misleo\_<fing, i:nfumJalion bas beeL prmO:ded or mampwated [O generate \u2022 raraflaire. Umll!d Stol<ls De.p:,rttnent ofAg,ir,ultme, Food Safety :mdlInspeclo,i Sem:r.e, Office ofPol,ry, Prognm & Detee!opmeni; Washicgto,i, DC \_0024 Label Submission and Approval System (LSAS) Industry User Guide LSAS displays the File Download screen. The submitter can either save the certificate to a dedicated directory or open it. NOTE: Certificates are not stored in LSAS, so it is

suggested you save your certificate. 10. Click Open file. LSAS will take a few moments to generate the certificate as a portable formatted file and display it on screen (Figure 6-8). Figure 6-8: Certificate for Generically Approved Labels September 09, 2019 100 Chapter 6 \u2013 Generic Label Advisor", "LSAS Label Submission and Approval System Home. Contact Us Logout Goto: Special Claims Information Label Documentation Display Panel Information 1--t-  
io\_n\_u\_n\_les:s -. it-d-lis\_.p\_la\_y.;\_. s.-va-1 i\_d\_O\_M\_B\_c:o---in F o rmu l a. Information. ing the time for reviewing ins1rLJctions, \u00b7 P'rocess1ng Information Approval Information 1-----  
-----i Submission Information 7234 Summary mberfor and Label Submission and Approval System (LSAS) Industry User Guide 7 Submit a Label Application Label Application Submission Process LSAS was designed to provide the submitter a step-by-step process for completing the 7234 application. The information requested is directly inherited from Form 7234. Some additional information is requested to streamline the submission process. A label application consists not only of the Form 7234, but also of a label image(s) and any supporting documentation. LSAS includes functionality to upload any label image and supporting document(s). Once a label application has been submitted, LPDS personnel will review and evaluate it. It is important to include all relevant information and documentation, i.e., special claims, so as not to delay the process and have the LAP returned. The actual application process consists of ten screens, as shown in Figure 7-1. As the Submitter completes all the required fields and saves each screen, LSAS will proceed to the next step (screen). If the submitter does not complete each screen in the process, LSAS will display an error message. Figure 7-1: Go To Drop-down for Accessing the Form 7234 Screens At the end of the process, the Submitter submits the application to LPDS. LSAS displays an acknowledgement that the submission was accepted and assigns an application number for future reference. LAPs will be neither evaluated nor adjudicated unless they are received by LPDS. Once received, LPDS will evaluate the label application and provide an adjudication decision. LSAS will send an email notification to the submitter\u2019s specified Firm or Agent email address to alert them of LPDS\u2019s adjudication decision. NOTE: Email notifications of adjudication decisions will be provided only for those applications that were submitted electronically via LSAS. The sections that follow guide the Submitter through the 7234 application process. September 09, 2019 101 Chapter 7 \u2013 Submit a Label Application", "I Submitter vi User: fsistestuser01, FSIS Role: Submitter Profile: LSAS Training | Switch profiles vi submit Label Applications ... Search Create Generic Label Advisor Import Applications Status Check Aelication, # | 11 Check Establishment Information According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0583-0092. The time required to complete this information collection is estimated to average 75 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Include all establishments associated with this label application .. Select establishments 528 -333 Meat Corporation M34814+P34814-701 Foods, Inc. A 691 -Global Egg Corporation 34 -Global Egg Corporation 85 -Hayters Turkey Products Inc. G1612+V1612 -Marshall Egg Products Company M5070+P5070 -Quality Beef Company V 203 - Stanbroke Beef Ply Ltd. 0 C: T.,,-l,,,...,\|\V...,11,...,. C-, I Include Selected I Do you want to add an establishment? I Add Establishments | Label Submission and Approval System (LSAS) Industry

User Guide Establishment Information 1. Click the Create menu option from the left-hand menu (Figure 7-2). Figure 7-2: Create Label Application Menu Option LSAS will display the Establishment Information screen (Figure 7-3). Figure 7-3: Establishment Information Screen The \u2018Select establishments\u2019 list box displays all establishments that are currently associated with your User Profile. The establishments are sorted in alphabetical order by Establishment Name. Establishment Names that begin with a number appear at the top of the list.

September 09, 2019 102 Chapter 7 \u2013 Submit a Label Application", "Sellect establishments 528 -333 Meat Corporation M34814+P34814 -701 Foods Inc 691 -Global Egg Corporation 34 -Global Egg Corporation 85 -Hayters Turkey Products Inc. G1612+V1612 - Marshall! Egg Products Company M5070+P5070 -Quality Beef Company V 203 -Stanbro<e Beef Ply Ltd. D7~&HI T, ,rt,\_,\_,\_, \\V,,,11,r,,, C-,m:,,,-. I I. r- Include Selected Included Establishments Establishment Number \u25a1 691 \u25a1 34 I Exclude Selected .. Required Fields Establishment Name Global Egg Corporation Global Egg Corporation I Save I I Save and Continue>> I I Exit Editor-I Organization Detail 283 Horner Avenue Toronto MBZ 4Y4 CANADA 115 Bonnie Crescent Elmira N3B 3G2 CANADA Label Submission and Approval System (LSAS) Industry User Guide 2. Select\highlight each establishment that you wish to associate with the label application, NOTE: If the establishment that you wish to associate with the label application is not displayed in the \u201cSelect establishments\u201d list box, then you have the option of adding a new establishment. Please refer to the Add an Establishment section on page 34. 3. Click the Include Selected button. LSAS adds the selected establishment(s) to the Included Establishments table (Figure 7-4) that appears at the bottom of the Establishment Information screen. Figure 7-4: Establishment Information Screen \u2013 Included Establishments If you wish to remove an establishment from the table, select its associated checkbox then click the Exclude Selected button. Every label application must be associated with at least one establishment. NOTE: If the establishment does not have an official establishment number from FSIS yet, it can be assigned a temporary number. Refer to the Temporary Establishments section on page 132 for details on how to identify an establishment number as temporary. 4. To continue to the next screen, click the Save and Continue button. LSAS opens the Product Information screen (Figure 7-5).

September 09, 2019 103 Chapter 7 \u2013 Submit a Label Application", "Product Information ;I,IDI<di .. ta th P\u25a0;p,o,rwcd: !h,duCDOII ,lI.ct cj 19:!lti, \u25a0a -W"\\"~ m\u25a0y net <XJOdu<:I Cl<,;p>rDCI<, \u2022 d \u25a0 poon ls ool requiro,d b:1 rnpond ta, \u25a0 a, hoaian ol irdam\u25a01ioon unllil it d\u2022\u25a0ljl \u25a0,,lid 0MB -"- \u00b7 T! \u2022 .-.1~ QMG--1>~1 nymw to, 1hl\u2022 lr,t\_bIQII c,:illt<llon If O,e),l)O~. VI-1\u2022 ~ \u2022~\u2022~IQ c,;mptlit1\u2022 ltl, Intonn!,tl\u00b0\\" QQII\u2022,,t~ Ul>ff!!!!'f'j \u2022o \_g. 7~ m nl,ltti p..\u2022-InclldoJ!Q ,,, ;\_ lo, ... 1-\\"D 1.,.....;,...\_ \u2022-lr,g a,cJ,;n,g, <f\u2022t.l .....\_ 911,\_o,; \u2022 ..., ,nal\\"t.III!IIQ ;i,.., d\u2022t. \"H<IK .r,d \"\\"\"\"\"\";\"\"\"I \u2022 .,, lr,g \\"\"\" coil-~ al In,....,.,..., 0 \u2022 03B: Raw Ptoduct -ground V Does tl'lIs llbel nelud:e ,lI USDA-AMS Cl'I d riutrtlon, Program CU-Lo,o ? \u2022 QYes @tIQ Child IIUlliliOm !!U mber As.sig\u25a1eil Enter our 6,cU ii CH number. ot Product V QYes Qtlo II you W1sn to Cl.!!signate maottlinaiy drc:umslances rot this pr Mu ct. please en eek 1ne rollo\iiitng M:t: \u25a1 1 c11rtir) mat lhls I MI meets lhe E sis exuaord[;QD D' CICWro\u00a7@IJ&e'i policy. \u2022 Reqlred: Fields << Previous 8 I S<1ve ;1nd Continue >> I Label Submission and Approval System (LSAS) Industry User Guide Product Information

Figure 7-5: Product Information Screen 5. Complete the required information:

\u2022 Enter the product name in the Name of Product field. \u2022 Select the HACCP Process Category. \u2022 Select \u201cYes\u201d or \u201cNo\u201d to the Child Nutrition question: Does this label include a USDA-AMS Child Nutrition Program CN-Logo? o If \u201cYes\u201d then you must enter the CN number. o If \u201cNo\u201d then you must leave the CN number field empty\blank.

September 09, 2019 104 Chapter 7 \u2013 Submit a Label Application", "Type of Product \* Egg Poultry Meat other-Non-Amenable other-Reimbursable other-Voluntary other other-Antelope Other-Buffalo/Bison other-Cattalo other-DeerNenison other-Elk Other-Migratory Water Fowl other-Pigeon other-Quail other-Reindeer other-Water Buffalo Product Information According to the Pepewod: Re-dud.ion Act of 1995, an agency may not conduct sponSOJ, and a pet'SOn is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0583-0092. The time required to complete this information collection is estimated to average 75 minute; !>El response, including the time-for reviewing instructions, searching existing data sourOES, gathering and maintaining the data nee-de-d, and completing and reviewing the collection of information.

Name of Product\u2022 I Danny's Sunshine Scrambled Eggs HACCP Process Category\u2022 I 03B: Raw Product-ground vi Does this label include a USDA-AMS Child Nutrition Program CtJ-Logo?. QYes @No Child Nutrition Number Assigned Enter your 6-digit CN number. Type of Product\u2022 Egg V (If Egg Product) Prior Egg Approval Number T043 Label Submission and Approval System (LSAS) Industry User Guide \u2022 Type of Product \u2013 Select the appropriate option from the drop-down list. o Note: If the selected Type of Product is \u201cEgg\u201d and the application was previously approved, then the prior egg approval number should be provided using the number on the previously approved Egg Label Notice (PY Form 221). Additional Information Specific to Egg Products: When the submitter checks the status of the application and it is approved, then the attached PY Form 221 (Egg Label Notice) will also be available for reference. The submitter can view the form and see the egg approval number. If the application is ever resubmitted, then the submitter can enter this number as the \u201cprior egg approval number\u201d if it is still appropriate for the new application. The prior egg approval number is provided on the Egg Label Notice if the label application was approved\u201d September 09, 2019 105 Chapter 7 \u2013 Submit a Label Application", "If you wish to designate extraordinary circumstances for this product, please check the following box: \u25a1 I certify that this label meets the FSIS, Extraordinary circumstances. poricy. Label Submission and Approval System (LSAS) Industry User Guide \u2022 Voluntary Review \u2013 If you believe your label application does not require review by FSIS because it complies with generic labeling requirements, then select \u201cYes\u201d for the question: \u201cAre you requesting a Voluntary Review of a submission which can be generically approved?\u201d o You cannot answer \u201cYes\u201d to the Voluntary Review question if your label application is for an egg product. o You cannot answer \u201cYes\u201d to the Voluntary Review question if you selected the Extraordinary Circumstances checkbox. If you are not sure whether your label application meets the minimum requirements to be considered for voluntary review, you can use the Generic Label Advisor Wizard to help you determine whether your label is a valid candidate. For complete details on the GLA Wizard, please see the Generic Label Advisor section on page 95. \u2022 Extraordinary Circumstances \u2013 If you believe your label application merits expedited evaluation by FSIS, select the Extraordinary Circumstances checkbox. The blue, underlined text is a hyperlink to

FSIS's extraordinary circumstances policy. If you are unsure whether your application qualifies for extraordinary circumstances, click the link to access the policy information to aid you in your decision. All label applications designated as having extraordinary circumstances will be vetted to validate the request. See the Extraordinary Circumstances section on page 129 for more information. The Extraordinary Circumstances checkbox can only be selected on the first (original) submission of a label application. If you select this checkbox on an original submission, then you cannot un-check the checkbox on any subsequent resubmission of the same label application. Likewise, if you did not select the EC checkbox on the original submission, then you cannot select it for a resubmission of the same label application. The same vetting decision that LPDS applied to the original submission will automatically be applied to any resubmission.

o You cannot select the Extraordinary Circumstances checkbox if you answered "Yes" to the Voluntary Review question.

6. To continue to the next screen, click the Save and Continue button. LSAS opens the Special Claims Information screen (Figure 7-6).

September 09, 2019 Chapter 7 "Submit a Label Application", "Special Claims Information"

PBates:el:ages to appear, are Oil till -1!el. (c\_k a.11 t ~ apply): \u25a1  
All'.er,g,en Statemse:nts \u25a1 Animal Produ:etim{BlreedJRaSjing \u25a1 O!rtfiektNerified  
\u25a1 Einvi ranmen.talfGreen \u25a1 EJc;po:rt only Labels wld:eviati o:ns from Do:rn,eSjt:c  
Requirements \u25a1 f:ore i g,n Lang;U!ag;e \u25a1 ~og;ra,\u00b5hi:clUnd!efinedl ~ D  
G:rad'in.g1 Tenna D G:Utarantees D Natu ral!Org;ani:c \u25a1 Nutriti an\Health \u25a1  
Religious Exemption \u25a1 Olh.-er 01:a.'ims (Indicate specific claim[s] in the space  
provided below in the other Claim Description field) ~ c.riipfon: << Previous Save and  
Continue>> || Exit Editor Label Submission and Approval System (LSAS) Industry User Guide

Special Claims Figure 7-6: Special Claims Information Screen

7. Mark the appropriate selections if any special claims, guarantees, or foreign language appears on the label or the paper Form 7234. A text field is available for entering other claims, e.g., "gluten free". Select the Other Claims checkbox, then enter text to describe the claim in the Other Claim Description textbox. If you select the Other Claims checkbox, then the Other Claim Description textbox is a required entry field. Likewise, if you enter text in the Other Claim Description textbox, then LSAS will require you to select the Other Claims checkbox.

8. To continue to the next screen, click the Save and Continue button. LSAS opens the Label Documentation screen (Figure 7-7).

September 09, 2019 Chapter 7 "Submit a Label Application", "Label Documentation"

According to the Paper, on the Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0583-(101)2. The time required to complete this information collection is estimated to average 7:5 minutes per response. including the time for reviewing instructions. The agency is archiving data sources, gathering and maintaining the data needed, and collecting information by reviewing the collection of information. Do not upload files that contain layers, comments, bookmarks, or hidden text, or which are password-protected. Files that are created in Adobe Illustrator--or similar imaging applications--must be flattened before being uploaded to LSAS. Upload the image(s) of your label along with any supporting documentation: Select the document type to associate with your file. Label Image Select a file to upload \* Upload

\u2022 Required Fields << Previous || Save || Save and Continue >> || Exit Editor || Discard || Browse ...



C:\Users\johnwhit\Desktop\MY PRODUCT LABEL IMAGE.doc Upload \u2022 Required Fields Message from webpage n Is this the correct file to upload? MY PRODUCT LABEL IMAGE.doc

\_\_\_\_\_ o\_K ..... || c\_a\_n\_c\_el \_\_ Browse ... << Previous Save and Continue>> || Exit Editor || Discard Label Submission and Approval System (LSAS) Industry User Guide Perform the following steps to upload the label image: 9. From the drop-down list under \u201cSelect the documentation type to associate with your file\u201d, ensure that the selected documentation type is \u201cLabel Image\u201d (this is the default value). 10. Click the Browse button. 11. Navigate to and select the image file, then click Open. LSAS will display a pop-up dialog box so that you can confirm the correct file was selected. Screen Differences Based On Type of Browser Used: \u2022 Using Internet Explorer, LSAS displays the full path to the file and the filename of the selected file on the screen as display-only text. \u2022 Using Firefox, LSAS displays the filename of the selected file on the screen as display-only text. It does not display the full path to the file. 12. If the correct file was selected, click the OK button. Otherwise, click the Cancel button and repeat Steps 9 to 11. 13. Click the Upload button. September 09, 2019 110 Chapter 7 \u2013 Submit a Label Application", "Upload the image(s) of your label along with any supporting documentation: Select the documentation type to associate with your file\u2022 !Label Image\u2022 vi Select a file to upload \u2022 I Browse ... 11 I Upload I Uploaded Files Document File I Name Documentation Type Upload Date Uploaded by Size \u25a1 I MY PRODUCT LABEL IMAGE.doc I Label Image \u2022 112114\2017 11:24:56 AM I SINGLETON, JANIE 171 KB I Delete Selected I \u2022 Required Fields I << Previous I I Save I I Save and Continue>> || Exit Editor || Discard I Label Submission and Approval System (LSAS) Industry User Guide An Uploaded Files table appears with the file that you just uploaded (Figure 7-8). Figure 7-8: Label Documentation Screen \u2013 Upload Steps Every supporting document must be associated with a document type by using the drop-down list under the label \u201cSelect the documentation type to associate with your file\u201d. If the desired selection is not available, go to the previous screen and mark the appropriate special claims checkbox. Remember to save the change. 14. To upload additional supporting documentation, i.e., special claims, select the appropriate documentation type from the drop-down, then repeat steps 10-12. To delete a file from the table, select its associated checkbox and click the Delete Selected button. 15. To continue to the next screen, click the Save and Continue button. LSAS opens the Display Panel Information screen (Figure 7-9). September 09, 2019 111 Chapter 7 \u2013 Submit a Label Application", "Area of Prin.cip.al DispIcay Pane'l (s:qJn.choes) \* 14 I Total available label's label's n.g s:p.aoe for en.ti re p<aelt~ (s:q.! rwhoes) \* 1\00b0 I fjs << Previous I Save, and Continue >> || Exit Edit!l:lor || Discard Product Formula According to the Pap.El'i'i'Dlt Redud:ion Act of 1995, an agem::y may not oond'uc:t or spon:iDf, and a person is not required to respond to, a. -oollcet:tioni of information unless it displ.a)j'S a valid OMB control number. The val id OM B control nu mba for th is information col I ed:ion is 0583-0092. The ti me required to complete th is information ool I ed:ion is -e.:ti mated to average 75 minutes pa response, including the time for reviewing ins'lrud:ions, searching -existing data source:., gathering and maintaining the data needed, and completing an.d r-eviaving the oollecti-o.n of information. UnitType \u2022 Percent I Change to Weight I Search Ingredient\2022 Enter or paste ingredients list,. one ingredient per line I Search I \u25a1 I certify that any appl'icable ingredients in my product formulation are used within the restricted conditions of us\00b7e listed in 9CFR 424.21, 424.22. and 424.23. \u2022 \u2022 Required Fields I << Previous I I Save I

I Save and Continue >> I I Exit Editor I I Discard I Label Submission and Approval System (LSAS) Industry User Guide Display Panel Information Figure 7-9: Display Panel Information Screen 16. Enter the dimensional values in both fields. These values are requested in Box 7a & 7b on Form 7234. Decimal values are permitted. The system only allows 2 digits after the decimal point or an error message is displayed. 17. To continue to the next screen, click the Save and Continue button. LSAS opens the Product Formula screen (Figure 7-10). Product (Ingredient) Formula Figure 7-10: Product Formula Screen September 09, 2019 112 Chapter 7 \u2013 Submit a Label Application", "Search Ingredient\* Enter or p, is, te in, gr, edtents. I'iis.t, one in, gredient per ITn,e Chedlctar cheese (chedlctar cheese [paste1.rnized milk, cheese rnlture, salt, enzymes], water, salt, annatto [color]) Modified dry milk Modified food starch Salt I Search I Label Submission and Approval System (LSAS) Industry User Guide The purpose of this screen is to add the product formula or ingredients and the values. Ingredients can be entered either by percentage or by weight. By default, LSAS uses percentages for ingredients. If you wish to change from percentage to weight, click the Change to Weight button. The Product Formula screen will display a Weight Type drop-down list from which you can select the appropriate weight type (grams, ounces, pounds, or kilograms). The Product Formula screen includes a textbox to add ingredients. 18. Type the ingredient names in the textbox, one ingredient per line. When listing your ingredients for Step 6-Formula Information, do not include special characters, bullets, numbered listings, etc. Simply list the ingredient name. This ensures that ingredients can easily be added to the database. Incorrect: Correct: # Cheddar cheese Cheddar cheese 109.Ham Ham \*\*Parsley Parsley --Tomato Paste Tomato Paste If an ingredient is composed of several sub-ingredients, then, as above, each major ingredient should be on a separate line, and the sub-ingredients should be listed in parentheses on the same line as the main ingredient. Please refer to the example shown in Figure 7-11. Figure 7-11: Product Formula \u2013 Enter Ingredient Names Note that \u201cCheddar cheese\u201d is composed of several ingredients enclosed by brackets or parentheses. Similar to single ingredients, it should be on a separate line just like the modified dry milk, modified food starch, and salt. TIP: If you already have a list of ingredients saved in digital format, you can use the universal Copy and Paste functions to add a list of multiple ingredients. 19. Click the Search button. September 09, 2019 113 Chapter 7 \u2013 Submit a Label Application", "The following Ingredients were not found: \u2022 Cheddar cheese (cheddar cheese [pasteurized milk, cheese culture, salt, enzymes], water, salt, annatto [color]) \u2022 Modified dry milk Add Anyway I I Make Corrections I I Discard Adde-d Ing,,edients Ingr di nt Name 0 MOCf.ili e-d Clry milk D Chee1e1ar-dleese (dle<1e1ar dle.ese [r>asteurizeCl milk:. clile.ese ru111.1re. sail, EIIIif.IYm~s] ,vats r, .salt a.nnalo [colorD Exolud se edted Weight Percentage NIA lo NIA lo NIA lo NIA lo Totals will lle recalCOlaiteCl upo:n s~ng. Label Submission and Approval System (LSAS) Industry User Guide LSAS will then search in its Master Ingredient List for the entered ingredient(s). After you have entered all the ingredient names, click the Search button. \u2022 If an ingredient is found, then the Product Formula screen displays a new table with the ingredient included. \u2022 If an ingredient is not found in the Master list, then a message will be displayed, as shown in Figure 7-12. LSAS will display three possible options for the ingredient: Make Corrections, Discard, and Add Anyway. Figure 7-12: Ingredients Not Found Message 20. Make the appropriate selection for each ingredient that was not found in the Master list: \u2022 If the ingredient is correctly spelled, then click the Add Anyway button. LSAS adds the new ingredient(s) to the list. \u2022 If you need to make

corrections to the spelling of an ingredient name, click the Make Corrections button. You will then be given an opportunity to re-enter the ingredient name. If you wish to remove the ingredient, click the Discard button. In Figure 7-13 below, the submitter chose to add the ingredients that were not found in the master list. Any ingredient that was found in the master list is displayed in all capital letters. Any ingredient that was not found in the master list will be in lowercase. Figure 7-13: Ingredients Add Anyway 21. For each ingredient, enter either the ingredient weight or percentage in the right-most column. Ingredient values must be positive numbers. Values of <0 or >1 are not allowed. Decimal values are permitted.

September 09, 2019 114 Chapter 7 Submit a Label Application", "Added Ingredients  
IngrMHent Na111e Weight Percentage \u25a1 MODIFIIBO FOOD STAROH NIA 16 \u25a1 SALT  
NIA 14 \u25a1 Oheddlar cheese (cheddlar cheese [pastel, rizedl milk, cheese NIA Iso cultlre,  
salt, enzymes), water, salt, annatto [color]) \u25a1 Modified dry milk NIA 1-10 Exclude Selected  
Totals will be recalculated Lipan saving . . Added Ingredients Gll8cli:lar M8H8 (MMClar M8H8  
[pasl.8ultt8(1 millt, M8H Ct!Jlurei, D sail. en~mesJ ater, salt annalo [color}) O r.todifie:d diy  
milk 0 ~ ODIFIE:DFOODSTAA.CH 0 SALT Weight NIA NIA NrA NIA 11?-e~nt ge !so 110 I -Is I la  
\u00b7~ II ~ I ~ Exdude e \u00b7 ected ( Galculated To1al: oot. ~ Totals will be r,ecalt\\fatecl  
u11on sa\\lingi. Label Submission and Approval System (LSAS) Industry User Guide Figure 7-14:  
Ingredients Enter Weights or Percentages NOTE: If you selected

\u201cPercentage\u201d as the Unit Type, then the Weight column will automatically display  
\u201cN/A\u201d for each ingredient. If you selected \u201cWeight\u201d as the Unit Type, then the Percentage column will display \u201cN/A\u201d for each ingredient. NOTE: for an ingredient formula that uses percentages, if you enter values such that the calculated total percentage is under or over one hundred percent (100%), then LSAS will display a validation error when you attempt to save the values. You will have to correct your entries so that the Calculated Total is exactly 100%. 22. Select the checkbox to confirm the associated statement:  
\u201cI certify that any applicable ingredients in my product formulation are used within the restricted conditions of use listed in 9CFR 424.21, 424.22, and 424.23. \*\u201d You can Save the ingredient information, but you can\u2019t Save & Continue without the box being checked. Additionally, the box must be checked before submitting the application. 23. Click the Save button to update the ingredient list. LSAS calculates the total of the weights or percentages for the entered ingredients. The calculated total will display in the lower right-hand corner of the list (Figure 7-15). Figure 7-15: Ingredients Calculated Total

September 09, 2019 115 Chapter 7 Submit a Label Application", "Product Formula 1)  
Seueh lllgred III:\\" E:\_11t \u2022 or m in r.diffib li1t. on. i Addi!!! I ~\u2022ni nlio lftgrtdi I W  
\u25a1 CM&ru~t~~[pu~ lccb11 \u25a1 SII!.T Unit ilfY11>e \*: Weight I Ohange to Percent W,elg  
ht Type,\\" J Grams vJ To WI'i I'll Pe~tl!Jil i,,., II A II NJA 116 A II\u25c4 C;i cubted J'gi;j; tllO\"A  
bR rac.b,l;i ad 11po<1 ~~\"V Label Submission and Approval System (LSAS) Industry User  
Guide After saving, if you change the unit type, the weight type, the values for any of the ingredients, or add or remove any ingredients, then you must click the Save button again to see the updated Calculated Total and units. Example: For the ingredients in Figure 7-15, the user clicks the Change to Weight button. The Unit Type field will now show a value of  
\u201cWeight\u201d and the screen will display a Weight Type drop-down list. The user selects the desired Weight Type from the drop-down. In this example, the user will select  
\u201cOunces\u201d. September 09, 2019 116 Chapter 7 Submit a Label

Application", "Added In redien~ D MM!fttd Ckfml 0 UOOIFIEO FOOO STARCH 0 SAIT [ Eledul!fe Selected Alilded IngredllenB 'I redietil !lame D Moeifit\J , mil 0 I\\100ifIE!D FOOD STfflCH \u25a1 S\!Li Wt\1;1~1 wet111 nm o fQltOfI) 80 I o 1~ 1-- Pere ge Nr >~1,1, ~ . PerDI!flage \u2019A I rii'A I A '\u2019\u2019 ~ Label Submission and Approval System (LSAS) Industry User Guide The Added Ingredients table changes to show \u201cN\A\u201d for all cells in the Percentage column and blank cells for the Weight column. The Calculated Total is reset to \u201c0\u201d (zero). The user enters the desired weight value for each ingredient and then clicks the Save button. When the user clicks Save, LSAS calculates the total and displays it below the table, along with the user\u2019s selected weight unit type. 24. To continue to the next screen, click the Save and Continue button. LSAS opens the Processing Information screen (Figure 7-16).

September 09, 2019 117 Chapter 7 \u2013 Submit a Label Application", "Processing Information According to the Paperworl: Reduci.ion Act of 10QS. an agency may not conduct or sponsor, and a person as not reciuired to respond to, a collection of inform3tion unless it displays. a Ya lid OMB control number. The Yalid OMB con!rol number for this information colleci.ion is 0583-0092. The time required to complete this infOI'TTlafion col!ection is estimated fo average 75 minutes per respon51!:!, including the time fur reYiewing instructiOlls, searching exisi.ing data sources. gathering and maintaining the d3la needed. and completing ancl reviewing the collection of information. Processing Procedures (Approval of the sketch does not convey approval of the processing procedures)\* (Maximum limit is 2000 characters) \* Required Fields I << Previous I I save I I save and continue >> I I Exit Editor I I Discard I Label Submission and Approval System (LSAS) Industry User Guide Processing Information The Processing Information screen allows you to enter the procedures that were used to prepare the product with a max limit of 2000 characters. Figure 7-16: Processing Information Screen As indicated by the asterisk (\*), processing information is required. 25. Either type the processing information into the textbox provided, or copy and paste the information into the field. 26. To continue to the next screen, click the Save and Continue button. LSAS opens the Approval Information screen (Figure 7-17). September 09, 2019 118 Chapter 7 \u2013 Submit a Label Application", "Approval Information ACC01ding to th.e Pal>Ef\\'ICld: Reduction Act of 1995, an .ageru:.y may not conduct a s,ponsCl, and a pas::rn1 is not r\u2022equire-d to r=pond to, a collectior1J of infounation unless it displays a valid OMB control number. The valid OMB control number for this inforrnati0n1J collection is 058'3-0092. The time required to ,complete this information collect:ioni is estimated to average 75 minutes per r.esponse, induding the time for reviewing instructions. semching existing data. sou,oe.s. gathering and rna.inta.ining the data needed. and completing and reviewing the \u2022collection of inforrna.tio.n. Type of Approval Requested~\u2022---~ I Sketch v I I Select Previously Approved Label Information (if applicable) Prior Approval! tiument>er Date of Approval! Numt>er of Lat>el's On Hand Numt>er of Days Requested I I \* Required Fields << Previ:ous I I Save I Save and Continue>> 11 Exit Editor I I Di.scard Label Submission and Approval System (LSAS) Industry User Guide Approval Information The Approval Information screen is used to specify the type of approval requested. Figure 7-17: Approval Information Screen Type of Approval Requested is a required field for all label applications. The three choices are \u201cSketch\u201d, \u201cTemporary\u201d, and \u201cExtension of Temporary\u201d. The default value is \u201cSketch\u201d. 27. Select the appropriate Type of Approval Requested. 28. Click the Select button. \u2022 If you selected \u201cSketch\u201d, you will then continue to enter the information requested at the bottom

of the screen (Prior Approval Number, Date of Approval, Number of Labels, and Number of Days). If you selected "Temporary" or "Extension of Temporary", then the Approval Information screen changes to display the required entry fields for temporary applications (Figure 7-18). September 09, 2019 119 Chapter 7 "Submit a Label Application", "Approval Information Type of Approval" Reguested, ... " -- I Ternpo:r.o.ry vi I Select Cond'itcms fo:r Temp,o:rary A!p.,;p,lieoafio:ns Provide th.e sip,eeific reas,o:n why tti,e llaool a,p pl i=ti o:n is submitted fo:r Tempo:rary Approval?\* te l)O'I.o.ry a;ppro,,..;1? Maoim: I imit is 2000 ch.arac!!\"rs. D I VE\"rify th.at I harve f.o'.llmved tti,e instructions f,o:r coon,pl!etin,g th.is Tem.po:rary Applfoatio:n reques,t\* Label Submission and Approval System (LSAS) Industry User Guide Figure 7-18: Approval Information Screen

Temporary Application The large textbox that takes up most of the screen is where you will enter a response to the question "Provide a specific reason why the label application is submitted for Temporary Approval?" Directly above the entry textbox, the screen displays four examples of the type of information that should be entered: "What are the reasons for seeking temporary approval?", "What ingredients have changed?", "What is in the product that is not on the label?", "What process has changed?". 29. Select the checkbox for the statement "I verify that I have followed the instructions for completing this Temporary Application request." This checkbox must be selected for all temporary applications. IMPORTANT: You can verify that you have followed the instructions for completing the temporary application request by clicking on the instructions link in the checkbox statement to open the USDA website on the Conditions for Temporary Applications.

September 09, 2019 120 Chapter 7 "Submit a Label Application", "Previousy .Apprcwci Lat!el1n,mnnation (if applicable) Prior AP.111roval ~umber || Date or A rova Humbe:r of Labels On Hand" ... \_\_ || Number of Days R@'fluested \* +--- 1 || .. Required Fields If "Temporary" or "Extension of Temporary" was selected, then LSAS will display an asterisk beside these two fields to indicate that they are required. Label Submission and Approval System (LSAS) Industry User Guide For temporary applications, in addition to the required condition text, two of the previously approved label information fields are also required: Number of Labels On Hand and Number of Days Requested. These fields are not required for "Sketch" applications. 30. To continue to the next screen, click the Save and Continue button. LSAS opens the Submission Information screen (Figure 7-19). September 09, 2019 121 Chapter 7 "Submit a Label Application", "Submission Information According to the Paperwork Reduction Act of 1995, \" age,acy may not cond cl a sponsor, a d a pe,sa is no1 m\2022-o:rm..alition is 0583-0:092. The time required to C:Ofl\\Pete this informatfm1 collection is esfima~ed to aVE neededl. and c\25a1mp.1e:1ing and reviewing the ca e.cti\25a1n of i:inform..ar~ion. Finn Infomniton----- Ffrm Name\2022 Address\2022 City\2022 State\* I -Please Select- lipCode \2022 Country\2022 I UNITED STATES Contact Name \2022 Phone\2022 (Ex: for.202-111-3333, enter 2021113333 and for 1~011,-256~5678 enter 1,8002565678) Fax Email\2022 Label Submission and Approval System (LSAS) Industry User Guide Submission Information The Submission Information screen allows you to enter the firm\establishment information and the agent\2019s information (if used).

Figure 7-19: Submission Information Screen 31. Enter the firm name, address, and contact information in the appropriate fields. Fields marked with asterisks are required. Format of Phone Number: Enter digits only. Do not enter any hyphens, spaces, parentheses, or any

characters other than the digits of the phone number. September 09, 2019 122 Chapter 7 \u2013 Submit a Label Application", "-Agent Name-----, this, a submission by an agent? @No Select Agent Organization Name\u2022 Address\u2022 City\u2022 State\u2022 I--Please Setot- ZipCode \u2022 Country\u2022 I UNITED STATES Co11tact Name \u2022 P1rlone \u2022 (Ex: for 202-111-3333, enter 2021113333 a111d for 1--300-256--5678 enter 18002565678) Iraq Email\* Label Submission and Approval System (LSAS) Industry User Guide Agent Fields: If your establishment is using an agent or label consultant, then the agent\u2019s information must be entered. Select \u201cYes\u201d and then click the Select button to display the agent information entry fields. The agent information fields will appear at the bottom of the screen (Figure 7-20). They are similar to the entry fields for the firm information. All fields marked with an asterisk are required. Figure 7-20: Submission Information Screen \u2013 Agent Information NOTE: If Agent information is provided, then LSAS will send all email notifications regarding this label application to the specified Agent email address. Otherwise, LSAS will send all email notifications regarding this label application to the specified Firm email address.

32. To continue to the next screen, click the Save and Continue button. LSAS will display the Summary screen (Figure 7-21). September 09, 2019 123 Chapter 7 \u2013 Submit a Label Application", "Summary ACCOfding to the Papawod: Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMS-control number for this information -collection is 0583--0092. The time required to complete this information collection is estimated to average 75 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Establishment Information Establishment Number Establishment Name M10828-eP10828 Hillside Turkey Farm EstablishmentType Domestic Organization Detail 30 Elm Street Thurmont Maryland 21788

Product Information-----<sup>1</sup> Name of Product: Southwest Turkey Burgers HACCP Process Category: 03B: Raw Product-ground Include a 'USDA-AMS Child Nutrition Program CN-Logo': No CN Identification Number Assigned: Type of Product: Poultry Voluntary Review of a Submission which can be generically approved: No Label Submission and Approval System (LSAS) Industry User Guide Summary The Summary screen allows you to review the data entered for the LAP one final time prior to submitting the application. The Summary screen is organized into sections that correspond to the previous entry screens. Note: If the user accesses the Summary screen via the Go To dropdown, the screen will display blanks for any required fields that have not yet been entered on the previous Create Label Application entry screens. The application can be submitted into the adjudication process by clicking on the Submit Application button located at the bottom of the screen. Figure 7-21: Summary Screen

33. Review the application information for completeness and accuracy. Use the vertical scroll bar to view the whole screen. 34. To make changes or corrections, use the Go To drop-down list, as described in the beginning of the chapter (Figure 7-1). September 09, 2019 124 Chapter 7 \u2013 Submit a Label Application", "Label Application Submission Confirmation The Application For Approval of Labels, Marking or Device: FSIS FORM 7234-1 has been submitted. Label Application Id: 91047606 View Application | Download Options Label Submission and Approval System (LSAS) Industry User Guide There are four buttons at the bottom of the Summary screen: Download PDF Generates a portable format of the completed 7234

application and its supporting documentation; You can open the Form 7234 for viewing or save the file for archiving purposes. Submit Application Submits the application to LPDS for review and adjudication Exit Editor Closes the Summary screen and saves the application as \u201cDraft\u201d; Click this button if you do not wish to submit the application at this time. A draft of the application will be saved and appear in the Drafts pool in the dashboard. Discard Closes the Summary screen and completely removes the label application 35. To complete the submission process, click the Submit Application button. If any information is invalid or if any required fields are missing values, LSAS will display validation error messages to alert you of items that must be corrected before you can submit the label application. LSAS displays a confirmation message that the application has been submitted (Figure 7-22). The message includes the label application\u2019s identification number. Label Application Submission Confirmation Figure 7-22: Label Application Submission Confirmation Message The Label Application Submission Confirmation screen includes two buttons: View Application View the application summary. Download Options Open the Label Application Documents screen (Figure 7-23). This screen allows you to download any or all documents that were attached to the application. September 09, 2019 125 Chapter 7 \u2013 Submit a Label Application", "-----  
----- Lab e I Application Documents LabellApplication Summary-----<  
Application Number | Barco de: 91047606 Name of Product: Submitted By: Current Status: Current Status Set By: Submission Type: SouthwestTurkey Burgers ACME Foods International Received 01-J.Williams, (Submitter) at 712612016 3:31 :53 PM Web Manage this application Select Documents to Download If you select more than one document, they will be combined into one PDF for the download. \u25a1 Sel ectAll Documents \u25a1 Fom17234.pdf \u25a1 Southwest Turkey Bur!lers.PDF \u25a1 Indl'ude Annotations ? Download Submitted Applications Application # Product Name 91047606 Southwest Turkey Burgers 91047598 Seasoned Organic Turkey Burgers 91047418 Turkey Pot Pie -Reduced Sodium Proouct Type Status Poultry Received Poultry Received last \u00b7 ~O<I ified Date 712612016 7\20\2016 6\13\2016 | Sel ect || Sel ect || Sel ect | Label Submission and Approval System (LSAS) Industry User Guide If you click the Download Options button, LSAS will displays the Label Application Documents screen for the label application (Figure 7-23). The downloaded files will be displayed in this order 7234 Form, Label image, supporting document(s) from original, Appeal Form, Supporting Documents for Appeal Figure 7-23: Label Application Documents Screen You have completed the application process. The LAP will be electronically distributed to LPDS for evaluation and adjudication by the LPDS technical staff. Your label is now an electronic label application that will be permanently stored within LPDS\u2019s database and be easily accessible for future queries. To return to the Dashboard screen, click the Home link in the top navigation bar. The application that was just submitted now appears in the Submitted Applications pool (Figure 7-24) with a Status of \u201cReceived\u201d. Figure 7-24: Submitted Applications Pool To submit another label application, repeat the above process. September 09, 2019 126 Chapter 7 \u2013 Submit a Label Application", "Product Information Aoi;ordin,g to the Peperwod: Redudion Act of 1995. ,1n \u2022genq-may not c:onidU'd or :fQOI1i:KII\", uncl u perJOn ii ncit ,~11,1i1ed to rH~nd to,\u2022 ocillec::tion of inJormetion unle55 it di1-ple)'1o e valid OM9 control numbef. The valid OMB oontrol n1.1mbef for thJs infomIE1tion oollelion is 05,83.-01)92. Tt,e time te(lured to complete this informati'on collection i:s e:\$timated to average 75 min1.1te:s pet\" rupon:w.

including the .. time for reviewing information, including the date of manufacture, the expiration date, and completing the product number, viewing the overall function of the form. Name of Product HACCP Process Category 03B: Raw Product-ground Does this label include a USDA-AMS Child Nutrition Program CN-Logo? QYes @No Child nutrition Number Assigned Enter your 6-digit CN number: 111 (If Egg Product) Prior Egg Approval Number Are you requesting a Voluntary Review of a Submission which can be generically approved? QYes QNo Label Submission and Approval System (LSAS) Industry User Guide Label Applications That Require Special Handling Child Nutrition (CN) Labels This section will highlight LSAS's functions specific to child nutrition labels. When a CN label is submitted, specific information provided by the submitter will flag LSAS to redirect the label application to AMS instead of LPDS. Specifically, on the Product Information screen, the submitter will select the "Yes" option for the question "Does this label include a USDA-AMS Child Nutrition Program CN-Logo?" and will enter the 6-digit CN Number. Figure 7-25: Product Information Screen 2013 Child Nutrition (CN) Fields AMS will evaluate the CN label and adjudicate it either as "Returned" or "AMS Approved". AMS Returned Status If AMS denies approval for the LAP or requests more information, then AMS will adjudicate the label application as "Returned". A draft label will be returned to the submitter/establishment. All AMS Returned labels will be put into the submitter's Returns and Rescinded Applications pool. The submitter has the option to resubmit the CN label to AMS via LSAS. AMS Approved (Final) If AMS approves the label application, then AMS will designate its adjudication decision as "AMS Approved". For the expiration date field, the default expiration date is five (5) years. All AMS Approved labels will be forwarded to LPDS for evaluation and adjudication. September 09, 2019 128 Chapter 7 2013 Submit a Label Application", "Product Information ACCCII" changing the letter Paperwork Requirements N: 199-5, agency may not include: or sponsor. and a penen 11 not required to respan. to, a mleec:bon c 2022-In.1Cfflllllcn u leu It dlspl11)11i a valcl Ot.18 control number. The valid OI'to'IB oonuo number f\00ab tn11 I fonnation-c:olleCllian Is OSSJ..CI0'9~ The time required to complete\00b7 tht.S information mleaa:lcn Is estimat~ 1.0 avil!fa,,ge-75 mlnuth ~ r;nwnR. inr;o!Ulding. lh 2022 tirn\2022 ro,-revi.willij, in:sttuQoOtU. H\"a.rdl\\" ~tirtQI d\25a0t\25a0 ~ -fil'lllh@i1:'U 111ld m\25a0intainir~ th\2022 d111a n,e.,Jed. and Q;JmpletiR9 1111d revirl!!'i\"1 the willadion , of ifofm8ti, on. Name of Product HACCP Process Category 03B: Raw Product-ground vJ Does this label include a USDA-AMS Child Nutrition Program CN-Logo? QYes @No Cnile 1m1r1t1on Number Assi.gne Enter your 6-(Jig1 CN number. 11 [pe of Product \2022 (If Egg Product) Prior Egg Approval Number 11 Are you requesting a Voluntary Review of a Submission which can be generic, approved? QYes QNo If you wish to designate extraordinary circumstances for this product, please check the following box: I certify that this label meets the [SIS extraordinary circumstances category. Label Documentation according to the Production Act of 1995, agency may not include: or sponsor, and a pen.on Is not required to respond to, a collection of information unless it displays a valid OMS control number. To\2022 \u2022\2022lid OMS c,c,nllol nombt fo, to\2022 Information oe>llaction \u2022 0583-0092. Th\2022 firm, requiring less than 10 minutes per review. This information collection is part of the HACCP process. ind1.1ding d\la: tlmfo, review.

irutrudion\u2022. aarching txil1ing d\u2022l 10urcm.. gathlling and maintaining th\u2022  
d\u2022t\u2022 naeded. end a:impleteing 1r,d revieNi~ U,e collection of information. Upload  
the image(s) of your label along with any supporting documentation: Do not upload files that  
contain layers, comments, bookmarks, or hidden text, or which are passwordprotected\_ Files  
that are created in Adobe Illustrator--or similar imaging applications--must be flattened before  
being uploaded to LSAS. Select the documentation type to associate with your file\* ----.

Extraordinary Circumstances\u2022 Other | Upload | | Browse ... \_ Label Submission and  
Approval System (LSAS) Industry User Guide Extraordinary Circumstances Current LPDS process  
provides establishments with a special service called Extraordinary Circumstance (EC). The EC  
service alerts LPDS that an establishment requests expedited attention on a label application.  
The Product Information screen provides a checkbox for the submitter to indicate this request  
(Figure 7-26). Figure 7-26: Product Information Screen \u2013 EC Checkbox If a submitter  
selects the EC checkbox on the Product Information screen, then documentation to support the  
EC claim must be attached to the application. The Label Documentation screen will display an  
additional \u201cExtraordinary Circumstances\u201d value in the documentation type drop-  
down, and the value will be shown with an asterisk to indicate that it is required (Figure 7-27).  
Figure 7-27: Label Documentation Screen \u2013 Required EC Documentation September 09,  
2019 129 Chapter 7 \u2013 Submit a Label Application", "Label Submission and Approval System  
(LSAS) Industry User Guide LPDS Vetting Process for EC Applications LPDS has a vetting process  
to determine the legitimacy of each EC request. The vetting stage occurs prior to the evaluation  
and adjudication process. The purpose of the vetting process is to evaluate whether the  
circumstance is truly valid. Selection of \u201cExtraordinary Circumstances\u201d is not a  
means to \u201cresubmit\u201d a returned application. The selection of \u201cExtraordinary  
Circumstances\u201d should only be chosen if the product has been retained ("tagged") by  
program personnel at official establishments or when there is some other unforeseeable  
impediment to movement of the product, and a temporary label approval would remove the  
impediment. For complete policy guidance, see the FSIS website:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labelingprocedures/procedures-evaluating-labeling> See Tip 5 posted in  
the Announcements pool on how to resubmit a returned application to LPDD. When a  
submitter specifies that an application is an EC application by checking the extraordinary  
circumstances checkbox, LSAS will redirect the application to the EC Gatekeeper. The EC  
Gatekeeper confirms or denies the submitter\u2019s EC request. Any requests that are  
confirmed will be given priority review. Notes on Resubmitted EC Applications: The system shall  
allow a submitter to identify a label application as an EC application only on the original  
submission. \u2022 If the submitter did not select the EC checkbox on the original submission,  
then LSAS will not allow the Submitter to select the EC checkbox for any subsequent  
resubmission \u2022 If an EC request was approved for an original submission, then the  
submitter will not be allowed to uncheck the EC checkbox for any subsequent resubmission.  
\u2022 If an EC request was denied for an original submission, then the submitter will not be  
allowed to check the EC checkbox for any subsequent resubmission. September 09, 2019 130  
Chapter 7 \u2013 Submit a Label Application", "Speaal ClamIS InFormauon \u25a1 1111\u2022-  
'\\"Stl..tt \u25a1 iNim,-11'~ - --ti\" 1.1] C.r'ti~..S.-lild Of~ \u25a1 Eipon,ont,LII>Il:O-  
\u2022frllffl~~\u00b7 \u25a1 t\"-ot.i;n ~ \u25a1 \_..p\V<,Uoidll n!d ~ii 0 ci.,r,\\"il Ttnu~

\u25a1 c.,...,,\_ -...0 \u00b7\u2022-III;k'g:1111~ 0 PMIIU--I ~ 0 IIllgi<,u ~\u2022 ~ \u25a1  
CIIIM<CIIIm1 ----- Label Documentation According lo the  
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\u25a0nd \u2022 pe,wn ij not r9Guired to rHPQnd to. \u25a0 c:olltd.ion of infocm\u25a0tion  
unltu it di1plays \u25a0 v\u25a0lid 0MB conb\"ol number. TJ\\e v\u25a0lid 0MB control  
numbtf fOf this inform\u25a0lio oolledioo is 0583-0092. Th time require<! to oomplete this  
infoon\u25a0tion collection is estimated 10 aver\u2022ge i5 minutes~ tHpOMe, in duding the  
time fo reviewing instructions, saan::hing e.xisting data sou,oes, gathering and mainlaining the  
data nffde-d, and completing and revi~ng the oolleation of infl)(mation. Upload the image(s) of  
your label along with any supporting documentation: Do not upload files that contain layers,  
comments, bookmarks, or hidden text, or which are passwordprotected. Files that are created  
in Adobe Illustrator--or similar imaging applications--must be flattened before being uploaded  
to LSAS. Select the documentation type to associate with your file\".,\u00b7 -\u00b7\u00b7  
Other CertifiedNerified . Natural\Organic Browse ... I Upload I Label Submission and Approval  
System (LSAS) Industry User Guide Special Claims Some label applications have special claims  
that require approval before they can appear on a product label. A submitter can enter any  
special claims on the Special Claims Information screen. For more information, see the Special  
Claims section on page 107. If a submitter enters any special claims for a label application on  
the Special Claims Information screen, then documentation supporting the special claim(s)  
should be attached to the application. The Label Documentation screen will display the  
submitter\u2019s special claim selections in the documentation type drop-down to indicate  
that this documentation should be included with the application. Example: A submitter selected  
the \u201cCertified\Verified\u201d and \u201cNatural\Organic\u201d claims on the Special  
Claims Information screen. The Label Documentation screen displays the selected claims in the  
documentation type drop-down. September 09, 2019 131 Chapter 7 \u2013 Submit a Label  
Application", "Establishment Informat1on Selecl est.l.blishments ES'I. lei>.,., USA. Ir.c. -  
ElooMvle EST. 20722 -Plu\""\u00b0 USA. loc. -Coand Siu lls A P..fZl~USA.Inc. -~\u2022 P-  
I!D722 -f'lur..ros, USA.. I . -Cou Bliflf\u2022 23-IIill \u00b7 osl-1.o<ai tl!:itV o\u2022\u2122 -Tftl  
Jndude S..led:ed Oo y,Ou Mff II) (\\"IC'.! lud~ ,1 tf'r\"r:lpotll:ty ll!ttl bli !S.l'In-.el'lit? ---+{ I  
Include Temporary Establishment ] ]I Establishment Information Create Establishment Profile Is  
the esta.b-lis.hment a domestic or international? @ Domestic 0 International Nam,,\u2022  
Address a City :r. State 1 Alabama Ziefode:r. I I Create and Indude I Cancel I Label Submission  
and Approval System (LSAS) Industry User Guide Temporary Establishments If the submitter  
does not yet have an establishment number for the establishment he is associating to a label  
application, then he can have LSAS generate a temporary establishment number until the  
official number is assigned. The submitter would perform the following steps to indicate that an  
establishment number is temporary: 1. Click the Include Temporary Establishment button on  
the Establishment Information screen. LSAS will display the Establishment Information screen  
for the temporary establishment. September 09, 2019 132 Chapter 7 \u2013 Submit a Label  
Application", "Esabl1shmerit Information Select establl shm4!11115 I illdude Seleded I O..~oo  
w.intto add an e~tabllshme<nt? I ~bUshments I embli~hm.,nl Nu I>K\" 2J.IWM Way Resloft  
'J'il'. 20 ~1 Label Submission and Approval System (LSAS) Industry User Guide 2. Select  
\u201cDomestic\u201d or \u201cInternational,\u201d as appropriate, and enter all required  
field information. 3. Click the Create and Include button. LSAS will generate the temporary

number and display it in the Included Establishments table on the Establishment Information screen. Note: In order to keep establishment data consistent among label applications, it is important that you select the actual establishment information from PHIS. The LSAS Temporary Establishment number should no longer be used once the establishment\u2019s information is included in PHIS. Submitters should follow the instructions to add an Establishment from PHIS for any new submissions. Please refer to the Add an Establishment section on page 34.

September 09, 2019 133 Chapter 7 \u2013 Submit a Label Application", "Drafts Application # Product Name Product Type Status Last Modified Date 91093378 Hearty Turtley Noodle Soup Poultry Withdrawn 12\3\2018 91093379 Tasty Chicken Noodle Soup Poultry Withdrawn 12\3\2018 - 91093380 Meatball Hero Sub Sandwich Meat Draft 11\27\2018 - 91092324 Thanksgiving Turtley & Dressing Dinner 32 OZ Poultry Draft 11\13\2018 | 91092238 Cheesy Ham & Egg Breakfast Scramble Egg Withdrawn 11\13\2018 Manage Application Label Application Summary-----< Application Number | Barco de 91047600 Name of Product: Submitted By: Current Status: Current Status Set By: Submission Type: Available Actions: | Edit Breaded Chicken Tenders with Honey Mustard Sauce Draft 01-J.Williams, (Submitter) at 71.2212016 9:53:56 AM Web Select | Select | Select | | Select Select r Label Submission and Approval System (LSAS) Industry User Guide 8 Edit a Draft Application There may be times when you have one or several LAPs not yet completed and submitted. These unsubmitted LAPs reside in the Drafts pool. The Submitter can open a LAP from the Drafts pool to complete and submit it by clicking its associated Select button. 1. To open a LAP in the Drafts pool, click on its Select button. Figure 8-1: Drafts Pool LSAS will open the Manage Application screen. Figure 8-2: Manage Application Screen \u2013 Draft Application 2. Select the \u2013Edit\u201d option from the Available Actions drop-down list. (\u2013Edit\u201d is the default option.) 3. Click the Select button. LSAS displays the entry screens for the label application in \u2013edit\u201d mode. The Submitter can proceed to make additions, deletions, changes, or corrections to the application information. All changes can be saved when the Save button is selected. To exit the application, click the Exit Editor button.

September 09, 2019 134 Chapter 8 \u2013 Edit a Draft Application", -----  
----- Application Locked Label Application SULLILLARY-----< Application Number | Barco de 91047600 Name of Product: Submitted By: Current Status: Current Status Set By: Submission Type: Breaded Chicken Tenders with Honey Mustard Sauce Draft 01-J.Williams, (Submitter) at 7122\2016 9:53:56 AM Web Manage this application Lock Information-----, Looking User: 01-J.Williams, (Submitter) Last Accessed At: 7122\2016 9:58:27 AM You already have a lock on this label application. This can occur if your browser or computer crashed, or if you have the application open for editing in a different window, tab, browser, or computer. By submitting this form you may release this lock. CAUTION: You will no longer be able to commit any unsaved information in any of these other locations and must re-open the label application for editing. Submit Label Submission and Approval System (LSAS) Industry User Guide NOTE: LSAS may display an Application Locked screen when a user attempts to open a LAP. This occurs whenever another user is currently editing the application, or for reasons indicated in the informational panel. If this screen appears and you wish to continue opening the application, click the Submit button. Then click the Confirm button to continue. Figure 8-3: Application Locked Screen September 09, 2019 135 Chapter 8 \u2013 Edit a Draft Application", "Label Submission and Approval System (LSAS)

Industry User Guide 9 View & Download Adjudicated Applications When a label application has been adjudicated, the submitter can locate the label application in either the Adjudicated Applications pool or the Returns and Rescinded Applications pool. If the submitter wishes to view the adjudication details, he can select \u201cSummary\u201d from the Available Actions drop-down. Scroll to the bottom to view comments entered by the LPDS. If the submitter wishes to download a copy of the approved label, select \u201cDownload\u201d from the Available Actions drop-down (see Figure 5-5). The Label Documentation screen opens and allows the submitter to download all documents associated with the label, including annotations made by LPDS. During the download, the submitter can save them to his local machine. How to Print An Adjudicated Label with Annotations (Stamps, Modifications, etc.) Select all the documents that you want to include in the download. Be sure to check the \u201cInclude Annotations\u201d checkbox. After downloading, in the Adobe Reader window, from the Print menu under \u201cComments & Forms\u201d, select \u201cDocument and Markups\u201d. Then proceed to print. My application was returned to me. Where do I find the reason(s) it was returned? You will find the reason(s) for the returned submission by viewing the Label Application Comment field located at the bottom of the Summary. Select your returned application from the Returns and Rescinded Applications pool. Then, from the Manage Application screen, select \u201cSummary\u201d from the Available Actions drop-down. On the Summary screen, scroll to the bottom of the page to view the Label Application\u2019s comments. I received a Sketch Modified label. Where do I find the explanation of the modifications that were made? Reason(s) for the modifications can be located on the annotated label image, application form, and\|or in the Comment field section of the Summary screen. September 09, 2019 136 Chapter 9 \u2013 View & Download Adjudicated Applications", "Label Submission and Approval System (LSAS) Industry User Guide 10 Handle a Returned Label Application When a label application is adjudicated as Returned, the reasons are usually due to insufficient information or the submitted information is not readable. The submitter should view the label application\u2019s Summary screen to see the reason(s) LPDS returned the application. How do I resubmit my returned application to LPDS? Select your returned application from the Returns and Rescinded Applications pool. Then, from the Manage Application screen, select \u201cEdit\u201d from the Available Actions drop-down. The Edit function allows you to make corrections, additions, deletions, etc. You can navigate to the specific area of the application by using the Go To function in the upper right corner of the dashboard. Be sure to save your changes. Finally, using the Go To function, select \u201c7234 Summary\u201d. On the Summary screen, review and submit your application. When the application is resubmitted, it will appear in the LPDD Pool as a resubmittal. NOTE: If you need to replace documents in a returned application, first remove the documents that were included in the original submission, and then upload the new\|corrected documents. August 15, 2019 137 Chapter 10 \u2013 Handle a Returned Label Application", "", "Label Submission and Approval System (LSAS) Industry User Guide 11 Manage an Appeal The purpose of the appeals process is to allow the submitter to appeal an LPDS decision, modification, or denial. The \u201cAppeal\u201d function should be used only if the establishment disagrees with a specific modification or reason for rejection. The creation of an appeal is not a means to \u201cresubmit\u201d a returned application. For example, if an LPDS reviewer returns a label application because the label image is not legible, the Submitter should not appeal this

decision, but should instead resubmit the label application with an updated, legible label image. See Tip 5 posted in the Announcements. LSAS provides a means for the submitter to appeal LAPs via the "Create Appeal" action in the Available Actions drop-down on the Manage Application screen. This action is discussed in complete detail in the Create Appeal section on page 71. For additional guidance, see the instruction page for Form 8822-4 in Appendix C on page 172.

September 09, 2019 139 Chapter 11 "Manage an Appeal", "Submitter User: 01-J.Williams, (Submitter) Role: Submitter Profile: Plumrose -Booneville I Switch profiles Submit Label Applications ... Search Or,ate Generic La be! Advis" Imp" rt A~licati" n.s Status Check ... Ap;p[tcati[Olil # III Check I Label Submission and Approval System (LSAS) Industry User Guide 12 Search for Label Applications The LAP Search function, accessible from the left navigation menu, allows you to search the LSAS database for labels based on the criteria entered in the search fields. To access the Label Application Search screen, click the Search menu option from the Label Applications menu on the left side of the home page.

March 14, 2019 140 Chapter 12 "Search for Label Applications", "Label Submission and Approval System (LSAS) Industry User Guide The Label Application Search screen, illustrated in Figure 12-1, is the interface used to search the LSAS database for all LAPs associated with the establishment(s) of the logged-in user.

March 14, 2019 141 Chapter 12 "Search for Label Applications", "Label Submission and Approval System (LSAS) Industry User Guide Search Fields The search fields available on the Label Application Search screen include the following fields. A short description of these fields can be found in Appendix A.

Date Fields: Enter desired date(s) or date ranges using the calendar icon ( ) to select date entries from a calendar, or by entering them manually in the mm\dd\yyyy format.

"Earliest Submission Date ; Latest Submission Date" "Earliest Status Date ; Latest Status Date" "Earliest Expiration Date ; Latest Expiration Date" "Earliest Appeal Adjudication Date ; Latest Appeal Adjudication Date"

Textbox Fields: Textbox fields allow a maximum of 30 characters.

"Establishment Number (see NOTE below)" "Approval Number" "Name of Product" "Name of Firm" Users can enter the percent symbol (%) as a wildcard in textbox fields to perform searches on partial text strings. Examples of wildcard searches in the Name of Product field include:

- "%hot dog - All label names ending in hot dog will be found."
- "hot dog%" -All label names beginning with hot dog will be found
- "%hot%dog%" -All label names that contain the words hot and dog will be found
- "hot dog" -Only label names with the exact name of hot dog will be found

NOTE: Although the Establishment Number field is a textbox, it is not necessary to use the % character to perform searches on partial values. For example, if you know the number starts with M15, you can enter just those three characters and the search results will include all label applications that are associated with an establishment that has M15 anywhere within the Establishment Number. The characters could appear at the beginning, the end, or anywhere within the Establishment Number in the search results.

NOTE: The Approval Number is the bar code number. All labels in LSAS are identified using the Approval Number.

Drop-down List Fields: Drop-down list fields allow you to select a single value from a list. Click the downward facing arrow to the right of the field label name to display the complete list, then click the desired value.

"Appeal Status" "Resubmission Listbox Fields: Listbox fields"

allow you to select one or multiple values simultaneously. To select multiple values, press and hold down the Shift key while you click on each of the desired values. \u2022 Application Status \u2022 Approval Request Type \u2022 Type of Product After entering or selecting your search criteria, click the Search button to initiate the search. (Alternatively, you can press the Enter key on your keyboard to initiate the search.) March 14, 2019 142 Chapter 12 \u2013 Search for Label Applications", "Label Appl1 cat1 on Search Results Items p,,r p.ag,>c ~ B Status. Name of A1>proval Ex[>iration !!!t!!fil! !!!t!!fil! ~ ~ A1>1>r.l Est.JI Statis 0..1\u2022 Sub. 0..1\u2022 R<>Sub Prod:u:ct ill:!:t Req.uMI 0..1\u2022 Status Status Info Firm Info ill:!:t Date Pl\"mrose USA, IBC.100 PJmnrose D.ril'e, 91009!!75 IOOS EST. Tem;po:rary 07\08f2013 OI\0812XI13 Yes Hain Water Me.t Temporary 10t!!l2013 'Boorte'a'iille, 20722 Ad<!:ts-Sissjppi, 38829, UNITED STA1'ES, (652)720-2815, :S.aked Elra.-n Pl\"mrose USA, li,c.- Sugar H.am .aod 100 Plmnrose Dri'a'e, EST. , Boo.rie.,iille, 91004121 2007 = Temporary 01 \01\0/2013 0110912{}13 Yes Water Prod.IJct Me.t Terrq:i01ary 7115\2013 1;sissjp,pi, 38829, 35%AIM.ed I re<lie ts UNITEDSTA1'ES, (~ 720-2815, Pl\"mrose USA, Inc.100 PJllruose on ... e, 91000..\57 WI EST. Tem,po.rary 07\28\2012 07 \u2022 ~ 12 Yes HONEY HI<IA l.ts,3t Teflip')rary 1 ~ 13 , Boc,nesille, 20722 WATER ADDED M\"tssissjppi, 33829, UNITiEDSTA1'ES, (e'J2) 720-2815, (P~ 1 oi 1) Records: 3 Sea\u00b7rdll a g,a i-n Label Submission and Approval System (LSAS) Industry User Guide Search Results Figure 12-2 shows the Label Application Search screen with search results that were retrieved based on the user\u2019s selected search field values. The screen displays all LAPs that meet the following search parameters: \u2022 Application Status = \u201cTemporary\u201d \u2022 Name of Product = \u201cham%\u201d (find all LAPs that have \u201cham%\u201d anywhere in the product name) \u2022 Resubmission = \u201cYes\u201d Figure 12-2: Label Application Search Results Screen The Label Application Search Results screen (Figure 8-2) contains features to sort search result data, and to view additional pages of search results. Search Again Click Search Again to return to the Label Application Search screen to perform a new search. NOTE: If you are currently on the search results screen and would like to view your original search criteria, do not click the Search Again button, as this will clear your search criteria. Instead, click on your browser\u2019s Back button. LSAS will display the Label Application Search screen with your original search criteria. Records field Displays the total number of label applications found in the search request. For additional pages, click the NEXT button. Column Headers Sort the search results list by a selected column. Click a column heading once to sort ascending, twice to sort descending. For example, if you wish to order the LAPs by their application numbers, click the App# column heading. The LAPs will be ordered from the lowest to the highest number. Click again, and the LAPs will be ordered from highest to lowest. March 14, 2019 143 Chapter 12 \u2013 Search for Label Applications", "Label Submission and Approval System (LSAS) Industry User Guide If there are more search results than can be displayed on a single page, two additional options will appear below the results list: Next The Next button will be visible\available only if there are too many search results to display on a single page. Click the link of the desired page to open the associated page of search results. Items per Page Select a value from the drop-down list to adjust the number of search result items displayed per page (10, 25, 50, 75, or 100). The default is 50. View a LAP from Search Results The search results screen (Figure 12-2) includes a feature that allows you to view a LAP in detail. From the search results, click on an application number. LSAS displays the Manage Application screen for the selected application. \u2022 To view the

LAP\u2019s Form 7234, select \u201cView\u201d from the Available Actions drop-down, then click Select. \u2022 To view the 7234 application data, select \u201cSummary\u201d from the Available Actions drop-down, then click Select. Depending on your role in LSAS, the options that appear in the Available Actions drop-down will vary. March 14, 2019 144 Chapter 12 \u2013 Search for Label Applications", "Label Submission and Approval System (LSAS) Industry User Guide 13 Import an Application via XML Format In some cases, the establishment may delegate the label submission task to an outside contractor, agent, or expeditor (aka an \u201cAgent\u201d in LSAS). In such cases, the Agent may use LSAS\u2019s Import XML process to quickly create label applications in LSAS without having to enter the information manually on the multiple input screens discussed in Chapter 7 -Submit a Label Application. The XML Import process is particularly useful when the establishment has an internal electronic data repository from which the raw data for a label application can be pulled and then inserted into an XML file. Once the XML file has been prepared, the Agent can initiate the import process which will read the XML file to automatically create an electronic label application in LSAS. Download the Schema In order to create the XML file, the Agent must first obtain the schema which specifies the required format for the XML data fields and values. The schema is an .xsd file that is available for download within LSAS. 1. Select Import Applications from the Label Applications menu in the left panel. Label Applications - Sea1ch ere te Generic Label Advisor \"\\"ort Appicatio ns, sta1us Checi.: ... Application# I II Checik I Label Import Download Schema Se[ec]t an X!ML fite to upload\* Browse ... 2. LSAS will display the Label Import screen (Figure 13-1). Figure 13-1: Label Import Screen 3. Click the Download Schema link. 4. You will be prompted to open or save the schema file. Select Save (or Save As) and save the file to your local machine. September 09, 2019 145 Chapter 13 \u2013 Import an Application via XML Format", "Label Submission and Approval System (LSAS) Industry User Guide Create XML Import File from XSD Schema In order for the import to succeed, the XML data must be in a valid format accepted by LSAS. Refer to the next section, LSAS XML Import Guidelines for Industry Users, for complete details on the requirements for the values that must be included in the XML file for the import process to be successful. When the label data in the XML file is formatted per the LSAS schema, the agent can import the XML into LSAS to create a label application that can be submitted to LPDS for review and adjudication. Note: If the Agent utilizes a separate software application for handling label applications, he must configure the in-house system to export label information using the XML schema so that it is readable by LSAS. Recommended XSD-to-XML Conversion Tool: Multiple sites online offer free XSD-to-XML conversion tools. Different sites will generate differently-formatted XML files. The conversion tool at the following site has been tested and verified to generate the XML file in a format that is accepted by LSAS. Online XSD to XML generator XSD2XML website\*: <http://xsd2xml.com/> Note: This conversion tool will only create the raw XML file in the appropriate format for LSAS; it does not enter the actual values required in the label application. You will need to edit this auto-generated XML file to include the label application data. \*USDA-FSIS has no affiliation with this site and does not guarantee the site\u2019s performance or availability. September 09, 2019 146 Chapter 13 \u2013 Import an Application via XML Format", "Label Submission and Approval System (LSAS) Industry User Guide LSAS XML Import Guidelines for Industry Users Default String Value for Text Fields The default string value in the generated XML file will vary depending on how you convert the XSD schema to XML. For example, if you use the online tool

from <http://xsd2xml.com>, then the default string in the XML file might be \"str1234\" while a different tool, located at <https://devutilsonline.com/xsd-xml/generate-xml-from-xsd>, might set all default string values to \"string\". This document will generally indicate \"str1234\" as the default XML string value. Please be aware that your particular XML file may have a different default string value, and adjust your steps accordingly.

**Required Fields** If the field description in this document indicates that a field value is required on the LSAS Web UI, but not required in the XML Import file, then you have the option of entering a value in the XML file or waiting to enter it via the UI. (LSAS will not prevent you from uploading the XML file if you did not enter a value for the field in the XML file.) If you did not enter a value for a field in the XML file, then, after importing the XML file, you must enter a value for it via the LSAS Web UI. LSAS will not allow you to save or submit the application via the UI until you have entered a value.

**Special Characters** In most cases, if you need to enter a special character into one of the text fields in the XML file, you can do so without having to add any special formatting in the XML file. However, there are five characters that require special formatting in the XML file in order for the import process to complete successfully. For these five characters, you can choose either of the methods shown in the table below (entity replacement or numeric replacement).

Original Character	XML Entity Replacement	XML Numeric Replacement
< (less than operator)	&lt;	&lt;
> (greater than operator)	&gt;	&gt;
\u201c (double quotes)	&quot;	&quot;
& (ampersand)	&	&
\u2018 (apostrophe \ single quotation mark)	&apos;	&apos;

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147 Chapter 13 \u2013 Import an Application via XML Format", "||||| Label Submission and Approval System (LSAS) Industry User Guide Field Descriptions \u2013 All Fields in the XML Import File XSD File Order XML Import File Field Name & Guidelines 1 NameOfProduct Required in XML file? Yes Required via manual\ /web entry? Yes Remove \"str1234\" from <NameOfProduct>str1234</NameOfProduct> and replace it with the name of the product. 2 ProductType Required in XML file? Yes Required via manual\ /web entry? Yes Remove \"NONE\" from <ProductType>NONE</ProductType> and replace it with any valid Product Type value. The selected ProductType must be entered exactly as it appears in the xsd schema file, including capitalization and underscores. Valid ProductType values include: Meat Poultry Egg Other\_Voluntary Other\_NonAmenable Other\_Reimbursable Other\_Buffalo\_Bison Other\_Water\_Buffalo Other\_Deer\_Vension Other\_Reindeer Other\_Antelope Other\_Elk Other\_Cattalo Other\_Quail Other\_Pigeon Other\_Migratory\_Water\_Fowl September 09, 2019  
148 Chapter 13 \u2013 Import an Application via XML Format", "||||| Label Submission and Approval System (LSAS) Industry User Guide XSD File Order XML Import File Field Name & Guidelines 3 HACCPProcessCategory Required in XML file? Yes Required via manual\ /web entry? Yes Remove \"NONE\" from <HACCPProcessCategory>NONE</HACCPProcessCategory> and replace it with the desired HACCP Process Category. The selected HACCP Process Category must be entered exactly as it appears in the xsd schema file, including capitalization and underscores. Valid HACCPProcessCategory values include: PC\_03J\_Slaughter\_all\_species PC\_03B\_Raw\_Product\_ground PC\_03C\_Raw\_Product\_not\_ground PC\_03D\_Thermally\_Processed\_commercially\_sterile PC\_03E\_Not\_heat\_treated\_shelf\_stable PC\_03F\_Heat\_treated\_shelf\_stable PC\_03G\_Fully\_Cooked\_not\_shelf\_stable PC\_03H\_Heat\_treated\_but\_not\_fully\_cooked PC\_03I\_Product\_with\_secondary\_inhibitors\_not\_shelf\_stable 4 Include\_USDA\_AMS\_Child\_Nutrition\_Program Required in XML file? Yes Required via

manual\|web entry? Yes If the label application is for a product that is included in the Child Nutrition program, then remove \"No\" from <Include\_USDA\_AMS\_Child\_Nutrition\_Program>No</Include\_USDA\_AMS\_Child\_Nutrition\_Program> and replace it with \u201cYes\u201d; otherwise, leave the default value of \u201cNo\u201d Note: The value in the XML Import file may include any of the following combinations of uppercase and lowercase characters: NO, No, no, YES, Yes, yes 5 CNIdentificationNumber Required in XML file? No Required via manual\|web entry? Required only if the answer to the CN-Logo question is \"Yes\" \u2022 If Include\_USDA\_AMS\_Child\_Nutrition\_Program = \u201cYes\u201d then remove \"str1234\" from <CNIdentificationNumber>str1234</CNIdentificationNumber> and replace it with your 6 digit CN number. \u2022 If Include\_USDA\_AMS\_Child\_Nutrition\_Program = \u201cNo\u201d then remove \"str1234\" from <CNIdentificationNumber>str1234</CNIdentificationNumber>. (Leave the value blank.) September 09, 2019 149 Chapter 13 \u2013 Import an Application via XML Format", "111111 - 111 Label Submission and Approval System (LSAS) Industry User Guide XSD File Field Order XML Import File Field Name & Guidelines 6 EggApprovalNumber Required in XML file? No Required via manual\|web entry? No If the selected Type of Product is \u201cEgg\u201d and the application was previously approved, then the prior egg approval number should be provided using the number on the previously approved Egg Label Notice (PY Form 221). The prior egg approval number is provided on the Egg Label Notice if the label application was approved. \u2022 If ProductType = \"Egg\" and you have a prior Egg Approval Number, then remove \"str1234\" from <EggApprovalNumber>str1234</EggApprovalNumber> and replace it with the prior Egg Approval Number. \u2022 If ProductType = anything other than \"Egg\", then remove \"str1234\" from <EggApprovalNumber>str1234</EggApprovalNumber>. (Leave the value blank.) 7 Label\_Meets\_FSIS\_Extraordinary\_Circumstances Required in XML file? Yes Required via manual\|web entry? Yes If you wish to designate the label application as an extraordinary circumstance, remove \"No\" from <Label\_Meets\_FSIS\_Extraordinary\_Circumstances>No</Label\_Meets\_FSIS\_Extraordinary\_Circumstances> and replace it with \u201cYes\u201d; otherwise, leave the default value of \u201cNo\u201d. If you are unsure whether your application qualifies for extraordinary circumstances, click on the following link to access the policy information to aid you in your decision: <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures/procedures-evaluatinglabeling> Using the manual entry process in LSAS, the Extraordinary Circumstances checkbox can only be selected on the first (original) submission of a label application. If you select this checkbox on an original submission, then you cannot un-check the checkbox on any subsequent resubmission of the same label application. Likewise, if you did not select the EC checkbox on the original submission, then you cannot select it for a resubmission of the same label application. The same vetting decision that LPDS applied to the original submission will automatically be applied to any resubmission. Likewise, using the XML Import process, LSAS will allow you to choose and enter either \u201cYes\u201d or \u201cNo\u201d for the first submission only. Any resubmitted application that is entered via the import process must have the same EC value as the original submission. 8 Is\_Voluntary\_Review Required in XML file? Yes Required via manual\|web entry? Yes If you wish to designate the label application as one that meets the

criteria for voluntary review, remove \"No\" from <Is\_Voluntary\_Review>No</Is\_Voluntary\_Review> and replace it with \u201cYes\u201d; otherwise, leave the default value of \u201cNo\u201d. If you are not sure whether your label application meets the minimum requirements to be considered for voluntary review, you can use the Generic Label Advisor Wizard to help you determine whether your label is a valid candidate. September 09, 2019 150 Chapter 13 \u2013 Import an Application via XML Format", "III Label Submission and Approval System (LSAS) Industry User Guide XSD File Field Order XML Import File Field Name & Guidelines 9 SpecialClaim Required in XML file? Yes. The value in the XML file cannot be blank. Leave the default value of \u201cNONE\u201d if the label application does not have any special claims. Required via manual\|web entry? No If you would like to enter a special claim, remove \"NONE\" from <SpecialClaim>NONE</SpecialClaim> and replace it with the name of the desired Special Claim. The selected Special Claim must be entered exactly as it appears in the .xsd schema file, including capitalization and underscores. Valid Special Claim values include: Allergen\_Statements Animal\_Production\_Breed\_Raising Certified\_Verified\_Environmental\_Green Export\_only\_Labels\_w\_deviations\_from\_Domestic\_Requirements Foreign\_Language Geographic\_Undefined\_Style Grading\_Terms Guarantees Natural\_Organic Nutrition\_Health Religious\_Exemption Other\_Claims Notes for entering multiple Special Claims: You can enter multiple Special Claims, if desired. Only one Special Claim field is displayed in the xsd schema template. If you wish to enter more than one Special Claim, then add another line using the same format. For example, enter: <SpecialClaim>Allergen\_Statements</SpecialClaim> <SpecialClaim>Natural\_Organic</SpecialClaim> 10 OtherClaimDescription Required in XML file? No Required via manual\|web entry? Required only if the \"Other Claims\" checkbox was selected \u2022 If you have a SpecialClaim of \u201cOther\_Claims\u201d then remove \"str1234\" from <OtherClaimDescription>str1234</OtherClaimDescription> and replace it with your description of the \"Other Claim\" \u2022 If you do not have a SpecialClaim of \u201cOther\_Claims\u201d then remove \"str1234\" from <OtherClaimDescription>str1234</OtherClaimDescription>. (Leave the value blank.) September 09, 2019 151 Chapter 13 \u2013 Import an Application via XML Format", "III Label Submission and Approval System (LSAS) Industry User Guide XSD File Field Order XML Import File Field Name & Guidelines 11 Area\_Of\_Principal\_Display\_Panel Required in XML file? Yes Required via manual\|web entry? Yes Remove \"3.1415926535\" from <Area\_Of\_Principal\_Display\_Panel>3.1415926535</Area\_Of\_Principal\_Display\_Panel> and replace it with the numeric value that represents the Area of Principal Display. The value of this field must be numeric. Decimal values are permitted. Other than the period symbol for a decimal point, no alpha characters or special characters are allowed. 12 Total\_Available\_Labeling\_Space\_For\_Entire\_Package Required in XML file? Yes Required via manual\|web entry? Yes Remove \"3.1415926535\" from <Total\_Available\_Labeling\_Space\_For\_Entire\_Package>3.1415926535</Total\_Available\_Labeling\_Space\_For\_Entire\_Package> and replace it with the numeric value that represents the Total Available Labeling Space. The value of this field must be numeric. Decimal values are permitted. Other than the period symbol for a decimal point, no alpha characters or special characters are allowed. 13 ProcessingProcedures Required in XML file? No Required via manual\|web entry? Yes Remove \"str1234\" from <ProcessingProcedures>str1234</ProcessingProcedures> and

replace it with a text description of the processing procedures used on this product. This is a free text entry field. All alphanumeric and special characters are allowed.

14 ApprovalType Required in XML file? No Required via manual\web entry? Yes Remove \"Sketch\" from <ApprovalType>Sketch</ApprovalType> and replace it with the desired Approval Type. The selected Approval Type must be entered exactly as it appears in the .xsd schema file, including capitalization and underscores. Valid Approval Type values include: Sketch Temporary Extension\_of\_Temporary September 09, 2019 152 Chapter 13 \u2013 Import an Application via XML Format", "111111 Label Submission and Approval System (LSAS) Industry User Guide XSD File Field Order XML Import File Field Name & Guidelines 15

Reasons\_For\_Seeking\_Temporary\_Approval Required in XML file? No Required via manual\web entry? Required only if ApprovalType = \u201cTemporary\u201d or \u201cExtension\_of\_Temporary\u201d Remove \"str1234\" from <Reasons\_For\_Seeking\_Temporary\_Approval>str1234</Reasons\_For\_Seeking\_Temporary\_Approval> and replace it with a text description that provides justification for the \"Temporary\" or \"Extension\_of\_Temporary\" Approval Type. Max limit = 2000 characters 16

Prior\_Approval\_Number Required in XML file? No Required via manual\web entry? No \u2022 If you have the previous application approval number, then remove \"str1234\" from <Prior\_Approval\_Number>str1234</Prior\_Approval\_Number> and replace it with the previous application approval number. \u2022 If you do not have a previous application approval number, then remove \"str1234\" from <Prior\_Approval\_Number>str1234</Prior\_Approval\_Number>. (Leave the value blank.) 17

Date\_Of\_Approval Required in XML file? No Required via manual\web entry? No Remove \"str1234\" from <Date\_Of\_Approval>str1234</Date\_Of\_Approval> and replace it with the date the label was previously approved (if one exists). The required entry format for this date in the XML Import file is YYYY-MM-DD. Example: 2016-05-08 18 Number\_Of\_Labels\_On\_Hand Required in XML file? Yes. The XML Import file requires the user to enter a value for this field, regardless of the selected ApprovalType. Leave the default value of \u201c0\u201d if you do not have a value for this field. Required via manual\web entry? Required only if Type of Approval Requested is either \u201cTemporary\u201d or \u201cExtension of Temporary\u201d If you would like to enter a value for this field, then remove \"0\" from <Number\_Of\_Labels\_On\_Hand>0</Number\_Of\_Labels\_On\_Hand> and replace it with a numeric value that represents the number of labels you have on hand for this product. This field accepts a maximum of 10 digits; alpha characters are not allowed. September 09, 2019 153 Chapter 13 \u2013 Import an Application via XML Format", "111111111111 Label Submission and Approval System (LSAS) Industry User Guide XSD File Field Order XML Import File Field Name & Guidelines 19 Number\_Of\_Days\_Required Required in XML file? Yes. The XML Import file requires the user to enter a value for this field, regardless of the selected ApprovalType. Leave the default value of \u201c0\u201d if you do not have a value for this field. Required via manual\web entry? Required only if Type of Approval Requested is either \u201cTemporary\u201d or \u201cExtension of Temporary\u201d If you would like to enter a value for this field, then remove \"0\" from <Number\_Of\_Days\_Required>0</Number\_Of\_Days\_Required> and replace it with a numeric value that represents the number of days the temporary label is required. This field accepts a maximum of 10 digits; alpha characters are not allowed. 20 Firm\_Name Required in XML file?

Yes Required via manual\|web entry? Yes Remove \"str1234\" from <Firm\_Name>str1234</Firm\_Name> and replace it with the name of the Firm. 21 Firm\_Address\_Line1 Required in XML file? Yes Required via manual\|web entry? Yes Remove \"str1234\" <Firm\_Address\_Line1>str1234</Firm\_Address\_Line1> and replace it with the first line of the Firm's address. 22 Firm\_Address\_Line2 Required in XML file? No Required via manual\|web entry? No Remove \"str1234\" <Firm\_Address\_Line2>str1234</Firm\_Address\_Line2> and replace it with the second line of the Firm's address (if it exists). 23 Firm\_City Required in XML file? Yes Required via manual\|web entry? Yes Remove \"str1234\" from <Firm\_City>str1234</Firm\_City> and replace it with the Firm's city name. 24 Firm\_State Required in XML file? Yes Required via manual\|web entry? Yes Remove \"Alabama\" from <Firm\_State>Alabama</Firm\_State> and replace it with the Firm State. The selected State name must be entered exactly as it appears in the .xsd schema file, including capitalization and underscores. Valid State values appear on Page 161. September 09, 2019 154 Chapter 13 \u2013 Import an Application via XML Format", "||||| Label Submission and Approval System (LSAS) Industry User Guide XSD File Field Order XML Import File Field Name & Guidelines 25 Firm\_ZipCode Required in XML file? Yes Required via manual\|web entry? Yes Remove \"str1234\" from <Firm\_ZipCode>str1234</Firm\_ZipCode> and replace it with the Firm's zip code. 26 Firm\_ContactName Required in XML file? Yes Required via manual\|web entry? Yes Remove \"str1234\" from <Firm\_ContactName>str1234</Firm\_ContactName> and replace it with the name of the contact person for the Firm. 27 Firm\_Phone Required in XML file? Yes Required via manual\|web entry? Yes Remove \"str1234\" from <Firm\_Phone>str1234</Firm\_Phone> and replace it with the phone number for the Firm. Valid format: 10 digits with no hyphens or spaces. Example: 8005551212 Note: If you enter an invalid value for the phone number (for example, \"ABCDE\"), you will still be able to perform the import operation, and you will not receive an error message when the operation completes. However, you will not be allowed to submit the application via the LSAS UI until you have corrected the value so that it is a valid phone number. 28 Firm\_Fax Required in XML file? No Required via manual\|web entry? No Remove \"str1234\" from <Firm\_Fax>str1234</Firm\_Fax> and replace it with the Firm's Fax number. Valid format: 10 digits with no hyphens or spaces. Example: 8005551212 Note: If you enter an invalid value for the fax number (for example, \"ABCDE\"), you will still be able to perform the import operation, and you will not receive an error message when the operation completes. However, you will not be allowed to submit the application via the LSAS UI until you have corrected the value so that it is a valid fax number. 29 Firm\_Email Required in XML file? Yes Required via manual\|web entry? Yes Remove \"str1234\" from <Firm\_Email>str1234</Firm\_Email> and replace it with the email address for the Firm. September 09, 2019 155 Chapter 13 \u2013 Import an Application via XML Format", "||||| Label Submission and Approval System (LSAS) Industry User Guide XSD File Field Order XML Import File Field Name & Guidelines 30 Is\_Submission\_By\_An\_Agent Required in XML file? No Required via manual\|web entry? Yes If this submission is being created by an agent, then remove \"No\" from <Is\_Submission\_By\_An\_Agent>No</Is\_Submission\_By\_An\_Agent> and replace it with \u201cYes\u201d; otherwise, leave the default value of \u201cNo\u201d. On the UI, the default value for this field is \"No\". If Agent information is provided, then LSAS will send all

email notifications regarding this label application to the specified Agent email address. Otherwise, LSAS will send all email notifications regarding this label application to the specified Firm email address.

31 Agent\_Name Required in XML file? No Required via manual\WEB entry? Required only if submission by an Agent = \"Yes\" If Is\_This\_Submission\_By\_An\_Agent = \"Yes\", then remove \"str1234\" from <Agent\_Name>str1234</Agent\_Name> and replace it with the name of the Agent. If Is\_This\_Submission\_By\_An\_Agent = \"No\", then remove \"str1234\" from <Agent\_Name>str1234</Agent\_Name> and leave the field blank.

32 Agent\_Address\_Line1 Required in XML file? No Required via manual\WEB entry? Required only if submission by an Agent = \"Yes\" If Is\_This\_Submission\_By\_An\_Agent = \"Yes\", then remove \"str1234\" from <Agent\_Address\_Line1>str1234</Agent\_Address\_Line1> and replace it with the first line of the Agent's address. If Is\_This\_Submission\_By\_An\_Agent = \u201cNo\", then remove \"str1234\" from <Agent\_Address\_Line1>str1234</Agent\_Address\_Line1> and leave the field blank.

33 Agent\_Address\_Line2 Required in XML file? No Required via manual\WEB entry? No If Is\_This\_Submission\_By\_An\_Agent = \"Yes\", then remove \"str1234\" from <Agent\_Address\_Line2>str1234</Agent\_Address\_Line2> and replace it with second line of the Agent's address (if one exists). If Is\_This\_Submission\_By\_An\_Agent = \u201cNo\", then remove \"str1234\" from <Agent\_Address\_Line2>str1234</Agent\_Address\_Line2> and leave the field blank.

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34 Agent\_City Required in XML file? No Required via manual\WEB entry? Required only if submission by an Agent = \"Yes\" If Is\_This\_Submission\_By\_An\_Agent = \"Yes\", then remove \"str1234\" from <Agent\_City>str1234</Agent\_City> and replace it with the Agent's City name. If Is\_This\_Submission\_By\_An\_Agent = \u201cNo\", then remove \"str1234\" from <Agent\_City>str1234</Agent\_City> and leave the field blank.

35 Agent\_State Required in XML file? Yes Required via manual\WEB entry? Required only if submission by an Agent = \"Yes\" If Is\_This\_Submission\_By\_An\_Agent = \"Yes\", then remove \"Alabama\" from <Agent\_State>Alabama</Agent\_State> and replace it with the Agent's State name. The selected State name must be entered exactly as it appears in the .xsd schema file, including capitalization and underscores. Valid State values appear on Page 161. If Is\_This\_Submission\_By\_An\_Agent = \u201cNo\", then remove \"Alabama\" from <Agent\_State>Alabama</Agent\_State> and leave the field blank.

36 Agent\_ZipCode Required in XML file? No Required via manual\WEB entry? Required only if submission by an Agent = \"Yes\" If Is\_This\_Submission\_By\_An\_Agent = \"Yes\", then remove \"str1234\" from <Agent\_ZipCode>str1234</Agent\_ZipCode> and replace it with the Agent's zip code. If Is\_This\_Submission\_By\_An\_Agent = \u201cNo\", then remove \"str1234\" from <Agent\_ZipCode>str1234</Agent\_ZipCode> and leave the field blank.

37 Agent\_ContactName Required in XML file? No Required via manual\WEB entry? Required only if submission by an Agent = \"Yes\" If Is\_This\_Submission\_By\_An\_Agent = \"Yes\", then remove \"str1234\" from <Agent\_ContactName>str1234</Agent\_ContactName> and replace it with the name of the contact person for the Agent. If Is\_This\_Submission\_By\_An\_Agent = \u201cNo\", then remove \"str1234\" from <Agent\_ContactName>str1234</Agent\_ContactName> and leave the field blank.

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||||||||||||| Label Submission and Approval System (LSAS) Industry User Guide XSD File

Field Order XML Import File Field Name & Guidelines 38 Agent\_Phone Required in XML file? No Required via manual\|web entry? Required only if submission by an Agent = \"Yes\" If Is\_Submission\_By\_An\_Agent = \"Yes\", then remove \"str1234\" from <Agent\_Phone>str1234</Agent\_Phone> and replace it with the phone number of the Agent. Valid format: 10 digits with no hyphens or spaces. Example: 8005551212 Note: If you enter an invalid value for the phone number (for example, \"ABCDE\"), you will still be able to perform the import operation, and you will not receive an error message when the operation completes. However, you will not be allowed to submit the application via the LSAS UI until you have corrected the value so that it is a valid phone number. If Is\_Submission\_By\_An\_Agent = \u201cNo\", then remove \"str1234\" from <Agent\_Phone>str1234</Agent\_Phone> and leave the field blank. 39 Agent\_Fax Required in XML file? No Required via manual\|web entry? Required only if submission by an Agent = \"Yes\" If Is\_Submission\_By\_An\_Agent = \"Yes\", then remove \"str1234\" from <Agent\_Fax>str1234</Agent\_Fax> and replace it with the fax number of the Agent. Valid format: 10 digits with no hyphens or spaces. Example: 8005551212 Note: If you enter an invalid value for the fax number (for example, \"ABCDE\"), you will still be able to perform the import operation, and you will not receive an error message when the operation completes. However, you will not be allowed to submit the application via the LSAS UI until you have corrected the value so that it is a valid fax number. If Is\_Submission\_By\_An\_Agent = \u201cNo\", then remove \"str1234\" from <Agent\_Fax>str1234</Agent\_Fax> and leave the field blank. 40 Agent\_Email Required in XML file? No Required via manual\|web entry? Required only if submission by an Agent = \"Yes\" If Is\_Submission\_By\_An\_Agent = \"Yes\", then remove \"str1234\" from <Agent\_Email>str1234</Agent\_Email> and replace it with the email address of the Agent. If Is\_Submission\_By\_An\_Agent = \"No\", then remove \"str1234\" from <Agent\_Email>str1234</Agent\_Email> and leave the field blank. September 09, 2019 158 Chapter 13 \u2013 Import an Application via XML Format", "11111 Label Submission and Approval System (LSAS) Industry User Guide XSD File Field Order XML Import File Field Name & Guidelines 41 UnitType Required in XML file? Yes Required via manual\|web entry? Yes If the ingredient values will be given in weight units like grams or ounces, then remove \"Percent\" from <UnitType>Percent</UnitType> and replace it with \u201cWeight\u201d; otherwise, if the values will be in percentages, then leave the default value of \u201cPercent\u201d. 42 WeightType Required in XML file? Yes. This value cannot be blank in the XML Import file. If your selected UnitType is \u201cP\u201d for Percent, then leave the default value of \u201cNONE\u201d for the WeightType field. Required via manual\|web entry? Required only if the Unit Type = \"Weight\" If your selected UnitType is \u201cW\u201d for weight, then remove \"NONE\" from <WeightType>NONE</WeightType> and replace it with the Weight Type. The selected Weight Type must be entered exactly as it appears in the .xsd schema file, including capitalization and underscores. Valid WeightType values include: Grams Ounces Pounds Kilograms 43 IngredientName Required in XML file? Yes Required via manual\|web entry? Yes Remove \"str1234\" from <IngredientName>str1234</IngredientName> and replace it with the Ingredient Name. Enter multiple ingredients in the XML file using the format shown in the following example: <Product\_Formula> <Product\_Formula> <IngredientName>Sugar</IngredientName> <UnitValue>50</UnitValue> </Product\_Formula> <Product\_Formula> <IngredientName>Milk</IngredientName>

<UnitValue>50</UnitValue> </Product\_Formula> </Product\_Formula> Note: Sometimes, the Import process will not capture all of the ingredients that are listed in the XML Import file. In this case, you will need to enter the remaining ingredient name and weight or percentage values via the LSAS GUI after the import process has completed. September 09, 2019 159 Chapter 13 \u2013 Import an Application via XML Format", "Label Submission and Approval System (LSAS) Industry User Guide XSD File Field Order XML Import File Field Name & Guidelines 44 UnitValue Required in XML file? No Required via manual\ /web entry? Yes Remove \"3.1415926535\" from <UnitValue>3.1415926535</UnitValue> and replace it with the weight or percentage value for the associated ingredient. September 09, 2019 160 Chapter 13 \u2013 Import an Application via XML Format", "Label Submission and Approval System (LSAS) Industry User Guide State Values Alabama Nebraska Alaska Nevada American\_Samoa New\_Hampshire Arizona New\_Jersey Arkansas New\_Mexico Armed\_Forces\_Africa\_Canada\_Europe\_Middle\_East New\_York Armed\_Forces\_Americas\_except\_Canada North\_Carolina Armed\_Forces\_Pacific North\_Dakota California Northern\_Mariana\_Islands Colorado Ohio Connecticut Oklahoma Delaware Oregon District\_Of\_Columbia Palau Federated\_States\_Of\_Micronesia Pennsylvania Florida Puerto\_Rico Georgia Rhode\_Island Guam South\_Carolina Hawaii South\_Dakota Idaho Tennessee Illinois Texas Indiana Utah Iowa Vermont Kansas Virgin\_Islands Kentucky Virginia Louisiana Washington Maine West\_Virginia Marshall\_Islands Wisconsin Maryland Wyoming Massachusetts Michigan Minnesota Mississippi Missouri Montana September 09, 2019 161 Chapter 13 \u2013 Import an Application via XML Format", "Label Submission and Approval System (LSAS) Industry User Guide Country Values (Additional valid Country names appear on the next two pages.) Abkhazia Afghanistan Aland Albania Algeria American\_Samoa Andorra Angola Anguilla Antigua\_and\_Barbuda Argentina Armenia Aruba Ascension Ashmore\_and\_Cartier\_Islands Australia Australian\_Antarctic\_Territory Austria Azerbaijan Bahamas\_The Bahrain Baker\_Island Bangladesh Barbados Belarus Belgium Belize Benin Bermuda Bhutan Bolivia Bosnia\_and\_Herzegovina Botswana Bouvet\_Island Brazil British\_Antarctic\_Territory British\_Indian\_Ocean\_Territory British\_Sovereign\_Base\_Areas British\_Virgin\_Islands Brunei Bulgaria Burkina\_Faso Burundi Cambodia Cameroon Canada Cape\_Verde Cayman\_Islands Central\_African\_Republic Chad Chile China China\_Republic\_of\_Taiwan Christmas\_Island Clipperton\_Island Cocos\_Keeling\_Islands Colombia Comoros Congo Congo\_Brazzaville Cook\_Islands Coral\_Sea\_Islands Costa\_Rica Croatia Cuba Cyprus Czech\_Republic Denmark Djibouti Dominica Dominican\_Republic Ecuador Egypt El\_Salvador Equatorial\_Guinea Eritrea Estonia Ethiopia Falkland\_Islands\_Islas\_Malvinas Faroe\_Islands Fiji Finland France French\_Guiana French\_Southern\_and\_Antarctic\_Lands Gabon Gambia\_The Georgia Germany Ghana Gibraltar Greece September 09, 2019 162 Chapter 13 \u2013 Import an Application via XML Format", "Label Submission and Approval System (LSAS) Industry User Guide Greenland Grenada Guadeloupe Guam Guatemala Guernsey Guinea GuineaBissau Guyana Haiti Heard\_Island\_and\_McDonald\_Islands Honduras Hong\_Kong Howland\_Island Hungary Iceland India Indonesia Iran Iraq Ireland Isle\_of\_Man Israel Italy Ivory\_Coast Jamaica Japan Jarvis\_Island Jersey Johnston\_Atoll Jordan Kazakhstan Kenya Kingman\_Reef Kiribati Korea\_North Korea\_South Kuwait Kyrgyzstan Laos Latvia Lebanon Lesotho Liberia Libya Liechtenstein Lithuania Luxembourg Macau Macedonia Madagascar Malawi Malaysia Maldives Mali Malta

Marshall\_Islands Martinique Mauritania Mauritius Mayotte Mexico Micronesia Midway\_Islands Moldova Monaco Mongolia Montenegro Montserrat Morocco Mozambique Myanmar\_Burma NagornoKarabakh Namibia Nauru Navassa\_Island Nepal Netherlands Netherlands\_Antilles New\_Caledonia New\_Zealand Nicaragua Niger Nigeria Niue Norfolk\_Island Northern\_Cyprus Northern\_Mariana\_Islands Norway Oman Pakistan Palau Palmyra\_Atoll Panama Papua\_New\_Guinea Paraguay September 09, 2019 163 Chapter 13 \u2013 Import an Application via XML Format", "Label Submission and Approval System (LSAS) Industry User Guide Peru Tajikistan Peter\_I\_Island Tanzania Philippines Thailand Pitcairn\_Islands TimorLeste\_East\_Timor Poland Togo Polynesia Tokelau Portugal Tonga Pridnestrovie\_Transnistria Trinidad\_and\_Tobago Puerto\_Rico Tristan\_da\_Cunha Qatar Tunisia Queen\_Maud\_Land Turkey Reunion Turkmenistan Romania Turks\_and\_Caicos\_Islands Ross\_Dependency Tuvalu Russia Uganda Ukraine Saint\_Bartelemy United\_Arab\_Emirates Saint\_Helena United\_Kingdom Saint\_Kitts\_and\_Nevis United\_States Saint\_Lucia Uruguay Saint\_Martin US\_Virgin\_Islands Saint\_Pierre\_and\_Miquelon Uzbekistan Saint\_Vincent\_and\_the\_Grenadines Vanuatu Samoa Vatican\_City San\_Marino Venezuela Sao\_Tome\_and\_Principe Vietnam Saudi\_Arabia Wake\_Island Senegal Wallis\_and\_Futuna Serbia Yemen Seychelles Zambia Sierra\_Leone Zimbabwe Singapore Slovakia Slovenia Solomon\_Islands Somalia Somaliland South\_Africa South\_Georgia\_\_South\_Sandwich\_Islands South\_Ossetia Spain Sri\_Lanka Sudan Suriname Svalbard Swaziland Sweden Switzerland Syria September 09, 2019 164 Chapter 13 \u2013 Import an Application via XML Format", "Label Import Up!.oad XML flies lo import Label Appl'ication: Download Schema Sel'eect an XML file to upl'oad\* I! Browse... I No file selected. Upload Label Import Up!.oad XML mes to import Label ApplTcation: Download Schema Sel:eect an XML fi'l'e to upl'.oa!J\u2022 11 Browse ... ! Turkey\_Breast\_and\_Stuffing.xml Upload Label Submission and Approval System (LSAS) Industry User Guide Upload an XML Import File Before performing the steps in this section, configure the in-house system to export label information using the downloaded XML schema so that it is LSAS-readable. 1. Select Import Applications from the Label Applications menu in the left panel. LSAS will display the Label Import screen. 2. Click the Browse button to select the XML file containing the label information. After selecting the desired file, the screen will display the filename next to the Browse option. 3. Click the Upload button to upload the XML file. September 09, 2019 165 Chapter 13 \u2013 Import an Application via XML Format", "Label Import I!lupload XML files to import Label Application: Download Schema Select an XML fil'e to upload\u2022 11 Browse... J No file selected. I Upload I Uploaded Files SelecUo Remove File Name Turkey\_Breast\_ancl\_Stuffing.xml Remove Selected Import All I Label Import Upload XML flies to import Label Application: Download Schema Select an XML file to upload\* I [ Browse... ] No file selected. Upload Uploaded Files Select to Remove File Name Turkey\_Breast\_and\_Stuffing.xml ID Turkey\_Meatballs\_Spaghetti.xml Remove Selected Import All Label Submission and Approval System (LSAS) Industry User Guide The screen will expand to display an Uploaded Files list that includes the newly uploaded file. Repeat Steps 2 and 3 for each XML file that you wish to import. XML File Upload Validation Rules \u2022 File extensions (.xml) are not case sensitive. \u2022 LSAS will not allow you to upload a file that has the same filename as a previously uploaded file. 4. 5. OPTIONAL: If you would like to remove an uploaded file, select its associated checkbox and then click the Remove Selected button. You can remove one or multiple files simultaneously. September 09, 2019 166 Chapter 13 \u2013 Import an

Application via XML Format", "Include all establishments associated with this label application \u2022 Select establishments 358 -Grand River Poultry Ltd. 443 -Atlantic Beef Products Inc M4037 + P 4037 -Plymouth Beef Company, Inc. I Include Selected Do you want to add an establishment? I Add Establishments I otherwise, You may create a temporary establishment or contact organization administrator to assign additional establishments to your organization. Do you need to include a temporary establishment? Include Temporary Establishment Upload the image(s) of your label along with any supporting documentation: Select the documentation type to associate with your file \u2022 I Label Image \u2022 v I Select a file to upload \u2022 Browse.u I I Upload I \u2022 Required Fields Label Submission and Approval System (LSAS) Industry User Guide 6. After all desired XML files have been uploaded, click the Import All button. LSAS will import all of the XML files that appear in the Uploaded Files table. Each file will be converted into a draft label application that has all of the label information pre-populated using the values from the associated XML file. 7. Select the label application from the Drafts pool on the dashboard to review the information. 8. Using Save and Continue at the bottom of every entry screen, you can step through the field validations. The Import XML process does not include all of the required information to create a label application. At a minimum, those who use the import process will still have to enter the following information manually: \u2022 Establishments screen \u2013 Enter the Establishment information. \u2022 Label Documentation screen \u2013 Upload the label image and relevant supporting documents. September 09, 2019 167 Chapter 13 \u2013 Import an Application via XML Format", "..... Added Ingredients Ingredient Ingredient Name Weight Percentage 1\u25a1 beef tenderloin medallions NIA 1140 1\u25a1 POTATOES NIA 1120 \u25a1 CARROTS NIA 115 \u25a1 ONION NIA 10 \u25a1 WATER NIA 110 1\u25a1 SALT NIA 11s I Exclude Selected I Calculated Total: 100% Totals will be recalculated upon saving. I certify that any applicable ingredients in my product formulation are used within the restricted conditions or use listed in 9CFR 424.21, 424.22, and 424.23. \u2022 Conditions for Temporary Applications Provide the specific reason why the label application is submitted for Temporary Approval?\u2022 (What are the reasons for seeking temporary approval? What ingredients have changed? What is in the product that is not on the label? What process has changed?) Maximum limit is 2000 characters . ..... 'I I verify that I have followed the instructions for completing this Temporary Application request \u2022 Label Submission and Approval System (LSAS) Industry User Guide \u2022 Product Formula screen \u2013 Select the verification checkbox. You can Save the ingredient information, but you can\u2019t Save & Continue without the box being checked. Additionally, the box must be checked before submitting the application. Additionally, for Temporary and Extension of Temporary applications only), the following fields require entry or selection: \u2022 Approval Information screen \u2013 Enter the reasons you are seeking temporary approval in the textbox provided and select the checkbox to confirm you have followed the instructions for completing a temporary application. This checkbox must be selected for all temporary applications. 9. Navigate to the 7234 Summary screen, review the label information, and click Submit Application. September 09, 2019 168 Chapter 13 \u2013 Import an Application via XML Format", "Label Submission and Approval System (LSAS) Industry User Guide Appendix A: Glossary of Common Terms Administrator: The term \u201cAdministrator\u201d can apply to different types of LSAS users: \u2022 LPDS Administrator (LSAS role = Administrator): An internal LPDS user who has authority to access all

functions within the system. \u2022 Organization Administrator (LSAS role = Submitter): An Organization Administrator is the main contact person representing a company or establishment. The main role of the Organization Administrator is to add or remove users accessing LSAS within their organization, in addition to all of the associate\u2019s tasks. Agent: An individual or organization that acts on behalf of an establishment for the purpose of submitting a label application. Appeal Status: An appeal may be Under Appeal, Appeal Approved, or Appeal Denied. Approval Number: An Approval Number is assigned to a label application that has been adjudicated and approved. Prior to adjudication, the same number is used as the Application Number to uniquely identify the label application within LSAS. The Approval Number replaces the barcode number. Approval Request Type: The submitter can request sketch, sketch modified, temporary, and extension of temporary. Application Status: A label\u2019s status in LSAS (Received, Pending, Returned, Sketch, or Sketch Modified) Area of Principal Display: The size of the label on the product. Associate: An associate will be an LSAS user assigned by the organization\u2019s administrator to perform label submission tasks, including checking LAP status, viewing LAPs, withdrawing, etc. CN Product: The label may be a product designated as a child nutrition product. The CN number must be obtained from AMS prior to submitting the label into LSAS. Consultant: (see Agent) Earliest and Latest Submission Date: The label\u2019s submission date. Earliest and Latest Status Date: The date the status of the label was changed. Earliest and Latest Expiration Date: The date the label expired. Earliest and Latest Appeal Adjudication Date: The date the label was adjudicated. Egg Approval Number: Labels for use on egg products (frozen, dried, liquid), must be preapproved. A separate label approval number containing one letter and a three-digit number (e.g., M001) is assigned to each label that has been approved. The assigned USDA approval number must be printed within a rectangular box and needs to be no larger than the smallest printing on the label. Labels identifying imported egg products will contain a twoletter prefix, (e.g., CN001) and labels approved for identification of products for export only will have a oneletter code.

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Establishment Number: An identification number assigned to an establishment. Establishment Type: Identifies an establishment as either domestic or foreign. Firm: The primary contact organization associated with a label application. The firm is usually, but not always, the same as the label application\u2019s establishment. HACCP Process Category: The category the product falls under based on the processing operations at establishment. Ingredient Name: An ingredient that is part of the product\u2019s formula. Name of Product: The field name as displayed on Form 7234-1 (block 5a), the Product Information screen, the Search screen, the Search Results screen, the Summary screen, and the downloaded PDF of the Summary. Number of Days Requested: For temporary approvals, the submitter provides the number of days he wants to use the existing labels. Number of Labels on Hand: For temporary approvals, the submitter must provide the number of labels to use in the temporary period. Processing Procedures: A description of the procedures or steps used to process the product. Profile: A profile represents a company or establishment. A company may have one or more facilities or establishments. LSAS allows companies to assign profiles for each facility or establishment. Resubmission: A label application that was submitted more than once. Specials Claims Type: A label may have allergen, nutritional, and other specific attributes requiring additional documentation. Total Available Labeling Space: The space available on the

label. Type of Product: Type of product can be meat, poultry, egg, or other. September 09, 2019  
170 Appendix A: Glossary", "INSTRUCTIONS FOR PREPARATION OF FSIS FORM 7234-1 Note: The following instructions should be typed unless otherwise noted. A. B. C. D. E. PREPARATION OF APPLICATION Application must be typed or it will be returned without evaluation. Submit two copies for each label application. TYPE OF APPROVAL REQUESTED Skelch: Selfexplanatory. (See9CFR317.4&381.132) Temporary and Extension of Temporary. Actual label or color litho take off to be used. FOREIGN LANGUAGE Labels printed in foreign languages must be accompanied by English language translation ASSEMBLY OF APPLICATION Application Form, Product Formula, Processing Procedures, Continuation Sheet if applicable, Label, and any Supporting Documentation Staple with one or as few staples as possible. (Do not use paper clips). MAIL COMPLETED APPLICATION TO: USDA, FSIS, OPPD, LPDD labeling Distribution Unit Stop Code 3786, Patriots Plaza III, 8-168 1400 Independence Avenue, SW Washington, DC 20250-3700 The following instructions relate to numbered items on form. 1. If using an Agent, provide the company name, address, and telephone number, otherwise leave blank. 2 & 3 Leave blank, for USDA use only. 4. Establishment No Foreign Country (if applicable)-Self Explanatory. 4a. 5a 5b Type of Product. Select one product type: Egg, Meat, Poultry, or Other (i.e. Exotic Species, Non-Amenable, Voluntary, etc.) Name of Product. Use common or descriptive product name, Le., "Frankfurter . Cereal Added" or "Meat Patties in Gravy. (Do not use trade brand names or coined names, such as "Joe's Corn Dogs" or "Joe's Sloppy Joes. j If coined names such as .. Corn Dogs~ are used, also show true product name, such as "Balter Wrapped Wiener." Provide HACCP process category for the product. See 9 CFR 417.2(b) (1), Example, Heat Treated -shelf stable, Not heat treated-shelf stable etc. Select one. 6a & b. Type of Approval Requested. If temporary approval or extension, insert number of days requested and number of labels on hand. If previous approval, attach copy of application and label. Include specific reason(s) why requesting a temporary or extension and include information required in 9 CFR 317.4(Q (1) or 381.132(Q (1) on the continuation sheet 7a. Be sure to include product name and block item. Area of Principal Display Panel (PDP). The PDP is the entire side of the package to which the label is affixed. See 9 CFR 317.2 (d) and 381.116(b). FSIS FORM 7234-1 (11/16/2011) 7b. 8. 9. 10. Total available labeling space in square inches for entire package. USDA-AMS Child Nutrition Program Logo. Indicate if the product includes a USDA-AMS Child Nutrition Program Logo. Leave Blank. For USDA-AMS use only. Special claims, guarantees, or foreign language. Indicate if there are any special claims, guarantees, or foreign language on the label. Check all that apply. If Other Claims is selected, indicate specific claim(s) in space provided. 11. Name and Address of Firm. Insert Firm's name and mailing address. Use 2 letter symbol for State. Show postal zip code. 12 & 13 Signature and Date of Applicant or Agent. To be signed and dated by the applicant or agent representing the official establishment or plant. 14. 15. 16. Leave blank for USDA use only. Conditions Applying to Use of Label or Device. (Any condition, modification or remarks applied to the application when approved are conditions governing use of the approved devices.) Product Formula. List the ingredients by percent or weight in order of their predominance. If product consists of several components, e.g., a frozen dinner, list each component separately and indicate the percentage or amount of each component in the product. If additional space is needed, check the box for continuation Sheet, and use the Continuation Sheet. Be sure to include the product name and number of the block item. Express all ingredients in the same units, i.e., do not list some in

pounds and others in ounces. Check whether weight or percent is used. It is preferred that percentages be used, and the total must equal 100 percent. If weights are used, show in pounds, kilograms or grams. (No gallons, pints, cups, teaspoons, etc.) The total must equal the weights of the individual units. (Example: Crust+ Cheese +Sauce+ Meat= Total new weight of unit.) DO NOT use fractions. Express as decimals carried to two places, Example: 1-1/4 lbs., show as 1.25 lbs. Example: 314 lbs., show as .75 lbs. Processing Procedures. Poultry Products provide complete processing procedures as required in 9 CFR 381.134. Meat Products, provide complete processing procedures as required. Note: Approval of the sketch does not convey approval of the processing procedures. If additional space is needed, check the box for "Continuation Sheet" and use the Continuation Sheet. Be sure to include the product name and number of the block item. Label Submission and Approval System (LSAS) Industry User Guide Appendix B: FSIS Form 7234 (Label Application) Preparation Instructions NOTE: Copy and mailing requirements not applicable for electronic submission. September 09, 2019 171 Appendix B: FSIS Form 7234", "Label Submission and Approval System (LSAS) Industry User Guide Appendix C: FSIS Form 8822-4 (Appeal) Preparation Instructions NOTE: Copy and mailing requirements not applicable for electronic submission. FSIS Form 8822-4 is used to request label reconsideration from USDA, FSIS, Labeling and Program Delivery Staff (LPDS) for label applications (FSIS Form 7234-1) which have been modified or rejected. A. PREPARATION OF APPLICATION Application must be typed, or it will be returned without evaluation. B. ASSEMBLY OF APPLICATION Attach two copies of the completed FSIS Form 8822-4 along with two copies of the rejected or previously modified approval FSIS Form 7234-1 for which you are appealing. Include the rejection letter if applicable. Staple with one or as few staples as possible. Do not use paper clips. C. MAIL COMPLETED APPLICATION TO: USDA, FSIS, OPPD, Labeling and Program Delivery Staff Labeling Distribution Unit -APPEAL Stop Code 3786, Patriots Plaza III, 8-168 1400 Independence Avenue, SW Washington, DC 20250-3700 Express Mail Only: USDA, FSIS, OPPD, Labeling and Program Delivery Staff Labeling Distribution Unit -APPEAL Patriots Plaza III, 8-168 355 E. Street, SW Washington, DC 20024-3221 FAX: 301-504-0873 or 301-504-0875 Telephone: 301-504-0883 (Distribution Unit) Instructions: Complete all sections of Page 1 on the FSIS Form 8822-4. COMPANY REASON(S) FOR REQUESTING LABEL RECONSIDERATION. Provide a reason(s) why the label should not have been modified or rejected. This can be a simple statement. If additional space is needed, check the box for "Continuation Sheet" and use the Continuation Sheet provided. Written arguments supporting the basis for the appeal must be enclosed with the appeal. In addition, all uncontested modifications to labeling must be made prior to the submission of an appeal. When prior approvals are mentioned in your argument, provide complete, legible copies of the prior approvals. If numerous prior approvals are involved, provide a listing of the approval numbers and a few legible copies of the prior approvals. REVIEWER'S REASON FOR DISAPPROVAL OR MODIFICATION. Include the label reviewer's reason(s) for the rejection and/or modification. If unsure, leave blank. September 09, 2019 172 Appendix C: FSIS Form 8822-4", "Label Submission and Approval System (LSAS) Industry User Guide Appendix D: LSAS Tips LSAS TIP 1 (updated) What is a temporary establishment? When should I utilize this function? If a submitter does not yet have an establishment number for an establishment he is associating to a label application, then LSAS can generate a temporary establishment number until the official number is assigned. NOTE: If you know the establishment's name or number, then you must utilize the "Add

Establishment from PHIS\button rather than using the temporary establishment function. This is to keep establishment data consistent in LSAS. LSAS TIP 2 \u2013 Label Image Resolution When attaching your Label Image to your submission, we recommend the resolution be set at 300 dpi when scanned and orientation set to portrait. LSAS TIP 3 \u2013 How to Print An Adjudicated Label with Annotations (Stamps, Modifications, etc.) Select all the documents that you want to include in the download. Be sure to check the \u201cInclude Annotations\u201d checkbox. After downloading, in the Adobe Reader window, from the Print menu under \u201cComments & Forms\u201d, select \u201cDocument and Markups\u201d. Then proceed to print LSAS TIP 4 (updated) \u2013 My application was returned to me. Where do I find the reason(s) it was returned? You will find the reason(s) for the returned submission by reviewing the Label Application Comments located at the bottom of the detailed Summary. Select your returned application from the Returned Pool. Select Manage Application, Select Summary from the Available Actions, and scroll to the bottom of the page to review the Label Application Comments entered by the technical reviewer. LSAS TIP 5 \u2013 How do I resubmit my returned application to LPDD? Select your returned application from the Returned Pool, Manage Application, and Select Edit from Available Actions. This function allows you to make corrections, additions, deletions, etc. You can navigate to the specific area of the application by using the Go To function in the upper right corner of the dashboard. Be sure to save your changes. Finally, using the Go To function, Select 7234 Summary to review and submit your application. When the application is resubmitted, it will appear in the LPDD pool as a resubmittal. LSAS TIP 6 (updated) \u2013 I received a Sketch Modified label. Where do I find the explanation of the modifications that were made? Reason(s) for the modifications can be located on the annotated label image, application form, and/or in the Comment field section of the Summary. LSAS TIP 7 \u2013 Appeal The \u201cAppeal\u201d function should only be used if an establishment disagrees with a specific modification or reason for rejection. For additional guidance see the instruction page for Form 8822-4. Selection of an appeal is not a means to \u201cresubmit\u201d a returned application, Example: reviewer request a legible copy of label. See Tip 5 posted in the Announcements. September 09, 2019 173 Appendix D: LSAS Tips", "Label Submission and Approval System (LSAS) Industry User Guide LSAS TIP 8 (updated) \u2013 Extraordinary Circumstances The selection of an \u201cExtraordinary Circumstances\u201d should only be chosen if the product has been retained ("tagged") by program personnel at official establishments or when there is some other unforeseeable impediment to movement of meat or poultry product, and a temporary label approval would remove the impediment. For complete policy guidance see the FSIS website:  
<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labelingprocedures/procedures-evaluating-labeling> LSAS TIP 9 \u2013 Formula Information When listing your ingredients for Step 6-Formula Information, DO NOT include any special characters, bullets, numbered listings, etc. Simply list the ingredient name. This ensures that ingredients can easily be added to the database. INCORRECT: # Cheddar cheese 109.Ham \*\*Parsley --Tomato Paste CORRECT: Cheddar cheese Ham Parsley Tomato Paste LSAS TIP 10 \u2013 Label Documentation To avoid unnecessary delays during label review: Do not upload images or documents that contain layers, comments, bookmarks, hidden text, or which are Password-Protected, i.e., FSIS Form 7234-1. Files that are created in Adobe Illustrator\u2014or similar imaging applications\u2014must be flattened before being uploaded

to LSAS. NOTE: Printer-ready labels are composed of multiple layers of information. In some cases, a layer consisting of a clear mask or \u201cvarnish\u201d overlays all underlying layers. It is important that this layer be disabled or turned off before uploading the image to LSAS.

LSAS TIP 11 -Egg Product Labels and Exotic Species To avoid unnecessary delays, labels for egg products and exotic species are NOT eligible for generic approval and they must be submitted to LPDS for review and approval. Therefore, please select \u201cno\u201d to the question: \u201cAre you requesting a voluntary review for a label that can be generically approved?\u201d

September 09, 2019 174 Appendix D: LSAS Tips", "Label Submission and Approval System (LSAS) Industry User Guide Appendix E: LSAS Links FSIS Labeling Links Labeling Guidance:

[http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/LabelSubmissionandApprovalSystem\(LSAS\)](http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/LabelSubmissionandApprovalSystem(LSAS)):

<https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/label-submission-and-approval-system> Food Standards and Labeling Policy Book: [http://www.fsis.usda.gov/wps/wcm/connect/7c48be3e-e516-4ccfa2d5b95a128f04ae/Labeling\\_Policy\\_Book\\_082005.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/7c48be3e-e516-4ccfa2d5b95a128f04ae/Labeling_Policy_Book_082005.pdf?MOD=AJPERES) A Guide to Federal Food Labeling Requirements for Meat, Poultry, and Egg Products:

[http://www.fsis.usda.gov/wps/wcm/connect/f4af7c74-2b9f-4484-bb16fd8f9820012d/Labeling\\_Requirements\\_Guide.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/f4af7c74-2b9f-4484-bb16fd8f9820012d/Labeling_Requirements_Guide.pdf?MOD=AJPERES) Child Nutrition (CN) Labeling Program: <http://www.fns.usda.gov/cnlabeling/child-nutrition-cn-labeling-program>

To obtain a CN Number if you do not currently have an assigned CN number, email AMS at: [cnlabeling@ams.usda.gov](mailto:cnlabelling@ams.usda.gov)

Labeling Areas of Specialization:

[http://www.fsis.usda.gov/wps/wcm/connect/386a393e-a650-4adb-876a37b376b2600e/Labeling\\_Areas\\_of\\_Specialization.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/386a393e-a650-4adb-876a37b376b2600e/Labeling_Areas_of_Specialization.pdf?MOD=AJPERES) Temporary Approval \u2013 Required Information:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures/requesting-temporaryapproval/requesting-temporary-approval> Special Statements or Claims:

<http://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Comp-Guide-Labeling-EvaluationApproval.pdf?MOD=AJPERES> Extraordinary Circumstances \u2013 Procedures for Evaluating Labeling:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures/procedures-evaluating-labeling> Code of Federal Regulations <https://www.govinfo.gov/app/collection/cfr>

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<https://www.govinfo.gov/content/pkg/CFR-2019-title9-vol2/xml/CFR-2019-title9-vol2-sec317-2.xml> 9 CFR Part 381, SubPart N: <https://www.govinfo.gov/content/pkg/CFR-2019-title9-vol2-part381-subpartN.xml> Ingredient Formula:

<https://www.govinfo.gov/content/pkg/CFR-2019-title9-vol2/xml/CFR-2019-title9-vol2-part424-subpartC.xml> FSIS General Links askFSIS: <http://askfsis.custhelp.com> Regulations, Directives, and Notices: [https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations](http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations) Federal Grant of Inspection Guide:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/apply-for-a-federal-grant>

of-inspection September 09, 2019 176 Appendix E: LSAS Links", "Label Submission and Approval System (LSAS) Industry User Guide Appendix F: FAQs Whom do I contact if I need assistance or have a technical issue concerning LSAS? The LSAS administrator will be your first contact. You may email the administrator at LSAS@fsis.usda.gov or call 301-504-0878. Whom do I contact if I need assistance or have a question concerning labeling, standards, product composition, generic labels, returned submissions, etc.? Contact LPDS at: (301) 504-0878 or submit a question through askFSIS: <http://askfsis.custhelp.com/> Whom do I contact if I need help with my e-Authentication account? For assistance with your Level 2 e-Authentication account or password issues, you may contact the USDA eAuthentication Service Desk at 1-800-457-3642, Option 1, or eAuthHelpDesk@ftc.usda.gov. How do I log on to LSAS? You can log on to LSAS by visiting the following website: <https://lsas.fsis.usda.gov> Is there a User Manual? Yes, you can download the latest version of the LSAS User Manual by visiting the website:

[http://www.fsis.usda.gov/Regulations\\_&\\_Policies/Label\\_Submission\\_Approval\\_System/index.asp](http://www.fsis.usda.gov/Regulations_&_Policies/Label_Submission_Approval_System/index.asp) September 09, 2019 177 Appendix F:

FAQs"]}, {"file\_name": "FSIS\_GD\_2015\_0018", "title": "Sanitary Dressing and Antimicrobial Intervention Implementation at Veal Slaughter Establishments: Identified Issues and Best Practices", "num": "FSIS-GD-2015-0018", "id": "23338ea07328f870afc9b11822042177f599eb5ee0bf0a92c903e62d591a2431", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Veal-Sampling-092015.pdf", "type": "pdf", "n\_pages": 16, "word\_count": 1450, "text\_by\_page": ["Sanitary Dressing and Antimicrobial Intervention Implementation at Veal Slaughter Establishments: Identified Issues and Best Practices The purpose of this document is to help veal slaughter establishments to implement effective sanitary dressing and process-control procedures. veal slaughter sanitary dressing best practices antimicrobial intervention implementation United States Department of Agriculture Food Safety and Inspection Service August 2015", "2 United States Department of Agriculture Food Safety and Inspection Service veal slaughter sanitary dressing best practices Table of Contents What issues has FSIS identified concerning veal slaughter establishments? ..... 4 What are some examples of the sanitary dressing deficiencies FSIS observed repeatedly during onsite visits to veal slaughter establishments? ..... 4 What are some examples of antimicrobial intervention implementation deficiencies FSIS observed repeatedly during onsite visits to veal slaughter establishments? ..... 8 What other issues did FSIS identify at veal slaughter establishments? ..... 10 What are some examples of best practices concerning sanitary dressing? ..... 10 How do veal slaughter establishments implement effective sanitary dressing procedures to prevent carcass contamination and the creation of insanitary conditions? ..... 13 What are some examples of best practices concerning antimicrobial intervention implementation? ..... 13 veal slaughter", "3 United States Department of Agriculture Food Safety and Inspection Service antimicrobial intervention best practices Table of Contents (continued) How do veal slaughter establishments implement antimicrobial interventions effectively? ..... 14 How do establishments properly assess

microbial testing results? .....14 Where do establishments find more information about sanitary dressing and process-control procedures? .....15 Where do establishments find more information about identifying scientific support and the critical operating parameters in the support for their interventions so they can implement their interventions effectively?

.....15 Who can establishments contact if they have questions or need additional information?

.....15", "4 United States Department of Agriculture Food Safety and Inspection Service veal slaughter sanitary dressing deficiencies What issues has FSIS identified concerning veal slaughter establishments? FSIS test results show that the percent positive for Shiga toxin-producing Escherichia coli (STEC) from trimmings produced from veal appears to be higher than that for trimmings produced from other cattle slaughter classes. FSIS identified common deficiencies: inadequate sanitary dressing, ineffective antimicrobial intervention implementation, and failure to use microbial data in decisionmaking. What are some examples of the sanitary dressing deficiencies FSIS observed repeatedly during onsite visits to veal slaughter establishments? Cutting through the weasand (esophagus) during sticking resulting in ingesta contaminating the carcass and head. Cutting through the hide and further processing without sanitizing knives, gloves, and equipment adequately to prevent carcass contamination.", "5 United States Department of Agriculture Food Safety and Inspection Service sanitary dressing deficiencies Cutting through the hide and into the carcass without sanitizing knives, resulting in carcass contamination. Hide flaps contaminating carcass. Bagged bung contacting hide and contaminating carcass.", "6 United States Department of Agriculture Food Safety and Inspection Service veal slaughter sanitary dressing deficiencies Exposed bung contaminating the carcass. Puncturing paunch and intestines during evisceration, resulting in carcass contamination. Ingesta from punctured paunch and intestines, resulting in carcass contamination.", "7 United States Department of Agriculture Food Safety and Inspection Service sanitary dressing deficiencies Eviscerating carcass with the hide on, resulting in carcass contamination. Cold skinning (removing the hide after the carcass has chilled down), resulting in carcass contamination. Contaminated carcass in cooler as a result of sanitary dressing deficiencies.", "8 United States Department of Agriculture Food Safety and Inspection Service veal slaughter sanitary dressing Contaminated packaged product in freezer as a result of sanitary dressing deficiencies. What are some examples of antimicrobial intervention implementation deficiencies FSIS observed repeatedly during onsite visits to veal slaughter establishments? Crosscontamination of heads from carcass intervention overspray.", "9 United States Department of Agriculture Food Safety and Inspection Service antimicrobial intervention deficiencies Intervention failing to achieve full carcass coverage, thus reducing the intervention\u2019s effectiveness. Intervention failing to achieve full product coverage, thus reducing the intervention\u2019s effectiveness. Intervention failing to achieve full product coverage, thus reducing the intervention\u2019s effectiveness.", "veal slaughter sanitary dressing best practices 10 United States Department of Agriculture Food Safety and Inspection Service veal slaughter sanitary dressing best practices What other issues did FSIS identify at veal slaughter establishments? FSIS observed that veal slaughter establishments were not properly evaluating testing results, including indicator organism results (e.g., generic E. coli, Aerobic Plant Count, or Enterobacteriaceae) on carcasses and STEC on beef manufacturing trimmings

and in ground veal to help determine how the results impact their slaughter operation. What are some examples of best practices concerning sanitary dressing? Misting hides in pens to reduce dust and dirt particles. Rodding the weasand to free the weasand from the trachea, making it easier to close the weasand.", "antimicrobial intervention deficiencies 11 United States Department of Agriculture Food Safety and Inspection Service sanitary dressing best practices Weasand clip to prevent leakage of rumen contents. Reflecting the hide away from the carcass during skinning to prevent contamination from the hide. Dual knife system for sterilizing knives.", "veal slaughter sanitary dressing best practices 12 United States Department of Agriculture Food Safety and Inspection Service veal slaughter sanitary dressing best practices Hide clips for preventing contamination from the hide. Tying and bagging bung to prevent spillage of fecal material. Preventing puncturing the paunch and intestines during evisceration.", "antimicrobial intervention deficiencies 13 United States Department of Agriculture Food Safety and Inspection Service sanitary dressing best practices How do veal slaughter establishments implement effective sanitary dressing procedures to prevent carcass contamination and the creation of insanitary conditions? Establishments should develop a comprehensive written sanitary dressing program. The program should include written procedures to prevent carcass contamination. The program should include verification activities that ensure employees are performing the procedures as written and the procedures effectively prevent contamination. Establishments should assess the effectiveness of their procedures using real-time data and assess the impact of microbial results on their slaughter operation. What are some examples of best practices concerning antimicrobial intervention implementation? Hind limbs are spread apart to allow intervention to achieve full carcass coverage. Applying intervention according to supporting documentation. All nozzles are operational, and critical operating parameters are met. Lactic acid dispenser with gauges for monitoring temperature and pressure that, depending on the establishment's supporting documentation, may be critical operating parameters.", "14 United States Department of Agriculture Food Safety and Inspection Service veal slaughter sanitary dressing best practices How do veal slaughter establishments implement antimicrobial interventions effectively? \u2022 Identify supporting documentation that closely matches selected intervention. \u2022 Identify critical operating parameters in the supporting documentation. Critical operating parameters are the specific conditions (such as contact time, pH, temperature, and concentration) of the intervention that must be met for the intervention to be effective. \u2022 Incorporate critical operating parameters into Hazard Analysis and Critical Control Point (HACCP) system. \u2022 Implement intervention so that it meets critical operating parameters. How do establishments properly assess microbial testing results? \u2022 Use test results to assess the effectiveness of their controls for preventing contamination. \u2022 Identify specific criteria for use when the slaughter process is determined to be out of control. \u2022 Verify that their slaughter controls are reducing STEC to a non-detectable level on an ongoing basis. \u2022 Review sanitary dressing procedures and intervention measures to investigate the cause when microbial test results indicate a loss of process control. \u2022 Perform increased microbial testing to demonstrate that the corrective actions taken in response to the loss of process control are effective. FSIS developed the Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers. This guidance has general information on verification testing, designing

sampling plans, and factors affecting the design of sampling.", "15 United States Department of Agriculture Food Safety and Inspection Service antimicrobial intervention best practices Where do establishments find more information about sanitary dressing and process-control procedures? Guidance for Minimizing the Risk of Escherichia coli O157:H7 and Salmonella in Beef Slaughter Operations at <http://www.fsis.usda.gov/wps/wcm/connect/74de2bea-74d6-491b-b2cf-0047650bf0c6/BeefSlauterGuide.pdf?MOD=AJPERES> Best Practices for Beef Slaughter, developed by the beef industry at <http://www.bifsc.org/CMDocs/BIFSCO/Best%20Practices/BestPracslaught%20Sept%2009.pdf> Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers at [http://www.fsis.usda.gov/wps/wcm/connect/e0f06d97-9026-4e1e-a0c2-1ac60b836fa6/Compliance\\_Guide\\_Est\\_Sampling\\_STEC\\_0512.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/e0f06d97-9026-4e1e-a0c2-1ac60b836fa6/Compliance_Guide_Est_Sampling_STEC_0512.pdf?MOD=AJPERES). FSIS PHIS Directive 6410.1 Rev. 1, Verifying Sanitary Dressing and Process Control Procedures by Off-line Inspection Program Personnel (IPP) in Slaughter Operations of Any Age at [http://www.fsis.usda.gov/wps/wcm/connect/5d100e39-8eab-4c88-85a3bb60147d6e10/PHIS\\_6410.1.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/5d100e39-8eab-4c88-85a3bb60147d6e10/PHIS_6410.1.pdf?MOD=AJPERES). Where do establishments find more information about identifying scientific support and the critical operating parameters in the support for their interventions so they can implement their interventions effectively? FSIS Compliance Guidance HACCP Systems Validation at [http://www.fsis.usda.gov/wps/wcm/connect/a70bb780-e1ff-4a35-9a9a-3fb40c8fe584/HACCP\\_Systems\\_Validation](http://www.fsis.usda.gov/wps/wcm/connect/a70bb780-e1ff-4a35-9a9a-3fb40c8fe584/HACCP_Systems_Validation). Who can establishments contact if they have questions or need additional information? Contact the Small Plant Help Desk by telephone at 1-877-FSISHelp (1-877-374-7435) or via email at [InfoSource@fsis.usda.gov](mailto:InfoSource@fsis.usda.gov) or contact the Office of Policy and Program Development through askFSIS at <http://askfsis.custhelp.com/> or by telephone at 1-800-233-3935.", "USDA is an equal opportunity provider and employer. Food Safety and Inspection Service [www.fsis.usda.gov](http://www.fsis.usda.gov)"], {"file\_name": "FSIS\_GD\_2015\_0019", "title": "FSIS Compliance Guidelines Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling", "num": "FSIS-GD-2015-0019", "id": "cc19586548e47399171d9c5508d164ab35cba291ef4372cc5e6cf2ef72d6f10f", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Allergens-Ingredients.pdf", "type": "pdf", "n\_pages": 26, "word\_count": 8153, "text\_by\_page": ["FSIS Compliance Guidelines Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling November 2015", "Purpose This document provides guidance to assist establishments in addressing the hazard posed by allergens in their products. In doing so, establishments must comply with the Food Safety and Inspection Service (FSIS) hazard analysis and critical control point (HACCP) and labeling regulations. This guidance document presents best practice recommendations by FSIS, based on the best scientific and practical considerations. The recommendations in this guidance do not represent requirements that must be met. The focus of this document is meat and poultry products, with an emphasis on FSIS-regulated establishments, state-regulated establishments, and operations where all or part of the premises meet the food processing plant definition as defined in the 2013 Food Code. This guidance represents FSIS's current thinking, and we encourage establishments to use it. This guidance is an update of the"]}]

document that was issued and announced in the Federal Register of April 21, 2014 (79 FR 22083). FSIS has updated this guidance based on comments it received during the public comment period, which closed on June 20, 2014. FSIS made the following changes in response to the comments: \u2022 Clarified and described a letter of guarantee (LOG), the difference between a LOG and a certificate of analysis (COA), and the communication and coordination between an establishment and its suppliers that FSIS recommends when establishments rely on LOGs. \u2022 Added Appendix 6 entitled, \u201cAllergenic Ingredients and Foods\u201d to the guidelines as a resource to identify potential sources of \u201cBig Eight\u201d allergens. \u2022 Clarified that the emphasis of the document is on FSIS-regulated establishments, state-regulated establishments, and operations where all or part of the premises meet the \u201cfood processing plant\u201d definition, as defined in the 2013 Food Code. \u2022 Changed to the text to emphasize the purpose of a hazard analysis, add recommendations for establishments, and clarify ingredients of public health concern. Although comments on this guidance document will no longer be accepted through regulations.gov, FSIS will update this document as necessary should new information become available.

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Chapter 1: Introduction and Background This document provides recommendations for identifying hazards when conducting a hazard analysis and for preventing and controlling hazards through hazard analysis and critical control point (HACCP) plans, Sanitation standard operating procedures (SOPs), or other prerequisite programs with respect to allergens and other ingredients of public health concern. The focus of the guidelines presented in this document is on meat and poultry products with an emphasis on FSIS-regulated establishments, state-regulated establishments, and operations where all or part of the premises meet the \u201cfood processing plant\u201d definition as defined in the Food Code. The guidelines provide information on proper procedures for processing, handling, storing, and labeling a product with an allergenic ingredient or ingredient of public health concern based on three basic principles: 1. Identify 2. Prevent and control 3. Declare Key components of the identify

principle include hazard analysis, inspection of incoming ingredients, cross-referencing product components, and separation of allergenic materials. The prevent and control principle focuses on recommendations for preventing cross-contact in processing areas, such as sanitation and cleaning of equipment and maintaining appropriate process flow. Finally, the declare principle emphasizes prevention of mislabeling during packing, labeling, and storage. These guidelines represent the best practice recommendations of FSIS, based on scientific and practical considerations. The recommendations are not requirements. By following these guidelines, establishments are likely to ensure that product labels declare all ingredients, as required in the regulations, and that products do not contain undeclared allergens or other undeclared ingredients. FSIS recommends that establishments consider incorporating the practices set out in this document in their HACCP plan or Sanitation SOPs or other prerequisite programs.

1.1 Why did FSIS develop this document? From 2008 through 2012, there has been a The \u201cBig Eight\u201d Allergens 1) Wheat 2) Crustacean shellfish (e.g. shrimp, crab, lobster) 3) Eggs 4) Fish 5) Peanuts 6) Milk 7) Tree nuts (e.g. almonds, pecans, walnuts) 8) Soybeans Recall Trends: FSIS-regulated Product Related to Undeclared Allergens \u2022 The number of recalls of FSIS-regulated product attributed to undeclared allergens and ingredients of public health concern has increased from 7 in 2008 to 29 in 2012 \u2022 The proportion of recalls attributed to undeclared allergens and ingredients of public health concern has also increased, from 13% in 2008 to 35% in 2012 4", "Food allergy: Adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food (NIAID) Signs and symptoms of food allergy: According to the CDC, depending on the individual and allergy, the signs and symptoms can vary from mild to sudden and severe, including one or more of the following: \u2022 Hives \u2022 Tingling in the mouth \u2022 Swelling in the tongue and throat \u2022 Difficulty breathing \u2022 Abdominal cramps \u2022 Vomiting or diarrhea \u2022 Eczema or rash \u2022 Coughing or wheezing \u2022 Loss of consciousness \u2022 Dizziness Anaphylaxis: Severe, life-threatening, whole body allergic reaction that occurs seconds to minutes after exposure and can result in respiratory distress, shock, and death According to the NIAID, some food allergens cause allergic reactions primarily if eaten raw; however, most food allergens can still cause reactions even after they have been cooked or have undergone digestion in the stomach and intestines. Ingredients of public health concern: Ingredients to which consumers have reported adverse reactions Food allergens: Specific components of food or ingredients within food (typically proteins) that are recognized by allergen-specific immune cells and cause specific immunologic reactions, resulting in characteristic signs and symptoms (NIAID) sustained increase in the number of recalls of FSIS-regulated product that contained undeclared allergens. These recalls are preventable as many have been the result of ingredient changes, product changes, products in the wrong package, or products with misprinted labels. The consumption of meat and poultry products containing ingredients of public health concern, such as undeclared allergens, may result in adverse health outcomes for certain individuals. According to the National Institute of Allergy and Infectious Diseases (NIAID), the \u201cBig Eight\u201d allergens account for approximately 90 percent of all food allergy reactions. Situations involving the non-declaration of the \u201cBig Eight\u201d allergens may result in a Class I or Class II recall. (Refer to FSIS Directive 8080.1 for additional information on product recall.)

1.2 What is a food allergen? More than 170 foods have been reported to cause allergic reactions; however, eight of the most common allergenic foods account for 90 percent of all food allergic reactions

and are the sources from which many other ingredients are derived. Food allergies are an important public health problem that affect adults and children and are increasing in reported prevalence. There is currently no cure for severe allergic reactions. Therefore, it is necessary to provide guidance on avoiding specific foods, reviewing labels, and managing the relevant signs and symptoms of those that are affected. Establishments are required to declare all ingredients on the label. While the \u201cBig Eight\u201d allergens are the most common allergenic foods, people may have adverse reactions to other substances as well. Consumption of some ingredients, such as sulfur-based preservatives (sulfites), lactose, FD&C Yellow 5 (Tartrazine), gluten, and monosodium glutamate (MSG), may result in an adverse reaction in certain susceptible individuals, yet they are not considered allergens. It should also be noted, especially for establishments producing product for export, that countries outside of the U.S. may have concerns for other allergens that may need to be addressed. For example, Canada and the European Union recognize more than the \u201cBig Eight\u201d allergens.

5", "1.3 What are the undeclared allergen trends that FSIS has observed in industry? FSIS has recognized a notable increase in the number of recalls that have occurred because of undeclared allergens and ingredients of public health concern in product. FSIS has found that many of these recalls occurred because of a change in product formulation by the establishment or a change in a supplier\u2019s ingredient formulation that was not reflected on the labeling of the finished meat or poultry product. If an establishment recalls product because of an undeclared ingredient, an establishment likely has: 1) failed to address the chemical (allergen) food safety hazard in its hazard analysis, 2) failed to support the decisions made in the hazard analysis, 3) failed to reassess the hazard analysis, or 4) failed to effectively implement the controls to support the decisions made in the hazard analysis (see 9 CFR 417.2(a)(1), 417.5(a)(1), 417.4(a)(3), 417.3(b) respectively). In some cases, FSIS requested that establishments recall product in commerce because FSIS in-plant inspection personnel or Enforcement, Investigations, and Analysis Officers (EIAs) found undeclared allergen problems.

Establishments should take steps to identify such problems instead of relying on FSIS to find them. Establishment controls should be in place to address the presence of undeclared allergens and ingredients of public health concern. Establishments are required to declare ingredients on the label if they are included in the product formulation (9 CFR 317.2 and 381.118). Allergen-containing products must be handled, processed, formulated, and stored properly. If allergens are not declared, then the product is adulterated and misbranded. If adulterated and misbranded product has already been shipped into commerce, FSIS would request that it be recalled.

1.4 What is the Food Allergen Labeling and Consumer Protection Act (FALCPA)? The 2004 Food Allergen Labeling and Consumer Protection Act (FALCPA) requires that products under the jurisdiction of the Food and Drug Administration (FDA) that contain a major food allergen clearly identify the allergen on the label (Public Law 108-282, Title II). FSIS supports the voluntary addition of allergen statements (e.g. \u201ccontains\u201d statements) on meat and poultry product labels immediately following the ingredients statement as discussed in the FSIS Compliance Assistance: Allergens-Voluntary Labeling Statements. All ingredients used in the formulation of meat, poultry, or egg products must be declared by their common or usual name in the ingredients statement. Occasionally a substance may be used in a meat, poultry, or egg product whose use in that product, consistent with FDA\u2019s labeling definition, would be as an incidental additive or a processing aid (21 CFR 101.100(a)(3)). If an

establishment believes that a substance is a processing aid or incidental additive in a meat, poultry, or egg product, it should contact FSIS for a determination. FSIS makes these determinations on a case-by-case basis, as discussed in the FSIS Compliance Guide on the Determination of Processing Aids. What is causing undeclared allergen recalls? \u2022 New Ingredient \u2022 New Supplier \u2022 Misprinted Label \u2022 Product in Wrong Package \u2022 Product Reformulation \u2022 Ingredient Reformulation 6", "Food safety hazard: Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption Chapter 2: Prevention and Control Measures for Undeclared Allergens For comprehensiveness, FSIS recommends control measures throughout an establishment\u2019s HACCP system to prevent the potential of undeclared allergens based on three basic principles: identify, prevent and control, and declare. Below are steps establishments should take that could be incorporated within the HACCP plan or Sanitation SOPs or other prerequisite program. As appendices to this document, there are several resources that can be used in conjunction with the identify, prevent and control, and declare concepts: \u2022 Page 14 depicts \u201cHow to Handle Labels of Incoming and Outgoing Products\u201d in a diagram detailing recommended procedures to maintain proper handling of labels. \u2022 Page 15 contains a process flow diagram that illustrates the targets for mitigation in a hypothetical flow diagram for fresh pork sausage. This mitigation targets are highlighted to correspond with the identify, prevent and control, and declare principles emphasized in this guidance. \u2022 Page 16 illustrates an allergen risk evaluation and labeling flow chart to assist with an establishment\u2019s evaluation of whether or not special labeling is needed. \u2022 Page 17 is the beginning of the specific \u201cEstablishment Checklists\u201d that are provided to assist establishments with questions to consider as they brainstorm the identification, prevention and control, and labeling of allergens. \u2022 Page 20 includes \u201cAllergen Scenarios and Possible Preventive Measures\u201d that are hypothetical scenarios along with preventive measures that could have been taken to illustrate the concepts from the guidelines. \u2022 Page 22 is the beginning of a resource entitled \u201cAllergenic Ingredients and Foods\u201d which was adapted from Food Allergy Research and Education (FARE) to help establishments identify \u201cBig Eight\u201d allergens. \u2022 Page 26 highlights the references and sources of information used throughout this document along with other resources for additional information.

2.1. Identify: Inspection of Incoming Ingredients, Cross-referencing Components, Separation A meticulous, comprehensive hazard analysis is crucial to identify and control allergens in an establishment. The hazard analysis serves as the foundation for a strong and successful HACCP plan. Therefore, it is important for the establishment to invest time and resources in the analysis, particularly in hazard identification. According to 9 CFR 417.2(a)(1), the establishment is required to identify all food safety hazards reasonably likely to occur through a hazard analysis. Doing so would include identifying any chemical hazards, such as allergens and ingredients of public health concern, as well as any biological and physical hazards that are reasonably likely to occur in the production process. The introduction of an allergen could occur anywhere during the production process. Therefore, an establishment should be sure to evaluate each step in its process from receiving to packaging and shipment. Allergens fall under the chemical hazards portion of the hazard identification. The introduction of ingredients into product must be taken into account during the hazard analysis 7", "FSIS has found that establishments have not been aware of the potential presence

of allergens within a new ingredient or formulation when changing suppliers or the formulation of an ingredient. It is essential that establishments routinely verify that the ingredient's label reflects its formulation. When a change in suppliers or formulation occurs, establishments should be on high alert for the presence of allergens in the new ingredient or product. It is the establishment's responsibility to routinely check the ingredient's formulation. A hazard analysis is not only used to assess the food safety hazards reasonably likely to occur in the production process but is also used to identify the measures through Critical Control Points (CCPs) that the establishment can apply to control those hazards. The hazard analysis must consider food safety hazards that can occur before, during, and after entry into the establishment. Establishments should be especially thorough during the hazard identification phase of their hazard analysis to identify food safety hazards and ultimately to mitigate the possibility of preventable recalls because of undeclared allergens and ingredients of public health concern. In these guidelines, FSIS has provided measures for controlling the presence of undeclared allergens in product that may be included in an establishment's HACCP system. Measures may also be included within an establishment's Sanitation SOPs or other prerequisite program that sufficiently and effectively prevent the presence of undeclared allergens in product. As a result of the identification of chemical hazards in the hazard analysis, an establishment should have a list of allergens and other ingredients of public health concern that are used in production. According to the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), establishments should evaluate each of these identified hazards based on severity as well as likelihood of occurrence. This evaluation could be based upon historical data, scientific literature, or establishment records. Once the hazard evaluation is completed, establishment personnel should work to develop approaches to control those hazards. As part of food safety and hazard control under federal regulation, every establishment is required to have a written HACCP plan based on its hazard analysis (9 CFR 417.2(b)(1)). The HACCP plan is required to include the food safety hazards reasonably likely to occur in the production process. The establishment is required to have a flow chart describing the steps of each control process and product flow in the establishment (9 CFR 417.2(a)(2)). Every establishment must validate the HACCP plan's adequacy in controlling the food safety hazards, such as undeclared allergens, identified during the hazard analysis. What are some straightforward, practical steps I can take to identify allergens in my establishment?

\u2022 Review a list of all ingredients and products that you use to determine whether they are or contain allergens \u2022 Using an establishment schematic, do a walkthrough noting paths of allergenic ingredients and products and areas of concern where crosscontact may occur \u2022 Keep a list of ingredients used in product formulations and label records at the receiving area to compare against incoming ingredients \u2022 Ensure that all incoming ingredients containing allergenic material are clearly labeled and identified \u2022 Use color coding for allergen-containing ingredients and products \u2022 Store ingredients containing allergenic materials in separate, designated areas that are clearly identified and marked \u2022 Become familiar with letters of guarantee from suppliers \u2022 Maintain open communication of expectations with suppliers and inquire about suppliers' allergen control programs

8", "What is a letter of guarantee (LOG)? A LOG is a document that provides details for components that are used in the areas of food processing, handling, and storage. Generally, a LOG contains:

- \u2022 Supplier name and address
- \u2022 Brand name
- \u2022 Statement that

the material is safe and effective under intended conditions of use and will not adulterate the food product \u2022 Signature of an official of the supplier The LOG may be attached to an invoice or may be a continuing LOG that does not accompany each shipment. and verify that the plan is being effectively implemented to reduce the potential for the presence of undeclared allergens in the product. To fully address all allergens and ingredients of public health concern in the final product, an establishment should first assess ingredients present in the incoming meat or poultry and non-meat or non-poultry components. The establishment should seek out information about the allergens and ingredients of public health concern used by its suppliers. In addition, it should seek information on its suppliers\u2019 production practices, such as whether they employ practices to prevent the cross-utilization of equipment or cross-contact of product. This information may come in the form of a Letter of Guarantee (LOG) that should not to be confused with a Certificate of Analysis (COA). A COA typically includes test results associated with a specific lot, while a LOG may be provided by the supplier to describe the ingredients used in the production of products. Based on the component and complexity of the supplier\u2019s process, the content of the LOG can vary significantly, from a general statement, which is common, to a more detailed description of the supplier\u2019s process (e.g., details including ingredient components, processing aids, rework, processing steps, environmental conditions, or product carry over). In either situation, the LOG should accomplish the same function and be detailed enough to support the decisions made in the hazard analysis. An establishment should review and update the LOGs regularly to ensure that the decisions made in the hazard analysis are supported and to ensure that any formulation changes made by its suppliers are detected prior to incorporating the associated ingredient into the production process. Generally, an annual LOG will not be sufficient to support decisions made in the hazard analysis. An establishment that fails to routinely review and verify the components and ingredients it receives may overlook the presence of an allergen. The result may be the inclusion of a component that is not declared in a product resulting in adulteration and misbranding, which could ultimately lead to a product recall. FSIS recommends that an establishment maintain an approved supplier list along with ingredient information from each supplier. The establishment should use the list when receiving incoming ingredients to verify proper identification of each lot of ingredients. For accuracy, an establishment should also cross-reference the sketch label approval, if applicable, to the actual label being used and the formulation data. It is imperative that the label approval, the actual label, and formulation all match for proper ingredient identification. If there is a discrepancy between the label and the formulation, Every establishment must reassess the adequacy of its HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan (9 CFR 417.4(a)(3)(i)). These changes may include: \u2022 Raw materials or source of raw materials \u2022 Product formulation \u2022 Slaughter or processing methods or systems \u2022 Production volume \u2022 Personnel \u2022 Packaging \u2022 Finishing product distribution systems \u2022 The intended use by consumers of the finished product \u2022 Outbreaks or illnesses associated with this type of product The reassessment and the reasons for any changes to the HACCP plan must be documented. Reasons that the HACCP plan is not changed must also be documented, unless it is an annual reassessment, and no changes are needed (9 CFR 417.4(a)(3)(ii)). 9", "Cross-contact: Inadvertent transfer of allergens to a food product from other food products, food contact surfaces, equipment, utensils, etc. if

ingredients or allergen-containing products are not handled properly establishment should separate the product and ingredients in question and hold them in a secure place, so that they are not used until the ingredients can be properly identified for use in specific products. FSIS labeling guidance, including the Food Standards and Labeling Policy Book, is available on the FSIS website. An establishment can prevent the presence of undeclared allergens by ensuring that appropriate mechanisms for labeling all ingredients are in place. A comprehensive chart, on page 15, details recommended procedures to maintain proper handling of labels on both incoming and outgoing product. As exhibited, this process should be conducted on an ongoing basis.

**2.2 Prevent and Control: Equipment, Sanitation, and Processing**

It is especially critical for establishments to address cleaning of equipment, utensils, and food contact surfaces (FCS) when producing both allergenic and non-allergenic product, to prevent cross-contact and misbranding. Personnel should be trained on the cleaning procedures the establishment employs to control food allergens and should be aware of which products contain allergenic ingredients. Establishments should track work-in-progress product with at least the product name, lot code, and allergenic ingredients or ingredients of public health concern to minimize potential cross-contact during processing. Equipment and utensils used for the preparation, processing, or other handling of all product, including allergenic product, in the establishment need to be suitable for the purpose intended and be of such material and construction that will facilitate thorough cleaning and ensure cleanliness in the preparation and handling of products. Cleaning of equipment, utensils, and FCS areas should be conducted after an allergenic product has had contact with a utensil, surface, or piece of equipment, and before the equipment, utensils, and FCS areas are used for an allergen-free product. It is important that equipment used to handle allergenic product be sufficiently sanitized before handling non-allergenic product. The type of product an establishment is producing, the food contact surfaces being used, and the allergens present in the product all should be considered when designing a cleaning program. A review by Jackson et al. presents cleaning, control, and validation strategies to prevent cross-contact with allergens. They note that, generally speaking, food proteins, which would include allergenic proteins, are some of the most difficult to remove from surfaces. Planning plays a key role when handling and processing both allergenic and non-allergenic product. The most effective and appropriate protocol for handling and processing both allergenic and non-allergenic What are some straightforward, practical steps I can take to prevent cross-contact in processing areas within my establishment? \u2022 Color coding of ingredient packages, supplies, uniforms, and utensils used for products containing allergens throughout processing to facilitate simple identification \u2022 Documenting cleaning procedures with checklists including procedures for spill clean-up \u2022 Employing a method for the verification and validation of cleaning \u2022 Maintaining documented process flow along with mapping the route of allergenic product through the establishment \u2022 Employing a method for tracking of lot codes through production \u2022 Carefully evaluating rework and work-in-progress \u2022 Dedicating equipment or, if not feasible, separate allergenic products by time, space, etc. 10", "FSIS does not recognize a threshold for any allergenic ingredient. Thus, all allergenic ingredients need to be declared on the product label. Allergen test kits as well as laboratory testing using reference laboratories targeted at allergens of interest are available. AOAC International maintains a listing of Performance Tested Methods which includes food allergen kits. This type of allergen testing program may be considered to

verify and document sanitation effectiveness in an establishment. Note that an allergen testing program would be a supplement to documenting cleaning procedures and a visual cleaning assessment. products is to handle and process non-allergenic products before handling and processing allergenic products to reduce the possibility of cross-contact and misbranding. This approach eliminates the need to hold utensils and equipment for proper cleaning before handling and processing allergenic product. FSIS recommends conspicuously and distinctly marking all equipment and utensils used for handling allergenic products. Cleaning and sanitizing equipment, FCS, and utensils is effective at not only removing soil and microorganisms but also food allergen residues. Additionally, FSIS recommends that establishments avoid using the same cooking medium (e.g., oil or water) when processing both allergenic and non-allergenic products. If an establishment chooses to utilize the same cooking medium, it is important that non-allergenic product does not become adulterated with the allergenic product in the cooking medium. Adulteration can be prevented by processing the non-allergenic product before the allergenic product.

**2.3 Declare: Packaging, Labeling, Storage**

Properly declaring allergens in product is just as important as properly identifying incoming ingredients and handling and processing allergenic product. Once an establishment has identified the potential allergens among the ingredients used and has handled and processed products according to its HACCP system, it is the establishment's responsibility to ensure that the product is properly packaged, labeled, and stored. An establishment should set procedures for personnel to easily distinguish allergenic product from non-allergenic product. Procedures should be in place to ensure that the label being applied to a given product within a production lot is correct and matches the label on other packaged units of product within the lot. These procedures should include the accurate identification of all potential allergens. If the product is incorrectly or insufficiently identified, it can lead to both adulteration and misbranding.

What are some straightforward, practical steps I can take to prevent mislabeling during packing, labeling, and storage of final product?

- \u2022 Systems and checklists in place for the labeling of final product
- \u2022 Conduct simulations with inaccurate product labels to test systems, checklists, and procedures
- \u2022 Color coding of products containing allergenic ingredients
- \u2022 Procedures in place for labeling discrepancies to ensure product disposition is evaluated
- \u2022 Verification of the accuracy of product labels
- \u2022 Methods of tracking lot codes through production, storage, and shipping
- \u2022 Storage of products containing allergenic materials in areas that are clearly identified and marked

**11"|"Question:** If an establishment produces a product that incorporates a non-meat or non-poultry ingredient that includes flour (an ingredient derived from wheat) and also produces a product that does not contain wheat, is the establishment required to note on the non-allergenic product's final label that the product may contain wheat or was manufactured in a plant with wheat to prevent false or misbranding information to consumers?

**Answer:** No, the presence of wheat in the establishment does not require a may contain statement on products formulated without wheat. Only in limited situations does FSIS allow the use of factual labeling statements about a product's manufacturing environment (e.g. Produced in an establishment that uses wheat). Statements of this type may only be used where good manufacturing practices cannot reasonably eliminate the unintended presence of ingredients of public health concern. In this case, the HACCP plan, Sanitation SOP, or other prerequisite program should be implemented by the establishment to control this

issue. Note: See the FSIS Compliance Assistance: Allergens-Voluntary Labeling Statements for additional information on the use of voluntary allergen statements of this type. Question: How should an establishment label its product when an incoming seasoning packet contains a \u201cmay contain\u201d statement on its labeling? Answer: All the ingredients in a \u201cmay contain\u201d or \u201cproduced in a facility\u201d statement of a purchased ingredient need not be listed on the final label if the official establishment: 1) Contacts the supplier and confirms in writing that the statement is a cautionary statement, and no such ingredient is in the product; and 2) Includes a written statement in its hazard analysis documentation to support why the \u201cmay contain\u201d or \u201cproduced in a facility\u201d statement is not carried forward to the finished meat or poultry product label. Additionally, the storage of the allergenic and non-allergenic products needs to be easily identifiable through product separation. An establishment should ensure that cross-contact of products does not occur when products are placed in freezers, refrigeration units, or dry warehouses. It should also take care when storing ingredients in dry warehouses or formulation rooms. An establishment should ensure that all ingredients in storage areas are properly identified to prevent employees from selecting the wrong ingredient during formulation. It is important that an establishment verify the accuracy of the final label to ensure that it includes all allergenic and non-allergenic ingredients in the product. An establishment should check the accuracy of labels in relation to the product being packaged. It may also include this procedure within its HACCP plan or other prerequisite program. The product in the package must precisely match the product described by the label on the package. Additionally, 9 CFR 317.2(b) and 9 CFR 381.116(a) require that the ingredients statement on the label be prominently placed with such conspicuously and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. The ingredients statement must also identify the common or usual names of the ingredients arranged in descending order of predominance. A complete and accurate ingredients statement is essential with the presence of an allergen. If a discrepancy is found between the packaged product and the label, or if a product has been mislabeled, it is critical that the product be separated from product entering commerce and held. The occurrence should be immediately reported to the establishment management on duty.

"Chapter 3: Allergen Training Commitment All staff that handle and order ingredients, supplies, and equipment, as well as those who are responsible for handling ingredients and products from receiving through shipping, should be aware of the dangers of allergens. Each establishment employee needs to understand his or her food safety role in this process. An establishment should maintain written procedures to identify, prevent and control, and declare allergens and make those procedures readily available to staff. Staff should review the procedures frequently, especially when changes occur. Management should communicate the importance of allergen control and the establishment\u2019s allergen control program to all employees. The success of any system depends on education and training of management and employees in the importance of their role in producing safe foods.

Key Training Areas

\u2022 Avoiding cross-contact

\u2022 Flow of allergenic ingredients and products

\u2022 Allergen control policies

\u2022 Hygiene procedures including handwashing and uniform requirements

\u2022 Waste control

\u2022 Rework and work-in-progress procedures

\u2022 Cleaning procedures and documentation including spill clean-up

\u2022 Dedicated supplies and equipment

\u2022 Storage of ingredients and final products

\u2022 Labeling procedures

\u2022 Scheduling of production \u2022 Management notification for discrepancies and other allergen and labeling issues \u2022 Product formulations \u2022 Letters of guarantee

13", "Appendix 1: How to Handle Labels of Incoming and Outgoing Products Step 1 Inspect every lot of incoming ingredients and letters of guarantee at receiving, including product codes; Compare each lot against formulation and final labels Step 2 Review HACCP system for correct identification and evaluation of potential allergenic ingredients Step 3 Inspect each lot of ingredients and ensure all allergenic ingredients are identified in product\u2019s final label Step 4 Confirm accurate and available formulation data for each lot Step 5 Verify that the facility has a label approval for each product Step 6 Cross-reference the label approval to the actual label being used and formulation data for accuracy Step 7 Ensure the list of ingredients includes sub-ingredients on incoming and outgoing packaged product in processing lot Step 8 Ensure that the correct label is being applied to the correct product 14", "Appendix 2: Process Flow Diagram with Mitigation Targets Receiving Packaging Materials Receiving NonMeat Ingredients Storage Packaging Materials Storage Non-Meat Ingredients Preparing Non-Meat Ingredients Grind Blend Process Meat Storage Meat Receiving Meat Sausage Stuffer Packaging\ Labeling Rework Finished Product\ Storage (cold) Shipping Process Flow Diagram Process Category: Raw Product, Ground Product: Fresh Pork Sausage Identify Prevent and Control Declare Mitigation Targets 15", "Appendix 3: Allergen Risk Evaluation and Labeling Yes No No Yes Yes No Is the product manufactured from materials that contain allergens? If allergens are contained in the product, you should declare all allergens contained in the product on the label. Is the product manufactured on a production line or with equipment that comes in direct contact with allergenic substances? If no allergens are present in the product, no special labeling is needed. Implement all necessary measures to eliminate the risk for allergens on the production line and equipment! HACCP and good manufacturing principles should be used. If it can be documented that no allergen residue is in the product, no special labeling is needed. If it cannot be documented that no allergen residue is in the product, special labeling should be applied. In some cases, \u201cmay contain\u201d labeling may be applied. Be specific, such as \u201cmay contain peanuts.\u201d Can it be documented through cleaning controls, test results, or other means that no allergens are present on the production line and equipment or in the product? 16", "Appendix 4: Establishment Checklist Identify: Hazard Analysis, Inspection of Incoming Ingredients, Cross-referencing Components, and Separation Questions Yes No Comment Do we use non-meat or nonpoultry ingredients from a supplier in our product? Have we created a listing of the non-meat or non-poultry ingredients that we use from a supplier in our product? Do suppliers of ingredients have a documented allergen control program? Do our non-meat or non-poultry ingredients contain allergens or other ingredients of public health concern? Are ingredient specifications reviewed for formula changes? Is there a system in place to verify that purchased ingredients are correct when received? Are we addressing the accuracy of incoming ingredient labels? Are ingredients labeled if they contain an allergen? Are the product codes of purchased ingredients monitored for changes?

17", "Prevent and Control: Equipment, Sanitation, and Processing Questions Yes No Comment Do we have preventive measures in place in our HACCP plan or other prerequisite program that prevent the presence of undeclared allergens? If so, what measures are applied? Are ingredients stored and transported through the establishment in a manner that prevents cross-contact? Is the labeling and identification of allergenic ingredients maintained throughout

establishment processing (from receiving to shipment)? Is it possible to process products with allergens with dedicated supplies and equipment? If not, are allergenic products separated to prevent cross-contact? Is rework that contains allergenic ingredients only used with \u201clike\u201d items? Does our establishment have standardized procedures for sanitation for food allergens? Does our establishment have an established procedure for verification of the sanitation effectiveness for food allergens? 18", "Declare: Packaging, Labeling, and Storage Overall Questions Yes No Comment Are we addressing the accuracy of outgoing final packaged product? Does the finished product label, including sub-ingredients, match both the final label and formulation data on the non-meat or non-poultry ingredient label? Is there a system in place for traceback of non-meat and nonpoultry ingredients in the event of a concern, investigation, or recall? Do we ensure that employees responsible for labeling are aware if there are formulation changes? Questions Yes No Comment Have we trained our employees on how to properly inspect, process, store, and label allergenic product? Do employees have an understanding of the establishment\u2019s allergen control program? Are our control procedures for allergens being applied appropriately and verified of their effectiveness? 19", "Appendix 5: Allergen Scenarios and Possible Preventive Measures NOTE: An establishment is required to notify the district office within 24 hours of learning or determining that it has shipped or received in commerce adulterated or misbranded product (9 CFR 418.2). Scenario 1: Establishment A notified in-plant inspection personnel of a problem that it has discovered with a particular meat snack stick that it produced on five separate days in the last two weeks. The establishment\u2019s supplier changed its seasoning blend to include eggs; however, the snack stick label was not updated to include the presence of this allergen. IDENTIFY: The establishment should communicate with suppliers of ingredients to ensure they advise them of any changes in product formulation and allergens in the final product. IDENTIFY: The establishment should routinely check an ingredient\u2019s formulation, in this case, the seasoning used in the snack sticks. One possible solution is to keep product formulation and label records at receiving to compare against incoming ingredients. Additionally, establishment management should maintain active and open communication with suppliers and become familiar with letters of guarantee, packaging of ingredients, and ingredient product codes. DECLARE: The establishment could verify the ingredients within each product during the packaging and labeling of the snack sticks. Establishments should verify the accuracy of all labels on products and ensure that they appropriately reflect the ingredients used in the formulation. Not identifying the presence of an allergen or ingredient of public health concern means that the label is false and misleading, and the product is misbranded and adulterated. Verification of the product labels should be carried out and include a comparison of the formulation and ingredients contained in non-meat products. Scenario 2: Establishment B produced multiple products including two chicken entrees: one containing shrimp, and one containing vegetables but no shrimp. On two days, the establishment packaged and shipped the chicken and shrimp entree in the chicken and vegetables package. The problem was discovered by two consumers who purchased the entree and reported the wrong packaging to FSIS. DECLARE: Properly declaring allergens using the appropriate package is just as important as identifying ingredients and processing product. The establishment should consider using color-coding of products containing allergenic ingredients and should have a mechanism for verification of product labels, such as checklists at the point of packaging and labeling. Scenario

3: As a result of rising costs for a teriyaki sauce mix used in a stir fry meal produced by Establishment C, establishment management searched for a less expensive supplier. The sauce produced by the current supplier contained wheat and soy, which were properly declared on the meal label. A new supplier was found that could supply teriyaki sauce at a much lower price, and the establishment began using the product. After an investigation of four consumer complaints, in-plant inspection personnel discovered that the new teriyaki sauce contained milk and almonds, which were not declared on the meal label. IDENTIFY: In instances when establishments are changing suppliers, it is essential to communicate about expectations regarding ingredients and allergens. Prior to the change, the establishment should thoroughly review the ingredients contained in non-meat products, such as mixes or sauces. Again, at receipt at the establishment, the establishment should cross-check the ingredients used by the supplier against formulation and label records before accepting the ingredient at the establishment.

Scenario 4: Store D conducted testing of a pizza product produced by Establishment D. The testing revealed a peanut-containing ingredient that was not declared on the label, and Store D reported the 20", "presence of the ingredient to Establishment D. An FSIS Enforcement, Investigations, and Analysis Officer (EIAO) was dispatched to the establishment to investigate. He discovered that on the day of production, a peanut-containing product was run prior to the pizza on some of the same equipment, and that the establishment routinely uses the same utensils throughout the production day.

PREVENT AND CONTROL: Cleaning procedures need to be in place at establishments that produce both allergenic and non-allergenic products to prevent cross-contact and misbranding. Dedicated equipment and supplies should be considered, although separation by time can also be carried out effectively. In this instance, maintaining a documented process flow may have suggested a better production schedule to minimize cross-contact.

21", "Appendix 6: Allergenic Ingredients and Foods

Food Allergy Research and Education is a source of information regarding food allergies. One of the organization\u2019s resources for consumers lists allergenic ingredients and foods that may contain allergenic ingredients. The list of ingredients and foods below can be used to help identify \u201cBig Eight\u201d allergens.

1. Wheat Consumers allergic to wheat products are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain wheat. bread crumbs Farina sprouted wheat wheat gluten bulgur flour\* triticale wheat grass cereal extract hydrolyzed wheat protein vital wheat gluten wheat malt club wheat Kamut wheat wheat protein isolate couscous matzoh\matzo, matzah\matza wheat bran wheat sprouts cracker meal Pasta wheat bran hydrolysate wheat starch durum Seitan wheat durum whole wheat berries einkorn semolina wheat germ emmer Spelt wheat germ oil \* all purpose, bread, cake, durum, enriched, graham, high gluten, high protein, instant, pastry, self-rising, soft wheat, steel ground, stone ground, whole wheat flour

Additionally, wheat is sometimes found in the following foods: baking powders (particularly imported) glucose syrup starch Worcestershire sauce bouillon soy sauce surimi

2. Crustacean Shellfish Consumers allergic to crustacean shellfish are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products have these ingredients, they contain a \u201cBig Eight\u201d allergen barnacle crawfish lobster shrimp crab Krill prawns

Additionally, crustacean shellfish are sometimes found in the following foods: bouillabaisse fish stock imitation fish\shellfish surimi cuttlefish ink glucosamine seafood flavoring

3. Eggs Consumers allergic to eggs are advised to avoid foods that may contain these ingredients. If meat or

poultry products contain any of these, they likely contain eggs. 22", "albumin\albumen egg white lysozyme ovalbumin dried egg egg yolk mayonnaise powdered eggs egg solids eggnog meringue surimi Additionally, eggs are sometimes found in the following foods: baked goods lecithin marzipan nougat egg substitutes macaroni marshmallows pasta 4. Fish It is generally recommended that consumers allergic to fish should avoid all fish. The most common kinds of fish that individuals are allergic to are salmon, tuna, and halibut. Additionally, fish is sometimes found in the following foods: Asian foods bouillabaisse meatloaf Worcestershire sauce barbecue sauce imitation fish\shellfish salad dressing 5. Peanuts Consumers allergic to peanuts are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain peanuts. artificial nuts ground nuts nut meat peanut flour beer nuts mixed nuts nut pieces peanut protein hydrolysate goobers monkey nuts peanut butter Additionally, peanuts are sometimes found in the following foods: African, Asian, Latin American foods Chili marzipan baked goods egg rolls mole sauce candy enchilada sauce nougat The FDA exempts highly refined peanut oil from being labeled as an allergen. 6. Milk Consumers allergic to milk are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain milk. butter caseinates half-and-half recaldent butter fat cheese lactalbumin rennet casein butter oil cottage cheese lactoferrin sour cream butter acid cream lactose sour milk 23", "butter ester curds lactulose tagatose buttermilk custard milk\* whey casein diacetyl milk protein hydrosylate whey protein hydrosylate casein hydrolysate ghee pudding yogurt \* milk in all forms (including condensed, derivative, dry, evaporated, goat\u2019s milk and milk from other animals, low fat, malted, milkfat, nonfat, powder, protein, skimmed, solids, whole) Additionally, milk is sometimes found in the following foods: artificial butter flavor chocolate margarine sausages baked goods hot dogs nisin bouillon lactic acid starter culture and other bacterial cultures nondairy products caramel candies luncheon meat nougat 7. Tree Nuts Consumers allergic to tree nuts are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain a \u201cBig Eight\u201d allergen. almond coconut Nangai nut pili nut artificial nuts filbert\hazelnut natural nut extract pine nut beechnut gianduja nut butters pistachio Brazil nut ginkgo nut nut meal praline butternut hickory nut nut paste shea nut cashew litchi\lichee\lychee nut nut pieces walnut chestnut macadamia nut pecan chinquapin marzipan\almond paste pesto Additionally, tree nuts are sometimes found in the following foods: alcoholic extracts black walnut hull extract nut distillates walnut hull extract Asian foods natural nut extract nut oils 8. Soybeans Consumers allergic to soybeans are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain soybeans. edamame soy fiber soy sprouts tamari miso soy flour soy yogurt tempeh natto soy grits soya textured vegetable protein shoyu soy ice cream soybean tofu soy albumin soy milk soy protein 24", "soy cheese soy nuts soy sauce \* FDA exempts highly refined soybean oil from being labeled as an allergen. However cold-pressed soybean oil, which is less commonly used, is not exempt from allergen labeling as it likely contains more residual protein. Additionally, soybeans are sometimes found in the following foods: Asian foods vegetable broth vegetable starch soy lecithin\* vegetable gum Worcestershire sauce \* With the exception of a few specific products, FDA does not exempt soy lecithin from allergen labeling as it generally contains residual protein. The use of soy lecithin in non-stick sprays and coatings (i.e. releasing agents) has led to recalls of FSIS-regulated product when the soy was not

properly declared. 25", "Appendix 7: References and Resources Atkins D, Bock SA. Fatal Anaphylaxis to Foods: Epidemiology, Recognition, and Prevention. Current Allergy and Asthma Reports, 2009;9:179-185. Beef Industry Food Safety Council Executive Committee (March 2008). Best Practices for Raw Ground Products. Retrieved at <http://www.bifsc.org/CMDocs/BIFSCO/Best%20Practices/groundproducts2933.pdf>

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0022","id":"17247667856af3256c771bd8cf5f5ec2d847bdea677df887985a73968495570","corpus":"fsis\_guidelines","source\_page\_url":"https:\V\www.fsis.usda.gov\policy\fsis-guidelines","url":"https:\V\www.fsis.usda.gov\sites\default\files\import\Comp\_Guide\_MTB.pdf","type":"pdf","n\_pages":31,"word\_count":10508,"text\_by\_page":["This guidance document is designed to help establishments that manufacture mechanically tenderized beef products to comply with the requirements in 9 CFR 317.2(e)(3)(iii) by: \u2022 Identifying the minimum components of validated cooking instructions; \u2022 Identifying the two elements to validating cooking instructions: o Scientific and technical support (design) and o In-plant validation data (execution) To help establishments meet the first element of validation, this document contains attachments establishments can use as scientific support for cooking instructions. 2012 FSIS Compliance Guideline for Validating Cooking Instructions for Mechanically Tenderized Beef Products 2015 i","Preface What is the purpose of this Compliance Guideline? The purpose of this guideline is to help establishments ensure that their labels on raw or partially cooked needle- or blade-tenderized beef products destined for household consumers, hotels, restaurants, or similar institutions contain validated cooking instructions that comply with the requirements in 9 CFR 317.2(e)(3)(iii). Note that these requirements are not in effect until May 17, 2016. In addition, FSIS will delay enforcing the labeling requirements for beef products with added solutions until the same date. Specifically, the guideline articulates: \u2022 The minimum components validated cooking instructions must contain; \u2022 The two elements to validating cooking instructions: o Scientific and technical support (design) and o In-plant validation data (execution) This document contains attachments that establishments can use as scientific support to meet the first element of validation. This document provides guidance to assist establishments in meeting FSIS regulations. Guidance represents best practice recommendations by FSIS based on the best scientific and practical considerations. It does not represent requirements that must be met. Establishments may choose to adopt different procedures than those outlined in this Guideline, but they would need to support why those procedures are effective. It is important to note that this Guideline represents FSIS's current thinking on this topic. Who is this Compliance Guideline designed for? This guideline is designed for all official FSIS regulated establishments that produce raw or partially cooked mechanically tenderized beef products destined for household consumers, hotels, restaurants, or similar institutions. Such products include raw or partially cooked needle or blade tenderized beef products, including mechanically tenderized beef products that have also been injected with marinade or solution. This guideline is not intended for establishments that produce mechanically tenderized product that will be fully cooked at an official establishment. Is this version of the guideline final? Yes, this version of the guideline, dated May, 2015 is final and replaces the previous version dated June, 2013. Guidelines will be continually updated to reflect the most current information available to FSIS and stakeholders, although comments will no longer be accepted through regulations.gov on this guideline. ii","What changes have been made to the guideline since the last version? The following changes have been made to the June, 2013 version of the guideline in response to public comments: \u2022 Based on findings from recent research shared in the comments, a recommendation to include the following statements as part of the validated cooking instructions was added: o \u201cFully thaw product before cooking,\u201d and o For mechanically tenderized steaks, \u201cTurn product over at least twice during cooking\u201d.

\u2022 Clarified that not all of the time and temperature combinations FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks are practical for consumers to follow. Specifically, the rest times associated with the temperatures less than 145\u00b0F (e.g., 144\u00b0F for 4 minutes, 143\u00b0F for 5 minutes, etc.) are not practical for consumers to maintain. \u2022 Portion size was addressed as a factor to consider when designing a validation study. \u2022 Based on findings from recent research shared in the comments, additional scientific support for cooking instructions was included in Attachment 1. In addition, outbreak data was revised to reflect outbreaks from mechanically tenderized beef products that occurred since 2000. This change was made to be consistent with the data reported in the Federal Register Notice. What if I still have questions after I read this guideline? If the desired information cannot be found within the Compliance Guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the AskFSIS database or submit questions through AskFSIS. Documenting these questions helps FSIS improve and refine present and future versions of the Compliance Guideline and associated issuances. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided: Subject Field: Enter FSIS Compliance Guideline for Validating Cooking Instructions for Mechanically Tenderized Beef Products Question Field: Enter question with as much detail as possible. Product Field: Select General Inspection Policy from the drop-down menu. Category Field: Select Sampling from the drop-down menu. Policy Arena: Select Domestic (U.S.) Only from the drop-down menu. When all fields are complete, press Continue. iii", "FSIS Compliance Guideline for Validating Cooking Instructions for Mechanically Tenderized Beef Products Table of Contents Who is this Compliance Guideline designed for?

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instructions? Effective May 17, 2016, 9 CFR 317.2(e)(3)(iii) requires that the labels on raw or partially cooked needle- or blade-tenderized beef products destined for household consumers, hotels, restaurants, or similar institutions contain validated cooking instructions. FSIS added this requirement because scientific evidence shows that mechanically tenderized beef products need to be fully cooked in order to sufficiently reduce the risk pathogenic bacteria. Pathogenic bacteria may be present on the interior of mechanically tenderized beef products because any contamination on the outside of the product may be carried to the inside through penetration by needles and other devices. As a result, it is important that mechanically tenderized beef products be cooked thoroughly as opposed to \u201crare\u201d or \u201cmedium rare\u201d. Consumers often request that restaurants cook steaks \u201crare\u201d or \u201cmedium-rare\u201d. Generally, intact cuts of muscle such as steaks are rendered free of pathogenic bacteria if cooked \u201drare\u201d or \u201cmedium rare\u201d provided the steaks are seared according to the recommendations in the Food Code. According to the 2009 Food Code \u00a773401.11(C)(3), a raw or undercooked whole-muscle, intact beef steak may be served or offered for sale in a ready-to-eat form if among other things, \u201cthe steak is cooked on both the top and bottom to a surface temperature of 63oC (145oF) or above and a cooked color change is achieved on all external surfaces.\u201d Seared intact steaks may be considered a ready-to-eat food without being fully cooked because contamination with pathogenic bacteria such as Escherichia coli O157:H7 (E. coli O157:H7) and other STEC organisms, if present, would only occur on the surface of the product. As long as the external surfaces are exposed to lethality temperatures, the product can be rendered safe without thoroughly cooking the product through the interior (NACMCF, 1997). Despite the safe handling instructions on mechanically tenderized beef products to \u201ccook thoroughly,\u201d recent outbreak data indicate that for needle or blade tenderized raw beef products, consumers, restaurants, and retail stores do not always thoroughly cook these products to a temperature and time combination sufficient to destroy harmful bacteria, such as E. coli O157:H7. Indeed, in many cases, patients associated with outbreaks reported preparing or ordering steaks as \u201crare\u201d or \u201cmedium-rare.\u201d Since 2000, the Centers for Disease Control and Prevention has received reports of six outbreaks attributable to needle or blade tenderized beef products prepared in restaurants and consumers\u2019 homes. Among these outbreaks, there were a total of 176 E. coli O157:H7 cases that resulted in 32 hospitalizations and 4 cases of hemolytic uremic syndrome (HUS). Failure to thoroughly cook a mechanically tenderized raw or 1", "partially cooked beef product was a significant contributing factor in all of these outbreaks (Culpepper et al., 2009; Swanson et al., 2005). Cooking instructions for these products should inform consumers that these products need to be cooked to a specified minimum internal temperature, and should identify whether they need to be held at that minimum temperature for a specified time before consumption, i.e., rest or dwell time, so that they are thoroughly cooked. This document provides guidance on how to validate such cooking instructions. What are the minimum components of validated cooking instructions that must be on the label to comply with the requirements in 9 CFR 317.2(e)(3)(iii)? The cooking instructions must include, at a minimum: (1) The method of cooking; (2) A validated minimum internal temperature that would destroy pathogens throughout the product; (3) A statement as to whether the product cooked in the manner described also needs to be held for a specific time at the specified temperature or higher before consumption; and (4) Instruction that the

internal temperature should be measured by the use of a thermometer. The cooking instructions included on the label should be practical and easily followed by consumers. To the right is an example of cooking instructions that meet these minimum components. Note that these instructions are in addition to the Safe Handling instructions required on raw beef products in 9 CFR 317.2(l)(1). In this example, to meet requirements, an establishment would need to validate that the cooking instructions will achieve the time and temperature combination on the label (i.e., 145°F for 3 minutes). Once it validates the cooking instructions, the establishment would not need any additional scientific support to meet the first element of validation. No additional documentation would be needed because the FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks supports that adequate reduction of For Food Safety and Quality Follow These Cooking Instructions: Gas Grill: 1) Heat gas grill on Medium-High. 2) Cook for 6 minutes to an internal temperature of 145°F as measured with a food thermometer. Flip steak over at least twice during cooking. 3) After removing from the gas grill, allow meat to rest for at least three minutes before serving. 2,"pathogens would be achieved with a desired endpoint temperature of 145°F and a rest time of 3 minutes. Are there additional instructions FSIS recommends establishments include on the label? FSIS reviewed the literature and found that achieving a consistent temperature throughout beef products is key to ensuring adequate lethality of pathogenic bacteria is achieved (Gill et al., 2013). Two factors identified in the literature that can affect even heating include the state of the product before cooking (e.g., frozen, refrigerated, or room temperature) and the amount of times during cooking steaks are turned over (i.e., flipped) (Berry, 2000; Gill et all, 2013; Luchansky, 2014). Based on these findings, FSIS recommends establishments include the following two additional instructions on the label of mechanically tenderized beef products in order to ensure that consumers achieve a consistent temperature throughout the product needed to sufficiently reduce the presence of potential pathogens: 1. "Fully thaw before cooking" FSIS recommends establishments include the instruction "fully thaw before cooking" on the labels of mechanically tenderized beef products to achieve even heating in the product. Research with patties has shown that temperatures tend to be more consistent across patties that are cooked from the thawed rather than the frozen state (Berry, 2000). Not surprisingly, other research has found that patties cooked from the frozen state take longer to achieve the target endpoint temperature than those that have been thawed (Luchansky, 2013). Even if this instruction is provided, establishments should consider conducting additional tests to assess the impact on cooking adequacy if the consumer does not fully thaw the product prior to cooking. Alternatively, two sets of validated cooking instructions could be provided: one for preparation of thawed product and one for preparation of frozen product. These practices are recommended in GMA's 2008 Guidelines for Validation of Consumer Cooking Instructions for Not-Ready-to-Eat (NRTE) Products and discussed further on page 10 of this guideline because consumers may ignore warnings and cook the product from the frozen state. When asked, consumers report cooking beef patties from the frozen state without thawing approximately 22% of the time (Phang and Bruhn, 2011). Including this instruction on the label may have additional benefits for quality as thawing frozen patties before cooking has also been found to improve sensory properties such as juiciness (BignerGeorge and Berry, 2000). 2. For mechanically tenderized steaks, "Turn steak over at least twice during cooking" For

mechanically tenderized steaks, FSIS recommends establishments also include the instruction to turn steak over at least twice during cooking so that consumers consistently achieve the desired endpoint temperature throughout the steak. This recommendation is based on research that shows turning steaks over at least twice results in more even heating and, as a result, more consistent reductions in E. coli 3", "O157:H7 than turning steaks over once (Gill et al., 2013). The recommendation to turn over mechanically tenderized steaks does not apply to other mechanically tenderized beef products such as roasts since larger cuts of mechanically tenderized beef will typically experience longer come up times contributing to additional lethality in the product over the entire cooking time. In addition, roasts and other large cuts are often cooked by consumers in moist environments that contain humidity contributing to even cooking (e.g., in cooking large cuts of meat in slow cookers with the lid in place and roasting large cuts of meat such as roasts by adding water or broth to the pan and tenting foil over the product). Consistent with this recommendation, the Food and Drug Regulations in Canada require the statement "turn steak over at least twice during cooking" on the principal display panel of mechanically tenderized steaks to achieve a consistent temperature throughout these products (Health Canada, 2014). NOTE: The final rule does not require establishments to include the instructions "fully thaw before cooking" and "turn steak over at least twice during cooking" on the label of mechanically tenderized beef products. These instructions are included in this guideline as recommendations. FSIS is recommending these additional instructions be included on the label of mechanically tenderized beef products because thawing steaks before cooking and flipping steaks over at least twice during cooking has been found to help ensure that consumers achieve a consistent temperature throughout the product. Achieving a consistent temperature throughout the product is critical to ensuring that potential pathogens in the interior of the product are sufficiently reduced. FSIS did not propose to include these instructions in the proposed rule (78 FR 34589) and is therefore, not requiring these instructions be included in the final rule. How can an establishment validate its cooking instructions? There are two main elements to validation which also apply to the process of validating cooking instructions.

**ELEMENT 1: Scientific or Technical Support (Design)** The first part to validating cooking instructions is providing scientific or technical support for the judgments made in designing the cooking instructions. The scientific support should demonstrate that: The cooking instructions provided can repeatedly achieve the desired minimum internal temperature and, if applicable, rest time and The minimum internal temperature and time at that temperature achieved by the instructions will destroy pathogens present in the product. To collect the first type of support, demonstrating that the cooking instructions can repeatedly achieve the desired minimum internal temperature and, if applicable, the rest time, the cooking instructions are generally repeatedly followed under actual consumer 4", "cooking conditions to show that the desired endpoint temperature and rest time can consistently be met. For example, if an establishment has instructions which state to cook a mechanically tenderized steak on a grill for 7 minutes in order to heat the steak to 160°F, then, put simply, the establishment would need to heat the steak on different types of grills several times to support that it actually takes 7 minutes to heat the steak to 160°F under different consumer cooking conditions. As a result, this first type of scientific support does not need to consist of microbiological data but rather should include data demonstrating the cooking instructions

consistently achieve the desired endpoint temperature under worst-case scenario conditions. It is the responsibility of the establishment to identify scientific support that demonstrates that consumers can achieve the endpoint temperature and rest time by following the cooking instructions. This type of documentation generally consists of a scientific article from a peer-reviewed journal, a published processing guideline, or data gathered in-plant or in a test kitchen. Data can be gathered anywhere the consumer cooking equipment is available. A number of journal articles have been published in which researchers have already validated cooking instructions for mechanically tenderized beef products. To assist establishments with developing cooking instructions, Attachment 1 of this guideline contains a summary of published scientific support for cooking instructions that have been found to achieve a sufficient endpoint temperature and rest time, along with the critical operational parameters included in each study. Establishments may utilize these cooking instructions on the labels of their products provided that the actual product being produced and labeled is similar to the product for which the instructions were developed. For example, if an establishment produced a 1 inch thick blade tenderized steak, the following instructions could be used as they have been validated according to the research conducted by Gill et al. (2013) provided in Attachment 1: For Food Safety and Quality Follow These Cooking Instructions: 1) Heat stainless steel skillet on electric stove to medium. 2) Add steak to skillet and cook for 26 minutes. Turn product over at least twice during cooking. 3) Cook until steak reaches an internal temperature of 145°F as measured by a food thermometer and allow to rest for 3 minutes before serving.\*\* In the research articles provided in Attachment 1, the authors determined the amount of time it would take using different cooking methods to reach different desired endpoint temperatures for steaks of different thicknesses. Only products that reached endpoint temperatures sufficient to produce a ready-to-eat product (that is one in which at least a 5-log<sub>10</sub> reduction of Salmonella and STEC organisms such as E. coli O157:H7 is achieved) are included in Attachment 1. Establishments using cooking instructions from Attachment 1 would not need to provide the original journal articles used to develop the instructions because all of the critical operational parameters have been provided in the Attachment. Therefore, if establishments utilize instructions from Attachment 1, no further scientific support is needed to meet the first element of validation. NOTE: Establishments should be aware that the cooking instructions developed from research by Luchansky et al., 2012 and provided on pages 17 and 18 of Attachment 1 are associated with a lower margin of safety because they instruct consumers to flip the product once part way through cooking. Newer research by Gill et al., 2013, shows turning steaks over at least twice results in more even heating and, as a result, more consistent reductions in E. coli O157:H7 than turning steaks over once. Cooking instructions developed from this newer research are provided on pages 19 through 21 and have been found to be associated with a greater margin of safety. The list of references provided in Attachment 1 is not exhaustive. Establishments may identify other articles published in peer-reviewed journals or other scientific support that can be used to support that cooking instructions have been validated. When selecting scientific support for cooking instructions, it is important that an establishment identify scientific support that closely matches its actual process. In order to determine that the scientific support closely matches the actual process and the cooking instructions on the label, establishments should ensure that the documentation was developed for a product KEY QUESTION Question: If I use Attachment 1 as

the scientific support for my cooking instructions, do I need additional scientific support to meet the first element of validation? Answer: No, Attachment 1 has been developed using published research. All critical operational parameters an establishment would be expected to meet are included in the Attachment. Therefore, the establishment does not need to maintain on file the original journal articles from which the instructions were developed. In addition, only cooking instructions that achieve the minimum internal temperature and, if applicable, rest time needed to destroy potential pathogens were selected. Therefore, the establishment also does not need to maintain additional scientific support for the internal temperature and, if applicable, rest time chosen. 6", "that is similar in terms of the: \u2022 Cut of beef, \u2022 Method of tenderization \u2022 Thickness \u2022 Cooking method and \u2022 Desired endpoint temperature and rest time (if applicable) that will be referenced in the cooking instructions on the label. It is important for establishments to ensure that the actual product being labeled is similar to the product studied because differences in the cut of beef, method of tenderization, thickness, and cooking method all have an impact on heat transfer and as a result, the amount of time it takes to reach the desired endpoint temperature. Therefore, if any of these parameters in the actual product or process differ from those used in the scientific support, the establishments should provide documentation as part of their validation records supporting why the desired endpoint temperature will still be reached. Such a justification could include reference to previously conducted research or scientific principles that would support that the desired endpoint temperature will still be reached. This justification is needed because the establishment cannot be sure that the desired endpoint temperature will be met if different critical operational parameters are used. If a justification cannot be provided, then additional support may be needed. For example, if an establishment produces a 2-inch thick steak, and the only available cooking instructions that have been validated are for a 1 inch steak, then the cooking instructions should not be used because it will take significantly longer to reach the desired endpoint temperature with a thicker steak (Gill, et al., 2013, Luchansky et al., 2012). The next section discusses how an establishment can validate their own cooking instructions if none are available in the literature for a similar product. In addition to identifying scientific or technical support demonstrating that the cooking instructions can repeatedly achieve the desired endpoint temperature, an establishment should also identify scientific support that demonstrates the expected level of bacterial pathogen reduction achieved when the desired endpoint temperature is reached. Such scientific support should demonstrate that the minimum internal temperature and, if applicable, rest time in the instructions (for example 160\u00b0F instantaneously) have been validated to destroy pathogens throughout the product. This means that if the product reaches the desired minimum internal temperature for the applicable rest time, at least a 5-log<sub>10</sub> reduction of Salmonella and STEC organisms such as E. coli O157:H7 will be achieved. As a result, the scientific support for the endpoint temperature and rest time should consist of or be developed from microbiological data demonstrating an adequate reduction in pathogens is achieved. NOTE: The cooking instructions provided in Attachment 1 of this guideline were developed to reach minimum internal temperature and rest time combinations found to achieve at least a 5-log<sub>10</sub> reduction of Salmonella and STEC organisms such as E. coli O157:H7. Therefore, these instructions were developed from 7", "microbiological data that demonstrate an adequate reduction in pathogens is achieved, and no further scientific support is needed. It is also the responsibility of the establishment to

identify scientific support for the endpoint temperature and, if applicable, rest time used for a product's cooking instructions. This type of documentation generally consists of a scientific article from a peer-reviewed journal, a published processing guideline, a challenge or inoculated pack study, or a regulatory performance standard. It is important to consider that not all cooking instructions have been developed to achieve a sufficient endpoint temperature, and if applicable, rest time. Often cooking instructions are developed to achieve a desired doneness of a product (i.e., medium, medium-well, or well-done). Cooking instructions for mechanically tenderized beef products should be developed to achieve desired endpoint temperatures in order to make a safe product.

According to the FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks from April 2009 (See Attachment 2 of this guideline), products cooked to 150°F should be held or allowed to rest for at least 52 seconds to achieve at least a 5-log<sub>10</sub> reduction of Salmonella and E. coli O157:H7. Products cooked above 160°F achieve a 5-log<sub>10</sub> reduction in these pathogens instantaneously without any additional rest time. The FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks also supports that adequate reduction of pathogens would be achieved with a desired endpoint temperature of 145°F and a rest time of 3 minutes. If establishments can validate that their cooking instructions will achieve that time and temperature combination, they would meet requirements, and no additional scientific support would be needed to meet the first element of validation. Establishments may utilize the FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks provided in Attachment 2 of this guideline as support for the endpoint temperature and rest time, or they may provide their own scientific support for other time and temperature combinations. If establishments use other time and temperature combinations, they must demonstrate that those other combinations achieve the same results (i.e., a 5-log<sub>10</sub> reduction of Salmonella) as the time and temperature combinations in the table. This is because the time and temperature combinations in the FSIS Guidance were developed from microbiological data demonstrating an adequate reduction in pathogens is achieved.

Although the FSIS Guidance was developed using microbiological data for Salmonella, the guidance can be used to support that an adequate reduction of STEC such as E. coli O157:H7 is also achieved because Salmonella is considered an indicator for lethality. Salmonella is used as an indicator for lethality because it is more heat resistant than other pathogens such as E. coli O157:H7. Therefore, if a 5-log<sub>10</sub> reduction of Salmonella is achieved, at least a 5-log<sub>10</sub> reduction of E. coli O157:H7 should be achieved as well (Goodfellow and Grown, 1978; Line et al., 1991). In addition to the FSIS guidance, establishments may also utilize the endpoint time and temperature combinations provided in the 2013 FDA Food Code for mechanically tenderized meats in § 3-401.11(A)(2). As with the FSIS guidance, although the Food Code does not contain actual microbiological data, the 8", "time and temperature combinations were developed from microbiological data demonstrating an adequate reduction in pathogens is achieved. NOTE: The time and temperature combinations in the FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks provided in Attachment 2 of this guideline were originally developed for FSIS regulated establishments that have a high degree of process control. Although establishments may utilize the guideline as support for the endpoint temperature and rest time of consumer cooking instructions, FSIS has determined that not all of the time and temperature combinations are practical for consumers to follow. Specifically,

the rest times associated with the temperatures less than 145°F (e.g., 144°F for 4 minutes, 143°F for 5 minutes, etc.) are not practical for consumers to maintain. Therefore, FSIS does not recommend an establishment design cooking instructions to achieve these time and temperature combinations unless it can document in its hazard analysis or decision-making documents contractual controls in place (e.g., agreements with Hotel, Restaurants, or Institutions) to ensure instructions are followed by the end user and why the establishment has concluded that these instructions will be effective. How can an establishment develop its own scientific support for its cooking instructions if a product doesn't match one of those in Attachment 1 of this guideline? If an establishment produces a product for which scientific support for cooking instructions is not readily available (for example, the product is of a different thickness or cut than one that has been studied or is partially cooked at the establishment), or if an establishment wants to provide cooking instructions for a cooking method that has not been studied, then additional scientific support will be needed. Such scientific support may be developed by collecting data in a test kitchen or other location where the cooking method (e.g., gas grill, broiler, stove top) is available for testing. Data may be collected by establishment employees or a third party, or an establishment may elect to conduct and to document a trial with consumers to monitor how well they are able to follow labeled cooking instructions. To develop scientific support for cooking instructions, the establishment should determine the temperature of the product after it is cooked following the instructions on the label. If instructions have not already been developed, the establishment can collect data during cooking to determine the length of time it takes to reach the desired endpoint temperature. As previously discussed, the endpoint temperature and if applicable, rest time should be selected to support at least a 5-log<sub>10</sub> reduction of Salmonella and STEC organisms such as E. coli O157:H7. The appropriate validation study should at least consider conditions likely to result in the lowest endpoint temperature or a worst-case scenario (NACMCF, 2006). In order to ensure the validation study represents the worst-case scenario, the following product and testing variables should be considered.

"Product variables": The method of tenderization - either needle/blade tenderized or injected - appears to affect the amount of cooking time needed to reach a desired endpoint temperature (Luchansky, et al 2011). Therefore, the product studied should be prepared using the same method of tenderization (ideally under actual in-plant conditions) as the product for which the cooking instructions are being developed.  
Thickness of the product: The thickness of the product is a critical factor for heat transfer. The thicker a product, the longer it will take for the core of the product to reach the desired endpoint temperature. Therefore, it is recommended that the thickness of products from at least three lots be measured. The validation study should be conducted using a product that represents the thickest product measured. If an establishment has a quality specification for thickness, the maximum thickness could also be used to select the thickest product to study. If an establishment packages products by portion size (e.g., 10, 12, or 14 ounces), then it should determine the variability in thickness of products packaged at that portion size and conduct the validation study using a product that represents the thickest product. It should do so because thickness is the factor that affects heat transfer. Again, products from at least three lots should be measured to determine the worst case scenario.  
Type of cut (e.g., steak or roast): Related to the thickness of the product, the type of cut can also affect heat transfer because of

differences in size, shape, presence or absence of a bone, and fat content. To account for these differences, cooking instructions for each cut should be validated separately.

Testing variables

\u2022 Method of cooking: Cooking instructions may be provided for multiple cooking methods\devices. Common methods of cooking for mechanically tenderized beef products such as steaks and roasts include cooking by conventional oven, gas grill, or stove top. When testing cooking instructions for conventional ovens, testing should be done on electric, gas, as well as convection ovens if possible to determine whether the instructions work on all types of ovens. Before beginning the validation study, a cold spot determination should be conducted to support that even in the coldest spot the desired endpoint temperature is reached. FSIS does not recommend that cooking instructions be developed for microwave ovens because of the difficulty in applying heat uniformly. For more considerations related to different cooking methods, see the Grocery Manufacturer\u2019s Association (GMA) 2008 Guidelines for Validation of Consumer Cooking Instructions for Not-Ready-to-Eat (NRTE) Products available at: [http://www.gmaonline.org/downloads/wygwam/121894\\_1.pdf](http://www.gmaonline.org/downloads/wygwam/121894_1.pdf).

10", "\u2022 State of the product at the start of cooking, e.g., frozen versus refrigerated, or room temperature: The initial temperature of the tested product should be the lowest expected temperature at the start of cooking. As recommended in GMA\u2019s 2008 Guidelines for Validation of Consumer Cooking Instructions for Not-Ready-to-Eat (NRTE) Products, even if the instructions require thawing before cooking, it may be worthwhile to consider additional tests to assess the impact on cooking adequacy if the consumer does not fully thaw the product before cooking.

Alternatively, two sets of validated cooking instructions could be provided: one for preparation of thawed product and one for preparation of frozen product.

\u2022 Multiple units: The amount of product cooked at the same time needs to be considered, particularly for products cooked in a conventional oven. The cooking instructions may need to be extended if multiple servings are cooked at once. If cooking instructions are written for cooking multiple units (for example two steaks), the instructions should be validated for the same number of units.

\u2022 Type of pan or cooking container: Establishments may also need to consider the type of pan\cooking container during the design of the validation study. Darker metals tend to heat more quickly than lighter ones. If the type of pan is not included in the cooking instructions, then the establishment should consider using a lighter pan during the validation study to represent a worst-case scenario.

\u2022 Number and location of temperature measurement sites during testing: Testing of the endpoint temperature should occur in the thickest part of the product. If possible, at least two temperature measurements should be taken per product.

\u2022 Number of replicates: In order to determine variability in the time it takes to reach the desired endpoint temperature, at least three replicates should be conducted for each type of cooking method studied. Conducting replicates is one of the KEY POINT: REPLICATES There is often confusion surrounding the principle of conducting replicates. Often times, multiple products will be tested under the same conditions at the same time (for example, multiple steaks may be placed in the same oven and cooked together); however, these would not be considered true replicates because variability in the oven conditions is not being measured. In order to determine variability in cooking, the steaks would need to be tested separately, under the same conditions, multiple times. For example, one steak would need to be cooked in the oven under the trial conditions. After the results are measured and the oven is cooled, the trial would need to be repeated again with another steak. Each piece of steak tested should be from

a different lot so that variability within the product is measured as well. 11","main principles of the scientific method and involves repeating the entire trial over again under the same conditions multiple times to determine the reproducibility of the results. Guidance is provided later in this document on how to evaluate the results from the different replicates. \u2022 Rest or dwell time after cooking: If the scientific support for the minimal internal endpoint temperature indicates a rest time is needed in order to achieve adequate reduction in pathogens, then this fact should be noted in the trial design so that the instructions are developed appropriately. A "rest or dwell time" is the amount of time the product remains at the final temperature, after it has been removed from a grill, oven, or other heat source. During the time after meat is removed from the heat source, its temperature remains constant or continues to rise, which destroys pathogens. If the product is covered during the rest time to help maintain the final temperature, this fact should be noted as well. \u2022 Rotation of product: If the product is flipped part way during cooking, this fact should be documented in the testing and included in the instructions. Testing methodology After the establishment has identified the product and testing variables, the testing methodology should be determined. If cooking instructions are already available for the product, the establishment can repeatedly prepare the product following the instructions and determine whether the desired endpoint temperature is consistently met. If instructions are not available, the establishment can collect data during cooking to determine the length of time it takes to reach the desired endpoint temperature. To make this measurement of the internal temperature during cooking, a stainless steel thermocouple can be inserted from one end into the center of the product. To achieve more accurate measurement, another stainless steel thermocouple can be inserted in the center of the product from the opposite end. The temperature can be continuously monitored with thermocouple data logger at 5 second intervals. The product can then be cooked using the desired cooking method until the desired endpoint temperature is reached, at which point the amount of time it took to reach the temperature can be recorded. If two thermocouples are used, the time recorded should be the time it takes for both thermocouples to reach the desired endpoint temperature. See Luchansky et al., 2011 and 2012 for an example of this testing methodology. In either case, the product should be prepared under the same conditions at least three separate times (i.e., three replicates should be conducted) to support the results are repeatable by consumers. Establishments may determine to conduct additional replicates after consulting with a statistician. An example of a trial that could be used to validate cooking instructions that takes these product and testing variables into account is provided in Attachment 3. 12","How to evaluate the results If labeling instructions were developed before the study is conducted, and the goal of the study was to validate whether these instructions achieved the desired endpoint temperature, when evaluating the data, if all of the temperatures taken following the instructions met or exceeded the target temperature, then the cooking instructions can be considered adequate. When not all data are at or above the target temperature a statistical analysis of the data points is recommended. As recommended in GMA\u2019s 2008 Guidelines for Validation of Consumer Cooking Instructions for Not-Ready-to-Eat (NRTE) Products, one approach is to calculate the z-value for the data. The Z-value formula is:  $Z = (\text{average temperature} - \text{target temperature}) / \text{standard deviation}$  The average temperature is calculated from all data for products cooked using the instructions being tested. The target temperature is the temperature

that the instructions are designed to achieve. The standard deviation is a calculation representing the variability or spread in the data for products cooked using the instructions being tested. The calculated Z-value is used to determine the probability that a random temperature value would be less than the target temperature by comparing it with Z-values from a statistical table (see Attachment 4). For example, using the Table in Attachment 4, a Z-value equal to or greater than 2.33 means that 99% of the time, when the product is cooked using the instructions, the temperature will be at or above the target temperature. One percent of the time (or about 1 in 100 times) the temperature will be below the target. From a public health perspective, establishments should try to achieve a Z-value greater than 2.33 to have a high degree of confidence, that when followed, the cooking instructions will result in a temperature at or above the target temperature. If instructions were not available prior to the study, and the study was used to determine the time it takes to reach the endpoint temperature, then the establishment should use the worst-case scenario result from all of the replicates as the cooking instructions. Thus, if there was variability in the length of time it took to reach the endpoint temperature, the cooking instructions should be developed using the longest amount of time needed to achieve the desired endpoint temperature. In some cases, the establishment may need to conduct statistical analyses to determine whether significant differences were found between testing scenarios. For example, if an establishment wants to provide a single set of instructions for both electric and gas ovens, the instructions should be validated using both types of cooking. The establishment should then conduct statistical analyses to determine whether there were any significant differences in the time it took to reach the desired endpoint temperature using the two methodologies. If no significant differences are found, then the establishment can conclude that a single set of instructions would be sufficient. 13", "If cooking instructions are changed for product quality reasons or if the product or testing variables are changed (e.g., the thickness of the steak increases), the new instructions should be validated to support product safety. In addition, establishments should closely monitor calls to their toll free numbers and other consumer complaints for signs that the cooking instructions are not easily followed or, when followed, do not adequately cook the product.

**ELEMENT 2: In-plant Validation Data (Execution)** Once an establishment has identified scientific support for the cooking instructions chosen, it then needs to implement the same critical operational parameters from the scientific support that were used to develop the cooking instructions. The critical operational parameters related to the product that should be implemented in the actual process include the: \u2022 Cut of beef, \u2022 Method of tenderization, and \u2022 Thickness. In order to meet the second element of validation, the establishment needs to demonstrate that the product the instructions are used for meet these critical operating parameters. To gather data demonstrating that they do, the establishment needs to collect in-plant data supporting that the cut of beef, method of tenderization, and thickness of product that bear the cooking instructions match those of the product for which the cooking instructions were developed. After collecting the in-plant validation data, the establishment should verify on an ongoing basis that the critical operational parameters continue to be met and match those used in the scientific support. It is up to the establishment to support the frequency with which the critical operational parameters are verified. These data may already be collected by establishments on an ongoing basis as part of quality specifications.

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R. N. Danila, K. M. Elfering, and K. E. Smith. 2005. Outbreak of Escherichia coli O157:H7 infections associated with nonintact blade-tenderized frozen steaks sold by door-to-door vendors. Journal of Food Protection. 68: 1198\u20131202. 16","Attachment 1: Summary of Published Scientific Support for Cooking Instructions Cut of Meat Method of Tenderization Thickness Cooking Method Endpoint Temperature Validated Cooking Instructions Reference Top butt steak Brine injection 1 in Openflame gas grill (380\u00b0F) 160\u00b0F For a 1 inch steak: Cook on a gas grill for 10 minutes, flip and cook for another 10 minutes until the steak reaches an internal temperature of 160\u00b0F as measured with a food thermometer.

Luchansky, J.B., Porto-Fett, A.C.S., Shoyer, B.A., Call, J.E., Schlosser, W., Shaw, W., Bauer, N., Latimer, H. 2011. Journal of Food Protection. 74(7): 10541064. \*Initial research did not include a rest or dwell time, however, in order to achieve a 5-log<sub>10</sub> reduction of Salmonella and E. coli O157:H7 a rest time should be included (see Attachment 2 of this guidance document for support). 17","Cut of Meat Method of Tenderization Thickness Cooking Method Endpoint Temperature Validated Cooking Instructions Reference Top butt steak Needle tenderized 1 in 1.5 Openflame gas grill (380\u00b0F) 150\u00b0F 160\u00b0F For a 1 inch steak: Cook on a gas grill for 3 \u00bd minutes, flip and cook for another 3 \u00bd minutes until the steak reaches an internal temperature of 150\u00b0F as measured with a food thermometer. Allow the steak to rest for 1 minute\*. For a 1\u00bd inch steak: Cook on a gas grill for 8.5 minutes, flip and cook for another 8.5 minutes until the steak reaches an internal temperature of 150\u00b0F as measured by a food thermometer. Allow the steak to rest for 1 minute\*. For a 1 inch steak: Cook on a gas grill for 5 minutes, flip and cook for another 5 minutes until the steak reaches an internal temperature of 160\u00b0F as measured by a food thermometer. For a 1\u00bd inch steak: Cook on a gas grill for 8 minutes, flip and cook for another 8 minutes until the steak reaches an internal temperature of 160\u00b0F as measured by a food thermometer.

Luchansky, J.B., Porto-Fett, A.C.S., Shoyer, B.A., Call, J.E., Schlosser, W., Shaw, W., Bauer, N., Latimer, H. 2012. Journal of Food Protection. 75(1): 62-70. \*Initial research did not include a rest or dwell time, however, in order to achieve a 5-log<sub>10</sub> reduction of Salmonella and E. coli O157:H7 a rest time should be included (see Attachment 2 of this guidance document for support). 18","Cut of Meat Method of Tenderization Thickness Cooking Method Endpoint Temperature Validated Cooking Instructions Reference Eye of round steak Blade tenderized\* 0.4 in (1.0 cm) 0.6 in (1.5 cm) 0.8 in (2.0 cm) Hot plate heated to 392\u00b0F (200\u00b0C) 145\u00b0F For a 0.4 in inch steak: Heat stainless steel skillet on electric stove to medium. Add steak to skillet and cook for 5 minutes. Turn product over at least twice during cooking. Cook until steak reaches an internal temperature of 145\u00b0F as measured by a food thermometer and allow to rest for 3 minutes\*\*. For a 0.6 in inch steak: Heat stainless steel skillet on electric stove to medium. Add steak to skillet and cook for 11 minutes. Turn product over at least twice during cooking. Cook until steak reaches an internal temperature of 145\u00b0F as measured by a food thermometer and allow to rest for 3 minutes\*\*. For a 0.8 in inch steak: Heat stainless steel skillet on electric stove to medium. Add steak to skillet and cook for 14 minutes. Turn product over at least twice during cooking. Cook until steak reaches an internal temperature of 145\u00b0F as measured by a food thermometer and allow to rest for 3 minutes\*\*. Gill, C.O., Yang, X., Uttaro, B., Badoni, M. and Liu, T.. 2013. Effects on survival of Escherichia coli O157:H7 in non-intact steaks of the frequency of turning over steaks during grilling. Journal of Food Research. 2(5): 77-89. \*Method of inoculation used in is an

approximation to contamination by bacteria from tenderizer blades. \*\*Initial research did not include a rest or dwell time, however, in order to achieve a 5-log10 reduction of Salmonella and E. coli O157:H7 a rest time should be included (see Attachment 2 of this guidance document for support). 19", "Cut of Meat Method of Tenderization Thickness Cooking Method Endpoint Temperature Validated Cooking Instructions Reference Eye of round steak Blade tenderized\* 1.0 in (2.5 cm) 1.2 in (3.0 cm) Hot plate heated to 392\u00b0F (200\u00b0C) 145\u00b0F For a 1.0 in inch steak: Heat stainless steel skillet on electric stove to medium. Add steak to skillet and cook for 26 minutes. Turn product over at least twice during cooking. Cook until steak reaches an internal temperature of 145\u00b0F as measured by a food thermometer and allow to rest for 3 minutes\*\*. For a 1.2 in inch steak: Heat stainless steel skillet on electric stove to medium. Add steak to skillet and cook for 25 minutes. Turn product over at least twice during cooking. Cook until steak reaches an internal temperature of 145\u00b0F as measured by a food thermometer and allow to rest for 3 minutes\*\*. Gill, C.O., Yang, X., Uttaro, B., Badoni, M. and Liu, T.. 2013. Effects on survival of Escherichia coli O157:H7 in non-intact steaks of the frequency of turning over steaks during grilling. Journal of Food Research. 2(5): 77-89. 20", "Cut of Meat Method of Tenderization Thickness Cooking Method Endpoint Temperature Validated Cooking Instructions Reference Eye of round steak Blade tenderized\* 0.8 in (2.0 cm) 1.2 (3.0 cm) Hot plate heated to 338\u00b0F (170\u00b0C) 145\u00b0F For a 0.8 inch steak: Heat stainless steel skillet on an electric stove to medium-high. Add steak to skillet and cook for 17 minutes. Turn product over at least twice during cooking. Cook until steak reaches 145\u00b0F and allow to rest for 3 minutes\*\*. For a 1.2 inch steak: Heat stainless steel skillet on an electric stove to medium-high. Add steak to skillet and cook for 33 minutes. Turn product over at least twice during cooking. Cook until steak reaches 145\u00b0F and allow to rest for 3 minutes\*\*. Gill, C.O., Yang, X., Uttaro, B., Badoni, M. and Liu, T.. 2013. Effects on survival of Escherichia coli O157:H7 in non-intact steaks of the frequency of turning over steaks during grilling. Journal of Food Research. 2(5): 77-89. Eye of round steak Blade tenderized\* 0.8 in (2.0 cm) 1.2 (3.0 cm) Hot plate heated to 446\u00b0F (230\u00b0C) For a 0.8 inch steak: Heat stainless steel skillet on an electric stove to high. Add steak to skillet and cook for 14 minutes. Turn product over at least twice during cooking. Cook until steak reaches 145\u00b0F and allow to rest for 3 minutes\*\*. For a 1.2 inch steak: Heat stainless steel skillet on an electric stove to high. Add steak to skillet and cook for 29 minutes. Turn product over at least twice during cooking. Cook until steak reaches 145\u00b0F and allow to rest for 3 minutes\*\*. \*Method of inoculation used in is an approximation to contamination by bacteria from tenderizer blades. \*\*Initial research did not include a rest or dwell time, however, in order to achieve a 5-log10 reduction of Salmonella and E. coli O157:H7 a rest time should be included (see Attachment 2 of this guidance document for support). 21", "Attachment 2: FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks April 2009 Temp \u00b0F Temp \u00b0C Time for 5.0log10Reduction Unit Time 130 54.4 86 min. 131 55.0 69 min. 132 55.6 55 min. 133 56.1 44 min. 134 56.7 35 min. 135 57.2 28 min. 136 57.8 22 min. 137 58.4 18 min. 138 58.9 14 min. 139 59.5 11 min. 140 60.0 9 min. 141 60.6 7 min. 142 61.1 6 min. 143 61.7 5 min. 144 62.2 4 min. 145 62.8 3 min. 146 63.3 130 sec. 147 63.9 103 sec. 148 64.4 82 sec. 149 65.0 65 sec. 150 65.6 52 sec. 151 66.1 41 sec. 152 66.7 33 sec. 153 67.2 26 sec. 154 67.8 21 sec. 155 68.3 17 sec. 156 68.9 14 sec. 157 69.4 11 sec. 158 70.0 0 sec. 159 70.6 0 sec. 160 71.1 0 sec. The required lethali

ties are achieved instantly when the internal temperature of a cooked meat product

reaches 158°F or above. This Time\Temperature table is based on Thermal Death Curve for Salmonella in Beef Emulsions in tubes derived from Goodfellow & Brown, 19781,2. 1 Goodfellow, S. J. and W. L. Brown. 1978. Fate of Salmonella Inoculated into Beef for Cooking. Journal of Food Protection. 41: 598-605. 2 All times that were a fraction of a minute or second was rounded up to the next whole number (e.g., 16.2 seconds for 155 °F was round up to 17 seconds. 22", "Example for Illustration Purposes Only Attachment 3: Example Validation of Conventional Oven Cooking Instructions for a Needle Tenderized Roast Validation Trial Product Summary Sheet Date: 12/5/2012 Product Name: Roast #456 Product variables Method of tenderization Needle Tenderized Thickness of the product 5 inches Type of cut Eye-round roast (3 lbs) Testing variables Method of cooking Both ovens were preheated to 350°F Electric oven \u2013 KitchenAid Model #: 5678 Serial #: LMN5678 Gas oven \u2013 LG Model #: 12345 Serial #: ABC12345 State of the product at the start of cooking, e.g., frozen versus refrigerated, or room temperature Refrigerated Multiple units Only one roast was tested at a time because this is how the consumer would ordinarily prepare the product Type of pan\cooking container The roast was cooked in a light pan (uncovered) to represent worst case scenario Number and location of temperature measurement sites during testing Two temperature measurements were taken in the center of the roast (the thermocouples were inserted into opposite ends of the roast) Number of replicates The testing methodology was repeated three times for each method of cooking (electric and gas) Endpoint temperature 150°F Rest time after cooking 1 minute Rotation of product None 23", "Example for Illustration Purposes Only Test methodology: First, a cold spot determination was conducted for each type of oven in which oven temperatures were taken in five different locations (front left, front right, back left, back right, and center) on each rack in the oven. After the cold spot determination was complete, the oven was heated to 350°F. Then product (at refrigeration temperature) was placed in the oven on a light colored pan in the location previously identified to be the coldest. Two calibrated, stainless steel thermocouples were inserted from opposite ends of the product into the center of the roast to measure the internal temperature of the roast during cooking. The temperature of the roast was continuously monitored with an eight-channel thermocouple data logger at 5 second intervals. The roast was removed from the oven when both thermocouples within the roast reached 150°F. Time was recorded at this point. The temperature of the roast was measured after the 1 minute rest time to ensure that the product temperature remained at 150°F while it was uncovered. 3 This entire procedure, beginning after the cold spot determination, was repeated three times. Results were recorded on the charts below. Results: Electric oven preheated to 350°F Time to reach 150°F Trial 1 91 minutes Trial 2 97 minutes Trial 3 90 minutes Gas oven preheated to 350°F Time to reach 150°F Trial 1 98 minutes Trial 2 89 minutes Trial 3 93 minutes A two-sample t-test was conducted and it was determined that the difference in the mean time to reach 150°F using the gas and electric oven was not statistically significant. Conclusions: A single set of instructions can be created for electric and gas ovens since the difference in time it took to reach the desired endpoint temperature was not statistically significant. Since the longest amount of time it took to reach 150°F was 98 minutes, this value will be rounded up for the instructions so that consumers are instructed to cook 3 This method was adapted from Luchansky et al. 2011 and 2012. 24", "Example for Illustration Purposes Only the product for 1 hour and 40 minutes (or 100 minutes). Consumers will also be instructed to allow the

product to rest for 1 minute. An example of the final validated cooking instructions are provided below. For Food Safety and Quality Follow These Cooking Instructions: Electric or gas oven: 1) Heat oven to 350\u00b0F. 2) Cook for 1 hour and 40 minutes to an internal temperature of 150\u00b0F as measured with a food thermometer. 3) Remove from oven and allow meat to rest for 1 minute. 25","Attachment 4: Z-Table (Cumulative Probabilities of the Standard Normal Distribution Entry) Z 0.00 0.01 0.02 0.03 0.04 0.05 0.06 0.07 0.08 0.09 -3.5 0.0002 0.0002 0.0002 0.0002 0.0002 0.0002 0.0002 0.0002 0.0002 -3.4 0.0003 0.0003 0.0003 0.0003 0.0003 0.0003 0.0003 0.0003 0.0003 -3.3 0.0005 0.0005 0.0005 0.0004 0.0004 0.0004 0.0004 0.0004 0.0004 -3.2 0.0007 0.0007 0.0007 0.0006 0.0006 0.0006 0.0006 0.0006 0.0006 -3.1 0.0010 0.0009 0.0009 0.0009 0.0009 0.0009 0.0008 0.0008 0.0008 -3.0 0.0013 0.0013 0.0013 0.0012 0.0012 0.0011 0.0011 0.0011 0.0010 0.0010 -2.9 0.0019 0.0018 0.0018 0.0017 0.0016 0.0016 0.0015 0.0015 0.0014 0.0014 -2.8 0.0026 0.0025 0.0024 0.0023 0.0023 0.0022 0.0021 0.0021 0.0020 0.0019 -2.7 0.0035 0.0034 0.0033 0.0032 0.0031 0.0030 0.0029 0.0028 0.0027 0.0026 -2.6 0.0047 0.0045 0.0044 0.0043 0.0041 0.0040 0.0039 0.0038 0.0037 0.0036 -2.5 0.0062 0.0060 0.0059 0.0057 0.0055 0.0054 0.0052 0.0051 0.0049 0.0048 -2.4 0.0082 0.0080 0.0078 0.0075 0.0073 0.0071 0.0069 0.0068 0.0066 0.0064 -2.3 0.0107 0.0104 0.0102 0.0099 0.0096 0.0094 0.0091 0.0089 0.0087 0.0084 -2.2 0.0139 0.0136 0.0132 0.0129 0.0125 0.0122 0.0119 0.0116 0.0113 0.0110 -2.1 0.0179 0.0174 0.0170 0.0166 0.0162 0.0158 0.0154 0.0150 0.0146 0.0143 -2.0 0.0228 0.0222 0.0217 0.0212 0.0207 0.0202 0.0197 0.0192 0.0188 0.0183 -1.9 0.0287 0.0281 0.0274 0.0268 0.0262 0.0256 0.0250 0.0244 0.0239 0.0233 -1.8 0.0359 0.0351 0.0344 0.0336 0.0329 0.0322 0.0314 0.0307 0.0301 0.0294 -1.7 0.0446 0.0436 0.0427 0.0418 0.0409 0.0401 0.0392 0.0384 0.0375 0.0367 -1.6 0.0548 0.0537 0.0526 0.0516 0.0505 0.0495 0.0485 0.0475 0.0465 0.0455 -1.5 0.0668 0.0655 0.0643 0.0630 0.0618 0.0606 0.0594 0.0582 0.0571 0.0559 -1.4 0.0808 0.0793 0.0778 0.0764 0.0749 0.0735 0.0721 0.0708 0.0694 0.0681 -1.3 0.0968 0.0951 0.0934 0.0918 0.0901 0.0885 0.0869 0.0853 0.0838 0.0823 -1.2 0.1151 0.1131 0.1112 0.1093 0.1075 0.1056 0.1038 0.1020 0.1003 0.0985 -1.1 0.1357 0.1335 0.1314 0.1292 0.1271 0.1251 0.1230 0.1210 0.1190 0.1170 -1.0 0.1587 0.1562 0.1539 0.1515 0.1492 0.1469 0.1446 0.1423 0.1401 0.1379 -0.9 0.1841 0.1814 0.1788 0.1762 0.1736 0.1711 0.1685 0.1660 0.1635 0.1611 -0.8 0.2119 0.2090 0.2061 0.2033 0.2005 0.1977 0.1949 0.1922 0.1894 0.1867 -0.7 0.2420 0.2389 0.2358 0.2327 0.2296 0.2266 0.2236 0.2206 0.2177 0.2148 -0.6 0.2743 0.2709 0.2676 0.2643 0.2611 0.2578 0.2546 0.2514 0.2483 0.2451 -0.5 0.3085 0.3050 0.3015 0.2981 0.2946 0.2912 0.2877 0.2843 0.2810 0.2776 -0.4 0.3446 0.3409 0.3372 0.3336 0.3300 0.3264 0.3228 0.3192 0.3156 0.3121 -0.3 0.3821 0.3783 0.3745 0.3707 0.3669 0.3632 0.3594 0.3557 0.3520 0.3483 -0.2 0.4207 0.4168 0.4129 0.4090 0.4052 0.4013 0.3974 0.3936 0.3897 0.3859 -0.1 0.4602 0.4562 0.4522 0.4483 0.4443 0.4404 0.4364 0.4325 0.4286 0.4247 -0 0.5000 0.4960 0.4920 0.4880 0.4840 0.4801 0.4761 0.4721 0.4681 0.4641 +0 0.5000 0.5040 0.5080 0.5120 0.5160 0.5199 0.5239 0.5279 0.5319 0.5359 0.1 0.5398 0.5438 0.5478 0.5517 0.5557 0.5596 0.5636 0.5675 0.5714 0.5753 0.2 0.5793 0.5832 0.5871 0.5910 0.5948 0.5987 0.6026 0.6064 0.6103 0.6141 0.3 0.6179 0.6217 0.6255 0.6293 0.6331 0.6368 0.6406 0.6443 0.6480 0.6517 0.4 0.6554 0.6591 0.6628 0.6664 0.6700 0.6736 0.6772 0.6808 0.6844 0.6879 0.5 0.6915 0.6950 0.6985 0.7019 0.7054 0.7088 0.7123 0.7157 0.7190 0.7224 0.6 0.7257 0.7291 0.7324 0.7357 0.7389 0.7422 0.7454 0.7486 0.7517 0.7549 0.7 0.7580 0.7611 0.7642 0.7673 0.7704 0.7734 0.7764 0.7794 0.7823 0.7852 0.8 0.7881 0.7910 0.7939 0.7967 0.7995 0.8023 0.8051 0.8078 0.8106 0.8133 0.9 0.8159

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27"]},{"file\_name":"FSIS\_GD\_2016\_0002","title":"FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork and Products Containing Pork","num":"FSIS-GD-2016-0002","id":"aa7da0e6881d3b2118e93ad94ba253da79a81e72b2d25d23a50dd303a5402aad","corpus":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/media\_file/2021-02/Compliance-Guidelines-Trichinella.pdf","type":"pdf","n\_pages":41,"word\_count":15044,"text\_by\_page":["DRAFT FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork Products 2018 This guideline is designed to help establishments, with a focus on small and very small establishments, understand available options that are effective for the prevention and control of Trichinella spiralis and other parasitic hazards in ready-to-eat (RTE) and not-ready-to-eat (NRTE) pork products. Raw and NRTE pork products, including all forms of fresh (i.e., raw or uncured) pork, do not need to be treated to destroy Trichinella because they are customarily wellcooked in the home or elsewhere before being served to the consumer. i FSIS USDA","Preface What is the purpose of this compliance guideline? FSIS developed this compliance guideline to assist establishments, particularly small and very small establishments, understand the available options that are effective for the prevention and control of Trichinella spiralis and other parasitic hazards, specifically, Toxoplasma gondii, in ready-to-eat (RTE) and not-ready-to-eat (NRTE) pork products. The guidance represents best practice recommendations by FSIS, based on current scientific and practical considerations, and does not represent regulatory

requirements that must be met. Establishments may choose to adopt different procedures than those outlined in the guideline, but they would need to support why or how those procedures are effective. On 5/31/18, FSIS published the final rule \u201cElimination of Trichinae Control Regulations and Consolidation of Thermally Processed, Commercially Sterile Regulations\u201d (83 FR 25302), which amends the Federal meat inspection regulations to eliminate the requirements that RTE and NRTE pork products be treated to destroy Trichina (Trichinella spiralis). FSIS removed these prescriptive regulations because they were inconsistent with the Hazard Analysis and Critical Control Point (HACCP) regulations, and are no longer necessary. Establishments now have the flexibility provided by the HACCP regulations (9 CFR Part 417) to develop appropriate science-based controls for Trichinella and other parasitic hazards in pork. All establishments producing pork products will have to determine whether Trichinella is a hazard reasonably likely to occur (RLTO) in their processes. If so, they will need to address this hazard in their HACCP system. All establishments producing pork products will need to assess whether their products are to be treated for elimination of Trichinella, special cooking instructions are necessary on the label of the products, or safe handling instructions on labels are sufficient to ensure that the products are cooked to temperatures necessary to eliminate any live Trichinella. Establishments may decide to treat their products to address Trichinella or to include special cooking instructions on labels based on how consumers typically prepare the products or the likelihood that consumers will confuse the products with RTE products. Establishments may also make decisions based on whether their suppliers participate in international trade and a voluntary preharvest pork safety program, such as the Animal and Plant Health Inspection Service\u2019s (APHIS\u2019s) U.S. Trichinae Certification Program, or another APHIS-approved validated Trichinella preharvest safety program that complies with the World Organisation for Animal Health\u2019s (OIE\u2019s) guidance<sup>1</sup> for 1 World Organisation for Animal Health Terrestrial Animal Health Code. Retrieved from [http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre\\_trichinella\\_spp.htm](http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_trichinella_spp.htm)

ii", "Trichinella. OIE\u2019s guidance includes maintaining controlled management conditions for swine herds by functional separation using biosecurity measures, having two years of slaughter surveillance data to establish the compartment, auditing farms, and ensuring animal identification and traceability to the farm of origin. APHIS is working to develop standards for a program that would ensure that product for export comes from facilities that meet the international standards for Trichinella. These standards, once developed, may replace the U.S. Trichinae Certification Program. This compliance guideline follows the procedures in the Office of Management and Budget\u2019s (OMB) \u201cFinal Bulletin for Agency Good Guidance Practices\u201d (GGP). More information can be found on GGP on the Food Safety and Inspection Service (FSIS) webpage at: <https://www.fsis.usda.gov/wps/portal/footer/policies-and-links/significantguidance-documents/significant-guidance>. Who is this guideline designed for? This guideline is designed for small and very small establishments in support of the Small Business Administration\u2019s initiative to provide compliance assistance under the Small Business Regulatory Enforcement Fairness Act (SBREFA). However, all FSIS regulated meat and poultry establishments may be able to apply the recommendations in this guideline. It is important that small and very small establishments have access to the scientific and technical support and assistance they need to establish safe and effective HACCP systems. Although large establishments can benefit from the

guidance that FSIS provides, focusing the guidance on the needs of small and very small establishments provides these segments of the industry with information that may be otherwise unavailable to them. What if I still have questions after I read this guideline? If the desired information cannot be found within this compliance guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the askFSIS database or submit questions through askFSIS. Documenting these questions helps FSIS improve and refine present and future versions of the compliance guideline and associated issuances. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided: Subject Field: Enter FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork Products. Question Field: Enter question with as much detail as possible. Product Field: Select General Inspection Policy from the drop-down menu. Category Field: Select Sampling -General from the drop-down menu. iii","Policy Arena: Select Domestic (U.S.) Only from the drop-down menu. When all fields are complete, press Continue. iv","FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork Products Table of Contents Preface

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.....35 v", "FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork Products Background Trichinella is a parasite that infects both humans and animals. Swine are the primary source of *Trichinella spiralis* infected meat that is ingested by humans (Hill et al., 2012). Humans can become infected with Trichinella by consuming encysted larvae in the muscle tissue of an infected animal. Trichinellosis in humans is caused by the consumption of raw or undercooked meat products containing Trichinella larvae. The occurrence of Trichinella infection in humans due to the consumption of pork has decreased significantly in the U.S. over the past 20 years, although occasional sporadic outbreaks persist (Burke et al., 2008; Wilson et al., 2015). Much of this reduction is due to swine being raised in confinement. However, in organic, pasture raised swine that have access to rodents and wildlife infected with Trichinella, the risk of Trichinella infection to swine and subsequently humans are increased. In the United States, trichinellosis cases are reported to CDC much less frequently now than in the past. During the late 1940s, when the U.S. Public Health Service began counting cases of trichinellosis, 400 cases in the U.S. were recorded each year on average. During 20082012, a median of 15 cases per year were reported to CDC. Over the past 40 years, few cases of trichinellosis have been reported in the U.S., and the risk of trichinellosis from commercially raised and properly prepared pork is very low. The overall number of cases reported has decreased because of improved swineraising practices in the pork industry such as grain-fed swine being raised in confinement, commercial and home freezing of pork, and public awareness of the danger of eating raw or undercooked meat products.

1 KEY DEFINITIONS *Trichinella spiralis* is a parasitic nematode (roundworm) which is found in many warm-blooded carnivores and omnivores, including swine. Trichinella is transmitted from one host to another host by ingestion of muscle tissue (meat) containing cysts (encysted larval stage of this parasite). Once the larvae encyst in the muscle tissue, they can remain alive and infective for years. The symptoms of trichinellosis often occur within 2 weeks after eating contaminated meat and can last up to 8 weeks. The classic symptoms of trichinellosis include: muscle pain; fever; swelling of the face, particularly the eyes; weakness or fatigue; headache; chills; itchy skin or rash; cough; diarrhea; and constipation.", "Risk Comparing Swine Raised in Confinement Systems vs. NonConfinement Systems FSIS is aware that the risk of infection with Trichinella is increased in pasture raised swine that have access to rodents and wildlife infected with Trichinella. An increasing number of swine are being raised in non-confinement systems because of increased consumer demand for \u2018free-ranging,\u2019 \u2018organically raised,\u2019 and \u2018humanely raised\u2019 pork products (Hill et al., 2012; Honeyman et al., 2006). Feral swine are also reservoirs of infection with Trichinella for domestic swine reared in non-biosecure (or nonconfinement) areas. Raising swine outdoors poses a major risk for swine of being infected with Trichinella because it increases exposure to potentially infected reservoir hosts (Hill et al., 2012; Gamble et al., 2000; Pyburn et al., 2005). The risk of Trichinella infection in non-confinement swine can be substantially reduced by employing swine production practices that eliminate the sources of exposures to this parasitic

hazard, thereby reducing the likelihood of human infection from consumption of pork infected with *Trichinella*. An establishment may determine in its hazard analysis that *Trichinella* is not reasonably likely to occur (NRLTO) in its products if the establishment gets its pork from swine producers who participate in an APHIS-approved validated *Trichinella* preharvest safety program; such programs are considered prerequisite programs. It is important for establishments to understand that such prerequisite programs designed to support a decision in their hazard analysis, are part of their overall HACCP system. Because FSIS has removed the prescriptive *Trichinæ* control regulations, establishments have greater flexibility to choose validated control procedures and to support their use as part of their HACCP system to control *Trichinella* and other parasitic hazards in pork products. Establishments producing RTE or NRTE pork products must assess in their hazard analysis if *Trichinella* and other parasites are hazards reasonably likely to occur (RLTO) or NRLTO in their processes. Establishments must include control procedures for these parasites in their HACCP plans if they determine that the parasites are a hazard that is RLTO, including critical control points (CCPs) designed to control the parasitic hazard [9 CFR 417.2(c)(2)] and critical limits that must be met at each CCP [9 CFR 417.2(c)(3)]. Establishments may determine that the parasitic hazard is NRLTO because a prerequisite program prevents the hazard, but they must have documentation to support the decisions in their hazard analysis [9 CFR 417.5(a)(1)]. The options for preventing and controlling *Trichinella* in pork products are described in the section \u201cOptions for Preventing and Controlling *Trichinella* in Pork.\u201d When an establishment determines that a hazard, such as *Trichinella*, is NRLTO because the prerequisite program prevents the hazard, then that prerequisite program becomes part of the HACCP system. (See \u201cOption 2: Obtain Pork Products from 2\u201d, "Swine Producers who Participate in the *Trichinæ* Certification Program or another APHIS-approved validated *Trichinella* preharvest safety program\u201d for more information.) Options for Preventing and Controlling *Trichinella* in Pork Products Under HACCP regulations, establishments are required to conduct a hazard analysis to determine the food safety hazards that are RLTO in their production processes, in accordance with 9 CFR 417.2(a)(1). Establishments must list the CCPs designed to control hazards identified as RLTO [9 CFR 417.2(c)(2)] and establish critical limits that must be met [9 CFR 417.2(c)(3)]. Establishments are also required to maintain documentation that supports the decisions made in their hazard analysis as a part of their records under 9 CFR 417.5(a)(1). If establishments determine in their hazard analysis that *Trichinella* is a hazard RLTO, then they need to implement a CCP to eliminate the hazard. FSIS recommends that establishments use one of the following treatment methods described in Option 4 to control *Trichinella* in their pork products: 1) heating, 2) freezing, 3) curing, 4) high pressure processing (HPP), or 5) irradiation. Establishments will need to be specific in their HACCP plans as to which treatment method they are using, and the critical parameters being measured [9 CFR 417.5(a)(2) and 417.2(c)(3)]. Establishments will also need to validate the selected method [9 CFR 417.4(a)(1)] by demonstrating that they are able to consistently meet the specific parameters outlined in the selected treatment method. Establishments may also develop alternative *Trichinella* control procedures, as described in Option 5. As part of the hazard analysis, establishments may determine that *Trichinella* is a hazard NRLTO in their products because of the implementation of a prerequisite program. If an establishment decides to prevent *Trichinella* in their pork product(s) by implementing a prerequisite program, then it must keep documentation that

supports the decisions made in its hazard analysis as a part of its records [9 CFR 417.5(a)(1)]. Additionally, the prerequisite program should meet the following criteria: 1.Written and describes procedures that the establishment will implement to show the hazard is NRTLTO; 2.Designed to prevent the hazard from being RLTO, and the establishment maintains supporting documentation that the program has been validated (i.e., scientific or technical support and in-plant validation data); 3.Describes records that the establishment will keep demonstrating that the program is being implemented as written; 3", "4.Describes records the establishment will keep to demonstrate that the program effectively prevents the hazard (i.e., on-going verification of the decision that the hazard is NRTLTO); and 5.Describes actions the establishment will take when it fails to implement the program, or when it finds the program has failed to prevent the hazard (i.e., corrective actions in response to an unforeseen hazard as per 9 CFR 417.3(b) and as per 9 CFR 416.15 if the program is a Sanitation SOP). If the design of the prerequisite program is not consistent with the criteria described above, then the establishment likely has not met the requirements of 9 CFR 417.5(a)(1). The following prerequisite programs, as further described in Options 1-2, may be used by establishments to prevent *Trichinella* in their pork products: 1) acquire pork products from carcasses or carcass parts found to be free of *Trichinella* by a validated testing method; or 2) obtain pork products from swine producers who participate in the Trichinae Certification Program or another APHIS-approved validated *Trichinella* preharvest safety program. List of Options used to Prevent and Control *Trichinella* in Pork and Products Containing Pork Option 1: Acquire pork products from carcasses or carcass parts found to be free of *Trichinella* post-slaughter by a validated testing method Option 2: Obtain pork products from swine producers who participate in the Trichinae Certification Program or another APHIS-approved validated *Trichinella* preharvest safety program Option 3: Label NRTE pork products, including all forms of fresh pork to clearly indicate the products require additional treatment by the consumer Option 4: Treat NRTE pork products for the destruction of *Trichinella* that might be eaten rare or without thorough cooking because of the appearance of the finished product Option 5: Develop alternative *Trichinella* control procedures not included in Option 4 Option 1: Acquire pork products from carcasses or carcass parts found to be free of *Trichinella* by a validated testing method Pork products from carcasses or carcass parts that have been found to be free of *Trichinella* by a validated post-slaughter testing method are not required to be treated for 4", "the destruction of *Trichinella*. The validated testing method is a prerequisite program, and establishments may determine that *Trichinella* is NRTLTO if their product has been found to be free of *Trichinella* through post-slaughter testing using a validated method. Testing must be performed using a validated method that is equivalent to or better than the tissue digestion assay method for detecting *Trichinella* in pork (known as the Magnetic Stirrer Method for Pooled Sample Digestion), using a 5-gram sample of tongue, muscles of the face (e.g., masseter muscle), diaphragm muscles, or neck muscles. A 5-gram sample of diaphragm, foreleg, or tongue should be used for nonconfinement raised swine (e.g., feral swine, pasture-raised swine, free-ranging swine). Any process-verification testing should be performed using a validated testing method that is equivalent to or better than the digestion assay method for detecting *Trichinella* in pork. Processors should be aware of the limitations of the readily available commercial test kits that test for antibodies that may not show up for several weeks following infestation. Such test results are not acceptable or equivalent to tissue digestion methods to rule out the presence of

trichinæ in meat product. If establishments select Option 1 to control *Trichinella* in pork and products containing pork, they should be aware of the following: \u2022 The establishment must keep on file and make available to FSIS inspection program personnel (IPP) its procedure for testing, to include identifying and pooling carcasses, collecting and pooling samples, testing samples, communicating test results, retesting individual carcasses, and maintaining positive identification and clear separation of pork found to be *Trichinella*-free by testing from untested pork or *Trichinella*-positive pork. \u2022 The establishment may test in-house or may contract for testing by a private testing laboratory. Personnel conducting the testing for *Trichinella* must be certified to perform the validated testing method, and laboratories where testing is performed must be certified for *Trichinella* testing. Certifications are obtained by participation in a USDA *Trichinella* testing program such as the Agricultural Marketing Service (AMS) *Trichinæ Analyst Program* or other FSIS approved certification programs. Certification must be based on adequacy of facilities, reagents, and equipment and on demonstration of continuing competency and reliability of personnel performing the validated testing method for *Trichinella*. A certificate is provided to the establishment\u2019s analyst (i.e., the personnel certified to perform the validated testing method) and laboratory manager, and the FSIS Inspector-in-Charge (IIC) as evidence of certification. Private testing laboratories would provide certification documentation to their customer. \u2022 Sampling and sample preparation are subject to inspection by FSIS. 5", "\u2022 Tested pork or products made from tested pork must not be released as *Trichinella*-free from the official establishment without treatment until the IIC receives a laboratory report that the tested pork has tested negative for *Trichinella*. Option 2: Obtain pork products from swine producers who participate in the *Trichinæ Certification Program* or another APHIS-approved validated *Trichinella* preharvest safety program Establishments may determine that *Trichinella* is NRTL in their products if they obtain pork from swine producers that participate in the U.S. *Trichinæ Certification Program* (9 CFR Part 149), which is a prerequisite program for *Trichinella*. This is a voluntary preharvest pork safety program in which APHIS certifies pork production sites that follow all the required good production practices (GPPs) that reduce, eliminate, or avoid the risk of exposure of swine from their sites to *Trichinella*. In the U.S. *Trichinæ Certification Program*, adherence to the GPPs is verified by periodic site audits conducted by APHIS. Establishments are also required to maintain documentation that supports the decisions made in their hazard analysis for this prerequisite program as a part of their records under 9 CFR 417.5(a)(1). The key GPPs components for the U.S. *Trichinæ Certification Program* include: \u2022 Feed integrity, source and storage. \u2022 Building construction and condition as it pertains to biosecurity (i.e., swine raised in confinement). \u2022 Integrity of rodent control programs. o Prevent exposure to rodents or other wildlife infected with *Trichinella*. Rodents can serve as a reservoir host for *Trichinella*. \u2022 General management and hygiene issues as they pertain to rodent control, cannibalism and other issues. o Prevent cannibalism among swine within an infected herd. o Boots worn solely in confinement facility. Pork products from carcasses or carcass parts from swine herds that have been raised by producers that follow these GPPs, and thus are certified under the U.S. *Trichinæ Certification Program*, should still be tested at slaughter to verify that the adherence to good manufacturing practices and GPPs is resulting in the absence of *Trichinella* infection in swine from that herd. It is recommended that the slaughter facility that is processing certified swine perform process-verification testing to determine the *Trichinella*

infection status of certified swine under its control. Process-verification testing should be performed using a validated testing method that is equivalent to or better than the tissue digestion assay method for detecting *Trichinella* in pork, described in Option 1. 6", "It is important for establishments to understand that pork products originating from *Trichinella*-free certified swine is certified pork, and these products are not required to be treated for the destruction of *Trichinella*. Establishments may also determine that *Trichinella* is NRTLTO in their products if they obtain pork from swine producers that participate in an APHIS-approved validated *Trichinella* preharvest safety program that is in compliance with OIE\u2019s guidance for *Trichinella*. Participation in such a program would be a voluntary preharvest pork safety program. As a part of the record keeping required under 9 CFR 417.5(a)(1), participating establishments would need to maintain documentation to support the decisions made in their hazard analysis for this prerequisite program. Establishments would also need to have the ability to trace product back to the farm of origin. International requirements for *Trichinella* include the ability to trace product back to the farm of origin, an audit process to ensure compliance, slaughter surveillance, and adherence to GPPs that include: \u2022 Ensuring the integrity of rodent and other wildlife control and mitigation programs. o Prevent swine exposure to rodents or other wildlife infected with *Trichinella*. Rodents can serve as a reservoir host for *Trichinella*. \u2022 Ensuring the integrity of the feed source and feed storage. o Raw food waste of animal origin is not present on the farm and is not fed to pigs. o Feed is not exposed to rodents or other wildlife potentially infected with *Trichinella*. \u2022 Practicing good general management and hygiene. o Prevent cannibalism among swine within a herd. \u2022 Sourcing swine. o Pigs originate from herds officially recognized as participating in an APHISapproved preharvest safety program for *Trichinella* that meets international standards. It is important for establishments to understand that pork products originating from swine produced in facilities that meet the standards of an APHIS-approved validated *Trichinella* preharvest safety program are not required to be treated for the destruction of *Trichinella*. However, it is recommended that the slaughter facility that is processing swine perform process-verification testing to determine the *Trichinella* infection status of swine under its control. Option 3: Label NRTE pork products, including all forms of fresh pork to clearly indicate the products require additional treatment by the consumer 7", "Establishments must decide in their hazard analysis whether *Trichinella* is NRTLTO or RLTO in their production process. To support in their hazard analysis that *Trichinella* is NRTLTO in their NRTE pork products, establishments can use special labeling of products to require additional treatment by the consumer. NRTE pork products, including all forms of fresh (i.e., raw or uncured) pork, do not need to be treated to destroy *Trichinella* because they are customarily well-cooked in the home or elsewhere before being served to the consumer. If an establishment chooses to label its product to control *Trichinella*, then it should label the product so that the consumer understands that the product is raw or NRTE and needs to be fully cooked to control for *Trichinella*. The use of labeling may be generically approved by FSIS\u2019s Labeling and Program Development Staff (LPDS) in accordance with 9 CFR 412.2, unless the establishment adds a claim to the label or takes some other action that would render the label ineligible for generic approval. If the establishment has a generically approved label, it would not be necessary to subject that product to treatment for *Trichinella* if the product\u2019s label clearly indicates the raw or NRTE nature of the product and provides consumers with the

following adequate food safety information:

- 1.A prominent statement on the principal display panel to indicate that the product is NRTE, for example, "Cook Thoroughly," or "Ready to Cook;"
- 2.Cooking instructions that result in a RTE product (e.g., "Cook to an internal temperature of 145 degrees Fahrenheit as measured by a food thermometer and allow to rest for 3 minutes before serving"); and

Note: If the minimum internal temperature above appears on the principal display panel, then the prominent statement in #1 above may be omitted.

- 3.Safe handling instructions (SHIs) if the product is raw or the pork ingredient is not RTE. An example label, along with the SHIs, is provided below.

8","U.S. INSn:CT\u00a3D ANO PASSED BY DEPARTMENT OF AGAICUL TUR[ ESt38 Safe Handling Instructions This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For protection, follow these safe handling instructions. Keep refrigerated until thawed in refrigerator or microwave. b Keep meat and poultry separate from other foods. Wash hands after handling surfaces (including boards), utensils, and/or hands after handling meat and/or poultry. ~ Cook thoroughly. ~ Keep hot foods hot!.

Refrigerate leftovers immediately or discard. Keep Frozen Smoked, Cured Pork Sausage

INGREDIENTS: Pork, water, salt, sugar, spices, and sodium nitrite Distributed by: ABS Company, City, State, 12345 COOK THOROUGHLY NET WEIGHT: 8 OZ (Principal Display Panel) Cook to an internal temperature of 145 degrees Fahrenheit as measured by a food thermometer and allow to rest for 3 minutes before serving (Back Panel) NOTE: The information in the SHIs cannot be used in lieu of the prominent statement described in #1 or the cooking directions in #2 above. These features need to be separate and distinct from the SHIs. 9","Establishments can submit labeling questions to the LPDS through askFSIS. LPDS can also be reached by telephone at 1-800-233-3935. When submitting a labeling question through askFSIS, use the Submit a Question tab, and enter the following information in the fields provided: Subject Field: Enter FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork Products. Question Field: Enter your question with as much detail as possible. Product Field: Select Labeling from the drop-down menu. Category Field: Select Labeling Regulations, Policies and Claims from the drop-down menu. Policy Arena: Select Domestic (U.S.) only from the drop-down menu. When all fields are complete, press Continue and at the next screen then press Finish Submitting Question. Option 4: Treat NRTE pork products for the destruction of Trichinella that might be eaten rare or without thorough cooking because of the appearance of the finished product Establishments that determine in their hazard analysis that Trichinella is a hazard RLTO need to employ process controls to eliminate the hazard. Pork products need to be treated for the destruction of Trichinella if they are to be prepared in such a manner that the product might be eaten rare or without thorough cooking because of the appearance of the finished product. Some ingredients (e.g., annatto, red wine, paprika, red pepper, etc.) may also alter the appearance of the finished product, making it difficult for the consumer to visually determine whether the product has been fully cooked. Certain pork products that require treatment for the destruction of Trichinella are mixtures of pork with other meats and poultry; bacon wrapped products; breaded pork; raw marinated pork in dark sauces; colored pork; cured pork; and cured and smoked pork. For these products, one or more processing steps make it difficult for the consumer to visually determine whether the product has been fully cooked, such as encasing the raw pork or coloring the raw pork. NOTE: Poultry products

containing pork muscle tissue are also required to be treated for the destruction of *Trichinella* in accordance with 9 CFR 424.21(a)(3)(iii). 10", "KEY QUESTION Question: Are certain pork products, such as pork cuts, pork sausage, and bacon, required to be treated for the destruction of *Trichinella*? Answer: No. Certain pork products, including fresh unsmoked sausage containing pork muscle tissue, and pork such as bacon and jowls are classed as products that are customarily well cooked in the home or elsewhere before being served to the consumer. Therefore, these products are not required to be treated to destroy *Trichinella*. As described in \u201cOption 4,\u201d pork products need to be treated for the destruction of *Trichinella* if they are prepared in such a manner that the product might be eaten rare or without thorough cooking because of the appearance of the finished product. Additionally, certain products requiring treatment for the destruction of *Trichinella* are mixtures of pork with other meats and poultry; bacon wrapped products; breaded pork; raw marinated pork in dark sauces; colored pork; cured pork; and cured and smoked pork. For these products, one or more processing steps make it difficult for the consumer to visually determine whether the product has been fully cooked, such as encasing the raw pork or coloring the raw pork. Also, poultry products containing pork muscle tissue are required to be treated for the destruction of *Trichinella* in accordance with the requirements addressed in 9 CFR 424.21(a)(3)(iii). As previously discussed, establishments must determine in their hazard analysis whether *Trichinella* is a hazard RLTO in their production processes [9 CFR 417.2(a)(1)]. If so, then establishments must list the CCPs designed to control *Trichinella* [9 CFR 417.2(c)(2)] and the critical limits that must be met at each of the CCPs [9 CFR 417.2(c)(3)]. Also, establishments must keep documentation that supports the decisions made in their hazard analysis as a part of their records [9 CFR 417.5(a)(1)]. Further, establishments are also required to validate the selected method, in this case to control the *Trichinella* hazard, as per 9 CFR 417.4(a)(1), by demonstrating that they are able to consistently meet the specific parameters outlined in the selected treatment method. If *Trichinella* has been determined to be RLTO, then the establishment may elect to use one of the following treatment methods to destroy the parasite in its pork products: 1) heating, 2) freezing, 3) curing, 4) HPP, or 5) irradiation. As an example, an establishment may use the freezing treatment method as a CCP in its HACCP plan to eliminate *Trichinella* in its pork product where the thickness of the meat or inside dimensions of the container does not exceed 6 inches (i.e., Group 1 products \u2013 see Table 2). The critical limits for Group 1 products would be a continuous temperature no higher than 5\u00b0F for 20 days. 11", "FSIS considers these methods, when properly applied and validated, to be sufficient to destroy *Trichinella*. Establishments can also elect to develop alternative treatments for the destruction of *Trichinella*, as described in Option 5. NOTE: If an establishment is producing RTE pork products, then compliance with the lethality performance standards for the reduction of *Salmonella* will ensure the elimination of *Trichinella* because the time\temperature combinations for *Salmonella* are higher than the heat treatment for *Trichinella*. However, because there are no published studies comparing the lethality rate of *Salmonella* to the destruction of *Trichinella* in dried, salt-cured, or fermented products, FSIS cannot state with absolute certainty that the lethality performance standards for *Salmonella* in these types of products would also eliminate *Trichinella*. Therefore, if an establishment identifies *Trichinella* as a hazard that is RLTO, then the establishment will have to ensure that the process is validated and verified to effectively eliminate *Trichinella*. Critical Operational Parameters for the Methods used for the Destruction

of Trichinella in Pork Critical operational parameters are the specific conditions that the intervention must operate under for it to be effective. The interventions, or methods, used to eliminate Trichinella from pork products include heating, freezing, curing, HPP, or irradiation. The critical operational parameters important for each treatment method are listed and described below.

Time\temperature combination It is important that the time and temperature combinations adhere to the specific parameters described in \u201cHEATING,\u201d \u201cFREEZING,\u201d and \u201cCURING.\u201d The specific timetemperature parameters apply only when the product reaches and maintains temperatures evenly distributed throughout the meat. Alternative methods of heating, particularly the use of microwaves, have been shown to give variable results, with parasites not completely inactivated when product was heated to reach a prescribed end-point temperature. Establishments must maintain on file the recording of actual times and temperatures as specified in their HACCP plans, 9 CFR 417.5(a)(3). Product, including product in containers, undergoing refrigeration must be spaced in such a way to ensure a free circulation of air between the pieces of meat, layers, blocks, barrels, and tierces for the desired temperature of the meat to be promptly and uniformly reduced. Equipment settings or calibrations In accordance with 9 CFR 417.4(a)(2), establishments are required to calibrate processmonitoring instruments as part of ongoing verification activities and are required to 12","support their verification procedures and the frequencies of those procedures. Further, establishments must have records on file documenting the calibration of processmonitoring instruments, 9 CFR 417.5(a)(3). The smokehouses, drying rooms, and other compartments used in the treatment of pork must be appropriately equipped with accurate automatic recording thermometers to ensure that temperatures that effectively eliminate Trichinella are maintained. Automatic recording thermometers and the thermometers used must be calibrated periodically (frequency determined as per HACCP plan) to ensure that they are functioning accurately.

Pressure HPP is an antimicrobial treatment that exposes the product to elevated pressures, with or without the addition of heat, to inactivate Trichinella. Pork processed with HPP is placed in a sealed flexible container. The flexible container is placed in a basket or barrel and moved to a high-pressure chamber filled with a pressure-transmitting fluid, usually water, which does not contact product. The chamber is equipped with pumping and decompression systems. The action of the high pressure causes inactivation of Trichinella larvae. Establishments must follow the specific parameters in \u201cHIGH PRESSURE PROCESSING\u201d for eliminating Trichinella in pork.

Irradiation The type of radiation used in irradiating food is ionizing radiation, which includes high energy gamma rays, X-rays and accelerated electrons. For Trichinella, the process involves exposing the food product to carefully controlled amounts of ionizing radiation for a specific time to destroy the parasite. Ionizing radiation does not increase the normal radioactivity level of the food, regardless of how long the food is exposed to the radiation, or how much of an energy dose is absorbed. The types of ionizing radiation include gamma rays (from radioactive isotopes cobalt-60 or cesium-137), beta rays generated by electron beam or \u201cE-beam,\u201d and X-rays (ICGFI, 1999; Smith et al., 2004). The amount of ionizing radiation that is absorbed by the food product is called the radiation absorbed dose. Ionizing radiation is measured in units of rads (1 rad=100 erg\g) or grays (1 Gy=100 rads), with 1,000 grays equal to 1 kiloGray (kGy) (ICGFI, 1999; Smith et al., 2004). The doses used to eliminate parasitic hazards in pork are listed in \u201cIRRADIATION.\u201d

Heat is an effective

method that is used to destroy *Trichinella* in pork products. If the steps described below are followed, FSIS considers the resulting product safe from *Trichinella*. The heating method is unnecessary if an establishment is producing RTE 13", "products containing pork in compliance with the higher lethality performance standards for *Salmonella*. However, FSIS cannot state with absolute certainty that the lethality performance standards designed to reduce *Salmonella* for dried, salt-cured, or fermented products will eliminate *Trichinella*. Therefore, establishments will have to ensure the lethality process used for these types of products effectively eliminates *Trichinella*. Table 1 - Time and Temperature Combinations to Eliminate *Trichinella*

Minimum internal temperature	Minimum time	Degrees F	Degrees C	120	49.0	21			
hours	122	50.0	9.5 hours	124	51.1	4.5 hours			
minutes	132	55.6	15 minutes	134	56.7	6 minutes			
hours	126	52.2	2.0 hours	128	53.4	1.0 hour			
minutes	136	57.8	3 minutes	138	58.9	2 minutes			
hours	140	60.0	1 minute	142	61.1	1 minute			
minutes	144	62.2	Instant	1.	All parts of the pork muscle tissue should be heated according to one of the timetemperature combinations in the above table to eliminate <i>Trichinella</i> .				
3.	Time and temperature must be monitored using a calibrated device that meets the requirements provided in \u201cGeneral Instructions for Recording Thermometers\u201d at the end of this section.								
4.	Time, in combination with temperatures of 138\u00b0F to 143\u00b0F, need not be monitored if the product's minimum thickness exceeds 2 inches (5.1 cm), and refrigeration of the product does not begin within 5 minutes of attaining 138\u00b0F.								
4.	The establishment should use procedures that ensure the uniform heating of the product. It is important that each piece of sausage, each ham, and other product treated by heating in water be kept entirely submerged throughout the heating period. The establishment must ensure the largest pieces in a lot, the innermost links of bunched sausage or other massed articles and pieces placed in the coolest part of a heating cabinet or compartment or vat, be included in the temperature tests.								
4.	14", "FREEZING <i>Trichinella</i> is susceptible to prolonged periods of cold temperatures. If one of the following procedures is followed, FSIS considers the resulting product safe from <i>Trichinella</i> . At any stage of preparation and after preparatory chilling to a temperature of no more than 40\u00b0F or preparatory freezing, all parts of the muscle tissue of pork or product containing such tissue should be subjected continuously to a temperature no more than one of those specified in Table 2. The duration of such freezing at the specified temperature is dependent on the thickness of the meat or inside dimensions of the container.								
Table 2 - Required Period of Freezing at Temperature Indicated	Temperature	\u00b0F	Group 1 Products	Group 2 Products (Days)	(Days)				
5	20	30	-10	10	20	-20	6	12	1.
Group 1 comprises product in separate pieces not exceeding 6 inches in thickness, or arranged on separate racks with the layers not exceeding 6 inches in depth, or stored in crates or boxes not exceeding 6 inches in depth, or stored as solidly frozen blocks not exceeding 6 inches in thickness.	2.	Group 2 comprises product in pieces or layers, the thickness of which exceeds 6 inches but not 27 inches. When the product is placed in containers, including tierces, barrels, kegs, and cartons, the containers do not exceed 27 inches in depth. Thus, the product will receive the effects of the refrigeration\freezing throughout its entire mass in the timeframes specified.	3.	The product, including in containers, undergoing such refrigeration must be spaced in such a way in the freezer as to ensure a free circulation of air between the pieces of meat, layers, blocks, boxes, barrels, and tierces so that the desired temperature of the meat will be promptly and uniformly reduced to no higher than 5\u00b0F, -10\u00b0F, or 20\u00b0F, as respectively per product group.	4.	As an alternative to the			

methods prescribed in Table 2, the treatment may consist of commercial freeze-drying or controlled freezing, at the center of the meat pieces, in accordance with the times and temperatures specified in Table 2A. 15", "Note: To control for *Trichinella* in whole pork carcasses, the product needs to be frozen solid. Table 2A - Alternate Periods of Freezing at Temperatures Indicated Maximum internal temperature Minimum Time Degrees F Degrees C 0 -17.8 106 hours -5 -20.6 82 hours -10 -23.3 63 hours -15 -26.1 48 hours -20 -28.9 35 hours -25 -31.7 22 hours -30 -34.5 8 hours -35 -37.2 1½ hour 5. During the period of freezing, the product should be stored in the rooms or compartments where the lots can be controlled and not comingled so that the product does not leave the rooms or compartments until it is fully treated. The rooms or compartments containing product undergoing freezing need to be equipped with accurate thermometers placed at or above the highest level at which the product undergoing treatment is stored and away from refrigerating coils. 6. Pork product that has been frozen needs to be controlled in such a way as to ensure that the treated product is designated and not comingled with untreated product. CURING Curing is another method recognized for the control of *Trichinella*. The curing methods described below are effective for destroying *Trichinella* in sausage, capocollo, coppa, hams, pork shoulder picnics, boneless pork loins, and loin ends. If any of these methods are followed for the appropriate products, then FSIS would consider the products safe from *Trichinella*. 16", "There is a great variety of processes used to prepare cured pork products (sausages, hams, pork shoulders, and other RTE products). All processes currently approved for commercial use have been tested to determine their efficiency in killing *Trichinella*. In the curing process, product is coated or injected with a salt mixture and allowed to equalize at refrigerated temperatures. Following equalization, product is dried, or smoked and dried, at various temperature\time combinations. The curing process involves the interaction of salt, temperature, and drying times to reach a desired water activity, percent moisture, or brine concentration. Unfortunately, no single or even combination of parameters achieved by curing has been shown to correlate definitively with *Trichinella* inactivation (Gamble et al, 2012). All cured products should be processed by validated methods, such as those described in this section, \u201cCURING.\u201d 1.Sausage The sausage may be stuffed in animal casings, hydrocellulose casings, or cloth bags. During any stage of treating the sausage to destroy live *Trichinella*, except as provided in Sausage Treatment Method 5, these coverings should not be coated with paraffin or like substance, nor should any sausage be washed during any prescribed period of drying. In the preparation of sausage, one of the following methods may be used: Sausage Treatment Method No. 1 -Drying The meat should be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry curing mixture containing not less than 3 1½ pounds of salt to each hundredweight of the unstuffed sausage should be thoroughly mixed with the ground or chopped meat. After being stuffed, sausage having a diameter not exceeding 3 1½ inches, measured at the time of stuffing, should be held in a drying room not less than 20 days at a temperature not lower than 45\u00b0F, except in the case of the variety of sausage known as pepperoni. If in casings not exceeding 1 3/8 inches in diameter measured at the time of stuffing, the period of drying may be reduced to 15 days. In no case, however, should the sausage be released from the drying room in less than 25 days from the time the curing materials are added, except that sausage of the variety known as \u201cpepperoni,\u201d if in casings not exceeding the size specified, may be released at the expiration of 20 days from the

time the curing materials are added. Sausage in casings exceeding 3 1/2 inches, but not exceeding 4 inches, in diameter at the time of stuffing should be held in a drying room not less than 35 days at a temperature not lower than 45 °F, and in no case, should the sausage be released from the drying room in less than 40 days from the time the curing materials are added to the meat. Sausage Treatment Method No. 2 Smoked, then Dried The meat should be ground or chopped into pieces not exceeding three fourths of an inch in diameter. A dry curing mixture containing not less than 3 1/3 pounds of salt to each hundredweight of the unstuffed sausage should be thoroughly mixed with the 17", "ground or chopped meat. After being stuffed, sausage having a diameter not exceeding 3 1/2 inches, measured at the time of stuffing, should be smoked not less than 40 hours at a temperature not lower than 80°F, and finally held in a drying room not less than 10 days at a temperature not lower than 45°F. In no case, however, should the sausage be released from the drying room in less than 18 days from the time the curing materials are added to the meat. Sausage exceeding 3 1/2 inches, but not exceeding 4 inches, in diameter at the time of stuffing, should be held in a drying room, following smoking as indicated above, not less than 25 days at a temperature not lower than 45°F, but in no case, should the sausage be released from the drying room in less than 33 days from the time the curing materials are added to the meat. Sausage Treatment Method No. 3 Held in Pickle Curing Medium, then Dried The meat should be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry-curing mixture containing not less than 3 1/3 pounds of salt to each hundredweight of the unstuffed sausage should be thoroughly mixed with the ground or chopped meat. After adding the salt and other curing materials and before stuffing, the ground or chopped meat should be held at a temperature not lower than 34 °F for not less than 36 hours. After being stuffed, the sausage should be held at a temperature not lower than 34°F for an additional period of time sufficient to make a total of not less than 144 hours from the time the curing materials are added to the meat, or the sausage should be held for the time specified in a pickle curing medium of not less than 50° strength (salometer reading) at a temperature not lower than 44°F. Finally, sausage having a diameter not exceeding 3 1/2 inches, measured at the time of stuffing, should be smoked for not less than 12 hours. The temperature of the smokehouse during this period at no time should be lower than 90°F; and for 4 consecutive hours of this period the smokehouse should be maintained at a temperature not lower than 128°F. Sausage exceeding 3 1/2 inches, but not exceeding 4 inches, in diameter at the time of stuffing should be smoked, following the prescribed curing, for not less than 15 hours. The temperature of the smokehouse during the 15-hour period should at no time be lower than 90°F, and for 7 consecutive hours of this period the smokehouse should be maintained at a temperature not lower than 128°F. In regulating the temperature of the smokehouse for the treatment of sausage under this method, the temperature of 128°F should be attained gradually during a period of not less than 4 hours. Sausage Treatment Method No. 4 Dried (After Stuffing - May be Heated or Smoked, or Both Heated and Smoked) The meat should be ground or chopped into pieces not exceeding one-fourth of an inch in diameter. A dry curing mixture containing not less than 2 1/2 pounds of salt to each hundredweight of the unstuffed sausage should be thoroughly mixed with the ground or chopped meat. After adding the salt and other curing materials and before stuffing, the ground or chopped sausage should be held as a compact mass, not more

than 6 inches in depth, at a temperature no lower than 36°F for not less than 10 days. At the termination of the holding period, the sausage should be stuffed in casings or cloth bags not exceeding 3 1/3 inches in diameter, measured at the time of stuffing. After being stuffed, the sausage should be held in a drying room at a temperature not lower than 45 °F for the remainder of a 35-day period, measured from the time the curing materials are added to the meat. At any time after stuffing, if the establishment's operator deems it desirable, the product may be heated in a water bath for a period not to exceed 3 hours at a temperature no lower than 85°F, or subjected to smoking at a temperature no lower than 80°F, or the product may be both heated and smoked as specified. The time consumed in heating and smoking, however, should be in addition to the 35-day holding period specified. Sausage

Treatment Method No. 5 May be Coated with Paraffin while Held The meat should be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry curing mixture containing not less than 3 1/3 pounds of salt to each hundredweight of the unstuffed sausage should be thoroughly mixed with the ground or chopped meat. After being stuffed, the sausage should be held for not less than 65 days at a temperature not lower than 45°F. The coverings for sausage prepared according to this method may be coated at any stage of the preparation before or during the holding period with paraffin or other substance approved by the Administrator. Sausage Treatment Method No. 6 Held for Two Time Periods (Holding Period and a Drying Period) (A) Basic Requirements. The meat should be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry-curing mixture containing not less than 3.33 pounds of salt to each hundred-weight of the unstuffed sausage, excluding the weight of dry ingredients, should be thoroughly mixed with the ground or chopped meat. After the curing mixture has been added, the sausage should be held for two-time periods, a holding period and a drying period. The holding period will be for a minimum of 48 hours at a room temperature not lower than 35°F. This holding period requirement may be fulfilled totally or in part before the drying period and then the remainder, if any, after the drying period or as an extension of the drying period. During the drying period, the sausage should be held in a drying room at a temperature not lower than 50°F (10.0°C) for a period determined by Tables 3, 3A, and 3B. The length of the drying period, established in Sausage Treatment Method No.6 (A) may be modified as provided in Sausage Treatment Method No.6 (B) or (C). Table 3 -Sausage Drying Room Times by Sausage Treatment Method No. 6 Diameter of casing at time of stuffing1 Days in drying room2 Up to: 1 inches 14 1 1/2 inches 15 2 inches 16 2 1/2 inches 18 3 inches 20 3 1/2 inches 23 4 inches 25 19", "4 1/2 inches 30 5 inches 35 5 1/2 inches 43 6 inches 50 1 The drying room times for flattened or oval sausages should use a diameter derived by measuring the circumference and dividing by 3.14 (pi). 2 Drying room time may be modified as set forth in Tables 3B and 4. (B) Reduction in Drying Room Time. During the holding period, the sausage may be smoked or fermented. If the temperature is increased to 70°F (21.1°C) or higher, while the sausage is being held after adding curing materials but before the drying period, the subsequent drying room times prescribed for this method may be reduced according to the schedule in Table 3B. No interpolation of values is permissible. Table 3A -Percentage Reduction in Drying Room Time (Table 3) Permitted by Holding Times and Temperatures Prior to Drying1 Minimum Temperature2 Minimum Time (hours) 24 48 72 96 120 70°F (21.1°C) 4 9 14 19 24 75°F (23.9°C) 5 12 19 26 33 80°F (26.7°C) 8 18 28 38 48 85°F

(29.5\u00b0C) 10 25 39 53 67 90\u00b0F (32.2\u00b0C) 15 35 55 75 95 95\u00b0F  
(35.0\u00b0C) 23 49 74 98 1003 100\u00b0F (37.9\u00b0C) 37 88 1003 100 100 105\u00b0F  
(40.6\u00b0C) 57 1003 100 100 100 110\u00b0F (43.3\u00b0C) 90 1003 100 100 100  
120\u00b0F (48.9\u00b0C) 1003 100 100 100 100 1 In computing the days to be deducted, the number with any fraction should be rounded to the next lower whole number and should be deducted from the required total drying time. Example: Sausage stuffed in 3inch diameter casing requires 20 days in the drying room (from Drying Room Times, Table 3). If allowed to ferment, after addition of curing materials, at 80\u00b0F for 48 hours, the 20 day drying time may be reduced 18% (from Table 3A). Eighteen percent of 20 days equals 3.6 days. Twenty days minus 3 days equals 17 days. The total drying time required in the drying room, therefore, will be 17 days. 2 Either room temperature or internal product temperature should be used for sausages that will be subsequently dried to a moisture-protein ratio of 2.3: 1 or less. Internal product temperature should be used for all other sausages. 3 Trichinella will be destroyed during fermentation or smoking at the temperature and length of time indicated. Therefore, no drying room period is required for products so treated. (C)Reduced Salt Content-Drying Room Times. 20", "Salt content of less than 3.33 pounds for each hundredweight of sausage formulation, excluding dry ingredients, (such as salts, sugars, and spices), may be permitted provided the drying time is increased according to the schedule contained in Table 3B. Table 3B - Reduced Salt Content-Drying Room Times [Required percentage increase in drying room time (Table 3) for added salt of less than 3.33 pounds per hundredweight of sausage] Minimum pounds of salt added to sausage1 Percent increase in drying room time2 3.3 1 3.2 4 3.1 7 3.0 10 2.9 13 2.8 16 2.7 19 2.6 22 2.5 25 2.4 28 2.3 31 2.2 34 2.1 37 2.0 40 1Calculate the salt content for column 1 as follows: Multiply the pounds of salt in the sausage formulation by 100. Then divide this number by the total weight of sausage formulation minus the weight of dry ingredients and round down to the next lowest 0.1%. The percent salt may be substituted for pounds of salt. Example: 120 lbs. pork, 3.56 lbs. salt, 2 lbs. spices, 0.5 lbs. wine, 1 lb. water and starter culture, 0.8 lbs. sugar, .012 lbs. sodium nitrite total weight is 127.872 lbs. (3.56 x 100)\/(127.872 -3.56 \u2013 2 -.8 -.012) = 356\121.5 = 2.93 pounds of salt added to sausage Therefore, the sausage drying time must be increased by 13 percent. 2 In computing the days to be added to the required total drying time, fractions should be rounded to the next higher whole number and added to the required total drying time. Example: Sausage stuffed in 3 1\u20442 inch diameter casing requires 23 days in the drying room (from Drying Room Times, Table 3). If the quantity of salt added per hundredweight of sausage is 2 pounds instead of 3.33 pounds, the drying room time must be increased by 40 percent (from Reduced Salt Content-Drying Room Times, Table 3B), or 9.2 days. The 9.2 is rounded up to 10 days and is added to the 23 days to equal 33 days. The total drying time required in the drying room for the scenario presented, therefore, will be 33 days. Sausage Treatment Method No. 7 \u2013 Holding, Heating, and Drying Treatment Dry Sausages. (A)General Requirements. The establishment should use meat particles reduced in size to no more than 1\u20444 inch in diameter. The establishment should add a curing mixture containing no less than 2.7 pounds of salt per hundred pounds of meat and mix it 21", "uniformly throughout the product. The establishment should hold, heat, and dry the product according to paragraph (B) or (C) below. (B)Holding, Heating, and Drying Treatment, Large Sausages. Except as permitted in (C)below, the establishment should subject sausages in casings not exceeding 105 mm in diameter, at the

time of stuffing, to all of the following minimum chamber temperatures and time periods. Table 3C -Treatment Schedule for Sausages 105 Millimeters (4 1\8 inches) or Less in Diameter

Minimum chamber temperature	Minimum time (hours)	(\u00b0F)	(\u00b0C)	50	10	12	90	32.2	1
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100	37.8	1	110	43.3	1	120	48.9	1	125	51.7	7
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Following the preceding treatment, the establishment should dry the sausages at a temperature not lower than 50\u00b0F

(10\u00b0C) for not less than 7 days. (C)Heating and Drying Treatment, Small Sausages.

Alternatively, the establishment may subject sausages in casings not exceeding 55 mm in diameter, at the time of stuffing, to all of the following minimum chamber temperatures and time periods. Table 3D -Treatment Schedule for Sausages 55 Millimeters (2 1\8 inches) or Less in Diameter

Minimum chamber temperature	Minimum time (hours)	(\u00b0F)	(\u00b0C)	50	10	12	100	37.8	1	125	51.7	6
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100	37.8	1	125	51.7	6
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Following the preceding heat treatment, the establishment should dry the sausages at a temperature not lower than 50\u00b0F (10\u00b0C) for not less than 4 days.

2.Capicollo (Capicola, Capacola) Boneless pork butts for capocollo should be cured in a dry curing mixture containing no less than 4 1\2 pounds of salt per hundredweight of meat for a period of no less than 25 22", "days at a temperature no lower than 36\u00b0F. If the curing materials are applied to the butts by the process known as churning, a small quantity of pickle may be added. During the curing period the butts may be overhauled (turned over for the application of additional cure) according to any of the usual processes of overhauling, including the addition of pickle or dry salt if desired. The butts should not be subjected during or after curing to any treatment designed to remove salt from the meat, except that superficial washing may be allowed. After being stuffed, the product should be smoked for a period of not less than 30 hours at a temperature not lower than 80\u00b0F, and should finally be held in a drying room for not less than 20 days at a temperature not lower than 45\u00b0F.

3. Coppa Boneless pork butts for coppa should be cured in a dry curing mixture containing no less than 4 1\2 pounds of salt per hundredweight of meat for a period of no less than 18 days at a temperature no lower than 36\u00b0F. If the curing mixture is applied to the butts by the process known as churning, a small quantity of pickle may be added. During the curing period the butts may be overhauled according to any of the usual processes of overhauling, including the addition of pickle or dry salt if desired. The butts should not be subjected during or after curing to any treatment designed to remove salt from the meat, except that superficial washing may be allowed.

After being stuffed, the product should be held in a drying room for not less than 35 days at a temperature not lower than 45\u00b0F.

4. Hams and Pork Shoulder Picnics In the curing of hams and pork shoulder picnics, one of the methods below should be used.

For calculating days per pound, the establishment should use the weight of the heaviest ham or picnic in the lot. Ham and Pork Shoulder Picnics Method No. 1 \u2013 Dry Salt Curing Process

The hams and pork shoulder picnics should be cured by a dry salt curing process for not less than 40 days at a temperature no lower than 36\u00b0F. The products should be laid down in salt, not less than 4 pounds to each hundredweight of product, the salt being applied in a thorough manner to the lean meat of each item. When placed in cure, the products may be pumped with pickle if desired. At least once during the curing process, the products should be overhauled and additional salt applied, if necessary, so that the lean meat of each item is thoroughly covered. After removal from cure, the products may be soaked in water at a temperature no higher than 70\u00b0F for not more than 15 hours, during which time the water may be changed once, but the products should not be subjected to any other treatment

designed to remove salt from the meat except that superficial washing may be allowed. The products should finally be dried or smoked at a time and temperature not less than a combination prescribed in Table 3F, titled Ham and Pork Shoulder Picnics Method No. 2. Ham and Pork Shoulder Picnics Method No. 2 \u2013 Controlled Temperature Methods for, Curing (other than Bag Curing) and Bag Curing followed by Drying (A)Curing (other than Bag Curing) 23", "Establishments should cure hams and shoulders by using a cure mixture containing not less than 70 percent salt by weight to cover all exposed muscle tissue and to pack the hock region. Total curing time consists of a mandatory cure contact time and an optional equalization time. (B)Cure Contact Time Establishments should keep exposed muscle tissue coated with the cure mixture at least 28 days but for no less than 1.5 days per pound of ham or shoulder. This is referred to as the cure contact time. Overhaul is optional during the cure contact time if the exposed muscle tissue remains coated with the curing mixture.

(C)Equalization The establishment may provide an equalization period after the minimum cure contact time in (B) above to permit the absorbed salt to permeate the product's inner tissues. Equalization is the period after the excess cure has been removed from the product at the end of the cure contact period up until the product is placed in the drying room and the drying period begins. The total curing time (cure contact plus equalization should be at least 40 days and in no case less than 2 days per pound of an uncured ham or shoulder. (D)Removing Excess Cure After the required cure contact period, the establishment may remove excess cure mixture from the product's surface mechanically or by rinsing up to 1 minute with water, but not by soaking. (E)Bag Curing. Bag curing is a traditional ham curing technique in which the manufacturer wraps the ham and all the cure mixture together in Kraft paper then hangs each ham individually. The paper keeps the extra cure mixture in close contact with the product making reapplication of salt unnecessary, and it protects the product from mites and insects. Establishments may employ the bag curing method as an alternative to (A) through (D) above. An establishment which elects to use the bag curing method should apply a cure mixture containing at least 6 pounds of salt per 100 pounds of uncured product. The establishment should rub the curing mixture into the exposed muscle tissue, pack the hock region with the curing mixture, and use uncoated wrapping paper to wrap the product together with any remaining curing mixture. The bag-cured product should remain wrapped throughout the curing period and may or may not remain wrapped during the drying period. In any case, the curing period should be at least 40 days but not less than 2 days per pound of an uncured ham or shoulder. After curing, the cured product should be exposed to a drying time and temperature prescribed in Table 3F. (F)Curing Temperature During the curing period the establishment should use one of the following procedures: (1) The establishment should control the room temperature at not less than 35\u00b0F (1.7\u00b0C) nor greater than 45\u00b0F (7.2\u00b0C) for the first 1.5 days per pound of an uncured ham or shoulder, and not less than 35\u00b0F (1.7\u00b0C) nor greater than 60\u00b0F (15.6\u00b0C) for the remainder of the curing period. (2) The establishment should monitor 24", "and record daily product temperature. The room temperature need not be controlled but days on which the product temperature drops below 35\u00b0F (1.7\u00b0C) should not be counted as curing time. If the product temperature exceeds 45\u00b0F (7.2\u00b0C) within the first period of 1.5 days (per pound of an uncured ham or shoulder) or if the product temperature exceeds 60\u00b0F (15.6\u00b0C), during the remainder of the curing period the establishment should

cool the product back to the appropriate temperature for the curing period as described above.

(3) The establishment should begin curing product only between the dates of December 1 and February 13. The room temperature need not be controlled, but the establishment should monitor and record daily room temperatures, and days in which the room temperature drops below 35°F (1.7°C) should not be counted as curing time. (G)Drying After the curing period, establishments should use one of the following three procedures for drying. (1) The establishment should subject the product to a controlled room temperature for a minimum time and minimum temperature combination prescribed in Table 3F or for a set of such combinations in which the total of the fractional periods (in column 4 of Table 3F) exceeds 1.5. (2) Establishments using uncontrolled room temperatures should monitor and record the internal product temperature. The drying period should be complete when, from the days which can be counted as curing time, one of the time\temperature combinations of Table 3F is satisfied or when the total of the fractional values for the combinations exceeds 1.5. (3) Establishments using uncontrolled room temperatures should dry the product for a minimum of 160 days including the entire months of June, July, and August. This procedure is obviously dependent on local climatic conditions and no problem exists with respect to current producers who use this procedure. Future applicants should demonstrate that their local monthly average temperatures and the local monthly minimum temperatures are equal to or warmer than the normal average temperatures and normal minimum temperatures compiled by the National Oceanic and Atmospheric Administration for Boone, North Carolina, station 31-0977, 1981 through 2010. Table 3E -Monthly Temperature (\u00b0 F) for Boone NC, 1981-2010 Jan. Feb. Mar. Apr. May June July Aug. Sep. Normal average temperatures 31.5 34.0 40.5 49.0 57.5 65.0 68.5 67.5 61.0 Normal minimum temperatures 21.0 23.0 29.0 37.0 46.0 54.0 58.0 57.0 50.0 1 https://www.currentresults.com/Weather/North-Carolina/Places/boone-temperatures-bymonth-average.php 25","Drying Times and Temperatures for Trichinella Inactivation in Hams and Shoulders Table 3F - Minimum Drying Days at a Minimum Temperature\* Minimum drying temperature Minimum days at drying temperature Fractional period for one day of drying Degrees F 130 Degrees C 54.4 1.5 .67 125 51.7 2 .50 120 48.9 3 .33 115 46.1 4 .25 110 43.3 5 .20 105 40.6 6 .17 100 37.8 7 .14 95 35.0 9 .11 90 32.2 11 .091 85 29.4 18 .056 80 26.7 25 .040 75 23.9 35 .029 \*Interpolation of these times or temperatures is not acceptable; establishments wishing to use temperatures or times not in this Table should first validate their efficacy. Ham and Pork Shoulder Picnics Method No. 3 -Controlled Temperature Methods for Drying Curing (A)Cure Establishments should cure hams and shoulders by using a cure mixture containing not less than 71.5 percent salt by weight to cover all exposed muscle tissue and to pack the hock region. Establishments may substitute potassium chloride (KCl) for up to half of the required salt on an equal weight basis. (B)Curing Establishments should apply the cure at a rate of not less than 5.72 pounds of salt and KCl per hundred pounds of fresh meat. The cure should be applied in either three or four approximately equal amounts (two or three overhauls) at separate times during the first 14 days of curing. (C)Cure Contact Time Establishments should keep the product in contact with the cure mixture for no less than 2 days per pound of an uncured ham or shoulder but for at least 30 days. Establishments should maintain the curing temperature at no less than 35°F (1.7°C) during the cure contact time. 26","(D)Equalization After the cure contact period, establishments should provide an added equalization period of no less than 1 day per pound of an uncured ham or shoulder but at least

14 days. Equalization is the time after the excess cure has been removed from the product, the end of the cure contact period, and before the drying period begins. Establishments may substitute additional cure contact days for an equal number of equalization days. (E) Removing Excess Cure After the required cure contact period, the establishment may remove excess cure mixture from the product's surface mechanically or by rinsing up to 1 minute with water, but not by soaking. (F) Drying After the curing period, establishments should use one of the controlled temperature methods for drying listed in Ham and Pork Shoulder Picnics Method No. 2 of this subparagraph. Ham and Pork Shoulder Picnics Method No. 4 \u2013 Dry Curing at a Minimum Temperature of 55\u00b0F (13\u00b0C) for at Least 150 Days (A) Curing The establishment should cure the ham to a minimum brine concentration of 6 percent by the end of the drying period. Brine concentration is calculated as 100 times the salt concentration divided by the sum of the salt and water concentrations. Percent brine =  $100 \times [\text{salt}] / ([\text{salt}] + [\text{water}])$  The Agency will accept the brine concentration in the biceps femoris as a reasonable estimate of the minimum brine concentration in the ham. (B) Drying and Total Process Times The establishment should dry the cured ham at a minimum temperature of 55\u00b0F (13\u00b0C) for at least 150 days. The total time of drying plus curing should be at least 206 days. (C) Ensuring an Acceptable Internal Brine Concentration (1) To establish process compliance, the establishment should take product samples from the first 12 lots of production as follows: From each lot, (i) One sample should be taken from each of 5 or more hams; (ii) Each sample should be taken from the biceps femoris. As an alternative to the use of the biceps femoris, the Agency will consider other methods of sampling dry cured hams to determine the minimum internal brine concentration, as long as the establishment submits data and other information to establish the alternative method\u2019s sufficiency to the processing authority; (iii) Each sample should weigh no less than 100 grams; (iv) The samples should be combined as one composite sample and sealed in a water vapor proof container; (v) The composite sample should be submitted to an accredited laboratory to be analyzed for salt and water content using validated methods. If the time between sampling and submittal of the composite sample to the accredited laboratory will exceed 8 hours, then the establishment should "freeze" the composite sample immediately after the samples are combined; (vi) Once the laboratory results for the composite sample are received, the manufacturer should calculate the internal brine concentration by multiplying the salt concentration by 100 and then dividing that figure by the sum of the salt and water concentrations; (vii) Compliance is established when the samples from the first 12 lots of production have a minimum internal brine concentration of 6 percent. Lots being tested to establish compliance should be held until the internal brine concentration has been determined and found to be at least 6 percent. If the minimum internal brine concentration is less than 6 percent, the lot being tested should be held until the establishment brings the lot into compliance by further processing. (2) To maintain compliance through on-going verification, the establishment should take samples, have the samples analyzed, and perform the brine calculations as set forth above at a minimum for one lot every 13 weeks. Lots being tested to maintain compliance as part of on-going verification do not need to be held. If the minimum internal brine concentration is less than 6 percent in a lot being tested as part of on-going verification, the establishment must take corrective action and develop and propose steps acceptable to FSIS to ensure that the process is corrected. (3) Accredited laboratory results and the brine calculations should be placed on file at the establishment and available for

review by FSIS inspection as HACCP verification records. Ham and Pork Shoulder Picnics Method No. 5 -Dry Curing at a Minimum Temperature of 110°F (43°C) for at Least 4 Days

(A)Curing The establishment should cure the ham to a minimum brine concentration of 6 percent by the end of the drying period. Brine concentration is calculated as 100 times the salt concentration divided by the sum of the salt and water concentrations. Percent brine =  $100 \times [\text{salt}] / ([\text{salt}] + [\text{water}])$  The Agency will accept the brine concentration in the biceps femoris as a reasonable estimate of the minimum brine concentration.

(B)Drying and Total Process Times The establishment should dry the cured ham at a minimum temperature of 110°F (43°C) for at least 4 days. The total time of drying plus curing should be at least 34 days.

(C)Ensuring an Acceptable Internal Brine Concentration

(1)To establish process compliance, the establishment should take product samples from the first 12 lots of production as follows: From each lot, (i) One sample should be taken from each of 5 or more hams; (ii) Each sample should be taken from the biceps femoris. As an alternative to the use of the biceps femoris, the Agency will consider other methods of sampling the dry cured hams to determine internal brine concentration, if the establishment validates the alternative sampling method. (iii) Each sample should weigh no less than 100 grams; (iv) The samples should be combined as one composite sample and sealed in a water vapor proof container; (v) The composite sample should be submitted to an accredited laboratory to be analyzed for salt and water content using validated methods. If the time between 28", "sampling and submittal of the composite sample to the accredited laboratory will exceed 8 hours, then the establishment should freeze the composite sample immediately after the samples are combined; (vi) Compliance is established when the samples from the first 12 lots of production have a minimum internal brine concentration of 6 percent. Lots being tested to establish compliance should be held until the internal brine concentration has been determined and found to be at least 6 percent. If the minimum internal brine concentration is less than 6 percent, the lot being tested should be held until the establishment brings the lot into compliance by further processing.

(2) To maintain compliance through on-going verification, the establishment should take samples, have the samples analyzed, and perform the brine calculations as set forth above at a minimum from one lot every 13 weeks. Lots being tested to maintain compliance as part of on-going verification do not need to be held. If the minimum internal brine concentration is less than 6 percent in a lot tested to maintain compliance, the establishment must take corrective action and develop and propose steps acceptable to FSIS to ensure that the process is corrected.

(3) Accredited laboratory results and the brine calculations should be placed on file in the establishment and available to FSIS inspection for review.

5.Boneless Pork Loins and Loin Ends In place of heating or freezing to destroy live Trichinella in boneless loins, the loins may be cured for a period of not less than 25 days at a temperature not lower than 36°F using one of the following methods:

Boneless Loins Method No. 1 -Application of Dry Salt Curing Mixture Application of a dry salt curing mixture containing no less than 5 pounds of salt to each hundredweight of meats.

Boneless Loins Method No. 2 -Application of Pickle Solution Application of a pickle solution of not less than 80° strength (salometer); pickle solution should be applied to achieve not less than 60 pounds of pickle to each hundredweight of meat.

Boneless Loins Method No. 3 -Application of Pickle Solution added to the Dry Salt Cure Application of a pickle solution added to the dry salt cure prescribed as Boneless Loins Method No. 1 in this section provided the pickle solution is not less than 80° strength (salometer). After removal from

the cure, the loins may be soaked in water for not more than 1 hour at a temperature not higher than 70°F or washed under a spray but should not be subjected, during or after the curing process, to any other treatment designed to remove salt. Following curing, the loins should be smoked for not less than 12 hours. The minimum temperature of the smokehouse during this period at no time should be lower than 100°F, and for 4 consecutive hours of this period the smokehouse should be maintained at a temperature not lower than 125°F. Finally, the product should be held in a drying room for a period of no less than 12 days at a temperature no lower than 45°F.

6. Country Ham, Country Style Ham, Dry Cured Ham, Country Pork Shoulder, Country Style Pork Shoulder, "Country Ham, Country Style Ham, or Dry Cured Ham, and Country Pork Shoulder, Country Style Pork Shoulder, or Dry Cured Pork Shoulder are the uncooked, cured, dried, smoked or unsmoked meat food products made respectively from a single piece of meat conforming to the definition of "Country Ham"\u201d, or from a single piece of meat from a pork shoulder. These products must be treated for the destruction of live Trichinella using tested and approved methods. These products are prepared by the dry application of salt (NaCl), or by the dry application of salt (NaCl) and one or more of the optional ingredients listed below. These products may not be injected with curing solutions or placed in curing solutions. Listed below are 4 dry application options.

(1) The entire exterior of the ham or pork shoulder should be coated by the dry application of salt or by the dry application of salt combined with other ingredients as permitted in paragraph (d) of this section.

(2) Additional salt, or salt mixed with other permitted ingredients, may be reapplied to the product as necessary to insure complete penetration.

(3) When sodium or potassium nitrate, or sodium or potassium nitrite, or a combination thereof, is used, the application of salt should be in sufficient quantity to ensure that the finished product has an internal salt content of at least 4 percent.

(4) When no sodium nitrate, potassium nitrate, sodium nitrite, potassium nitrite or a combination thereof is used, the application of salt should be in sufficient quantity to ensure that the finished product has a brine concentration of not less than 10 percent or a water activity of not more than 0.92.

The optional ingredients for these products are:

(1) Nutritive sweeteners, spices, seasonings and flavorings; and

(2) Sodium or potassium nitrate and sodium or potassium nitrite.

General Instructions for Recording Thermometers

When necessary to comply with heating, freezing, and curing treatment requirements described in this section, the smokehouses, drying rooms, and other compartments used in the treatment of pork to destroy live Trichinella must be suitably equipped, by the operator of the official establishment, with accurate automatic recording thermometers. Equipment such as automatic recording thermometers or any thermometers used in drying rooms, and other compartments must be checked periodically to make sure they are functioning accurately.

Special Consideration for Certain Processes

That do not rely on High Temperatures to Control Trichinella in Pork

Certain processes, including those used to produce dried, salt-cured, or fermented products, do not rely on high temperatures to control Trichinella. Establishments need to ensure that further controls are in place to control Trichinella when such processes are used to produce these types of pork products. An establishment that processes a dried, 30", "salt-cured, or fermented\acidified product must address Trichinella in their HACCP system, and must also have written documentation to support the decisions made in their hazard analysis. An establishment must validate its process

(i.e., either CCPs or prerequisite programs) used to eliminate *Trichinella* when it is determined to be RLTO in the production process. As previously discussed in \u201cCURING,\u201d the effectiveness of curing to eliminate *Trichinella* larvae is dependent upon a combination of various processing parameters and on the product formulation; specifically, on the temperature and time of fermentation\drying and the salt level, respectively. Unfortunately, no single or even combination of parameters achieved by curing has been shown to correlate definitively with *Trichinella* inactivation (Gamble et al, 2012). All cured products should be processed by validated methods, such as those described in this section, \u201cCURING.\u201d HIGH PRESSURE PROCESSING (HPP) HPP is an antimicrobial treatment for use on meat, poultry, and processed egg products. HPP exposes food to elevated pressures, with or without the addition of heat, to inactivate microorganisms and extend microbiological shelf life. HPP treatment has been shown to be effective in eliminating *Trichinella spiralis*. In one study (Porto-Fett et al., 2010), HPP treatment of either 483 or 600 megapascals (MPa) for 1.0 or 0.5 min, respectively, was effective in inactivating *Trichinella spiralis* larvae in masseter muscle (about 3.4 log larvae\g) collected from infected swine. Therefore, it is recommended that a HPP treatment of a minimum of 483 MPa for 1 minute be used to eliminate *Trichinella* in pork. (Note \u2013 300 MPa = 29,007 psi (pounds per square inch); 483 MPa = 70,053 psi; and 600 MPa = 87,022 psi.) IRRADIATION Treatment of fresh pork with 40 - 50 krad (0.4 \u2013 0.6 kGy) of cesium-137 has been proven to render *Trichinella* completely non-infective. Irradiation with cobalt-60 or high energy x-rays at this same level should also be effective for inactivating these parasites. Option 5: Develop alternative *Trichinella* control procedures not included in Option 4 Establishments may decide to develop alternative procedures to control *Trichinella*. If so, establishments must ensure that their alternative procedures are properly validated. FSIS developed FSIS Compliance Guideline HACCP Systems Validation to provide establishments with assistance in meeting the validation requirements in 9 CFR 417.4 and to ensure that their HACCP systems are properly validated. 31", "Control of Other Parasitic Hazards in Pork Products Producers of RTE or NRTE pork products must also assess in their hazard analysis whether other parasites in addition to *Trichinella* are hazards that are RLTO in their production processes (9 CFR 417.2). If establishments determine that other parasites represent a hazard that is RLTO, then they must include control procedures for these parasites in their HACCP plans. Options 4-5 may be used to control other parasites in addition to *Trichinella* in pork products. Further, establishments are required to have documentation that supports the decisions made in their hazard analysis as a part of their records in accordance with 9 CFR 417.5(a)(1). As with *Trichinella*, establishments must list the CCPs designed to control other parasites [9 CFR 417.2(c)(2)] and the critical limits that must be met at each of the CCPs [9 CFR 417.2(c)(3)]. Establishments may determine in their hazard analysis that other parasites are NRLTO in their pork products if they are prevented by using a prerequisite program. If this is the case, Options 1-3 may be used to prevent other parasites in the establishment\u2019s pork products. In addition to *Trichinella*, *Toxoplasma gondii* (*Toxoplasma*) is a protozoan parasite of public health significance. *Toxoplasma* can cause toxoplasmosis, and infects most species of warm-blooded animals, including humans. Members of the family Felidae (domestic cats and their relatives) are the primary host for *Toxoplasma*. Felids can contaminate the KEY DEFINITIONS Toxoplasmosis is caused by the protozoan parasite *Toxoplasma gondii* (*Toxoplasma*). *Toxoplasma* infects most species of warm blooded animals, including humans, and can cause the disease toxoplasmosis. The only known definitive hosts for

Toxoplasma are members of family Felidae (domestic cats and their relatives). Members of the cat family are infected by eating animals infected with cysts of Toxoplasma parasites. Cats can also become infected by ingesting Toxoplasma eggs (oocysts) from contaminated food or water. Toxoplasma completes its life cycle in the cat, which produces millions of Toxoplasma eggs in its stool. Once outside of the cat, the eggs mature and become infectious for people and other animals. The tissue form of Toxoplasma (a microscopic cyst consisting of bradyzoites, a slower reproducing form contained in tissue cysts) can be transmitted to humans by food.

People become infected by: \u2022 Eating undercooked, contaminated meat (especially pork, lamb, and venison) \u2022 Accidental ingestion of undercooked, contaminated meat after handling it and not washing hands thoroughly (Toxoplasma cannot be absorbed through intact skin; however, Toxoplasma cysts containing bradyzoites can be inadvertently ingested from small bits of meat on the hands, and Toxoplasma tachyzoites have been shown to penetrate intact mucous membranes). \u2022 Eating food that was contaminated by knives, utensils, cutting boards, or other foods that had contact with raw, contaminated meat.

32", "environment by excreting the environmentally resistant stage of this parasite, the oocyst, in their feces (Jones et al., 2012). Domestic food animals, including swine, can be infected by Toxoplasma, and infected animals can harbor Toxoplasma cysts in muscle tissue. Humans can become infected by ingesting tissue cysts from raw or undercooked meat (Hill et al., 2010).

Toxoplasmosis is one of the most common parasitic infections in humans. Toxoplasma is the second leading cause of death due to foodborne illnesses in the United States, accounting for an estimated 327 deaths annually. Toxoplasma is also the fourth leading cause of hospitalizations related to foodborne illnesses, accounting for an estimated 4,428 hospitalizations annually (Scallan et al., 2011). The risk of infection with Toxoplasma is significantly increased in pasture raised swine that are exposed to cat feces in soil, grass, feed, or water (Jones et al., 2012). In the U.S., the prevalence of Toxoplasma in confinement raised swine is approximately 2.7% (Hill et al., 2010). For swine raised in pastures, the prevalence has been reported to be between 50-100% (Gamble et al., 2000). The risk of infection in swine that are raised outdoors is increased because of potential exposure to soil contaminated with Toxoplasma oocysts (Hill et al., 2012; Hill et al., 2010). Compliance with the HACCP regulations for RTE products will ensure the reduction of Toxoplasma. However, there are no certification programs to address the risk of Toxoplasma infection in swine

(<http://porkgateway.org/resource/toxoplasma/>). Prevention of Toxoplasma infection in swine is achieved through GPPs on the farm, including: \u2022 Creating a level of biosecurity that reduces or eliminates exposure of swine to cats and wildlife (e.g., bobcats, raccoons, skunks, and opossums) that may be infected with Toxoplasma. o Eliminating feral cats and securing feed, water, and swine areas from access by cats. The contribution of cats to the spread of Toxoplasma infection in swine cannot be overemphasized. \u2022 Establishing and maintaining an effective rodent control program. \u2022 Preventing cannibalism among swine within an infected herd through the prompt removal of dead swine. \u2022 Changing or thoroughly washing boots before entering barns to avoid tracking in oocysts. \u2022 Preventing deliberate or inadvertent feeding of raw or undercooked meat scraps. There is no available direct testing method that can be performed at slaughter for Toxoplasma. If the establishment identifies Toxoplasma as a hazard RLTO, then the establishment will have to use a validated process that effectively eliminates this parasitic hazard. The methods for heating, freezing, HPP,

and irradiation that are used to eliminate *Trichinella* in pork products are also sufficient to eliminate *Toxoplasma* from pork products. For *Toxoplasma*, HPP treatment of equal to or greater than 300 MPa for 33", "30 seconds is effective in eliminating *Toxoplasma* tissue cysts in ground pork (Lindsay et al., 2006). NOTE: The available information on the effect of various curing processes on *Toxoplasma* is limited and additional studies are needed to determine the effectiveness of curing for the destruction of *T. gondii* in pork and pork products. However, pumping of pork products with salt solutions containing 2% NaCl or \u22651.4% potassium or sodium lactate has been shown to inactivate *T. gondii* tissue cysts in pork (Gamble et al, 2012). 34", "References Burke, R., Masuoka, P., and Murrell, K.D. 2008. Swine Trichinella Infection and Geographic Information System Tools. Emerging Infectious Diseases 14: 1109 \u2013 1111. Gamble, H.R., Bessonov, A.S., Cuperlovic, K., Gajadhar, A.A., Van Knapen, F., Noeckler, K., Schenone, H., and Zhu, X. 2000. International commission on trichinellosis: recommendations on methods for the control of *Trichinella* in domestic and wild animals intended for human consumption. Veterinary Parasitology 93: 393\u2013408. Gamble, H.R., and Hill, D. 2012. PORK Safety \u2013 Preharvest\Postharvest,Trichinella Fact Sheet. National Pork Board. Gamble, H.R., and Hill, D. 2012. PORK Safety \u2013 Preharvest\Postharvest,Toxoplasma Fact Sheet. National Pork Board. Guidelines for the Control of *Trichinella* Spp. in Meat of Suidae (2015).

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additional work to validate them. However, attachment 2 does not include information concerning the cooking method. Q2: To meet requirements for validated cooking instructions on the labels of mechanically tenderized raw beef products, can producers use a grid or table format to display cooking times and temperatures based on product thickness? See the example below. A: Yes. Below is an example of how a chart could be used on labels of mechanically tenderized product to meet these requirements. Cook the following size steaks on a grill for the time indicated until the cooked steak reaches 145 as measured with a meat thermometer. Then allow the product to rest for 3 minutes.

Size (Thickness)	Cooking time
0.5"	1 \u00bd min, flip and cook for 1 \u00bd min
1.0"	1 \u00bd min, flip and cook for 2 min
1.5"	2 min, flip and cook for 2 min
2.0"	2 \u00bd min, flip and cook for 2 \u00bd min
2.5"	2 \u00bd min, flip and cook for 3 min
3.0"	3 min, flip and cook for 3 min
3.5"	3 min, flip and cook for 4 min

Q3: If a Federal establishment mechanically tenderizes a larger beef cut that is sold to hotels, restaurants, and institutions where it is fabricated into smaller cuts and cooked, how should the Federal establishment validate its cooking instructions to comply with 9 CFR 317.2(e)(3)(iii)? A: The cooking instructions included on the label should be practical and easily followed by the customer. If possible, the Federal establishment should have knowledge of the types of cuts fabricated and cooked by the hotels, restaurants, and 2", "institutions it supplies to and provide validated cooking instructions for those cuts. If an establishment does not have knowledge of the types of products its customers cook, then it may choose to include one of the validated cooking instructions provided in Attachment 1 of the FSIS Compliance Guideline for Validating Cooking Instructions for Mechanically Tenderized Beef Products. on pages 17-21. The instructions have been provided for steaks of common thicknesses and therefore, represent cuts that would commonly be cooked by hotels, restaurants, and institutions.

3"]}, {"file\_name": "FSIS\_GD\_2016\_0006", "title": "Areas of Specialization for the Labeling and Program Delivery Staff", "num": "FSIS-GD-2016-0006", "id": "a8c6ff7476242ca266d6768da5b80b1c88a7887be9ef36e4be787c75003775e6", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/LPDS-Specialization.pdf", "type": "pdf", "n\_pages": 3, "word\_count": 474, "text\_by\_page": ["Labeling and Program Delivery Staff (LPDS) Main Office: (301) 504-0878 Areas of Specialization Air Chill Allergens AskFSIS Amenability AMS Programs \u2013 Process Verified, Certified Animal Raising Claims Appeals Baby Food Catfish\Siluriformes Child Nutrition Labeling Country of Origin Labeling Custom Exemptions Disclaimer\Instructional Labeling Duplicate Label Approval Request Egg Products Experimental\Sample Product Exotic Species Export Labeling Flavorings FOIA (Freedom of Information Act) Requests Team Members (Alphabetical Order) Tammie Ballard, Tawana Harrington, Kristin McNeely, Janice \u201cCindy\u201d Watkins Janice Fabina, Tawana Harrington, Janice \u201cCindy\u201d Watkins Lynn Yoder -Knowledge-Base Administrator for LPDS Or visit: http://askfsis.custhelp.com/ Beth McKew, Gail Smith (exports) Tammie Ballard, Tawana Harrington, Kierra Lucas, Kristin McNeely, Janice \u201cCindy\u201d Watkins, Tammie Ballard, Tawana Harrington, Kierra Lucas Kristin McNeely, Janice \u201cCindy\u201d Watkins, Jeff Canavan (Deputy Director), Rosalyn MurphyJenkins (Director) Janice Fabina, Sally Jones Beth McKew Janice Fabina Sally Jones Or visit: www.ams.usda.gov/cool Beth McKew, Lisa Powell Beth McKew, Melinda Mallon Jeanette Mims, Sheila Simmons, Lynn Yoder Tawana Harrington, Kierra Lucas, Kristin McNeely Janice

Fabina, Beth McKew, Gail Smith Tammie Ballard, Beth McKew, Lisa Powell Tawana Harrington, Gail Smith Tawana Harrington Jeanette Mims, Gianfranco Santaliz, Luis Santana, Lynn Yoder", "Food Standards Sally Jones, Melinda Mallon Geographic Claims Sally Jones, Gail Smith High Pressure Processing Tawana Harrington, Janice \u201cCindy\u201d Watkins Ingredients and Additives Tawana Harrington, Janice \u201cCindy\u201d Watkins Kits Janice Fabina, Beth McKew Label Submission and Approval System (LSAS) Lynn Yoder \u2013 Administrator for LSAS Or visit:

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..... 9 2","Preface What is the purpose of this Compliance Guideline? The purpose of this compliance guideline is to help industry determine which statements are permitted on the labeling of their products and the criteria for their use. The Food Safety and Inspection Service (FSIS) ensures that the labeling of meat, poultry and egg products is truthful and not misleading. FSIS considers labeling bearing any reference to Omega fatty acids to be a special statement or claim. The regulations require establishments to submit all labels bearing special statements or claims to the Agency\u2019s Labeling and Program Delivery Staff for evaluation and approval before use. However, once a label with a statement on Omega fatty acids is approved, there are many types of changes to the label that are generically approved and don\u2019t require submission to the Agency for approval prior to use (for example, change in net weight, label color, vignettes, cooking instructions, and the addition of information that is not considered a special statement or claim). The key for making the change generically is that the change cannot affect the special statement or claim (see slide 40 on the following PowerPoint Presentation Generic Label Approval). Who is this guideline designed for? This guidance is for establishments that are designing or modifying meat, poultry or egg product labels with statements related to Omega fatty acids. What changes have been made to the guidance from the last version? FSIS previously issued guidance on omega fatty acids claims on July 11, 2007. FSIS has updated the guideline to include further details and explanations on the different types of claims and a key-points reference chart. How can I comment on this guideline? FSIS is seeking comments on this guideline as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days and the Agency will update the document in response to the comments. Comments may be submitted by either of the following methods: Federal eRulemaking Portal Online submission at regulations.gov: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. 3","Mail, including - CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, 8-163A, Washington, DC 20250-3700. All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title: Food Safety and Inspection Service Statement of Labeling Guideline on Omega Fatty Acid Claims April 2016. Comments received will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>. Although FSIS is requesting comments on the guidance and may update it in response to comments, the guidance reflects FSIS\u2019s current position, and establishments may start using it now. What if I still have questions after I read this guideline? If the desired information cannot be found within the Compliance Guidance, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the askFSIS database or submit questions through askFSIS. Documenting the questions helps FSIS improve and refine present and future versions of the Compliance Guidance and associated issuances. When submitting a question, use the Submit a Question tab, and enter the following information in

the fields provided: Subject Field: Enter FSIS Labeling Guideline on Omega Fatty Acid Claims April 2016 Question Field: Enter question with as much detail as possible Product Field: Select Labeling from the drop-down menu Category Field: Select Labeling Regulations, Policies and Claims from the dropdown menu Policy Arena: Select Domestic (U.S.) only from the drop-down menu When all fields are complete, press Continue. 4","KEY-POINTS REFERENCE CHART Claim Type Permitted Examples Criteria and Requirements for Approval FACTUAL STATEMENTS (fatty acid content from naturally occurring food sources) Yes (requires FSIS approval under 9CFR 412.1) - \u201cX grams of Omega-3 Fatty Acids per serving from canola oil\u201d - \u201cX milligrams of Omega-3 Fatty Acids per serving from flax seed in breading\u201d 1) Omega fatty acid content cannot come from fortification; 2) Include the nutrition facts panel on label ; 3) Provide data to support Omega fatty acid content; plus 4) Name the food(s) responsible for the omega fatty acid content. FACTUAL STATEMENTS (fatty acid content from raising animals with naturally occurring foods added to feed) Yes (requires FSIS approval under 9CFR 412.1) - \u201cX milligrams of CLA (Conjugated Linoleic Acid) per serving\u201d - \u201cX grams of Omega-3 Fatty Acids per serving\u201d 1) Omega fatty acid content cannot come from fortification; 2) Include the nutrition facts panel on label; 3) Provide data to support Omega fatty acid content; plus 4) Provide feed formulation and animal raising documentation. LEVEL CHARACTERIZATION No - \u201cGood Source of Omega-3 Fatty Acids\u201d - \u201cMore than X grams of Omega-3 Fatty Acids\u201d These statements are not permitted because there are no defined claims for Omega fatty acids. COMPANY\BRAND NAMES (Trademarked company\brand name associated with omega fatty acids) Yes (in signature line only; requires FSIS approval under 9CFR 412.1) - \u201cOmega 3 Company\u201d Signature line is placed on information panel and is not given undue prominence. TRADEMARKED SYMBOLS\LOGOS (Trademarked symbols\logos associated with omega fatty acids) No These symbols and similar logos are not permitted because there are no defined claims or synonyms for Omega fatty acids 5","Omega Fatty Acid Claims on the Labeling of Meat, Poultry and Egg Products TYPES OF OMEGA FATTY ACIDS This guidance document applies to making factual statements for Omega-3 fatty acids, Omega-6 fatty acids, and Omega-9 fatty acids. It is also applicable for statements that identify specific Omega fatty acids by name, for example, Alpha-Linolenic Acid (ALA), which is a specific omega-3 fatty acid or Conjugated Linoleic Acid (CLA), which is a specific Omega-6 fatty acid. FACTUAL STATEMENTS FSIS permits factual statements on the labeling of meat, poultry, and egg products that declare the amount of Omega fatty acids per serving, provided: 1) Establishments obtain sketch approval through FSIS, LPDS for Labeling that includes Omega fatty acid statements or any reference (direct or implied) to omega fatty acids; 2) The product is not fortified to provide the Omega fatty acid content, 3) The labeling bears a nutrition facts panel in compliance with 9 CFR 317.309, 381.409, or 590.411(e) to identify the serving size of the product, 4) Data documenting the Omega fatty acid content per labeled serving is provided with the label application submitted to LPDS for approval, and 5) The labeling includes a statement identifying the type and amount of Omega fatty acid(s) per serving and the common or usual name of the food source(s)1 from which the Omega fatty acids are obtained (for example, \u201cX milligrams of Omega-3 Fatty Acids per serving from flax seed in breading\u201d). NOTE: See label example 1 When the level of Omega fatty acids is integral in the animal tissue as a result of specialized diets fed to animals, for example, grass fed cattle or raising chickens on a feed formulated with flaxseeds or other whole food sources1 with

naturally occurring (indigenous) Omega fatty acids, the same criteria above apply except that the food source<sup>1</sup> of the Omega fatty acid does not need to be declared on the labeling. For example, grass fed beef might include the statement "\u201cXmg of Omega-6 fatty acids per serving.\u201d In this situation, documentation to support the specialized feeding formula and raising plan for the animal will also need to be included as part of the label application submitted for approval. When making statements about specific Omega fatty acids, use the full fatty acid name with the statement not just the abbreviation, for example, "\u201cXmg Conjugated Linoleic Acid (CLA) per serving\u201d, (on grass fed beef) or prominently link the abbreviated name to the full name with an asterisk or other symbol on the same label panel as the statement.

1 Commonly used foods sources with naturally occurring (indigenous) Omega fatty acids include: fish oil, canola oil, flaxseeds, and walnuts. When adding omega fatty acid sources to animal feeds the food sources would also include plant material such as grass.

6", "For example, "\u201cXmg of CLA\* per serving\u201d displayed on same panel as "\u201c\*Conjugated Linoleic Acid.\u201d Grams and milligrams The amount of the Omega fatty acids per serving on the label may be expressed either as the number of milligrams per serving or the number of grams per serving. The number of grams may be declared to the nearest one thousandth gram, for example, "\u201c0.125 grams Omega-3 fatty acids per serving from flax seed.\u201d NOTE: See label example 2 LEVEL CHARACTERIZATION STATEMENTS FSIS will not approve statements that declare or imply that the product is a good or excellent source of Omega fatty acids per serving. The nutrition labeling regulations in Title 9, Code of Federal Regulations (9 CFR), Subpart B, Section 317.313(b), for red meat products, Subpart Y, Sections 381.413(b), for poultry products, and Title 21 CFR Subpart A, Section 101.13(b) clearly state that \u201cA claim which, expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling \u2026, may not be made on a label or in labeling of that product unless the claim is made in accordance with the applicable provisions in this subpart.\u201d Therefore, without regulations defining such claims, the use of statements with expressed Omega-3 fatty acid claims, including, but not limited to "\u201cGood Source of Omega-3 Fatty Acids\u201d and "\u201cExcellent Source of Omega-3 Fatty Acids,\u201d cannot be approved. Likewise, labeling for meat, poultry, and egg products that bear claims that imply that the level of Omega fatty acids in a product is high or place significance on a specific level of Omega Fatty Acids, including, but not limited to "\u201cContains X grams of Omega-3 Fatty Acids,\u201d "\u201cMore than X grams of Omega-6 Fatty Acids\u201d and "\u201cFortified with X grams of Omega-9 Fatty Acids,\u201d "\u201cWith\u2026\u201d, "\u201cProvides\u2026\u201d, "\u201cPacked with\u2026\u201d, etc., cannot be approved.

TRADEMARKS, AND COMPANY NAMES Trademarked company brand names, trademarked symbols or phrases, and statements included in ad-copy on labeling that declare or imply that the product is a good or excellent source of Omega fatty acids per serving, or declare or imply a particular level of Omega fatty acids per serving using a similar wording a level of Omega fatty acids in a product cannot be approved. One exception, is that the company name may be labeled as part of the signature line for compliance with 9 CFR 317.2(g), 381.122, and 590.411 (c) (2) provided the signature line is only displayed on the information panel in normal size font so that it is not given undue prominence which would cause the use of the company name to be a false or misleading. For additional information about FSIS labeling policies and programs, including Generic Label Approval, please review the FSIS Web Site at:

http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/ or contact the Labeling and Program Delivery Staff at (301) 504-0878 or (301) 504-0879. 7","Label Example 1 [Back to reading] Label Example 2 [Back to reading]  
8","http://askfsis.custhelp.com/ FSIS/USDA www.fsis.usda.gov 2016  
9"]},{"file\_name":"FSIS\_GD\_2016\_0010","title":"Guideline for Countries on the Food Safety and Inspection Service's Equivalence Process","num":"FSIS-GD-2016-0010","id":"0c8e6afa78eb022d894154f68c7543663b6ba065f9d99b57dba12693b5bd2a99","corpus":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/import/Equivalence-Process-Guidance.pdf","type":"pdf","n\_pages":16,"word\_count":4881,"text\_by\_page":[{"This guideline provides countries information about equivalence and the types of equivalence determinations. This guideline also provides information concerning the Food Safety and Inspection Service\u2019s (FSIS) equivalence process. This document includes: - Background on the United States\u2019 (US) equivalence process within the context of the World Trade Organization\u2019s (WTO) Agreement on the Application of Sanitary and Phytosanitary (SPS Agreement) Measures; - Information on the different types of equivalence determinations; and - The steps that countries are to follow to obtain an equivalence determination from FSIS. Guideline for Countries on the Food Safety and Inspection Service\u2019s Equivalence Process September 2016","ii Table of Contents Purpose

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.....	13","1 Purpose The purpose of this guideline is to explain to a country\u2019s Central Competent Authority (CCA) how to request and maintain an equivalence determination in order to export meat (including beef, veal, pork, lamb, mutton, goat, and fish of the order Siluriformes), poultry (including chickens, turkeys, ducks, geese, guineas, ratites, or squabs), or egg products (including pasteurized or

unpasteurized egg products) to the United States (US). The CCA is a country's national government authority that is responsible for ensuring the safety and truthful labeling of the food supply. This guideline provides information about the: - Background on the US equivalence process within the context of the Agreement on the Application of Sanitary and Phytosanitary Measures and the World Trade Organization; - Information on the different types of equivalence determinations; and - The steps that countries are to follow to obtain an equivalence determination from FSIS.

What is Equivalence? Equivalence is the process of determining whether a country's food safety inspection system achieves FSIS's appropriate level of protection for public health as applied domestically in the US. Additionally, the country's food safety inspection system is to provide standards equivalent to FSIS to ensure other non-food safety requirements (such as humane handling, accurate labeling, and assurance that meat, poultry, or egg products are not economically adulterated) are met. This means that the country is not required to develop and implement the same procedures that the US does, but rather the country must objectively demonstrate how its procedures meets the US level of protection.

Countries wishing to become eligible to export meat, poultry, or egg products to the US must demonstrate that they have a regulatory food safety inspection system that is equivalent to that of the US. The following is an example of when FSIS determined that a country's raw beef products inspection system was equivalent and the country's food safety procedures were different than the US procedures.

Example of an Equivalent Food Safety Procedure Different from FSIS

FSIS has a food safety objective-based criterion that requires the CCA to ensure that raw beef products are free of shiga toxin-producing *Escherichia coli* (STEC) at the end of the production process. In the US, beef slaughter and processing establishments use a combination of antimicrobial treatments and sanitary dressing procedures to control STEC. However, other countries prohibit the use of antimicrobial treatments and have submitted requirements that raw beef establishments are to implement robust sanitary dressing procedures with additional controls and government verification procedures to prevent STEC. In this situation, the CCA has verification procedures (including rigorous microbial sampling) that demonstrate sanitary dressing procedures ensure that raw beef products are free of STEC at the end of the production process. Additionally, the CCA's controls include a focus on carcasses as well as other conditions (high event periods) and classes of raw products that collectively increase the likelihood of detecting STEC if present. Based upon the evaluation of the CCA's verification procedures, controls, and receipt and evaluation of ongoing microbial results from the CCA, FSIS has determined this approach to be equivalent because the CCA demonstrates that it meets the food safety criterion.

Equivalence Background

Determining equivalence of a country's food safety inspection system is important because it protects public health and facilitates trade. An equivalence determination of an exporting country's regulatory food safety inspection system for meat, poultry, or egg products is a prerequisite for trade for the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS). USDA-FSIS is the US CCA responsible for regulating and inspecting meat, poultry, and egg products. FSIS implements an equivalence process to ensure that US treaty obligations under the World Trade Organization's (WTO) Agreement on the Application of Sanitary and Phytosanitary

Measures (SPS Agreement) is met. The SPS Agreement sets out the basic international rules for food safety, animal, and plant health standards. FSIS ensures during the equivalence process that the following SPS Agreement standards are met through the implementation of the following principles: science, risk assessments, transparency, harmonization, and equivalence. To ensure that meat, poultry, or egg products (including imported products) do not pose any public health risks to US consumers, FSIS implements the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), Egg Products Inspection Act (EPIA), Humane Methods of Slaughter Act (HMSA), and regulations under Title 9 Code of Federal Regulations (CFR) Parts 300-590. FSIS ensures that a country's food safety inspection system addresses FSIS' food safety regulatory-based objectives. Food safety regulatory-based objectives are food safety goals for preventing the occurrence of an identified food safety hazard. The criteria by which FSIS assesses the equivalence of a country's food safety inspection system can be found under Title 9 CFR §7327.2 (for meat products), §7557.2 (for fish of the order Siluriformes products), §7381.196 (for poultry products), and §7590.910 (for egg products).", "3 Types of Equivalence Determinations There are four (4) types of equivalence determinations: (1) Initial Equivalence, (2) Ongoing Equivalence Verification, (3) Reinstatement of Equivalence, and (4) Individual Sanitary Measure. How to Start the Equivalence Process Countries wishing to export meat, poultry, or egg products to the US for the first time are to have their CCA contact FSIS' Office of International Coordination (OIC) by submitting a formal written to request an initial equivalence determination. In response to a country's request, FSIS will provide the country a packet of information that includes guidance and a Self-Reporting Tool (SRT). The SRT is a questionnaire that provides an organized means for the country's government to demonstrate that its inspection system achieves an equivalent level of protection as applied domestically in the US. The SRT is arranged into six components: \u2022Explanation About the Type of Equivalence Determination Types of Equivalence Determinations \u2022For countries seeking to export meat, poultry, or egg products to the US for the first time \u2022FSIS evaluates a country's food safety inspection system to make an initial equivalence determination before the country can export products to the US. \u2022Rulemaking is only required for initial equivalence determinations. (1) Initial Equivalence \u2022For countries that have an equivalence determination and are exporting meat, poultry, or egg products to the US \u2022Countries are to maintain communication with the US concerning updates to their food safety inspection system. (2) Ongoing Equivalence Verification \u2022For countries that FSIS has determined to have an equivalent food safety inspection system and stopped exporting to the US for an extended period of time \u2022FSIS will reassess the food safety inspection system before the country can export products to the US again. (3) Reinstatement of Equivalence \u2022For countries that have an equivalence determination and want to change a procedure in their food safety inspection system \u2022FSIS will assess the new procedure before the country can implement the procedure for products it exports to the US. (4) Individual Sanitary Measure", "4.1. Government Oversight (e.g., Organization and Administration) 2. Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling) 3. Government Sanitation 4. Government Hazard Analysis and Critical Control Point (HACCP) System 5. Government Chemical Residues Testing Programs 6. Government Microbiological Testing Programs NOTE:

Please refer to the Self-Reporting Tool (SRT) for additional information on how a country should categorize its food safety inspection system and respond to the SRT. Countries wishing to (1) reinstate previous equivalence determinations to start exporting meat, poultry, or egg products to the US again, or (2) change a procedure (sanitary measure) that the US has previously determined to be equivalent in their food safety inspection system are to submit a formal written request to OIC. A possible reason for a country to request a reinstatement of equivalence determination includes the lifting of a trade ban after an extended period of time due to a change in animal disease status allowing the export of certain animal products to the US. An example of an individual sanitary measure equivalence determination request is when a country wants to change its postmortem inspection procedures for livestock from traditional (hands-on) inspection to a visual assessment. NOTE: Reinstatement and individual sanitary measure equivalence determination requests are only applicable to countries that have received an initial equivalence determination of their food safety inspection system for meat, poultry, or egg products. Written requests must clarify the type of equivalence determination (for example, initial, reinstatement, or individual sanitary measure), as well as the commodity the request is for. Some examples of requests include: reinstatement of equivalence for raw beef, or initial equivalence for heat-treated and thermally processed poultry. Please submit all written equivalence requests to: United States Department of Agriculture Food Safety and Inspection Service Office of International Coordination 1400 Independence Avenue, SW Room 3143, South Building Washington, DC 20250 Phone: (202) 708-9543 Fax: (202) 690-3856", "5 E-mail: InternationalCoordination@fsis.usda.gov Letters can be transmitted by e-mail (preferred), mail, or fax.

**Initial Equivalence Process**

An initial equivalence determination by FSIS of a country's meat, poultry, or egg products food safety inspection system is a prerequisite for trade with the US. The FMIA, PPIA, and EPIA require FSIS to establish the equivalence of a country's food safety inspection system before accepting meat, poultry, or egg products from the exporting country for sale in US commerce. To establish equivalence, FSIS assesses a country's food safety inspection system through the country's responses to the SRT, including a review of supporting documentation (for example, food safety legislation, policies, and annexes) that the country provides to support its answers in the SRT, and through an on-site verification audit. The following six (6) steps briefly outline the initial equivalence process for a country wishing to secure an initial equivalence determination to export meat, poultry, or egg products to the US for the first time.

**Step 1 \u2013 Country Submits Written Request to FSIS**

Any country can request eligibility to export meat, poultry, or egg products to the US. The eligibility process begins with a formal written request submitted to FSIS's OIC. For more information on submitting a formal written request, please refer to subsection "\u201cHow to Start the Equivalence Process,\u201d under the "\u201cTypes of Equivalence Determinations\u201d section.

**Step 2 \u2013 Document Submission Through a Self-Reporting Tool**

In response to a country's request for equivalence, FSIS will provide the country a packet of information that includes guidance and the SRT. NOTE: Please refer to the Self-Reporting Tool (SRT) for additional information on how a country should categorize their food safety inspection system and respond to the SRT.

**Initial Equivalence Process**

1. Country Submits Written Request to FSIS
2. Document Submission Through Self-Reporting Tool
3. Document Review
4. On-site Verification Audit
5. Public Notification-Proposed Rule in Federal Register
6. Final Determination of Equivalence-Final Rule in Federal Register;

"6 A country can submit a

complete SRT by mail, electronic mail, or through FSIS\u2019s Public Health Inspection System (PHIS). PHIS is FSIS\u2019s web-based database that countries can access to complete an SRT and upload supporting documentation. The benefits of using PHIS to submit the information include an expedited SRT review, transparency, and security. To ensure an expedited review of a submitted SRT, particularly an SRT submitted in PHIS, FSIS encourages countries to submit SRT responses and supporting documentation in English. Countries are to contact FSIS\u2019s OIC for: \u2022 Questions and requests for technical assistance; \u2022 To submit a completed SRT and referenced supporting documentation in paper or electronically in Microsoft Word for FSIS\u2019s review ; or \u2022 To notify FSIS that an SRT has been submitted through PHIS.

NOTE: Please refer to FSIS\u2019s guide on Steps to Obtain Level 2 eAuthentication Credentials and PHIS Access for additional information on how to get access to PHIS. Please also refer to FSIS\u2019s presentation on How to Complete and Submit the SRT Using PHIS for additional information on how to complete and submit an SRT through FSIS\u2019s PHIS. Step 3

\u2013 Document Review After FSIS receives an SRT with all referenced supporting documentation, FSIS reviews the information to determine whether the country\u2019s documented food safety inspection system appears equivalent. If FSIS needs further information or clarification, OIC will advise the country\u2019s CCA of data, programs, or other information that the CCA needs to provide FSIS. If a country submits SRT responses with supporting documentation in a language other than English, FSIS will: 1. Send the documentation for translation into English, and place translated English responses into the SRT in PHIS. This provides the CCA the opportunity to verify the accuracy of the English-translated SRT responses and documents. 2. FSIS, using food safety objective-based criteria, will then review the SRT responses and supporting documentation to determine whether the country\u2019s documented food safety inspection system appears equivalent. 3. After FSIS completes its review, FSIS will send any questions requiring clarification to the CCA, or inform the CCA that its documented food safety inspection appears equivalent and advise on next steps. Key Point FSIS encourages countries to submit SRT responses and supporting documentation in English through PHIS to expedite the review process."

"7 IMPORTANT: Submitting SRT answers and documents in languages other than English will significantly delay FSIS\u2019s review process of the SRT. The translation process may take several months. To facilitate an efficient review of an SRT and supporting documentation, particularly an SRT submitted in PHIS, FSIS strongly encourages that countries submit their SRT responses and supporting documentation in English. NOTE: FSIS will accept SRT responses and supporting documentation submitted in any of the three (3) official languages of the WTO: English, French, or Spanish. Step 4 \u2013 On-Site Verification Audit An on-site verification audit is an audit of the country\u2019s food safety inspection system with the goal of verifying, through objective evidence, that the country\u2019s inspection system has an equivalent level of public health protection as applied domestically in the US. If FSIS determines that a country\u2019s food safety inspection system is tentatively equivalent based on the SRT document review process, OIC will work with the country\u2019s CCA to arrange an on-site verification audit of the country\u2019s food safety inspection system. Initial equivalence audits are conducted by FSIS International Auditors. The audit scope includes visual observations of all aspects of the country\u2019s food safety inspection system and may include the following: \u2022 Review of the country\u2019s laws, regulations, directives, notices, and other program implementation

documents; \u2022 Review of records of potential exporting establishments\u2019 operations, inspection results, and enforcement activities; \u2022 Review of the government chemical residue testing program; \u2022 Review of government microbiological testing programs; \u2022 Review of third party audit reports; and \u2022 Review of other US import requirements, such as pathogen reduction and HACCP system programs. During the on-site audit, International Auditors verify that the CCA implements, monitors, and verifies all of the procedures in the country\u2019s food safety inspection system. Typically, International Auditors will need to visit multiple sites that may include the following: \u2022 Central, regional, and local government offices; \u2022 Potential exporting establishments (slaughter and processing establishments) and warehouses (including cold storage); and \u2022 Laboratories." , "8 After the on-site audit, FSIS sends a draft audit report to the country applying for equivalence for the country\u2019s review and comment. FSIS then takes the country\u2019s comments into account and generates the final audit report. Step 5 \u2013 Public Notification - Proposed Rule in a Federal Register Based on the outcome of FSIS\u2019s SRT and supporting documentation review and the onsite audit, FSIS initiates rulemaking to propose that the country be listed in the CFR as eligible to export meat, poultry, or egg products to the US. To initiate rulemaking, the country will need to provide 5 years of projected economic analysis information. Upon publication, the public can submit comments (generally up to 60 days after publication) to FSIS about the proposed rule. Step 6 \u2013 Final Determination of Equivalence - Final Rule in Federal Register FSIS analyzes any received comments and publishes a final rule to list the country in the CFR as eligible to export meat, poultry, or egg products to the US. FSIS sends the country a letter notifying it of the published rule. The letter includes instructions about exporting meat, poultry, or egg products to the US. After the rule becomes effective, the country then certifies establishments as being eligible to export meat, poultry, or egg products to the US. After a country has compiled a list of eligible certified establishments, the country sends the completed list to OIC. A certified establishment is an establishment that the CCA determines as meeting US requirements and, therefore, eligible to export meat, poultry, or egg products to the US. NOTE: Equivalent countries are required to notify FSIS when there are changes in the eligibility of certified establishments, and must confirm with FSIS at least annually (by May 18th), after FSIS determines the country\u2019s food safety inspection system to be equivalent, all certified establishments eligible to export to the US. Additionally, countries are to submit to OIC a sample of the health certificate they propose to use for exported meat, poultry, or egg product shipments to the US. Each eligible country\u2019s CCA is responsible for the certification of shipments of meat, poultry, or egg products to the US. Please refer to Title 9 CFR \u00a7327.4 (for meat), \u00a7557.4 (for fish of the order Siluriformes products), \u00a7381.197 (for poultry), and \u00a7590.915 (for egg products). Please see FSIS Directive 9770.1, Determining the Initial Equivalence of Foreign Food Safety Systems, for additional information on how FSIS personnel make initial equivalence determinations. Animal Health Considerations It is important to note that FSIS only determines whether a country\u2019s meat, poultry, or egg products food safety inspection system is equivalent. Countries should be aware that animal diseases are regulated by the USDA\u2019s Animal and Plant Health Inspection", "9 Document Reviews On-Site Audits Point-of-Entry Reinspection Service (APHIS) (Title 9 CFR Parts 92 through 95), and a country\u2019s animal disease status can impact what products the country can export to the

US. For a list of USDA recognized animal health status of countries, please visit APHIS\2019s Animal Disease Status webpage ([https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-andanimal-product-import-information/ct\\_animal\\_disease\\_status](https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-andanimal-product-import-information/ct_animal_disease_status)). FSIS recommends that countries work with both FSIS and APHIS to address each Agency\2019s eligibility requirements to successfully export meat, poultry, or egg products to the US. If countries have questions or require further information related to imports of animal products or by-products, please contact APHIS\2019s National Center for Import and Export at: USDA, Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS) National Center for Import and Export 4700 River Road, Riverdale, MD 20737 Phone: (301) 851-3300, option 1 E-mail:

AskNIES.Products@aphis.usda.gov Ongoing Equivalence Verification Determination Process  
FSIS will continuously evaluate and verify the equivalency of an exporting country\2019s food safety inspection system through a three (3) part process: (1) document reviews, (2) on-site audits, and (3) point-of-entry reinspection of meat, poultry, and egg products. Part 1 \2013 Document Reviews Countries are to submit the following for review at least annually by May 18th: 1. Either (1) updated SRT responses, or (2) communicate to FSIS that the CCA has verified its SRT responses, as recorded in PHIS (i.e., by reviewing the SRT electronically in PHIS) or by mailed hard copy of the version of SRT responses FSIS has entered for the CCA, are accurate and complete. 2. An up-to-date list of all certified establishments eligible to export meat, poultry, or egg products the US. 3. An updated government residue control program, including the previous year\2019s residue test results and reactions to residue findings.", "10 4. Updated government microbiological sampling and testing programs, including the previous year\2019s test results and reactions to: (A) indicator organism results for intestinal or fecal contamination; (B) Salmonella and Campylobacter results for raw meat and poultry products; (C) Listeria monocytogenes, Salmonella, or other pathogens of public health concern in ready-to-eat (RTE) meat and poultry products and all lots of pasteurized egg products; and (D) STEC in raw beef products. Part 2 \2013 On-Site Audits FSIS will periodically conduct an on-site audit of every eligible country\2019s food safety inspection system. These audits will be performed by FSIS International Auditors and are similar to the on-site verification audits that FSIS does as part of the initial equivalence process. If a country has implemented any new individual sanitary measures since the previous audit, International Auditors will verify that the CCA is implementing the procedures as described in the submitted documentation for the individual sanitary measure that FSIS found equivalent. In addition, if a country has received multiple point-of-entry reinspection violations, the International Auditors may need to visit those certified establishments with the violations during the audit to determine whether there is a breakdown in the implementation of the country\2019s food safety inspection system. Please refer to Part 3 below for more information on point-of-entry reinspection. In addition, please refer to Step 4 subsection under the \201cInitial Equivalence Process\201d section for additional information about on-site audits performed by International Auditors. Part 3 \2013 Point-of-Entry Reinspection All imported shipments of meat, poultry, and egg products that enter the US are presented to FSIS for reinspection. FSIS has import inspection facilities located across the US at major ocean ports and land border crossings. At these import inspection facilities, FSIS checks every shipment for eligibility, certification, transportation damage, and labeling. The purpose of point-of-entry reinspection is to monitor the effectiveness of an

eligible exporting country's food safety inspection system, not to assess the performance of an individual certified establishment. In addition to point-of-entry shipment reinspection, FSIS performs more detailed, random reinspection activities on select lots within received shipments of meat, poultry, and egg products. These reinspection activities may include physical product examinations, condition-of-container reinspection, and laboratory sampling. Imported meat, poultry, and egg products determined to meet FSIS import requirements are stamped as "Inspected and Passed," and the products are released into US commerce. Non-compliant products are marked as "Refused Entry," and FSIS notifies the Importer of Record that the products are prohibited from entering US commerce."<sup>11</sup> Please see FSIS Directive 9780.1, Verifying the Ongoing Equivalence of Foreign Food Safety Systems, for additional information on how FSIS personnel verify the ongoing equivalence of foreign countries' food safety inspection systems. Please see FSIS Directive 9900.2, Import Reinspection of Meat, Poultry, and Egg Products, for additional information on FSIS's reinspection procedures.

Reinstatement of Equivalence Process A reinstatement of equivalence process is undertaken when a country wants to start exporting meat, poultry, or egg products again to the US. A country requests a reinstatement of equivalence determination for a specific commodity (for example, raw beef) after a long period of trade inactivity. The trade inactivity is typically due to the implementation of a trade ban preventing the exportation of certain animal products to the US due to a country's animal disease status. A reinstatement of equivalence process follows the same process as the initial equivalence process, except that the country may be subjected to a verification audit, and will not be subjected to the rulemaking steps. The rulemaking steps are not applicable for a reinstatement of equivalence determination because the country's food safety inspection system has already been determined to be equivalent. The following five (5) steps briefly outline the process for reinstating equivalence: Please refer to Steps 1 through 4 under the "Initial Equivalence Process" subsections for additional information. After FSIS completes its document review and, as needed, an on-site verification audit, OIC will notify the country of FSIS's decision through a formal written letter. The letter will discuss FSIS's basis for its decision to reinstate equivalence. If FSIS does not perform an audit as part of the reinstatement of equivalence process, then FSIS will verify the reinstated process during the next scheduled audit. Please see FSIS Directive 9770.1, Determining the Initial Equivalence of Foreign Food Safety Systems, for additional information on how FSIS personnel make reinstatement of equivalence determinations.

Reinstatement of Equivalence Process 1. Country submits written request to FSIS 2. Document submission through Self-Reporting Tool 3. Document review 4. On-site verification audit (may or may not be needed) 5. FSIS notifies country of equivalence determination through a formal written letter (no rulemaking is necessary)<sup>12</sup>

Individual Sanitary Measure Equivalence Process Eligible countries currently exporting meat, poultry, or egg products to the US request an individual sanitary measure when they want to change a procedure in their food safety inspection system. An eligible country is to request an individual sanitary measure equivalence determination before the country implements the new procedure on products destined for export to the US. Countries are to submit a formal written request for an individual sanitary measure to FSIS's OIC. If a country does not notify FSIS of changes in its food safety procedures, a possible disruption of trade could result. FSIS will evaluate a request for an individual sanitary measure equivalence

determination to ensure that the new procedure: \u2022 Is equivalent to FSIS\u2019s relevant food safety regulatory objective-based criteria, and \u2022 Achieves an appropriate level of protection from identified food safety hazards. There are two (2) reasons an eligible country requests an individual sanitary measure equivalence determination. 1. The country wants to make a change to a procedure in its food safety inspection system that FSIS previously determined was equivalent. 2. FSIS has updated its US domestic food safety procedures or requirements and identified that the procedures or requirements affect previous equivalence determinations for specific eligible countries. If FSIS determines that eligible countries may be affected by a change in US domestic procedures or requirements, OIC provides notice through the WTO and directly communicates to all countries exporting meat, poultry, or egg products to the US. After FSIS publishes the procedures or requirements as part of final rulemaking through a Federal Register Notice, they become an import requirement. The following five (5) steps briefly summarize the individual sanitary measure equivalence process: Please refer to Steps 1 through 3 under the \u201cInitial Equivalence Process\u201d subsections for additional information.

**Individual Sanitary Measure Equivalence Process**

1. Country submits written request to FSIS
2. Document submission through Self-Reporting Tool
3. Document review
4. FSIS notifies country of its individual sanitary measure equivalence determination through a formal written letter.
5. Countries that request an individual sanitary measure will need to update their SRT and submit supporting documentation to FSIS for review. The submitted documentation should demonstrate that the measure provides an equivalent level of public health protection. After FSIS completes its review, OIC will notify the country of FSIS\u2019s decision through a formal written letter. The letter will discuss FSIS\u2019s basis for its decision to either accept or reject the proposed individual sanitary measure. If FSIS accepts the individual sanitary measure, FSIS will verify the application of the individual sanitary measure during the next scheduled on-site verification audit.

**Whom to Contact for Questions or Request Additional Information**

Countries are to contact FSIS\u2019s OIC for:

1. All questions and requests for technical assistance,
2. To submit formal equivalence requests,
3. To submit a paper copy of an SRT and supporting documentation for review, or
4. To notify FSIS that an SRT was submitted in PHIS.

OIC can be contacted at: United States Department of Agriculture Food Safety and Inspection Service Office of International Coordination 1400 Independence Avenue, SW Room 3143, South Building Washington, DC 20250 Phone: (202) 708-9543 Fax: (202) 690-3856 E-mail: InternationalCoordination@fsis.usda.gov

**Helpful Equivalence Resources**

The following additional FSIS equivalence resources are available to help countries better understand the equivalence process, how to complete the SRT, obtain level 2 eAuthentication credentials, and access PHIS to view and complete an SRT.

- \u2022 FSIS\u2019s Equivalence Webpage
- \u2022 FSIS\u2019s presentation on The FSIS Equivalence Process
- \u2022 2019 Self-Reporting Tool
- \u2022 Steps to Obtain Level 2 eAuthentication Credentials and PHIS Access
- \u2022 FSIS\u2019s presentation on How to Complete and Submit the SRT Using the PHIS

],{"file\_name":"FSIS\_GD\_2016\_0011","title":"\u201cAt Least Equal To\u201d Guideline for State Meat and Poultry Inspection Programs","num":"FSIS-GD-2016-0011","id":"c123e121189bd85c0df788f6208bac7ff5ce8486648eba96bc7e5ebd0917897f","corp\_us":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/import/At\_Least\_Equal\_to\_Guidelines.pdf","type":"pdf","n\_pages":111,"word\_count":29659,"text\_by\_page":["United

States Department of Agriculture Food Safety and Inspection Service State-Federal Cooperation \u201cAT LEAST EQUAL TO\u201d GUIDELINE FOR STATE MEAT AND POULTRY INSPECTION PROGRAMS November 2016 Page 1", "What if I still have questions after I read this guideline? If the desired information cannot be found within the Guideline, FSIS recommends users search the publicly posted Questions & Answers (Q&As) in the AskFSIS database or submit questions through AskFSIS. Documenting these questions helps FSIS improve and refine present and future versions of the Compliance Guideline and associated issuances. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided: Subject Field: Compliance Guideline for State Meat and Poultry Inspection Programs. Question Field: Enter question with as much detail as possible. Product Field: Select General Inspection Policy from the drop-down menu. Category Field: Select Cooperative State Inspection Programs from the drop-down menu. Policy Arena: Select Domestic (U.S.) Only from the drop-down menu. When all fields are complete, press Continue and at the next screen press Finish Submitting Question. NOTE: Refer to FSIS Directive 5620.1, Using AskFSIS, for additional information on submitting questions. Page 2", "\u201cAT LEAST EQUAL TO\u201d GUIDELINE FOR STATE MEAT AND POULTRY INSPECTION PROGRAMS Table of Contents I. \u201cAt Least Equal To\u201d Definition 4 II. Purpose 5 III. Background 5 IV. Annual Self-Assessment 6-10 V. Onsite Review 11-13 VI. Determination Process 13-14 VII. Appeal Process 14-15 VIII. FSIS Reports 15 IX. Nine Program Components Component 1: Statutory Authority and Food Safety 15-25 Regulations Component 2: Inspection 26-44 Component 3: Sampling Programs 45-51 Component 4: Staffing, Training, and Supervision 52-60 Component 5: Humane Handling 61-63 Component 6: Compliance 64-70 Component 7: Laboratory Methods and Quality Assurance 71-75 Program Component 8: Civil Rights 75-80 Component 9: Financial Accountability 81-85 X. Additional Resources 85-99 Reference Table of Related FSIS Policy Documents 100-111 Page 3", "The \u201cat least equal to\u201d standard requires State MPI programs operate in a manner that is not less effective than those standards adopted for the Federal inspection program. The standard does not require the States operate their MPI programs in a manner that is the same as or identical to FSIS\u2019s inspection program, nor does it prohibit the State MPI programs from establishing safeguards they believe to be more effective than those employed by FSIS. KEY DEFINITION AND STATE MPI PROGRAM REQUIREMENT \u201cAt Least Equal To\u201d Page 4", "I. PURPOSE This guideline provides information to State Cooperative Inspection programs on the criteria that the Food Safety and Inspection Service (FSIS) uses to determine each year whether State Meat and Poultry Inspection (MPI) programs are operating verifiably in accordance with requirements that are \u201cat least equal to\u201d the Federal inspection requirements. The guideline contains information that State MPI programs need to establish and maintain such programs. II. BACKGROUND The Federal Meat Inspection Act (FMIA) (21 U.S.C. 661) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 454) authorize FSIS to cooperate with State agencies in developing and administering their own Meat and Poultry Inspection (MPI) programs. Individual State MPI programs are required to operate under authorities that are \u201cat least equal to\u201d the provisions for ante-mortem and post-mortem inspection, reinspection, sanitation, recordkeeping, and enforcement in the FMIA and PPIA and implementing regulations. State MPI programs are also expected to ensure livestock are treated humanely by assuring the methods of handling livestock are \u201cat least equal to\u201d those outlined in the Humane

Methods of Slaughter Act of 1978 (HMSA)(7 U.S.C. 1901-906). The FMIA (21 U.S.C. 661(b)) and the PPIA (21 U.S.C. 454 (b)) authorize FSIS to cooperate with a single State agency and subordinate governmental unit primarily responsible for the coordination of a State MPI program. In matters concerning the State MPI program, FSIS will communicate and coordinate with designated State employees assigned to the single State agency identified by the State as responsible for ensuring that all applicable inspection and compliance activities outlined in these guidelines comply with specified laws, regulations and policies. The activities include those conducted by State or contract laboratories, public health departments, law enforcement agencies, State human resource departments, budget departments and other State regulatory agencies. This guideline replaces the previous version, issued July 2008. FSIS updated the guideline to consolidate components, add new components and resource information, and to revise tables. The most notable changes are as follows: The date for the States\u2019 annual self-assessment submission has changed from November 15th to November 1st of each year. Component 1 - Statutory Authority and Food Safety Regulations has a new table titled \u201cStatutory Side-by-Side Comparison Table\u201d Component 2 - Inspection includes: \u2022 Former Component 6 \u2013 Non- Food Safety Consumer Protection is added in its entirety; \u2022 The Quarterly New Issuance Review process is a new section added to this component; and \u2022 The guideline titled, \u201cAt least equal to data system requirements for State Cooperative Meat and Poultry Inspection (MPI) programs electing not to use FSIS\u2019s Public Health Information System (PHIS)\u201d published in January 2015 is added at the end of Component 2. Component 3 \u2013 Sampling Programs (formerly known as \u201cProduct Sampling\u201d) has been retitled. SIGNIFICANT CHANGES Page 5", "III. ANNUAL SELF-ASSESSMENT FSIS expects the State MPI programs to submit their annual self-assessment documents to FSIS\u2019s FederalState Audit Branch (FSAB) on or before November 1st of each year. Each State MPI program should start its annual self-assessment with a review of the prior-year selfassessment. Each component of the annual selfassessment should include a written narrative statement and documentation demonstrating the program continuously meets the criteria to be \u201cat least equal to\u201d the Federal program. The self-assessment should identify any program changes in the previous 12 months and include documentation which will support the State\u2019s ability to maintain its program for the next 12 months. State MPI programs should also submit sufficient documentation to demonstrate the State MPI program has stayed current with FSIS statutes, regulations, applicable FSIS Directives and Notices, and has implemented any changes necessary to maintain its \u201cat least equal to\u201d status. The annual self-assessment submission should also include one or more narratives describing internal controls used by the State MPI program that: \u2022 Provide assurances that internal controls can measure the effectiveness of the program under the \u201cat least equal to\u201d criteria; \u2022 Demonstrate how nonconformances will be addressed by corrective actions; and \u2022 Demonstrate how the State MPI program will be maintained throughout the next 12 months. These internal controls should provide an objective assessment of the State MPI program\u2019s operations and processes to determine whether: \u2022 Financial and operating information is accurate and reliable; \u2022 Operational risks are appropriately identified and managed; \u2022 Applicable regulations and internal policies and procedures are followed; and \u2022 The \u201cat least equal to\u201d standard is maintained. Component 6 \u2013 Compliance (formerly known as \u201cComponent 7 \u2013

Compliance\u201d) has been retitled and includes a new table titled \u201cSummary of Statutory Authority per Business Type.\u201d Component 7 \u2013 Laboratory Methods and Quality Assurance Program is a new component for laboratory methods and quality assurance criteria. This information was previously published in June 2014 as a separate guideline titled \u201cAt Least Equal To Compliance Guideline for State Meat and Poultry Inspection (MPI) Programs for Laboratory Methods\u201d and has been updated and added as a component. The following Tables have been updated to better reflect the information needed by FSIS in the evaluation of State MPI program operations: Component 3 \u2013 State MPI Program Sampling Activity Table. Component 4 \u2013 State MPI Program Establishment Count and the State MPI Program Employee Primary Roles. Component 6 \u2013 Compliance Activity Report. Additional Resources is a new section added at the end of the guideline to provide State MPI program Directors with reference material that may be needed to perform business processes related to budget submissions, training and Federal resource information, cooperation between State and Federal Compliance programs, and information on internal controls. The section also includes a Reference Table of Related FSIS Policy Documents, which is a reference guide to FSIS policy documents relevant to the implementation of the nine program components. Page 6", "Ultimately, State MPI programs need to operate in a manner that protects the health and welfare of consumers within their State by ensuring the meat and poultry products distributed by the program establishments are wholesome, not adulterated, and properly marked, labeled, and packaged. More specifically, the annual self-assessment should also address each of the following nine program components so as to demonstrate the State\u2019s MPI program is administered in a manner that is \u201cat least equal to\u201d the Federal inspection requirements and describe how it will maintain this status for the following 12 months. FSIS Directive 5720.3, Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs, provides the FSIS review methodology and criteria for each component. For each of the first six (1-6) components, State MPI programs need to submit selfassessment documentation demonstrating the State MPI program is meeting the \u201cat least equal to\u201d Federal inspection requirements. Such documentation should include the attached Annual Certification \u2013 \u201cAt Least Equal To\u201d Meat and Poultry Inspection Program (Attachment 1, page 10) and a narrative describing any changes made in the State MPI program during the previous 12 months. For Component 2, State MPI programs that have elected not to use the FSIS Public Health Information System (PHIS), should refer to guidance information (Attachment 3, Component 1 Statutory Authority and Food Safety Regulations Component 2 Inspection Component 3 Sampling Programs Component 4 Staffing, Training, and Supervision Component 5 Humane Handling Component 6 Compliance Component 7 Laboratory Methods and Quality Assurance Program Component 8 Civil Rights Component 9 Financial Accountability The Nine Program Components Page 7", "page 38) titled, \u201cAt least equal to\u201d data system guidance for State Cooperative Meat and Poultry Inspection (MPI) programs electing not to use Public Health Information System (PHIS) can be found at the end of Component 2. State MPI program Directors are to submit the requested data system information with the annual self-assessment submission to FSAB for review. For Component 7, State MPI programs need to submit the following self-assessment documentation to FSIS, Office of Public Health Science (OPHS): \u2022 A list of current State laboratory and/or contract laboratory test methods and copies of new or revised methods

accompanied by a Laboratory Method Notification Form; and \u2022 A completed FSIS Form 5720-14, FSIS MPI Program Laboratory Quality Management System Checklist or use another easy to read format for each State or contract laboratory performing MPI-related analyses or their current ISO 17025 certificates of accreditation for each State and/or contract laboratory performing MPI-related analyses For Component 8, the State MPI programs are to complete and submit FSIS Form 1520-1, Civil Rights Compliance of State-Inspection Programs, or use another easy to read format to the FSIS Civil Rights Staff. Relative to Component 9, the State MPI programs should submit specified financial reports as requested throughout the fiscal year. Although deadlines for submitting certain financial reports may coincide with FSIS\u2019s self-assessment submission deadline of November 1. Financial Reviews and Analysis Section (FRAS) does not require the inclusion of these financial reports as part of the annual self-assessment submission for Component 9. Component 9 includes a list of supporting documentation the State agencies should have readily available for FSIS reviewers, upon request, prior to or during the on-site financial review. State MPI program Directors should submit the self-assessment for the various program components and any required or requested documents as follows:

Components 1\u20136 Email: StateMPIProgramSubmissions@fsis.usda.gov USDA, FSIS, OIEA, MCAD, FSAB Chief Edward Zorinsky Federal Building 1616 Capital Avenue, Suite 260 Omaha, NE 68102-5908 Telephone: 402-344-5018 Fax: 402-344-5104 Page 8","Component 7 Email:

Statelabinquiry@fsis.usda.gov Director, USDA, FSIS, OPHS, Laboratory Quality Assurance Staff 950 College Station Road Athens, GA 30605 Telephone: 706-546-3559 Component 8 FSIS Civil Rights Staff 5601 Sunnyside Avenue, Mail Drop 5261 Beltsville, MD 20705-5261 Telephone: 800-269-6912 Fax: 301-504-2141 Component 9 Email: FRAS@fsis.usda.gov Financial Reviews and Analysis Section USDA\FSIS\OAV\OCFO\FMD\FASMB 5601 Sunnyside Avenue, Mail Drop 5264 Beltsville, MD 20705-5264 Telephone: 301-344-0479 Fax: 301-504-5914 Page

9","Attachment 1 Annual Certification \u201cAt Least Equal To\u201d Meat and Poultry Inspection Program I have reviewed the attached self-assessment submission of the [insert name of State] State-Federal Cooperative Inspection program. Based on current information, I certify that the State Meat and Poultry Inspection (MPI) program is \u201cat least equal to\u201d the requirements specified in the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), the Humane Methods of Slaughter Act (HMSA) and current FSIS regulations, directives, notices and policies. The State MPI program officials intend to maintain the program as \u201cat least equal to\u201d the applicable requirements specified in the FMIA, PPIA and HMSA, and certify that the program is able to stay current with applicable FSIS regulations, directives, notices and policies to ensure an \u201cat least equal to\u201d status. If conditions change that impact this certification, I will immediately notify the Chief of the Federal-State Audit Branch. USDA, FSIS, OIEA, MCAD, FSAB Chief Edward Zorinsky Federal Building 1616 Capital Avenue, Suite 260 Omaha, NE 68102-5908 Telephone: 402-344-5018 Fax: 402-344-5104 Name of Responsible State Official \_\_\_\_\_

Title of Responsible State Official \_\_\_\_\_ Signature of  
Responsible State Official \_\_\_\_\_ Date

Number \_\_\_\_\_ State \_\_\_\_\_ Contact Telephone

\_\_\_\_\_ Contact E-Mail

\_\_\_\_\_ Contact Fax Number

\_\_\_\_\_ Page 10","Page 11 IV. ON-SITE

**REVIEW** In addition to the annual self-assessment submission, State MPI programs are subject to an on-site review at a minimum frequency of once every three years to verify the accuracy and implementation of the self-assessment submissions. In the year that a State MPI program is scheduled for an on-site review, FSIS\u2019s annual determination of whether the program is \u201cat least equal to\u201d the Federal inspection program will be based on a review of the annual self-assessment submission and the on-site review. Please refer to FSIS Directive 5720.3, Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs, for the FSIS Review Methodology. The purpose of the on-site review is for FSIS to verify the State MPI program implements and maintains its inspection system in accordance with its annually submitted self-assessment, and to determine whether the State MPI program is \u201cat least equal to\u201d the Federal inspection program in its administration and enforcement of requirements. The FSIS review team will review the State MPI program\u2019s current annual self-assessment submission in advance so that they are able to begin the on-site review of the State MPI program with a thorough understanding of the State program\u2019s current self-assessment submission. FSIS will review a selected number of establishments within the State MPI program and examine and evaluate documentation at the central office to verify the State MPI program\u2019s implementation, oversight, and management controls. In October of each year, FSIS will announce the State MPI programs scheduled for an on-site review in the upcoming federal fiscal year. FSIS will send a written notification to State MPI programs at least 30 days before the start of the on-site review process. The on-site review will begin with a teleconference serving as the entrance meeting between FSIS and State MPI program officials. To facilitate FSIS\u2019s selection of establishments to review, State MPI program officials are to supply information from the last 12 months (12 months prior to review) to FSIS within 10 business days after the conclusion of the entrance meeting. The information is to include the following: \u2022 A current list of establishments and their operating schedules (please omit ID warehouses and establishments which slaughter or process only non-amenable species), supervisory boundaries, program updates, and HACCP process categories for all establishments with the 5 highest producers for each category identified. \u2022 Positive Shiga toxin-producing E. coli (STEC) results \u2022 Positive Listeria monocytogenes (Lm) or Salmonella results in RTE products \u2022 Failures of Salmonella and Campylobacter Performance Standards for raw products \u2022 Enforcement actions taken \u2022 Recalls conducted and associated documentation", "\u2022 Establishments that sustained structural damage in production areas due to natural disasters \u2022 Establishments that the State MPI program reviewed, e.g., FSAs, supervisory reviews, internal reviews, management control audits At least one week before the scheduled on-site review, FSIS will notify the State MPI program of the establishments chosen for the on-site review. Should the State MPI program officials ask FSIS to omit a chosen State establishment from its review, they will need to provide written justification for their request (e.g., the establishment is closed the day of the review, the establishment is a seasonal operator). FSIS travels to the chosen State establishment and follows the on-site review protocol. If a chosen State establishment decides not to operate after the on-site review process begins, FSIS selects an alternate State establishment to visit. An electronic draft report of individual establishment findings will be provided to the State MPI program officials by the next business day. At the end of each establishment review, after a short correlation with FSIS, the State MPI program

personnel will lead an exit meeting with State establishment management. Within 10 working days of completing the on-site review, FSAB will schedule a teleconference exit meeting with State MPI program officials. Before the teleconference exit meeting, FSAB will provide a summary report of all findings to the State MPI program officials. The types of findings detailed in the aforementioned FSAB summary report that requires corrective actions will include: \u2022 Processes that are not operating or functioning in the manner intended as detailed in the State\u2019s annual self-assessment or that are not included in the self-assessment submission; \u2022 Processes that are ineffective; and \u2022 Regulatory noncompliances. The State MPI program has 10 working days after the teleconference to present an action plan designed to address all findings that require corrective actions. The State MPI program is to identify any underlying causes for findings that require corrective actions. Corrective actions may include the implementation of preventive measures e.g., targeted staff training, increased supervisory oversight, where applicable. If the State MPI program is unable to identify underlying causes for certain findings they are to share and explain the method they used in their attempts to identify the underlying causes and the results of the associated evaluation conducted to draw the conclusion. They are to also justify why they believe the corrective actions identified in the action plan for such findings are adequate. After receiving documentation demonstrating implementation of the action plan, FSAB will assess the plan and determine if actions taken are sufficient. If the action plan is adequate FSAB will issue a determination Page 12", "memorandum and Interim Annual Comprehensive Review and Determination Report to the State MPI program Director. FSIS may request clarification of specific items regarding the State MPI program\u2019s implementation of its action plan, and in certain cases, may perform a targeted on-site review before the issuance of a determination memorandum. A targeted on-site review conducted prior to the issuance of a determination memorandum is an in-depth evaluation of the State MPI program\u2019s implementation of its action plan. FSIS uses the targeted review to verify resolution of any public health concerns and compliance with the \u201cat least equal to\u201d criteria. The Annual Comprehensive Review and Determination Report will summarize the results of the State\u2019s self-assessment submission and on-site review of the State MPI program (including the results of the targeted on-site review, if applicable). The report will include the FSIS review team\u2019s final \u201cat least equal to\u201d determination supported by individual component determinations.

V. DETERMINATION PROCESS

FSIS makes a determination after evaluating the State\u2019s annual self-assessment and the results of the on-site review, as applicable. The definitions for the three FSIS determinations on the status of the State MPI program are:

1. \u201cAt Least Equal To\u201d The State MPI program has adopted laws, regulations, and programs, and implements them in a manner that is \u201cat least equal to\u201d FSIS\u2019s Federal inspection program for all review components.
2. \u201cAt Least Equal To,\u201d with Provisions\u2014FSIS makes a provisional determination of the State MPI program\u2019s \u201cat least equal to,\u201d status provided the program takes additional action to resolve review findings.
3. Not \u201cAt Least Equal To\u201d The State MPI program has not adopted laws, regulations, or programs, or does not implement them in a manner that is \u201cat least equal to\u201d FSIS\u2019s Federal inspection program for one or more of the review components. At the conclusion of each annual self-assessment review, FSIS decides whether the State MPI program is or is not meeting the \u201cat least equal

to\ud requirements. If the State MPI program is not scheduled for an on-site review during the current fiscal year, FSIS makes an annual determination based only on the results of the self-assessment review. If the State MPI program is scheduled for an on-site review during the current fiscal year, FSIS bases the annual determination on the results of the self-assessment and the on-site review. If the determination of the self-assessment, or self-assessment and the on-site review, if applicable, is that the State program meets the \udat least equal to\ud standard, FSIS promptly gives the State program officials written notification of that Page 13", "fact. If additional clarification is needed for a determination, FSIS requests supplemental information from the State MPI program and issues an Interim Annual Comprehensive Review and Determination Report. When an analysis of all findings, clarifications, and corrective actions from the selfassessment or on-site review indicates a State MPI program cannot support an \udat least equal to\ud determination, FSIS recommends to the Secretary of Agriculture that the State be designated for Federal inspection.<sup>1</sup> If a State cannot immediately implement an action plan but is committed to making the corrections and has the resources to support the changes, FSIS defers designation instead of making a final determination that the State program is not \udat least equal to\ud FSIS\ud 19s Federal inspection program. Before the Secretary initiates the Federal designation process that results in State establishments being subject to the Federal inspection program, FSIS and the State agency confer on the State MPI program\ud 19s deficiencies. If the State MPI program is unable to meet the \udat least equal to\ud requirements or if its responsible officials are unwilling to do so, the Secretary of Agriculture notifies the Governor of the State that the State does not have an \udat least equal to\ud MPI program and is not in compliance with the cooperative agreement between FSIS and the State, and is subject to the Federal designation of its MPI program. If deficiencies are not resolved, the Secretary will designate the State MPI program for Federal meat and poultry inspection and publish a notice of the designation in the Federal Register. Upon the expiration of thirty days after the publication of the Federal Register notice the State-inspected establishments will become subject to Federal inspection.

VI. APPEAL PROCESS State officials have the right to appeal any program status determination made by FSIS. The appeal process follows the Office of Investigation, Enforcement and Audit\ud 19s (OIEA) chain of command. The chain of command ensures that Agency employees most familiar with the facts of the appeal will perform the initial evaluation of the appeal. The Appeal process gives State officials the right to appeal to the next highest level if not satisfied with the outcome. The OIEA chain of command is: 1) FSIS employee who made the finding (e.g., FSAB Program Auditor); 2) FSAB Team Lead; 3) FSAB Chief; 4) Management Controls and Audit Division (MCAD) Director; 5) OIEA Deputy Assistant Administrator; 1 Directive 5710.1, Designation of States for Federal Meat or Poultry Inspection, outlines the procedures for designation of States for Federal meat or poultry inspection. Page 14", "6)OIEA Assistant Administrator; and 7)FSIS Administrator.

VII.FSIS REPORTS The State MPI program officials are notified in writing when FSIS makes a determination after analysis of the self-assessment and on-site review, as applicable. An individual end-of-year report is sent to each State MPI program summarizing program findings. Additionally, each year FSIS publishes on its Web site an overall end-of-year summary report of the findings and final determinations for all State MPI programs at <http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/state-inspectionprograms/state-inspection-and-cooperative-agreements/reviews-of-state->

programs VIII.NINE PROGRAM COMPONENTS Criteria for \u201cat least equal to\u201d determination State MPI programs need to have meat and poultry inspection laws and regulations that impose mandatory ante-mortem and post-mortem inspection, reinspection, sanitation requirements, recordkeeping requirements, and enforcement authorities \u201cat least equal to\u201d those prescribed by the FMIA<sup>2</sup> (21 U.S.C. 601, et seq.) and PPIA<sup>3</sup>(21 U.S.C. 451, et seq.). State MPI programs need to also enforce requirements that are \u201cat least equal to\u201d those imposed under the Humane Methods of Slaughter Act of 1978 (HMSA)<sup>4</sup> (7 U.S.C. 1901, et seq.). 2 The Federal Meat Inspection Act (21 U.S.C. 601, et seq.) governs the slaughter of livestock and the processing and distribution of meat products in the United States. Passed by Congress in March 1907, the FMIA authorizes the Secretary of Agriculture to set national standards for meat inspection. The FMIA was amended in the Wholesome Meat Act of 1967, granting the Secretary of Agriculture the authority to authorize each State to develop its own meat inspection program if their requirements are \u201cat least equal to\u201d Federal requirements. The amended FMIA assures uniformity in regulation of products shipped interstate, intrastate, and in foreign commerce. 3 The Poultry Products Inspection Act (21 U.S.C. 451, et seq.) governs the slaughtering, processing, and distribution of poultry products in the United States. Passed by Congress in August 1957, the PPIA authorizes the Secretary of Agriculture to make rules and regulations setting national standards for poultry inspection. The PPIA was amended in the Wholesome Poultry Products Act of 1968, granting the Secretary of Agriculture the authority to authorize each State to develop its own poultry inspection program if their requirements are \u201cat least equal to\u201d federal requirements. The amended PPIA assures uniformity in regulation of products shipped interstate, intrastate, and in foreign commerce. 4 The Humane Methods of Slaughter Act (7 U.S.C. 1901 et seq.) governs the humane treatment of animals at official establishments. Passed by Congress in 1978, the HMSA authorizes the Secretary of Agriculture to make rules and regulations setting national standards for livestock inspection. The HMSA prevents needless suffering of animals, Component 1: Statutory Authority and Food Safety Regulations Page 15 Component 1: Statutory Authority and Food Safety Regulations", "State MPI programs need to also be in compliance with Federal Civil Rights laws: \u2022 Title VI of the Civil Rights Act of 1964 [42 U.S.C. 200 (d)]; \u2022 Section 504 of the Rehabilitation Act of 1973, as Amended (29 U.S.C. 794); \u2022 Age Discrimination Act of 1990 (42 U.S.C. 12101, et seq.); \u2022 Applicable USDA Civil Rights regulations; \u2022 Financial Accountability requirements pursuant to the Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments (7 Code of Federal Regulations (CFR) Part 3016), (previously known as the Common Rule); \u2022 The Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments (7CFR Part 3016), (previously known as the Common Rule); and \u2022 FSIS Directive 3300.1, Rev. 2, Fiscal Guidelines for Cooperative Meat and Poultry Inspection Programs. To ensure States are in compliance with the statutory and regulatory requirements detailed above, State MPI programs need to: \u2022 Adopt by reference the FMIA, PPIA, and HMSA and implementing regulations; or impose State laws that meet the \u201cat least equal to\u201d requirements of the FMIA, PPIA, and HMSA, and explain in their submission to FSIS how those requirements provide a level of protection that is \u201cat least equal to\u201d that which is imposed by the FMIA, PPIA, HMSA and implementing regulations FSIS allows time for the State\u2019s rulemaking process when

necessary, because there are States that have legislatures that do not always meet on an annual basis. The State MPI program needs to ensure there are measures in place to verify compliance and take enforcement actions for non-compliance findings until the final rulemaking process has been completed. The State MPI program needs to have the authority to expedite the rulemaking process in a manner \u201cat least equal to\u201d that provided for in the Administrative Procedure Act, 5 U.S.C. \u00a7553. If a State MPI program has enacted its own comparable State statutes and regulations that are \u201cat least equal to\u201d those governing the Federal inspection requirements, it needs to ensure that the statutes and regulations establish requirements that State produces safer and better working conditions, brings about improvement of products and economies, and produces other benefits for producers, processors and consumers. Nothing in the HSSA shall be construed to prohibit, abridge, or in any other way hinder the religious freedom of any person or group. Page 16", "establishments maintain sanitary conditions and operate in a manner that includes evaluating hazards, taking steps to control hazards, and routinely verifying that product is safe, wholesome, not adulterated, and properly marked and labeled. States need to ensure that their statutes and regulations adequately address, in an \u201cat least equal to\u201d manner, mandatory ante-mortem and post-mortem inspection, reinspection, sanitation requirements, recordkeeping requirements, compliance provisions, and enforcement authorities to ensure that product is wholesome and not adulterated. In addition, State regulations need to address the humane treatment of animals at establishments under inspection. Outcome The expected outcome is a set of laws and regulations in place that, when objectively reviewed by FSIS, are determined to be \u201cat least equal to\u201d FSIS\u2019s Federal laws and regulations.

\u201cAt least equal to\u201d Requirements State MPI program officials need to stay current with applicable laws, administrative rules, FSIS regulations, FSIS directives and notices, and any other policies, and be able to explain how their State programs are \u201cat least equal to\u201d FSIS\u2019s Federal inspection program requirements. The State officials should include a narrative that describes any changes in the State laws and regulations over the past 12 months, and of any proposed changes that may affect their \u201cat least equal to\u201d status over the subsequent 12 months. Objective State MPI programs need to periodically review applicable State laws, regulations, FSIS Directives and Notices and other FSIS policies to ensure the State programs provide a level of protection that is \u201cat least equal to\u201d those imposed by FMIA, PPIA, HSSA and regulations in section 9 of the CFR.

Statutory Authority and Food Safety Regulations Methods and Procedures State MPI programs need to have methods to periodically evaluate changes to Federal laws and regulations for applicability to State MPI programs, and need to revise State MPI laws and regulations as necessary. The methods should, at a minimum, address the following critical aspects: \u2022 Procedures for periodic evaluation of changes to applicable laws and regulations; \u2022 State legislative procedures; \u2022 State emergency legislative procedures; Page 17", "\u2022 State rulemaking procedures; and \u2022 State emergency rulemaking procedures. Evidence of system application State MPI programs should provide evidence which demonstrates implementation of methods and procedures that are \u201cat least equal to\u201d those of FSIS\u2019s Federal inspection program. At a minimum, the State MPI program should submit:

\u2022 Documentation of periodic evaluations of current State laws, regulations and other policies; \u2022 The State laws and regulations applicable when species other than those

covered by the FMIA and PPIA are considered amenable under State laws; \u2022 Current copies or Web links to State laws, regulations, and other policies with specific cross-references to 9 CFR; \u2022 Current copies or Web links to State rulemaking and emergency rulemaking procedures; \u2022 Documentation of laws and regulations currently undergoing State rulemaking and emergency rulemaking processes which affect the State MPI program; \u2022 Documentation that verify State laws are \u201cat least equal to\u201d the provisions of the FMIA, PPIA, and HMA as specified in Attachment 2; and NOTE: The Statutory Side-by-Side Comparison Table (Attachment 2, page 19) has been provided as a tool for the State MPI programs to demonstrate comparable State statutes, laws, or regulations for each of the applicable FMIA, PPIA, and HMA provisions. \u2022 Legal documentation that State MPI programs have the authority to impose meat and poultry inspection laws and regulations with the same purposes as the Federal laws that govern FSIS\u2019s Federal inspection program.

Page 18", "Attachment 2 STATE MPI PROGRAM STATUTORY SIDE-BY-SIDE COMPARISON TABLE FEDERAL Acts Comparable Specific State Statutes, Laws, Rules or Regulations Federal Meat Inspection Act Subchapter I - Inspection Requirements; Adulteration & Misbranding.

\u00a7601. Definitions. \u00a7602. Congressional statement of findings. Not applicable to \u201cat least equal to\u201d criteria Ante-Mortem And Post-Mortem Inspection Requirements \u00a7603. Inspection of meat and meat food products. Authority To Take Action Against Any Persons Found To Be Engaging In Inhumane Methods Of Slaughter

b)Humane methods of slaughter. In conjunction with: 7 U.S.C. \u00a7 1902 - Humane methods. \u00a7604. Post mortem examination of carcasses and marking or labeling; destruction of carcasses condemned; reinspection. Re-inspection Requirements \u00a7605. Examination of carcasses brought into slaughtering or packing establishments, and meat food products issued from and returned thereto; conditions for entry. \u00a7606. Inspection and labeling of meat food products. \u00a7607. Labeling, marking, and container requirements. Sanitation Requirements \u00a7608. Sanitary inspection and regulation of slaughtering and packing establishments; rejection of adulterated meat or meat food products. \u00a7609. Examination of animals and food products thereof, slaughtered and prepared during nighttime. Not applicable for \u201cat least equal to\u201d criteria Prohibited Acts \u00a7610. Prohibited acts. Devices, Marks, Labels, and Certificates; Simulations Page 19", "\u00a7611. Devices, marks, labels, and certificates; simulations. Notification \u00a7612. Notification. Plans and Reassessment \u00a7613. Plans and reassessments. \u00a7614. Repealed. Not applicable for \u201cat least equal to\u201d criteria \u00a7615. Inspection of carcasses, meat intended for export. Not applicable for \u201cat least equal to\u201d criteria \u00a7616. Inspectors of carcasses, etc., meat intended for export; certificates of condition. Not applicable for \u201cat least equal to\u201d criteria \u00a7617. Clearance prohibited to vessel carrying meat for export without inspector's certificate. Not applicable for \u201cat least equal to\u201d criteria \u00a7618. Delivery of inspectors' certificates, and of copies. Not applicable for \u201cat least equal to\u201d criteria \u00a7619. Marking, labeling, or other identification of kinds of animals of articles' derivation; separate establishments for preparation and slaughtering activities. Not applicable for \u201cat least equal to\u201d criteria \u00a7620. Imports. Not applicable for \u201cat least equal to\u201d criteria \u00a7621. Inspectors make examinations provided for; appointment; duties; regulations. Bribery \u00a7622. Bribery of or gifts to inspectors or other officers and acceptance of gifts. \u00a7623. Exemptions from inspection requirements.

\u00a7624. Storage and handling regulations; violations; exemption of establishments subject to non-Federal jurisdiction. Not applicable for \u201cat least equal to\u201d criteria

\u00a7625. Inapplicability of certain requirements to catfish. Not applicable for \u201cat least equal to\u201d criteria Prohibition of articles not intended for use as human food; denaturation or other identification prior to distribution in commerce; inedible articles

Subchapter II - Meat Processors & Related Industries \u00a7641. Prohibition of subchapter I inspection of articles not intended for use as human food; denaturation or other identification prior to distribution in commerce; inedible articles. Page 20","Record-Keeping Requirements And Examination Of Records \u00a7642. Recordkeeping requirements. Registration Of Business, Name Of Person, And Trade Names. \u00a7643. Registration of business, name of person, and trade names. \u00a7644. Regulation of transactions, transportation, or importation of 4-D animals to prevent use as human food. \u00a7645. Federal provisions applicable to State or Territorial business transactions of a local nature and not subject to local authority. Not applicable for \u201cat least equal to\u201d criteria Subchapter III - Federal & State Cooperation \u00a7661. Federal and State cooperation. Not applicable for \u201cat least equal to\u201d criteria Inspection Services; Refusal Or Withdrawal; Hearing; Business Unfitness Based Upon Certain Convictions; Other Provisions For Withdrawal Of Services Unaffected; Responsible Connection With Business; Finality Of Secretary's Actions; Judicial Review; Record.

Subchapter IV - Auxiliary Provisions \u00a7671. Inspection services; refusal or withdrawal; hearing; business unfitness based upon certain convictions; other provisions for withdrawal of services unaffected; responsible connection with business; finality of Secretary's actions; judicial review; record. Detention \u00a7672. Administrative detention; duration; pending judicial proceedings; notification of governmental authorities; release. Seizure and Condemnation \u00a7673. Seizure and condemnation. \u00a7674. Federal court jurisdiction of enforcement and injunction proceedings and other kinds of cases; limitations of section 607(e) of this title. Not applicable for \u201cat least equal to\u201d criteria Assualts-Intimidation

\u00a7675. Assaulting, resisting, or impeding certain persons; murder; protection of such persons. Violations \u00a7676. Violations. \u00a7677. Other Federal laws applicable for administration and enforcement of chapter; location of inquiries; jurisdiction of Federal courts. Not applicable for \u201cat least equal to\u201d criteria \u00a7678. Non-Federal jurisdiction of federally regulated Not applicable for \u201cat least equal to\u201d criteria Page 21","matters; prohibition of additional or different requirements for establishments with inspection services and as to marking, labeling, packaging, and ingredients; recordkeeping and related requirements; concurrent jurisdiction over distribution for human food purposes of adulterated or misbranded and imported articles; other matters. \u00a7679. Application of Federal Food, Drug, and Cosmetic Act. Not applicable for \u201cat least equal to\u201d criteria \u00a7679a. Safe Meat and Poultry Inspection Panel. Not applicable for \u201cat least equal to\u201d criteria \u00a7679b. Pasteurization of meat and poultry. Not applicable for \u201cat least equal to\u201d criteria \u00a7679c. Expansion of Food Safety Inspection Service activities. Not applicable for \u201cat least equal to\u201d criteria \u00a7680. Authorization of appropriations. Not applicable for \u201cat least equal to\u201d criteria Subchapter IV-A - Inspections By Federal and State Agencies \u00a7683. Interstate shipment of meat inspected by Federal and State agencies for certain small establishments. Not applicable for \u201cat least equal to\u201d criteria Subchapter V - Inspections by Federal and State Agencies \u00a7691.

Omitted. Not applicable for \u201cat least equal to\u201d criteria \u00a7692. Inspection extended to reindeer. Not applicable for \u201cat least equal to\u201d criteria \u00a7693. Inspection of dairy products for export. Not applicable for \u201cat least equal to\u201d criteria \u00a7694. Authorization of appropriations. Not applicable for \u201cat least equal to\u201d criteria \u00a7695. Payment of cost of meat-inspection service; exception for cost of overtime. Not applicable for \u201cat least equal to\u201d criteria Poultry Products Inspection Act Comparable Specific State Statutes, Laws, or Rules \u00a7451. Congressional statement of findings. Not applicable for \u201cat least equal to\u201d criteria \u00a7452. Congressional declaration of policy. Not applicable for \u201cat least equal to\u201d criteria \u00a7453. Definitions. \u00a7454. Federal and State cooperation in development and administration of State poultry product inspection programs. Not applicable for \u201cat least equal to\u201d criteria Ante-mortem and Post-mortem inspection and Reinspection requirements Page 22", "\u00a7455. Inspection in official establishments. Sanitation Requirements \u00a7456. Operation of premises, facilities and equipment. \u00a7457. Labeling and container standards. Prohibited Acts \u00a7458. Prohibited acts. Devices, Marks, Labels, and Certificates; Simulations (b) No brand manufacturer, printer, or person \u2026 (c) No person shall forge \u2026 Notification \u00a7459. Compliance by all establishments. (b) Notification. Plans and Reassessment (c) Plans and reassessments. Prohibition Of Articles Not Intended For Use As Human Food; Denaturation Or Other Identification Prior To Distribution In Commerce; Inedible Articles \u00a7460. Miscellaneous activities subject to regulation. Record-Keeping And Examination Of Records (b) Recordkeeping requirements; persons liable; scope of disclosure; access to places of business; examination of records, facilities, and inventories; copies; samples. (c) Registration of business, name of person, and trade names. (d) Regulation of transactions, transportation, or importation of dead, dying, disabled or diseased poultry or carcasses to prevent use as human food. (e) Federal provisions applicable to State or Territorial business transactions of a local nature and not subject to local authority. Assaults and Intimidation \u00a7461. Offenses and punishment. \u00a7462. Reporting of violations; notice; opportunity to present views. \u00a7463. Rules and regulations. Not applicable for \u201cat least equal to\u201d criteria \u00a7464. Exemptions. \u00a7465. Limitations upon entry of poultry products and Page 23", "other materials into official establishments. \u00a7466. Imports. Not applicable for \u201cat least equal to\u201d criteria Inspection Services; Refusal Or Withdrawal; Hearing; Business Unfitness Based Upon Certain Convictions; Other Provisions For Withdrawal Of Services Unaffected; Responsible Connection With Business; Finality Of Secretary's Actions; Judicial Review; Record. \u00a7467. Inspection services. Detention \u00a7467a. Administrative detention; duration; pending judicial proceedings; notification of government authorities; release; removal of official marks. Seizure and Condemnation \u00a7467b. Seizure and condemnation. \u00a7467c. Federal court jurisdiction of enforcement and injunction proceedings and other kinds of cases; limitations; United States as plaintiff; subpoenas. Not applicable for \u201cat least equal to\u201d criteria \u00a7467d. Administration and enforcement; applicability of penalty provisions; conduct of inquiries; power and jurisdiction of courts. Not applicable for \u201cat least equal to\u201d criteria \u00a7467e. Non-Federal jurisdiction of federally regulated matters; prohibition of additional or different requirements for establishments with inspection services and as to marking, labeling, packaging, and ingredients; recordkeeping and related requirements; concurrent

jurisdiction over distribution for human food purposes of adulterated or misbranded and imported articles; other matters. Not applicable for \u201cat least equal to\u201d criteria \u00a7467f. Federal Food, Drug, and Cosmetic Act applications. (a) Exemptions; authorities under food, drug, and cosmetic provisions unaffected. (b) Enforcement proceedings; detainer authority of representatives of Secretary of Health and Human Services. Not applicable for \u201cat least equal to\u201d criteria \u00a7468. Cost of inspection; overtime. Not applicable for \u201cat least equal to\u201d criteria \u00a7469. Authorization of appropriations. Not applicable for \u201cat least equal to\u201d criteria \u00a7470. Omitted. Not applicable for \u201cat least equal to\u201d criteria \u00a7471. Safe Meat and Poultry Inspection Panel. Not applicable for \u201cat least equal to\u201d criteria \u00a7472. Interstate shipment of poultry inspected by Not applicable for \u201cat least equal to\u201d criteria Page 24", "Federal and State agencies for certain small establishments. Humane Methods of Livestock Slaughter Act Comparable Specific State Statutes, Laws, or Rules \u00a71901. Findings and declaration of policy. Not applicable for \u201cat least equal to\u201d criteria \u00a71902. Humane methods. \u00a71904. Methods research; designation of methods. Not applicable for \u201cat least equal to\u201d criteria \u00a71906. Exemption of ritual slaughter. \u00a71907. Practices involving nonambulatory livestock. Not applicable for \u201cat least equal to\u201d criteria Page 25", "Criteria for \u201cat least equal to\u201d Determination Each State MPI program need to submit a current narrative describing the State inspection system used to enforce all applicable laws, regulations, and FSIS policies. The State system should have the capability to correct any deviations from regulatory requirements that may affect its program\u2019s being \u201cat least equal to\u201d FSIS\u2019s Federal inspection program. State MPI programs need to submit any supporting documentation (preferably completed reports and documents) to demonstrate the State inspection system, as described in the narrative, has been implemented, is functioning as intended, and will ensure the State MPI program has the ability to remain \u201cat least equal to\u201d FSIS\u2019s Federal inspection program for the next 12 months. Inspection methods and procedures followed under a State MPI program must be \u201cat least equal to\u201d the FMIA, PPIA, HMA, the applicable regulations in 9 CFR 300 to end, and applicable policies issued for FSIS\u2019s Federal inspection program. At a minimum, the State inspection program should include the following criteria: \u2022 Ante-mortem A State MPI program is to examine and inspect all livestock and poultry before slaughter to determine whether animals are fit for slaughter and can be used for human food. A State MPI program should verify that establishments present all animals for ante-mortem inspection in accordance with the FMIA, PPIA, and 9 CFR, ensuring animals with abnormalities and signs that could otherwise indicate disease are removed from human edible food channels. \u2022 Post-mortem State Inspection Program Personnel (IPP) should examine and inspect carcasses in the slaughter process and post-mortem in State inspected establishments to determine whether carcasses and parts are wholesome and not adulterated and thus permitted to receive the State mark of inspection. Inspection of meat and poultry carcasses, including applicable parts, is conducted in a manner \u201cat least equal to\u201d FSIS\u2019s processes, as described in 9 CFR 311 and 381, Subpart K, respectively. \u2022 Sanitation A State MPI program should verify that establishments have developed, implemented, and maintained Sanitation Standard Operating Procedures (Sanitation SOPs) consistent with requirements in 9 CFR 416. \u2022 Food Safety Requirements A State MPI program should verify each State inspected

establishment\u2019s food safety system, including Hazard Analysis and Critical Control Point (HACCP) plans are consistent with requirements in 9 CFR 417. \u2022 Non-Food Safety Requirements A State MPI program should verify all products produced for distribution in intrastate commerce are wholesome, and properly labeled. State IPP need to perform the appropriate activities for verifying Component 2: Inspection Page 26", "compliance with applicable requirements to those in the FMIA, PPIA, and 9 CFR. These activities include verifying accuracy of State inspected establishment product formulation for labeling and product standard of identity requirements; observing preparation or processing procedures; reviewing establishment records; and performing a variety of in-plant measurements and calculations.

\u2022 Regulatory Enforcement A State MPI program should develop and apply administrative enforcement consistent with those in 9 CFR 500 (Rules of Practice) to ensure establishments are provided due process of law and bring noncompliant establishments back into compliance with the FMIA, PPIA, HMSA, and 9 CFR. \u2022 Exempt Facility Reviews A State MPI program should verify that all products produced in State exempt facilities (either in official State inspected establishments or a separate facility) comply with regulatory and statutory requirements for sanitation, adulteration, and labeling. \u2022 New Issuance Reviews A State MPI program should evaluate the applicability of new FSIS laws, regulations, FSIS Directives and Notices and any other policies, and ensure they are implemented, as appropriate. Outcome When objectively reviewed by FSIS, the State MPI program is determined to be \u201cat least equal to\u201d FSIS\u2019s Federal inspection program. A State MPI program has: \u2022 A series of standards and policies that define how State inspected establishments can operate to produce safe, wholesome, not adulterated and properly labeled and packaged products.

\u2022 A comprehensive State regulatory inspection system (e.g., Public Health Information System (PHIS)) that collects, consolidates, and analyzes data and enforces the meat and poultry regulations at State-inspected establishment. NOTE: State MPI program Directors that have elected not to use FSIS\u2019s PHIS can find guidance information titled, \u201cAt least equal to\u201d data system guidance for State Cooperative Meat and Poultry Inspection (MPI) Programs electing not to use Public Health Information System (PHIS) (Attachment 3, page 38). State MPI program Directors are to submit the requested data system information with the annual selfassessment submission to the FSAB for review. By August 1st of each year, FSIS will provide State MPI programs with guidance on the PHIS inspection tasks. \u2022 Assurances that State-inspected establishments can maintain food safety systems to reduce, eliminate, or prevent food hazards (i.e., any biological, chemical, or physical property that may cause a food to be unsafe for human consumption) Page 27", "\u2022 A system to carry out administrative actions when State inspected establishments are not meeting the provisions of \u201cat least equal to\u201d the FMIA, PPIA, HMSA, applicable State laws, and 9 CFR \u2022 A system to review exempt facilities to determine their compliance under the sanitation, adulteration, labeling, and other statutory and regulatory requirements \u2022 A system to evaluate the applicability of new FSIS policies and determine how to implement the policies in the State MPI program \u201cAt least equal to\u201d Requirements The State MPI program is required to maintain: \u2022 A Slaughter Inspection System; \u2022 A Food Safety Verification System; \u2022 A Non-Food Safety Verification System; \u2022 An Exempt Facility Review System; and \u2022 A New Issuance Review System. NOTE: State MPI program Directors need to submit the data integrity information for the data collected and maintained in their system in place of the

PHIS. The data integrity information should include: \u2022 The type of data maintained outside of PHIS (e.g., FSAs, custom exempt reviews, NOIEs); \u2022 How the data integrity is maintained (e.g., safeguards to restrict access, security tools); and \u2022 The State law or administrative rule that governs the security and integrity preservation of meat and poultry inspection program records. Slaughter Inspection System State MPI programs should maintain a slaughter inspection system that is able to verify whether State inspected establishments comply with requirements consistent with the FMIA, PPIA, and HMSCA. The slaughter inspection system should have a method for assigning tasks and documenting task results for slaughter inspection requirements at State inspected establishments. The slaughter inspection system needs to be able to capture the results of ante-mortem and post-mortem inspection activities (e.g., suspected animals, condemned carcasses and parts) including the capability to capture any regulatory noncompliance and regulatory control actions taken. State MPI program officials should create or adopt slaughter inspection policies and procedures for conducting ante-mortem and post-mortem inspection activities that ensure compliance with Federal and State laws and regulations. Page 28", "Objective To implement state inspection activities which ensure animals are suitable for slaughter; products are not adulterated, wholesome, properly labeled, marked, and packaged, and carcasses and parts are eligible for human consumption. Inspection Methods and Procedures State MPI programs should implement slaughter inspection methods and procedures \u201cat least equal to\u201d those of FSIS\u2019s Federal inspection program. The methods and procedures at a minimum should include: \u2022 Methods and procedures to inspect livestock and poultry before slaughter (antemortem inspection) and verify that animals offered for slaughter have received ante-mortem inspection \u2022 Procedures to follow when State IPP observe animals showing symptoms of disease or abnormalities and signs that could indicate disease or other health conditions that would prohibit the animal from entering the food supply \u2022 Procedures to mark and document dispositions of livestock following antemortem inspections \u2022 Methods and procedures to inspect livestock and poultry after slaughter (postmortem inspection) to make and document dispositions of carcasses following post-mortem inspections \u2022 Procedures to verify State inspected establishments that slaughter cattle and establishments that process the carcasses or parts of cattle are complying with 9 CFR 310.22, requiring the removal, segregation, and disposition of specified risk materials (SRMs) \u2022 Methods and procedures used to document and maintain case files supporting administrative enforcement and other actions taken under the authority of FMIA, PPIA, and applicable State laws \u2022 Methods and procedures to assess whether slaughter inspection activities successfully meet the State MPI program management\u2019s expectations for: \u2022 In-Plant Level Slaughter Inspections \u2022 Ante-mortem \u2022 Post-mortem \u2022 Noncompliance regulatory documentation \u2022 Enforcement actions \u2022 Product recalls (e.g., uninspected animals and carcasses) \u2022 Central Office Level Assessments \u2022 Administrative case development Page 29", "\u2022 Program personnel competency Evidence of system application A State MPI program should provide evidence that demonstrates the implementation of a State slaughter inspection system that is \u201cat least equal to\u201d that of the FSIS\u2019s Federal inspection program. At a minimum, the State MPI program should submit: \u2022 Representative State Animal Disposition Summary\PHIS analogous reports that list animal and carcass dispositions performed within the last 12 months \u2022 Documentation of regulatory

control, withholding, suspension, enforcement, or administrative actions taken when noncompliance is identified (e.g., Noncompliance Records (NRs), 30 day letters, Notice of Intended Enforcement (NOIE) letters, Suspension letters, or notification to withhold the marks of inspection) \u2022 Management\u2019s evaluation and results of State slaughter inspection system performance Food Safety Verification System The sanitation criteria incorporate the regulations that address SPS, Sanitation SOPs, and HACCP, which are identified as essential parts of a food safety system. The regulations require that State inspected establishments maintain Sanitation SOPs and meet the SPS requirements. Sanitation SOPs are a prerequisite to an establishment\u2019s HACCP plan, and establishments may use Sanitation SOPs to support decisions in the hazard analysis that certain hazards are not reasonably likely to occur. State inspected establishments may also maintain other prerequisite programs to support decisions in their hazard analyses. The State MPI programs are required to maintain a food safety verification system capable of identifying noncompliances in an establishment\u2019s food safety systems. The State MPI system should have the ability to identify deleterious trends that occur in State inspected establishments\u2019 food safety system (e.g., increased number of NRs, increased positive sample results), and should also be able to document the results of food safety verification activities, including regulatory noncompliance and regulatory actions taken. Additionally, State MPI program managers are required to adopt or create policies for conducting food safety verification activities to ensure compliance with Federal and State laws and regulations. Objective To implement food safety verification activities that ensure all State inspected meat and poultry products found in intrastate commerce are safe, wholesome, not adulterated and properly marked, labeled and packaged, and can verify State inspected establishments comply with applicable State laws, regulations and policies. Page 30", "Food Safety Verification System Methods and Procedures State MPI programs need to implement food safety verification system methods and procedures \u201cat least equal to\u201d those of FSIS\u2019s Federal inspection system. The methods and procedures at a minimum should include: \u2022 Methods to schedule tasks, record food safety verification tasks, and document noncompliance with regulatory requirements \u2022 Procedures to protect the public health by properly verifying State inspected establishments\u2019 compliance with the pathogen reduction, sanitation, and the HACCP regulations \u2022 Procedures to verify that State inspected establishments that slaughter cattle and establishments that process the carcasses or parts of cattle are complying with 9 CFR 310.22 and prescribe to requirements for the removal, segregation, and disposition of SRMs \u2022 Procedures to verify State inspected slaughter operations are implementing sanitary dressing and process control procedures that prevent contamination of carcasses \u2022 Procedures to verify that State inspected establishments implement other prerequisite programs as described and in accordance with 9 CFR 417 \u2022 Procedures for protecting public health by verifying, documenting, and enforcing the requirements for no visible fecal material, milk, or ingesta on livestock carcasses at or immediately after the final rail, and by verifying feces, ingesta, and milk are not present on head meat, cheek meat, and weasand meat \u2022 Procedures for verifying visible fecal material are not present on State inspected poultry carcasses entering the chill tank \u2022 Procedures to protect the public health by properly verifying State inspected establishments\u2019 compliance with the pathogen reduction, sanitation, and the HACCP regulations \u2022 Procedures for holding weekly meetings with State inspected establishment

management to discuss topics pertaining to the establishments\u2019 food safety system and other issues which could affect public health \u2022 Methods to investigate and analyze all food safety aspects (e.g., FSA) that relate to State inspected establishments and their individual products, the design and validity of the establishments\u2019 hazard analyses, HACCP plans, Sanitation SOP, pre-requisite programs, testing programs, and any other programs that constitute the establishments\u2019 HACCP systems \u2022 Methods to categorize State inspected processing and slaughter establishments into a priority level for FSA scheduling, using public health decision criteria, in addition to traditional event-based scheduling Page 31", "\u2022 Methods used to document and maintain case files that support administrative enforcement and other actions taken under the authority of the FMIA, PPIA, and applicable State laws \u2022 Methods to assess whether food safety verification activities successfully meet the State MPI program management\u2019s expectation for: \u2022 In-Plant Level Food Safety Verifications \u2022 SPS \u2022 SSOP \u2022 Prerequisite programs \u2022 HACCP \u2022 Noncompliance regulatory documentation \u2022 Enforcement actions \u2022 Product recalls \u2022 Central Office Level Assessments \u2022 FSA \u2022 Administrative case development \u2022 Program personnel competency Evidence of system application A State MPI program should provide evidence that demonstrates implementation of a food safety verification system \u201cat least equal to\u201d that of the Federal inspection system. At a minimum, the State MPI program should submit: \u2022 Representative HACCP Summary\PHIS analogous reports by State inspected establishments\circuits\districts that list all food safety verification tasks performed within the last 12 months \u2022 Documentation of enforcement and administrative actions taken when regulatory noncompliance was identified (e.g., Noncompliance Records (NRs), 30 day letters, Notice of Intended Enforcement (NOIEs) letters, Suspension letters, withhold the marks of inspection letters) \u2022 In-depth establishment food-safety reviews (e.g., FSAs, and supervisory establishment reviews) \u2022 State issuances and policies that are different than those issued by FSIS \u2022 Completed grant-of-inspection approval process, and withdrawal documents \u2022 Evidence and verification methods that State MPI programs use as an assurance that their program is effectively implemented Page 32", "\u2022 Documentation of actions taken (e.g., rejection of the knock box, suspension) in response to identified SPS, Sanitation SOP, or HACCP noncompliance State MPI programs should submit completed supporting documentation to demonstrate that these programs, as described in the narrative, have been implemented. The State MPI programs need to ensure controls exist and are functioning as intended to maintain their operations over the next 12 months. Non-Food Safety Verification System5 The State MPI program should maintain a non-food-safety verification system that includes methods and procedures for verifying that State inspected meat and poultry products are wholesome, not economically adulterated, truthfully labeled, and meet the non-food-safety regulatory requirements. The system should also document identified noncompliances and regulatory actions taken. State MPI program managers should adopt policies for conducting non-food-safety verification to ensure compliance with Federal and State laws and regulations. Objective To implement State inspection activities that ensure all State inspected meat and poultry products found in intrastate commerce are safe, wholesome, not adulterated and properly marked, labeled and packaged to verify State-inspected establishments comply with applicable State laws, regulations and policies. Non-food Safety Verification System Methods

and Procedures State MPI programs need to implement methods and procedures \u201cat least equal to\u201d those of FSIS\u2019s Federal inspection program. The methods and procedures at a minimum should include: \u2022 Methods to schedule and record non-food safety verification tasks, and document noncompliance with regulatory requirements \u2022 Methods to verify State inspected establishments comply with non-food safety regulatory requirements \u2022 Procedures for: \u2022 Observing establishment product formulation \u2022 Verifying the accuracy of labeling \u2022 Observing preparation or processing procedures 5 \u201cNon-food safety consumer protection\u201d refers to consumer protection activities other than those focused directly on food safety and public health. Under the FMIA and the PPIA, FSIS is responsible for ensuring that products are wholesome; are properly marked, labeled, and packaged; and are not economically adulterated or do not contain components that, while not actually unsafe, are undesirable. Page 33", "\u2022 Reviewing establishment records \u2022 Examining product \u2022 Checking product identification, condition and temperature \u2022 Performing a variety of other in-plant measurements, testing, and calculations \u2022 Procedures to verify and determine whether product labels are not false or misleading and meet applicable requirements of 9 CFR 412 (formerly 9 CFR 317.4, 317.5, 381.132, and 381.133). \u2022 Methods to review and approve sketch labels and supporting documentation \u2022 Methods used to document and maintain case files supporting administrative enforcement and other actions taken under the authority of the FMIA, PPIA, and applicable State laws \u2022 Methods to assess whether State non-food safety requirements and label approval verification activities successfully meet the State MPI program management\u2019s expectation for: \u2022 In-Plant Level Non-Food Safety Verifications \u2022 Net weights \u2022 Standards of identity \u2022 Generic label requirements \u2022 Noncompliance regulatory documentation \u2022 Enforcement actions \u2022 Product recalls for non-food safety situations \u2022 Central Office Level Assessments \u2022 Label approval process \u2022 Administrative case development \u2022 Program personnel competency Evidence of System Application A State MPI program needs to provide evidence that its non-food-safety verification system is \u201cat least equal to\u201d \u201d FSIS\u2019s Federal inspection program. At a minimum, the State MPI program should submit: \u2022 Representative Summary or PHIS-analogous reports by establishments\circuits\districts that list all non-food-safety requirement verification tasks performed within the last 12 months \u2022 Final labels including supporting documentation (e.g., sketch labels, label applications, ingredient formulation worksheets) Page 34", "\u2022 Approved label tracking logs \u2022 In-depth establishment reviews (e.g., supervisory establishment reviews) \u2022 Evidence and verification methods State MPI programs use to assure their program is effectively implemented (e.g., label approvals, label reviews) \u2022 Documentation of actions taken in response to non-food safety requirements verification noncompliance Exempt Facility Review System The State MPI program needs to maintain a system to conduct reviews of exempt facilities (either within official State inspected establishments or separate facilities) to determine their compliance with the FMIA, PPIA, applicable State laws, regulations and policies. State MPI program managers should adopt or create policies for conducting reviews of exempt and poultry exempt facilities. Objective To ensure State exempt facilities comply with applicable State laws, regulations and policies. Exempt Facility Review Methods and Procedures State MPI programs need to implement

review methods \u201cat least equal to\u201d those of FSIS\u2019s Federal inspection program. The methods, at a minimum, should include: \u2022 A review of the State exempt operation to verify livestock and poultry carcasses and products are: \u2022 Not adulterated or misbranded \u2022 Handled humanely (livestock) \u2022 Prepared under sanitary conditions \u2022 Properly marked and packaged \u2022 Stored separately from State inspected products \u2022 Documented according to regulatory requirements \u2022 A method to assess whether the State exempt facility activities successfully meet the State MPI program management\u2019s expectations Page 35", "Evidence of system application A State MPI program needs to provide evidence that demonstrates implementation of an exempt facility review system that is \u201cat least equal to\u201d that of FSIS\u2019s Federal inspection system. At a minimum, the State MPI program should submit: \u2022 Documentation and tracking logs for State exempt facility reviews \u2022 Management\u2019s evaluation and results of the State exempt facility review system performance New Issuance Review System Objective The new issuances list is updated quarterly and is used to verify that State MPI programs are staying current with new FSIS policies. FSIS routinely issues regulations and notices in the Federal Register to communicate new policies and requirements to the public. FSIS also routinely issues Directives and Notices to Federal IPP to provide direction and guidance regarding inspection and enforcement activities. Each quarter, FSIS provides State MPI programs with an updated list of all applicable issuances published since the previous quarter. FSIS continues to provide this information in an effort to better communicate the \u201cat least equal to\u201d criteria for State MPI programs. State MPI programs are to review all issuances and incorporate any necessary modifications in their programs. State MPI programs are to submit a response to the Quarterly List of Applicable FSIS Issuances within 30 days after receipt of the list. New Issuances Methods and Procedures While State MPI programs are not required to follow FSIS issuances verbatim or to issue similar documents to their inspection program personnel, they need to consider the implications of each issuance and are expected to be able to explain their \u201cat least equal to\u201d actions (even if their decision is to do nothing) related to the activity or issue covered by the FSIS issuances. When a policy is issued by FSIS, State MPI programs need to have methods in place to determine the applicability of the policy to their State program, and decide how to communicate instructions for its implementation within their State inspection programs. The State\u2019s results will be documented as a response to each new issuance on the Quarterly List of Applicable FSIS Issuances. For each new issuance, using one of the alternatives listed below, the State MPI program should document that the State: \u2022 Determined that the issuance has no application for its State MPI program maintaining its \u201cat least equal to\u201d status; the State should fully explain why; Page 36", "\u2022 Adopted essentially the same approach in its State MPI program; and submitted documentation demonstrating implementation; or \u2022 Adopted measures in the State MPI program that the State considers to be \u201cat least equal to\u201d FSIS\u2019s Federal inspection program; provided the reason and justification for doing so, explained why and how they became convinced that they are \u201cat least equal to\u201d FSIS\u2019s Federal inspection program, and provided documentation demonstrating implementation. Evidence of system application State officials need to be able to provide a justification for their \u201cat least equal to\u201d determination for each new Federal issuance. State MPI programs are to respond to the Quarterly List of Applicable FSIS Issuances

sent on or before the first day of each quarter of the Federal fiscal year (e.g., October, January, April, and July) within 30 calendar days of receipt. The response should include a description of the methods used to distribute the issuances and evidence of delivery, and a summary of how the new issuance or policy change is being implemented. States should submit any documentation that demonstrates how each issuance was implemented. Examples of the manner in which issuances are implemented are included in the Quarterly List of Applicable FSIS Issuances. However, other documents may be used to demonstrate the implementation. States should enter information into the designated column on the Quarterly List of Applicable FSIS Issuances, and attach the responses to an email to the Federal State Audit Branch (FSAB) at: StateMPIProgramSubmissions@fsis.usda.gov, or by USPS, FedEx, UPS, or FAX (402-344-5104). Page 37", "Attachment 3 \u201cAt Least Equal To\u201d Data System Guidance for State Cooperative Meat and Poultry Inspection (MPI) Programs Electing Not to Use Public Health Information System (PHIS) I. PURPOSE To provide guidance to State Cooperative Meat and Poultry Inspection (MPI) programs electing to use a data system other than FSIS\u2019s PHIS for meeting the \u201cat least equal to\u201d data system essentials. II. BACKGROUND The Federal Meat Inspection Act (FMIA) (21 U.S.C. 661) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 454) authorize FSIS to cooperate with State agencies in developing and administering their own Meat and Poultry Inspection programs. Individual State MPI programs are required to operate in a manner and with authorities that are \u201cat least equal to\u201d the ante-mortem and post-mortem inspection, reinspection, sanitation, recordkeeping, and enforcement provisions as provided for in the FMIA and PPIA. Therefore, State MPI programs are required to develop a data system with characteristics that can produce inspection and recordkeeping outcomes \u201cat least equal to\u201d FSIS\u2019s procedures. FSIS maintains PHIS as its data system. FSIS developed PHIS to maintain detailed records of regulatory compliance verification activities. The activities are conducted by FSIS\u2019s Federal inspectors and the information is entered into PHIS by FSIS personnel at official establishments, official import establishments, and registered facilities. The PHIS database maintains establishment and facility data, and the results of inspection verifications. FSIS uses this information to identify issues that require Agency attention. PHIS supports documentation of appeals to inspection decisions, scheduling, and documentation of Food Safety Assessments (FSA) and the ability to identify and notify suppliers of beef products that have tested positive for E. coli O157:H7. FSIS uses PHIS to manage FSIS\u2019s inspection assignments and FSIS\u2019s employee assignments to roles and establishments. The PHIS sample scheduler distributes product sample requests to Establishment Task Lists. FSIS uses PHIS to apply business rules and risk-based algorithms for sample selection and output reports of scheduled samples. These scheduled sample requests tasks are performed by FSIS\u2019s Federal IPP. FSIS uses PHIS to process information about imported products. FSIS\u2019s Federal IPP input reinspection results for imported products in to PHIS. PHIS\u2019s functionality includes a means for FSIS\u2019s Office of Policy and Program Development (OPPD), International Equivalence Staff (IES) and the Office of Investigation, Enforcement and Audit (OIEA) Management Control and Audit Staff (MCAD) to schedule and track foreign country audit activities. Page 38", "The information held in PHIS is shared with the Microbial (M2K) transactional database and the FSIS data warehouse. Information is written to the data warehouse from the PHIS transactional database to be used by other systems including the

Enterprise Reporting System (ERS). The FSIS data warehouse provides a source of legacy system data which is used to support the analysis of inspection, audit, and assessment outcomes, and it maintains data from VetNet and PulseNet. FSIS analyses the data collected in PHIS through its regulatory verification, compliance and enforcement, and sampling activities to assess the appropriateness of policy design and policy implementation. The analysis informs further policy development. Additionally, FSIS uses the information gathered from data analysis to ensure that policy and program components are effective in meeting the FSIS\u2019s public health goals and objectives. FSIS recognizes that an integrated infrastructure with high-quality data and feedback interaction is essential to a data-driven approach to inspection. A data-driven approach to inspection requires quality data collection methods, ongoing data analysis to refine analytical decision-making tools, and performance measures to assess the impact of policies and programs. The Task Library in PHIS supports the assignment of tasks to Establishment Task Lists. Each task is distributed to the Establishment Task List with a due date for completing the task. FSIS\u2019s Federal IPP have the ability to schedule the assigned tasks by moving the tasks from the Establishment task List to the Establishment Task Calendar. FSIS designed PHIS to allow IPP the flexibility to decide on which days they will perform the tasks. Alerts are issued when specific events requiring immediate attention occur. Alerts are also used to remind FSIS\u2019s Federal IPP to take a particular action, such as, acquiring a product sample for laboratory analysis. An alert consists of a \u201ctrigger\u201d and a \u201cnotification\u201d function. The trigger is a feature that automatically scans the data for a specific event, and upon finding it, issues the notification. The notification can take the form of an email sent by PHIS, a message on the user\u2019s PHIS Alerts Dashboard, or both. PHIS issues Public Health Regulation (PHR) alerts when there is a pattern of noncompliance at the establishment. Each month the Office of Data Integration and Food Protection (ODIFP) uses the results of inspection tasks to calculate the PHR noncompliance rate for each meat and poultry establishment as well as egg products plants. A PHR alert is issued to FSIS\u2019s Federal IPP when an establishment has a noncompliance rate that is elevated. Examples of other events that trigger alerts are: a large number of inspection tasks not completed at an establishment, high rates of noncompliance in an establishment, and a positive adulterant pathogen test result at an establishment (e.g., Escherichia coli (E. coli) O157:H7 in raw ground beef, Shiga toxin-producing Escherichia coli (STEC) in beef manufacturing trimmings, or Listeria monocytogenes (Lm)\u201c/Salmonella in ready-to- eat (RTE) products). The alert text gives directions to FSIS\u2019s Federal IPP by pointing them to the appropriate regulations and directives needed for the response. PHIS Dashboard Alerts and e-mail notifications are issued to Headquarters and FSIS\u2019s Federal IPP as events occur. The alerts and notifications provide FSIS\u2019s Federal IPP and FSIS\u2019s Headquarters personnel with information that is important to the execution of their work assignments. The PHIS includes a set of standard reports available to all FSIS administrative levels. FSIS produces a wide range of PHIS reports. The reports are run by FSIS personnel on an as needed basis. The reports are run for specific time frames identified by the user. The reports are available to FSIS personnel based on their assigned PHIS role. So, District management teams see aggregated reports for a District while FSIS\u2019s Federal IPP assigned to an establishment see reports for the assigned establishment. An example of a standard report is the monthly report of noncompliances by FSIS District Offices. Reports are used at all levels of FSIS to monitor operations, to identify areas needing corrective actions, and

to communicate progress towards goals. Users can review the reports and identify results that require investigation and establishment response. PHIS reports provide FSIS\u2019s Federal IPP and FSIS\u2019s Headquarters personnel with information that is important to the execution of their work assignments.

### III. ELEMENTS OF AN \u201cAT LEAST EQUAL TO\u201d DATA SYSTEM

To be \u201cat least equal to\u201d the FSIS\u2019s system, the State MPI data system needs to:

- \u2022 Collect, analyze and respond to State inspected establishment and State MPI program data;
- \u2022 Monitor data streams to determine State inspected establishment performance; and
- \u2022 Respond, near real-time, to State inspected establishments that may pose a risk to public health

To be \u201cat least equal to\u201d the State MPI data system needs to collect data from the following four activities:

- \u2022 Daily inspection verification activities at operating State inspected establishments
- \u2022 State MPI program HACCP verification testing
- \u2022 State MPI program in-depth food safety reviews
- \u2022 State MPI program administrative enforcement actions

Set out below are guidance and recommendations for State MPI programs to use in developing their data systems if they choose not to participate in PHIS. State MPI programs should monitor data collected from the four activities listed above. The data collected should be compared to different data sets (e.g., data of multiple circuits, data Page 40," of multiple establishments, and data from previous months) and analyzed to determine whether the State MPI program is meeting program goals and objectives. State MPI programs should take appropriate actions, based on the analysis, when goals and objectives are not being met.

1. Daily inspection verification activities at operating State inspected establishments

Data Collection State MPI programs need to collect State inspected establishment demographics (profiles). These profiles should include critical up-to-date information about the establishment\u2019s size, products produced, production volume, recall history, noncompliance history, and food defense plans. HACCP information for the establishment should be available in the profile and include summary information, processing categories, food safety hazards, critical control points, and prerequisite programs. A State MPI program should ensure State IPP are able to verify that State inspected establishments\u2019 profile information is accurate and current at set intervals (e.g., at least every thirty days or whenever the HACCP plan changes).

NOTE: By August 1st of each year, FSIS provides State MPI programs with guidance on the PHIS inspection tasks. The FSIS PHIS Inspection Task Catalog will be updated annually to reflect current PHIS task information and then distributed separately as an addendum to the State MPI programs.

Data Analysis The State MPI program\u2019s data system should contain public health-based decision criteria to identify State inspected establishments requiring more frequent inspection activities (e.g., increased directed food safety verification tasks). The State MPI program\u2019s data system should also include a mechanism to react to State inspection results. Examples of events or trends that would trigger the State MPI program to react to State inspection results include:

- \u2022 A large number of inspection activities not completed in State inspected establishments;
- \u2022 High rates of non-compliance in State inspected establishments;
- \u2022 A positive pathogen test result in State inspected establishments (e.g., E. coli O157:H7 in raw ground beef or Lm in RTE products)
- \u2022 Infrequent State inspected establishment profile updates (e.g., HACCP plan changes failed to be identified or documented)
- \u2022 Tasks are not being performed at frequencies sufficient to ensure the safety of public health Page 41","The State MPI programs should ensure data quality and accuracy so that the integrity of the information is not compromised (i.e.,

system identifying outdated establishment profile information or unperformed tasks). 2. State MPI program HACCP verification testing Data Collection The State MPI programs should maintain a system for tracking pathogen and residue testing results. Data Analysis The State MPI program's verification testing system should contain public healthbased decision criteria to identify establishments requiring more frequent inspection activities (e.g., increased directed sampling due to positive sampling results or concerns with establishment's production process). The system should include a mechanism to react to sampling results. Examples of events that would trigger the State MPI program to react to sampling results may include but are not limited to: A large number of sampling activities not completed at State inspected establishments A large number of laboratory discards Positive sampling results in State inspected establishments for adulterant pathogens (e.g., E. coli O157:H7 in raw ground beef, STEC in beef manufacturing trimmings, or Lm/Salmonella in RTE products) Violative residues Identifying long-term processes that may have exceeded their schedule (e.g., a Salmonella sample set that has not been finished) 3. State MPI program in-depth food safety reviews State MPI programs should have procedures (e.g., Food Safety Assessments (FSA)) to verify that an establishment's food-safety systems are effective and yielding products that are wholesome and not adulterated, properly marked, labeled and packaged. Data Collection A State MPI program system should track routine and "for cause" in-depth foodsafety reviews. Data Analysis Page 42,"The State MPI program's data system includes a mechanism to react to sampling and inspection results that could lead to a "for cause" in-depth food safety system review. Examples of events that may trigger the State MPI program to conduct a "for cause" in-depth food safety system review may include, but are not limited to: State inspected establishments not in compliance with specific laws and regulations A positive for STECs in raw ground beef or raw ground beef components A positive Lm or Salmonella in RTE products or a positive Lm food contact surface sample A Class I recall or a food-safety-related enforcement action (e.g., Notice of Intended Enforcement) that is not the result of an in-depth food safety system review State inspected establishments that fail Salmonella or Campylobacter performance standards A State inspected establishment that is the supplier of a product that tested positive for STECs in raw beef products Human illness linked to a product from a State inspected establishment A State inspected establishment that has a high level of public health-related Non-compliance Records (NR) 4. State MPI program administrative enforcement action State MPI programs should have procedures in place to initiate enforcement actions, as needed, to ensure food safety compliance. Data Collection The State MPI programs should maintain a system to collect data and facts to support administrative enforcement actions, and to track the results of actions taken (e.g., NRs, in-depth food-safety system reviews, intensified verification testing (IVT), suspensions, and recall information). Data Analysis The State MPI program's data system should include a mechanism to react to the data collected in support of administrative enforcement actions. Examples of events that may trigger the State MPI program to take administrative enforcement actions may include: Positive STECs in raw ground beef or raw ground beef components Page 43,"Positive Lm, Salmonella, or E. coli O157:H7 in RTE products or a positive Lm food-contact-surface sample A State inspected establishment that is the supplier of a product that tested positive for STECs in raw beef

products \u2022 Human illness linked to State inspected product from an establishment (possible recall) \u2022 State inspected establishments not in compliance with specific State laws and regulations An explanation of the data system and supporting documents should be included in the annual State Self-Assessment that is submitted to the Federal State Audit Branch by November 1 of each year.

IV. REFERENCES FSIS Public Health Information System (PHIS) Reference Information: FSIS Strategic Data Analysis Plan for Domestic Inspection

[http://www.fsis.usda.gov/wps/wcm/connect/84fa563e-0f5c-4df5-8e0499a04e9ce102/2010\\_Strategic\\_Data\\_Analysis\\_Plan.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/84fa563e-0f5c-4df5-8e0499a04e9ce102/2010_Strategic_Data_Analysis_Plan.pdf?MOD=AJPERES)

Data-Driven Inspection for Processing and Slaughter Establishments

[http://www.fsis.usda.gov/wps/wcm/connect/fcaeabab-b89e-4bd4-b990c697f34a797f/2010\\_Public\\_Health\\_Decision\\_Criteria\\_Report.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/fcaeabab-b89e-4bd4-b990c697f34a797f/2010_Public_Health_Decision_Criteria_Report.pdf?MOD=AJPERES)

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<http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/fsis-dataanalysis-and-reporting/data-reporting/public-health-regulations> Page 44", "Criteria for \u201cat least equal to\u201d Determination Each State MPI Program needs to submit a current narrative describing the complete verification sampling program used to evaluate the effectiveness of each State inspected establishment\u2019s food safety system. The narrative should identify the various chemical and microbiological sampling projects that are a part of the State MPI program\u2019s verification sampling program. The State MPI program should ensure that the product and the production environment are tested for microbiological contaminants or chemical residues, in a manner that is \u201cat least equal to\u201d FSIS\u2019s Federal sampling programs. NOTE: State MPI programs should not include any sampling activities (e.g., generic E. coli) conducted by establishments in the narratives. State MPI programs need to submit documentation that the verification sampling programs, as described in the narrative, have been implemented and have been functioning as intended over the last 12 months. Documentation should include factual information on the State\u2019s ability to maintain its program for the next 12 months. State MPI program officials report laboratory sample results per sample project in an easy-to-read format of the State MPI Program Sampling Activity Table (Attachment 4, page 5051). To be considered \u201cat least equal to\u201d FSIS\u2019s Federal inspection program in its verification sampling program, at a minimum, the State MPI sampling program needs to include the following criteria:

\u2022 Sampling Project Eligibility \u2013 State MPI programs consider product risk, product class, the product\u2019s intended use, and production volume when determining the eligibility for each sampling project. State programs are to include the criteria for determining the scope of sampling, including the frequency of scheduled samples on an average basis per year across all applicable State inspected establishments.

\u2022 Sample Result Analysis \u2013 State MPI programs analyze sample results for trends (e.g., samples collected but not analyzed, increased positive test results, and product non-availability for sample collection) that may influence program inspection activities.

\u2022 Response Plan for Positive Test Results \u2013 State MPI programs have action plans for responding to positive results, including actions taken by the State MPI program to recall product (See Component 6) and prevent adulterated product from entering commerce.

\u2022 Sampling Project Adaptability \u2013 The State MPI program\u2019s sampling verification projects should be adaptable to keep pace with changes, such as emerging Component 3: Sampling Programs Page 45", "pathogens, new products and

processes, new or revised policies, and new laboratory analytical methods. By August 1st of each year, FSIS provides State MPI programs with guidance on minimum testing frequencies for small and very small establishments. State MPI programs need to maintain a verification testing program, with laboratory capacity, to address food safety (e.g., adulterants) and other regulatory requirements (e.g., standards of identity, species identification). The verification program needs to include more specific criteria for routine analysis for the following product classes: Raw Product \u2022 Adulterant \u2022 Shiga toxin-producing Escherichia coli (STEC) in non-intact beef or intact product used to produce non-intact beef \u2022 Violative chemical compound residues (e.g., antibiotic drugs, pesticides, etc.) \u2022 Measure of food-safety system process control \u2022 Pathogen reduction performance standards for Salmonella in certain raw meat and poultry products. \u2022 Pathogen reduction performance standards for Campylobacter in certain raw poultry products. Ready-to-eat (RTE) product \u2022 Adulterant \u2022 Salmonella in meat and poultry products \u2022 Listeria monocytogenes in meat and poultry products NOTE: Listeria monocytogenes is also a food-contact-surface and environmental contaminant associated with meat and poultry products. Thus, the sampling project (e.g., routine Listeria monocytogenes (RLm) sampling project) needs to address the post-lethality environment in which RTE products are produced. State MPI programs need to have the capability to conduct the following analyses as needed: Raw and ready-to-eat (RTE) product \u2022 Adulterant Page 46", "\u2022 Unexpected biological, chemical, or physical hazards sufficient to cause illness (e.g., allergens) \u2022 Misbranding \u2022 Significant nutrition labeling deviations \u2022 Central nervous system tissue in boneless meat derived from advanced meat recovery systems \u2022 Species not identified on the label NOTE: It is not expected that the State MPI programs have a special laboratory for atypical analyses (e.g., bovine tuberculosis), but rather, that the State MPI program be able to procure atypical analyses when needed. Outcome When objectively reviewed by FSIS, the State MPI Program is determined to be \u201cat least equal to\u201d the Federal inspection system. The State MPI program has a system for preventing products adulterated with pathogenic bacteria or violative residues from reaching the public through reliable and timely laboratory analyses of samples. \u201cAt least equal to\u201d requirements State MPI programs should maintain a system for periodic verification of each State inspected establishment\u2019s food-safety system. NOTE: State MPI program Directors are to submit the data integrity information for the data collected and maintained in a system elected in place of PHIS. The data collected may include State laboratory or contract laboratory sample test results. The data integrity information should include: \u2022 The type of data maintained in the State MPI program system elected in place of PHIS (e.g., FSAs, custom exempt reviews, NOIEs). \u2022 How the State MPI program\u2019s data integrity is maintained (e.g., restriction to access the data, ability to track data changes). \u2022 The State law or administrative rule governing the security and integrity preservation of meat and poultry inspection program records. Objective To verify the effectiveness of each State inspected meat and poultry establishment\u2019s food-safety system to ensure that only safe, wholesome, not adulterated, properly marked, labeled and packaged meat and poultry products enter commerce. Page 47", "Verification Sampling Methods and Procedures State MPI programs need to apply verification sampling methods that are \u201cat least equal to\u201d those of FSIS\u2019s Federal inspection program. At a minimum, to \u201cbe at least equal\u201d verification sampling program methods need to: \u2022 Create sampling

frequencies based on product risk, product type, production volume, time of year, product availability, etc. \u2022 Ensure current sampling projects include all State inspected establishments producing eligible products (e.g., raw beef non-intact, RTE post-lethality exposed (see 9 CFR 430)) \u2022 Ensure current sampling projects include all State inspected establishments slaughtering eligible livestock and poultry classes and use the Kidney Inhibition Swab (KIS\u2122) test to screen for violative drug residues in applicable livestock NOTE: The KIS\u2122 test can detect residues for Tilmicosin, Tulathromycin, Bacitracin, Penicillin G, Neomycin, and Sulfonamide. \u2022 Respond to public health concerns associated with products that test positive for adulterants (e.g., increase inspection activity, perform \u201cfor cause\u201d FSA, conduct Intensified Verification Testing (IVT), initiate product recalls) \u2022 Respond to performance standard failures (e.g., based on Salmonella Performance Standards, Campylobacter Performance Standards) \u2022 Analyze sample results for trends (e.g., samples collected but not analyzed, increased positives results, product not available for sample collection) \u2022 Respond to adverse trends (e.g., adapting sample frequency, evaluate State inspection program personnel (IPP) understanding of sample collection) \u2022 Obtain serotype and Pulse-Field Gel Electrophoresis (PFGE) patterns of positive pathogens (partner with FSIS) \u2022 Assess whether sampling activities successfully meet the State MPI program management\u2019s expectation for: \u2022 Creating sampling frequencies \u2022 Sampling eligibility \u2022 Responding to positive sampling results \u2022 Managing positive pathogen results \u2022 State IPP competency Evidence of System Application Page 48", "A State MPI program needs to provide evidence that demonstrates implementation of a verification sampling program that is \u201cat least equal to\u201d FSIS\u2019s Federal inspection program. At a minimum, State MPI programs should submit: \u2022 A list of applicable sampling projects that identify the target agent (microbial or chemical), eligible establishments, projected sampling frequency, actual samples analyzed, and the number of positive or violative samples \u2022 Completed tracking log showing the scheduling and collection of samples per project (both microbiological and chemical) \u2022 Laboratory results (e.g., completed lab forms) \u2022 Documentation verifying how sample integrity is maintained (e.g., use of sample seals) \u2022 Directed and inspector generated residue sampling and results \u2022 Follow-up actions to positive results (e.g., recall actions, \u201cfor cause\u201d FSA, IVT, administrative enforcement) The information can be submitted using the table below or in another format.

Page 49", "Attachment 4 State MPI Program Sampling Activity Table (Suggested Format)

Name of State Agency:	Sampling Dates Covered:	Microbial and Residue Sampling	Number of ESTs Eligible for Sampling	Number Samples Targeted per EST (Intended Frequency)*	Number of Samples Actually Requested	Program wide Number of Viable Samples Analyzed per Program wide	Number of Confirmed Positives
		E. coli O157:H7 in raw ground beef and Salmonella (MT43)					
		E. coli O157:H7 and Non-O157 STEC (O26, O45, O103, O111, O121, O145) in raw beef trimmings (MT60)					
		E. coli O157:H7 in components other than trim (MT64)					
		E. coli O157:H7 in raw beef bench trim (MT65)	MT 44**	\u2022			
		Follow-up Testing for E. coli O157:H7 in Response to Ground Beef Positive Results (MT43)	MT 52**	\u2022			
		Testing of Beef Manufacturing Trimmings or Other Components from Originating Slaughter Suppliers(Based on a Positive Result (MT43))	MT 53**	\u2022			
		Follow-up Testing in Response to Positive Beef Manufacturing Trimmings Results (MT52 or MT60)					
		Listeria monocytogenes and Salmonella in RTE products not due to risk (RTEPROD- random)					
		Listeria monocytogenes and Salmonella in RTE					

products \u2013 risk based post-lethality exposed RTE products (RTEPROD- risk) Listeria monocytogenes in RTE products \u2013 risk based per 9 CFR 430 (RLm) Listeria monocytogenes in RTE products \u2013 risk based per 9 CFR 430 (IVT\*\*) Page 50", "By August 1st of each year, FSIS will provide the Guidance to States on Frequency of Microbiological Testing to identify the minimum testing frequencies for small and very small establishments. \*\*Complete for State MPI program follow-up testing as a result of a positive sample. Names and addresses of all laboratories used: (attach additional sheets if needed) Name: Address: Phone number: Salmonella in RTE products \u2013 risk based per 9 CFR 430 (IVT\*\*) Microbial and Residue Sampling # ESTs Eligible for Sampling # Samples Targeted per EST (Intended Frequency)\* # Samples Actually Requested Program wide # Viable Samples Analyzed per Program wide # Confirmed Positives Program wide Salmonella in Young Chicken Salmonella in Young Turkey Salmonella in comminuted Chicken Salmonella in comminuted Turkey Campylobacter in Young Chicken Campylobacter in Young Turkey Campylobacter in Ground Chicken Campylobacter in Ground Turkey Salmonella in raw Ground Beef (HC01) Residue Directed Residue inspector Generated Food Chemistry Other Page 51", "Criteria for \u201cat least equal to\u201d Determination Each State MPI program needs to submit a current narrative describing the personnel management system used to staff State-inspected establishments, the training of State inspection program personnel, and the supervision of inspection and compliance enforcement activities. State MPI programs need to submit any supporting documentation (preferably completed reports and documents) to show the system, as described in the narrative, has been implemented, is functioning as intended, and that the State MPI program remains \u201cat least equal to\u201d FSIS\u2019s Federal inspection program requirements for the next 12 months. State MPI program officials report the number of State-inspected establishments and number of State personnel performing duties, States can use the format of the State MPI Program Establishment Count (Attachment 5, page 59) and State MPI Program Employee Primary Roles (Attachment 6, page 60). State MPI programs are required to be \u201cat least equal to\u201d FSIS\u2019s Federal inspection program. The Staffing, Training, and Supervision system at a minimum need to include the following criteria: \u2022 Daily Inspection Coverage \u2013 State MPI programs provide and maintain inspection coverage at State inspected meat and poultry establishments every day the State inspection marks are applied to products; at least once per shift at processing establishments and inspection on the line during all slaughter operations. \u2022 Employee Training \u2013 State MPI programs provide MPI employees with sufficient knowledge, skills, and training that provide them with the ability to carry out State meat and poultry inspection and compliance enforcement duties in a manner that is \u201cat least equal to\u201d FSIS\u2019s Federal inspection program. \u2022 Supervision \u2013 State MPI programs provide direction to daily State inspection and compliance enforcement activities performed by State MPI program personnel. Outcome When objectively reviewed by FSIS, the State MPI program is determined to be \u201cat least equal to\u201d FSIS\u2019s Federal inspection program in its staffing, training, and supervision systems. The State MPI program needs to have: \u2022 State inspectors that perform inspection activities at State inspected meat and poultry establishments, as required by State laws to ensure only safe, wholesome, not adulterated, properly marked, labeled and packaged meat and poultry products receive the State mark of inspection. Component 4: Staffing, Training, and Supervision Page 52", "\u2022 Trained State inspection program personnel

capable of applying State MPI program methods and procedures in accordance with applicable State laws, regulations and directives, and are capable of making sound decisions based upon facts and evidence. \u2022 State MPI program managers and supervisors who can objectively evaluate the effectiveness of implemented program systems and competency MPI of State MPI program personnel \u201cAt least equal to\u201d Requirements The State MPI program needs to maintain: \u2022 A Staffing System, \u2022 A Training Program, and \u2022 A Supervisory System. NOTE: State MPI program Directors need to submit the data integrity information for the data collected and maintained in a system used in place of PHIS. The data integrity information should include: \u2022 The type of data maintained in the system used in place of PHIS (e.g., FSAs, custom exempt reviews, NOIEs). \u2022 How the data integrity is maintained (e.g., restriction to access the data, ability to track data changes). \u2022 The State law or administrative rules governing the security and integrity preservation of meat and poultry inspection program records. Staffing System The State MPI program needs to maintain a staffing system which periodically assesses the State\u2019s personnel needs required to meet the organizational objectives and public health goals. As priorities and needs shift, the State MPI program should be capable of considering changing factors when creating inspection assignments. State MPI programs also should be able to modify staffing policies to accommodate inspection demands of State inspected meat and poultry facilities without compromising the State MPI program\u2019s staffing objectives. Objective To provide daily inspection coverage at State meat and poultry establishments to ensure that only safe, wholesome, not adulterated, properly marked, labeled and packaged meat and poultry products receive the State mark of inspection. Page 53", "Staffing System methods and procedures State MPI programs need to implement staffing methods \u201cat least equal to\u201d those of FSIS\u2019s Federal inspection program. Staffing methods and procedures at a minimum should include: \u2022 Methods to determine the workload (e.g., complexity of State inspected establishment operations, distances between establishments, availability of inspection personnel) of inspection assignments (i.e., single establishment, multiestablishment assignments) and ensure daily inspection coverage is provided at all establishments producing products under the marks of inspection \u2022 Methods to verify inspectors perform required inspection activities on the scheduled inspection days: \u2022 Procedure to analyze staffing data for trends in missed inspections \u2022 Procedure to verify regulatory compliance at an establishment that applies marks of inspection to products on a day when State MPI program personnel miss a scheduled inspection \u2022 Procedure for providing inspection services (i.e., relief coverage) at an establishment when the assigned inspector is absent from duties \u2022 Methods to assess whether staffing successfully meets the State MPI program management\u2019s expectation for: \u2022 Creating State inspection assignments \u2022 Verifying performance of scheduled and missed State inspection activities \u2022 Scheduling relief coverage for State inspection assignments Evidence of System Application A State MPI program needs to provide evidence to demonstrate the implementation of a State staffing system that is \u201cat least equal to\u201d that of FSIS\u2019s Federal inspection program. At a minimum, the State MPI program should submit: \u2022 State staffing documentation (e.g., calendars, inspection activity logs, daily inspection assignments) to support they maintain inspection coverage on each shift at each State inspected establishment on days when the marks of inspection are being applied to products. The documentation should identify any

changes made to inspection assignments to accommodate for annual and emergency leave taken. Page 54", "\u2022 Follow-up documents confirming food safety requirements are met at State inspected establishments on days when products receiving the marks of inspection are produced and the State MPI program is unable to provide inspection services \u2022 Information regarding the number and types of State inspected establishments currently operating under the State MPI program in a plain language format (see the suggested table, State Establishment Count, at the end of this section) \u2022 Information identifying, by job description, the number of State employees who currently perform duties for the State MPI program in a plain language format (see the suggested table, State MPI Employee Primary Roles, at the end of this section) \u2022 A current organization chart identifying all State personnel who carry out aspects of the State meat and poultry inspection at all program levels. The State organization chart should include any personnel who are employed by other State programs outside of the State MPI program to assist in accomplishing their mission. In addition, the organizational chart should show supervisory boundaries and reporting lines of all State personnel involved. The submission of an organizational chart can provide the FSIS audit team with a clear understanding of how each State MPI program carries out its daily operational and administrative functions. Training Program Training and development of employees are key elements to the success of any organization. FSIS invests a considerable amount of time and resources in improving the skills of their workforce. State MPI programs need to have a State program in place to meet the training and development needs of their employees in a manner that is comparable to FSIS\u2019s Federal inspection program. Objective To provide the necessary knowledge, skills, and abilities, through formal and informal training, to ensure personnel can successfully complete inspection and other critical job duties. Training System The training system should include methods that provide State MPI program employees with both formal and informal learning experiences that contribute to individual growth and improved performance in their assigned positions. Formal training courses should be developed to provide employees with sufficient knowledge, skills, and the ability to carry out State meat and poultry inspection or enforcement duties in a manner that is \u201cat least equal to\u201d FSIS\u2019s Federal inspection program. The training methods and procedures at a minimum should address: Page 55" "\u2022 Inexperienced and newly hired employees in performing the specific job positions of the State MPI program \u2022 Ongoing professional and skill development for current employees (e.g., AgLearn courses, field workshops, professional conferences, on-the-job training) \u2022 Core inspection activities (e.g., ante-mortem inspection, humane handling, postmortem inspection, pathogen reduction/HACCP, Sanitation SOPs, Sanitation Performance Standards, Inspection Methods) \u2022 Core compliance enforcement activities (e.g., surveillance, follow-up surveillance, investigation, evidence collection, case development, compliance sample collection) \u2022 Training needs of all State employees who perform MPI program related duties \u2022 Testing criteria used to determine if employees have mastered the objectives and concepts of training courses \u2022 Standards for evaluating the competency of State MPI program trainers \u2022 Techniques for determining whether training activities meet the State MPI program management\u2019s expectations for: \u2022 Newly hired and inexperienced employees \u2022 Experienced employees \u2022 Core inspection activities \u2022 Core compliance enforcement activities \u2022 Assessment of training needs for all State MPI program employees Evidence of system

application A State MPI program needs to provide evidence that demonstrates implementation of a training system \u201cat least equal to\u201d FSIS\u2019s Federal inspection program. At a minimum, the State MPI program should submit: \u2022 A list of training courses offered to State MPI program personnel \u2022 Training certificates for employees\u2019 training completed within the last 12 months \u2022 Tracking logs (e.g., personnel, training class, circuit) \u2022 Management\u2019s evaluation and results of State training system performance Supervisory System A State MPI program needs to maintain a State supervisory system that aligns individual work with its public health and regulatory goals, and ensures recognition of strong performance and correction of unsatisfactory performance. State MPI program managers should adopt or create policies that encourage employee development and strengthen workforce competency. Page 56", "Objective To implement an effective State MPI inspection program, the program managers should establish and effectively communicate clear and measurable employee performance standards, analyze performance results and trends, provide unbiased feedback to assess individual performance, and manage resources.

Supervisory Methods and Procedures State MPI programs need to implement supervisory methods \u201cat least equal to\u201d those of FSIS\u2019s Federal inspection program to ensure effective implementation of the program\u2019s public health and regulatory obligations. The supervisory methods and procedures at a minimum should include: \u2022 Methods and procedures used in developing policies for the State MPI program\u2019s critical inspection and compliance activities: \u2022 Methods and procedures to draft and distribute policies in a timely manner to all State MPI program personnel \u2022 Methods and procedures to assess FSIS issuances (i.e., FSIS Directives, Notices, and Compliance Guidelines) for applicability to the State MPI program \u2022 Methods and procedures to evaluate job performance and competency of State MPI program personnel during their probationary periods (if applicable) \u2022 Methods and procedures to evaluate job performance and competency of all State MPI program personnel to verify all State MPI program policies are implemented (e.g., IPPS, OPPS, annual performance appraisals) \u2022 Methods and procedures to measure and analyze implementation of new and existing State MPI program policies and instructional documents for inspection and compliance activities \u2022

Techniques for determining whether State supervisory activities meet the State MPI program management\u2019s expectation for: \u2022 Distribution and implementation of State MPI program policies \u2022 Employee performance feedback Evidence of System Application A State MPI program needs to provide evidence that demonstrates the implementation of supervisory methods and procedures \u201cat least equal to\u201d FSIS\u2019s Federal inspection program requirements. At a minimum, the State MPI program needs to submit: \u2022 Letters, instructions, memoranda of interview or data tracking logs documenting the distribution and implementation of State MPI program policies regarding critical inspection and compliance enforcement activities Page 57", "\u2022 Completed evaluations of performance standards and results of trend analyses (i.e., reasons why policies are not effectively implemented by State IPP) Completed performance and competency evaluation documents (redacted if necessary) for program employees (e.g., annual performance appraisals, IPPS reviews) States may use the tables below to submit this information. Page 58", "Attachment 5 State MPI Program Establishment Count Suggested Format Name of State Agency: As of Date: Instruction In the section below, list each establishment only once. If the establishment

performs multiple processes, identify the best category that encompasses all the establishment processes. Establishment Type Slaughter Only Processing Only Combination Slaughter and Processing TOTAL Number of State Inspected Establishments Meat Only Poultry Only Combination Meat and Poultry TOTAL Number of Exempt Establishments Meat Only Poultry Only Combination Meat and Poultry TOTAL Number of CIS, TA, or CU Establishments Meat Only Poultry Only Combination Meat and Poultry TOTAL Remarks: Page 59", "Attachment 6 State MPI Employee Primary Roles Suggested Format Name of State Agency: As of Date: # State MPI employees Total: Instruction In the section below, list each employee only once. If the employee has multiple roles, identify the employee under their primary role only and provide details of additional roles in the adjacent comment box. Employee Roles Full time Part time Comments Headquarters\ Central Office Managers Administrative EIAOs VMO\PHVs Other Circuit\Area\ District\Etc. Field Supervisors VMO\PHVs Other In-Plant State Inspection VMO\PHVs Inspectors Relief Other CIS, CU, or TA Inspection VMO\PHVs Inspectors Relief Other Compliance Program Managers Compliance Officers Other Remarks: Page 60", "Criteria for \u201cat least equal to\u201d Determination Each State MPI program needs to submit a current narrative describing the State verification system used to enforce all applicable laws, regulations, and FSIS policies. The system should have the capability to correct any deviations from regulatory requirements that may affect its program being \u201cat least equal to\u201d FSIS\u2019s Federal inspection program in its humane treatment of animals. State MPI programs should submit supporting documentation (e.g. completed reports and documents) to show the State verification system (as described in the narrative, has been implemented) is functioning as intended, and ensures that the State MPI program remains \u201cat least equal to\u201d FSIS\u2019s Federal inspection program over the next 12 months. State verification methods and procedures provided under a State MPI program are \u201cat least equal to\u201d the FMIA, PPIA, HMA, FSIS Directives and Notices, Federal Register publications, regulations, and other applicable policies provided under FSIS\u2019s Federal inspection program in its humane treatment of animals and good commercial practices with poultry. At a minimum, the humane handling system should include the following criteria: \u2022 Humane Slaughter \u2022 A State MPI program verifies all livestock are slaughtered in accordance with one of two humane methods specified in the HMA or applicable State laws. \u2022 The first humane method requires that livestock be rendered insensible to pain on the first application of the stunning device before being shackled, hoisted, cast, or cut. \u2022 The second humane method is in accordance with the ritual requirements of any religious faith that prescribes a method of slaughter where the animal suffers loss of consciousness by anemia of the brain caused by the simultaneous and instantaneous severance of the carotid arteries with a sharp instrument. \u2022 In addition, State IPP are to verify State inspected establishments that slaughter poultry follow good commercial practices described in 9 CFR 381. Outcome When objectively reviewed by FSIS, the State MPI program is determined to be \u201cat least equal to\u201d FSIS\u2019s Federal inspection program in its humane treatment of animals. A State MPI program has capabilities to ensure State inspected establishments humanely handle all livestock presented for slaughter and follow good commercial practices when poultry are slaughtered and processed on premises. Component 5: Humane Handling Page 61", "\u201cAt least equal to\u201d Requirements The State MPI program is required to maintain \u2022 A Humane Handling Verification System. NOTE: State MPI program Directors need to submit data

integrity information for the data collected and maintained in a system elected in place of PHIS. The data integrity information should include: \u2022 The type of data maintained in the elected data system in place of PHIS (e.g., FSAs, custom exempt reviews, NOEs \u2022 How the data integrity is maintained (e.g., restriction to access the data, ability to track data changes) \u2022 The State law or administrative rule governing the security and integrity preservation of State meat and poultry inspection program records Objective To implement State verification activities that ensure State inspected establishments are humanely handling all livestock when presented for slaughter, follow good commercial practices when poultry are slaughtered, and comply with applicable State laws, rules, and policies. Humane Handling Verification System methods and procedures State MPI programs need to implement State slaughter verification methods and procedures \u201cat least equal to\u201d those of FSIS\u2019s Federal inspection program in the humane treatment and handling of animals and good commercial practices with poultry. The methods and procedures at a minimum should include: \u2022 Methods to schedule and record humane handling tasks, and document noncompliance with the requirements consistent with 9 CFR 313 \u2022 Procedures to verify whether State inspected establishment personnel humanely handle all livestock presented for slaughter throughout the time they are on establishment premises \u2022 Methods to conduct and document humane handling verification reviews (e.g., District Veterinary Medical Specialist (DVMS) reviews) at livestock establishments and conduct poultry good commercial practices reviews at poultry establishments \u2022 Methods to assess whether slaughter verification activities successfully meet the State MPI program management\u2019s expectation for: \u2022 In-Plant Level Slaughter Verifications \u2022 Humane handling Page 62","\u2022 Good commercial practices \u2022 Noncompliance regulatory documentation \u2022 Enforcement actions \u2022 Central Office Level Assessments \u2022 Humane handling oversight \u2022 Administrative case development \u2022 Program personnel competency Evidence of System Application A State MPI program needs to provide evidence that demonstrates the implementation of a slaughter verification system \u201cat least equal to\u201d FSIS\u2019s Federal inspection program in the humane treatment and handling of animals and good commercial practices with poultry. At a minimum, the State MPI program should submit: \u2022 Documentation of regulatory control, withholding, suspension, enforcement, or administrative actions taken when humane handling noncompliance is identified (e.g., NRs, 30 day letters, NOIE Letters, Suspension letters, notification to withhold the marks of inspection) \u2022 Humane handling verification reviews (e.g., DVMS analogous reports, in-depth supervisory establishment reviews) \u2022 Management\u2019s evaluation and results of humane handling verification system performance Page 63","Criteria for \u201cat least equal to\u201d Determination Each State MPI program needs to submit a narrative describing the State\u2019s compliance system used to enforce all applicable laws, regulations, and FSIS policies, and takes appropriate enforcement action in the event that misbranded or adulterated product is identified in commerce. The US Code Title 21, Sections 643, 644, 645 and 460 require businesses to register with the Secretary of Agriculture. FSIS compliance conducts surveillance reviews at these registered firms which may lead to investigations and enforcement actions. Under 21 U.S.C. 661 and 454, FSIS expects the States to impose \u201cat least equal to\u201d FSIS\u2019s Federal inspection program assurances that affected individuals, firms, and corporations are complying with applicable State statutes when producing, transporting,

storing, and distributing meat and poultry products in intrastate commerce. The State MPI program's narrative should address and cite the State MPI program's statutory authority for performing surveillance reviews, investigations, and taking enforcement actions at the following business types: If the State MPI program is not granted statutory authority under State law to review, investigate, or take enforcement actions for any of the business types above, the narrative should identify the State agency with the State's statutory authority and cite the applicable statute. The narrative should also describe how the State MPI program cooperates with the authorized State agency when meat and poultry products are involved in the surveillance reviews, investigations, and enforcement actions. State MPI program officials may provide the narrative information in the plain language format of the Summary of Statutory Authority per Business Type, (Attachment 7, page 69) or another format. FSIS identifies the State MPI program as the State Agency responsible for coordinating with other State agencies to ensure all applicable compliance activities outlined in the guidelines comply with specified laws, regulations, and policies. This includes State or contract laboratories, health departments, law enforcement, State human resources division, and other State regulatory agencies. State MPI programs need to submit supporting documentation to demonstrate the compliance system, as described in the narrative, has been implemented and is functioning as intended, to ensure that the State MPI program remains at least equal to the FSIS's Federal inspection program in its compliance activities over the next 12 months. State MPI program officials may provide a report on compliance activities in a Component 6: Compliance Distributors 3D/4D operators Institutions Warehouses Salvages Restaurants Food banks Animal food Retailers Brokers Renderers Transporters Exempt poultry Page 64,"plain language format of the Compliance Activity Report (Attachment 8, page 70) or in another format. State MPI programs are at least equal to the Federal inspection program in its compliance system activities. Compliance system activities need to include the following criteria: Surveillance - State MPI compliance investigators conduct surveillance of persons, firms, and corporations operating in intrastate commerce who are subject to the provisions of the FMIA, PPIA, HMA, 9 CFR, or State laws as applicable. Investigation - State MPI compliance investigators conduct investigations of apparent violations, food safety incidents, or other allegations or incidents using the FMIA, PPIA, HMA, 9 CFR, or State laws as applicable. Product Control Action - State MPI compliance investigators take appropriate control of product found in intrastate commerce that may be adulterated, misbranded, or has not received the mark of inspection, and ensure proper disposition of such product (e.g., detention, seizure, condemnation, destruction). Case Development and Referral - The State MPI compliance program is to include case development and referral mechanisms to take criminal, civil, and administrative enforcement actions, including sanctions, when firms and individuals violate Federal and State statutes. The State MPI compliance program recommends cases of criminal and civil violations for prosecution by the State legal system, or refers them to USDA, FSIS, OIEA, and CID for action. Outcome When objectively reviewed by FSIS, the State MPI program is determined to be at least equal to the FSIS's Federal inspection program in its compliance activities. The State MPI program has: Assurances that affected individuals, firms, and corporations are complying with applicable State statutes or the Federal Acts when producing, transporting, storing, and distributing meat and poultry products in intrastate commerce Documentation of

surveillance activities, investigations, and enforcement actions (i.e., including sample collection that supports administrative, civil or criminal actions imposed against individuals or firms that have violated the State\u2019s laws) \u201cAt least equal to\u201d Requirements The State MPI program is expected to maintain: \u2022 A Compliance System Page 65", "NOTE: State MPI program Directors need to submit the data integrity information for the data collected and maintained in a system elected in place of PHIS. The data integrity information should include: \u2022 The type of data maintained in a State compliance system elected in place of PHIS (e.g., Review and Compliance Records, LOW, ROIs, physical evidence). \u2022 Where the State compliance data is stored (e.g., server name, name of SharePoint or share drive, hard copy file cabinet). \u2022 How the State compliance data integrity is maintained (e.g., restriction to access the data, ability to track data changes). \u2022 The State law or administrative rule governing the security and integrity preservation of meat and poultry inspection program records. Compliance System The State MPI program needs to maintain a compliance system to investigate violations of food safety, food defense, and other consumer protection statutory requirements, and controls unsafe or violative products through detentions, seizures, and voluntary recalls. State MPI program managers should create or adopt State compliance policies for conducting surveillance and investigation activities, and the development of cases to ensure the imposition of criminal, administrative, and civil enforcement actions are in accordance with State laws. Objective To ensure State MPI program\u2019s compliance activities are carried out in accordance with applicable State laws, rules and policies, ensuring all State inspected meat and poultry products found in intrastate commerce are safe, wholesome, not adulterated, properly marked, labeled and packaged and all enforcement actions imposed are legally supported. Compliance Methods and Procedures State MPI programs need to implement compliance methods \u201cat least equal to\u201d those of FSIS\u2019s Federal inspection program\u2019s compliance activities. The compliance methods and procedures should include: \u2022 Methods for conducting State surveillance and follow-up surveillance of individuals, firms and corporations operating in intrastate commerce subject to State laws, regulations and policies pertaining to meat and poultry inspection program \u2022 Procedures to prioritize State surveillance resources on intrastate commerce businesses with the highest public health risk Page 66", "\u2022 Procedures to determine the collection of raw ground beef samples for E. coli O157:H7 testing as part of the intrastate commerce surveillance activities at retail stores \u2022 Methods for conducting investigations of apparent violations, food safety incidents, other allegations or incidents subject to State laws, rules, and policies pertaining to the State meat and poultry inspection program \u2022 Procedures for State MPI program compliance investigators to collect, safeguard, and dispose of evidence in the performance of surveillance, investigations and other activities subject to the State laws, rules, and policies pertaining to the State MPI program \u2022 Procedures for State MPI program compliance investigators to follow when detaining or in preparation for seizing meat and poultry products found in intrastate commerce, when there is reason to believe that the products are adulterated or misbranded \u2022 Methods for preparing a report (e.g., Report of Investigation (ROI)) to support findings of apparent violations, food safety incidents, or other allegations subject to the applicable State laws \u2022 Procedures for the evaluation of case documents to support appropriate criminal, civil, or administrative enforcement actions (e.g., letters of warning, consent orders, fines, penalties, hearings) \u2022 Methods for the

State MPI program to determine whether to recommend a product recall \u2022 Methods for documenting, prioritizing, and investigating consumer complaints directly related to State inspected meat and poultry products \u2022 Methods to assess whether compliance activities successfully meet the State MPI program management\u2019s expectation for: \u2022 Surveillance \u2022 Investigation \u2022 Documentation and reports \u2022 Product recall \u2022 Consumer complaints \u2022 Compliance personnel competency Evidence of System Application A State MPI program needs to provide evidence demonstrating the implementation of a compliance system that is \u201cat least equal to\u201d FSIS\u2019s Federal inspection program in its compliance activities. The State MPI program should submit: \u2022 Documentation and tracking logs for surveillance and follow-up surveillance activities of State MPI program compliance officers Page 67", "\u2022 Retail and investigative product sample results \u2022 Complete case files that include reports of investigation, evidence collected, notices of detention, notices of seizure, letters of warning, fines, consent orders, and documentation from legal proceedings. \u2022 Evidence preservation and chain of custody verification documents \u2022 Recall effectiveness checks, public notification of recalls, and other related documentation \u2022 Documentation and tracking logs for consumer complaints \u2022 Documentation and communications for surveillance reviews, investigations, and enforcement actions for the business types where the State MPI program is not granted statutory authority \u2022 Management\u2019s evaluation and results of compliance system performance States can use the tables below to provide this information. Page 68", "Attachment 7 State MPI Program Summary of Statutory Authority per Business Type Suggested Format Name of State Agency: Time Period Covered: Instruction: List the State agency or program that is granted statutory authority to review, investigate, or take enforcement actions for the business types listed. Cite the applicable statute that grants that authority, and describe how the State MPI Program cooperates with the authorized agency. (E.G., a State MPI program may not have authority at retail stores in the State because another State agency has the authority). The State MPI program should provide in this chart the applicable laws State laws and the name of the State agency that has the authority to enforce the laws. Business Type State Agency Granted Authority and Statutory Citation State MPI Program Cooperation with the Authorized Agency (if applicable) Distributors Warehouses Transporters 3D\4D operators Salvages Renderers Food banks Exempt poultry Restaurants Retailers Institutions Animal food Brokers Remarks: Page 69", "Attachment 8 Compliance Activity Report Suggested Format Name of State Agency: Time Period Covered: Compliance Activities TOTAL NUMBER Surveillance per FSIS Directive 8010.1 Distributors, Warehouses, and Transporters 3D\4D Operators, Salvages, Renderers, Food Banks, and Exempt Poultry Restaurants, Retailers, Institutions, Animal Food, Custom Exempt, Abattoir, Processor, Port-of-Entry, Bonded Area, Broker, and Miscellaneous Surveillance Follow-ups Violation Cases or Investigations Referrals to FSIS Letters of Warning Administrative Hearings Consent Orders Court Actions or Prosecutions Consumer Complaints State Recalls Effectiveness Checks Registrations of Meat and Poultry Handlers Miscellaneous Actions \ Special Projects \ Personal Contacts (Please itemize) Detentions TOTAL NUMBER Laboratory TOTAL NUMBER Number of Detentions Retail Ground Beef samples per FSIS Directive 8010.1 Pounds of Product Detained Investigative Samples (other than retail ground beef) Pounds of Product Released Pounds of Product Donated Pounds of Product Condemned Pounds of Product Voluntarily

Destroyed Remarks: Page 70", "Criteria for \u201cat least equal to\u201d Determination State MPI programs need to have product sampling and laboratory methods with capabilities and safeguards that are \u201cat least equal to\u201d FSIS\u2019s Federal inspection program\u2019s product sampling and laboratory methods. State MPI programs should update and maintain their laboratory microbiological and chemical detection methods so they are \u201cat least equal to\u201d FSIS\u2019s Federal inspection program methods as detailed in the FSIS Microbiology Laboratory Guidebook. To achieve and maintain \u201cat least equal to\u201d laboratory methods, each State MPI program should meet the criteria in the following areas: \u2022 Laboratory Quality Assurance programs \u2022 Laboratory Testing Methods Outcome When objectively reviewed by FSIS, the State MPI program is determined to be \u201cat least equal to\u201d FSIS\u2019s Federal inspection program in Laboratory methods. FSIS integrates ongoing documents and on-site reviews of the applicable analytical methods in its annual comprehensive review of State MPI programs. FSIS determines if a participating State MPI testing program is \u201cat least equal to\u201d the corresponding FSIS Laboratory testing program. \u201cAt least equal to\u201d Requirements Sampling methods need to provide analytical results \u201cat least equal to\u201d corresponding FSIS testing programs. Each State MPI program should provide documentation through self-assessment and on-site review to demonstrate that its program includes the following:

1. Laboratory Quality Assurance (QA) Programs State MPI program laboratories, or contract laboratories, should have an appropriate QA program \u201cat least equal to\u201d the methods of FSIS\u2019s laboratories to ensure the reliability and integrity of analytical results. State MPI program laboratories, or contract laboratories, should ensure that each laboratory meets the criteria outlined in the FSIS MPI Program Laboratory Quality Management System Checklist. A laboratory QA program assessment consists of the following:

\u2022 Assurances for sample integrity and identity. Laboratories that analyze samples for State MPI programs maintain procedures to ensure that samples are not compromised within the laboratory. These procedures include a documented Component 7: Laboratory Methods and Quality Assurance Program Page 71", "chain of custody as well as traceability to the sample, equipment, and critical supplies used to analyze the sample.

\u2022 Demonstrated confidence in test results and an assurance that it does not resample or re-test pathogen-positive and non-compliant products

\u2022 Documented program of quality control procedures and an assurance that these procedures are followed

\u2022 Properly trained personnel; suitable facilities and equipment; and verified, calibrated, and maintained equipment in a manner consistent with international norms (e.g., European co-operation for Accreditation (EA) 04/10 or Analytical Laboratory Accreditation Criteria Committee (ALACC) guidance)

\u2022 Appropriate proficiency testing schemes for food analysis

\u2022 Use of validated method protocols

\u2022 Reporting and recordkeeping capabilities that track and link a test result to the correct establishment

2. Laboratory Testing Methods Methods used in support of the State MPI program should be validated for the product type sampled and are to be \u201cat least equal to\u201d FSIS\u2019s laboratory requirements. State MPI programs should provide documentation necessary to explain the methods used and the scientific basis for their selection. Such documentation should include detailed testing method protocols, supplemental testing procedures, and evidence of method validation and sustained proficiency testing for microbiology methods and sustained proficiency testing for chemistry methods. Evidence of analyst training in each subject method should be provided.

Method assessment by FSIS considers the following: Microbiology \u2022 Methods of analysis are designed to detect the lowest possible level of stressed pathogens from State inspected meat, poultry, and environmental samples in accordance with current FSIS testing programs for each pathogen (e.g., the method includes an enrichment step, adequate enrichment time, immunobead capture step for E. coli) \u2022 Methods of analysis are validated through an experimental study. When methods are modified, it may be necessary to conduct a supplemental validation against a reference method (e.g., USDA FSIS Microbiology Laboratory Guidebook (MLG), FDA Bacteriological Analytical Manual, or International Organization for Standardization (ISO) Standards). For validation studies conducted outside Association of Analytical Communities (AOAC), Association Fran\u00e7aise de Normalisation (AFNOR), the French national organization for standardization, or similar organizations, refer to FSIS Guidance for Test Kit Manufacturers, Laboratories: Evaluating the Performance of Pathogen Test Kit Methods at: Page 72", "[http://www.fsis.usda.gov/wps/wcm/connect/966638c7-1931-471f-a79e4155ce461d65/Validation\\_Studies\\_Pathogen\\_Detection\\_Methods.pdf?MOD=AJ PERES](http://www.fsis.usda.gov/wps/wcm/connect/966638c7-1931-471f-a79e4155ce461d65/Validation_Studies_Pathogen_Detection_Methods.pdf?MOD=AJ PERES)

\u2022 Methods of analysis detect the same pathogens as the corresponding FSIS MLG method. Alternative methods are inclusive for strains defined as positive by the biochemical, genetic, and serological confirmation tests described in the FSIS MLG. \u2022 Methods of analysis use appropriately-sized test portions or sampling methodology and frequency for samples offering enhanced opportunity for detecting foodborne pathogen contaminations. Information on the test portions used for FSIS testing programs is available at the USDA FSIS Microbiology Laboratory Guidebook website at the following link:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-andprocedures/guidebooks-and-methods/microbiology-laboratoryguidebook/microbiology-laboratory-guidebook> \u2022 Each method includes culture confirmation testing using a validated method. If additional non-validated confirmatory tests are performed by the laboratory, those tests are not relied upon to invalidate the previous results. \u2022 Shipping enrichments to a second confirmatory laboratory is avoided. FSIS guidance for evaluating microbiological testing methods are found in the Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory at the following link at:

<http://www.fsis.usda.gov/wps/wcm/connect/464a4827-0c9a-4268-8651b417bb6bba51/Guidance-Selection-Commercial-Private-Microbiological-Testing-lab062013.pdf?MOD=AJPERES> Food Chemistry \u2022 Methods of analysis are capable of measuring food chemistry components as a percentage of sample weight. Moisture, protein, fat, and salt are included. FSIS conducts limited food chemistry analysis of products at official establishments when in-plant inspection personnel believe the product is misbranded. \u2022 Acceptable methods of analysis are available on the USDA FSIS Chemistry Laboratory Guidebook website at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-andprocedures/guidebooks-and-methods/chemistry-laboratory-guidebook/chemistrylaboratory-guidebook> \u2022 AOAC Official Methods of Analysis for food chemistry are also acceptable. \u2022 Alternative methods for food chemistry analysis are acceptable if they measure the same components with sufficient accuracy. Evidence to support the use of Page 73", "an alternative method includes proficiency-testing data generated by the

State MPI program laboratories or contract laboratories completing the analysis. The FSIS Accredited Laboratory Program (ALP) provides proficiency-testing services for food chemistry. For further information, visit the following link:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-andprocedures/accredited-laboratories/accredited-laboratories>

Residue \u2022 Information on in-plant screening of residues in meat and poultry products is available at: FSIS Directive 10.800.1, Residue Sampling, Testing and Other Verification Procedures Under the National Residue Program For Meat and Poultry Products NOTE: The results of laboratory analyses are reported simultaneously to the State MPI program and the establishment. Submission of Laboratory Methods and Quality Assurance Records State MPI programs need to submit a list of current State laboratory and contract laboratory test methods along with copies of new or revised methods of Standard Operating Procedures (SOPs) on or before November 1 as part of the annual selfassessment submission process and whenever their methods are changed throughout the year. Submission of revised test method SOPs should be submitted on the Laboratory Method Notification Form available at: FSIS Form 5720-15, Laboratory Method Notification Form State MPI programs should submit a completed State Meat and Poultry Program Laboratory Quality Management System Checklist form available at: FSIS Form 5720-14 - State Meat and Poultry Inspection Program Laboratory Quality Management System Checklist NOTE: States may also submit the information on another easy to read format. State and contract laboratories accredited to ISO 17025, with all applicable methods under their scope of accreditation, should provide current certificates of accreditation and only complete applicable portions of the QA checklist. They should also provide the list of method SOPs along with any updated copies of methods new or revised since the previous year\u2019s submission. The State MPI programs may contract with a laboratory that meets the same requirements and are to ensure that the contract laboratory submits the same documentation as described for State MPI program laboratories. Page 74", "In the submission, State MPI program Directors should divide the document submissions into Microbiology methods, Chemistry methods, and QA records. All three sections should be submitted electronically to the FSIS Outlook mailbox: Statelabinquiry@fsis.usda.gov NOTE: The subject line for all submissions to the FSIS Outlook mailbox should contain the name of the applicable State MPI program to allow efficient routing to assigned FSIS personnel. If hard copies need to be submitted, please mail them to the following address: Director, USDA, FSIS, OPHS, Laboratory Quality Assurance Staff 950 College Station Road Athens, Georgia 30605 On-Site Review of Laboratory Methods and Quality Assurance Records The State MPI program laboratories and their contract laboratories are subject to periodic record and on-site reviews by FSIS to evaluate the QA program in comparison to submitted self-assessments and to verify the accuracy and implementation of the laboratory methods. Records related to FSIS laboratory reviews are submitted to the FSIS Outlook mailbox: Statelabinquiry@fsis.usda.gov Criteria for Review Determination The State MPI programs need to provide accurate documentation to demonstrate that they are operating and will continue to operate in a manner that is \u201cat least equal to\u201d FSIS\u2019s Federal inspection program requirements for the next 12 months. The State MPI program: \u2022 Complies with Federal civil rights laws; \u2022 Complies with USDA civil rights regulations; and \u2022 Achieves the intended outcome. Component 8: Civil Rights Page 75", "Outcome State MPI programs need to be conducted in a

manner that respects civil rights, ensures a non-discriminatory environment, and complies with the laws and regulations cited below. Civil Rights authorities State MPI programs should comply with the following civil rights laws, regulations, and policies: \u2022 Statutory \u2022 Title VI of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000(d) (discrimination on the basis of race, color or national origin) \u2022 Section 504 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 794 (discrimination on the basis of disability) \u2022 Age Discrimination Act (ADA) of 1975, 42 U.S.C. 6102 (discrimination on the basis of age) \u2022 Title IX of the Education Amendments of 1972, 20 U.S.C. Section 1681 (discrimination on the basis of sex) \u2022 Regulatory and Executive Orders \u2022 7 CFR Part 15 Subpart A, Non-discrimination in Federally Assisted Programs \u2022 7 CFR Part 15 a, Education Programs or Activities Receiving or Benefiting from Federal Financial Assistance \u2022 7 CFR Part 15 b, Non-discrimination on the Basis of Disability Programs and Activities Receiving Federal Financial Assistance \u2022 45 CFR Part 91, Non-discrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance from HHS \u2022 Executive Order 13166 on Limited English Proficiency, dated August 11, 2000 \u2022 Departmental and Agency Policies \u2022 USDA Regulation 4330-002, dated March 3, 1999, Non-discrimination in Programs and Activities Receiving Federal Financial Assistance from USDA \u2022 USDA Regulation 4300-3, dated November 16, 1999, Equal Opportunity Public Notification Policy \u2022 FSIS Directive 1510.1, Equal Opportunity Notification on Material for the Public, dated January 25, 2001 Page 76", "\u2022 FSIS Directive 5720.3, Revision 1, dated March 14, 2011, Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs; and \u201cAt Least Equal to\u201d Guidelines for State Meat and Poultry Cooperative Inspection Programs, dated July 2008 The statutes, regulations and policies listed above prohibit discrimination on the basis of a person's race, color, religion, sex (including gender identity, sexual orientation, and pregnancy), national origin, age (40 or older), disability or genetic information. It is also illegal to retaliate against a person for complaining about discrimination, filed a charge of discrimination, or participating in an employment discrimination investigation or lawsuit.

Acceptance of annual Federal financial assistance under State/Federal Cooperative agreements triggers Title VI, Section 504, of the Americans with Disabilities Act (ADA). Title IX covers and authorizes compliance reviews of federally assisted program delivery (not employment practices that fall under EEO). Areas of review

1. Civil Rights Assurances Requires the State to submit written assurances that its Federally assisted programs and activities are conducted in compliance with Title VI and other nondiscrimination authorities.
2. State Infrastructure and Program Accountability Requires that State MPI programs identify individuals and offices responsible for ensuring program accountability and its compliance with civil rights laws, regulations, policies and guidelines.
3. Public Notification Requires that all State MPI programs include a public notification system to inform applicants, participants, and potentially eligible persons of program availability, program rights and responsibilities, the program\u2019s policy of nondiscrimination, and the procedures for filing a complaint.
4. Racial and Ethnic Data Collection and Reporting Requires the State to obtain race and ethnic data on potentially eligible populations, applicants, and participants in their program service area.
5. Complaints of Discrimination Assesses the complaint procedures for all complaints alleging discrimination in the delivery of State MPI programs on the basis of race, color, national origin, disability, age and sex. NOTE: Complaints can be processed through State

procedures or can be reported directly to USDA for processing. 6. Civil Rights Training Requires State to ensure all employees involved in administering Federally- assisted MPI programs understand their obligations under civil rights related laws, regulations, procedures, and instructions. Page 77", "7. Disability Compliance Requires that State agencies ensure equal access to State MPI program personnel with disabilities. 8. Limited English Proficiency Requires that State MPI programs provide free language access services to potentially eligible applicants and program participants who are Limited English Proficient (LEP). 9. Compliance with the Age Discrimination Act of 1975 Requires Federal agencies to annually report on steps taken to enforce the Act, including non-employment related affirmative outreach actions of its recipients of Federal financial assistance. Instructions State MPI programs need to complete FSIS Form 1520-1, Civil Rights Compliance of State Inspected Programs (Attachment 9, page 79-80) or provide another easy to read format. The self-assessment Form 1520-1 or format needs to be signed by the designated State Official (such as a Director, Commissioner or Secretary) who would be deemed appropriate and responsible for signing the State-Federal Cooperative agreement and the annual application for Federal financial assistance. Signing the form consents to the assurance that the State\u2019s MPI program is conducted in compliance with all Federal statutes relating to nondiscrimination. The completed form needs to be mailed (hard copy), with an original signature, to the FSIS Civil Rights Staff by November 1st each year.

Submission Address: FSIS Civil Rights Staff 5601 Sunnyside Avenue, Mail Drop 5261 Beltsville, MD 20705-5261 Telephone: 800-269-6912 Fax: 301-504-2141 AskCRD@fsis.usda.gov Page 78", "Attachment 9 Civil rights Compliance of State Inspected Programs Page 79", "Page 80", "State MPI programs need to ensure State agency conformance with USDA 7 CFR Part 3016, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments (previously known as the Common Rule). State agencies should follow FSIS Directive 3300.1, Rev. 2,\u201cFiscal Guidelines for Cooperative Meat and Poultry Inspection Programs.\u201d Criteria for Review Determination -- Certification for Component 9 The following actions are necessary to complete the Component 9 certification: 1. Timely submission of the annual budget to FSIS\u2019s Office of Field Operations (OFO) and submission of all data requested (See Section IX, Additional Resources, Procedures for the Preparation of the Cooperative State Meat and Poultry Inspection Program Budget Submissions, page 112) 2. Timely submission of annual indirect cost proposals to the applicable Federal Agency (due within six months after close of State fiscal year). Proposals are sent to the Financial Reviews and Analysis Section (FRAS) of the Financial Management Division (FMD). 3. Timely submission of Federal Financial Reports (SF 425) to FSIS. Quarterly Reports are due within thirty days after the close of each quarter (e.g., 4th Quarter SF 425 is due by October 30). The Final report is due within 90 days of the end of the Federal Fiscal Year (e.g., by December 30). 4. Timely resolution of all corrective action on financial findings pursuant to the onsite fiscal review Documentation Needed for On-site Financial Review and are to be provided to FSIS auditors prior to the onsite financial review. \u2022 State\u2019s centralized accounting reports containing State MPI program expenditures, \u2022 Worksheets or schedules used to reconcile the centralized accounting reports to the SF 425, \u2022 Manual adjustments made to the accounting report expenses (vehicle mileage, terminal leave payments, etc.), \u2022 Monthly, quarterly, or final worksheets or schedules that were used to collect, adjust, calculate indirect costs, and summarize the total costs that were reported on the Expense Reports (SF

425) for the grant years indicated, \u2022 A reconciliation by year of Federal Financial Reports and Federal Share of Expenditures with accounting records for grant years covered by the fiscal review, \u2022 Application for Federal Assistance (Form 424) for the grants years covered by fiscal review, Component 9: Financial Accountability Page 81", "\u2022 Expenditure chart accounts for the grant years covered by the fiscal review, \u2022 Documentation for any other FSIS cooperative agreement renewals (e.g. Public Health Data Communication Infrastructure Systems (PHDCIS), Talmadge-Aiken Overtime (TAOT), Cross Utilization (CU), and Cooperative Interstate Shipping program (CIS) employee roster with the Employee Name, Job Title ID Number, Date of Hire Hourly, Bi-weekly, or Monthly Salary, \u2022 Single or departmental audit reports, \u2022 Detailed organizational chart with employee names, \u2022 Equipment inventory list as defined by State requirements, \u2022 Contractual agreements, \u2022 Procedures for the \u201cPreparation and Review of the Federal Financial Report\u201d, \u2022 List of employee retirements\terminations by quarter (e.g. April-June) with disposition of annual and sick leave balances. This is only required if a State MPI program claims indirect costs and the State\u2019s centralized accounting reports do not have object codes for terminal leave payments), and \u2022 List if applicable names of State inspected plants, inspectors and methods separate from cooperative MPI program reimbursable costs involved in voluntary programs, or 100% State Inspection (defined as inspection of the slaughtering and\or processing of animals that are not covered by the FMIA\PPIA). The above documents are items that State agencies are to send to the FSIS auditors prior to the onsite financial review. Instructions for Self-Assessment The FRAS verifies the State MPI program\u2019s compliance with financial reporting requirements throughout the Federal fiscal year. Financial reporting compliance will be determined by FRAS as outlined in this section entitled \u201cCriteria for review determination \u2013 Certification for Component 9.\u201d If the State agency has satisfied the elements outlined in this section, the State agency will sign the Certification Statement for Component 9 (Attachment 10, page 85) and submit the signed certification statement to the appropriate contact in FRAS in order to completely satisfy self-assessment for Component 9. If the State has not satisfied the elements in this section, the State agency complete the following: \u2022 Submit any outstanding documents for Component 9 Certification to FRAS. For a list of required documents for Component 9 Certification see the section above titled Criteria for review determination \u2013 Certification for Component 9. Page 82", "\u2022 Submit a letter to FRAS indicating the reasons for the State program\u2019s delinquency. \u2022 Upon completion of steps (1) and (2), sign the certification statement at the end of the section entitled \u201cCertification Statement for Component 9,\u201d and submit the signed certification statement to the appropriate contact in FRAS to completely satisfy self-assessment for Component 9. Guidance FSIS Directive 3300.1, Rev. 2, Fiscal Guidelines for Cooperative Meat and Poultry Inspection Programs, contains instructions for the preparation and submission of both the Annual Budget and SF 425. Additional guidance for the submission of SF 425, and Federal Financial Reports, is contained in USDA regulation 7 CFR Part 3016.40 (b)(1). State agency grantees maintain supporting documentation for their final SF 425, and Federal Financial Reports, for three years after submission (7 CFR Part 3016.42). Additional guidance for the analysis of budget submissions is contained in the FSIS document, titled \u201cA Guide for the Preparation of the Cooperative State Meat and Poultry Inspection program Budget Submissions,\u201d dated September 2004

\u201cGuidelines for the preparation and submission of Indirect Cost Proposals are contained in OMB Circular A87, Cost Principles for State, Local, and Indian Tribal Governments, Revised 5/10/04. Annual Assurance Statements FMD\FRAS and OFO provide annual assurance statements to the OIEA Federal\State Audit Branch by February 1st that the State agencies are current in the financial reporting activities required throughout the Federal Fiscal Year. OFO reviews and reports on matters associated with the submission of annual budgets. FRAS will review and report regarding the submission of annual Indirect Cost Proposals, submission of Quarterly and Final SF 425, Federal Financial Reports, and timely responses to financial review findings in the form of corrective action. State agencies need to sign the certification statement and submit it to the appropriate contacts in the FRAS to completely satisfy self-assessment for Component 9. Please follow the general mailing procedures and specific procedures for the listed financial documents: \u2022 Email account for FRAS is: FRAS@fsis.usda.gov \u2022 Physical location mailing address for FRAS is: Financial Reviews and Analysis Section USDA\FSIS\OA\OCFO\FMD\FASMB 5601 Sunnyside Avenue, Mail Drop 5264 Beltsville, MD 20705-5264SF-425 Expense Reports Page 83", "Signed electronic copies are sent to the FRAS email address only. NOTE: Please submit electronic SF 425 only. Do not send the SF 425 to the auditor in charge of the State Agency except as a carbon copy (cc). Indirect Cost Rate Proposals (ICP) Electronic ICPs are sent to the FRAS email address only. NOTE: Please submit only electronic ICPs. Hard copies are to the FRAS physical location mailing address. Billing Rate Proposals (CU\CE\EPI) Electronic copies with signed cover letters are sent to the FRAS email address. NOTE: Please submit electronic billing rate proposals only. Do not email any proposals to the auditor in charge of the State Agency except as a cc. Page 84", "Attachment 10 Certification Statement for Component 9 We, the State agency entitled,

\_\_\_\_\_ for the calendar year ending

\_\_\_\_\_ understand that self-certification for Component 9 entails compliance with the following: \u2022 Timely submission of annual budget to FSIS; submission of all data requested. \u2022 Timely submission of annual Indirect Cost Proposal to the Applicable Federal Agency (due within six months after close of State fiscal year). \u2022 Timely submission of Federal Financial Reports (SFs 425) to FSIS. Quarterly Reports are due within thirty days after the close of each quarter (e.g., 4th Quarter SF 425 is due by October 30). The Final report is due within 90 days of the end of the Federal Fiscal Year (e.g., by December 30). \u2022 Timely resolution of all financial findings pursuant to the onsite fiscal review. I certify to the best of my knowledge and belief that the aforementioned State agency has complied with the applicable directives and guidelines set forward by the Food Safety and Inspection Service Agency for successful and complete self-certification for Component 9, and certify compliance with all Component 9 requirements for the State agency. Typed or Printed Name & Title Telephone (area code, Number and extension) Signature of Authorized Certifying Official Date of Submission Page 85", "IX. ADDITIONAL RESOURCES \u201cAdditional Resources\u201d provides State MPI program Directors with additional information that may be needed to perform business processes related to the budget submissions, training and Federal resources, cooperation between State and Federal Compliance Programs, and reference material for internal controls. Contributors to the new Additional Resources section are OFO, OOEET, and OIEA. Page 86", "OFFICE OF FIELD OPERATIONS (OFO) Resource Management and Financial Planning Staff (RMFPS) Procedures for the Preparation of Cooperative State Meat and Poultry

Inspection Program Budget Submissions General Budget submission guidelines for the Cooperative Meat and Poultry Inspection (MPI) State programs are contained in the FSIS Directive 3300.1, Fiscal Guidelines for Cooperative Inspection Programs. The procedures below provide further details on the preparation of MPI program budget submissions.

I. Current Year Budget Execution Analysis There are two components of the current year budget analysis: a) projection of current year expenditures for determination of fund availability for the current year, and b) determination of a basis for analysis of the budget submission for the ensuing year.

A. Current Budget Execution Analysis 1. The analysis of the current year Cooperative State MPI program budget begins in June of each year. At that time, the Financial Reviews and Analysis Section, Financial Management Division requests that each State Agency to submit their estimated projection of the total current fiscal year obligations by object classes on the Budget Information form (SF-424A). 2. The data is utilized to determine a total projection of estimated fund utilization for all State MPI agencies. Annual estimates allow FSIS to determine any requirement for fund reallocation.

B. Budget Submission Base 1. Data collected serves as an annual expenditure basis for comparison and analysis of budget submissions for the following year.

II. Budget Submission for New Fiscal Year Each August, RMFPS prepares the budget call letter for the next fiscal year. Page 87", "A. Budget Call Letter 1. The budget call letter is addressed to the head of the State agency for each Cooperative State MPI program, and is prepared for the signature of the Assistant Administrator for OFO. 2. The call letter provides specific guidance relative to operational and budgetary considerations that State agencies take into account when preparing the budget submission. 3. The call letter has many enclosures for presentation of the budget submission:

- a. Application for Federal Assistance (SF-424) - Attachment 2-2
- b. Budget Information \u2013 Non-Construction Programs (SF-424A) - Attachment 2-3
- c. Assurances \u2013 Non-Construction Programs (SF-424B) - Attachment 2-4
- d. State Assignment and Employment Report (FSIS Form 5720-5) - Attachments 2-6
- e. State Establishment Profile (FSIS Form 5720-4) - Attachments 2-5

NOTE: The attachment examples are found in FSIS Directive 3300.1, Fiscal Guidelines for Cooperative Inspection Programs

B. Budget Submission Form Requirements FSIS forms 5720-4 and 5720-5 are prepared prior to filling out the other forms.

- 1. Form SF-424 (Application for Federal Assistance) Note that section 15, Estimated funding is consistent with form SF-424A.
- 2. Form SF-424A (Budget Information \u2013 Non-Construction Programs) The amounts in form SF-424A are consistent with the data contained in forms 5720-5 and SF-424. The activities to be used for \u2013 Grant Program Function or Activity\u201d are in-plant, Compliance, Laboratory and other. Costs in section B of Form SF-424A are reported by Object Class Category as follows:

- a. Personnel costs are salaries for State permanent full time (PFT) and other than permanent (OTP) personnel including base salaries, overtime, holiday pay, differentials, lump sum payments and annual and sick leave payments. Costs for contract veterinarians should appear in \u2013 Contractual.\u201d
- b. Fringe Benefits are costs paid on behalf of State employees, including retirement, social security, insurance, clothing allowances, relocation benefits, workmen\u2019s compensation, etc. This object class is calculated as a percentage of salary based on historical data or by using the latest payroll information available. Page 88", "c. Travel provides for travel costs incurred by State employees in the performance of their assigned duties whether paid directly by the State or reimbursed to the employee. Some items used in determining overall travel costs are: mileage costs based on the estimated miles to be traveled times the rate per mile (the state

approved mileage rate or latest approved Federal rate, whichever is lower); vehicle rental costs; motor pool costs; auto leases; repairs for State vehicles; auto insurance; and depreciation. Other allowed expenses include per diem, subsistence, and meal allowances. d. Equipment includes the purchase of durable property with an expected useful life in excess of one year and for more than \$500 per unit or in accordance with the State classification of equipment. Requests for equipment acquisitions are fully justified. e. Supplies include commodities, supplies, materials and other expendable items that are normally expended or consumed within a year of being put to use. They may also be used to form a minor part of equipment. Small equipment, costing less than \$500 per unit, may also be included. When estimating for the budget year, prior year one-time purchases are eliminated. Estimates are based on prior year costs adjusted for inflation. f. Contractual includes all contracts for service in support of the program. The salaries of contract veterinarians are included in this object class. This item includes any contractual laboratory costs. Budget year estimates are based on contract costs adjusted upward for inflation and anticipated changes and downward for discontinued services. g. Other includes all items of expenditure not included in the above object classes.

3. Form SF-424B (Assurances \u2013 Non-Construction Programs) 4. Two copies of FSIS Form 5720-5 (State Assignment and Employment Report). The first shows data on personnel as of September 30 of the current year. The second shows data on personnel positions as projected for the ensuing budget year. In both cases, the OTP positions are shown in terms of PTF. 5. Two copies of FSIS Form 5720-4 (State Establishment Profile) The first shows data on plants as of September 30 of the current year. The second form shows a projection of plants expected to be in the cooperative inspection program during the ensuing budget year.

C. Budget Submission Justifications

State MPI program agencies fully justify and explain all changes in the budget submission compared to the current year estimated expenditures. Justifications Page 89", "are in narrative form referencing the affected object class. If there is no change in level of spending or program, it must be indicated in a narrative form.

1. The justification for the budget submission compares and contrasts current year estimated expenditures, staffing, and workloads with those proposed in the budget submission. Changes in staffing and workload are reflected on forms FSIS 5720-4 and FSIS 5720-5. A narrative explanation accompanies the two forms.

2. Justifications for increases in funding are attached to form SF-424A. The narrative justification explains, by object class, the reasons for changes in expenditure levels, including items such as pay raises, inflation, changes in staffing, and training required to maintain \u201cat least equal to\u201d status. If inflation factors are used to justify an increase for an object class, the rate used, as well as the publication source of the inflation index, should be provided.

3. Justifications for increases in salaries, benefits and other salary changes:

a. Provide the following information for all State employees on an attachment:

1. Name of employee  
2. Position title  
3. Date employee entered on duty  
4. Annual salary  
5. Calculated salary cost for the fiscal year

b. Any promotions are justified by providing the following information:

1. Name of employee  
2. Position title  
3. Annual salary  
4. Date of Promotion  
5. Calculated salary cost for the fiscal year

c. For merit increases, the following is provided:

1. Name of employee  
2. Percentages used and the amount of the increase  
3. Date of increase  
4. Justifications for increases or decreases in travel items are included in the submission:

a. The effective date for change in mileage rate, the current rate, and the new rate  
b. Increases in job assignments Page 90", "c. Increase in travel due to training  
d. Decrease in number of personnel traveling

5. An itemized

list of all equipment to be purchased during the fiscal year. D. Talmadge-Aiken (T\A) Submission State programs with plants inspected under the Federal-State T\A Cooperative Inspection program provide the following information attached to form SF-424A: 1. The number of personnel performing inspection at Federally inspected plants (T\A) 2. Total amount of their salaries 3. Staff years and estimated overtime costs(a staff year equals a full-time workload for an individual for a full year) E. Cooperative Interstate Shipment (CIS) Budget Submission States with plants inspected under the CIS program are to prepare a separate budget request for their CIS program. Each form submitted for base program budget request is also submitted for the CIS program. The CIS program budget request includes specific information for the State CIS program. In some instances States will footnote CIS information on the appropriate forms. Note: The Employee Roster is expanded to include employees working in CIS establishments. If a State employee performs inspection at a CIS establishment in addition to inspection in a cooperative establishment, the appropriate percentages of the employees\u2019 time in each type of establishment noted on the roster. Page 91", "OFFICE OF OUTREACH, EMPLOYEE EDUCATION AND TRAINING (OOEET) Outreach Partnership Division (OPD) The Outreach Partnership Division (OPD) is a part of USDA\u2019s Food Safety and Inspection Service, Office of Outreach, Employee Education and Training. OPD provides information and support to State MPI programs, as well as to operators of small and very small meat, poultry and processed egg products establishments, including State-inspected plants. OPD delivers assistance to State MPI programs and State-inspected plants through several different avenues. Resource Library OPD offers food defense materials, help for dealing with plant emergencies, generic HACCP models and guidebooks, informational DVDs on humane handling, control of Listeria monocytogenes, new plant orientation, compliance guidelines, as well a vast array of other useful food safety resources for industry. These materials are available free of charge and can be shipped on request. For a complete listing of available resources, view the \u201cFood Safety Resources for Small and Very Small Plants\u201d brochure at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatorycompliance/haccp/resources-and-information/food-safety-resources-svsp-outreach> Small Plant Help Desk FSIS\u2019s Small Plant Help Desk assists operators of small and very small meat, poultry and processed egg product establishments seeking help with agency requirements with direct access to knowledgeable staff specialists. The helpdesk provides assistance to State and local food regulatory agencies (FSIS's partners in keeping meat, poultry and egg products safe for consumers). The Help Desk is open from 8:00 a.m.-4:00 p.m. EST, Monday through Friday, excluding Federal holidays. To speak to a staff specialist during this time, call 1-877-FSISHelp (1-877-374-7435). Customers may also contact the help-desk by email at

InfoSource@fsis.usda.gov. Management of State MPI Directors Contact List OPD manages and keeps an up-to-date list of Agriculture Commissioners and MPI Directors for the 27 States that have their own meat and poultry inspection programs, as well as the States in which FSIS has entered into cooperative agreements with to conduct reviews of custom exempt slaughter and processing operations for OFO. This list is maintained on FSIS\u2019s Web site at:

[www.fsis.usda.gov/wps/portal/fsis/topics/inspection/state-inspection-programs/stateinspection-and-cooperative-agreements/state-officials](http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/state-inspection-programs/stateinspection-and-cooperative-agreements/state-officials). Page 92", "Monthly State MPI Program Directors Correlation Webinar OPD coordinates a monthly Webinar with all

27 State MPI Directors and their personnel to discuss new FSIS policies and any other issues that States need to know to maintain \u201cat least equal to\u201d status to FSIS\u2019s Federal meat and poultry inspection programs. OPD, in conjunction with FSAB and other FSIS programs encourage States to provide issues or topics that need further clarification before the monthly scheduled Webinar so that the appropriate FSIS subject matter experts can provide updates and answer questions. OPD solicits topics from the State MPI Directors for upcoming Webinars; however, State personnel are also welcome to submit suggestions for Webinar topics through the Small Plant Help Desk. Management and Renewal of Federal and State Cooperative Agreements The FMIA and PPIA allow FSIS to cooperate with State agencies in developing and administering their own MPI programs. OPD administers the base cooperative agreements between FSIS and the individual States to operate their \u201cat least equal to\u201d meat and poultry inspection programs. Provided the State continues to operate it\u2019s \u201cat least equal to\u201d program in good standing, these cooperative agreements are renewed on an annual basis through OPD. OPD administers, and renews, the Tallmadge-Aiken (TA) and Cross Utilization (CU) agreements with States that provide inspection coverage for FSIS-regulated establishments, as well as the Cooperative Interstate Shipment (CIS) agreements where State-inspected establishments can sell product outside of their respective State boundaries and in foreign commerce. OFO has direct oversight of these three programs, and ensures that State inspection personnel assigned to any TA, CU or CIS establishment have received FSIS-conducted training. OPD assists the States that have these programs by ensuring their personnel are registered in the required FSIS-conducted training courses and providing both the States and OFO with the pass\fail results of the State employees. There are several other unique cooperative agreements that OPD administers and renews based on OFO\u2019s needs. There is a cooperative agreement with Utah\u2019s Egg and Poultry Grading Program to have Utah State Inspectors provide continuous inspection in several of FSIS\u2019s egg products inspection plants. Furthermore FSIS has cooperative agreements with California and Colorado for their personnel to conduct reviews of custom exempt slaughter and processing operations within those respective States, which are procedures that OFO would normally perform. Directors seeking advice or assistance with State MPI programs, or wishing to obtain copies of current and archived cooperative agreements, are welcome to contact OPD through the Small Plant Help Desk. Page 93", "Training OPD provides assistance to the State programs by ensuring they receive course announcements from FSIS and any assistance to State personnel in securing enrollment in the classes they might need. This service is especially essential for the States that have TA, CU or CIS programs where their personnel must have successfully completed FSIS trainer-led courses in order to conduct inspection activities within TA, CU or CIS establishments. OPD provides both the States and OFO with the pass\fail results of the State employees. Furthermore, OPD assists States by providing CDs, DVDs, or other hard copy resources on food safety and public health-related training materials for reference offered through FSIS\u2019s Center for Learning. Many of these titles are interactive computer-based training on disk. State personnel can request a copy of the catalog and submit any orders through the Small Plant Help Desk, since the online catalog is only available through FSIS\u2019s Intranet site, which the States cannot access. Page 94", "OFFICE OF INVESTIGATION, ENFORCEMENT AND AUDIT (OIEA) Compliance Investigation Division (CID) Cooperation Between Compliance Investigation Division (CID) and State

Compliance Programs Federal and State Compliance programs are encouraged to integrate and coordinate their respective programs to the maximum extent possible to eliminate or avoid duplication of efforts. CID assists and encourages State Compliance programs in assuming full responsibility for and jurisdiction over the enforcement of meat and poultry laws within States. State Compliance programs assist CID in coordinating and channeling various State efforts into a comprehensive national compliance program. The coordination of CID and State Compliance programs necessitate close communications in administration of the respective programs. The compliance personnel of CID and State Compliance programs are cross-utilized fully to inquire into alleged violations, conduct compliance reviews, develop evaluation material, and make necessary contacts with the various Federal, State, County, or Municipal officials and informants. When there is overlapping jurisdiction and authority, compliance personnel of either CID or State Compliance programs are authorized to handle the matter and represent fully both Federal and State interests. CID and State Compliance programs are encouraged to refer cases dependent on resources to obtain optimal results. These operational details are resolved on a caseby-case basis between CID and State Compliance programs. CID training programs are open for participation by members of both groups to the extent possible and feasible. CID Regions and Contact Information Western Region (CA, HI, AZ, AK, NM, NV, UT, CO, OR, WA, ID, WY, MT) 620 Central Avenue Building 2B, 2nd Floor Alameda, CA 94501 Telephone: 510-769-5733 Southwest Region (TX, OK, KS, MO, NE, IA, SD, ND, IL, MN) 1100 Commerce Street, Room 557 Dallas, TX 75242 Telephone: 214-767-2783 Page 95", "Southeast Region (FL, PR, AR, LA, GA, AL, TN, MS, MD, VA, KY, SC, NC, WV, DE, DC) 100 Alabama Street, SW 1924 Building Suite 3R95 Atlanta, GA 30303-3104 Telephone: 404-562-5962 Northeast Region (PA, NJ, CT, NY, MI, WI, IN, OH, MA, ME, NH, VT, RI) BNY Mellon Independence Center 701 Market Street, Suite 4100 C Philadelphia, PA 19106 Telephone: 215-430-6222 Page 96", "Management Control and Audit Division (MCAD) Development of a Federal Program Management Control System Background The Federal Managers\u2019 Financial Integrity Act of 1982 (FMFIA) requires the General Accounting Office (GAO) to issue standards for internal control in government. The standards provide the overall framework for establishing and maintaining internal control and for identifying and addressing major performance and management challenges in areas at greatest risk of fraud, waste, abuse, and mismanagement. Office of Management and Budget (OMB) Circular A-123, Management Accountability and Control, revised June 21, 1995, provides the specific requirements for assessing and reporting on controls. As a result, Federal program managers continually seek better ways to achieve agencies\u2019 missions and program results. In other words, they seek ways to improve accountability. A key factor in helping achieve such outcomes and minimize operational problems is to implement appropriate internal control. Effective internal control helps manage change to cope with shifting environments and evolving demands and priorities. The term internal control is synonymous with the term management control (as used in OMB Circular A-123) that covers all aspects of an agency\u2019s operations (programmatic, financial, and compliance). Recently, other laws have prompted renewed focus on internal control. The Government Performance and Results Act of 1993 requires agencies to clarify their missions, set strategic and annual performance goals, and measure and report on performance toward those goals. The internal control system helps the program\u2019s management to provide reasonable assurance of the effectiveness and efficiency of operations, of reliability of financial

reporting, and of compliance with applicable laws and regulations. Terminology The following includes definitions for commonly used terms of the Federal management control systems:

- Risk Assessment - Internal control provide for an assessment of the risks the agency faces from both external and internal sources. A precondition for risk assessment is the establishment of clear and consistent agency objectives. Risk assessment is the identification and analysis of relevant risks associated with achieving the objectives, such as those defined in strategic and annual performance plans developed under the Government Performance and Results Act, and forming a basis for determining how risks is managed.
- Page 97", "Internal Control (Management Control) - An internal control is comprised of control activities, control document (control), and performance measures (i.e., performance standards or action level).
- Control - Control documents (control) provide direction to program personnel for the execution of the control activity to meet the expectation of the program's management. Controls are policies, procedures, techniques, and mechanisms that enforce management's directives, such as the process of adhering to requirements for budget development and execution. Controls are clearly documented, and the documentation is readily available for examination. The control document is measurable and appears in management directives, administrative policies, or operating manuals and may be in paper or electronic form. All documentation and records are properly managed and maintained.
- Control Activity \u2013 Internal control activities help ensure that management's directives (mission and strategic goals) are carried out. Control activities are effective and efficient in accomplishing the agency's control objectives. They help ensure that actions are taken to address risks.
- Objective of Control Activity - Objective of control activity specifies the purpose for program in executing a control activity. The purpose of the control activity directly relates to and supports the program's mission and strategic goals.
- Implementation (Monitoring) - Internal control monitoring assesses the quality of the control activity performance over time and ensures the findings of audits and other reviews are promptly resolved.
- Performance Measure - A performance measure (i.e., performance standard or action level) is an indicator of the effectiveness and efficiency of a control activity. Programs need to establish activities to monitor performance measures. These activities may include comparisons and assessments of different sets of data to one another and the performance measures to analyze the relationships so conclusions can be made and appropriate actions taken.
- Controls are aimed at validating the correctness and integrity of the performance measures.

Page 98", "Management Control Helper Questions Key Function (Functional Area) \u2022 Why do we exist? How do we accomplish our program's mission and strategic goals? Does our existence require us to produce any products?

- Risk Assessment \u2022 What can happen if we do not meet our objective? \u2022 How will our failures to meet our objectives affect the program's function or existence? \u2022 How will our failures affect the program's accomplishment of its mission and strategic objectives?
- Control Activity \u2022 What must be done consistently and well for the program to continue to function successfully? (NOTE: This does not relate to how it is done)
- Objective (Desired Outcome) \u2022 What is the objective of the control activity?
- Management Control \u2022 What procedures or activities will provide personnel clear instructions for implementing the control activity and ensure the attainment of the objective? \u2022 How can we demonstrate our implementation of the controls? (proof)
- Page 98", "What is our proof of implementation? (NOTE: The proof is management control, because it is measurable\u2014e.g., a form, tracking log,

etc.) NOTE: Reference for performing the control \u2013 e.g., 9 CFR, Directives, Notices, State Policies Performance Measure \u2022 How do we define a success? \u2022 How can we measure successful completion of the objective? \u2022 What is our tolerance level of risk for the control activity? Page 99", "Reference Table of Related FSIS Policy Documents Component 2 \u2013 Inspection Related FSIS Directives Slaughter Inspection 5100.3 Administrative Enforcement Reporting (AER) System - Revision 2 (Oct 18, 2011; 18 pp) 6000.1 Responsibilities Related to Foreign Animal Diseases (FADs) and Reportable Conditions - Revision 1 (Aug 3, 2005; 6 pp) 6030.1 Religious Exemption for the Slaughter and Processing of Poultry - Revision 1 (Aug 10, 2005; 11 pp) 6100.1 Ante-Mortem Livestock Inspection - Revision 2 (Jul 24, 2014; 18 pp) Bovine Spongiform Encephalopathy (BSE) and Specified Risk Material (SRM) Guidance Materials and Resources 6100.2 Post-Mortem Livestock Inspection (Sep 17, 2007; 31 pp) 6100.3 Ante-Mortem and Post-Mortem Poultry Inspection - Revision 1 (Apr 30, 2009; 16 pp) 6100.4 Verification Instructions Related to Specified Risk Materials (Sep 13, 2007; 22 pp) Questions and Answers Verification of SRM Removal Including Tonsils 6240.1 Inspection, Sampling, and Disposition of Animals for Tuberculosis - Revision 1 (Jan 29, 2009; 10 pp) PHV Training: Multi-species Disposition Basics with a Public Health Focus FSIS Guideline No. 4, Inspection of Tuberculin Reactors Tuberculosis Sample Submission Manual for Meat Inspection Personnel (USDA-APHIS) 6410.1 Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age - Revision 1 (Nov 3, 2011; 23 pp) Page 100", "6420.2 Verification of Procedures for Controlling Fecal Material, Ingesta and Milk in Slaughter Operations (Mar 31, 2004; 14 pp) PHIS FSIS Directive 6420.1 Questions and Answers on FSIS Directives 10,010.1, Revision 1, 5000.2, and 6420.2 Questions and Answers Regarding Directives 5000.2, 6420.2 and 10,010.1, Revision 1, and the Compliance Guidelines on E. coli O157:H7 Workshops on E. coli O157:H7 Regulations Food Safety Verification 5000.1 Verifying an Establishment's Food Safety System - Revision 4 (Mar 4, 2014; 76 pp) Meat and Poultry Hazards and Controls Guide (Oct 4, 2005) 5000.2 Review of Establishment Data by Inspection Personnel - Revision 2 (Dec 4, 2008; 6 pp) Questions and Answers on FSIS Directives 10,010.1, Revision 1, 5000.2, and 6420.2 Questions and Answers Regarding Directives 5000.2, 6420.2 and 10,010.1, Revision 1, and the Compliance Guidelines on E. coli O157:H7 Compliance Guidelines For Establishments On The FSIS Microbiological Testing Program And Other Verification Activities For Escherichia coli O157:H7 5000.3 Identification and Segregation of Products (Dec 21, 2006; 3 pp) 5000.4 Performing the Review Component of PBIS 01b02 Procedure and PHIS Pre-Op Sanitation SOP Review and Observation Task in Federally Inspected Processing, Slaughter and Import Establishments- Revision 1 (Sep 28, 2011; 12 pp) 5000.5 Verification of Less Than Daily (LTD) Sanitation Procedures In Processing Operations- Revision 1 (Sep 28, 2011; 19 pp) Less than Daily Sanitation Procedures Compliance Guideline (Oct 19, 2009) 5000.6 Performance of the Hazard Analysis Verification (HAV) Task - Revision 1 (Mar 4, 2014; 29 pp) Questions and Answers Related to Performance of the Hazard Analysis Verification (HAV) Task (Aug 14, 2012) 9 CFR Part 417 Docket No. 00-022N - E. coli O157:H7 Contamination of Beef Products FSIS Directive 5020.1 - Verification of Salmonella Initiative Program Page 101", "FSIS PHIS Directive 5300.1 - Managing the Establishment Profile in the Public Health Information System (PHIS) FSIS PHIS Directive 13000.1 - Scheduling In-plant Inspection Tasks in the Public Health Information System Meat and Poultry Hazards and Controls Guide (Oct 4, 2005) 5000.8 Verifying Compliance with Requirements for Written Recall Procedures (Dec 18, 2013; 2 pp) 5000.9

Verifying Video or Other Electronic Monitoring Records (Aug 26, 2011; 5 pp) Compliance Guidelines for Use of Video or Other Electronic Monitoring or Recording Equipment in Federally Inspected Establishments (Aug 26, 2011) 5010.1 Food Safety Related Topics for Discussion During Weekly Meetings with Establishment Management - Revision 2 (Apr 17, 2014; 6 pp) 5020.1 Verification of Salmonella Initiative Program (Aug 12, 2011; 10 pp) 5100.1 Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology - Revision 4 (May 29, 2015; 23 pp) Food Safety Assessment Tools 5100.2 Enforcement, Investigations, and Analysis Officer (EIAO) Responsibilities Related to Recalls and Consumer Complaints (Oct 4, 2005; 6 pp) Meat and Poultry Hazards and Controls Guide 5100.3 Administrative Enforcement Reporting (AER) System - Revision 2 (Oct 18, 2011; 18 pp) 5100.4 Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology - Revision 1 (May 22, 2015; 8 pp) 5220.1 Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection under PHIS - Revision 1 (Jan 30, 2013; 21 pp) 5220.3 Issuance of a Ten-Day Letter for Inactive Operations (Apr 11, 2011; 3 pp) 5300.1 Managing the Establishment Profile in the Public Health Information System (PHIS) (Apr 13, 2011; 22 pp) Page 102", "6410.1 Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age - Revision 1 (Nov 3, 2011; 23 pp) 6420.2 Verification of Procedures for Controlling Fecal Material, Ingesta and Milk in Slaughter Operations (Mar 31, 2004; 14 pp) PHIS FSIS Directive 6420.1 Questions and Answers on FSIS Directives 10,010.1, Revision 1, 5000.2, and 6420.2 Questions and Answers Regarding Directives 5000.2, 6420.2 and 10,010.1, Revision 1, and the Compliance Guidelines on E. coli O157:H7 Workshops on E. coli O157:H7 Regulations 7520.2 Procedures for Condition of Canned Product Container Examination (May 12, 1988; 10 pp) 7530.1 Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile Canned Product - Revision 2 (Mar 25, 2010; 15 pp) 7530.2 Verification Activities in Canning Operations that Choose to Follow the Canning Regulations (Oct 20, 2005; 22 pp) 10,010.1 Sampling Verification Activities for Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef Products (Aug 20, 2015; 88 pp) 10,010.2 Verification Activities for Shiga Toxin-Producing Escherichia Coli (STEC) in Raw Beef Products (Aug 20, 2015; 22 pp) 10,010.3 Traceback Methodology for Escherichia Coli (E. Coli) O157:H7 in Raw Ground Beef Products and Bench Trim (Jan 21, 2015; 16 pp) Non-Food Safety Verification 5100.3 Administrative Enforcement Reporting (AER) System - Revision 2 (Oct 18, 2011; 18 pp) 7000.1 Verification of Non-Food Safety Consumer Protection Regulatory Requirements (Dec 11, 2006; 24 pp) 7000.4 Verifying Certain Transferred Labeling (Dec 8, 2008; 4 pp) Questions and Answers (Jan 7, 2009) 7110.1 Guidelines for Specified Cuts of Poultry (Feb 26, 1986; 2 pp) Page 103", "7110.3 Time\Temperature Guidelines for Cooling Heated Products- Revision 1 (Jan 24, 1989; 10 pp) 7111.1 Performance Standards for the Production of Certain Meat and Poultry Products (Mar 3, 1999; 15 pp) 7120.1 Safe and Suitable Ingredients Used in the Production of Meat, Poultry and Egg Products - Revision 20 (Sep 8, 2014; 69 pp) Access additional information 7124.1 Standards of Identify or Composition--Use of Cooked or Cured Product (Jul 28, 1986; 3 pp) 7220.1 Food Labeling Division Policy Memoranda (Aug 2, 2005; 133 pp) 7221.1 Prior Labeling approval - Revision 1 (Jan 6, 2014; 5 pp) 7235.1 Mandatory Safe Handling Statements on Labeling of Raw and Partially Cooked Meat and Poultry Products (May 11, 1994; 10 pp) 7237.1 Labeling of Ingredients - Revision 1 Amendment 1 (Aug 9, 1994; 4 pp) 7270.1 Sampling and Testing Procedures for Raw Poultry Products Labeled \"Fresh\"-Revision 1

(Aug 13, 1998; 5 pp) 7310.5 Presence of Foreign Material in Meat or Poultry Products - Revision 3 (May 30, 2003) 7320.1 Treatment of Certain Meat and Poultry Products Containing Pork to Destroy Trichinae (Apr 27, 1993; 2 pp) 7355.1 Use of Sample Seals for Program Samples and Other Applications - Revision 2 (Dec 3, 2002; 13 pp) 7620.3 Processing Inspectors' Calculations Handbook (Revised 1995; 138 pp) Exempt Facility Review 5930.1 Custom Exempt Review Process - Revision 4 (Jul 15, 2009; 17 pp) Poultry Slaughter Exemption Guideline 8010.1 Methodology for Conducting In-Commerce Surveillance Activities \u2013 Revision 4 (Apr 24, 2014; 27 pp) Component 3 \u2013 Program Sampling Related FSIS Directives and Compliance Guidelines Page 104", "FSIS Directives 10,010.1 Sampling Verification Activities for Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef Products (Aug 20, 2015; 88 pp) 10,010.2 Verification Activities for Shiga Toxin-Producing Escherichia Coli (STEC) in Raw Beef Products (Aug 20, 2015; 22 pp) 10,010.3 Traceback Methodology for Escherichia Coli (E. Coli) O157:H7 in Raw Ground Beef Products and Bench Trim (Jan 21, 2015; 16 pp) 10,200.1 Accessing Laboratory Sample Information via LEARN (Jul 19, 2001; 7 pp) 10,210.1 Unified Sampling Form - Amendment 1 (Jun 10, 1999; 31 pp) Amendment 6 - Change Transmittal Sheet (Dec 18, 2003; 63 pp) Amendment 5 - Change Transmittal Sheet (Feb 11, 2003; 9 pp) Amendment 4 - Change Transmittal Sheet (Dec 19, 2002; 7 pp) Amendment 3 - Change Transmittal Sheet (May 22, 2002; 25 pp) Amendment 2 - Change Transmittal Sheet (Dec 12, 2001; 9 pp) 10,230.2 Procedures for Collecting and Submitting Domestic Samples for Microbiological Analysis (Aug 6, 1992; 14 pp) 10,230.4 Salmonella Surveillance Program for Liquid and Frozen Egg Products (Aug 6, 1992; 4 pp) 10,230.6 Submitting Tissue Specimens for Pathological or Diagnostic Microbiological Evaluation to the Laboratory (Jan 10, 2006; 9 pp) 10,240.4 Verification Activities for the Listeria monocytogenes (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program - Revision 3 (Jan 10, 2014; 48 pp) Attachments and Related Documents 10,240.5 Verification Procedures for Enforcement, Investigations and Analysis Officers (EIAs) for the Listeria monocytogenes (Lm) Regulation and Routine Risk-Based Listeria monocytogenes (RLm) Sampling Program - Revision 3 (Mar 28, 2013; 17 pp) 10,250.1 Salmonella and Campylobacter Verification Program for Raw Meat and Poultry Products (Sep 20, 2013; 70pp) FSIS Establishment Eligibility Criteria for the Salmonella Verification Sampling Program and FSIS Scheduling Algorithm for the Salmonella Verification Sampling Program for Raw Meat and Poultry (Feb 2013; 4 pp) Page 105", "10,300.1 Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces and Environmental Surfaces for Listeria Monocytogenes - Revision 1 (Mar 28, 2013; 19 pp) 10,400.1 Sample Collection from Cattle Under the Bovine Spongiform Encephalopathy (BSE) Ongoing Surveillance Program (Apr 11, 2013; 6 pp) 10,630.1 Federal and Contract Servicing Laboratories for Domestic Food Chemistry Samples (May 13, 1991; 4 pp) 10,700.1 Procedures for New Technology and Experimental Protocols for InPlant Trials (Jun 24, 2003, 10 pp) Guidance Procedures for Notification and Protocol Submission of New Technology | PDF (16 pp) Other Related Documents 10,800.1 Residue Sampling, Testing and Other Verification Procedures under the National Residue Program for Meat and Poultry Products - Revision 1 (Mar 3, 2014; 43 pp) KIS\u2122 Test Instructions (Oct 13, 2011) Examples of Official Ear Tags Additional Related Documents FSIS Compliance Guidelines FSIS Revised Action Plan for Control of Listeria monocytogenes for the Prevention of Foodborne Listeriosis (2000) Best Practices Guidance for Controlling Listeria monocytogenes (Lm) in Retail Delicatessens FSIS Compliance Guideline: Controlling Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Meat and

Poultry Products (Updated Jan 2014; PDF Only) FSIS Scheduling Criteria for Routine Lm Risk-Based (RLm) Sampling Program (Mar 21, 2008; PDF Only) Verification Procedures for the Listeria monocytogenes Regulation and Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification - FSIS Directive 10240.4 (Feb 3, 2009; PDF Only) FSIS Compliance Guideline for Validating Cooking Instructions for Mechanically Tenderized Beef Products (Jun 2013; PDF Only) Docket No. FSIS-2008-0017 | PDF (Aug 9, 2013) Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Page 106","Added Solutions and Mechanically Tenderized Raw Meat and Poultry Products (Feb 2012; PDF Only) View Comments on regulations.gov FSIS Compliance Guideline for Controlling Meat and Poultry Products Pending FSIS Test Results (Feb 1, 2013; PDF) FAQs: FSIS Hold and Test Conference Call with Industry held February 7, 2013 (PDF Only) Docket No. FSIS-2005-0044 - Not Applying the Mark of Inspection Pending Certain Test Results | PDF (Dec 10, 2012) Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory (Revised Jun 2013; PDF Only) Foodborne Pathogen Test Kits Validated by Independent Organizations | PDF FSIS Guidance for Evaluating Test Kit Performance (PDF Only) Compliance Guideline for Controlling Salmonella in Market Hogs Docket No. FSIS-2012-0026 | PDF (Jan 6, 2014) Baseline Data Reports Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products (Sep 19, 2012; PDF Only) Compliance Guideline for Controlling Salmonella and Campylobacter in Poultry Third Edition May 2010 (May 10, 2010; PDF Only) Review of FSIS Compliance Guidelines for Controlling Salmonella in Small and Very Small Plants that Produce Raw Poultry Products (PDF Only) Chemical Antimicrobials (Jun 29, 2009; PDF Only) Component 4 \u2013 Administrative FSIS Directives Staffing 12,700.1 Operations Occurring Outside Approved Hours - Revision 1 (Nov 25, 2008; 4 pp ) Training 4200.2 New Employee Orientation (Jul 12, 2007; 9 pp) 4338.1 Training as a Condition of Employment - Amendment 2 (Mar 1, 2013; 36 pp) Supervision 2610.1 FSIS Issuance System - Revision 6 (Apr 23, 2012; 18 pp) Page 107","4200.2 New Employee Orientation (Jul 12, 2007; 9 pp) 4315.2 Probationary Period (Mar 3, 1982; 4 pp) 4315.3 Probationary Period for Newly Appointed Supervisors and Managers - Revision 1 (May 3, 1989; 17 pp) 4335.1 Merit Promotion Plan - Revision 2 (May 6, 1999; 84 pp) 4338.1 Training as a Condition of Employment - Amendment 2 (Mar 1, 2013; 36 pp) 4410.1 Employee Development- Revision 1 Amendment 2 (Dec 14, 2007; 15 pp) 4410.2 Career Development Program (Oct 18, 1982; 12 pp) 4430.1 Performance Evaluation Plan - Revision 6 (Dec 15, 2009; 31 pp) 4430.3 In-Plant Performance System (IPPS) - Revision 2 (Feb 19, 2010; 23 pp) Component 5 - Humane Handling Related FSIS Directives 6030.1 Religious Exemption for the Slaughter and Processing of Poultry - Revision 1 (Aug 10, 2005; 11 pp) 6900.2 Humane Handling and Slaughter of Livestock - Revision 2 (Aug 15, 2011; 40 pp) 6910.1 District Veterinary Medical Specialist (DVMS) - Work Methods - Revision 1 (Dec 7, 2009; 18 pp) Component 6 \u2013 Compliance Related FSIS Directives 8010.1 Methodology for Conducting In-Commerce Surveillance Activities - Revision 4 (Apr 24, 2014; 27 pp) 8010.2 Investigative Methodology - Revision 4 (Apr 24, 2014; 16 pp) 8010.3 Procedures for Evidence Collection, Safeguarding and Disposal - Revision 4 (Apr 24, 2014; 18 pp) 8010.4 Report of Investigation - Revision 5 (Apr 24, 2014; 6 pp) Page 108","8010.5 Case Referral and Disposition - Revision 4 (Apr 24, 2014; 6 pp) 8080.1 Recall of Meat and Poultry Products - Revision 7 (Sep 9, 2013; PDF; 41 pp) 8410.1 Detention and Seizure - Revision 6 (Apr 24, 2014; 12 pp) 8420.1 Transportation Accidents (Nov 7, 1985; 2 pp) Component 7 \u2013 Relevant FSIS Laboratory Quality Assurance Compliance

Guidelines FSIS Form 5720-14, State Meat and Poultry Inspection Program Laboratory Quality Management System Checklist FSIS Form 5720-15, Laboratory Method Notification Form FSIS Accredited Laboratory Program USDA FSIS Chemistry Laboratory Guidebook USDA FSIS Microbiology Laboratory Guidebook FDA Bacteriological Analytical Manual ISO Standards AOAC Official Methods of Analysis Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory (Revised Jun 2013; PDF Only) Foodborne Pathogen Test Kits Validated by Independent Organizations | PDF FSIS Guidance for Evaluating Test Kit Performance (PDF Only) FSIS Directive 10,800.1, Residue Sampling, Testing and Other Verification Procedures Under The National Residue Program For Meat and Poultry Products KISTM Test Instructions (Oct 13, 2011) Examples of Official Ear Tags Additional Related Documents Component 8 \u2013 Federal Civil Rights Statutes, Regulations and Policies Federal Statutes Title VI of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000d (discrimination on the basis of race, color or national origin) Page 109", "Section 504 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 794 (discrimination on the basis of disability) Age Discrimination Act (ADA) of 1975, 42 U.S.C. 6102 (discrimination on the basis of age) Title IX of the Education Amendments of 1972, 20 U.S.C. Section 1681 (discrimination on the basis of sex) Regulatory and Executive Orders 7 CFR Part 15 Subpart A, Non-discrimination in Federally Assisted Programs 7 CFR Part 15 a, Education Programs or Activities Receiving or Benefiting from Federal Financial Assistance 7 CFR Part 15 b, Non-discrimination on the Basis of Disability Programs and Activities Receiving Federal Financial Assistance 45 CFR Part 91, Non-discrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance from HHS Executive Order 13166 on Limited English Proficiency, dated August 11, 2000 Departmental and Agency Policies USDA Regulation 4330-002, dated March 3, 1999, Non-discrimination in Programs and Activities Receiving Federal Financial Assistance from USDA USDA Regulation 4300-3, dated November 16, 1999, Equal Opportunity Public Notification Policy FSIS Directive 1510.1, Equal Opportunity Notification on Material for the Public, dated January 25, 2001 FSIS Directive 5720.3, Revision 1, dated March 14, 2011, Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs; and \u201cAt Least Equal to\u201d Guidelines for State Meat and Poultry Cooperative Inspection Programs, dated July 2008 Component 9 - Relevant Financial FSIS\USDA Regulations and Policies Departmental and Agency Regulations 7 CFR Part 3016 Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments (previously known as the Common Rule) Page 110", "FSIS Directive 3300.1 Fiscal Guidelines for Cooperative Meat and Poultry Inspection Programs \u2013 Revision 2 Additional Compliance Guidelines A Guide for the Preparation of the Cooperative State Meat and Poultry Inspection Program Budget Submissions, dated September 2004 OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments, Revised 5/10/04 - Guidelines for the preparation and submission of Indirect Cost Proposals Page 111"]}, {"file\_name": "FSIS\_GD\_2016\_0012", "title": "Steps to Obtain Level 2 eAuthentication Credentials and PHIS Access", "num": "FSIS-GD-2016-0012", "id": "ed81844d5cba7cd6c4e5ad672ae92e4463707c7c5e7e2117277005d96414283e", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/eAuth-Credentials-PHIS-"}]

Access.pdf", "type": "pdf", "n\_pages": 2, "word\_count": 920, "text\_by\_page": ["11\03\2016 Steps to Obtain Level 2 eAuthentication Credentials and PHIS Access In February 2015, FSIS announced to countries that are interested in exporting product to the United States (US) the availability of its web-based Self-Reporting Tool (SRT) within FSIS\u2019s web-based Public Health Information System (PHIS). Please refer to the Federal Register announcement (80 FR 9428) for additional information. The benefits for using the web-based SRT are expedited SRT review process, transparency, and security. Each year it will only be necessary for countries to reflect any changes that have occurred within their inspection systems since the last submission of the SRT. Participating countries will be able to log onto PHIS at any time to view their SRT and its status on a personalized homepage. It is important to understand that the level 2 eAuthentication credentialing and PHIS enrollment are two separate processes. It is important to note that when the designated central competent authority (CCA) official becomes level 2 eAuthentication credentialed, the PHIS enrollment process is not automatically initiated. As these processes are independent from one another, it will take time to complete both of these processes. To start the level 2 eAuthentication credentialing process, a country first needs to identify a designated CCA official. This identified official will be responsible for entering the SRT responses and uploading supporting documents into PHIS. This official is responsible for first obtaining level 2 eAuthentication credentials, and then requesting to be enrolled in PHIS to complete the SRT. The following steps clarify how an official can obtain access to the SRT. 1. To obtain level 2 eAuthentication credentials, the official must first complete the level 2 registration form. Please visit <http://1.usa.gov/1rbeFcL> to complete registration. REMINDER: All red asterisk (\*) fields must be filled in to successfully complete the registration form. 2. The official will receive a confirmation e-mail with the subject line, \u201c>eAuthentication - Action Required - Instructions to Activate Your USDA Account with Level 2 Access\u201d within 1 hour. The official must activate the account within seven (7) days to complete the registration form process. Please check your junk e-mail for the confirmation e-mail. For more information on eAuthentication please visit the eAuthentication Help webpage (<https://www.eauth.usda.gov/MainPages/eauthHelp.aspx>) or review the eAuthentication Frequently Asked Questions document ([https://www.eauth.usda.gov/\\_GlobalAssets/Documents/USDA\\_eAuth\\_FAQ.pdf](https://www.eauth.usda.gov/_GlobalAssets/Documents/USDA_eAuth_FAQ.pdf)). If you have not received your confirmation e-mail once you have activated your account, please contact Ms. Monica Marcelli at [monica.marcelli@fsis.usda.gov](mailto:monica.marcelli@fsis.usda.gov) or via telephone at 1 (202) 720-0473. Ms. Marcelli will help the official to schedule the appointment with the Local Registration Authority (LRA) to verify his or her government issued photo identification. If the official is based at an embassy in Washington DC, or visiting Washington DC, he or she can meet with the LRA at the United States Department of Agriculture building to complete the eAuthentication credentialing process. If the official is not in the US, FSIS can make arrangements to complete the credentialing process while in country. 3. Upon confirming the official\u2019s identity, the LRA will send the official a confirmation e-mail stating that level 2 eAuthentication credentials have been granted. Upon receiving confirmation, the official will now be able to enroll in PHIS in order to manage and submit its SRT to FSIS electronically. To enroll in PHIS, visit <https://phis.fsis.usda.gov> and login using your Level 2 eAuthentication credentials. To login, use the same username and password created when the level 2 registration form was completed. Use the following steps to complete the PHIS enrollment process. a. On the

Welcome to FSIS Enrollment Application page, click Submit Enrollment Request. b. On the FSIS Enrollment Request Wizard (1) select Foreign Country, (2) enter the Central Competent Authority contact information, (3) select Central Competent Authority, (4) select your country, and (5) enter specific personal contact information. c. Once you have completed the Enrollment Request Wizard, review. If you need to edit information, click Previous until you get to the desired page to edit. Once complete, click Finish and click Logout eAuth (in upper", "11\03\2016 right hand corner). An enrollment confirmation number will appear. Please document (or print) that number for your records. Once the official has submitted his or her enrollment request for PHIS, please contact Ms. Marcelli to provide her the enrollment number, or the e-mail address or last name of the contact person entered into the PHIS enrollment form. An e-mail will be sent to the official notifying them that their request has been approved. Once PHIS enrollment has been approved if the official cannot log into PHIS after 24 hours, please contact Ms. Marcelli. REMINDERS: Log into PHIS at least every 60 days to prevent your account from being disabled. If the official\u2019s PHIS account becomes disabled, he or she must make sure that his or her level 2 eAuthentication password is up-to-date, and then contact Ms. Marcelli for further assistance. For officials that are enrolled in PHIS, FSIS will send reminder e-mails to log into PHIS. For security reasons, eAuthentication will occasionally prompt you to change your password. If it is time to change your password, the system will prompt you to change your password. If the official is not able to log into PHIS because he or she has locked the level 2 eAuthentication account by trying to enter his or her password too many times, please contact the eAuthentication Help Desk at 1-800-457-3642, and select Option 1 or e-mail eAuthHelpDesk@ftc.usda.gov. The official may be prompted to answer security questions that he or she set up while completing the eAuthentication registration form. Lastly, the USDA does not permit sharing accounts or passwords."], {"file\_name": "FSIS\_GD\_2016\_0013", "title": "Supplemental Questions and Answers on Descriptive Designation for Needle-or Blade - Tenderized (Mechanically Tenderized) Beef Products", "num": "FSIS-GD-2016-0013", "id": "6cb431bef474e08261c5e2a91ad183bdb60fce584011d2274966aeea7c49228", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/FAQ-Supplement-2008-0017.pdf", "type": "pdf", "n\_pages": 4, "word\_count": 1229, "text\_by\_page": ["SUPPLEMENTAL QUESTIONS AND ANSWERS ON DESCRIPTIVE DESIGNATION FOR NEEDLE-OR BLADE - TENDERIZED (MECHANICALLY TENDERIZED) BEEF PRODUCTS November 17, 2016 Compliance Documents Q1. Where can I find information on the new \"mechanically tenderized beef products regulation per 9 CFR 317.2(e)(3)? Information on \u201cmechanically tenderized beef products\u201d is available from the following locations: \u201cDocket No. FSIS-2008-0017 | PDF \u201cCompliance Guideline for Validating Cooking Instructions for Mechanically Tenderized Beef Products Labeling Issues Q2. Under this final rule, will the product need to be labeled with the specific method of mechanical tenderization used to prepare the product? No, the label need not include the specific type of mechanical tenderization used. To provide flexibility, FSIS is allowing the phrase \u2018mechanically tenderized\u2019 to be used as the descriptive designation on any type of mechanically tenderized product. In addition, in lieu of \u201cmechanically tenderized,\u201d such product may be labeled as"]}]

\u2018\u2018needle tenderized\u2019\u2019 or \u2018\u2018blade tenderized,\u2019\u2019 as applicable. Q3. Can \u201cneedle injected\u201d be used as the descriptive designation on the labels of raw or partially cooked beef products that have been mechanically tenderized? No, needle injected may not be used as the descriptive designation. The terms \u201cneedle tenderized\u201d or \u201cmechanically tenderized\u201d must be used as the descriptive designation for needle tenderized raw or partially cooked beef products and the terms \u201cmechanically tenderized\u201d or \u201cblade tenderized\u201d must be used as the descriptive designation for raw or partially cooked blade tenderized beef products. Q4. Are the descriptive designations \"mechanically tenderized,\" \"blade tenderized,\" or \u201cneedle tenderized\u201d only required on raw or partially cooked beef products? Yes, unless the product is destined to be fully cooked or to receive another full lethality treatment at an official establishment, such product must be labeled accordingly. Q5. Do the new labeling requirements apply to mechanically tenderized pork, lamb, or goat products?", "SUPPLEMENTAL QUESTIONS AND ANSWERS ON DESCRIPTIVE DESIGNATION FOR NEEDLE-OR BLADE - TENDERIZED (MECHANICALLY TENDERIZED) BEEF PRODUCTS No. The rule applies only to raw or partially cooked beef products that have been mechanically tenderized. Q6. Can establishments put both mechanically tenderized beef products and nonmechanically tenderized beef products in the same immediate container and label it with the descriptive designation \u201cmechanically tenderized?\u201d No. To label product as \u201cmechanically tenderized\u201d when it was not would be false and misleading. Q7. If we sell mechanically tenderized raw or partially cooked beef or veal products in protective coverings, must the protective coverings meet the mechanical tenderization labeling requirements when the immediate container of this product is labeled \"For Institutional Use Only?\" No. Under 9 CFR 317.1(a)(1), protective coverings should not bear any mandatory labeling information.\u201d In this case, the immediate container, which also serves as the shipping container, is required to be labeled with the descriptive designation and bear validated cooking instructions and all other applicable labeling features. Q8. Is beef cubed steak subject to the new labeling requirements? No, this regulation will not apply to raw or partially cooked beef products that have been cubed. The regulation is specific to needle and blade tenderized beef products. FSIS stated in the final rule: The descriptive designation will only apply to raw or partially cooked beef products that have been needle tenderized or blade-tenderized, including beef products injected with marinade or solution. Other tenderization methods, such as pounding and cubing, change the appearance of the product, putting consumers on notice that the product is not intact. Moreover, most establishments already label cubed products as such. (80 FR 28157) Q9. Must the labels for raw or partially cooked mechanically tenderized beef products be submitted to the FSIS Labeling and Program Delivery Staff (LPDS) for approval? No. The descriptive designations, \u201cmechanically tenderized,\u201d \u201cblade tenderized,\u201d and \u201cneedle tenderized\u201d are not considered special statements or claims under 9 CFR 412.1(c). Therefore, as stated in the final rule, simply adding the descriptive designation and validated cooking instructions to a label would not require LPDS approval, given the label is otherwise in accordance with FSIS\u2019s regulations.", "SUPPLEMENTAL QUESTIONS AND ANSWERS ON DESCRIPTIVE DESIGNATION FOR NEEDLE-OR BLADE - TENDERIZED (MECHANICALLY TENDERIZED) BEEF PRODUCTS Q10. Do the new labeling requirements apply to raw or partially cooked mechanically tenderized beef

products that are produced at establishments that use a validated intervention during the production of such products? Yes, the new labeling requirements would apply to products treated with a validated antimicrobial intervention, unless the establishment applies a lethality treatment that achieves a 5-log reduction in pathogens. Mechanically tenderized beef product treated at an official establishment with an intervention or process, including HPP, that has been validated to achieve at least a 5-log reduction for *Salmonella* and *Shiga Toxin-producing E. coli* (STEC) organisms (including *E. coli* 0157:H7) would not be subject to the requirements in this final rule because it has received a full lethality treatment. (See 80 FR 28153) Q11. Do the new labeling requirements apply to mechanically tenderized beef products labeled or prepared at retail stores? Yes, the new labeling requirements would apply to raw or partially cooked mechanically tenderized beef products produced, packaged, and labeled at a retail store.

Cooking Instructions Q12. Is there compliance guidance available on validating cooking instructions for mechanically tenderized beef products? Yes, at: FSIS Compliance Guideline for Validating Cooking Instructions for Mechanically Tenderized Beef Products Q13. Where can I find scientific studies on validated cooking instructions? Attachment 1 of the above FSIS Compliance Guideline for Validating Cooking Instructions for Mechanically Tenderized Beef Products contains a summary of published scientific support for cooking instructions. Q14. Do the new labeling requirements apply to raw or partially cooked mechanically tenderized beef products that are too thin to practically measure their internal temperature using a food thermometer? No, the new labeling requirements do not apply to raw or partially cooked mechanically tenderized (including through injection with a solution) beef products that are too thin to measure their internal temperature using a food thermometer, such as beef bacon or carne asada. FSIS does not intend to enforce the requirements for these products because they are customarily prepared in a manner that is sufficient to destroy pathogenic bacteria."}, {"file\_name": "FSIS\_GD\_2016\_0017", "title": "Retail Recordkeeping for Establishments and Retail Stores That Grind Raw Beef Products", "num": "FSIS-GD-2016-0017", "id": "35c184f1471a9e0b03179c64e73b598b244ecd07078231dca701c685e621e564", "co

"SUPPLEMENTAL QUESTIONS AND ANSWERS ON DESCRIPTIVE DESIGNATION FOR NEEDLE-OR BLADE - TENDERIZED (MECHANICALLY TENDERIZED) BEEF PRODUCTS Note that the thickness of many food thermometers used by consumers is approximately 1\8\u201d making it difficult to measure the end product temperature of products 1\8\u201d thick or less through use of a thermometer. Q15. Where on the label of raw or partially cooked mechanically tenderized beef products can the validated cooking instructions appear? Validated cooking instructions must appear on the immediate containers of all raw or partially cooked mechanically tenderized beef products destined for household consumers, hotels, restaurants, or similar institutions. These instructions can appear anywhere on the product label. Mechanically Tenderized Beef With Solutions Q16. Must the label of a raw or partially cooked mechanically tenderized beef product that contains added solution also declare the percentage of added solution? Yes. However, there are different options for declaring the total amount of solution added. See 9 CFR 317.2(e)(2). Q17. Do the new labeling requirements apply to raw or partially cooked beef products that have been marinated in a tumbler or vacuum tumbled? The rule only applies to raw or partially cooked beef products that have been mechanically tenderized by needle or blade. This rule does not apply to other processes, such as tumbling or vacuum tumbling, unless the product is also mechanically tenderized by needle or blade."}]

pus":"fsis\_guidelines","source\_page\_url":"https:\/\/www.fsis.usda.gov\/policy\/fsis-guidelines","url":"https:\/\/www.fsis.usda.gov\/sites\/default\/files\/import\/Retail-Grinder-Log-Webinar.pdf","type":"pdf","n\_pages":40,"word\_count":2209,"text\_by\_page":["Food Safety and Inspection Service:","Food Safety and Inspection Service: Retail Recordkeeping for Establishments and Retail Stores That Grind Raw Beef Products 2","Food Safety and Inspection Service: Agenda \u2022Introduction \u2022Policy Overview of the Retail Recordkeeping Rule \u2022Enforcement of the Rule \u2022Questions and Answers \u2022Wrap Up and Adjournment 3","Food Safety and Inspection Service: Policy Overview of the Retail Recordkeeping Rule 4","Food Safety and Inspection Service: Foodborne Illness Outbreaks 5 \u2022 Foodborne illnesses cost the US economy \$15.6 billion every year. \u2022 The Centers for Disease Control estimates that each year roughly 1 in 6 Americans (or 48 million people) contract a foodborne illness. This includes 128,000 hospitalizations and 3,000 deaths. \u2022 Contaminated meat and poultry are responsible for 22% of these illnesses and 29% of these deaths. \u2022 Between 2007 and 2013, FSIS investigated 130 outbreaks of human illness. Of those, 31 (24 percent) were linked to beef ground at a retail venue.", "Food Safety and Inspection Service: Why Ground Beef? 6 \u2022 Ground beef can be produced from materials from multiple suppliers, and multiple production lots. \u2022 The grinding process can spread pathogens throughout each lot of ground beef, and between lots if grinding equipment and\or food contact surfaces are not properly cleaned. \u2022 Additionally, ground beef is not always cooked sufficiently to destroy pathogens.", "Food Safety and Inspection Service: Previous Approaches to Retail Recordkeeping 2002: \u2018\u2019E. coli O157:H7 Contamination of Beef Products\u2019\u2019 Federal Register Notice \u2022 When collecting a ground beef sample for O157:H7 testing at retail, FSIS announced that it would also gather: \u2013Names and establishment numbers of the establishments supplying the source materials for the lot of ground beef sampled \u2013Supplier lot numbers and production dates \u2013Any other information that would be useful to suppliers if they were later notified of an E. coli O157:H7 positive finding 7", "Food Safety and Inspection Service: Previous Approaches to Retail Recordkeeping 2009: FSIS provided guidance on its Web site \u2022 Recommended that retail stores keep records of: \u2013The lot\batch number of source materials used to prepare raw ground beef \u2013Exact name\type of product produced 8", "Food Safety and Inspection Service: Why do we need this rule? 9 \u2022 It will improve FSIS\u2019 ability to accurately trace the source of foodborne illness outbreaks involving ground beef products and identify the source materials that need to be recalled. \u2022 It will provide FSIS with proper documentation in efforts to trace ground beef products back to supplier(s).", "Food Safety and Inspection Service: Why do we need this rule? 10 \u2022 Despite efforts by FSIS, industry associations, and other regulators to provide retailers and official establishments with guidance and examples of best practices, the level of recordkeeping was still less than what was needed for timely and accurate traceability investigations.", "Food Safety and Inspection Service: \u2022 The cleaning and sanitizing of equipment used to grind raw beef is important because it prevents the transfer of E. coli O157:H7 and other bacteria from one lot of product to another. \u2022 When records are available and complete, FSIS is often able to identify specific production in an official establishment. Status of retail grinding record Number of investigations Number resulting in recalled product Available and complete 11 6 Not available 11 1 Available, but incomplete 6 1 11 How to detect Foodborne Illness Outbreaks?", "Food Safety and

Inspection Service: Legal Basis for Recordkeeping 21 U.S.C. 642 \u2022 Official establishments and retail stores that grind raw beef products for sale in commerce must keep records that will fully and correctly disclose all transactions involved in their businesses that are subject to the FMIA. \u2022 Records specifically required to be kept under 9 CFR 320.1(b) include, but are not limited to, bills of sale, invoices, bills of lading, and receiving and shipping papers. \u2022 Businesses must also provide access to and permit inspection of these records by FSIS personnel (9 CFR 320.4). 12", "Food Safety and Inspection Service: FSIS Rulemaking \u2022 In 2009 and 2011, FSIS held two public meetings, in Washington, DC, to discuss the traceability issue, using ground beef as an example. \u2022 On July 22, 2014, FSIS published a proposed rule, \u201cRecords To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products.\u201d \u2022 On December 14, 2015, FSIS published the final rule, \u201cRecords to be Kept by Official Establishment and Retail Stores That Grind Raw Beef Products.\u201d 13 [www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/interim-and-final-rules](http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/interim-and-final-rules)", "Food Safety and Inspection Service: Final Rule The authority citation for 9 CFR part 320 continues to read as follows: \u201cAuthority: 21 U.S.C. 601\u2013695; 7 CFR 2.7, 2.18, 2.53.\u201d Main recordkeeping provisions for grinding activities: (1)Mandatory recordkeeping (2)Location of records (3)Retention Period 14", "Food Safety and Inspection Service: Final Rule Mandatory Recordkeeping 9 CFR 320.1(b) \u2013 Records to be kept. Added (4)(i) In the case of raw ground beef products, official establishments and retail stores are required to keep records that fully disclose: (A) The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product; (B) All supplier lot numbers and production dates; (C) The names of the supplied materials, including beef components and any materials carried over from one production lot to the next; (D) The date and time each lot of raw ground beef product is produced; and (E) The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized. 15", "Food Safety and Inspection Service: Final Rule Mandatory Recordkeeping (cont.) Table 3: Sample Grinding log with final rule requirements. 16", "Food Safety and Inspection Service: Final Rule \u2022 9 CFR 320.1(b)(4) continued: \u2022(ii) Official establishments and retail stores covered by this part that prepare ground beef products that are ground at an individual customer\u2019s request must keep records that comply with paragraph (b)(4)(i) of this section. \u2022(iii) For the purposes of this section of the regulations, a lot is the amount of ground raw beef produced during particular dates and times, following clean up and until the next clean up, during which the same source materials are used. 17", "Food Safety and Inspection Service: Final Rule 9 CFR 320.2(b) (added) For beef grinding, the records must be kept at the location where the beef is ground. This requirement will save investigators valuable time and will reduce the risk that records will be lost or misplaced. 9 CFR 320.2(a) In general, establishments and retail stores must keep the records required by paragraph 320.1(b) \u201cat the place where such business is conducted.\u201d But, if the business giving rise to the records occurs at multiple locations, the records may be kept at a \u201cheadquarters\u2019 office.\u201d Location of Records 18", "Food Safety and Inspection Service: Final Rule 9 CFR 320.2 Place of maintenance of records. (a) Except as provided in paragraph (b) of this section, any person engaged in any business described in \u00a7 320.1 and required by this part to keep records must maintain such records at the place where such business is conducted, except that if such person conducts such business at multiple locations,

he may maintain such records at his headquarters\ufe0f office. When not in actual use, all such records must be kept in a safe place at the prescribed location in accordance with good commercial practices. (b) Records required to be kept under paragraph (b)(4) of \u00a7 320.1 must be kept at the location where the raw beef was ground. Location of Records (cont.)

19","Food Safety and Inspection Service: Final Rule \ufe0f In general, records required by paragraph 320.1(b) must be retained for 2 years after December 31 of the year in which the transaction occurred, meaning a period of up to 3 years. \ufe0f FSIS shortened the retention period for beef grinding records to one year after the date of the recorded grinding activity.

Retention Period 9 CFR 320.3 20","Food Safety and Inspection Service: Final Rule Retention Period (cont.) 21 9 CFR 320.3 Record retention period. (a) Except as provided in paragraphs (b) and (c) of this section, every record required to be maintained under this part must be retained for a period of 2 years after December 31 of the year in which the transaction to which the record relates has occurred and for such further period as the Administrator may require for purposes of any investigation or litigation under the Act, by written notice to the person required to keep such records under this part. (b) Records of canning as required in subpart G of this subchapter A, 9 CFR chapter III, must be retained as required in \u00a7 318.307(e); except that records required by \u00a7 318.302(b) and (c) must be retained as required by those sections. (c) Records required to be maintained under paragraph (b)(4) of \u00a7 320.1 must be retained for one year.","Food Safety and Inspection Service: Imports \ufe0f To be eligible to export raw beef product to the United States, countries must maintain an equivalent inspection system for beef; traceback and traceforward systems for beef products that allow the country to identify the source of contamination. \ufe0f This means grinding operations that export raw ground beef products to the U.S. will have to maintain a recordkeeping system equivalent to this final rule. 22","Food Safety and Inspection Service: Frequently Asked Questions Which products are covered by the Final Rule? 23 \ufe0f The Final Rule does not apply to specific products. It requires that official establishments and retail stores that grind raw beef keep records of their grinding activities. \ufe0f But, if the ground beef is cooked before being put into commerce, FSIS does not intend to enforce the recordkeeping requirements. \ufe0f The rule does not set new recordkeeping requirements for mechanically-tenderizing or needle-injecting raw beef.","Food Safety and Inspection Service: Frequently Asked Questions \ufe0f 9 CFR 320.1(b)(4)(iii) defines a ground beef lot as the amount of ground raw beef produced during particular dates and times, following clean up and until the next clean up. \ufe0f As long as the date and time of cleaning is recorded, the lot will be clearly identifiable. \ufe0f Lots may include raw beef from multiple suppliers and\ufe0f or source materials. How is a ground beef lot defined in the final rule? 24","Food Safety and Inspection Service: Frequently Asked Questions \ufe0f Only raw beef that is ground must be recorded. \ufe0f For example, spices, casings, vegetables, or other types of meat or poultry in a product containing raw ground beef do not have to be recorded. \ufe0f Product labels do not have to contain any additional information under this rule. Which ingredients have to be recorded? 25","Food Safety and Inspection Service: Frequently Asked Questions Where can I find the production dates and supplier lot numbers? 26 \ufe0f Production dates and supplier lot numbers should be evident on boxes of source materials. \ufe0f If this information is not apparent, FSIS recommends contacting the supplier for the information. If the information is not available at the time of grinding, FSIS recommends recording any other available source

material information that may facilitate a swifter traceback, such as bar code numbers, invoice numbers, etc.", "Food Safety and Inspection Service: Enforcement of the Retail Recordkeeping Rule 27", "Food Safety and Inspection Service: Implementation The rule became effective on June 20, 2016. It will be enforced by FSIS investigators and inspection personnel beginning on October 1, 2016. 28", "Food Safety and Inspection Service: Implementation 29", "Food Safety and Inspection Service: Grinding Log Enforcement How will the final rule be enforced? 30 \u2022 October 1, 2016 \u2022 March 31, 2017 \u2022 OIEA Investigators will review grinding logs and educate retailers \u2022 After April 1, 2017 \u2022 OIEA will re-evaluate enforcement next steps (e.g. Letter of Information, Notice of Warning)", "Food Safety and Inspection Service: Frequently Asked Questions \u2022 In retail stores, FSIS\u2019 Office of Investigations, Enforcement and Audit (OIEA) Compliance Investigators will verify compliance by following the instructions found in FSIS Directive 8010.1, Methodology for Conducting In-Commerce Surveillance Activities. \u2022 In FSIS establishments, FSIS\u2019 Office of Field Operations (OFO) Consumer Safety Inspectors will verify compliance. How will the final rule be enforced? 31", "Food Safety and Inspection Service: Frequently Asked Questions \u2022 A recall is a firm\u2019s removal of distributed meat products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act. \u2022 Recall will be initiated if there is reason to believe there is adulterated or misbranded product in commerce. Will failure to maintain records result in a recall? 32", "Food Safety and Inspection Service: Education Materials Sanitation Guidance for Beef Grinders: [http://www.fsis.usda.gov/wps/wcm/connect/b002d979-1e1e-487e-ac0bf91ebd301121/Sanitation\\_Guidance\\_Beef\\_Grinders.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/b002d979-1e1e-487e-ac0bf91ebd301121/Sanitation_Guidance_Beef_Grinders.pdf?MOD=AJPERES). Ground Beef and Food Safety: <http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/getanswers/food-safety-fact-sheets/meat-preparation>. 33", "Food Safety and Inspection Service: Retail Recordkeeping for Establishments and Retail Stores That Grind Raw Beef Products Questions and Answers 34", "Food Safety and Inspection Service: Wrap Up and Adjournment Retail Recordkeeping for Establishments and Retail Stores That Grind Raw Beef Products 35", "Food Safety and Inspection Service: 36 askFSIS Submit questions to askFSIS: [www.askfsis.custhelp.com](http://www.askfsis.custhelp.com)", "Food Safety and Inspection Service: Small Plant Help Desk 37 Telephone: 1-877-FSIS-Help (1-877-374-7435) Web site: <http://www.fsis.usda.gov/sphelpdesk> Email: [sphelpdesk@custhelp.com](mailto:sphelpdesk@custhelp.com) 8:00 a.m. \u2022 5:00 p.m. Monday through Friday ET", "Food Safety and Inspection Service: Media Inquiries 38 Congressional and Public Affairs Office Telephone: (202) 720-9113 Email: [Press@fsis.usda.gov](mailto:Press@fsis.usda.gov)", "Food Safety and Inspection Service: Final Rule 39 [www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/interim-and-final-rules](http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/interim-and-final-rules)", "Food Safety and Inspection Service: Retail Recordkeeping for Establishments and Retail Stores That Grind Raw Beef Products Adjournment 40"]}, {"file\_name": "FSIS\_GD\_2016\_0018", "title": "Questions and Answers related to the Final Rule \"Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products\"", "num": "FSIS-GD-2016-0018", "id": "edc10dbf5a5d672def0dfc2ad420487e2795a000612c56b0a7ea9aa7ae459b9d", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-02/faq-final-"}]

rule.pdf", "type": "pdf", "n\_pages": 3, "word\_count": 1362, "text\_by\_page": ["Questions and Answers related to the Final Rule \u201cRecords To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products\u201d Question 1: What raw ground beef products are covered by the Final Rule? Answer: The Final Rule does not apply to specific products. It requires that official establishments or retail stores that grind raw beef keep records concerning their grinding activities. If official establishments have records to show that the product they grind is going to be fully cooked, the record requirements in the Final Rule do not apply. Question 2: For the Final Rule, how is a ground beef lot defined? Answer: Under 9 CFR 320.1(b)(4)(iii), a ground beef lot is defined, for the purpose of raw ground beef recordkeeping, as the amount of ground beef produced during particular dates and times, following clean up and up until the next clean up. All of the information specified in 9 CFR 320.1(b)(4)(i) must be recorded for each raw ground beef production lot, including the identity of supplier(s) and the time when each cleaning of grinding equipment and related food-contact surfaces occurs. This lot definition is separate from FSIS sampling of E. coli O157:H7, where, pending test results, official establishments must define and hold the sampled lot on the basis of microbiological independence from other production lots. FSIS has issued guidance on defining a lot in this context in Directive 10,010.1, Sampling Verification Activities for Shiga Toxin-Producing Escherichia Coli (STEC) in Raw Beef Products, and in the FSIS Compliance Guideline for Controlling Meat and Poultry Products Pending FSIS Test Results. Retailers have the option to hold potentially implicated product when FSIS samples and tests for E. coli O157:H7 as part of its in-commerce surveillance. See Directive 8010.1, Methodology for Conducting In-commerce Surveillance Activities. If a retailer opts to hold product pending receipt of the sampling results, it must similarly show microbiological independence, typically through information related to grinder and food contact surface cleaning and the source materials used. A \u201clot\u201d in this context is not necessarily limited to the ground beef produced between cleanings.

Question 3: If an official establishment or retail store switches source materials but does not do a complete grinder clean up, do the regulations allow the subsequent product to be a separate lot? Answer: No, if the grinding equipment and product contact surfaces are not cleaned, all of the product that came in contact with that equipment since the last clean-up is considered part of the same lot due to the opportunity for cross-contamination. Question 4: For the Final Rule, is a lot defined by the USDA, the official establishment, or the retail store? Answer: For the purpose of the raw ground beef recordkeeping regulation, USDA has defined a lot as the amount of ground raw beef produced during particular dates and times, following clean up and until the next clean-up (9 CFR 320.1(b)(4)(iii)). In accordance with this definition, the actual size of each lot will depend on the production practices of an official establishment or retail store. Question 5: For the Final Rule, must each lot of raw ground beef produced at an official establishment or retail store be from a single supplier? Answer: No, the Final Rule requires that the official establishment or retail store maintain the specified information for each raw ground beef lot that includes \u201cthe establishment numbers of establishments supplying material\u201d and the \u201csupplier lot numbers and production dates\u201d (9 CFR 320.1(b)(4)(i)). The Agency realizes that there may be more than one source supplier for a lot of raw ground beef product produced by the retailer or establishment. Question 6: For the Final Rule, must the grinding log at the retail store contain an individual entry for a customer-requested grind? FSIS OPPD July 12, 2016", "Questions and Answers related to the Final Rule

\u201cRecords To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products\u201d Answer: Not necessarily. An additional entry is not needed if the customer-requested product is ground at the same time and from the same supplier production lot as other material being ground. If a retailer grinds materials from a different supplier, or the same supplier but a different production lot or date, it will have to record the customer grind as a separate lot. Question 7: If an official establishment or retail store makes meatloaf, do all the spices and other ingredients, in addition to ground beef components, need to be included in the records? Answer: No, the official establishment or retail store only needs to maintain grinding records for beef ground at the establishment or store. The establishment or store is not required to record the same information for spices and other ingredients used in the raw ground beef product. Question 8: In a facility that houses both a federally-inspected official establishment and a retail store, which FSIS program staff will verify whether the retail store complies with the new recordkeeping requirements for ground beef? Answer: The FSIS Office of Investigations, Enforcement and Audit (OIEA) Compliance Investigators will verify whether the retail store complies with the recordkeeping requirements by following the instructions found in FSIS Directive 8010.1, Methodology for Conducting In-Commerce Surveillance Activities. The in-plant FSIS Office of Field Operations (OFO) Consumer Safety Inspectors will verify whether the official establishment meets the new recordkeeping requirements. Question 9: If the source material used to grind the raw beef product does not contain a readily identifiable lot number, what should be recorded on the grinding record? Answer: If the supplier lot number on the source material is not apparent, FSIS recommends that the official establishment or retail store contact the supplier for the lot number information. If no lot number is available to be recorded at that time, FSIS recommends that the grinder write down any other available supplier or source material information that may facilitate a swifter traceback, such as bar code numbers, invoice numbers, etc. Question 10: What are the penalties for a retail store if the required records are not maintained? What are the penalties for an official establishment if the required records are not maintained? Answer: If a retail store fails to maintain the required records, FSIS personnel may issue a Notice of Warning or in the event of repeated violations, request the Department of Justice to initiate a civil proceeding to enjoin the defendant from further violations of the applicable laws and regulations, or take other action as authorized by law. If FSIS personnel find non-compliance at an official establishment, the Agency could issue noncompliance records (NRs), warning letters, or in the event of repeated violations, refer the matter for additional enforcement actions, as authorized by law. Question 11: If FSIS discovers that the required records are not being maintained by the retail store or official establishment, will FSIS request a recall? Answer: Unless there is reason to believe that there is adulterated or misbranded product in commerce, FSIS will not request that the official establishment or retail store recall the product corresponding to the records that were not maintained. Question 12: Is the use of ditto marks an acceptable way to carry information down to the next line of the grinding log without having to write the information all over again? Answer: Yes, ditto marks may be used as long as the information is identical. FSIS OPPD July 12, 2016", "Questions and Answers related to the Final Rule \u201cRecords To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products\u201d Question 13: Besides raw ground beef, does the Final Rule apply to other non-intact raw beef produced by an official establishment or retail store? Answer: No, the rule requires that official establishments or retail stores that grind raw

beef keep records concerning their grinding activities. The final rule does not apply to other activities such as mechanically tenderizing or needle-injecting raw beef. Question 14: If an official establishment or retail store is purchasing ground beef that it portions and repackages, is it required to keep records under this Final Rule? Answer: No, an official establishment or retailer store is not subject to the Final Rule, unless it actually grinds the raw beef. FSIS OPPD July 12, 2016"]}, {"file\_name": "FSIS\_GD\_2017\_0001", "title": "Labeling Policy Guidance - Uncooked, Breaded, Boneless Poultry Products", "num": "FSIS-GD-2017-0001", "id": "7b9772d4463de7b43d923239d631563f82171ffc13932c632fdfbfa7abb110d1", "corp\_us": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Labeling\_Policy\_Guidance\_Uncooked\_Breaded\_Boneless\_Poultry\_Products.pdf", "type": "pdf", "n\_pages": 9, "word\_count": 3537, "text\_by\_page": ["Food Safety and Inspection Service (FSIS) Labeling Policy Guidance Uncooked, Breaded, Boneless Poultry Products Purpose of the Guidance The intent of this document is to provide guidance to the industry on the modifications that are necessary for the labeling of uncooked, breaded (both pre-brown and not prebrowned), boneless poultry products that also may be stuffed or filled, char-marked, or artificially colored, in accordance with the letter to the manufacturers of these types of products posted on the FSIS website on March 20, 2006 (see the following web link:

[http://www.fsis.usda.gov/OPPDE/larc/Policies/Letter\\_to\\_Industry\\_on\\_Frozen\\_Uncooked\\_Poultry.pdf](http://www.fsis.usda.gov/OPPDE/larc/Policies/Letter_to_Industry_on_Frozen_Uncooked_Poultry.pdf)). Products of these types are similar to the products associated with the recall that was posted on the FSIS website on March 10, 2006, involving frozen, stuffed chicken entrees. As explained in the recall notice, the frozen state, labeling, and cooked appearance of the uncooked chicken products may have caused consumers to believe that they were precooked. Thus products may not have been cooked by consumers to a safe internal temperature. FSIS is concerned that the labeling of products of this type be adequate to inform the public of the manner of handling required to maintain the products in a wholesome condition and to prepare them safely. Moreover, the cooking instructions need to be validated to address the intended use by the consumer. While consumers may be directed to cook the products to an internal temperature of 165 degrees Fahrenheit (F), if they are directed to use a cooking method that is not practical or not likely to achieve the necessary level of food safety (e.g., cooking frozen product in a toaster oven or microwave oven), the cooking instructions may not be valid. As a result of the recall, the letter noted above was posted on the FSIS website and sent directly to manufacturers of these products and similar products recommending that labels be modified to emphasize that such products are not cooked. A statement on the principal display panel of the packaging, such as \u201cUncooked: For Safety, Must be Cooked to an Internal Temperature of 165 degrees F as Measured by Use of a Thermometer,\u201d is an appropriate way to help consumers understand the need for the safe preparation of the products on their part. The cooking instructions should also be revised commensurate with validation that lethality is achieved with all the methods of cooking preparation that are declared on the labels. By improving the cooking instructions, as well as documenting that cooking methods are validated as part of the official labeling record, a situation like the one that led to the recent recall could be avoided. Additional guidance was made available in the March 2006 Report of the Subcommittee on Consumer Guidelines for the Safe Cooking of Poultry Products of the National Advisory Committee on Microbiological Criteria for Foods

(NACMCF). This report should serve as a guide on how an establishment can make the necessary modifications to", "product labeling and for cooking method validation such that the subject products can be assured to result in safe and wholesome products, and that the revised labeling is not misleading. The report can be found on the FSIS website at:

[www.fsis.usda.gov/PDF/NACMCF\\_Report\\_Safe\\_Cooking\\_Poultry\\_032406.pdf](http://www.fsis.usda.gov/PDF/NACMCF_Report_Safe_Cooking_Poultry_032406.pdf) I. Suggestions on the Modifications of Affected Labeling Consumer-Packaged Product and Products Directed to Food Preparation Establishments \u2022 The principal display panel of labels should bear prominent and clear terms that convey that the product contains raw or uncooked poultry, i.e., \u201craw,\u201d \u201cuncooked,\u201d or \u201cnot ready to eat.\u201d Based on the recommendations of the NACMCF, the term \u201cready to cook\u201d should not be used unless used in conjunction with a term such as one of those listed above. Consumer-Packaged Product \u2022 Only validated cooking instructions should appear on labeling. The cooking instructions should include, at a minimum, (1) the method of cooking, (2) an endpoint temperature of 165 degrees F or higher, and (3) instruction that the endpoint temperature is measured by use of a thermometer. Products Directed to Food Preparation Establishments \u2022 For food products directed to food preparation establishments, i.e., hotels, restaurants, and institutions (HRI), FSIS will accept references to the Food Code or equivalent State and local requirements as adequately addressing the need for adequate cooking. Because the food preparation establishments have standard operating procedures, e.g., cooking procedures consistent with Food Code or State standards, there is no need for further evidence of validation regarding the cooking instructions. In these instances, a statement of limited use should be applied to the labeling of these products, stating that the product is for preparation at food preparation establishments or specific restaurants. Examples of such statements are \u201cFor preparation by a food preparation establishment,\u201d \u201cfor HRI use only,\u201d or \u201cMade exclusively for XYZ restaurants only.\u201d This statement should appear on the label as well as the label application form. II. Procedures for Submitting Labels for Approval \u2022 Submittals of modified labeling that respond to the March 20 Letter should be submitted to the Agency in the usual manner. Labels may be submitted individually or, to help establishments that may have several labels that need to be modified, label submissions may be presented as a", "\u201cblanket\u201d sketch submissions. A \u201cblanket\u201d sketch submission consists of a completed FSIS Form 7234-1 to which is attached at least one representative label that indicates the proposed modifications, i.e., a prominent statement on the PDP designating the product as raw, uncooked, or not-ready-to-eat, and the planned modifications of the cooking instructions, or a statement of limited use if the product is designated for use at a food preparation establishment, and a listing of all other product labels that will be revised in the same manner (in duplicate). Such blanket sketch submissions are being accepted by the Agency as a means of accommodating manufacturers of the types of products in question when the only changes to the subject labels are those that are the subject of the March 20 Letter. \u2022 The Agency understands that establishments may have existing stocks of labels for the affected products on-hand. Existing stocks can be used by November 1, 2006, without submitting to the Agency for a temporary approval. However, every effort should be made to submit revised labeling to the Agency in accordance with the dates noted below. Dates by Which Labels Need to be Submitted \u2022 All products packaged and labeled for consumer retail purchase, i.e., those sold directly to consumers and prepared by consumers,

should be submitted to the Agency for sketch approval by May 1, 2006, in accordance with the March 20 Letter. \u2022 Manufacturers of products to be prepared by food preparation establishments, such as a hotels, restaurants, or institutions, need to submit a listing of the labels and the planned changes, (i.e., one representative label that includes the terms or statements about being uncooked product and validated cooking instructions or examples of statements of limited use) to the Agency by July 1, 2006. \u2022 FSIS recognizes that labeling for the subject products that bear Child Nutrition (CN) statements must be submitted directly to the Food and Nutrition Service (FNS) for evaluation prior to submission to FSIS. Because such labels cannot be submitted as a blanket approval, individual label submittals must be prepared. For that reason, labels for the subject products that bear CN statements must be submitted to FNS by June 1, 2006. After the labels have been evaluated by FNS, they need to be sent to FSIS for sketch approval. \u2022 All labels (i.e., for consumer packaged retail products, products for food preparation establishments, and products bearing CN statements) that have been sketch-approved by FSIS (either through a blanket approval or individual label approvals) should be in final form no later than September 30, 2006." ,\u2022 The Office of Field Operations (OFO) will not be taking enforcement action on the labeling changes expected to be initiated by May 1, 2006, until FSIS issues specific verification procedures in an FSIS Notice expected in early September 2006. Meanwhile, FSIS will convey the labeling implementation strategy to the District Offices, who will inform field personnel about the implementation strategy. **QUESTIONS AND ANSWERS CONCERNING THE REVISION OF LABELING OF UNCOOKED, BREADED, BONELESS, POULTRY PRODUCTS THAT MAY BE STUFFED OR FILLED, CHARMARKED OR ARTIFICIALLY COLORED**

1. Will all types of products need the label changes described in the March 20, 2006 letter to industry concerning uncooked breaded, poultry products that is posted on FSIS website? The types of products include uncooked, raw or not ready to eat, breaded (both pre-brown and not pre-brown), boneless poultry products that also may be stuffed or filled, char-marked, or artificially colored. The frozen state, labeling, and cooked appearance of these uncooked poultry products may cause consumers to believe that they are ready to eat. Examples of such products include but are not limited to: breaded chicken patties, breaded, pre-brown, chicken cordon bleu, chicken Kiev, chicken stuffed with broccoli and cheese, turkey patties, and chicken nuggets.

2. Does this action apply to both refrigerated and frozen products? Yes, the food safety concern regarding the adequacy of the labeling for uncooked, raw or not ready to eat, breaded, boneless poultry products that also may be stuffed or filled, charmarked, or artificially colored, exists whether the product is frozen or refrigerated.

3. Will the labels for single ingredient products, such as leg quarters, drumsticks, chicken wings, or other whole muscle products, or poultry products with added solution but no breading, that have a cooked appearance, need to be revised? The products to which the March 20, Letter relates are frozen or refrigerated, breaded, boneless not-ready-to-eat poultry with a cooked appearance. If a product is other than breaded, boneless not-ready-to-eat poultry, the Letter does not apply. However, if the product is not-ready-toeat and has a cooked appearance or it is not obvious that the product is raw, the product should bear special labeling alerting the user that the product is not-ready-to-eat. The labeling should bear safe handling instructions if the poultry component is not ready to eat; a prominent statement on principal display panel indicating product is not-ready-to-eat, e.g., \u201cCook thoroughly\u201d or \u201cRaw,\u201d validated cooking instructions that have been shown to be understood by

the food preparers and that are sufficient to destroy", "pathogens to result in a microbiologically safe product and if nutrition facts are present, the serving size should be based on the ready to cook reference amount customarily consumed (9 CFR 381.412). 4. Why do the labels for the products described above need to be revised? FSIS is concerned that the labeling of products of this type should be revised to adequately inform consumers and food preparers about the uncooked nature of the products and of the manner of handling required to maintain the products in a wholesome condition and to prepare them safely; i.e., provide a lethal heating step to achieve a microbiologically safe product. 5. Why does FSIS want to take this action so quickly? It is clear from the recent events that labels for uncooked, breaded, boneless poultry products on the market today may not be understood or followed by consumers. This lack of understanding may result in consumers not cooking the products to the minimum internal temperature (165 degrees F) necessary for the destruction of foodborne bacteria and viruses, even though the cooking instructions on the product labeling tell them to do so. 6. Does this guidance only affect the labeling of retail product labels or are all product labels of the type described above, even those destined for food preparation establishments such as hotel, restaurants and institutions, as defined by the Food Code, need to be revised? No, there is no distinction between the labeling needed for consumer packaged retail products; and food preparation establishments, such as hotels, restaurants or institutions or other food preparers, because the same food safety concerns exist. 7. If an official establishment is selling its uncooked or not-ready-to-eat breaded, boneless, poultry product to a food preparation establishment that already has specific cooking instructions for that product, is it necessary that cooking instructions be added to the label? It depends on whether the product has the potential of being released into commerce. If a federal establishment can ensure that given the circumstances of its relationship with a food preparation establishment and there is no real chance of the product getting into commerce, the Agency will consider whether or not the cooking instructions for that product are necessary. In all cases, a specific statement of limited use, e.g., "\u201cFor preparation by a food preparation establishment only, according to the food code or equivalent; \u201d \u201cPrepared exclusively for XYZ Restaurants; \u201d or \u201cFor HRI use only,\u201d will be required to ensure the product is confined to the food preparation industry only." 8. What types of terms or statements should be included when revising labels for uncooked breaded, boneless poultry product labels to convey to consumers that these products are not ready to eat? Although the statement in the Letter to Industry, i.e., "\u201cUncooked: For Safety, Must be Cooked to an Internal Temperature of 165 degrees F as Measured by a Thermometer\u201d clearly conveys that the product is not-ready-to-eat and needs to be cooked before it can be safely consumed, other statements may be used on the principal display panel as well. The three key elements for an effective statement are: (1) terms that reflect that the product is not ready to eat, for example, \u201cUncooked,\u201d \u201cRaw,\u201d \u201cRaw - Cook Thoroughly,\u201d \u201cSee Cooking Instructions;\u201d (2) a specific endpoint internal temperature, i.e., 165 degrees F or higher; and (3) a direction to measure the endpoint safe minimum temperature by a food thermometer. Statements that include these three key elements need to appear on the principal display panel of consumer packaged products in order to give consumers consistent and prominent information about the nature of the product. 9. Where does the statement that will convey that the product is uncooked or partially cooked need to appear on the label? Such

statements need to appear on the principal display panel of the product label. The principal display panel of the package should be the focal point for certain safety information to make it clear that the product is not ready to eat. 10. When do affected establishments need to submit revised labels to the Agency? Establishments need to submit labeling for consumer packaged retail products by May 1, 2006. Products prepared for food preparation establishments (not sold directly to the consumer) need to submit by July 1, 2006. For labels bearing a child nutrition (CN) statement, labeling must be submitted to the Food Nutrition Service (FNS) by June 1, 2006, and then subsequently sent for approval by FSIS. 11. Why do CN labels have a different deadline date for submission of revised labeling? That is because labels bearing CN statements require evaluation by FNS for each label submitted. FNS needs adequate time to handle the expected increase in label rescissions, requests for temporary approval and new label submissions. The extended date for submitting such labeling to FNS is June 1, 2006. The date by which modified labels need final label approval is September 30, 2006. Labels for FNS evaluation should be directed to USDA, FNS, CND, 3101 Park Center Drive, Alexandria, VA 22302, Attn: CN Label Reviewer, Phone: 703-305-2609". 12. If a company believes that its current labeling is sufficient to meet the criteria in the March 20 Letter, do they need to resubmit their labels to the Agency by one of the dates cited above? Yes, if a company has reevaluated their current labeling and feels that it is sufficient to inform the consumer that cooking is required for safety (and the cooking instructions are validated), then they should resubmit their labeling to the Agency for consideration of sketch approval. In other words, establishments cannot self-determine that the labeling is sufficient. 13. We have several labels that need to be revised according to the March 20, 2006, letter. Do we need to submit each label separately? Establishments do not need to send in every label in for sketch approval by the dates mentioned above. Establishments can submit a \u201cblanket\u201d sketch approval indicating the modifications they intend to make to the labels of products that are the subject of the letter. An example of one of the products with the proposed changes would need to be submitted attached to a completed FSIS Form 7234-1 (in duplicate). 14. Why are labels for products bearing CN statements excluded from blanket approvals? A blanket request is a label application for multiple label approvals sharing the same problem. All CN labels with proper documentation must be submitted to FNS prior to submission to FSIS. Acceptable label applications for FSIS evaluation contain a FNS sign-off. In order to remind industry of the proper label approval procedure for CN labels, a statement will be placed on all blanket requests indicating that CN labels are excluded and will also indicate that all CN labels must be submitted through FNS prior to submission to FSIS, LCPS. Labels for FNS evaluation should be directed to USDA, FNS, CND, 3101 Park Center Drive, Alexandria, VA 22302, Attn: CN Label Reviewer, Phone: 703-305-2609. 15. Our establishment is prepared to make the necessary changes to its labeling; however, we have several hundreds of label on-hand. Will we need to get temporary approval on existing inventory of labels? The Agency understands that establishments may have existing stocks of labels on hand. Existing stocks must be used by November 1, 2006, without submitting for a temporary approval. 16. Can a pressure sensitive sticker that includes the necessary terms be used to update labels?", "If a pressure sensitive sticker is used to modify current labeling, the sticker must be submitted for evaluation, as well. Once approved, the pressure sensitive sticker policy guidance on the FSIS website would be in effect; all existing stocks bearing a sticker with acceptable terminology may be used until stocks are exhausted.

17. Will my inspector take action against my labeling associated with this issue after May 1, 2006? The Office of Field Operations has been informed of the issue and will not take enforcement action on this issue until the Agency provides verification procedures through an FSIS Notice. It is anticipated that FSIS will publish an FSIS Notice in early September 2006, in order to ensure that labels are modified and applied to new production after November 1, 2006.

18. Does the statement of limited use that a food preparation establishment adds to labeling in lieu of cooking instructions need to be on the principal display panel? No, the statement of limited use does not need to appear on the principal display panel but may appear in a prominent manner anywhere on the label.

19. Do the cooking instructions need to be on the principal display panel (PDP)? No, the cooking instructions may appear anywhere on the label. However, on consumer packaged products, the endpoint internal temperature and the need to measure the endpoint internal temperature by use of a food thermometer need to appear on the principal display panel.

20. Is it necessary to revise the cooking instructions on uncooked, breaded, boneless poultry products if it does not include the internal temperature of 165 degrees F? Yes, as recommended by the NACMCF, a single minimum internal temperature of 165 degrees F for cooking without time limitation will ensure that the cooked poultry product is microbiologically safe. This temperature will destroy Salmonella, the most heat resistant pathogen of public health concern in raw poultry.

21. Why do the cooking instructions on these uncooked, breaded, boneless, poultry products need to be validated? Cooking instructions need to be validated to ensure that the method by which the product is prepared is adequate to achieve the lethality of any pathogens that may be present in a raw product. When validating the cooking instructions establishments should take into account how the consumer is likely to interpret the cooking instructions and what the consumer may actually do in preparing and cooking the product.

22. How can I assure FSIS that the cooking instructions have been validated? Does the validation data need to be included with the label submittal? Validation data should be included as part of the official labeling record for the product.

23. Why is it necessary to include cooking instructions on the label if the statement on the principal display panel includes both an endpoint temperature and the need to measure the temperature with a meat thermometer; e.g., \u201cUncooked: For Safety, Must be Cooked to an Internal Temperature of 165 degrees F as Measured by Use of a Thermometer\u201d The cooking method by which the endpoint temperature is achieved needs to be included on the label in the cooking instructions because the consumer needs explicit information about the way to achieve a safe product for consumption.

24. If the statement on the PDP includes an internal temperature and the use of a thermometer to measure the temperature; does this information need to be included in the cooking instructions as well? Yes, the endpoint temperature and the need for a thermometer to ensure that the endpoint temperature is met, should also be included in the cooking instructions would further emphasize that 165 degrees F is necessary to achieve a microbiological safe product using the method described in the cooking instructions.]}, {"file\_name": "FSIS\_GD\_2017\_0012", "title": "Guideline on Whole Grain Statements on the Labeling of Meat and Poultry Products", "num": "FSIS-GD-2017-0012", "id": "becac3a3fd520f7374a5004f460e400eba271169390bad89965cd0b3733dc580", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Guideline-Whole-Grain-Statements-"}]

Labeling.pdf", "type": "pdf", "n\_pages": 15, "word\_count": 3905, "text\_by\_page": ["1 This guideline is designed to help establishments determine: \u2022 Whether a whole grain statement can be made or not; \u2022 The types of statements that may be made; and \u2022 The supporting documentation needed for each type of statement. Food Safety and Inspection Service Guideline on Whole Grain Statements on the Labeling of Meat and Poultry Products October 2017", "2 FSIS Compliance Guideline for Label Approval Table of Contents Preface

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15", "3 Preface What is the purpose of this compliance guideline? The purpose of this compliance guideline is to help industry determine which whole grain statements are permitted on meat and poultry products and the criteria for their use. The Food Safety and Inspection Service (FSIS) is the agency in the United States Department of Agriculture (USDA) with the responsibility for assuring that the labeling of meat, poultry and egg products is truthful and not misleading. Labeling bearing any reference to whole grains is a special statement. All labels bearing special statements or claims must be sent to the Agency\u2019s Labeling and Program Delivery Staff (LPDS) for evaluation and approval before use according to the Code of Federal Regulations (CFR) Title 9 Section 412.1. However, once a label with a statement on whole grains is approved, there are many types of changes to the label that do not require submission to the Agency prior to use and can be generically approved (e.g., change in net weight, label color, vignettes, cooking instructions, and the addition of information that is not considered a special statement or claim). The key for making the change \u201cgenerically\u201d is that the change cannot affect the special statement or claim. Slide 40 of the Generic Label Approval PowerPoint Presentation from the link below provides an example of a special claim.

<http://www.fsis.usda.gov/wps/wcm/connect/1364c48d-214b-41bf-bab86289f951cb31/Generic-Final-Rule-Overview-Industry.pdf?MOD=AJPERES>. Who is this guideline designed for? This guideline is for establishments that are designing or modifying meat or poultry product labels with statements related to whole grains. What changes have been made to the guideline from the last version? FSIS previously issued guideline on whole grains claims in October 2005. This previous version was focused on references to

USDA\u2019s MyPyramid. FSIS has updated the guideline to include further details and explanations on the different types of claims and a key-points reference chart. How can I comment on this guideline? FSIS is seeking comments on this guideline as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days and the Agency will update the document in response to the comments. Comments may be submitted by either of the following methods:","4 Federal eRulemaking Portal Online submission at regulations.gov: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Mail, including - CD-ROMs, and hand- or courier-delivered items: Send to: Docket Clerk U.S. Department of Agriculture (USDA), FSIS, Patriots Plaza 3 1400 Independence Avenue SW, Mailstop 3782, 8-163A Washington, DC 20250-3700. All items submitted by mail or e-mail must include the Agency name, FSIS, and document title: Food Safety and Inspection Service Guideline on Whole Grain Statements on the Labeling of Meat and Poultry Products October 2017. Comments received will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>. Although FSIS is requesting comments on the guideline and may update it in response to comments, the guideline reflects FSIS\u2019s current position, and establishments may start using it now. What if I still have questions after I read this guideline? If the desired information cannot be found within the Compliance Guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the askFSIS database or submit questions through askFSIS. Documenting the questions helps FSIS improve and refine present and future versions of the Compliance Guideline and associated issuances. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided: Subject Field: Enter FSIS Interim Policy Guide on Whole Grain Claims Question Field: Enter question with as much detail as possible Product Field: Select Labeling from the drop-down menu Category Field: Select Labeling Regulations, Policies & Claims from the drop-down menu Policy Arena: Select Domestic (U.S.) only from the drop-down menu When all fields are complete, press Continue.","5 BACKGROUND Since a petition was submitted in 2004 to the Food and Drug Administration (FDA) regarding the uses of Whole Grain Descriptive Claims, the use of these statements has increased and diversified. Companies have shown interest in making claims such as: \u201cwhole wheat pasta.\u201d For that reason, this guideline aims to help the meat and poultry industry determine which claims are permitted on the labeling of their products. GENERAL WHOLE GRAIN STATEMENTS The Agency will allow, with LPDS sketch approval, factual statements and certain whole grain claims provided the statements\claims do not conflict with FSIS regulations and are not false or misleading. Factual statements simply state the level of a grain component in a serving of the product, e.g., 10 grams whole grain per serving. FSIS will also allow certain claims that do not expressly state or imply a specific level of whole grains through sketch approval, e.g., \u201cmade with 100% whole grain brown rice\u201d or the label has a product name declaring a whole grain, e.g., \u201cwhole wheat pepperoni pizza.\u201d NOTE: See Label Example 1 for a factual statement representation The basis for all whole grain factual statements and claims is that the product contains a minimal

quantity of the specified whole grain component. FSIS considers these statements to be false or misleading if the product does not contain at least 8 grams of dry whole grain ingredient per labeled serving size of the meat or poultry product as declared in the nutrition facts panel on the label and per the appropriate Reference Amount Customarily Consumed (RACC) for the meat or poultry product (9 CFR 317.312 Table 2 or 381.412 Table 2). Labeling for institutional use products that are exempt from including the nutrition facts panel may make whole grain statements or claims but the labeling application that needs to be submitted to FSIS will still need to show that the product meets the 8 gram minimum requirement per recommended serving size and per the appropriate RACC. FDA STANDARDIZED WHOLE GRAIN PRODUCTS When a claim specifies the product component that contains the whole grain, for example, \u201cmade with whole wheat spaghetti\u201d or \u201cpepperoni pizza made with whole grain crust,\u201d the whole grain component apart from the total meat or poultry product will need to meet an additional requirement which will be determined based on the standards of identity for whole grain products in 21 CFR 139.138. Products that have a whole grain standard of identity in 21 CFR must meet the FDA standard in order to use that product name, for example, in order to make the claim \u201cmade with whole wheat spaghetti\u201d the whole wheat spaghetti must meet the FDA standard of identity in 21 CFR 139.138, which requires 100% of the grain used to make the spaghetti be whole wheat." 6 SPECIFYING THE COMPONENT THAT CONTAINS WHOLE GRAIN When the component identified in the claim does not have a standard of identity for the whole grain product in 21 CFR, for example, there is no FDA standard for \u201cwhole wheat pizza crust\u201d or \u201cwhole wheat tortillas,\u201d then FSIS requires that whole grains make up at least 51% of the total dry grain used to formulate the non-standard grain product. CALCULATION EXAMPLES In order to obtain label approval, the label application form should provide calculations to support and verify that the product meets the above requirements. The calculations provided will need to correspond to the formula provided for the particular product. Because the calculations will vary depending on the statement or claim made and the nature of the formulation, below are several examples of the calculations that could be acceptable with a label application: A. Example calculations for a factual statement, such as, \u201cmade with whole grains\u201d which needs to show a minimum of 8g whole grain per labeled serving size as provided in the nutrition facts panel, and a minimum of 8 grams whole grains per RACC: Serving size of meat or poultry product in grams \u00d7 % dry whole grains in total formula = grams whole grains per serving (must be 8 grams or higher) AND RACC in grams for the meat or poultry product \u00d7 % dry whole wheat in total formula = grams whole wheat per RACC (must be 8 grams or higher) B. Example calculations for a factual statement, such as, \u201c10 grams whole wheat per serving,\u201d which needs to show a minimum of 10 grams of whole wheat per labeled serving size as provided in the nutrition facts panel, and a minimum of 10 grams whole wheat per RACC: Serving size of meat or poultry product in grams \u00d7 % dry whole wheat in total formula = grams whole wheat per serving (must be 10 grams or higher) AND RACC in grams for the meat or poultry product \u00d7 % dry whole wheat in total formula = grams whole wheat per RACC (must be 10 grams or higher) C. Example calculations for a \u201cpepperoni pizza made with whole grain crust\u201d that requires 8 grams or more whole grain per labeled serving size as provided in the nutrition facts panel, 8", "7 grams or more whole grain per RACC, and a minimum of 51% dry whole grain in the total dry grain used to make the crust: Serving size of

pizza in grams \u00d7 % crust \u00d7 % whole grain in the crust = grams of whole grain per serving (must be 8 grams or higher) AND RACC in grams for the meat or poultry product \u00d7 % crust \u00d7 % whole grain in the crust = grams of whole grain per RACC (must be 8 grams or higher) AND (Grams of whole grain in the crust \u00f7 grams of total grain in the crust) \u00d7 100 = % of whole grain in the grain component (must be 51% or higher) When the whole grain factual statements and claims meet the outlined requirements above, such statements and claims may be declared on any panel of the labeling of meat and poultry products. Declaring a whole grain component in the ingredients statement alone is not considered a claim and does not need to meet the 8 grams criteria but it should still meet the 51% criteria (or 100% criteria if there is a FDA standard). For example, if the product name is \u201cpepperoni pizza\u201d and the ingredients statement declares \u201cwhole wheat crust\u201d then the crust should be at least 51% whole wheat of the total grain component in the crust. This is because there is no FDA standard for whole wheat crust and the product does not need to meet the 8 grams criteria per labeled serving size or per RACC. LEVEL CHARACTERIZATION The nutrition labeling regulations in 9 CFR 317.313(b) and 381.413(b) clearly state that claims that, expressly or by implication, characterize the level of a nutrient may not be made on the labeling of a meat or poultry product unless the claim is made in accordance with the nutrition labeling regulations. The FSIS nutrition regulations do not include provisions to make claims about whole grains, whole grain cannot be included within the nutrition facts panel as a nutrient, and there is no regulatory percent Daily Value for whole grains. Therefore, claims such as \u201cgood source of whole grains,\u201d and \u201cexcellent source of whole grains\u201d are not permitted on meat and poultry product labeling. FSIS regulations in 9 CFR 317.313 and 381.143 do not allow statements or claims that imply that the level of whole grains in a product is high, or places significance on a specific level of whole", "8 grains, including, but not limited to:

\u201cccontains X grams of whole grains,\u201d \u201cmore than X grams of whole grains,\u201d \u201cat least X grams whole grains\u201d and \u201cfortified with X grams of whole grains.\u201d COMPANY NAMES or BRAND NAMES Trademarked company or brand names that name or imply a level of whole grain in a product cannot be approved when given prominence on the label. One exception is that a company or brand name that includes a whole grain claim or implies a whole grain claim may be part of the signature line as required by 9 CFR 317.2(g) and 381.122 provided that the signature line is normally placed, for example, in normal size font at the bottom of the information panel, and is not given undue prominence which would cause the use of the company name to be a false or misleading claim. AD-COPY FSIS needs to review and approve ad-copy as labeling and the above mentioned statements and claims criteria will be applied. Ad-copy may make general statements about whole grains provided it does not make a specific claim or relate to specific health benefits, for example, the statement, \u201cinclude whole grains as part of your daily life\u201d provides general nutrition advice without making a specific unapproved claim and would be acceptable on labeling through LPDS sketch approval, but a statement such as, \u201cwhole grains are chock full of nutrients\u201d is making a claim about whole grains which is undefined and not permitted. TRADEMARKED SYMBOLS Trademarked company or brand names, trademarked symbols or phrases, and statements used in ad-copy on labeling that name or imply a level of whole grain in a product cannot be approved. Certain non-specific trademarked symbols may be eligible to include on labeling of meat and poultry products provided the product provides a

minimum of 8 grams whole grain (or specific grain) per serving and per RACC for the product and obtains LPDS sketch approval. Trademarked company or brand names, trademarked symbols or phrases, and statements associated with whole grains are evaluated in the context of the label on which it is used. Just because a symbol is trademarked does not mean it can be added to labeling if it creates a false or misleading statement or claim about the product.

USDA\u2019s CHOOSE MY PLATE The Choose MyPlate: The USDA MyPyramid program was replaced by USDA\u2019s Choose MyPlate in 2011. Thus, companies referencing MyPyramid on labeling will need to revise such labeling to eliminate the outdated references. USDA\u2019s Center for Nutrition Policy and Promotion (CNPP) provides guidance to companies if they wish to include Choose MyPlate on labeling. Including Choose MyPlate on labeling is a special claim that requires LPDS sketch approval. Contact CNPP for questions about Choose MyPlate: <http://www.choosemyplate.gov/>, "9 Choose MyPlate Whole Grain Food Group Statements Statements declaring the amount of a food group or food sub-group that a product contributes as it relates to the 2015-2020 Dietary Guidelines for Americans (DGA) recommendations are considered special claims that require LPDS sketch approval. In order to make such statements, the product should be in compliance with CNPP, who, on their MyPlate Style Guide and Conditions of Use for the Icon , states that the use of whole grain content calculations based on MyPlate will only be granted on the labeling of meat and poultry products that: 1) Meet the criteria for \u201chealthy\u201d as defined by USDA and FDA in 9 CFR 317.363(d) and 381.463(d), and 21 CFR 101.65(d)(2), respectively; and 2) Contain little or no added sugars. Statements that FSIS would approve include: \u201cOne whole grain ounce equivalent per serving, MyPlate recommends at least 3 one-ounce equivalents of whole grains per day,\u201d and \u201cWhole Grains = 2 one-ounce equivalents\* \*MyPlate recommends at least 3 one-ounce equivalents of whole grains per day.\u201d Moreover, in order to not be viewed as misleading, the label that bears the claim must provide an adequate explanation for the consumer, for example, include content calculations, or references, based on a 2,000 calorie diet, and specify that the information is based on MyPlate recommendations. In addition, FSIS asks for the following to be taken into account when making this kind of statements: 1) Ounce equivalents of whole grain may be declared by half or whole numbers and should be declared as \u201counce equivalents\u201d in harmony with the language found in MyPlate; 2) Ounce equivalents may not be rounded up to the nearest half or whole ounce, but products should contain at least the amount declared by any claim or information; and 3) Calculations of the amount of whole grain ingredient or ounce equivalent must be provided with the label for sketch approval when statements are made regarding ounce equivalents of whole grains. To calculate whole grain ounce equivalents: <http://www.choosemyplate.gov/grains> MULTI-GRAIN Because the claim \u201cmulti-grain\u201d is not specifically a \u201cwhole grain\u201d claim, FSIS permits the use of \u201cmulti-grain\u201d when the product includes more than one grain source without the need to submit the label for review and approval prior to its use. For example, if the label declared a product name as \u201cmulti-grain pepperoni pizza\u201d and the ingredients statement showed that the crust was made with two or more different grains (whole grain or not whole grain when derived","10 from different grains), then no further documentation is needed to support the claim \u201cmultigrain.\u201d GRAINS CONSIDERED WHOLE GRAINS Examples of grains that are commonly considered a whole grain by the Whole Grains Council or FDA can be found below. - Amaranth - Unhulled barley -

Buckwheat - Whole kernel corn (including popcorn) - Millet - Oats (including rolled, quick and steel cut varieties) - Quinoa - Brown rice (including wild varieties) - Sorghum - Teff - Triticale - Whole wheat (including Kamut and other varieties) Legumes and oilseeds such as: soy, chickpeas, flax seeds, chia and sunflower seeds are not considered whole grains. Lastly, any labeling sketches granted approval with references to whole grains that are not in compliance with this policy should be brought into compliance with this policy. Consistent with the Agency's regulations about generic label approval, labels bearing special statements, such as those described above, must be submitted to LPDS for evaluation and approval before use for compliance with 9 CFR 412.1. However, once a label is approved with a whole grains statement or claim, additional changes may be made to the label such as to the brand name, net weight, handling statement, ad copy, and label design. These types of changes to the previously approved label are generically approved under 9 CFR 412.2 because they do not affect the special statement or claim. For additional information about FSIS labeling policies and programs, review the FSIS website for labeling at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatorycompliance/labeling/> or contact the LPDS at (301) 504-0878 or (301) 504-0879.,"11 Label Example 1 [Back to reading],"12 KEY-POINTS REFERENCE CHART Claim Type Permitted Examples Criteria and Requirements1 for Approval GENERAL STATEMENTS Yes (requires FSIS approval under 9 CFR 412.1) - \u201cWhole Wheat Pepperoni Pizza\u201d - \u201cX grams of whole grain per serving\u201d 1) A minimum of 8 grams of dry whole grain per both labeled serving size and Reference Amount Customarily Consumed (RACC) for the product; 2) Demonstrate that \u201cX\u201d grams per serving size is accurate when specifying the amount; plus 3) Provide calculations for points 1 and/or 2 according to claim. FDA STANDARDIZED WHOLE WHEAT PRODUCTS Yes (requires FSIS approval under 9 CFR 412.1) - \u201cWhole Wheat Spaghetti and Meatballs\u201d 1) A minimum of 8 grams of dry whole grain per both, labeled serving size and RACC for the product; 2) Grain portion of the product needs to be 100% whole wheat; plus 3) Provide calculations for points 1 and 2 (based on 21 CFR 139.138). SPECIFYING THE COMPONENT THAT CONTAINS WHOLE GRAIN Yes (requires FSIS approval under 9 CFR 412.1) - \u201cPepperoni Pizza with Whole Grain Crust\u201d - \u201cWhole Grain Breaded Chicken Patty\u201d - \u201cMade with Whole Grain Brown Rice\u201d 1) A minimum of 8 grams of dry whole grain per both labeled serving size and RACC for the product; 2) At least 51% of the grain components are whole grain; plus 3) Provide calculations for points 1 and 2. LEVEL CHARACTERIZATION No - \u201cGood Source of Whole Grains\u201d These statements are not permitted because there are 1 The basis for all whole grain factual statements and claims is that there should be a significant amount of the specified whole grain component in the product. FSIS considers these statements to be false or misleading if the product does not contain at least 8 grams of dry whole grain ingredient per labeled serving size of the meat or poultry product as declared in the nutrition facts panel on the label and per the appropriate Reference Amount Customarily Consumed (RACC)" "13 - \u201cMore than X grams \u201d Contains X grams \u201d At least X grams \u201d Fortified with X grams of Whole Grains\u201d no defined claims for whole grains. COMPANY\BRAND NAMES (Trademarked company\brand name associated with whole grains) Yes (in signature line only; requires FSIS approval under 9 CFR 412.1) - \u201cWhole Grain Company\u201d The name of the packer, manufacturer, or distributor (i.e., the signature line) is normally placed at bottom of information panel; not given undue

prominence. AD COPY and TRADEMARKED SYMBOLS (Ad-Copy, Trademarked symbols associated with whole grains in the context of the label on which it is used) Yes (requires FSIS approval under 9 CFR 412.1) - \u201cInclude whole grains as part of your daily life\u201d Evaluated on a case by case basis; documentation would be required if found to be a claim.

WHOLE GRAIN COUNCIL Yes (requires FSIS approval under 9 CFR 412.1) - 1) A minimum of 8 grams of dry whole grain per both labeled serving size and RACC for the product; 2) Demonstrate that \u201cX\u201d grams per serving size is accurate when specifying an amount different from 8 grams; 3) Cannot state \u201cor more,\u201d because it implies level characterization; 4) Cannot state \u201ceat 48 grams or more whole grain daily,\u201d because there is no Daily Reference Value in the nutrition regulation for whole grains; plus; 5) Provide calculations for points 1 and\or 2. USDA\u2019s CHOOSE MY Yes (requires - Including the 1) Not to be used with what", "14 PLATE FSIS approval under 9 CFR 412.1) USDA Choose MyPlate on label or how much to eat, plus 2) Use with \u201cLearn about healthy eating at ChooseMyPlate.gov\u201d MY PLATE WHOLE GRAIN FOOD GROUP STATEMENTS Yes (requires FSIS approval under 9 CFR 412.1) - \u201cOne whole grain ounce equivalent per serving, MyPlate recommends at least 3-one ounce equivalents of whole grain per day\u201d 1) Meets \u201chealthy\u201d; 2) Contains little or no added sugars; 3) Keep separate from Choose MyPlate; plus 4) Calculations for whole grain ounce equivalents (contact CNPP for methodology)", "15 <http://askfsis.custhelp.com/> FSIS\USDA www.fsis.usda.gov 2017"]}, {"file\_name": "FSIS\_GD\_2018\_0001", "title": "Data Samples and Guidelines for Using the Partner Government Agency (PGA) Message Set for Electronic Completion of the U.S. Department of Agriculture (USDA), Food Safety Inspection Service (FSIS) Application for Import Inspection (FSIS Form 9540-1)", "num": "FSIS-GD-2018-0001", "id": "03278adc38bfe07132d74b4dd9deb28dbf8cc0696841f8d9a3741618d0e45f3c", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Data\_Samples\_Guidelines\_PGA\_Message\_Set.pdf", "type": "pdf", "n\_pages": 51, "word\_count": 13423, "text\_by\_page": ["Data Samples and Guidelines for Using the Partner Government Agency (PGA) Message Set for Electronic Completion of the U.S. Department of Agriculture (USDA), Food Safety Inspection Service (FSIS) Application for Import Inspection (FSIS Form 9540-1) Version 3, February 2018", "Summary of Changes \u2022 This revision provides new codes in the PG10 record to accommodate the electronic submission of data required for Siluriformes fish and fish products. \u2022 This revision also clarifies data input instructions in the PG19, PG25 and PG30 records. Document Summary This document is intended as a supplemental guide to the United States Department of Agriculture\u2019s (USDA) Food Safety and Inspection Service (FSIS) data requirements when an Automated Broker Interface (ABI) filer (broker or self-filing importer) is using the Automated Commercial Environment (ACE) System of Customs and Border Protection (CBP) to provide PGA Message Set data. Specifically this guidance covers the data to be provided when a filer is submitting an Entry Summary certified for Cargo Release for products regulated by FSIS. The CBP Customs and Trade Automated Interface Requirements (CATAIR) chapters and appendices can be found on CBP.gov at: <http://www.cbp.gov/document/guidance/pga-message-set> The PGA Message Set and its related Appendix PGA can be found on CBP.gov at: <http://search.usa.gov/search?query=pga+message+set&affiliate=cbpgov> Other related"]}

appendices that could be used when submitting an entry can be found at:

<http://search.usa.gov/search?utf8=%E2%9C%93&affiliate=cbpgov&query=appendix+b> It should be noted that the PGA Message Set does not stand alone and must be submitted with an entry filing (i.e. ACE Entry Summary certified for cargo release (AE)). The Entry Summary contains certain data elements that are common to both FSIS and CBP requirements. The PGA Message Set data requirements for FSIS will not duplicate those common data elements, but rather provide the additional data needed to complete the FSIS application for import inspection (FSIS Form 9540-1) electronically. This guidance provides data samples of frequently imported products. The samples include a grid and accompanying text. The grid represents the 80-character limit, per record, allowed by ABI. The PGA Message Set defines the character length, class and position required by ABI for transmission to CBP and the grid shows how the data would be represented in ABI. 1", "FSIS Overview FSIS is the public health regulatory agency responsible for ensuring that domestic and imported meat, poultry, and processed egg products are safe, wholesome, and correctly labeled and packaged. Through the 2008 and 2014 Farm Bills, FSIS now inspects Siluriformes, including catfish, under the Federal Meat Inspection Act. FSIS ensures that meat, poultry, egg products, and Siluriformes imported to the United States originate from eligible countries and are produced under standards equivalent to U.S. inspection standards. In order to enhance the Agency's ability to protect public health, FSIS has launched the Public Health Information System (PHIS) as part of its effort to collect, consolidate, and analyze data. The PHIS interface with ACE enables seamless transfer of data required for the application for FSIS import inspection in advance of the shipment arrival. The inclusion of the data in the PGA Message Set eliminates the need to submit a paper copy of FSIS Form 9540-1 eliminates the manual data entry by FSIS inspection personnel and thereby, expedites the clearance of FSIS regulated shipments. All shipments of meat, poultry, egg products, and Siluriformes (including catfish) imported to the United States must be presented to FSIS at an official import inspection establishment for reinspection prior to release into commerce in the United States. Eligibility of the foreign country, foreign establishment, and product will be determined by the PHIS when the Importer of Record or U.S. Customs Broker files the mandatory application for FSIS import inspection. FSIS ensures that the exporting country\u2019s inspection certificates are authentic and accurate, and when assigned by the PHIS, FSIS performs a more in-depth reinspection of product, including product examination and laboratory testing for pathogens and chemical residues. FSIS sampling is allocated by country, process category, product category, product group, and species and the inspection results are entered into the PHIS. If the shipment fails reinspection, the noncompliant product is refused entry and the rate of inspection is intensified to ensure product compliance of subsequent shipments. FSIS PGA Message Set \u2013 FSIS Electronic Application (FSIS Form 9540-1) Data Requirements Below is the set of data elements FSIS requires from the trade, depending on the commodity and depending on whether electronic certification (government-to-government eCert) is applicable. Required PG Records for eCert Country (Currently Australia, New Zealand, and the Netherlands) PG Record Description OI Commercial Description PG01 Government Agency Code, PGA Line Number, Supplemental Product Codes (if applicable) PG02 Always P for Product PG06 Process Country, Source Country (if applicable) 2", "PG13 Official Inspection Certificate Country of Issuance PG14 Official Inspection Certificate Number PG19 Processing Establishment Number, Exporting Establishment Number, Source Establishment

Number (if applicable) PG21 Importer\Broker\Consignee Individual First and Last Name, Telephone number of the individual, Email address and\or fax number for the individual PG22 Document Identifier, Entity Role Code, Declaration Certification, Date of Signature PG30 Official Import Inspection Establishment and Estimated Date of Arrival Required PG Records for non-eCert Country PG Record Description OI Commercial Description PG01 Government Agency Code, PGA Line Number, Supplemental Product Codes (if applicable) PG02 Always P for Product PG06 Process Country, Source Country (if applicable) PG10 Species, Process Category, Product Category and Product Group (codes in Appendix PGA) PG13 Official Inspection Certificate Country of Issuance PG14 Official Inspection Certificate Number PG19 Processing Establishment Number, Exporting Establishment Number, Source Establishment Number (if applicable) PG21 Importer\Broker\Consignee Individual First and Last Name, Telephone number of the individual, Email address and\or fax number for the individual PG22 Document Identifier, Entity Role Code, Declaration Certification, Date of Signature PG25 Lot Number, Lot Production Dates (if applicable) PG26 Shipping and Immediate Container (if applicable) Package Types, Count, Shipping Mark PG29 Net Weight of Lot PG30 Official Import Inspection Establishment and Estimated Date of Arrival Foreign Inspection Certificate FSIS requires that all imported shipments of meat, poultry, egg products and Siluriformes (including catfish) be properly certified by the exporting foreign country. Some of the data elements needed to complete the ABI entry is supplied from the foreign inspection certificate, which accompanies each shipment. It is important to note that currently, FSIS receives official certification electronically from Australia, New Zealand and the Netherlands. For filers making entries from these three countries, the filer only needs to identify the inspection certificate number in PG14. 3","The PGA Message Set requirement for records identifying specific lot information will automatically populate from the data received from the foreign country\u2019s electronic certification into PHIS. Point(s) of Contact If you have questions about the content of these data samples, please contact: Mary Stanley USDA, FSIS Office of International Coordination (OIC) mary.stanley@fsis.usda.gov 202-708-9543 Phone Robert Berczik USDA, FSIS Office of Policy and Program Development (OPPD) robert.berczik@fsis.usda.gov 202-690-4163 Phone 4","CATAIR: The following are FSIS input and descriptions in the CATAIR format followed by the applicable FSIS codes from Appendix PGA and other related appendices. Data elements marked M in the Status block are mandatory. Data elements marked O in the Status block are optional. Data elements marked N\A in the Status block are not applicable for FSIS form 9540-1 in the message set. Record Identifier OI (Input) Since only one OI record is allowed per HTS code, a generalized commercial description is acceptable for FSIS purposes. Record Identifier OI (Input) Data Element Length\ Class Position Status Description Note Control Identifier 2A 1-2 M Must always equal OI. Filler 8AN 3-10 M Space fill. Commercial Description 70X 11-80 M A generalized commercial description is acceptable for FSIS purposes (e.g. Beef Cuts, Pork Loins, Lamb Shanks, etc.) Record Identifier PG01 (Input) FSIS Government Agency Code is FSI. FSIS can accept Globally Unique Product Identification Codes, Intended Use Codes in positions below, but they are not required. FSIS is not utilizing the Document Imaging System (DIS) for the purposes of supporting images relating to the electronic submission of FSIS form 9540-1. Record Identifier PG01 (Input) Data Element Length\ Class Position Status Description Note Control Identifier 2A 1-2 M Must always equal PG. Record Type 2N 3-4 M Must always be 01. PGA Line Number 3N 5-7 M Number required by PGAs beginning with 001 within a CBP line and

sequentially incremented on subsequent PG01 records, if applicable. Government Agency Code 3AN 8-10 M FSIS code is \u201cFSI\u201d Government Agency Program Code 3X 11-13 M Refer to Appendix PGA. FSIS code is \u201cFSI\u201d 1\| Government Agency Processing Code 3AN 14-16 N\|A Electronic Image Submitted 1A 17 N\|A 5", "I I Record Identifier PG01 (Input) Data Element Length\| Class Position Status Description Note Confidential Information Indicator 1A 18 N\|A Globally Unique Product Identification Code Qualifier 4AN 19-22 O Code indicating the type of globally unique number used to identify the commercial product or commodity. Valid codes are listed in Appendix PGA of this publication. 2\| Globally Unique Product Identification Code 19X 23-41 O FSIS can accept GTIN or UPC codes, but they are not required. Intended Use Code 16X 42-57 O FSIS can accept Intended Use Codes, but they are not required. Refer to Appendix R Intended Use Codes for ACE for valid codes. Intended Use Description 22X 58-79 N\|A Disclaimer 1A 80 N\|A FSIS has no specific business rules regarding Disclaims. Any disclaimer codes available through ACE can be utilized. 1\| Appendix PGA, PG01 \u2013 Agency Program Codes FSIS Programs Code Definition FSI Applicable to all USDA\FSIS programs 2\| Appendix PGA, PG01 \u2013 Globally Unique Product Identification Code Qualifiers Code Name Definition SRV GS1 Global Trade Item Number A globally unique 14-digit number assigned to a product according to the numbering structure of the GS1 system. AI UPC (Universal product code) A globally unique number assigned to consumer units of a product for use at point-of-sale registers according to the numbering structure of the GS1 system. Record Identifier PG02 (Input) At this time, FSIS will only expect a \u2018P\u2019 in position 5 of this record. Record Identifier PG02 (Input) Data Element Length\| Class Position Status Description Note Control Identifier 2A 1-2 M Must always equal PG. Record Type 2N 3-4 M Must always be 02. 6", "Record Identifier PG02 (Input) Data Element Length\| Class Position Status Description Note Item Type 1A 5 M Always \u201cP\u201d for FSIS. Product Code Qualifier 4AN 6-9 N\|A Product Code Number 19X 10-28 N\|A Product Code Qualifier 4AN 29-32 N\|A Product Code Number 19X 33-51 N\|A Product Code Qualifier 4AN 52-55 N\|A Product Code Number 19X 56-74 N\|A Filler 6X 75-80 N\|A Record Identifier PG06 (Input) FSIS requires the country of production, meaning the country that has certified the product for export to the U.S. on the foreign inspection certificate. Use code 39 from Appendix PGA in positions 5-7. If needed, repeat this record to identify the country of source (code 30 from Appendix PGA) in positions 57. The source country (when needed) is identified on the foreign inspection certificate. The ISO country code is then required in position 8-9. FSIS can accept Canadian Province codes in position 10-29, but is not required. Record Identifier PG06 (Input) Data Element Length\| Class Position Status Description Note Control Identifier 2A 1-2 M Must always equal PG. Record Type 2N 3-4 M Must always be 06. Source Type Code 3AN 5-7 M FSIS requires the country of production, meaning the country that has certified the product for export to the U.S. on the foreign inspection certificate. Use code \u201c39\u201d from Appendix PGA in positions 5-7 for country of production. If needed, repeat this record to identify the country of source (code \u201c30\u201d from Appendix PGA) in positions 5-7. The source country (when needed) is identified on the foreign inspection certificate. 1\| Country Code 2X 8-9 M A two-letter code that identifies where production or raw material came from. Valid International Organization for Standardization (ISO) Country and Currency Code codes are in Appendix B in the ACS ABI CATAIR. 7", "I I Record Identifier PG06 (Input) Data Element Length\| Class Position Status Description Note Geographic Location 20X 10-29 N\|A Processing Start Date 8N 30-37 N\|A

Processing End Date 8N 38-45 N\A Processing Type Code 5AN 46-50 N\A Processing Description 30X 51-80 N\A 1\ Appendix PGA, PG06 \u2013 Source Type Codes Code Name Definition 39 Country of Production Country where item has been produced. 30 Country of Source Country in which raw material or components originated. Record Identifier PG10 (Input) FSIS requires this record for non-eCert countries. These records identify the species, process category, product category, and product group data fields from FSIS form 9540-1 and are certified on the official foreign inspection certificate. Category Type Code is always FS1 in position 5-10. Category codes for FS1 Product Species Name are in Appendix PGA for position 11-15. The Commodity Characteristic Qualifier Codes for position 20-23 are in Appendix PGA; Example RPNI 1A means Raw Product NonIntact [Process Category] Raw ground, comminuted, or otherwise non-intact beef: Ground beef [Product Category: Product Group] Record Identifier PG10 (Input) Data Element Length\ Class Position Status Description Note Control Identifier 2A 1-2 M Must always equal PG. Record Type 2N 3-4 M Must always be 10. Category Type Code 6AN 5-10 M \u2013FS1\u2013d is Category Type Code for FSIS. See Appendix PGA (Category Type Code) of this publication for valid codes. 1\ Category Code 5AN 11-15 M See Appendix PGA (Category Code) of this publication for valid codes. Use FS1 Product Species Name list in Appendix PGA. Example: 5= Meat: Mutton. 2\ Commodity Qualifier Code 4X 16-19 M Enter the code for the process category (example: RPNI). See Appendix PGA (Commodity Qualifier Code) of this publication for valid codes. 3\ 8","I Commodity Characteristic Qualifier 4AN 20-23 M Enter the code for the process category: product group (Example 1A= Raw ground, comminuted, or otherwise non-intact beef: Groundbeef).SeeAppendixPGA (Commodity Characteristic Qualifier) of this publication for valid FSIS codes. 4\ Commodity Characteristic Description 57X 24-80 N\A 1\ Appendix PGA, PG10 \u2013 Category Type Codes Code Name FS1 FSIS \u2013 Product Name Category 2\ Appendix PGA, PG10 \u2013 Category Codes Code Name 1 Meat: Beef 2 Meat: Veal 3 Meat: Goat 4 Meat: Lamb 5 Meat: Mutton 6 Meat: Pork 7 Meat: Horse 8 Meat: Equine other than horse 9 Poultry: Chicken 10 Poultry: Turkey 11 Poultry: Duck 12 Poultry: Goose 13 Poultry: Guinea 14 Poultry: Squab 15 Poultry: Emu 16 Poultry: Ostrich 17 Poultry: Rhea 18 Eggs: Chicken 19 Eggs: Turkey 20 Eggs: Duck 21 Eggs: Goose 22 Eggs: Guinea 9","23 Egg Products: Chicken 24 Egg Products: Turkey 25 Egg Products: Duck 26 Egg Products: Goose 27 Egg Products: Guinea 28 Meat: Siluriformes -Ictaluridae (Catfish) 29 Meat: Siluriformes -Other 3\ Appendix PGA, PG10 \u2013 Commodity Qualifier Codes Code Name RPNI Raw Product \u2013 Non-intact RPI Raw Product \u2013 Intact TPCS Thermally Processed \u2013 Commercially Sterile NHTS Not Heat Treated \u2013 Shelf Stable HTSS Heat Treated \u2013 Shelf Stable FCNS Fully Cooked \u2013 Not Shelf Stable NFC Heat Treated but Not Fully Cooked \u2013 Not Shelf Stable PWSI Products with Secondary Inhibitors \u2013 Not Shelf Stable. EEP Eggs\Egg Products 4\ Appendix PGA, PG10 \u2013 Commodity Characteristic Qualifiers RPNI: Raw Product \u2013 Non-Intact Code Name Definition 1A Raw ground, comminuted, or otherwise non-intact beef: Ground beef [319.15(a)] 1B Raw ground, comminuted, or otherwise non-intact beef: Hamburger [319.15(b)] 1C Raw ground, comminuted, or otherwise non-intact beef: Beef Patty Product [319.15(c)] 1D Raw ground, comminuted, or otherwise non-intact beef: Formed Steaks [319.15(d)] 1E Raw ground, comminuted, or otherwise non-intact beef: Sausage [319.142; 319.143] 1F Raw ground, comminuted, or otherwise non-intact beef: Advanced Meat Recovery Product (AMR) [318.24] 1G Raw ground, comminuted, or otherwise non-intact beef: Finely Textured Beef 10","RPNI:

Raw Product \u2013 Non-Intact Code Name Definition 1H Raw ground, comminuted, or otherwise non-intact beef: Non-Intact Cuts 1I Raw ground, comminuted, or otherwise non-intact beef: Trimmings from Non-Intact 1J Raw ground, comminuted, or otherwise non-intact beef: Bench Trim from non-intact 1K Raw ground, comminuted, or otherwise non-intact beef: Other NonIntact 1L Raw ground, comminuted, or otherwise non-intact beef: Low Temperature Rendered Product 1M Raw ground, comminuted, or otherwise non-intact beef: Partially Defatted Chopped Beef (PDCB) 1N Raw ground, comminuted, or otherwise non-intact beef: Partially Defatted Beef Fatty Tissue (PDBFT) 2A Raw ground, comminuted, or otherwise non-intact pork: Ground Product 2B Raw ground, comminuted, or otherwise non-intact pork: Sausage (319.142; 319.143; 319.144; 319.145) 2C Raw ground, comminuted, or otherwise non-intact pork: Other NonIntact 2D Raw ground, comminuted, or otherwise non-intact pork: Advanced Meat Recovery Product (AMR) (318.24) 2E Raw ground, comminuted, or otherwise non-intact pork: Mechanically Separated (319.5) 3A Raw ground, comminuted, or otherwise non-intact meat \u2013 Other: Ground Product 3B Raw ground, comminuted, or otherwise non-intact meat -Other: Sausage 3C Raw ground, comminuted, or otherwise non-intact meat -Other: Other Non-Intact 3D Raw ground, comminuted, or otherwise non-intact meat -Other: Advanced Meat Recovery Product (AMR) [318.24] 3E Raw ground, comminuted, or otherwise non-intact meat -Other: Mechanically Separated [319.5] 4A Raw ground, comminuted, or otherwise non-intact chicken: Ground Product 4B Raw ground, comminuted, or otherwise non-intact chicken: Sausage 4C Raw ground, comminuted, or otherwise non-intact chicken: Other Non-Intact 4D Raw ground, comminuted, or otherwise non-intact chicken: 11", "RPNI: Raw Product \u2013 Non-Intact Code Name Definition Mechanically Separated [319.5] 5A Raw ground, comminuted, or otherwise non-intact turkey: Ground Product 5B Raw ground, comminuted, or otherwise non-intact turkey: Sausage 5C Raw ground, comminuted, or otherwise non-intact turkey: Other NonIntact 5D Raw ground, comminuted, or otherwise non-intact turkey: Mechanically Separated [319.5] 6A Raw ground, comminuted, or otherwise non-intact poultry -other: Ground Product 6B Raw ground, comminuted, or otherwise non-intact poultry -other: Sausage 6C Raw ground, comminuted, or otherwise non-intact poultry -other: Other Non-Intact 6D Raw ground, comminuted, or otherwise non-intact poultry -other : Mechanically Separated [319.5] 7A Raw ground comminuted or otherwise non-intact Siluriformes or Ictaluridae (Catfish), Siluriformes \u2013 Other: Ground Product 7B Raw ground comminuted or otherwise non-intact Siluriformes or Ictaluridae (Catfish), Siluriformes \u2013 Other: Non-Intact Cuts 7C Raw ground comminuted or otherwise non-intact Siluriformes or Ictaluridae (Catfish), Siluriformes \u2013 Other: Other Non-Intact RPI: Raw Product \u2013 Intact Code Name Definition 1A Raw Intact Beef: Carcass (including halves or quarters) 1B Raw Intact Beef: Primals and Subprimals 1C Raw Intact Beef: Cuts 1D Raw Intact Beef: Bnls. Mftg. Trimmings 1E Raw Intact Beef: Head Meat 1F Raw Intact Beef: Cheek Meat 1G Raw Intact Beef: Weasand Meat 1H Raw Intact Beef: Heart Meat 1I Raw Intact Beef: Edible Offal 1J Raw Intact Beef: Other Intact 2A Raw Intact Pork: Carcass (including halves or quarters) 12", "RPI: Raw Product \u2013 Intact Code Name Definition 2B Raw Intact Pork: Primals and Subprimals 2C Raw Intact Pork: Cuts 2D Raw Intact Pork: Bnls. Mftg. Trimmings 2E Raw Intact Pork: Edible Offal 2F Raw Intact Pork: Other Intact 3A Raw Intact Meat \u2013 Other: Carcass (including halves or quarters) 3B Raw Intact Meat \u2013 Other: Primals and Subprimals 3C Raw Intact Meat \u2013 Other: Cuts 3D Raw Intact Meat \u2013 Other: Bnls. Mfg. Trimmings 3E Raw

Intact Meat \u2013 Other: Edible Offal 3F Raw Intact Meat \u2013 Other: Other Intact 3G Raw Intact Meat \u2013 Other: Whole Fish 4A Raw Intact Chicken: Whole Bird 4B Raw Intact Chicken: Poultry Parts (including necks\feet & giblets) 4C Raw Intact Chicken: Boneless and\or Skinless Parts 4D Raw Intact Chicken: Bnls. Mfg. Trimmings 5A Raw Intact Turkey: Whole Bird 5B Raw Intact Turkey: Poultry Parts (including necks\feet & giblets) 5C Raw Intact Turkey: Boneless and\or Skinless Parts 5D Raw Intact Turkey: Bnls. Mfg. Trimmings 6A Raw Intact Poultry -Other: Whole Bird 6B Raw Intact Poultry \u2013 Other: Poultry Parts (including necks\feet & giblets) 6C Raw Intact Poultry \u2013 Other: Boneless and\or Skinless Parts 6D Raw Intact Poultry \u2013 Other: Bnls. Mfg. Trimmings TPCS: Thermally Processed \u2013 Commercially Sterile Code Name Definition 1A Meat Thermally Processed \u2013 Commercially Sterile: Meat Species Sausage [319.140; 319.180; 319.181] 1B Poultry Thermally Processed \u2013 Commercially Sterile: Poultry Species Sausage 1C Meat and Poultry Thermally Processed \u2013 Commercially Sterile: Meat and Poultry Species Soups 1D Meat and Poultry Thermally Processed \u2013 Commercially Sterile: Meat and Poultry Species Corned (Species) 13", "TPCS: Thermally Processed \u2013 Commercially Sterile Code Name Definition 1E Meat and Poultry Thermally Processed \u2013 Commercially Sterile: Meat and Poultry Species Other 1F Pork Thermally Processed \u2013 Commercially Sterile: Pork Species Ham (includes shoulders, picnics, butts, loins, chopped ham, pressed ham, spiced ham, etc.) 1G Siluriformes Thermally Processed \u2013 Commercially Sterile: Siluriformes species Other NHTS: Not Heat Treated \u2013 Shelf Stable Code Name Definition 1A Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Rendered Fats, Oils 1B Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Bacon 1C Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Meals\Di\u00f1ners\Entrees 1D Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Sandwiches\Filled Rolls\Wraps 1E Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Sauces 1F Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Pies\Pot Pies 1G Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Smoked Parts 1H Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Soups 1I Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Other 2A Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Rendered Fats, Oils 2B Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Bacon 2C Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Meals\Di\u00f1ners\Entrees 2D Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Sandwiches\Filled Rolls\Wraps 2E Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Sauces 2F Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Pies\Pot Pies 2G Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Smoked Parts 2H Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Soups 2I Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Other 3A Ready-To-Eat (RTE) Acidified\Fermented Meat (w\o cooking): Sausage\Salami \u2013 Not sliced 3B Ready-To-Eat (RTE) Acidified\Fermented Meat (w\o cooking): Sausage\Salami \u2013 Sliced 14", "NHTS: Not Heat Treated \u2013 Shelf Stable Code Name Definition 3C Ready-To-Eat (RTE) Acidified\Fermented Meat (w\o cooking): Other \u2013 Not sliced 3D Ready-To-Eat (RTE) Acidified\Fermented Meat (w\o cooking): Other \u2013 Sliced 3E Ready-To-Eat (RTE) Acidified\Fermented Meat (w\o cooking): Sausage\Salami 4A Ready-To-Eat (RTE) Acidified\Fermented Poultry (w\o cooking): Sausage\Salami \u2013 Not sliced 4B Ready-To-Eat (RTE) Acidified\Fermented Poultry (w\o cooking): Sausage\Salami \u2013 Sliced 4C Ready-To-Eat (RTE) Acidified\Fermented Poultry (w\o cooking): Other \u2013 Not sliced 4D Ready-To-Eat (RTE) Acidified\Fermented Poultry (w\o cooking): Other \u2013 Sliced 5A

Ready-To-Eat (RTE) Dried Meat: Jerky 5B Ready-To-Eat (RTE) Dried Meat: Other, Sliced (except Ham) 5C Ready-To-Eat (RTE) Dried Meat: Other, Not Sliced (except Ham) 5D Ready-To-Eat (RTE) Dried Meat: Other 6A Ready-To-Eat (RTE) Dried Meat: Pork Species: Ham, Sliced (includes shoulders, picnics, butts, loins, chopped ham, pressed ham, spiced ham, etc.) 6B Ready-To-Eat (RTE) Dried Meat: Pork Species Ham, Not Sliced (includes shoulders, picnics, butts, loins, chopped ham, pressed ham, spiced ham, etc.) 7A Ready-To-Eat (RTE) Dried Poultry: Jerky 7B Ready-To-Eat (RTE) Dried Poultry: Other, Sliced 7C Ready-To-Eat (RTE) Dried Poultry: Other, Not Sliced 8A Ready-To-Eat (RTE) Salt Cured Meat, Not Sliced 8B Ready-To-Eat (RTE) Salt Cured Meat, Sliced 8C Ready-To-Eat (RTE) Salt Cured Meat: Other 9A Ready-To-Eat (RTE) Salt Cured Poultry, Not Sliced 9B Ready-To-Eat (RTE) Salt Cured Poultry, Sliced 15", "HTSS: Heat Treated \u2013 Shelf Stable Code Name Definition 1A Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Rendered Fats, Oils 1B Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Bacon 1C Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Meals\|Dinners\|Entrees 1D Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Sandwiches\|Filled Rolls\|Wraps 1E Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Sauces 1F Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Pies\|Pot Pies 1G Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Smoked Parts 1H Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Soups 1I Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Other 2A Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Rendered Fats, Oils 2B Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Bacon 2C Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Meals\|Dinners\|Entrees 2D Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Sandwiches\|Filled Rolls\|Wraps 2E Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Sauces 2F Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Pies\|Pot Pies 2G Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Smoked Parts 2H Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Soups 2I Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Other 3A Ready-To-Eat (RTE) Acidified\|Fermented Meat (w\o cooking): Sausage\|Salami \u2013 Not Sliced 3B Ready-To-Eat (RTE) Acidified\|Fermented Meat (w\o cooking): Sausage\|Salami \u2013 Sliced 3C Ready-To-Eat (RTE) Acidified\|Fermented Meat (w\o cooking): Other \u2013 Not Sliced 3D Ready-To-Eat (RTE) Acidified\|Fermented Meat (w\o cooking): Other \u2013 Sliced 3E Ready-To-Eat (RTE) Acidified\|Fermented Meat (w\o cooking): Sausage\|Salami 4A Ready-To-Eat (RTE) Acidified\|Fermented Poultry (w\o cooking): Sausage\|Salami \u2013 Not Sliced 4B Ready-To-Eat (RTE) Acidified\|Fermented Poultry (w\o cooking): 16", "HTSS: Heat Treated \u2013 Shelf Stable Code Name Definition Sausage\|Salami \u2013 Sliced 4C Ready-To-Eat (RTE) Acidified\|Fermented Poultry (w\o cooking): Other \u2013 Not Sliced 4D Ready-To-Eat (RTE) Acidified\|Fermented Poultry (w\o cooking): Other \u2013 Sliced 5A Ready-To-Eat (RTE) Dried Meat: Jerky 5B Ready-To-Eat (RTE) Dried Meat: Other, Sliced 5C Ready-To-Eat (RTE) Dried Meat: Other, Not Sliced 5D Ready-To-Eat (RTE) Dried Meat: Other 6A Ready-To-Eat (RTE) Dried Meat: Pork Species Ham, Sliced (includes shoulders, picnics, butts, loins, chopped ham, pressed ham, spiced ham, etc.) 6B Ready-To-Eat (RTE) Dried Meat: Pork Species Ham, Not Sliced (includes shoulders, picnics, butts, loins, chopped ham, pressed ham, spiced ham, etc.) 7A Ready-To-Eat (RTE) Dried Poultry: Jerky 7B Ready-To-Eat (RTE) Dried Poultry: Other, Sliced 7C Ready-To-Eat (RTE) Dried Poultry: Not Sliced 8B Ready-To-Eat (RTE) Salt Cured Meat: Sliced 8C Ready-To-Eat (RTE) Salt Cured Meat: Other 9A Ready-To-Eat (RTE) Salt Cured Poultry, Not Sliced 9B Ready-To-Eat (RTE) Salt Cured Poultry,

Sliced FCNS: Fully Cooked \u2013 Not Shelf Stable Code Name Definition 1A Ready-To-Eat (RTE) Fully Cooked Meat : Hot Dog Products (including applicable sausages) [319.180; 319.181] 1B Ready-To-Eat (RTE) Fully Cooked Meat : Sausage products [319.140] 1C Ready-To-Eat (RTE) Fully Cooked Meat : Salad\Spread\Pate 1D Ready-To-Eat (RTE) Fully Cooked Meat : Meat + Non-meat Component 1E Ready-To-Eat (RTE) Fully Cooked Meat : Diced\Shredded 1F Ready-To-Eat (RTE) Fully Cooked Meat : Nuggets 1G Ready-To-Eat (RTE) Fully Cooked Meat : Parts 1H Ready-To-Eat (RTE) Fully Cooked Meat : Other, Sliced (except ham) 1I Ready-To-Eat (RTE) Fully Cooked Meat : Other, Not Sliced (except ham) 17","FCNS: Fully Cooked \u2013 Not Shelf Stable Code Name Definition 1J Ready-To-Eat (RTE) Fully Cooked Meat : Patties (except Ham) 1K Ready-To-Eat (RTE) Fully Cooked Meat : Other 2A Ready-To-Eat (RTE) Fully Cooked Meat: Pork Species Ham Sliced (includes shoulders, picnics, butts, loins, chopped ham, pressed ham, spiced ham, etc.) 2B Ready-To-Eat (RTE) Fully Cooked Meat: Pork Species Ham Not Sliced (includes shoulders, picnics, butts, loins, chopped ham, pressed ham, spiced ham, etc.) 2C Ready-To-Eat (RTE) Fully Cooked Meat : Pork Species Ham Patties [319.105(d)] 3A Ready-To-Eat (RTE) Fully Cooked Poultry : Hot Dog Products 3B Ready-To-Eat (RTE) Fully Cooked Poultry : Salad\Spread\Pate 3C Ready-To-Eat (RTE) Fully Cooked Poultry : Poultry + Non-poultry component 3D Ready-To-Eat (RTE) Fully Cooked Poultry : Sausage Products 3E Ready-To-Eat (RTE) Fully Cooked Poultry : Diced\Shredded 3F Ready-To-Eat (RTE) Fully Cooked Poultry : Patties\Nuggets 3G Ready-To-Eat (RTE) Fully Cooked Poultry : Parts 3H Ready-To-Eat (RTE) Fully Cooked Poultry : Other, sliced 3I Ready-To-Eat (RTE) Fully Cooked Poultry : Other, not sliced 4A Ready-To-Eat (RTE) Fully Cooked Meat (w/o subsequent exposure to the environment): Hot Dog Products (including applicable sausages) [319.180; 319.181] 4B Ready-To-Eat (RTE) Fully Cooked Meat (w/o subsequent exposure to the environment): Sausage products [319.140] 4C Ready-To-Eat (RTE) Fully Cooked Meat (w/o subsequent exposure to the environment): Salad\Spread\Pate 4D Ready-To-Eat (RTE) Fully Cooked Meat (w/o subsequent exposure to the environment): Meat + Non-meat Component 4E Ready-To-Eat (RTE) Fully Cooked Meat (w/o subsequent exposure to the environment): Diced\Shredded 4F Ready-To-Eat (RTE) Fully Cooked Meat (w/o subsequent exposure to the environment): Nuggets 4G Ready-To-Eat (RTE) Fully Cooked Meat (w/o subsequent exposure to the environment): Parts 4H Ready-To-Eat (RTE) Fully Cooked Meat (w/o subsequent exposure to the environment): Other, Sliced (except Ham) 4I Ready-To-Eat (RTE) Fully Cooked Meat (w/o subsequent exposure to the environment): Other, Not Sliced (except Ham) 18","FCNS: Fully Cooked \u2013 Not Shelf Stable Code Name Definition 4J Ready-To-Eat (RTE) Fully Cooked Meat (w/o subsequent exposure to the environment): Patties (except Ham) 4K Ready-To-Eat (RTE) Fully Cooked Meat (w/o subsequent exposure to the environment): Other 5A Ready-To-Eat (RTE) Fully Cooked Meat (w/o subsequent exposure to the environment): Pork Species Ham, Sliced (includes shoulders, picnics, butts, loins, chopped ham, pressed ham, spiced ham, etc.) 5B Ready-To-Eat (RTE) Fully Cooked Meat (w/o subsequent exposure to the environment): Pork Species Ham, Not Sliced (includes shoulders, picnics, butts, loins, chopped ham, pressed ham, spiced ham, etc.) 5C Ready-To-Eat (RTE) Fully Cooked Meat (w/o subsequent exposure to the environment): Pork Species Ham Patties [319.105(d)] 6A Ready-To-Eat (RTE) Fully Cooked Poultry (w/o subsequent exposure to the environment): Hot Dog Products 6B Ready-To-Eat (RTE) Fully Cooked Poultry (w/o subsequent exposure to the environment): Salad\Spread\Pate 6C Ready-To-Eat (RTE) Fully Cooked Poultry (w/o

subsequent exposure to the environment): Poultry + Non-poultry component 6D Ready-To-Eat (RTE) Fully Cooked Poultry (w/o subsequent exposure to the environment): Sausage Products 6E Ready-To-Eat (RTE) Fully Cooked Poultry (w/o subsequent exposure to the environment): Diced\Shredded 6F Ready-To-Eat (RTE) Fully Cooked Poultry (w/o subsequent exposure to the environment): Patties\Nuggets 6G Ready-To-Eat (RTE) Fully Cooked Poultry (w/o subsequent exposure to the environment): Parts 6H Ready-To-Eat (RTE) Fully Cooked Poultry (w/o subsequent exposure to the environment): Other, sliced 6I Ready-To-Eat (RTE) Fully Cooked Poultry (w/o subsequent exposure to the environment): Other, not sliced NFC: Heat Treated but Not Fully Cooked \u2013 Not Shelf Stable Code Name Definition 1A Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Rendered Fats, Oils 1B Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Bacon 1C Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Meals\ /Dinners\ /Entrees 1D Not Ready-To-Eat (NRTE) Otherwise Processed Meat: 19", "NFC: Heat Treated but Not Fully Cooked \u2013 Not Shelf Stable Code Name Definition Sandwiches\ /Filled Rolls\ /Wraps 1E Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Sauces 1F Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Pies\ /Pot Pies 1G Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Smoked Parts 1H Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Soups 1I Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Other 1J Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Sausage products [319.140] 2A Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Rendered Fats, Oils 2B Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Bacon 2C Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Meals\ /Dinners\ /Entrees 2D Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Sandwiches\ /Filled Rolls\ /Wraps 2E Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Sauces 2F Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Pies\ /Pot Pies 2G Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Smoked Parts 2H Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Soups 2I Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Sausages 2J Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Other PWSI: Products with Secondary Inhibitors \u2013 Not Shelf Stable Code Name Definition 1A Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Rendered Fats, Oils 1B Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Bacon 1C Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Meals\ /Dinners\ /Entrees 1D Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Sandwiches\ /Filled Rolls\ /Wraps 1E Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Sauces 1F Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Pies\ /Pot Pies 1G Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Smoked Parts 1H Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Soups 1I Not Ready-To-Eat (NRTE) Otherwise Processed Meat: Other 20", "PWSI: Products with Secondary Inhibitors \u2013 Not Shelf Stable Code Name Definition 2A Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Rendered Fats, Oils 2B Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Bacon 2C Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Meals\ /Dinners\ /Entrees 2D Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Sandwiches\ /Filled Rolls\ /Wraps 2E Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Sauces 2F Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Pies\ /Pot Pies 2G Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Smoked Parts 2H Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Soups 2I Not Ready-To-Eat (NRTE) Otherwise Processed Poultry: Other 3A Ready-To-Eat (RTE) Salt Cured Meat: Not Sliced 3B Ready-To-Eat (RTE) Salt Cured Meat: Sliced 3C Ready-To-Eat (RTE) Salt Cured Meat: Other 4A Ready-To-Eat

(RTE) Salt Cured Poultry: Not Sliced 4B Ready-To-Eat (RTE) Salt Cured Poultry: Sliced EEP: Eggs\Egg Products Code Name Definition 1A EP: Pasteurized (Tankers\Large Totes) -Whole egg (with or without added ingredients) 2A EP: Pasteurized (Tankers\Large Totes) -Egg whites (with or without added ingredients) 2B EP: Pasteurized (Tankers\Large Totes) -Yolk (with or without added ingredients) 2C EP: Pasteurized (Tankers\Large Totes) -Egg Products (blends of whole egg, egg whites and or yolks with or without added ingredients) 3A EP: Pasteurized (Frozen or Liquid) -Whole egg (with or without added ingredients) 3B EP: Pasteurized (Frozen or Liquid) -Egg whites (with or without added ingredients) 3C EP: Pasteurized (Frozen or Liquid)-Yolk (with or without added ingredients) 3D EP: Pasteurized (Frozen or Liquid)-Egg Products (blends of whole egg, egg whites and or yolks with or without added ingredients) 4A EP: Dried \u2013 Whole egg (with or without added ingredients) 4B EP: Dried \u2013 Whites (with or without added ingredients) 21","EEP: Eggs\Egg Products Code Name Definition 4C EP: Dried \u2013 Yolks (with or without added ingredients) 4D EP: Dried \u2013Egg Products (blends of whole egg, egg whites and or yolks with or without added ingredients) 5A EP: Unpasteurized (Frozen or Liquid) -Whole egg (with or without added ingredients) 5B EP: Unpasteurized (Frozen or Liquid) -Whites (with or without added ingredients) 5C EP: Unpasteurized (Frozen or Liquid) -Yolks (with or without added ingredients) 5D EP: Unpasteurized \u2013 Egg Products (blends of whole egg, egg whites and or yolks with or without added ingredients) 6A EP: Unpasteurized (Tankers\Large Totes) -Whole egg (with or without added ingredients) 6B EP: Unpasteurized (Tankers\Large Totes) -Egg whites (with or without added ingredients) 6C EP: Unpasteurized (Tankers\Large Totes) -Yolk (with or without added ingredients) 6D EP: Unpasteurized (Tankers\Large Totes) -Egg Products (blends of whole egg, egg whites and or yolks with or without added ingredients) Record Identifier PG13 (Input) FSIS requires this record to identify the country that issued the foreign inspection certificate. If using this record, Record Identifier PG14 is mandatory. This record is repeatable in combination with the PG14. Record Identifier PG13 (Input) Data Element Length\ Class Position Status Description Note Control Identifier 2A 1-2 M Must always equal PG. Record Type 2N 3-4 M Must always be 13. Issuer of LPCO 35X 5-39 N\A LPCO Issuer Government Geographic Code Qualifier 3A 40-42 M The code relating to the location of the issuer of the foreign inspection certificate. FSIS can accept province code for Canada only: Canadian Province = PR Country Code = ISO 22","Location (Country\State\Province) of Issuer of the LPCO 3A 43-45 M Enter the appropriate country code from Appendix B in the ACS ABI CATAIR. FSIS can accept province code for Canada only. 1\ Country Codes and 2\ CA Province Codes Regional description of location of Agency Issuing the LPCO 25X 46-70 N\A Filler 10X 71-80 N\A 1\ Appendix B ISO Country Codes Country Code AFGHANISTAN AF ALBANIA AL ALGERIA DZ AMERICAN SAMOA AS ANDORRA AD ANGOLA AO ANGUILLA AI ANTIGUA & BARBUDA AG ARGENTINA AR ARMENIA AM ARUBA AW AUSTRALIA AU AUSTRIA AT AZERBAIJAN AZ BAHAMAS BS BAHRAIN BH BANGLADESH BD BARBADOS BB BELARUS BY BELGIUM BE BELIZE BZ BENIN BJ BERMUDA BM BHUTAN BT BOLIVIA BO BOSNIA & HERCEGOVINA BA BOTSWANA BW BOUVENT ISLAND BV BRAZIL BR BRITISH INDIAN OCEAN TERRITORY IO 23","Country Code BRUNEI DARUSSALAM BN BULGARIA BG BURKINA FASO BF BURUNDI BI CAMBODIA KH CAMEROON, CM CANADA CA CAPE VERDE CV CAYMAN ISLANDS KY CENTRAL AFRICAN REPUBLIC CF CHAD TD CHILE CL CHINA CN CHRISTMAS ISLANDS CX COCOS (KEELING) ISLANDS CC COLOMBIA CO COMOROS KM CONGO CG CONGO , THE DEMOCRATIC REPUBLIC OF CD COOK ISLANDS CK COSTA RICA CR COTE D\u2019IVOIRE CI CROATIA HR CUBA

CU CYPRUS CY CZECH REPUBLIC CZ DENMARK DK DJIBOUTI DJ DOMINICA DM DOMINICAN REPUBLIC DO ECUADOR EC EGYPT EG EL SALVADOR SV EQUATORIAL GUINEA GQ ERITREA ER ESTONIA EE ETHIOPIA ET FALKLAND ISLANDS (MALVINAS) FK FAROE ISLANDS FO FIJI FJ FINLAND FI FRANCE FR FRENCH GUIANA GF FRENCH POLYNESIA PF 24","FRENCH SOUTHERN TERRITORIES TF GABON GA GAMBIA GM GEORGIA GE GERMANY DE GHANA GH GIBRALTAR GI GREECE GR GREENLAND GL GRENADA GD GUADELOUPE GP GUAM GU GUATEMALA GT GUINEA GN GUINEA-BISSAU GW GUYANA GY HAITI HT HEARD AND McDONALD ISLANDS HM HOLY SEE (VATICAN CITY STATE) VA HONDURAS HN HONG KONG HK HUNGARY HU ICELAND IS INDIA IN INDONESIA ID INTERNATIONAL MONETARY FUND (I.M.F.) IRAN, ISLAMIC REPUBLIC OF IR IRAQ IQ IRELAND IE ISRAEL IL ITALY IT JAMAICA JM JAPAN JP JORDAN JO KAZAKHSTAN KZ KENYA KE KIRIBATI KI KOREA, DEMOCRATIC PEOPLE\u2019S REPUBLIC OF KP KOREA, REPUBLIC OF KR KOSOVO KV KUWAIT KW KYRGYZSTAN KG LAOS PEOPLE\u2019S DEMOCRATIC REPUBLIC LA LATVIA LV LEBANON LB LESOTHO LS 25","LIBERIA LR LIBYA ARAB JAMAHIRIYA LY LIECHTENSTEIN LI LITHUANIA LT LUXEMBOURG LU MACAO MO MACEDONIA, THE FORMER YUGOSLAV REPUBLIC OF MK MADAGASCAR MG MALAWI MW MALAYSIA MY MALDIVES MV MALI ML MALTA MT MARSHALL ISLANDS MH MARTINIQUE MQ MAURITANIA MR MAURITIUS MU MAYOTTE YT MEXICO MX MICRONESIA, FEDERATED STATE OF FM MOLDOVA, REPUBLIC OF MD MONACO MC MONGOLIA MN MONTENEGRO ME MONTSERRAT MS MOROCCO MA MOZAMBIQUE MZ MYANMAR MM NAMIBIA NA NAURU NR NEPAL NP NETHERLANDS NL NETHERLANDS ANTILLES AN NEW CALEDONIA NC NEW ZEALAND NZ NICARAGUA NI NIGER NE NIGERIA NG NIUE NU NORFOLK ISLAND NF NORTHERN MARIANA ISLANDS MP NORWAY NO OMAN OM PAKISTAN PK PALAU PW PANAMA PA PAPUA NEW GUINEA PG 26","PARAGUAY PY PERU PE PHILIPPINES PH PITCAIRN PN POLAND PL PORTUGAL PT PUERTO RICO PR QATAR QA REUNION RE ROMANIA RO RUSSIAN FEDERATION RU RWANDA RW ST. HELENA SH ST. KITTS-NEVIS KN ST. PIERRE AND MIQUELON PM SAINT LUCIA LC SAINT VINCENT AND THE GRENADINES VC SAMOA WS SAN MARINO SM SAO TOMES AND PRINCIPE ST SAUDI ARABIA SA SENEGAL SN SERBIA RS SEYCHELLES SC SIERRA LEONE SL SINGAPORE SG SLOVAKIA SK SLOVENIA SI SOLOMON ISLANDS SB SOMALIA SO SOUTH AFRICA ZA SPAIN ES SRI LANKA LK SUDAN SD SURINAME SR SVALBARD AND JAN MAYEN, ISLANDS SJ SWAZILAND SZ SWEDEN SE SWITZERLAND CH SYRIAN ARAB REPUBLIC SY TAIWAN, PROVINCE OF CHINA TW TAJIKISTAN TJ TANZANIA, UNITED REPUBLIC OF TZ THAILAND TH TIMOR-LESTE TL TOGO TG 27","TOKELAU TK TONGA TO TRINIDAD AND TOBAGO TT TUNISIA TN TURKEY TR TURKMENISTAN TM TURKS AND CAICOS ISLANDS TC TUVALU TV UGANDA UG UKRAINE UA UNITED ARAB EMIRATES AE UNITED KINGDOM GB UNITED STATES US UNITED STATES MINOR OUTLYING ISLANDS UM URUGUAY UY UZBEKISTAN UZ VANUATU VU VENEZUELA VE VIET NAM VN VIRGIN ISLANDS (BRITISH) VG VIRGIN ISLANDS (U.S.) VI WALLIS AND FUTUNA ISLANDS WF WESTERN SAHARA EH YEMEN YE ZAMBIA ZM ZIMBABWE ZW 2\ Appendix B \u2013 Canadian Province Codes Canadian Provinces Code Description AB Alberta BC British Columbia MB Manitoba NB New Brunswick NL New Foundland and Labrador Nova Scotia NT Northwest Territories NU Nunavut 28","PE Prince Edward Island QC Quebec SK Saskatchewan YT Yukon Territory Record Identifier PG14 (Input) FSIS requires the foreign inspection certificate number from the certificate that was issued by the Central Competent Authority of the foreign country identified in the PG13. There may be more than one certificate number in the entry. This record may be grouped to the PG13 and repeated. Record Identifier PG14 (Input) Data Element Length\ Class Position Status

Description Note Control Identifier 2A 1-2 M Must always equal PG. Record Type 2N 3-4 M Must always be 14. LPCO Transaction Type 1N 5 N\A LPCO Type 3AN 6-8 M Identify the foreign inspection certificate type. See Appendix PGA (LPCO Type Code) for valid codes. FSIS will accept FS7, FS8, or FS9 for meat, poultry or egg products. Note that FSIS no longer requires separate certificate types and Appendix PGA will be updated. 1\| LPCO Number (or Name) 33X 9-41 M FSIS requires the foreign inspection certificate number. Include any dashes or slashes as seen on the foreign inspection certificate. LPCO Date Qualifier 1N 42 N\A LPCO Date 8N 43-50 N\A LPCO Quantity 16N 51-66 N\A LPCO Unit of Measure 5AN 67-71 N\A Exemption Code 9X 72-80 N\A 29","1\| Appendix PGA, PG14 \u2013 Type Codes Code Name Definition FS7 FSIS Meat , Poultry and Egg Products Foreign Inspection Certificate Document or message issued by the competent authority in the exporting country evidencing that meat, poultry or egg products comply with the requirements set by the importing country. FS8 FSIS Meat, Poultry and Egg Products Foreign Inspection Certificate Document or message issued by the competent authority in the exporting country evidencing that meat, poultry or egg products comply with the requirements set by the importing country FS9 FSIS Meat, Poultry and Egg Products Foreign Inspection Certificate Document or message issued by the competent authority in the exporting country evidencing that meat, poultry or egg products comply with the requirements set by the importing country Record Identifier PG19 (Input) FSIS requires this record to identify the trade entities and foreign establishment numbers associated to this shipment. This record can be repeated if there are multiple entities. Enter foreign establishment numbers in the same format seen on this link to the FSIS web site Record Identifier PG19 (Input) Data Element Length\| Class Position Status Description Note Control Identifier 2A 1-2 M Must always equal PG. Record Type 2N 3-4 M Must always be 19. Entity Role Code 3AN 5-7 M FSIS requires entity role codes for the foreign exporting establishment (EXE), the foreign producing establishment (PE), and when applicable, the foreign source establishment (SOE). FSIS also requires additional entity information of the Consignee (CN), Customs Broker (CB), Importer (IM) and Certifying Individual (CI). The trade entity codes will precede the applicable PG21 records. See Appendix PGA (Entity Role Code) of this publication for valid codes. 1\| Entity Identification Code 3AN 8-10 N\A Entity Number 15X 11-25 M FSIS requires the foreign establishment numbers for the foreign exporting establishment, the foreign producing establishment, and when applicable the foreign source establishment. 30","Entity Name 32X 26-57 N\A Entity Address 1 23X 58-80 N\A 1\| Appendix PGA, PG19 \u2013 Entity Role Codes Code Name Definition CI Certifying Individual Individual who is certifying the shipment. CN Consignee Party on whose account the merchandise is shipped. CB Customs broker Agent, representative, or a professional Customs clearing agent who deals directly with Customs on behalf of the importer or exporter. IM Importer Party on whose behalf a Customs clearing agent or other authorized person makes an entry. EXE Exporting Establishment The establishment where the export originated PE Producing Establishment The establishment that produced the finished product. SOE Source Establishment The establishment where the product raw material was sourced. Record Identifier PG21 (Input) FSIS requires this input record to provide additional data about the Importer (IM), the Customs Broker (CB), the Consignee (CN) and the Certifying Individual (CI) identified in the PG19. FSIS requires the First Name, Last Name for the CI and the First Name, Last Name, Phone Number (10 digits including area code) and Email address of the CB, IM, and CN. This record can be repeated and should follow each trade entity designated in the PG19

record. Record Identifier PG21 (Input) Data Element Length\ Class Position Status Description Note Control Identifier 2A 1-2 M Must always equal PG. Record Type 2N 3-4 M Must always be 21. Individual Qualifier 3AN 5-7 N\A Individual Name 23X 8-30 M First Name, Last Name of the Individual. Telephone Number of the Individual 15AN 31-45 M 10 digit telephone number of the individual. Do NOT enter with spaces or dashes. Email Address for the Individual 35X 46-80 M Email Address of the individual. 31","I I Record Identifier PG22 (Input) FSIS requires this information to validate the FSIS form 9540-1 application. Record Identifier PG22 (Input) Data Element Length\ Class Position Status Description Note Control Identifier 2A 1-2 M Must always equal PG. Record Type 2N 3-4 M Must always be 22. Importers Substantiating Signed Document \Signed Confirmation Letter 1A 5 N\A Document Identifier 7AN 6-12 M Code for FSIS form 9540-1 is \u201c956\u201d. See Appendix PGA (Document Identifier) of this publication for valid codes. 1\ Conformance Declaration 5X 13-17 N\A Entity Role Code 3AN 18-20 M FSIS expects code \u201cCl\u201d for the Certifying Individual identified in the PG19. Declaration Code 4AN 21-24 M \u201cFS3\u201d is the declaration code for FSIS form 9540-1. See Appendix PGA (Declaration Code) of this publication for valid codes. 2\ Declaration Certification 1A 25 M A code of \u201cY\u201d (yes) indicating that the entity certifies the application. No other code is accepted. Date of Signature 8N 26-33 M Date of the signature in MMDDCCYY (month, day, century, and year) format. Invoice Number 17X 34-50 N\A Compliance Description 30X 51-80 N\A 1\ Appendix PGA, PG22 \u2013 Document Identifiers Code Name Definition 956 FSIS 9540-1 Import Inspection Application and Report (Meat, Poultry & Egg Products) 32","I I 2\ Appendix PGA, PG22 \u2013 Declaration Codes Code Name Definition FS3 Agreement to hold goods intact (Form 9540-1) IN CONSIDERATION of the U.S. Director of Customs and Border Protection granting me\us permission to transfer the packages of foreign food product described on this form which are offered for entry into the United States, I\we agree, under bond filed with said director of Customs and Border Protection and subject to penalties prescribed in laws enacted by Congress and regulations issued there under by the Secretary of Homeland Security, to hold the said food product intact at the location indicated below until it has been inspected and passed by a food inspector from the Food Safety and Inspection Service or has been otherwise disposed of under the supervision of a U.S. Customs and Border Protection Officer or a FSIS inspector. Record Identifier PG24 (Input) FSIS only requires a seal number for certain egg products and carcass shipments that are not packaged in anything but the shipping conveyance. Record Identifier PG24 (Input) Data Element Length\ Class Position Status Description Note Control Identifier 2A 1-2 M Must always equal PG. Record Type 2N 3-4 M Must always be 24. Remarks Type Code 3AN 5-7 O When providing a seal number to FSIS, enter code \u201cGEN\u201d. See Appendix PGA (Remarks Type Code) of this publication. 1\ Remarks Code 5AN 8-12 N\A Remarks Text 68X 13-80 O Enter the seal number. 1\ Appendix PGA, PG24 \u2013 Remarks Type Codes Code Name Definition GEN General Remarks 33","Record Identifier PG25 (Input) FSIS requires the Lot Number and Production Date Ranges of the Lot (when applicable). This record is not required for eCert countries. This record is repeatable for multiple lot numbers. Lot numbers for FSIS purposes are line items on the official inspection certificate. They are NOT production lot numbers. For example, if a foreign inspection certificate has two line items of product, then the first line item is Lot 1. The second line item is Lot 2. Do NOT enter any alpha characters as lot numbers. Record Identifier PG25 (Input) Data Element Length\ Class Position Status Description Note

Control Identifier 2A 1-2 M Must always equal PG. Record Type 2N 3-4 M Must always be 25. Temperature Qualifier 1A 5 N\A Degree Type 1A 6 N\A Negative Number 1A 7 N\A Actual Temperature 6N 8-13 N\A Location of Temperature Recording 1A 14 N\A Lot Number Qualifier 1AN 15 N\A Lot Number 25X 16-40 M Enter the lot number (e.g. as shown on the foreign inspection certificate). The number of lots on a certificate is not more than 3 digits. Lot numbers are line items on the official inspection certificate; they are NOT production lot numbers. Production Start Date of the Lot 8N 41-48 O The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format. Production End Date of the Lot 8N 49-56 O The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format. PGA Line Value 12N 57-68 N\A PGA Unit Value 12N 69-80 N\A Record Identifier PG26 (Input) FSIS requires this record to provide data pertaining to shipping and immediate container types, numbers of cartons\packages, and shipping marks applied to the shipping containers. This record can be repeated. This record is not required from eCert countries. The first record is used to describe the shipping container (outermost container) and the number of containers. The second record is used to describe the immediate container. 34","Data Element Length\Class Position Status Description Note Control Identifier 2A 1-2 M Must always equal PG. Record Type 2N 3-4 M Must always be 26. Packaging 1N 5 M This code identifies the level of packaging for the Qualifier product. Outermost (shipping container=1). The innermost (immediate container=2). There can be up to 2 levels of packaging for FSIS. If reporting only one level, show the total quantity for the item and report that as level 1. Quantity 12N 6-17 M The total quantity for the packaging level. Two decimal places are implied. The base quantity must always be the last quantity transmitted. Unit of 5X 18-22 M Enter the code for the package type for the 1\ Measure packaging level. Must use codes in Appendix (Packaging PGA (FDA Units of Measure for Packaging Level) Containers) and in Appendix B. Package Identifier 25X 23 -47 M Enter the shipping mark\identification mark on the shipping containers. Packaging Method 3AN 48-50 N\A Package Material 15X 51-65 N\A Package Filler 15X 66-80 N\A 1\ Appendix PGA and Appendix B, PG26 \u2013 Unit of Measure Code Description BX Box CS Case CT Carton CX Can, Cylindrical DR Drum MB Bag, Multi-ply PK Package PO Pouch 35","BG Bag BI Bin BJ Bucket CA Can, Rectangular COM Combo Bins CS Case JR Jar PAL Pallet PL Pail PU Tray or Tray Pack SW Shrink Wrapped TB Tub TN Tin TU Tube TY Tank, Cylindrical VA Vat VP Vacuum-packed Record Identifier PG29 (Input) FSIS requires the net weight of the lot (always in pounds). This record is not required for eCert countries. Record Identifier PG29 (Input) Data Element Length\ Class Position Status Description Note Control Identifier 2A 1-2 M Must always equal PG. Record Type 2N 3-4 M Must always be 29. Unit of Measure (PGA line -net) 3AN 5-7 M Enter code \u201cLB\u201d for pounds. 1\ 36","Record Identifier PG29 (Input) Data Element Length\ Class Position Status Description Note Commodity Net Quantity (PGA line -net) 12N 8-19 M Enter the net weight of the lot. Two decimals are implied. \u201cCommodity Net Quantity (PGA line -net)\u201d is required when \u201cUnit of Measure (PGA line -net)\u201d is reported in positions 5-7 of this record. Unit of Measure (PGA line -gross) 3AN 20-22 N\A Commodity Gross Quantity (PGA line -gross) 12N 23-34 N\A Unit of Measure (Individual Unit net) 3AN 35-37 N\A Commodity Net Quantity (Individual Unit -net) 12N 38-49 N\A Unit of Measure (Individual Unit gross) 3AN 50-52 N\A Commodity Gross Quantity (Individual Unit -gross) 12N 53-64 N\A Filler 16X 65-80 N\A 1\ Appendix PGA, Units of Measure Code Description LB Pounds (avdp) (Weight) Record Identifier

PG30 (Input) FSIS requires this record to provide data pertaining to the date, location of inspection, and anticipated date of arrival for the shipment at the FSIS official import inspection establishment. Record Identifier PG30 (Input) Data Element Length\ Class Position Status Description Note Control Identifier 2A 1-2 M Must always equal PG. Record Type 2N 3-4 M Must always be 30. Inspection\ Laboratory Testing Status 1A 5 M Enter: \u201c\u201d = Product location authority inspection for regulatory 37", "Requested or Scheduled Date of Inspection; Date of Previous Inspection\ Laboratory Testing; Arrival date 8N 6-13 M Enter a numeric date in MMDDCCYY (month, day, century, and year) format. Requested or Scheduled Time of Inspection; Time of Previous Inspection\Laborato ry Testing; Arrival time 4N 14-17 N\A Inspection or Arrival Location Code 4AN 18-21 M For FSIS 9540-1, enter \u201c8\u201d for government assigned number for import establishment to conduct inspections. Enter \u201c10\u201d for an egg processing establishment. See Appendix PGA of this publication for valid codes. 1\ Inspection or Arrival Location 50X 22-71 M Enter the FSIS official import inspection establishment where the shipment will present. The \u201c1\u201d is not necessary to enter. Do not enter with spaces or dashes. Filler 9X 72-80 N\A 1\ Appendix PGA, PG30 \u2013 Inspection or Arrival Location Codes Code Name Definition 8 Inspection Establishment Number Qualifier Government assigned number for Import establishment to conduct inspections. 10 FSIS Processing Establishment Number Qualifier Government assigned number for egg processing establishment. Record Identifier PG50 (Input) This is a conditional PGA input record used (along with the PG51 record) to indicate that the data immediately following specific records should be associated together. The PG50 record is used to indicate the start of a grouping. For FSIS, the following records can be followed by the PG50 grouping indicator: PG13, PG14. Use the grouping indicators following the PG13 for multiple certificates in an entry. Use the grouping indicators following the PG14 for multiple lots on a certificate.

38", "Record Identifier PG50 (Input) Data Element Length\ Class Position Status Description Note Control Identifier 2A 1-2 M Must always equal PG. Record Type 2N 3-4 M Must always be 50. Filler 76X 5-80 N\A Record Identifier PG51 (Input) The PG51 record is used to indicate the end of the grouping. Record Identifier PG51 (Input) Data Element Length\ Class Position Status Description Note Control Identifier 2A 1-2 M Must always equal PG. Record Type 2N 3-4 M Must always be 51. Filler 76X 5-80 N\A 39", "~lo,.....\_lit ..... AddffOII, .. \_\_\_\_\_, ..... \_ ..... ...., ..\_,,lo, \u2022 .....,,Gl ..... \u2022 ....,Olill1c,ae,n1 -.lhe...MO!rill-\*d\_b,,,W."\\\"\*-.....\_la~ \\"-,.....,\_~ .. --,.....\_.....\_ .. ..\_,, .. \_\_,1 ..... 19-l~ ..... \_ ..... lioohd-.... h;~4--~^ ... -.....\_ ..,.....,~ ..... ,.....\_ U.S. DEPARTMENT Of AGIUCUL TURE 1.

OOUNIR\ "I" OF ORIGIN 2. INSPECTION CERTFICAT'E N..IIIIleR FOOOSMETY ANDINSPECTION SERVICE IMPORT INSPECTION APPLICATION (Mea~ Poultry & Egg Products) \"-US. PORT OF anRVICBP PORT COCE S. U.8. PORT OF~ PORT COOE 6. F818ESTM!USHIENTNJM8ER 17. HAWE & MX>RE:88 Of FSI8 ESTM!USHMENT 8 ~ . BUSINE88 ~ & ADDRESS OFCU8TOM8 BROICERORN'PUCNII' I 8c. E-WM. ADDRESS 9. ~ BU81NE88 HAWE & MXIRE:88 OF OONSIONEE 10.tw,E.8UDE88HAME&ADORE880FMPORTEROFREOORO Block6 13 through 32 repeat. for Heh lot on the inspection c\u00abtificate \u00b7--\u00b7\u00b7J \"\u00b0\\" \\" 16. NET W\u00a3IG-IT 17.SHPPNOLNT ..... 8. IMMECAATE LNT 20. NJMBERPER ~\u00b7 SEA&.NJMSEAIS) OFLOT(~I PJII:\u00a3NIE. TYPE~ OFUNIT8 PACKNJETYPE)WIE 8-IPPINQ~FT 22. PROCES8INI3 EST. NO. 2180UACE COUNTR!'(S)C,.....,\_.... 11 la. 80UACE EST. HO. 25. I-n'8 OOOE (St ~. '17. PROOUCT CATEOORY \\" PROIIUCT ..... 20.SPECIE8~ 291. ADOITIONAL.SPECIES

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\u2022\u2022RISI...-, 3 & DATE FSIS 9540-1, IMPORT INSPECTION APPLICATION (Meat, Poultry  
& Egg Products) 40", "Sample 1: The FSIS form 9540-1 has been modified to capture more  
detailed information about shipments. Below are the instructions that accompany the revised  
form. Additionally, in red font, are fictitious data representing a shipment of Boneless Beef  
Trimmings from a non eCert country (Mexico) and how that information would be entered in  
ABI for the message set. This example is two foreign inspection certificates on the entry. One  
certificate has 2 lots and one certificate has 1 lot. Block: 1. Country of Origin. Enter the name of  
the country that issued the inspection certificate for the export of the product. Mexico is the  
name of the country that issued the foreign inspection certificates. This information comes  
from the entry. 2. Inspection Certificate Number. Enter the serial number, including  
dashes\slashes, from the foreign country inspection contained on the inspection certificate.  
Certificate numbers are 123456AAAA and 123456BBBB. 3. Exporting Establishment Number.  
Enter the official number of the foreign facility that the product was exported from the  
inspection certificate. Foreign establishment number 5555A is the exporting establishment  
certified on both foreign inspection certificates. 4. U.S. Port of Entry\CBP Port Code. This is the  
name of the port of entry and the associated CBP port code designation where the entry is filed  
with U.S. Customs and Border Protection (CBP). This information comes from the entry. 5. U.S.  
Port of Unlading\CBP Port Code. This is the name of the U.S. port of entry and the associated  
CBP port code for merchandise. This information comes from the entry. 6. FSIS Establishment  
Number. This is the official number assigned by FSIS to the establishment where the product  
will move for FSIS import inspection. 425. 7. Name and Address of FSIS Establishment. The name  
and address of the FSIS establishment where the product is to be moved for FSIS import  
inspection. This information comes from PHIS based on the number provided in block 6 above.  
8. Name (first\last), Business Name and Address of Customs Broker or Applicant, as applicable  
(including zip code). NOTE: the name of a responsible person is required, in addition to the  
name of the business). Business name and address come from the entry. Broker name is  
Martha Stewart. 8a. Phone Number. Martha Stewart\u2019s phone number is 3136667777 8b.  
Facsimile Number. Martha Stewart\u2019s fax number is 3136667771 8c. E-Mail Address. The  
email address is used for refused entry notifications and communication with the applicant.  
Martha Stewart\u2019s email address is JAS2@HOTMAIL.COM 9. Name (first\last), Business  
Name and Address of Consignee (including zip code): The name and address, including zip code,  
of the company or person to which the product is consigned. Business name and address come

from the entry. Consignee's name is Hilda Brand. Hilda Brand's phone number is 8566667777. Hilda Brand's email address is HILDA@HOTMAIL.COM

41","10. Enter Name (first\last), Business Name and Address of Importer of Record (IR) (including zip code). The name and address of the Importer of Record as declared to Customs when the entry is filed. Business name and address come from the entry. Importer's name is Hilda Brand. Hilda Brand's phone number is 8566667777. Hilda Brand's email address is HILDA@HOTMAIL.COM

11. Bill of Lading Number(s). Enter the applicable bill of lading numbers for this application. This information comes from the entry.

12. Lot No. The lot number of each line item of product identified on the foreign inspection certificate. Start with 1 and continue with 2, 3, etc. Certificate number 123456AAAA certifies 2 lots of boneless beef trimmings and certificate number 123456BBBB certifies 1 lot of boneless beef trimmings.

NOTE: Blocks 13 through 32 repeat for each lot on an inspection certificate. FSIS expects that each line item on the inspection certificate is one (1) lot on the form 9540-1.

13. Shipping\Identification Mark. Enter the unique number from the inspection certificate that links the product in the lot to the inspection certificate. Include slashes\dashes as appropriate. The shipping mark applied by the government of Mexico on the shipping containers (cartons; outermost package type) and certified on foreign inspection certificate number 123456AAAA for both lots 1 and lot 2 is XYXYXY123. The shipping mark applied by the government of Mexico on the shipping containers (cartons; outermost package type) and certified on foreign inspection certificate number 123456BBBB for lot 1 is ABABAB1239.

14. Custom Entry Number(s). Enter each applicable 11 digit custom entry number associated with the shipment. For locations where the custom entry number is not 11 characters long, enter enough zeros at the beginning to make an eleven digit number. This information comes from the entry.

15. Production Date(s). Enter the range of production dates from the foreign inspection certificate for each lot when applicable. These products were produced between 01012011 and 02012011. These production dates are certified for all lots on both foreign inspection certificates.

16. Net Weight of Lot. Enter the net weight of each lot in pounds from the inspection certificate. The net weight of Lot 1 certified on certificate number 123456AAAA is 23325 pounds. The net weight of Lot 2 certified on certificate number 123456AAAA is 23300 pounds. The net weight of Lot 1 certified on certificate number 123456BBBB is 23325 pounds.

17. Shipping Unit Package Type Name. Enter the type of shipping unit. Cartons as certified on both foreign inspection certificates and all lots.

18. Number of Units. Enter the number of shipping units from the inspection certificate. The number of cartons certified on certificate number 123456AAAA for Lot 1 is 1000 cartons. The number of cartons certified on certificate number 123456AAAA for Lot 2 is 1000 cartons. The number of cartons certified on certificate number 123456BBBB for Lot 1 is 2000 cartons.

19. Immediate Unit Package Type Name. Enter the type of immediate container packaging. There are no immediate containers in this shipping carton; however, we will show 100 Multi-Bags (MB) as an example in all lots.

42","20. Number per Shipping Unit. Enter the number of immediate containers contained in a shipping unit. When the amount is not standard in each shipping container, enter an average\approximate number. There are no immediate containers in this shipping carton; however, we will show 100 Multi-Bags (MB) as an example in all lots.

21. Seal Number(s). Enter the conveyance seal number(s) from the inspection certificate (egg products, red meat carcass shipments, etc.). Seal numbers are not needed for this shipment. Only certain egg products and red meat carcass shipments require seal numbers. If they were

needed, this information would be provided in a PG24 record. 22. Processing Est. No. Enter the foreign establishment number from the inspection certificate of the foreign plant that produced the product (e.g., last processed the product). Foreign establishment number 5555A is the processing\producing establishment certified on both foreign inspection certificates. 23. Source Country(s). Enter each country, other than the exporting country, from which product was sourced to produce the product in this lot. There is not a source country in this example. If there were, the source country would be identified in a repeating PG06 record as identified on the foreign inspection certificate. 24. Source Est. No. Enter each establishment, other than an establishment in the exporting country, from which product was sourced to produce the product in this lot. There is not a source establishment in this example. If there were, the source establishment would be identified in a repeating PG19 record as certified on the foreign inspection certificate. 25. HTS Code(s): Enter the 10 number Harmonized Tariff Schedule code(s) for the product(s) in the lot. This information comes from the entry. 26. Process Category. Enter the process category from the inspection certificate. The process category is Raw Product-Intact as certified on both foreign inspection certificates for all lots. 27. Product Category. Enter the product category from the inspection certificate. The product category is Raw Intact Beef as certified on both foreign inspection certificates for all lots. 28. Product Group. Enter the product group from the inspection certificate. The product group is Bnls.Mfg.Trimmings as certified on both foreign inspection certificates for all lots. 29. Species (dominant:) Enter one of the following species that the product predominantly contains: Beef, Veal, Goat, Lamb, Mutton, Pork, Horse, Equine other than horse, Chicken, Duck, Goose, Guinea, Squab, Turkey, Emu, Ostrich, or Rhea. The species is Beef as certified on both foreign inspection certificates for all lots. 29a. Additional Species (if applicable). Enter the less predominant additional species from the inspection certificate, when applicable. Refer to #29 for the applicable entries. There are no additional species for this example. FSIS is not yet capturing additional species designations in the message set. 30. Description of the Product. Enter the name or description of the product from the inspection certificate. For example, lamb legs, beef short loin, etc. Boneless Beef Trimmings. 31. Supplemental Product Code. Enter the GTIN, Intended Use Code, UPC, or other product code that is used in commerce for the product. GTIN is 100578620002680. Intended Use Code is 230.000. FSIS does not require these codes presently. FSIS will map these codes at the entry line level if provided. 43", "32. Estimated Date of Arrival. Enter the date that the product is expected to arrive at the FSIS establishment for import inspection. The importer has chosen I-425 as the official import inspection establishment for all lots associated with both certificates to present to FSIS for reinspection. The estimated date of arrival for the products associated to this customs entry at the official import inspection establishment is 08012011. 33. Printed Name of Customs Broker or Applicant. Enter actual name of person signing this application. Martha Stewart is the broker and has prepared this 9540-1 application. 34. Signature. Signature of person filing this application. Martha Stewart is the broker and has prepared this 9540-1 application. 35. Date. Enter the date the application is completed. Martha Stewart prepared\entered this application on 07262011. 44", "1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 20 1 2 3 4 5 6 7 8 9 30 1 2 3 4 5 6 7 8 9 40 1 2 3 4 5 6 7 8 9 50 1 2 3 4 5 6 7 8 9 60 1 2 3 4 5 6 7 8 9 70 1 2 3 4 5 6 7 8 9 80 0 1 B O N E L E S S B E E F T R I M M I N G S P G 0 1 0 0 1 F S I F S I S R V 1 0 0 5 7 8 6 2 0 0 0 2 6 8 0 2 3 0 . 0 0 0 P G 0 2 P P G 0 6 3 9 M X P G 1 3 I S O M X P G 1 4 F S 7 1 2 3 4 5 6 A A A A P G 5 0 P G 1 0 F S 1 1 R P

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APG2520101201102012011PG26500000010000CTXYXXY123PG  
26600000010000MBPG29LB000002330000PG51PG13ISOMXPG1  
4FS7123456BBBBPG50PG10FS11RPI1DPG19PE5555APG19EXE555  
5APG2510101201102012011PG265000000200000CTABABAB1239  
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MARTHASTEWART313666777JAS2@HOTMAIL.COM PG213136667  
771PG19CIPG21MARTHASTEWARTPG19CNPG21HILDABRAND85666  
67777HILDA@HOTMAIL.COM PG19IMP21HILDABRAND85666777  
7HILDA@HOTMAIL.COM PG22956CIFS3Y07262011PG30108012011  
842545", "Sample 2: The FSIS form 9540-1 has been modified to capture more detailed information about shipments. Below are the instructions that accompany the revised form. Additionally, in red font, are fictitious data representing a shipment of Boneless Beef Trimmings from an eCert country (New Zealand) and how that information would be entered in ABI for the message set. This example is three foreign inspection certificates on the entry. Block: 1. Country of Origin. Enter the name of the country that issued the inspection certificate for the export of the product. New Zealand is the name of the country that issued the foreign inspection certificates. This information comes from the entry. 2. Inspection Certificate Number. Enter the serial number, including dashes\slashes, from the foreign country inspection contained on the inspection certificate. Certificate numbers are NZL\2014\AAAA, NZL\2014\BBBB and NZL\2014\CCCC. 3. Exporting Establishment Number. Enter the official number of the foreign facility that the product was exported from the inspection certificate. This information comes from eCert and is not required in the message set. 4. U.S. Port of Entry\CBP Port Code. This is the name of the port of entry and the associated CBP port code designation where the entry is filed with U.S. Customs and Border Protection (CBP). This information comes from the entry. 5. U.S. Port of Unlading\CBP Port Code. This is the name of the U.S. port of entry and the associated CBP port code for merchandise. This information comes from the entry. 6. FSIS Establishment Number. This is the official number assigned by FSIS to the establishment where the product will move for FSIS import inspection. I425. Note the FSIS can accept this official import inspection establishment with or without the \u201c\201d. Example 1 does not reflect the \u201c\201d but this example shows the \u201c\201d. 7. Name and Address of FSIS Establishment. The name and address of the FSIS establishment where the product is to be moved for FSIS import inspection. This information comes from PHIS based on the number provided in block 6 above. 8. Name (first\last), Business Name and Address of Customs Broker or Applicant, as applicable (including zip code). NOTE: the name of a responsible person is required, in addition to the name of the business). Business name and address come from the entry. Broker name is Martha Stewart. 8a. Phone Number. Martha Stewart\u2019s phone number is 3136667777 8b. Facsimile Number. Martha Stewart\u2019s fax number is 3136667771 8c. E-Mail Address. The email address is used for refused entry notifications and communication with the applicant. Martha Stewart\u2019s email address is JAS2@HOTMAIL.COM 9. Name (first\last), Business Name and Address of Consignee (including zip code): The name and address, including zip code, of the company or person to which the

product is consigned. 46", "Business name and address come from the entry. Consignee\u2019s name is Hilda Brand. Hilda Brand\u2019s phone number is 8566667777. Hilda Brand\u2019s email address is HILDA@HOTMAIL.COM 10. Enter Name (first\last), Business Name and Address of Importer of Record (IR) (including zip code). The name and address of the Importer of Record as declared to Customs when the entry is filed. Business name and address come from the entry. Importer\u2019s name is Hilda Brand. Hilda Brand\u2019s phone number is 8566667777. Hilda Brand\u2019s email address is HILDA@HOTMAIL.COM 11. Bill of Lading Number(s). Enter the applicable bill of lading numbers for this application. This information comes from the entry. 12. Lot No. The lot number of each line item of product identified on the foreign inspection certificate. Start with 1 and continue with 2, 3, etc. This information comes from eCert and is not required in the message set. NOTE: Blocks 13 through 32 repeat for each lot on an inspection certificate. FSIS expects that each line item on the inspection certificate is one (1) lot on the form 9540-1. 13. Shipping\Identification Mark. Enter the unique number from the inspection certificate that links the product in the lot to the inspection certificate. Include slashes\dashes as appropriate. This information comes from eCert and is not required in the message set. 14. Custom Entry Number(s). Enter each applicable 11 digit custom entry number associated with the shipment. For locations where the custom entry number is not 11 characters long, enter enough zeros at the beginning to make an eleven digit number. This information comes from the entry. 15. Production Date(s). Enter the range of production dates from the foreign inspection certificate for each lot when applicable. This information comes from eCert and is not required in the message set. 16. Net Weight of Lot. Enter the net weight of each lot in pounds from the inspection certificate. This information comes from eCert and is not required in the message set. 17. Shipping Unit Package Type Name. Enter the type of shipping unit. This information comes from eCert and is not required in the message set. 18. Number of Units. Enter the number of shipping units from the inspection certificate. This information comes from eCert and is not required in the message set. 19.Immediate Unit Package Type Name. Enter the type of immediate container packaging. This information comes from eCert and is not required in the message set. 20. Number per Shipping Unit. Enter the number of immediate containers contained in a shipping unit. When the amount is not standard in each shipping container, enter an average\approximate number This information comes from eCert and is not required in the message set. 21. Seal Number(s). Enter the conveyance seal number(s) from the inspection certificate (egg products, red meat carcass shipments, etc.). Seal numbers are not needed for this shipment. Only certain egg products and red meat carcass shipments require seal numbers. If they were needed, this information would be provided in a PG24 record. 47", "22. Processing Est. No. Enter the foreign establishment number from the inspection certificate of the foreign plant that produced the product (e.g., last processed the product). This information comes from eCert and is not required in the message set. 23. Source Country(s). Enter each country, other than the exporting country, from which product was sourced to produce the product in this lot. This information comes from eCert and is not required in the message set. 24. Source Est. No. Enter each establishment, other than an establishment in the exporting country, from which product was sourced to produce the product in this lot. This information comes from eCert and is not required in the message set. 25. HTS Code(s): Enter the 10 number Harmonized Tariff Schedule code(s) for the product(s) in the lot. This information comes from the entry. 26.Process Category. Enter the process category

from the inspection certificate. This information comes from eCert and is not required in the message set. 27. Product Category. Enter the product category from the inspection certificate. This information comes from eCert and is not required in the message set. 28. Product Group. Enter the product group from the inspection certificate. This information comes from eCert and is not required in the message set. 29. Species (dominant:) Enter one of the following species that the product predominantly contains: Beef, Veal, Goat, Lamb, Mutton, Pork, Horse, Equine other than horse, Chicken, Duck, Goose, Guinea, Squab, Turkey, Emu, Ostrich, or Rhea. This information comes from eCert and is not required in the message set. 29a. Additional Species (if applicable). Enter the less predominant additional species from the inspection certificate, when applicable. Refer to #29 for the applicable entries. This information comes from eCert and is not required in the message set. 30. Description of the Product. Enter the name or description of the product from the inspection certificate. For example, lamb legs, beef short loin, etc.

Boneless Beef Trimmings. 31. Supplemental Product Code. Enter the GTIN, Intended Use Code, UPC, or other product code that is used in commerce for the product. This information is optional, and was not provided in this example. 32. Estimated Date of Arrival. Enter the date that the product is expected to arrive at the FSIS establishment for import inspection. The importer has chosen I-425 as the official import inspection establishment for all lots associated with these three certificates to present to FSIS for reinspection. The estimated date of arrival for the products associated to this customs entry at the official import inspection establishment is 08012011. 33. Printed Name of Customs Broker or Applicant. Enter actual name of person signing this application. Martha Stewart is the broker and has prepared this 9540-1 application. 34. Signature. Signature of person filing this application. Martha Stewart is the broker and has prepared this 9540-1 application. 48", "35. Date. Enter the date the application is completed.

Martha Stewart prepared\entered this application on 07262011. 1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6  
7 8 9 20 1 2 3 4 5 6 7 8 9 30 1 2 3 4 5 6 7 8 9 40 1 2 3 4 5 6 7 8 9 50 1 2 3 4 5 6 7 8 9 60 1 2 3 4 5 6  
7 8 9 70 1 2 3 4 5 6 7 8 9 80 O I B O N E L E S S B E E F T R I M M I N G S P G 0 1 0 0 1 F S I F S I P G  
0 2 P P G 0 6 3 9 N Z P G 1 3 I S O N Z P G 5 0 P G 1 4 N Z L \ 2 0 1 4 \ / A A A A P G 1 4 N Z L \ 2 0  
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M A R T H A S T E W A R T P G 1 9 C N P G 2 1 H I L D A B R A N D 8 5 6 6 6 6 7 7 7 7 H I L D A @ H O T M  
A I L . C O M P G 1 9 I M P G 2 1 H I L D A B R A N D 8 5 6 6 6 6 7 7 7 7 H I L D A @ H O T M  
A I L . C O M P G 2 2 9 5 6 C I F S 3 Y 0 7 2 6 2 0 1 1 P G 3 0 1 0 8 0 1 2 0 1 1 8 1 4 2 5 4 9", "Other  
Links General information for importing meat, poultry or egg products under the jurisdiction of the Food Safety and Inspection Service (FSIS) into the United States:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products> Listing of eligible countries, products and foreign establishments:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligiblecountries-products-foreign-establishments> Information for importer and brokers regarding the import final rule publication and the PHIS:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/phis-importcomponent> FSIS Product Categorization:

<http://www.fsis.usda.gov/wps/wcm/connect/abbf595d-7fc7-4170-b7be37f812882388/Product-Categorization.pdf?MOD=AJPERES> Listing of FSIS official establishments:

[http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/mpidirectory/50"\]}, {"file\\_name": "FSIS\\_GD\\_2018\\_0007", "title": "FSIS guideline for Determining Whether a Livestock Slaughter or Processing Firm is Exempt from Inspection Requirements of the Federal Meat Inspection Act", "num": "FSIS-GD-2018-0007", "id": "849070c7ea94891b694d45463a4909c621e7b8df6c4f82728f8b6000cd36d174", "corpus": "fsis\\_guidelines", "source\\_page\\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Compliance-Guideline-Livestock-Exemptions.pdf", "type": "pdf", "n\\_pages": 36, "word\\_count": 12848, "text\\_by\\_page": \["FSIS Guideline for Determining Whether a Livestock Slaughter or Processing Firm is Exempt from the Inspection Requirements of the Federal Meat Inspection Act May 24, 2018 This guideline is designed to help firms that slaughter livestock or process meat and meat products determine whether they are exempt from required Federal inspection under the Federal Meat Inspection Act. USDA-FSIS", "\( \\ \"----~ What is the purpose of this guideline? Many businesses are interested in slaughtering livestock or producing meat or meat food products but are not sure if they are required to operate under Federal inspection. This guideline explains each of the exemptions from inspection, when they apply, and which Food Safety and Inspection Service \(FSIS\) regulatory requirements must still be met. Who is this guideline designed for? This guideline is designed for any person or business seeking more information about the exemptions from the requirements for inspection by FSIS, or emerging business model operators that handle meat or meat food products that are exempt from inspection requirements. FSIS currently requires inspection, unless exempted, for meat or meat food products from cattle, sheep, swine and goats. This guideline will be especially useful for producers and businesses that are exempt from inspection by regulation: \u2022 small and very small slaughter or processing establishments wishing to provide custom exempt services \(see page 4\) to owners of livestock; \u2022 retail stores making sales directly to consumers at a single location or at satellite stores owned or operated by the retail store; FSIS currently requires inspection, unless exempted, for meat or meat food products from cattle, sheep, swine, and goats. \u2022 restaurants selling or serving ready-to-eat \(RTE\) meals to individual consumers; \u2022 caterers delivering or serving RTE meals to individual consumers; \u2022 restaurant central kitchens sending RTE meals to their satellite restaurant locations or vending machines; \u2022 businesses that are a combination of a retail store and a restaurant; \u2022 internet advertisers, marketers, and brokers of meat or meat food products to consumers; \u2022 firms using common couriers to transport meat or meat food products to consumers; and \u2022 farmers wishing to engage in direct purchase agreements with school food service authorities for livestock slaughtered and prepared under State or Federal inspection. This guideline reflects FSIS\u2019s policies and procedures and can be used now. However, FSIS is requesting comments on this guideline and may make changes to it based on comments. How can I comment on this guideline? FSIS seeks comments on this guideline as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days and the document will be updated in response to the comments. Comments may be submitted by either of the following methods: Federal eRulemaking Portal Online submission at"\]}\]}](http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/mpidirectory/50)

regulations.gov: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to http:\www.regulations.gov and follow the online instructions at that site for submitting comments. Mail, including -CD-ROMs, and hand-or courier-delivered items: Send to Docket Clerk, U.S.Department of Agriculture (USDA), FSIS, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, 8-163A, Washington, DC 20250-3700. All items submitted by mail or electronic mail must include the Agency name -FSIS, and document title: FSIS Guideline for Determining Whether a Livestock Slaughter or Processing Operation is Exempt from the Inspection Requirements of the Federal Meat Inspection Act 2017. Comments received will be made available for public inspection and posted without change, including any personal information, to http:\www.regulations.gov. What if I still have questions after I read this guideline? If the desired information cannot be found within the Guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the askFSIS database or submit questions through askFSIS. Documenting these questions helps FSIS improve and refine present and future versions of the Guideline and associated issuances. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided: Subject Field: Enter Guideline for Livestock Exemptions Question Field: Enter question with as much detail as possible. Product Field: Select General Inspection Policy from the drop-down menu. Category Field: Select Agency Issuances from the drop-down menu. Policy Arena: Select Domestic (U.S.) Only from the drop-down menu. When all fields are complete, press Continue.", "TABLE OF CONTENTS INTRODUCTION

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## MEAT FOOD PRODUCTS?

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UNDERSTANDING THE EXEMPTIONS.

26", "Introduction Under the Federal Meat Inspection Act (FMIA), FSIS conducts inspection in all establishments where cattle, goats, sheep and swine are slaughtered or processed for sale as articles of commerce, unless an exemption from inspection applies. See page 23 for more about what is meant by \u201commerce.\u201d The USDA\u2019s Food Safety and Inspection Service (FSIS) is the public health agency responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. FSIS does this by verifying compliance with its regulations, found in 9 Code of Federal Regulations (CFR) 300-599. Daily inspection is provided by FSIS or by States that operate their own meat and poultry inspection (MPI) programs that are \u201cat least equal to\u201d FSIS\u2019s inspection program. The FMIA exempts some slaughter and processing activities and operations from its inspection requirement. Those exemptions are found in 21 U.S.C. 623 and 661, and FSIS issued regulations on those exemptions (9 CFR 303.1). Facilities operating under an exemption are not exempt from the adulteration and misbranding requirements of the FMIA and may be subject to State or local regulatory requirements. Note: Exemption guidance for poultry products can be found in Guidance for Determining Whether a Poultry Slaughter or Processing Operation is Exempt from Inspection Requirements of the Poultry Products Inspection Act. What requirements apply to persons, firms or corporations wishing to conduct business under the livestock inspection exemptions? Although exempt from the daily inspection requirements, these exempt facilities remain subject to the access and examination provisions of the FMIA (21 U.S.C. 642). Therefore, business records, per 9 CFR 320.1, must be maintained and access to places of business and opportunity for examinations of facilities, inventory, and records must be provided to authorized FSIS personnel. As is noted above, meat products exempt from inspection are not exempt from the adulteration or misbranding provisions of the FMIA. The adulteration and misbranding provisions of the FMIA can be found in 21 U.S.C. 601. \u2022 A meat food product is adulterated if it o was prepared, packed or held under insanitary conditions; o is for any reason unsound, unhealthful, unwholesome or unfit for human food; o consists in whole or part of any filthy, putrid, or decomposed substance; o may have been rendered injurious to health; or o bears or contains any poisonous or deleterious substance which may render it injurious to health (i.e. undeclared allergen, chemical residue). \u2022 A meat food product is economically adulterated when any valuable constituent, in whole or in part, has been omitted or removed, or in which a less valuable substance has been substituted. \u2022 A meat food product is misbranded if its label is false or misleading, or if it does not contain the required labeling features. 1", " A \_\_ \_ ( '\\"'----\_\_ ) y Who determines whether an operation qualifies for an exemption? There is no registration requirement with FSIS or approval process The person operating the from FSIS to operate under an exemption. The person operating business determines if he the business makes the initial determination and decides which, if or she is qualified for an any, exemption applies. However, FSIS Office of

Investigation, exemption. Enforcement and Audit (OIEA) Compliance Investigators periodically verify whether the firm meets the relevant exemption FSIS OIEA Compliance requirements in 9 CFR 303.1. Investigators may verify For assistance in understanding the regulations applicable to that the establishment exempt operations, please contact the FSIS Policy Development meets the exemption Staff at 1-800-233-3935 or submit your questions through requirements in 9 CFR askFSIS. 303.1. What are the exemptions from USDA FSIS inspection? The FMIA, in 21 U.S.C. 623(a), exempts from routine Federal inspection: \u2022 Livestock slaughtered for personal use \u2022 Livestock custom slaughtered or prepared The FMIA, in 21 U.S.C. 661(c)(2), exempts from routine Federal inspection, operations of types traditionally and usually conducted at: \u2022 Retail stores \u2022 Restaurants \u2022 Restaurant central kitchen facilities \u2022 Caterers Criteria and Notes for Each Exemption A.PERSONAL USE Mandatory inspection for the slaughter and processing of privately owned livestock is not required, provided the criteria below are met (21 U.S.C. 623; 9 CFR 303.1(a)(1)): (a)The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to: (1)The slaughtering by any individual of livestock of their own raising, and the preparation by them and transportation in commerce of the carcasses, parts thereof, meat and meat food 2", "products of such livestock exclusively for use by them and the members of their household and their nonpaying guests and employees. Personal Use Criteria: 1. The resulting product from the animal slaughtered and processed under this exemption is exclusively for the private use by the: a. owner raising the livestock, b. members of their household, c. household nonpaying guests, or d. household employees. 2. The slaughter and processing of the livestock is performed by the owner of the livestock. 3. No livestock are slaughtered which are unfit for human consumption. Specified risk materials (SRMs)are inedible and prohibited for use as human food. 4. The carcass and parts are not prepared, packed, or held under insanitary conditions. Personal Use Notes: 1. All of the criteria above must be met, otherwise, the livestock is not eligible to be slaughtered and processed under this exemption, and inspection is required. 2. There is no limit on the number of livestock that an owner may slaughter and process for their personal use. 3. A person may purchase livestock from a farm or ranch and then slaughter it onsite using the farm or ranch facilities or equipment. a. If a person purchases livestock, and uses the onsite facilities without assistance from the seller, then the activity remains personal use. b. If the seller participates in the slaughter or processing activity, then the facility owner is subject to the custom exempt criteria described below. 4. Personal use products, although uninspected, may move across State lines. 5. The owners of the livestock may or may not reside at the same physical location as the animal. 6. The exempt meat food products may not be sold or donated. B. CUSTOM SLAUGHTER AND CUSTOM PROCESSING A custom exempt operator slaughters livestock belonging to someone else and processes the carcasses and parts, for the exclusive use, in the household of that owner, by the owner, members of the owner\u2019s household, non-paying-guests, and employees. The custom exempt operator may also engage in the business of buying or selling other meat and meat food products, derived from State or Federal inspected sources. A custom exempt operator may slaughter, or process custom exempt product, or do both. The owner of the livestock may opt to have his or her livestock slaughtered under the custom exemption by one 3", "\_\_\_ A \_\_\_ ( \\'----\_\_ ) y custom exempt operator, and then choose to have a second custom exempt operator do the processing. The owner of the livestock may also slaughter the animal and then

have the carcass further processed at a custom exempt processing facility. The applicable regulatory requirements are found in 9 CFR 303.1(a)(2): (a)The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to: (2)The custom slaughter by any person of cattle, sheep, swine, or goats delivered by the owner thereof for such slaughter, and the preparation by such slaughterer and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such livestock, exclusively for use, in the household of such owner, by the owner and members of their household and their nonpaying guests and employees; nor to the custom preparation by any person of carcasses, parts thereof, meat or meat food products derived from the slaughter by any individual of cattle, sheep, swine, or goats of their own raising or from game animals, delivered by the owner thereof for such custom preparation, and transportation in commerce of such custom prepared articles, exclusively for use in the household of such owner, by the owner and members of their household and their nonpaying guests and employees. Custom Slaughter and Custom Processing Criteria: Custom exempt operations must result in meat and meat food products that are fit for human consumption. 1. The resulting product from the animal slaughtered and processed under this exemption is exclusively for the private use of the: a. owner of the livestock; b. members of his the owner\u2019s household; c. nonpaying guests; or d. household employees. 2. Records of the names and addresses of the owner of the livestock and products must be kept by the custom exempt operator. The recordkeeping requirements of 9 CFR 320.1 apply to custom exempt operations. 3. No livestock are slaughtered which result in food unfit for human consumption. a. For reference, in official establishments non-ambulatory disabled cattle are considered unfit for human food and must be condemned, including those that become nonambulatory after passing ante-mortem inspection (9 CFR 309.3). However, custom operators may slaughter for human food cattle that become non-ambulatory disabled after they are delivered to the custom slaughter facility if the operator of the facility does not observe any other condition that would render the animal unfit for human food (74 FR 11463, 11464). b. Field-dressed livestock (cattle, sheep, swine, goats) may be brought in for custom exempt processing. The custom exempt operator may ask the owner of any field-dressed cattle to provide a written statement that the animal was ambulatory at the time of slaughter. This statement helps to support that the beef products are safe, wholesome and unadulterated. 4", "c. The facility must handle and maintain inedible material to prevent the diversion of inedible animal products (including SRMs) into human food channels, resulting in the adulteration of human food (9 CFR 303.1(a)(2)(i), 303.1(b)(4), 381.10(a)) (4), 416.2(b)(4), and 416.3(c)). d. The regulation 9 CFR 303.1(b)(1) states that \u201cxempted custom prepared products \u2026 shall not be adulterated as defined in paragraph 1(m) of the Federal Meat Inspection Act.\u201d Therefore, custom exempt product cannot contain SRMs, including the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord, and dorsal root ganglia of cattle 30 months of age and older. The distal ileum of the small intestine and tonsils from all cattle are SRMs, considered inedible and, therefore, are not to enter the food supply (9 CFR 310.22). See FSIS Using Dentition to Age Cattle for more information. 4. Livestock must be slaughtered and handled in compliance with the Humane Methods of Livestock Slaughter Act. 5. The facility must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated. a. The regulatory requirements of 9 CFR 416.1 to 416.6, except for 416.2(g)(2)-

(6), apply to all custom exempt facilities. b. The additional regulatory requirements, including recordkeeping, of 9 CFR 416.12 to 416.16, apply to custom exempt operations that are conducted in an official establishment, 9 CFR 303.1(a)(2)(i). 6. The custom exempt product cannot be sold or donated as it is exclusively for the use by the owner in their household. Articles which are capable for use as human food, if not delivered to the owner, must be denatured or otherwise identified in accordance with 9 CFR 325.13, so as to be made distinguishable from human food, per 9 CFR 303.1(b)(4). 7. The carcasses and parts prepared on a custom exempt basis shall be marked as \u201cNot for Sale,\u201d or if placed in immediate containers labeled with \u201cNot for Sale,\u201d until delivered to the owner, per 9 CFR 316.16. 8. In a facility that hosts both an official establishment and an unofficial custom exempt operation, the custom exempt prepared livestock products must be kept separate and apart, per 9 CFR 303.1(a)(2)(ii), from any products that are for sale. Separation can be achieved by time or space. For example, the same cooler can be used to store both custom exempt products and inspected products. The custom exempt products are stored on separate rails or shelves and marked \u201cNot for Sale,\u201d which makes them separate and distinct from the inspected product. Custom Slaughter and Custom Processing Notes: 1. There is no registration requirement with FSIS or approval process from FSIS to operate under the custom exemption. FSIS recommends that operations that are exempt from FSIS inspection are appropriately permitted through the State and local (county, city) authorities. Check with those authorities for their applicable licensing requirements. FSIS will verify compliance with the FMIA statutory requirements, and 9 CFR regulatory requirements, annually. 2. There is no limit to the amount of livestock that an owner may slaughter and process for their personal use under the custom exemption. 5", "3. If any of the eight criteria above are not met, the custom exempt operator may be ineligible for the exemption. 4. If the custom operations are conducted in a facility that also has an official USDA inspected operation, an owner\u2019s animal may be slaughtered under USDA inspection if so desired by the owner. After the animal passes both ante-mortem and post-mortem inspections, it can be returned to the owner, unless condemned. The animal should be kept separate throughout the process in order to be returned to the owner. 5. Selling livestock to a customer does not disqualify a business from the custom exemption. A custom exempt operator may sell livestock to a person(s) prior to slaughter and then custom slaughter the animal for the new owner. The custom exempt operator would be required, upon request, to provide records, per 9 CFR 320.1(a), that fully disclose the transfer of ownership prior to slaughter or processing of the livestock. 6. The operator of a custom exempt facility may also slaughter and process their own livestock for their exclusive consumption, or members of their household, nonpaying guests or employees, under the personal use exemption. 7. Selling livestock to a customer and then allowing that owner to use onsite facilities for the slaughter of the livestock still constitutes personal use slaughter. However, once the seller assists in the slaughter or processing, then the facility becomes a custom exempt facility, subject to 9 CFR 303.1(a)(b). 8. A custom exempt operation may use a mobile slaughter and processing unit. 9. The equipment used for custom exempt slaughter and processing must be thoroughly cleaned and sanitized prior to their use for preparing any inspected products, per 9 CFR 416.12(a), to prevent direct contamination or adulteration of product(s). 10. The risk of infection from Trichinae is increased in swine that have access to rodents and wildlife, such as pasture-raised, free-range and feral swine. All forms of fresh pork, including fresh unsmoked sausage, are

customarily well cooked in the home by the consumer, and therefore the treatment of such products for the destruction of trichinae is not needed. However, in order to produce a safe, wholesome and unadulterated product, pork products that might be eaten rare or without thorough cooking because of the appearance of the finished product, may require treatment for the destruction of trichinae. 11.FSIS recommends, but does not require, that custom exempt operators keep production records of cooking and cooling of meat food products to support that they produce safe, wholesome, unadulterated products as required by the FMIA. 12.Any canned product from custom exempt livestock must be prepared in accordance with 9 CFR 318 Subpart G \u2013 Canning and Canned Products, including written processing schedules.

13.Although the items listed below are not specifically required by the HMSA, FSIS recommends the custom exempt operators: a. provide water and feed for animals in pens, 6", "b. maintain facilities in good repair to prevent injury to animals, c. drive the livestock with a minimum of excitement and discomfort, d. separate disabled animals from ambulatory animals, e. not drag disabled animals while still conscious, and f. handle animals in accordance with applicable state and local laws. 14.If an owner of the livestock wishes to transport custom exempt product from one custom exempt facility to another for further processing, they may do so. (The product must be marked \u201cNot for Sale\u201d during transportation, per 9 CFR 303.1(a)(2)(iii).)

15.Commingling of fat trimmings and meat trimmings from custom exempt animals to facilitate rendering or sausage production is allowed with each owner\u2019s written consent. All of the resulting commingled product must be clearly marked \u201cNot for Sale.\u201d See FSIS Directive 5930.1, Custom Exempt Review Process, page 9, for more information. 16.There may be more than one owner of the live animal. Sharing a live animal is acceptable provided proof of ownership of the live animal is available, upon request to the custom exempt operator, for Agency review. 17.The custom exempt operator must maintain records showing the identity of the individual owners\u2019 names prior to slaughter. In the case of more than one owner of the livestock, a list of the individual owners\u2019 names is required prior to slaughter, per 9 CFR 303.1(b)(3). 18.Carcasses and other products of custom slaughter are not eligible to be sold. Therefore, sale or purchase of the live animal using the services of a custom exempt operator would be based on live weight, price-per-head, or other quantity pertaining to the live animal. The custom exempt operator can only charge the owner a service fee for the livestock slaughtered or prepared on a custom basis, not for the meat food product itself which is derived from the custom slaughter or processing because the custom exempt operator does not own the live animal nor the resultant product. 19.The custom exempt operator can arrange the purchase of a live animal for a customer, conduct the subsequent slaughter and processing, and arrange the delivery of the \u201cNot for Sale\u201d product to the owner because the FMIA does not preclude the custom exempt operator from acting as an agent on behalf of the livestock owner. The custom operator would be required, per 9 CFR 303.1(b)(3), to provide the name and address of the owner prior to custom slaughter. C.RETAIL STORES A retail

store\u2019s sales could consist solely of orders placed by the consumer via fax, phone, or online, and shipped from the retail store. The FMIA and meat inspection regulations provide a retail store exemption for businesses that further prepare meat and meat food products for sale to consumers. Traditionally, a retail store in the 1970s, when the 9 CFR 303.1(d) regulations were implemented, consisted of a physical brick-and-mortar store. It typically included a butcher counter, where consumers could buy steaks, chops, roasts, ground meats, or meat

food products that were cooked, cured, or smoked. 7", "With the rise of catalog sales and use of the internet, today\u2019s retail venues may differ greatly from that traditional retail store. Consumers can now easily order meat food products, further prepared without FSIS inspection, under the retail store exemption, without leaving their homes. The applicable regulatory requirements are found in 9 CFR 303.1(d)(1): (d)(1) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to operations of types traditionally and usually conducted at retail stores and restaurants, when conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities or service of such articles to consumers at such establishments. (2)For purposes of paragraph (d)(1) of this section: (i)Operations of types traditionally and usually conducted at retail stores and restaurants are the following: (a)Cutting up, slicing, and trimming carcasses, halves, quarters, or wholesale cuts into retail cuts such as steaks, chops, and roasts, and freezing such cuts; (b)Grinding and freezing products made from meat; (c)Curing, cooking, smoking, rendering or refining of livestock fat, or other preparation of products, except slaughtering or the retort processing of canned products; (d)Breaking bulk shipments of products; (e)Wrapping or rewrapping products. Retail Store Criteria: 1.The retail exempt operation must have sales to consumers at the location where the meat food products are prepared under the exemption, as defined in 303.1(d)(1). a.Traditionally, this means a walk-in brick-and-mortar facility where a consumer can purchase meat from a retail display case. b.However, a retail store\u2019s sales can consist solely of orders placed by the consumer via fax, phone, or online, and shipped from the retail store, without actually having customers walk into the store. 2.In order to maintain eligibility for the retail store exemption sales can only be to consumers. There are two types of consumers: a. individual household consumers, and b. \u201cother-than-household\u201d consumers, more commonly known as hotels, restaurants and similar institutions (HRI) as determined by the Administrator in specific cases, as defined by 303.1(d)(2)(vi). 3.Neither slaughtering of livestock, nor retort processing (canning) of meat food products, can occur under the retail store exemption. Those activities require either Federal or State inspection in states that operate their own Meat and Poultry Inspection (MPI) programs (referred to as non-designated States). 8", "4. A retail store can prepare multi-ingredient meat food products for sale to other-than-household consumers, within the limitations defined in 303.1(d)(2)(i)(c). Limitations on sales to other-thanhousehold-consumers: a. If a retail exempt store prepared the meat food product by curing, cooking or smoking, rendering or refining the product, it cannot sell that product to other-than-household consumers, as defined in 303.1(d)(2)(iii)(f). b. A retail store could slice or grind meat that was cured, cooked or smoked under Federal or State inspection and sell that product to HRI accounts. c. Sales to HRI accounts cannot exceed 25% of total sales to consumers of retailprepared meat. At least 75%, in terms of dollar value, of total sales of product represents sales of product to household consumers. This is known as the 75\25 Rule. d. Sales to HRI accounts cannot exceed the calendar year dollar limitation set by the Administrator. 5. For all sales, whether to individual household consumers or to HRI, no sale is made in excess of normal retail quantities, as defined in 9 CFR 303.1(d)(2)(ii). Any quantity or product purchased by a consumer from a particular retail supplier shall be deemed to be a normal retail quantity if the quantity so purchased does not in the aggregate exceed one-half carcass. The following amounts of product will be accepted as representing one-half carcass of the species identified: One-half carcass pounds Cattle 300

Calves 37.5 Sheep 27.5 Swine 100 Goats 25 6. Only federally inspected source materials can be used in the preparation of meat food products made for sales to consumers destined for interstate commerce. In states that operate their own MPI programs, State inspected source materials can be used in the preparation of meat food products that are limited to intrastate sales. 7. Records, such as bills of sale to consumers or cash register receipts, and raw ground beef production records (if applicable) are maintained as required by 9 CFR 320.1. FSIS OIEA Investigators are to have access to examine such records to verify compliance. The misbranding provisions of the FMIA apply to meat food products that are prepared under exemption from inspection requirements. Labeling of retail exempt meat food products is enforced by FSIS investigators, and by State or local authorities. State and local authorities use the FDA Food Code as guidance for labeling. Absent the following label features, per 9 CFR 301.2, Misbranded, a retail meat food product would be misbranded, if in a package or container, unless it bears a label showing: a. the name and place of business of the manufacturer, packer, or distributor; 9", "b. an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; c. any word, statement, or other information (such as Safe Handling Instructions for meat products that are not RTE) required by or under authority of the Act; d. the common or usual name of the food, if any there be; e. the common or usual name of each ingredient if the product is fabricated from two or more ingredients; f. a handling statement such as \u201cKeep Refrigerated\u201d or \u201cKeep Frozen\u201d if product requires special handling to maintain its wholesomeness; g. nutrition labeling as specified in 9 CFR 317, Subpart B Nutrition Labeling, unless an exemption in 9 CFR 317.400 applies. Retail Store Notes: 1. FSIS recommends that operations that are exempt from inspection are appropriately permitted through the State, local (county, city), and tribal authorities. Check with those authorities for their applicable licensing requirements and applicable foodservice ordinances. 2. Typically, after permitting, the exempt operation will be subject to periodic inspections by the local authorities. Those inspections often compare the operations to the Food and Drug Administration\u2019s Food Code. 3. To ensure the product does not become unwholesome or adulterated during mail order deliveries to consumers by a retail exempt operation, or its contracted couriers, the retailer and courier must safeguard against adulteration due to temperature abuse during transportation, per FMIA 21 U.S.C. 610(d), until the consumer takes possession of such product. USDA's Identifying Food Safety Risk Factors And Educational Strategies For Consumers Purchasing Seafood And Meat Products Online can be a valuable resource to retailers for making food safety determinations regarding mail order sales. Retailers and couriers need to be aware of the FDA\u2019s Sanitary Transportation of Human and Animal Food requirements for shippers, loader and couriers. 4. The FMIA does not prohibit retail exempt store operators from using third-party businesses, such as a food hub, to: a. advertise, b. market, c. store product in commerce at an independent warehouse or food hub, prior to delivery to the consumer, d. deliver, and e. collect the money for the sale of their exempt products to consumers, but the retailer must sell the exempt meat or meat food product to the consumer in order to be exempt. The retailer cannot sell the product to the third-party business for re-sale to the consumer. 5. The FMIA does not prohibit a person, firm or corporation from preparing exempt meat food products at a central retail store location, for sale to consumers at that central location, and for unlimited distribution and subsequent sale to consumers at their satellite retail outlets, owned 10", "or operated by them, such as their

additional retail stores, kiosks, farmers market booths, or mobile food pantries.

6. FSIS recognizes that consumers may purchase raw meat or RTE meat products from a retail store via phone, fax, or online orders, and have that purchase delivered. Retailers that sell meat food products must maintain records, such as bills of sale, in accordance with 9 CFR 320, that disclose that sales were made to consumers at such location.

7. The total sales of product (303.1(d)(2)(iii)), and the annual dollar limitations for sales to otherthan-household consumers, apply to individual retail stores, rather than cumulative retail stores operating under a corporate structure.

8. The sales of pass-through (box-in, box-out, not opened) meat food products that were federally inspected do not apply to the total sales of product found in 9 CFR 303.1(d)(2)(iii)(b). Those total sales limitations apply only to products prepared under the retail exemption. There is no limit on the sales of federal or state inspected products that are not further prepared at the retail establishment.

9. A retail store can donate meat food products that they prepared, or are selling, to non-profit organizations, but that product must have been from federally or state inspected source materials.

10. Meat food product prepared under the retail exemption will NOT bear the USDA marks of inspection on the label as it was prepared without inspection.

11. Labels applied at retail are not required to have FSIS sketch approval. A retailer may carry forward any special claims found on inspected source materials. A retailer cannot apply any new claim to the product prepared under the retail store exemption. It would be false and misleading (misbranding) to apply a claim which was not found on the source material. FSIS labeling guidance can be found in A Guide to Federal Food Labeling Requirements for Meat, Poultry, and Egg Products.

D. RESTAURANTS

A restaurant is a business where meals, which may include meat food products, may be purchased. While a traditional restaurant experience may involve dining in, other restaurant business models include drive-thru windows, delivery, or carry-out options. The applicable regulatory requirements are found in 9 CFR 303.1(d)(2)(iv).

**Restaurant Criteria:**

1. RTE meat food products are prepared for sale or service in meals or as entrees directly to individual consumers at such establishments.
2. Only federally or state inspected and passed product, or product prepared at a retail store exempted by 303.1(d)(2)(iii), is handled or used in the preparation of any product.
3. No sale of product is made in excess of a normal retail quantity as defined in 303.1(d)(2)(ii). See page 10.
4. The preparation of product is limited to traditional and usual operations as defined in 303.1(d)(2)(i). See page 8.
5. Records are maintained as required by 9 CFR 320.1.

**Restaurant Notes:**

1. The restaurant serves the individual consumers directly at the physical location where the RTE meat is prepared for immediate consumption.
2. Sales made by the restaurant are not subject to the 75/25 rule, nor the calendar year dollar limitation for retail stores, as restaurants do not sell exempt product to other-than-household consumers (HRI: hotels, restaurants and similar institutions).
3. The restaurant is subject to the State and local (county, city), and tribal inspection laws. Check with those authorities for their applicable licensing requirements and applicable foodservice ordinances.
4. The restaurant is subject to the adulteration provisions of the FMIA per 9 CFR 303.1(f), therefore, the RTE meals must not be prepared, packed or held under insanitary conditions.

E. CATERERS

A caterer is a person who delivers or serves product in meals to individual consumers.

**Caterer Criteria:**

1. The definition of a restaurant includes a caterer, per 9 CFR 303.1(d)(2)(iv)(b). Product is prepared only for sale or service in meals or as entrees to individual consumers.
2. Only federally or state inspected and passed product, or such product prepared at a retail store exempted by 303.1(d)(1), is handled or used in the

preparation of any product. Meals prepared from State-inspected source material are eligible solely for sale within such State. 3. No sale of product is made in excess of a normal retail quantity as defined in 303.1(d)(2)(ii) of this section. 4. The preparation of product is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section. 5. Records are maintained as required by the FMIA 21 U.S.C. 642 and 9 CFR 320.1, which include records that fully and correctly disclose all transactions involved in their business. Caterer Notes: 1. The caterer is a subset of the restaurant exemption. Caterers must meet the terms of the restaurant exemption, delineated above in 1-5, in order to be eligible for the exemption from Federal inspection. 2. The caterer, or their employees delivers or serves the meals, or entr\u00e9es, to the individual consumers, per 9 CFR 303.1(d)(2)(iv)(b). 12", "3. In order to maintain eligibility for the catering exemption sales can only be to individual consumers. Products not sold to consumers disqualify the caterer from the exemption and the caterer must apply for a grant of inspection. Records which fully and correctly disclose the sale of the catered product to the consumer are required per 9 CFR 320.1(b)(1). 4. The caterer is subject to in-commerce surveillance reviews by FSIS OIEA investigators, including access and examination of facilities, inventory, and records, per FMIA 21 U.S.C. 642. The caterer is also subject to State and local licensing requirements and periodic inspection by local authorities to ensure proper sanitation and food handling. 5. The caterer is subject to the adulteration provisions of the FMIA per 9 CFR 303.1(f), therefore, the catered RTE meals must not be prepared, packed or held under insanitary conditions. The caterer, or their employees, should consider storage, holding, and reheating conditions in order to ensure delivery to consumers of a safe, unadulterated meal. Inadequate storage, holding, or reheating temperatures could lead to dangerous levels of pathogens in the foods.

F. RESTAURANT CENTRAL KITCHENS

The increase in large restaurant chains and fast food operations has contributed to a trend in the centralization of meat preparation systems. By centralizing preparation of products, a restaurant business can improve its efficiency. A restaurant central kitchen (RCK) exemption is provided, in 9 CFR 303.1(d)(2)(iv))(c), for a central kitchen that prepares RTE meat products for sale to consumers at their satellite restaurants.

Restaurant Central Kitchen Criteria:

1. The product is RTE upon departure from the RCK (i.e., no further preparation such as cooking is needed, except that it may be reheated prior to serving).
2. The transportation is direct between the RCK and satellite restaurant or vending machine location with no intervening transfer or storage. Only federally inspected source materials can be used in the preparation of meat food products destined for interstate sales.
3. The product is to be served, without intervening sale, in meals or as entr\u00e9es only to customers at satellite restaurants, or through vending machines, owned or operated by the same individual, firm, or corporation owning or operating the restaurant central kitchen.
4. The facilities are maintained in a sanitary manner.
5. Records are maintained as required by 9 CFR 320.1.

Restaurant Central Kitchen Notes:

1. The RCK may or may not serve consumers at the RCK location.
2. The RCK is subject to the State and local (county, city) inspection laws. Check with those authorities for their applicable licensing requirements and applicable foodservice ordinances.
3. All RCKs are subject to periodic inspection by local governments and by FSIS to ensure proper sanitation and food handling.
4. To lessen the likelihood of product mishandling and potential adulteration, the RTE product must be sent directly to the satellite restaurant by satellite restaurant or RCK employees.

Distribution to

franchise restaurants is acceptable if the franchises are owned or operated by the same person, firm or corporation that owns or operates the RCK. 5. If refrigerated prior to delivery, good manufacturing practices should be used that ensure the RTE meals are kept at 40\u00b0F or below. 6. RCKs operated by a city, county, or State also qualify for the exemption, provided meals are served at facilities controlled by the city, county, or State. 14", "11 ) \u009d 11 i ~ 11 ) \u009d 11 i ! \u009d 11 .... , ! ~ .... \u009d 11 , ! ~ How do I determine if I am eligible for one of these exemptions? In order to determine whether your livestock slaughter or meat processing operation qualifies for an exemption from the Federal Meat Inspection Act, ask yourself the question in the bold type and then follow the appropriate Yes or No response arrow. Do you slaughter and process livestock for human food? Yes No Inspection requirements of FMIA not applicable Is the livestock you slaughter and process for your personal use? Personal Use Exemption 9 CFR 303.1(a)(1) No Yes Livestock slaughter exemptions Are the products from the livestock you slaughter returned to the owner of the livestock for his \ her personal use? Yes Custom slaughter exemption 9 CFR 303.1(a)(2) Custom Processing Exemption No Inspection is required by the Federal Meat Inspection Act. Contact your District Office to apply for a grant of inspection. Do you custom process carcasses or cuts or meat food products delivered by the owner of the livestock and return those processed products to the owner for his \ her personal use? Custom Processing exemption 9 CFR 303.1(a)(2) Yes Inspection is required by the Federal Meat Inspection Act. Contact your District Office to apply for a grant of inspection No 15", "order to determine whether your retail, restaurant, central kitchen or catering operation qualifies for an exemption from the Federal Meat Inspection Act, ask yourself the question in the bold type and then follow the appropriate response arrow. Do you purchase and prepare inspected livestock carcasses and\ or inspected meat or meat products and sell products to consumers at your retail store(s) or outlet(s)? --~);Ji> Yes Do you purchase meat or meat products1 and prepare the products as ready to eat entrees for meals sold directly to consumers? 1----~\u2022 Yes Do you purchase meat or meat products\\ prepare these products, and then sell them in meals as a catering business? Do you purchase meat or meat products1 and prepare them in a central kitchen for distribution as ready to eat meals or vending machines which you own\ operate? --->\u2022 Yes ) Yes Retail exemption: sales to household ---), consumers only 9 CFR 303.1(d)(2)(iii)(a) Restaurant exemption 9 CFR --) 303.1(d)(2)(iv) Catering Exemption 9CFR ---,) 303.1(d)(2)(iv)(b) ) Central kitchen Exemption 9 CFR 303 .1( d )(2 )( iv )( c ) Do you purchase meat products, further process these products and then wholesale these products? --->~ Yes ) Inspection is required by the Federal Meat Inspection Act. Contact your District Office to apply for a grant of inspection. 1 Must start with inspected and passed product or raw product prepared at a retail exempt store 16", "Considerations for Meat Sold in Local and Regional Markets Growing consumer demand for local food is creating new challenges and opportunities for producers. Farmers and ranchers selling into local and regional food systems have unique needs from navigating seeds, breeds, and production systems to adopting on-farm risk management and food safety activities. USDA supports and invests in local and regional food systems from coast to coast, in every state, as part of the department\u2019s commitment to revitalizing rural America. USDA strengthens local and regional food systems by coordinating relevant activities across its 17 agencies and by investing in projects that recruit and train farmers and ranchers, expand economic opportunities for small businesses, and increase access to healthy foods. Consumers across the country can find

locally produced food at their neighborhood grocery stores, restaurants, and farmers markets. Learn more about USDA's tools and programs to help farmers, ranchers, processors, and distributors produce food for local and regional markets at USDA Agricultural Marketing Service, Local and Regional Food Sector. The information below provides guidance for meat production in a variety of local market business models. Local Marketing and Direct-to-Consumer sales Consumers and businesses are increasingly interested in direct, regional, and local markets that minimize the distance that food products travel from production to consumption. Local and regional sales can be either direct-to-consumer (for example, through farmers markets or Community Supported Agriculture) or sold through so-called intermediated markets such as food hubs, which then market to consumers. Local and regional marketing can add value to a food product by maintaining farm identity in marketing, building relationships and loyalty between consumers and producers, targeting specialty or niche markets, and making production practices and ingredients more transparent. USDA does not officially define local or regional, so the exact meaning of the terms currently used in commerce may vary depending on the goals of the producer, buyer, or organization promoting local market connections. Local and Regional Marketing and Direct-to-Consumer Sales Notes: When selling locally-produced meat direct to consumers, keep in mind that only livestock slaughtered and processed under Federal inspection can be sold across state lines (interstate). Meat from livestock slaughtered and processed under State inspection is limited to commerce within the state (intrastate). If slaughtered and processed under Federal or State inspection, local meat can be sold direct to household consumers through farmers markets and to other-than-household consumers, within limitations described above in Retail Store Criteria, page 8. If local meat products are slaughtered under Federal or State inspection and are then further prepared (i.e. operations of types traditionally and usually conducted at retail stores: see 9 CFR 303.1(d)(2)), by a local seller, the local seller must be inspected unless it is eligible for the retail store exemption (see page 8). Retail stores that are exempt from Federal inspection, however, are subject to State and local (city, county) inspection laws. For all local and regional food markets, FSIS recommends: Farmers and businesses follow voluntary food safety practices to ensure a standard of care for their products and to reassure buyers regarding the steps taken to reduce risks of foodborne illness. Farmers and businesses reduce the risk of dangerous bacteria or toxins in farm products by following established food safety guidance, including the following: o develop a food safety plan, o train employees in proper food safety management, and o document all farm practices. Emerging Local and Regional Food Business Models What are some of the emerging business models? Business models, including those described below, are emerging as a result of the growing demand for locally and regionally produced food. Farmers Markets A farmers market is an open retail market that features fruits, vegetables, meats, eggs, and other commodities sold directly from producer to consumers. Typically, each producer brings their own booth, tables, or stands, and consumers purchases products directly from the farmers. This facilitates personal connections and creates mutual benefits for local producers, consumers, and communities. USDA's Agricultural Marketing Service (AMS) defines a farmers market as markets that feature two or more farm vendors selling agricultural products directly to customers at a common, recurrent physical location. Farmers Markets Notes: 1. Livestock meat food products, like beef jerky, must have been prepared from federally or state inspected

source material. If the meat food product sold at the farmers market is moved in interstate commerce, then the source material used to prepare the meat food product must be federally inspected. 2. FSIS OIEA Compliance Investigators may do reviews of booths selling meat food products, in accordance with FSIS Directive 8010.1. 3. Typically, the booths are appropriately permitted by the local (county, city) authorities and regulated by the local food establishment requirements. 4. Onsite preparation of meat food products at farmers markets may be regulated by State and local laws, or the farmers market's own food safety rules. 5. A farmers market booth can be an additional retail outlet of a retail store, where product is sold to individual household consumers in normal retail quantities. 6. Perishable meat should be properly refrigerated at the market and be kept in closed coolers with adequate amounts of ice to maintain cool temperatures. See FSIS Refrigeration and Food Safety guidance for more information. 18", "7. Raw meat should be handled appropriately so that the juices, which may contain harmful bacteria, do not come in contact with other foods or food contact surfaces. 8. RTE meat products should not be handled with bare hands, or by ill food handlers. 9. Packaged meat food products must not be misbranded. Be sure the label contains: a. The common name of the meat food product. b. A list of ingredients if there are more than two ingredients, in descending order of predominance. c. Net quantity specifications (weight, volume). d. Name and address of the business that prepared the meat food product. e. No marks of USDA inspection, or state inspection, unless the meat food product was actually prepared under inspection and is still intact as prepared and packaged by the federally or state inspected establishment. h. Safe-handling instructions if the product is raw. i. A handling statement such as \u201cKeep Refrigerated\u201d or \u201cKeep Frozen\u201d if product requires special handling to maintain its wholesomeness. f. nutrition labeling as specified in 9 CFR 317, Subpart B Nutrition Labeling, unless an exemption in 9 CFR 317.400 applies. 10. Check with your State and local (county, city) authorities about using a private kitchen in a person's living quarters for preparing meat food products sold at farmers markets. Food Hubs A food hub is a business or organization that actively manages the aggregation, distribution, and marketing of source-identified food products primarily from local and regional producers to strengthen their ability to satisfy wholesale, retail, and institutional demand. They provide a bridge from food producer to consumer by creating a business that actively works to distribute and market locally and regionally sourced food products. By providing small producers with access to larger volume markets, food hubs can support producers while also helping buyers meet the growing consumer demand for local food. Food Hub Notes: 1. Food hubs can advertise, broker, and deliver retail exempt meat food products for the exempt operator, but the exempt operator must maintain ownership of the product and make the sale to the consumer in order to be exempt from inspection. The records maintained by the retailer must fully and correctly disclose the sale of the meat food product from the retailer to the consumer. 2. The food hub may market: o federally inspected product in intact packages from the federally inspected establishment, which is eligible to move in interstate commerce, o State inspected product in intact packages from the state inspected establishment, which is eligible to move only in intrastate commerce, 19", "o Retail exempt product prepared under the retail store exemption, which is owned by the retailer. The retail exempt operator must own and sell the retail exempt product to the consumer. Bills of sale, which fully and correctly disclose the sale of the exempt product by the retail exempt operator to the consumer, must be maintained.

\uf0a7 Retail exempt product prepared from Federally inspected source materials product may move in interstate commerce. \uf0a7 Retail exempt product prepared from state inspected source material, in those States that operate their own meat and poultry inspection (MPI) programs, are restricted to intrastate commerce only.

3. The food hub must maintain records, per 9 CFR 320.1, such as invoices, bills of lading, and receiving and shipping papers for any meat food product that is shipped, received, transported or otherwise handled. All such records are subject to examination by USDA Investigators.

4. The food hub must register with the USDA as a meat food handler (transporting in commerce) with FSIS Form 5020-1, Registration of Meat and Poultry Handlers.

5. Generally speaking, food hubs do not prepare meat food products. If a food hub prepares (see: 9 CFR 301.2 definition for prepared) meat food products, then it must do so under inspection, or under one of the exemptions described above.

Farm to School Within local and regional markets, schools offer a compelling opportunity to connect young people to local food and agriculture. Farm to school initiatives include efforts to bring locally or regionally produced foods into school cafeterias; hands-on learning activities such as school gardening, farm visits, and culinary classes; and the integration of food-related education into the regular, standardsbased classroom curriculum. Locally sourced food (which creates economic opportunities for local food producers) can span the school meal tray and include everything from fresh fruit and vegetable servings to the wheat in the pizza crust, beans in the chili, rice in the stir fry, turkey in the sandwiches, and cheese in the quesadillas.

Farm to school includes all types of producers and food businesses, including farmers, ranchers, and fishermen, as well as food processors, manufacturers, and distributors.

Farm to School Notes: FSIS requirements:

1. All meat products that are to be served in a school lunch program must be, at a minimum, slaughtered in a federally or state inspected facility.
2. Meat and meat food products may be further prepared under the exemptions described above only if sold to consumers. Consumers are defined in 9 CFR 303.1(d)(2)(vi). Schools are an other-than-household consumer as an institution similar to a hotel.
3. Animals that are slaughtered or processed under a custom exemption, or under the personal use exemption, are not allowed to be used in school lunch programs. That meat is to be used exclusively by the owner of the animal in their household.

Additionally, FSIS recommends that farmers and schools involved in farm to school or school garden programs follow accepted food safety practices and have a food safety plan in place to reduce the risk of foodborne illnesses. More guidance for schools interested in procuring local meat, poultry, 20", "game, and eggs for child nutrition programs is available here: <http://www.fns.usda.gov/procuringlocal-meat-poultry-game-and-eggs-child-nutrition-programs>.

Online Markets Online markets are much like food hubs in that they bridge the gap from food producer to consumer, but instead of having a physical market, all transactions are performed through the Internet. This gives consumers the convenience of placing orders online with established producers who sell fresh, local goods. Often, an online market will feature products from many different producers. In some cases, the online marketplace does not take ownership of the product, but simply provides services such as: \u2022 advertising\marketing, \u2022 hosting the platform on which the products are marketed to consumers, \u2022 transporting or distributing the product, \u2022 collecting the money for the sale of the products to consumers. The FMIA does not prohibit a person, firm or corporation from performing these online marketing services for a retail exempt operator. The FSIS policy is, therefore, that an online market (or a food hub) is not precluded from acting as an agent of the

retailer. The online market and the retail exempt operator would be expected to provide documentary proof of their agency relationship. Both the retail exempt operator and the online market would be required to keep records and to fully and correctly disclose all transactions involved in their business, per 9 CFR 320.1, including bills of sale from the retail exempt operator to the consumer for the meat food product produced under exemption and sold to the consumer. Online Market Notes: 1. Retail exempt meat food products offered on an online market must be owned by the retailer, not by the online market. 2. In order to be exempt, the retail store must sell the product to the consumer. 3. The online market must register with the USDA as a meat food handler (broker or transporter) with FSIS Form 5020-1. Home Delivered Meals Home delivered meals programs deliver prepared meals or meal kits for in-home preparation to consumers. Many new companies are following this idea and creating businesses that design and deliver fresh, healthy meals to consumer's doorsteps. These companies may market their products as a way to lose weight or conveniently follow a healthier lifestyle by including fresh, locally sourced products in their meals. Home Delivered Meals Notes: 1. Since they sell either RTE or uncooked meals to consumers, they are a retail store. As such, see the retail store exemption criteria and notes above starting on page 8. 2. The Home Delivered Meals business is subject to the state and local (county, city) inspection laws. Check with those authorities for their applicable licensing requirements and applicable food establishment ordinances. 21", "How does FSIS verify that facilities exempt from inspection meet applicable requirements? States with \u201cequal to\u201d meat inspection programs, or FSIS\u2019s Office of Field Operations (OFO) District Office, or FSIS OIEA designated personnel typically review custom exempt operations. At retail stores, warehouses, and other in-commerce establishments, OIEA Compliance Investigators conduct onsite reviews to verify compliance with the FMIA and FSIS\u2019s regulations. The investigators, or any duly authorized representative of the Secretary, also have access to your place of business at all reasonable times and have the opportunity to examine your facility, inventory, and records. Although your business may not be subject to the daily inspection requirements by the FSIS, FSIS still has statutory authority, per FMIA 21 U.S.C. 672, to detain (to officially prevent the meat food product from leaving a place) your exempt product should it be found to be adulterated or misbranded. At facilities that house both an official establishment and a retail exempt establishment, the OFO inspectors will verify that sanitary conditions are maintained for the federally inspected establishment. The State and local government, or the FSIS OIEA Compliance Investigators, will verify the exempt operations meets sanitation and recordkeeping requirements. If your facility houses both an official establishment and an exempt establishment, be aware you will have to maintain separation between the official (inspected) and unofficial (exempt) establishments per 9 CFR 305.2(a), and, as always, maintain sanitary conditions for both operations. If OFO inspectors have concerns about the exempt facility, they will not inspect that operation, but they will turn over their concerns to the OIEA Compliance Investigators. What other government entity will have an active role in my exempt business While FSIS maintains jurisdiction over amenable meat food products that are \u201cin-commerce,\u201d the Department of Health and Human Service Food and Drug Administration (FDA) regulates all food service establishments and food processing establishments that are not under FSIS jurisdiction. FDA regulates food products not under FSIS inspection such as rabbit, buffalo, venison (if none of these are under FSIS voluntary

inspection), fish (except of the order Siluriformes), seafood, and food ingredients introduced into or offered for sale in interstate commerce. The FDA's regulations are in Title 21 of the CFR. The FDA also provides a uniform Food Code that many States and local authorities have adopted to safeguard public health and ensure that food is unadulterated and honestly presented when offered to consumers. To carry out certain provisions of the Bioterrorism Act, FDA established regulations requiring that food facilities register with FDA. Be aware of any impact the FDA's rules under the Food Safety and Modernization Act has on your exempt business or related business. Generally, the FDA does not inspect retail food service establishments. The retail food establishments are regulated by State and local (county, city) governments, although FDA retains jurisdiction over these retail operations. More than 3,000 State, local, and tribal agencies have primary responsibility to regulate the retail food and foodservice industries in the United States. They are responsible for the inspection and oversight of over 1 million food establishments (2013 restaurants 22," and grocery stores, as well as vending machines, cafeterias, and other outlets in health-care facilities, schools, and correctional facilities. Most custom exempt operations are under State or local regulation as well. You can use the Directory of State and Local Officials to obtain more information from State and local regulatory officials involved with food and food defense. The slaughter of other animals for food is regulated by the Food and Drug Administration (FDA). However, FSIS provides voluntary inspection on a fee-for-service basis for certain species, including bison, buffalo, deer, rabbits, migratory water fowl, and game birds (see 9 CFR 352, 354, and 362). Some States do consider these species to be inspected under State inspection. What is meant by "commerce" with regards to exempted meat food products? For the purpose of this regulation, the Agency defines "commerce" as product that is out of the producing establishment's direct control and is in distribution (e.g., in another Federal establishment, in a warehouse, distribution center, retail facility, restaurant, or other institution). Domestic product is considered in commerce if it has been shipped from a firm without Agency or firm controls or restrictions and is free to be moved to any consignee or to consumers. The term "of commerce" (9 CFR 302.1(a)(1), or "for commerce" (9 CFR 320.1(a)(1)) means an article of human food being offered for commercial gain. Custom exempt meat food products may be transported "from the location where the animal was slaughtered or processed to the owner of the animal from which the meat was derived. The custom exempt meat food products must not bear the mark of inspection, since they were not prepared under USDA inspection, and must be marked Not for Sale. Meat food products prepared under the retail store or restaurant exemptions from federally inspected meat sources may move in interstate commerce. Therefore, products sold to consumers in other states (including products shipped to consumers in other states) must be derived from USDA inspected source materials. Retail-exempt meat food products prepared from state inspected product can be sold solely within such State. 23," "r-----, '-----' Additional Guidance (2022 Sanitation Guidance for Beef Grinders (2022 Best Practices Guidance for Controlling Listeria monocytogenes (Lm) in Retail Delicatessens (2022 FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments (2022 Guidance for Determining Whether a Poultry Slaughter or Processing Operation is Exempt from Inspection Requirements of the Poultry Products Inspection Act (2022 Sanitation Performance Standards

Compliance Guide \u2022 USDA National Agricultural Library, Food Safety Information Center  
\u2022 MOBILE SLAUGHTER UNIT COMPLIANCE GUIDE \u2022 USDA\u2019s Farm to School Program \u2022 Local Meat in Schools Fact Sheet \u2022 USDA FNS Procuring Local Meat, Poultry, Game, and Eggs for Child Nutrition Programs \u2022 FDA Food Safety Modernization Act \u2022 Sanitary Transportation of Human and Animal Food \u2022 Requirements for the Disposition of Cattle that Become Non-Ambulatory Disabled Following Ante-Mortem Inspection \u2022 FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork and Products Containing Pork \u2022 AFDO Retail Meat and Poultry Processing Guidelines \u2022 Using Dentition to Age Cattle Attachment 1: A Summary Table of Exemptions and Limitations 24", "25 Attachment 2: Definitions Criteria Personal Use Exemption Custom Slaughter Exemption Custom Processing Exemption Retail Store Exemption Restaurant Exemption Restaurant Central Kitchen Exemption Catering Exemption Do I need to own the animal? Yes Yes, client must own the livestock Yes, client must own the livestock Not Applicable Not Applicable Not Applicable Not Applicable Required to start with Inspected and Passed product? No No No Yes Yes, or certain products prepared at a retail exempt store Yes, or certain products prepared at a retail exempt store Yes, or certain products prepared at a retail exempt store I can sell my product to\u2026? Not Applicable personal use only Not Applicable personal use only Not Applicable personal use only Directly to individual consumers at the restaurant Directly to individual consumers at the restaurants The individual consumers the product or meals are being delivered to Donate to nonprofit organization? No No No Yes Yes Yes Yes Slaughter Limit? Retort Processing (canning) allowed? Yes Not Applicable Yes No No No No Curing, Cooking, Smoking Allowed? Not Applicable Yes -Individual Household consumers; No -Other-thanhousehold Consumer (HRI) Yes, must be ready to eat when they leave the facility Sales allowed in normal retail quantities? Cannot be sold or donated Cannot be sold or donated Cannot be sold or donated Yes, sales to HRI cannot exceed 25% of total sales. Sales to HRI cannot exceed yearly dollar limitations Yes, cannot be made in excess of normal retail quantity Yes, cannot be made in excess of normal retail quantity Yes, cannot be made in excess of normal retail quantities Must have sales to consumers at the location the product is prepared? Not Applicable Not Applicable Not Applicable No, but sales must be made to consumers at satellite restaurants or vending machines owned or operated by the same entity that owns or operates the central kitchen To consumers only No limit No limit No limit Not Applicable Not Applicable Not Applicable Not Applicable Yes Yes Yes Yes Yes Yes Yes", "1 THE FOLLOWING REGULATORY AND COMMON STANDARD DICTIONARY DEFINITIONS WILL BE USEFUL IN UNDERSTANDING THE EXEMPTIONS. Regulatory definitions (found in 9 CFR 300-599): Exotic animal. Any reindeer, elk, deer, antelope, water buffalo, yak or bison Firm. Any partnership, association, or other unincorporated business organization. Further processing. Smoking, cooking, canning, curing, refining, or rendering in an official establishment of product previously prepared in official establishments. \u201cInspected and passed\u201d or \u201cU.S. Inspected and Passed\u201d or \u201cU.S. Inspected and Passed by Department of Agriculture\u201d (or any authorized abbreviation thereof). This term means that the product so identified has been inspected and passed under the regulations in this subchapter, and at the time it was inspected, passed, and identified, it was found to be not adulterated. Label. A display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article. Livestock. Cattle, sheep, swine, or goat. Meat. (1) The part of the

muscle of any cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing. As applied to products of equines, this term has a comparable meaning. (i) Meat does not include the muscle found in the lips, snout, or ears. (ii) Meat may not include significant portions of bone, including hard bone and related components, such as bone marrow, or any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG). Misbranded. This term applies to any carcass, part thereof, meat or meat food product under one or more of the following circumstances: (1) If its labeling is false or misleading in any particular; (2) If it is offered for sale under the name of another food; (3) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word \u201cimitation\u201d and immediately thereafter, the name of the food imitated; (4) If its container is so made, formed, or filled as to be misleading; (5) If in a package or other container unless it bears a label showing: (i) The name and place of business of the manufacturer, packer, or distributor; and (ii) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; except as otherwise provided in part 317 of this subchapter with respect to the quantity of contents; (6) If any word, statement, or other information required by or under authority of the Act to appear on the label or other labeling is not prominently placed thereon with such conspicuously (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; (7) If it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by the regulations in part 319 of this subchapter unless: (i) It conforms to such definition and standard, and (ii) Its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food; (8) If it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by the regulations in part 319 of this subchapter, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; (9) If it is not subject to the provisions of paragraph (v)(7)(ii) of this section unless its label bears: (i) The common or usual name of the food, if any there be, and (ii) In case it is fabricated from two or more ingredients, the common or usual name of each such ingredient, except as otherwise provided in part 317 of this subchapter; (10) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as is required by the regulations in part 317 of this subchapter. (11) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears a label stating that fact; except as otherwise provided by the regulations in part 317 of this subchapter; or (12) If it fails to bear, directly thereon or on its containers, when required by the regulations in part 316 or 317 of this subchapter, the inspection legend and, unrestricted by any of the foregoing, such other information as the Administrator may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain

the article in a wholesome condition. Official establishment. Any slaughtering, cutting, boning, meat canning, curing, smoking, salting, packing, rendering, or similar establishment at which inspection is maintained under the regulations in this subchapter. Official inspection legend. Any symbol prescribed by the regulations in this subchapter showing that an article was inspected and passed in accordance with the Act. Official mark. The official inspection legend or any other symbol prescribed by the regulations in this subchapter to identify the status of any article or animal under the Act. Person. Any individual, firm, or corporation. Prepared. Slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed. 27", "Ready-to-eat (RTE) product. A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear a safehandling instruction (as required for non-RTE products by 9 CFR 317.2(l) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products. Restaurant. A food establishment where product is prepared for sale or service as RTE meals to individual consumers at such establishments. Retort. A pressure vessel designed for thermal processing of product packed in hermetically sealed containers. Voluntary inspection service. An inspection and certification service for wholesomeness relating to the slaughter and processing of exotic animals and the processing of exotic animal products. Regulatory definitions (found in FDA Food Code 2017) CFR. Code of Federal Regulations Commminated. Reduced in size by methods including chopping, flaking, grinding, or mincing. Consumer. A person who is a member of the public, takes possession of FOOD, is not functioning in the capacity of an operator of a FOOD ESTABLISHMENT or FOOD PROCESSING PLANT, and does not offer the FOOD for resale. Employee. The PERMIT HOLDER, PERSON IN CHARGE, FOOD EMPLOYEE, PERSON having supervisory or management duties, PERSON on the payroll, family member, volunteer, PERSON performing work under contractual agreement, or other PERSON working in a FOOD ESTABLISHMENT. FDA. The U.S. Food and Drug Administration. Food employee. An individual working with unPACKAGED FOOD, FOOD EQUIPMENT or UTENSILS, or FOOD-CONTACT SURFACES. Food Establishment. (1) \"Food establishment\" means an operation that: (a)stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides FOOD for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides FOOD directly to a CONSUMER or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or FOOD bank; and (b)relinquishes possession of FOOD to a CONSUMER directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers. (2) \"Food establishment\" includes: (a) An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the REGULATORY AUTHORITY; and 28", "(b)An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the PREMISES; and regardless of whether there is a charge for the FOOD. (3) \"Food establishment\" does not include: (a) An establishment that offers only prePACKAGED FOODS that are not TIME\TEMPERATURE CONTROL FOR SAFETY FOODS; (b)A produce stand that only offers whole, uncut fresh fruits and vegetables; (c)A FOOD

PROCESSING PLANT; including those that are located on the PREMISES of a FOOD ESTABLISHMENT (d)A kitchen in a private home if only FOOD that is not TIME\TEMPERATURE CONTROL FOR SAFETY FOOD, is prepared for sale or service at a function such as a religious or charitable organization\u2019s bake sale if allowed by LAW and if the CONSUMER is informed by a clearly visible placard at the sales or service location that the FOOD is prepared in a kitchen that is not subject to regulation and inspection by the REGULATORY AUTHORITY; (e)An area where FOOD that is prepared as specified in Subparagraph (3)(d) of this definition is sold or offered for human consumption; (f) A kitchen in a private home, such as a small family day-care provider; or a bed-andbreakfast operation that prepares and offers FOOD to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and the CONSUMER is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the FOOD is prepared in a kitchen that is not regulated and inspected by the REGULATORY AUTHORITY; or (g)A private home that receives catered or home-delivered FOOD. Game Animal. (1)\\"Game animal\\" means an animal, the products of which are FOOD, that is not classified as livestock, sheep, swine, goat, horse, mule, or other equine in 9 CFR 301.2 Definitions, or as Poultry. (2)\\"Game animal\\" includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and nonaquatic reptiles such as land snakes. (3)\\"Game animal\\" does not include RATITES. HACCP plan. Means a written document that delineates the formal procedures for following the HAZARD Analysis and CRITICAL CONTROL POINT principles developed by The National Advisory Committee on Microbiological Criteria for Foods. Law. Means applicable local, state, and federal statutes, regulations, and ordinances. Permit. Means the document issued by the REGULATORY AUTHORITY that authorizes a PERSON to operate a FOOD ESTABLISHMENT. 29","Premises. Means: (1)The PHYSICAL FACILITY, its contents, and the contiguous land or property under the control of the PERMIT HOLDER; or (2)The PHYSICAL FACILITY, its contents, and the land or property not described in Subparagraph (1) of this definition if its facilities and contents are under the control of the PERMIT HOLDER and may impact FOOD ESTABLISHMENT personnel, facilities, or operations, and a FOOD ESTABLISHMENT is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison. Regulatory authority. Means the local, state, or federal enforcement body or authorized representative having jurisdiction over the FOOD ESTABLISHMENT. Vending machine. Means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses unit servings of FOOD in bulk or in packages without the necessity of replenishing the device between each vending operation. Terms with no regulatory definition (If neither 9 Code of Federal Regulations (CFR), nor 21 CFR, nor the Statute defines a term, then the usage found in any Standard American English dictionary applies.) Broker: a person who helps other people to reach agreements, to make deals, or to buy and sell property (such as stocks or houses) 1.1.1.1 Community Supported Agriculture (CSA): a system in which a farm operation is supported by shareholders within the community who share both the benefits and risks of food production. Courier: a person who transports a meat food product to the consumer Mail order: a meat food product that is sent by mail to the consumer who bought it Operate: control the functioning of (a machine, process, or system). 30","<http://askfsis.custhelp.com/> FSIS\USDA

www.fsis.usda.gov YEAR 31"]},{"file\_name":"FSIS\_GD\_2018\_0008","title":"Minimizing the Risk of Campylobacter and Salmonella Illnesses Associated with Chicken Liver","num":"FSIS-GD-2018-0008","id":"96d90f67eaa1c9d4dae667c97eafb32229a785fb928ce95499f4a6d29bc06fa7","corp\_us":"fsis\_guidelines","source\_page\_url":"https:\V\www.fsis.usda.gov\policy\fsis-guidelines","url":"https:\V\www.fsis.usda.gov\sites\default\files\import\Chicken-Liver-Guidance-July-2018.pdf","type":"pdf","n\_pages":9,"word\_count":3000,"text\_by\_page":["FSIS Guideline: Chicken Liver July 2018 Minimizing the Risk of Campylobacter and Salmonella Illnesses Associated with Chicken Liver What is the purpose of this guideline? FSIS is issuing this guideline to help FSIS-regulated establishments, retail food outlets, and foodservice entities mitigate the public health risks from chicken liver. Who is this guideline designed for? This document is designed for FSIS-regulated establishments, and retail food outlets, and foodservice entities, including hotels, restaurants, and institutions, that produce raw (not-ready-to-eat) chicken liver, or products made from chicken liver, for human consumption. It provides guidance to assist establishments in reducing the public health risk associated with chicken liver. Additionally, retail food outlets and foodservice entities may find this guidance useful when considering suppliers for chicken liver for use in p\u00e2t\u00e9 or similar dishes. These entities may also find it useful when considering preparation practices, as this guidance explains the need to fully cook chicken liver due to the potential for the external and internal presence of pathogens. The document discusses recommendations by FSIS, based on currently available scientific evidence and practical considerations. The recommendations are not requirements that must be met. Establishments may choose to adopt different procedures than those outlined in the guideline, but they would need to support why those procedures are effective. This guideline represents FSIS\u2019s current thinking on this topic, and FSIS encourages official establishments and others to use it. Why was this guidance developed? Several reports of outbreaks of Campylobacter and Salmonella illnesses associated with chicken liver consumption have been published (USDA-FSIS, 2011; CDC, 2013; CDC, 2015; CDC, 2017). According to a recent presentation summarizing a review of these outbreaks, 22 chicken liver\u2013associated campylobacteriosis and salmonellosis outbreaks were reported to public health authorities in the United States during 2000\u20132015, comprising 331 total reported illnesses (Lanier et al., 2017). Over half of these outbreaks occurred during 2014\u20132015 and represented 21\u201334% of chicken-related outbreaks (CDC, 2016; CDC, 2017). Commonly reported outbreak features included: 1) Consumption of a blended chicken liver dish (e.g., p\u00e2t\u00e9); 2) Inadequate cooking of the chicken liver dish; and/or 3) Consumption of the chicken liver dish outside the home (e.g., in a restaurant). Another factor that likely contributed to these outbreaks is the potential for pathogens to 1", "FSIS Guideline: Chicken Liver July 2018 be present both on the surface and internally. These findings led to the recommendations in this guideline to promote a reduction in pathogens in raw chicken liver products and to promote thorough cooking of these products. Can chicken liver be contaminated with pathogens? Yes, similar to other raw poultry products, chicken liver can be contaminated with pathogens such as Campylobacter and Salmonella. Surface contamination can result from insanitary dressing procedures, as well as from the processing environment. In addition to surface contamination, chicken liver can contain pathogens internally, even when chickens are dressed in a sanitary manner. Studies have demonstrated the presence of

Campylobacter in the internal tissue of between 10% and 90% of tested chicken livers after the external surface was sanitized (Boukraa et al., 1991; Barot et al., 1983; Baumgartner et al., 1995; Firleyanti et al., 2016; Whyte et al., 2006). Additionally, researchers have detected Campylobacter and Salmonella in the liver of chickens previously free of these pathogens after experimental oral inoculation (Chaloner et al., 2014; Knudsen et al., 2006; Sanyal et al., 1984; Borsoi et al., 2009; Gast et al., 2013; He et al., 2010). Pathogens are thought to spread from the intestine to the internal liver tissue via the biliary, lymphatic, or vascular systems, although the exact route is unclear. Why is the presence of pathogens in the internal tissue of chicken liver a problem? Some recipes for chicken liver dishes, such as p\u00e2t\u00e9, instruct the preparer to only partially cook the liver (e.g., by searing). Partial cooking may kill pathogens on the external surface, but will likely not kill all pathogens in the internal tissue. Any internal pathogens that survive in products made from inadequately cooked chicken liver could make consumers sick. Inadequate cooking was a contributing factor in many of the reported illness outbreaks associated with chicken liver. How should retail food outlets, foodservice entities, and consumers prepare chicken liver? The main message for food preparers at retail food outlets and foodservice entities and at home is that chicken liver dishes, like all poultry products, should be consumed only after being cooked throughout to a safe minimum internal temperature of 165 \u00b0F (73.9 \u00b0C) as measured with a food thermometer (Food Code, 3-401.11). For food safety reasons, this should be done regardless of preferences. In addition, with respect to storage, FSIS recommends using chicken liver within one to two days if stored in a refrigerator set at 40 \u00b0F or below, or within three to four months if 2 frozen at 0 \u00b0F or below. Further information on the safe handling of chicken liver and "FSIS Guideline: Chicken Liver July 2018 other giblets is available on Foodsafety.gov. What can establishments do to lower the risks to consumers associated with chicken liver? The Hazard Analysis and Critical Control Points (HACCP) system of each establishment that produces chicken liver for human consumption is required to adequately address food safety hazards reasonably likely to occur, including external and internal pathogens. As part of the HACCP requirements, establishments must identify the intended use for consumers of the finished product (9 CFR 417.2(a)(2)). When identifying the intended use, establishments should consider whether chicken liver will be sold to foodservice entities that prepare p\u00e2t\u00e9 or similar dishes and consider the potential hazards that could result from inadequate cooking at foodservice entities. Official establishments that sell chicken liver to foodservice entities should consider any contractual controls that can be put in place to ensure customers will prepare the liver in a manner whereby pathogens would not be a significant health risk. Establishments that do not know the intended use of the chicken liver should consider the possibility that the liver will be used to prepare p\u00e2t\u00e9 or similar dishes and the hazards that could result from inadequate cooking. As described below, freezing, washing with organic acids, proper labeling, and other interventions may help establishments address these hazards. Freezing Studies have demonstrated that freezing can reduce, but not eliminate, Campylobacter contamination of chicken liver. In a study involving homogenized chicken liver, Harrison et al. (2013) found that freezing caused significant reductions in Campylobacter counts. In liver placed in a freezer set at 5 \u00b0F (-15 \u00b0C), Campylobacter counts were reduced by approximately 0.8 log after 24 hours or by approximately 1.5 log after 7 days. Campylobacter counts more rapidly decreased in liver placed in a freezer set at -13 \u00b0F (-25 \u00b0C). An approximately 1.5-

log reduction in Campylobacter counts was achieved after 24 hours; there was no significant difference between this reduction and the 7-day reduction at the same temperature.

Additionally, these researchers observed an overall approximately 3-log reduction in Campylobacter counts after two periods of freezing at -13 °F (-25 °C) for 24 hours separated by a 24-hour thaw at 39.2 °F (4 °C). Baumgartner et al. (1995) found Campylobacter less often in chicken liver that had been frozen, then thawed, than in liver that had not been frozen (16% vs. 31%). These researchers also found that Campylobacter, when present, was generally present in lower numbers in previously frozen chicken liver than in fresh. Freezing the entire liver is likely to affect Campylobacter organisms existing on both the external liver surface and in the internal tissue. 3", "FSIS Guideline: Chicken Liver July 2018

Foodservice preparers and consumers may be concerned that freezing chicken liver negatively affects palatability. However, in a study of cooking practices and consumer preferences in the United Kingdom, Hutchinson et al. (2015) observed among consumers an overall sensory preference for chicken liver pâté made from liver that had been frozen. Organic Acid Washes Some antimicrobials have been validated to reduce Campylobacter on the surface of chicken liver. For example, Hutchinson et al. (2015) found that 2-minute washes at 69.8 °F (21 °C) with either 5% lactic or 5% ethanoic (acetic) acid reduced Campylobacter counts on the surface of naturally contaminated chicken liver by ~1.5 log. Any antimicrobial interventions applied by official establishments to chicken liver need to be considered safe and suitable by FSIS. A list of approved antimicrobials can be found in 9 CFR 424.21(c) and in FSIS Directive 7120.1, Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products. Although acid washes will likely not be effective in reducing internal pathogen contamination, they may reduce pathogens on the external surface of chicken liver.

**Labeling/Cooking Instructions** FSIS recommends that chicken liver be fully cooked because freezing and organic acid washes can reduce, but not eliminate, pathogens. For this reason, FSIS recommends that labels of all chicken liver include validated cooking instructions that are sufficient to destroy pathogens. FSIS recommends that cooking instructions indicate that the product should be cooked to a safe minimum internal temperature of 165 °F (73.9 °C), or other validated time/temperature combination, as measured with a food thermometer. This recommendation is consistent with the cooking recommendations in the (Food Code, 3-401.11). In addition, if the product appears ready-to-eat (RTE), but is not (e.g., because chicken liver is broiled, but not fully cooked to lethality, it appears RTE), the label needs to have features that are conspicuous so that the intended user is fully aware that product must be cooked for safety. This is best conveyed through language on the principal display panel of the label (e.g., "cook and serve," needs to be fully cooked," see cooking instructions, or "cook before eating"). In a 2011 outbreak of salmonellosis involving 190 reported illnesses associated with chicken liver products (Hanson et al., 2014), potentially misleading labeling (i.e., "broiled") and product appearance may have given the impression that the product was fully cooked when, in fact, it was not. FSIS requires raw meat and poultry products (including those that are partially cooked) to be labeled with safe handling instructions (9 CFR 317.2(k) and 9 CFR 381.125(b)). In addition, if it is not obvious the product is raw, based on appearance, FSIS recommends establishments include other cues on the label, such as those mentioned in the paragraph above, to increase consumer awareness that the product needs to be 4", "FSIS Guideline:

Chicken Liver July 2018 cooked. Other Interventions Additional interventions listed in the Draft FSIS Compliance Guide for Controlling Salmonella and Campylobacter in Raw Poultry, such as high-pressure processing (HPP), may also be effective in controlling pathogens in chicken liver. Generally, HPP has been found effective in reducing pathogen contamination in other chicken parts; however, FSIS is not aware of any published reports of its effectiveness specifically in chicken liver. Therefore, if an establishment uses HPP to support decisions in its hazard analysis related to pathogen reduction in chicken liver, it would need to gather its own scientific support to meet the validation requirements in 9 CFR 417.4(a)(1). Does this guideline apply to liver from other species? This document is specific to chicken liver. However, illness outbreaks associated with the liver of other poultry species, including goose and duck, have been reported; the recommendations contained in this document may also be effective for other species. Helpful Webpages \u2022 AskKaren Webpages o How do you cook giblets? o How are giblets inspected? \u2022 Giblets and Food Safety \u2022 Safe Minimum Internal Temperature Chart \u2022 FoodSafety.gov blog about cooking chicken liver dishes \u2022 Draft FSIS Compliance Guideline for Controlling Salmonella and Campylobacter in Raw Poultry What if I still have questions after I read this guideline? If the desired information cannot be found within the guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the AskFSIS database or submit questions through AskFSIS. Documenting these questions will help FSIS improve and refine present and future versions of this guideline and associated issuances. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided: 5", "FSIS Guideline: Chicken Liver July 2018 Subject Field: Chicken Liver\u2013Associated Outbreaks: Food Safety Guideline for Official Establishments, Retailers, and Foodservice Entities Question Field: Enter question with as much detail as possible. Product Field: Select General Inspection Policy from the drop-down menu. Category Field: Select Sampling from the drop-down menu. Policy Arena: Select Domestic (U.S.) Only from the drop-down menu. When all fields are complete, press Continue. How can I comment on this guideline? FSIS is seeking comments on this guideline as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days and the document will be updated in response to the comments submitted. Comments may be submitted by any of the following methods: Federal eRulemaking Portal Online submission at regulations.gov: This web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700. Hand or courier-delivered submittals: Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700. All items submitted by mail or electronic mail must include the Agency name (FSIS) and document title: Chicken Liver\u2013Associated Outbreaks: Food Safety Guideline for Official Establishments, Retailers, and Foodservice Entities. Comments received will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>. References Barot MS, Mosenthal AC, and Bokkenheuser VD.

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[https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodC7/FSIS\\_Guideline\\_Chicken\\_Liver\\_July\\_2018.pdf](https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodC7/FSIS_Guideline_Chicken_Liver_July_2018.pdf)

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the final rule \u201cElimination of Trichinæ Control Regulations and Consolidation of Thermally Processed, Commercially Sterile Regulations\u201d (83 FR 25302). The final rule became effective July 30, 2018. Raw and undercooked pork products may present a public health risk when consumed. Of concern, are those pork products: \u2022 Prepared in such a manner that the product might be eaten rare or without thorough cooking because the appearance of the finished product makes it hard for the consumer to visually determine if the product has been fully cooked. Such pork products include ground meat mixtures including those containing pork and beef as well as pork and other ingredients; poultry products containing pork muscle tissue; bacon wrapped products; breaded pork; raw marinated pork in dark sauces; pork products containing ingredients such as annatto, red wine, paprika, red pepper, etc. that can alter the appearance; cured pork; and cured and smoked pork. ; and \u2022 Prepared from feral swine that have an increased risk of infection with *Trichinella*. . When the pork products described above are not cooked at a sufficient internal temperature, any *Trichinella* present may not be destroyed and these products are therefore not rendered safe under normal consumer preparation practices. .This is not the case for all raw fresh pork products, specifically those that are customarily wellcooked in the home or elsewhere before being served to the consumer. Such products include fresh pork from market swine, including fresh unsmoked sausage containing", "pork muscle tissue, and bacon and jowls that were previously listed in 9 CFR 318.10(a). These products are usually prepared at an internal cooking time and temperature combination sufficient to destroy *Trichinella* throughout the product (e.g., 145\u00b0 F for 3 minutes), which renders the product safe under normal consumer preparation practices. If determined to be NRTLTO, an establishment may support this decision in the aforementioned raw fresh pork products by justifying that they are customarily wellcooked as described in Chapter I., Section III., C. of FSIS Directive 7320.1, Prevention and Control of *Trichinella* in Pork Products.", "Subject: *Trichinella*\u201c/Fresh Raw Pork Products\u201d/Noncompliance Question: Should FSIS inspection program personnel (IPP) document a noncompliance record (NR) when an establishment has determined that *Trichinella* is NRTLTO in fresh raw pork products from market swine and has justified the decision because those products are customarily well-cooked and the product bears Safe Handling Instructions (SHIs)? No. Establishments may determine that *Trichinella* is NRTLTO in fresh raw pork products produced from market swine, only if they have support that the product(s) are customarily well-cooked in the home or elsewhere before being served to the consumer. Such products include fresh pork, including fresh unsmoked sausage containing pork muscle tissue, and bacon and jowls that were previously listed in 9 CFR 318.10(a). If *Trichinella* is determined to be NRTLTO in an establishment\u2019s hazard analysis, IPP are to review the decisions made and determine whether supporting documentation is on file to comply with 9 CFR 417.5 (a)(1), and whether that documentation supports the decisions made in the hazard analysis. Support may include consumer preparation practices, such as SHIs or special handling\u201c/descriptive cooking instructions to ensure their customers will prepare the product in a manner that is customarily well-cooked. If IPP have questions after reviewing FSIS Directive 7320.1, Prevention and Control of *Trichinella* in Pork Products, regarding the adequacy of the establishment\u2019s support, they are to seek guidance from their immediate supervisor or an Enforcement, Investigation, and Analysis Officer (EIAO) to determine whether there is a basis to question the adequacy of support for the hazard analysis."], {"file\_name": "FSIS\_GD\_2018\_0011", "title": "FSIS"}]

Establishment Eligibility Criteria for the Salmonella and Campylobacter Verification Sampling Program and FSIS Scheduling Algorithm for the Salmonella and Campylobacter Verification Sampling Programs for Raw Poultry","num":"FSIS-GD-2018-0011","id":"c03ccde8d433864ac640dda3ec43b0a157d25ba67f0082ab528098a13c308029","corpus":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/import/Salmonella\_Scheduling\_Algorithm\_Functions.pdf","type":"pdf","n\_pages":4,"word\_count":1254,"text\_by\_page":[{"1 FSIS Establishment Eligibility Criteria for the Salmonella and Campylobacter Verification Sampling Program1 and FSIS Scheduling Algorithm for the Salmonella and Campylobacter Verification Sampling Programs for Raw Poultry Introduction FSIS assesses establishment performance for various poultry products against performance standards published in the Federal Register. In particular, the Salmonella and Campylobacter standards are assessed for young chicken carcasses, comminuted chicken, chicken parts (specifically legs, breasts, and wings), young turkey carcasses, and comminuted turkey. FSIS assigns samples for various poultry products each month under the Salmonella and Campylobacter Verification Sampling Programs for Raw Poultry through the Public Health Inspection System (PHIS). This is known as routine sampling2. The establishments and products selected monthly for sampling are chosen according to an algorithm from a list of eligible establishments and their respective products. These are the criteria used to create a list of establishments and products that are eligible for inclusion in the Salmonella and Campylobacter Verification Sampling Program, and the methods used to assign establishments for sampling. Only the five product classes above have performance standard criteria and are assigned samples under routine sampling. For those establishments that do not pass the performance standard follow-up samples can be assigned as well. FSIS does test other poultry products such as mechanically-separated chicken, mechanically-separated turkey, and chicken parts other than legs, breasts and wings under exploratory projects. This document specifically describes how establishments are determined to be either eligible or ineligible for testing and how the algorithm for assigning routine and follow-up samples to establishments specifically for products under performance standards operates. Eligibility Criteria and the Sampling Frame The Salmonella and Campylobacter Verification Sampling Program currently schedules five (5) different poultry product classes for routine sampling: Young Chicken Carcasses, Young Turkey Carcasses, Ground or other Comminuted Chicken, Ground or other Comminuted Turkey, and Chicken Parts (specifically, legs, breasts, and wings). Eligibility requirements for the Poultry Carcasses differ from the Raw Comminuted Poultry Products and from the Raw Chicken Parts. The first step in the scheduling process is to assemble the sampling frame, which is the list of eligible establishments and their respective products. An establishment's HACCP size does not factor into its eligibility. I. Establishments Producing Eligible Product a. The first step is to create a list of all establishments that produce sufficient volumes of eligible products. Currently, the smallest-volume producers are excluded (as defined below) from the program, as are ineligible products such as mechanically-separated chicken or turkey and raw product intended to be made into a ready-to-eat (RTE) product. 1 This includes Salmonella and Campylobacter testing for Raw Young Chicken Carcasses, Raw Young Turkey Carcasses, Raw Ground or Other Comminuted Chicken, Raw Ground or Other Comminuted Turkey, and Raw Chicken Parts. 2 Defined in 81 FR 3940 and 81 FR 7285."}, {"2 b. Intact Raw Poultry Carcasses a. Using slaughter volume data recorded in

PHIS, the total heads of young chickens and young turkeys slaughtered at FSIS establishments over the last 12 months is collected. Based on data from a PHIS questionnaire, the proportion of birds slaughtered under a religious exemption is excluded from the total production in determining an establishment's eligibility. For example, if an establishment slaughters 30,000 young chickens over the course of a 12-month period, but the questionnaire indicates 50 percent are slaughtered under a religious exemption, then the production estimate used to determine eligibility is 15,000 birds. Such an establishment would not be eligible for sampling in the Verification Program. Establishments that meet the minimum production volume requirements are further evaluated in the next step. The current minimum production volume to be included is:

- 1. Young Chickens: minimum of 20,000 heads slaughtered per year
- 2. Young Turkeys: minimum of 20,000 heads slaughtered per year
- c. Raw Chicken Parts a. Establishments whose establishment profiles indicate they produce at least the minimum volume of chicken legs, breasts, or wings are eligible for Salmonella and Campylobacter Verification Sampling. The current minimum production volume to be included is 1,001 pounds per day.
- d. Raw Ground and Other Commminuted Poultry a. Establishments whose PHIS profiles indicate they produce at least the minimum volume of ground or other comminuted (but not mechanically separated) chicken or turkey are eligible for sampling in the Salmonella and Campylobacter Verification Program. The average daily raw ground or comminuted chicken or turkey production volume listed in the establishment profile is used to determine whether an establishment meets minimum production volume requirements:

  - 1. Raw Ground Chicken: minimum of 1,001 pounds produced per day.
  - 2. Raw Ground Turkey: minimum of 1,001 pounds produced per day.

- II. Active Establishments a. The second step is to eliminate establishments that are not currently listed as active in their profiles, with one exception. If an establishment is inactive, but produced product within the last 12 months, samples may be scheduled on occasion to ensure seasonal producers are scheduled for sampling. Otherwise, establishments that are shut down, withdrawn from inspection, or otherwise not producing product are removed from eligibility.
- III. Scheduling Algorithm a. Once the sampling frame has been assembled, the list of eligible establishments and their respective products is weighted by production volume and past rates of Salmonella-positive product across all establishments in that product's production volume category, where available. The total number of samples allotted to each project is then assigned across establishments, with replacement, using these weights. FSIS intends to schedule at least the minimum number of samples per year per product published in 81 FR 7285 for as many establishments as practicable.
- b. If an establishment produces multiple eligible types of products tested in separate FSIS sampling projects, these products are scheduled independently. Assignment of samples in multiple eligible product types and projects is expected in such establishments. However, a ceiling exists so that no establishment is assigned more than five (5) samples per sampling project.
- IV. Scheduling Follow-up Samples Establishments that do not meet the Salmonella performance standard in poultry carcasses are assigned samples in the corresponding follow-up sampling project(s). Raw chicken parts, raw ground or otherwise comminuted chicken, and raw ground or otherwise comminuted turkey follow-up sampling projects are expected to begin later in 2018. Follow-up samples are included in establishment category determinations. The details of this sampling are summarized below.
- a. When any establishment is identified as having failed to meet the Salmonella standard in either young chicken or young turkey carcasses, it is assigned 8 or 16 follow-up

samples from the associated product as described in FSIS Notice 01-18. These follow-up samples are in addition to routine samples. b. When an establishment moves out of Category 3, it will continue to be scheduled for routine samples under the sampling algorithm as described in section III. If it subsequently fails to meet the standard, follow-up samples will once again be scheduled.

V. Exploratory Sampling

a. FSIS published in 81 FR 7285 that the agency would begin testing establishments that:

- i. produced product under a religious exemption, or
- ii. did not produce the minimum amount of product listed in Section I of this document.

b. These establishments are currently excluded from performance standard testing. Sampling of these establishments was implemented in Fiscal Year 2017 under new exploratory sampling projects to begin gauging the levels of pathogens in these populations, as addressed in FSIS Notice 27-17.

c. FSIS currently samples certain poultry products that are not included under performance standards in exploratory sampling projects. These products include mechanically-separated chicken, mechanically-separated turkey, and chicken parts", "4 other than legs, breasts, and wings. The eligibility criteria and sampling algorithm are not described here for those projects."]}, {"file\_name": "FSIS\_GD\_2019\_0001", "title": "How to Request Duplicate Copies of Approved Labels", "num": "FSIS-GD-2019-0001", "id": "40fe2ff38ecdaef7590a78ff577bf17665a8532bc5422a18283e63afadb95d47", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Requesting\_Approved\_Label\_Copies.pdf", "type": "pdf", "n\_pages": 1, "word\_count": 289, "text\_by\_page": ["HOW TO REQUEST DUPLICATE COPIES OF APPROVED LABELS Revised April 10, 2019 In order to receive copies of your labels which have been approved by the Labeling and Program Delivery Staff (LPDS), please MAIL your request on COMPANY LETTERHEAD, an ORIGINAL, DATED, and SIGNED LETTER (no copies) with the following information: 1) The complete product name for each meat and\or poultry product needed, 2) The dates for which the labels were approved, 3) The establishment number(s), 4) The label approval number, and 5) The reason for the request If you are using an expeditor firm or other agent on your behalf and wish this information to be mailed or picked up by them, please indicate that information in the letter as well. You may send your request to: Via UPS, FedEx, Or Other Courier Service Via U.S. Postal Service USDA, FSIS, OPPD, LPDS USDA, FSIS, OPPD, LPDS Labeling Distribution Unit Labeling Distribution Unit Patriots Plaza III, 9-171A Stop Code 3786, Patriots Plaza III, 9-171A 355 E. Street, SW 1400 Independence Ave., SW Washington, DC 20024-3221 Washington, DC 20250-3700 Please allow at least 10 business days to complete your request. For an electronic copy (limited to 3 label approvals), please provide an email address in your letter. Please do not send multiple requests. If you are an INSPECTOR and wish to request copies, please contact our office immediately or contact us through askFSIS. If you need additional assistance or have question on the information that needs to be submitted as part of your request, please contact our office at 301-504-0878. Note: Copies of label approvals are kept on file for a period of 5 years in compliance with record keeping requirements. Any request before that time can not be granted."]}, {"file\_name": "FSIS\_GD\_2019\_0004", "title": "Labeling Guideline on Statements that Bioengineered or Genetically-Modified Ingredients or Animal Feed were not used in Meat, Poultry, or Egg Products", "num": "FSIS-GD-2019-0004", "id": "51210303c2406c2f1861e4a9c70648e7c003b7036ef8d6f7bba992bb12a049b2", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines"}]

guidelines","url":"[https://www.fsis.usda.gov/sites/default/files/media\\_file/2020-08/labeling-guideline-bioengineered.pdf](https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/labeling-guideline-bioengineered.pdf)","type":"pdf","n\_pages":6,"word\_count":1833,"text\_by\_page":["All Natural\*\* Raised without Added Antibiotics Fed a vegetarian diet with No GMO feed  
Ingredients\* Oi\$trib!Jted by A Good Win! F;trm~ 122f Unique Dr. Or1ando. VE 00122 Cliftifl'd  
Organic by ABC GrMn. Premium Fresh Young Chicken KEEP REFRIGERATED NET WT. 48 OZ(3 LB)  
-----=====;::::: J@~@~M r@~r~ m@J ,~@~ \*Certified by True 2 Earth.  
true2earth.netnon-ge ,~~t~@fi6 ~m@~ KEEP REFRIGERATED NET WT. 48 OZ (3 LB) Ingredients:  
Chicken, Cheddar cheese (pasteurized milk, cheese cultures, salt, enzymes and annatto color),  
water, red peppers, seasoning (sugar, salt, spices), Jalapeno peppers (jalapeno peppers, water,  
citric acid). Distributed by PROGRISITIVE MEATS Co. 1234 Unique Rd. Calambia, VE 00123 Food  
Safety and Inspection Service Labeling Guideline on Statements That Bioengineered or  
Genetically-Modified Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg  
Products December 2019 This guideline is designed to help establishments that want to make  
labeling claims about: \u2022 Whether Bioengineered or Genetically- Modified Ingredients  
were not used in Meat Poultry, or Egg Products. \u2022 Whether a product was produced from  
livestock or poultry that were not fed bioengineered or geneticallymodified feed. 1","I. Purpose  
This document provides guidance for companies that want to make label or labeling claims  
concerning the fact that bioengineered or genetically-modified (GM) ingredients were not used  
in a meat, poultry or egg product. This guidance also provides information on how companies  
can make label or labeling claims that a product was produced from livestock or poultry that  
were not fed bioengineered or GM feed. For purposes of this guidance document, these claims  
will be referred to as \u201cnegative claims.\u201d This version of the Guideline replaces the  
version that published in August 2016. FSIS solicited comments on the previous version. Many  
of the issues raised in the more substantive comments were about how the statutory definition  
of \u201cbioengineering\u201d in Pub. L. 114-216 should be interpreted and applied. FSIS  
believes these comments are beyond the scope of this guidance. However, the same issues  
were raised as responses to questions posted in 2017 by the Agricultural Marketing Service  
(AMS) as part of the development of the proposed National Bioengineered Food Disclosure  
Standard (NBFDS). On December 21, 2018, AMS addressed these and other issues in the NBFDS  
final rule (83 FR 65814). In response to other comments, FSIS has updated the guideline to  
clarify that it approves negative claims verified under a thirdparty certifying organization  
consistent with how it approves other special statements or claims and by adding information  
about the certification and labeling for certified-organic products. Although comments will no  
longer be accepted through www.regulations.gov on this guidance, FSIS will update this  
document as necessary if new information becomes available. II. Congressional Review Act  
Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and  
Regulatory Affairs has determined that this guideline is not a \u201cmajor rule,\u201d as  
defined by 5 U.S.C. 804(2). III. Background FSIS approves negative claims through its prior label  
approval process. Because FSIS does not have the ability to independently verify negative  
claims for ingredients or feed, FSIS has required establishments that make these claims to  
comply with standards established by a thirdparty certifying organization. FSIS also requires  
that the third-party\u2019s standards be publicly available on a website and that the label or  
labeling disclose the website address of the thirdparty organization.1 FSIS requires that the

establishment demonstrate that its claims of thirdparty certification are truthful and not misleading in accordance with 9 CFR 317.8 or 381.129. As a policy matter, FSIS has allowed the use of the terms \u201cgenetically modified organism\u201d or \u201cGMO\u201d on product labels or labeling only if the name of the third-party certifying organization contains these terms (e.g., \u201cNon-GMO Project\u201d). However, as mentioned above, recent 1 Products certified as \u201corganic\u201d would not need to disclose a website address on the label, except when the address is required under 7 CFR Part 205. 2", "----\_) legislation was enacted (Pub. L. 114-216) requiring the Secretary of Agriculture to develop and implement a mandatory NBFDS. This legislation also addresses negative claims, providing that: \u2022 \u201cThe definition of \u2018bioengineering\u2019 under Section 291 shall not affect any other definition, program, rule, or regulation of the Federal government\u201d (Pub. L. 114-216, Sec. 292. Applicability); \u2022 \u201cA food may not be considered to be \u2018not bioengineered\u2019, \u2018non-GMO\u2019, or any other similar claim describing the absence of bioengineering in the food solely because the food is not required to bear a disclosure that the food is bioengineered under this subtitle\u201d (Pub. L. 114-216, Section 294. Savings provisions); and \u2022 In the case of a food certified under the USDA organic regulations, the certification \u201chall be considered sufficient to make a claim regarding the absence of bioengineering in the food, such as \u2018not bioengineered\u2019, \u2018non-GMO\u2019\u201d or other similar claim in accordance with the USDA organic regulations (Pub L. 114-216, Sec. 2. Organically produced food). Accordingly, FSIS reconsidered its past position. In 2016, FSIS began allowing the use of the terms \u201cgenetically modified organism\u201d or \u201cGMO\u201d in negative claims as long as the label or labeling is otherwise truthful and not misleading. At this time, FSIS approves negative claims that contain the terms \u201cgenetically modified organism\u201d or \u201cGMO\u201d for meat, poultry and egg products that do not contain bioengineered ingredients and\or that are derived from livestock or poultry that do not consume bioengineered feed when substantiated with evidence of compliance with standards verified by a third-party certifying organization. FSIS does not define \u201cbioengineered.\u201d Instead, FSIS relies on third-party certifiers to verify that products meet their standards for the absence of bioengineered or nonGMO material. The certifier can utilize either the AMS\u2019s definition of \u201cbioengineering\u201d in Pub. L. 114-216 or the U.S. Food and Drug Administration\u2019s (FDA\u2019s) definition of \u201cmodern biotechnology.\u201d FSIS also will continue to allow the use of synonymous terms such as \u201cgenetically engineered\u201d or \u201cGE.\u201d In evaluating such claims, FSIS will verify their accuracy. Consistent with our longstanding practice for other special statements and claims, if an official Key Point establishment submits documentation demonstrating The following are documentation needed to that the third-party certifying organization\u2019s program substantiate a negative claim: for a particular negative claim is being followed, 1. A current copy of the third-party FSIS will allow the claim on their labels. certificate; and 2. A written description for the IV. EXAMPLES OF LABEL identification, control, and segregation of conforming and non-conforming CLAIMS animals or products, except when these activities are a condition of Examples of negative claims for the meat or poultry certification. component that was raised on feed containing nongenetically modified ingredients that FSIS would accept include, but are not limited to: \u201cPasture raised beef fed a vegetarian diet with no 3", "bioengineered ingredients,\u201d \u201cChicken raised on a

diet containing no genetically engineered ingredients,\u201d or \u201cDerived from beef fed no GMO feed.\u201d NOTE: See label example 1 With respect to acceptable claim terminology for multi-ingredient products, examples of negative claims FSIS would accept include, but are not limited to: \u201cContains No GMO ingredients,\u201d \u201cNo genetically modified ingredients,\u201d \u201cIngredients used are not bioengineered,\u201d or \u201cNo genetically engineered ingredients through the use of modern biotechnology.\u201d NOTE: See label example 2 Noting the aforementioned website exception for certified organic foods, negative claims will be approved only if the third-party certifying organization is identified on the label and the labeling discloses a website address where consumers can obtain additional information regarding the claim and the certification process. This information must be connected to the negative claim by an asterisk or other symbol and include an explanatory statement, e.g., \u201cProduced in accordance with [certifying entity]\u2019s standards\u201d or \u201cCertified by [certifying entity].\u201d A USDA-accredited organic certifier is one example of a third-party certification organization. For products that qualify for an \u201corganic\u201d claim under the USDA organic regulations, establishments are not required to provide FSIS with additional documentation for approval of negative claims. The USDA organic regulations (7 CFR Part 205) prohibit the use of geneticallymodified organisms in the production and handling of an organic product. Furthermore, certified-organic products must be derived from animals that did not consume feed or feed supplements that contain genetically-modified organisms. Therefore, a current Organic Certificate is sufficient documentation to support a negative claim. Any negative claims on products labeled as \u201corganic\u201d must be connected by an asterisk or other symbol to the explanatory statement: \u201cProduced in compliance with the USDA Organic Regulations.\u201d NOTE: See label example 3 LABEL APPROVAL SUBMISSION Negative claims are \u201cspecial statements and claims\u201d as defined in 9 CFR 412.1(e) and cannot be generically approved unless previously approved in the manner described in the section below. Therefore, establishments are required to submit labels with negative claims to FSIS for prior approval before using them on labels or labeling (9 CFR 412.1(c)(3)). GENERIC APPROVAL FOR CERTAIN LABELS For meat, poultry or egg products with negative claims that FSIS has previously approved, the establishment is allowed to change the terms \u201cnon-genetically engineered\u201d or \u201cnon-GE\u201d to \u201cnonGMO\u201d or \u201cno genetically modified organisms\u201d without prior-approval from FSIS. Such changes 4", "Natural\*\* Raised without Added Antibiotics \"\"Minimally Processed, No Artificial Ingredients ~Coal,~. a~~-::---~ Distributed by A Good Win! Farmstl 1224 Unique Or. Oriando, VE 00122 Cartified Organic by ABC GrNn. KEEP REFRIGERATED NET WT. 48 OZ (3 LB) Fed a vegetarian diet with No GMO feed ingredients\* green abc reen.or \"Produced in accordance with ABC Green COOP st3ndards for avoidance of genetically engineered ingredients. are generically approved under 9 CFR 412.2. If FSIS has approved an organic claim on the product label, establishments may add an applicable negative claim of the kind discussed in this guidance, provided the explanatory statement described above (linked by an asterisk or other symbol) also appears on the label. Any other changes to the label or labeling must be submitted to FSIS for prior approval. FSIS IN-PLANT VERIFICATION FSIS inspection personnel will verify that the labeling record is complete during in-plant inspection. The official establishment will be given a non-compliance record during label verification activities under FSIS Directive 7221.1 if FSIS approval of the negative

claim is not properly documented in the establishment's labeling records. Label Example 1 \u2013 SINGLE INGREDIENT LABEL WITH \u201cRaised on a diet containing no genetically engineered ingredients\u201d [Back to reading] 5", "J@~@\u00a9 ~@~~r ,~~(e~@f\0 ~IW @~ \u2022certified by True 2 Earth. true2ea rth .net.In on-ge All Natural\*\* Raised without Added Antibiotics Distributed by A Good Win! Fanns\\CI 1224 Unique Dr. Orlando, VE 00122 C\u00abtitled Organic by ABC GrNrl. KEEP REFRIGERATED NET WT. 48 OZ (3 LB) KEEP REFRIGERATED NET WT. 48 OZ (3 LB) Ingredients: Chicken, Cheddar cheese (pasteurized milk, cheese cultures, salt, enzymes and annatto color), water, red peppers, seasoning (sugar, salt, spices), Jalapeno peppers Uak!peno peppers, water, citric acid). Distributed by PROGRESSIVE MEATS Co. 1234 Unique Rd. Calamb,i, VE 00123 Fed a vegetarian diet with No GMO feed ingredients\* -Produced in compliance with the USDA Organic Regulations. Label Example 2 \u2013 MULTI-INGREDIENT LABEL WITH \u201cNo GE Ingredients\u201d [Back to reading]

Label Example 3 \u2013 ORGANIC LABEL WITH \u201cFed a vegetarian diet with no GMO feed ingredients\u201d 6"]}, {"file\_name": "FSIS\_GD\_2019\_0005", "title": "Guideline: Modernization of Swine Slaughter Inspection - Developing Microbiological Sampling Programs in Swine Slaughter Establishments", "num": "FSIS-GD-2019-0005", "id": "d7c4a6dde226ea3ba049dfc0e186327fb0378dc0c3b969b82d049abac70ff258", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/modernization-swine-slaughter-microbiological-sampling.pdf", "type": "pdf", "n\_pages": 25, "word\_count": 7638, "text\_by\_page": ["FSIS Guideline: Modernization of Swine Slaughter Inspection Developing Microbiological Sampling Programs in Swine Slaughter Establishments September 2019 1111 1 This guideline is designed to help swine slaughter establishments (especially small and very small) meet the sampling requirements under the final rule to modernize swine slaughter inspection. This guideline is designed to assist all swine slaughter establishments, regardless of swine class to: \u2022 Develop a microbiological sampling plan; \u2022 Use microbial test results to assess their ability to maintain process control; and \u2022 Make process control decisions throughout the swine slaughter process.", "Table of Contents Purpose of this Guideline.....", "3 Changes from Previous Version ..... 3 Questions Regarding Topics in this Guideline ..... 4 Microbial Sampling Requirements Addressed by this Guideline..... 5 Process Control Procedures and Measurable Science-Based Parameters..... 5 Requirements for Written Procedures and Microbiological Sampling ..... 6 Microbial Sampling Plan for Carcasses ..... 7 Sampling Frequency..... 7 Table 1. Performance Criteria for Generic E. coli for Swine Carcasses Using Excisional Sampling..... 9 Table 2. Indicator Organism Optional Upper Control Limits for Market Hog Carcasses", "10 Table 3. Requirements for Microbial Sampling for Indicator Organisms in Swine Random Selection and Sampling of Carcasses..... 10 Slaughter Establishments..... 12 Pre-Sampling Preparation and Aseptic Technique ..... 12 Sample Analysis"]}

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19 Congressional Review Act.....  
20 Appendix 1:  
Microbiological Sampling Plan Self-Assessment Tool .....  
21 Appendix 2: Process Control Chart Examples.....  
23 2","This document follows the procedures for guidance documents in the Office of Management and Budget\u2019s (OMB) \u201cFinal Bulletin for Agency Good Guidance Practices.\u201d More information can be found on the Food Safety and Inspection Service (FSIS) webpage:  
<https://www.fsis.usda.gov/wps/portal/footer/policies-and-links/significantguidance-documents>. This is the revised version of the document titled FSIS Guidance: Modernization of Swine Inspection System -Microbiological Sampling in Swine Slaughter Establishments and reflects comments received during the comment period for the Modernization of Swine Slaughter Inspection Proposed Rule. This guideline represents FSIS\u2019s current thinking on this topic. FSIS encourages establishments to use it to comply with requirements that apply to all establishments that slaughter swine. The information in this guideline is provided to assist swine slaughter establishments (especially small and very small) and is not legally binding from a regulatory perspective. Purpose of this Guideline The purpose of this guideline is to assist all swine slaughter establishments, regardless of swine class, to comply with new microbiological sampling and analysis requirements that apply to all official swine slaughter establishments as published in the final rule \u201cModernization of Swine Slaughter Inspection.\u201d Establishments may also find the information in this guideline helpful for developing their sampling plan programs prior to the implementation of the final rule. Note that this guideline includes a list of references as additional resources on technical concepts specific to the development of a microbiological sampling plan. An establishment can always seek guidance from State HACCP contacts, coordinators and University extension specialists on developing and maintaining written sanitary dressing procedures, developing a written microbiological sampling plan, developing sample collection procedures, and using statistical process control to evaluate process control. Changes from Previous Version FSIS made changes throughout the guideline to clarify information and recommendations. In addition, FSIS made the following specific changes to the guideline to reflect changes in the final rule and comments received during the comment period for the proposed rule: 3"," \u2022 Removed the word \u201ccompliance\u201d from the document title and throughout the document to clarify that this document does not constitute regulatory requirements. \u2022 Removed all references to pre-operational environmental sampling, consistent with changes to the final rule. \u2022 Moved example control charts to Appendix 2 and clarified the recommendations for using such control charts without defining the specific format for displaying the data. \u2022 Added Table 2 -Indicator Organism Optional Upper Control Limits for Market Hog Carcasses to replace the previous Table 4 -Indicator Organism Geometric Mean Values for Market Swine, providing better guidance for establishments that may want to use data from the 2011 FSIS Market Hog Baseline Survey to set their upper control limits. Questions Regarding Topics in this Guideline

FSIS recommends that users who have questions regarding the information covered in this guideline search the publicly posted Questions & Answers (Q&As) in the askFSIS database or submit questions through askFSIS. Documenting these questions helps FSIS improve and refine present and future versions of the guideline and associated issuances. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided: Subject Field: Enter Swine Modernization Sampling Guideline. Question Field: Enter question with as much detail as possible. Product Field: Select General Inspection Policy from the drop-down menu. Category Field: Select Sampling from the drop-down menu. Policy Area: Select Domestic (U.S.) Only from the drop-down menu. When all fields are complete, press Continue. 4", "FSIS Guideline: Modernization of Swine Slaughter Inspection Developing Microbiological Sampling Programs in Swine Slaughter Establishments Microbial Sampling Requirements Addressed by this Guideline Livestock, including swine, have been identified as reservoirs for pathogens. The intestinal tract, mouth, skin, and hooves of swine can contain pathogens. Pathogens can be transferred to the carcass during the slaughter process and to pork parts throughout processing. Slaughter establishments typically employ a variety of controls to prevent, eliminate, or reduce pathogens during slaughter and processing. In the food production environment, \u201ccontrol measures can be applied to prevent an unacceptable increase in a hazard, eliminate it, or reduce it to an acceptable level\u201d (Scientific Criteria to Ensure Safe Food. IOM, 2003). Under Hazard Analysis and Critical Control Points (HACCP) regulations, an establishment is required to have controls in place to properly monitor and maintain its food safety system. Controls includes process control procedures supported by science-based standards that prevent, eliminate, or reduce biological, chemical, and physical hazards. An establishment can determine if the food safety system demonstrates either effective process control or loss of process control by analyzing the measurable attributes that are tailored to its system. One means for establishments to verify whether they maintain process control is through microbiological testing for indicator organisms.

Microbiological sampling and testing identify the presence of enteric pathogens in the context of the establishment\u2019s production process and processing steps, thus providing a microbiological measure of process control in addition to observation of carcasses and parts to detect visible contamination. Through statistical process control, an establishment defines what, in this context, are its control limits (i.e., upper and lower control limits) for indicator microorganisms. Process Control Procedures and Measurable Science-Based Parameters An establishment should design its operating conditions to meet defined food safety outcomes. This includes process control procedures and measurable science-based standards that affect establishment operating conditions. An establishment\u2019s process control procedures may include: \u2022 Sanitary dressing procedures effectively implemented to prevent carcass contamination and to minimize cross-contamination; \u2022 Procedures for decontamination of carcasses that become contaminated; \u2022 Procedures to prevent the creation of insanitary conditions; 5", "\u2022 Antimicrobial intervention treatments; and \u2022 Implementation of other best practices (e.g., those described in FSIS guidance documents). An establishment\u2019s measurable science-based standards or parameters may include: \u2022 Sanitary dressing monitoring; \u2022 Zero tolerance for visible contamination checks; \u2022 Microbiological testing results, for indicator organisms (e.g., Aerobic Plate Counts (APC), Enterobacteriaceae (EB), generic E. coli, total coliforms) and pathogens (e.g., Salmonella); and

\u2022 Critical operational parameters for antimicrobial interventions (e.g., concentration, pH, temperature). These procedures and parameters should be incorporated into the establishment\u2019s HACCP plan, sanitation standard operating procedures (sanitation SOPs), or other prerequisite programs (collectively referred to as the establishment\u2019s HACCP system). Requirements for Written Procedures and Microbiological Sampling Under the final rule to modernize swine slaughter inspection, all swine slaughter establishments, regardless of swine class, are required to develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens, and visible fecal matter, ingesta, and milk throughout the entire slaughter process and dressing operation. FSIS recommends establishments consider potential contamination sources, such as incised lymph nodes, intestinal rupture, and stick wounds, when designing its sampling plan (Garrido 2014, Vieira-Pinto 2005, Bonardi 2013). To demonstrate the effectiveness of such procedures in their food safety systems, all swine slaughter establishments are required to sample and test for microbial organisms at prescribed locations and frequencies, and to analyze the results obtained to assess the establishment\u2019s ability to maintain process control. Swine slaughter establishments are required to incorporate their written procedures, including their microbiological sampling plans, into their HACCP system. The final rule modernizing swine slaughter requires all swine slaughter establishments to:

\u2022 Develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal material throughout the entire slaughter and dressing operation. To demonstrate effectiveness of such procedures using their HACCP system (i.e., HACCP plan, sanitation SOPs, or other prerequisite programs), establishments are required to sample for microbial organisms and analyze results at prescribed locations and frequencies to assess the establishment\u2019s ability to maintain process control.

6", "Predominant Species:

Establishments that slaughter more than one type of livestock must test the type of livestock slaughtered in the greatest number. \u2022 Incorporate their written procedures, including their microbiological sampling plans, into their HACCP system (i.e., HACCP plan, sanitation SOPs, or other prerequisite programs).

\u2022 Maintain records associated with these procedures.

**Microbial Sampling Plan for Carcasses**

The final rule removed the requirement that swine slaughter establishments sample and test carcasses for generic Escherichia coli (E. coli Biotype I) to monitor process control and removed the codified Salmonella pathogen reduction performance standards for hogs and replaced them with the new sampling and testing requirements. The new sampling and testing requirements allow an establishment to develop a sampling plan that is tailored to its process and, consequently, allows for more effective monitoring of process control than the current generic E. coli criteria. An establishment that slaughters swine should determine which microbial organism(s) will be most effective in assessing its process control when developing its sampling plan. Each establishment has a configuration and process unique to the facility, the food safety system in place, and the hazards deemed reasonably likely to occur. Appendix 1 highlights the key elements that an establishment should address as part of its written microbiological sampling plan and can be used by an establishment as a self-assessment tool. FSIS recommends that an establishment choose one or more indicator organism that will provide meaningful data in assessing process control. Potential indicator organisms include APC, EB, generic E. coli, and total coliforms. FSIS recommends an establishment use APC because it is less specific than generic E. coli and

provides more quantifiable data. Enumeration allows an establishment to plot these data on a process control chart and monitor trends in its data and process over time. The more quantifiable microbiological data available to an establishment, the better it can assess and subsequently control variations in its process (Williams 2015). In contrast, generic E. coli is a smaller group (subset) of the Enterobacteriaceae family of bacteria; analysis of samples for generic E. coli often results in numerous non-detectable results (\u201czero values\u201d) which makes it difficult for an establishment to detect changes in microbial load at different points in establishment\u2019s process, and to identify trends in its data to make process control decisions. Sampling Frequency Under the final rule, swine slaughter establishments, except for very low volume (VLV) establishments, will be required to collect pre-evisceration and post-chill carcass samples at a frequency of one sample each per every 1,000 head slaughtered. As described in the preamble of the rule, VLV establishments are those which annually 7", "slaughter no more than 20,000 swine, or a combination of swine and other livestock not exceeding 6,000 cattle and 20,000 total of all livestock. As is stated in the preamble to the final rule, establishments that slaughter more than one type of livestock must test the type of livestock slaughtered in the greatest number. Establishments must analyze one carcass sample at pre-evisceration and one carcass sample at post-chill per sampling event; these samples do not need to be from the same carcass. Samples must be collected and analyzed at a frequency of once per 1,000 carcasses, with a minimum of one sampling event during each week of operation. VLV swine slaughter establishments, starting June 1 of every year, are required to take a minimum of one post-chill carcass sample per sampling event during each week of operation. If, after consecutively collecting and testing 13 weekly carcass samples, VLV establishments can demonstrate that they are not exceeding their upper control limit for microbial organisms and that they are effectively maintaining process control, they can modify their sampling plans to collect carcass samples less frequently. VLV establishments that slaughter swine and are operating under traditional inspection may choose to continue conducting generic E. coli testing at post-chill to meet the sampling requirements in the final rule. FSIS considers the requirements under the former regulations for generic E. coli testing of swine to be a \u201csafe harbor\u201d for assessing process control. Former provisions that FSIS considers to be integral to that safe harbor include the following: A. Testing for generic E. coli, FSIS requires an establishment to collect a series of 13 samples, at a minimum, to be able to assess process control. B. To collect the sample, the establishment must collect an excision or swab sample of the ham, belly, and jowl from the carcass at the end of the chilling process. FSIS Guideline: Guidelines for Escherichia coli Testing for Process Control Verification in Cattle and Swine Slaughter Establishments provides more detailed guidance on the sampling procedures. C. Laboratories analyzing the samples should use a quantitative method for generic E. coli analysis that is approved and published: 1) as an official method of the Association of Official Analytical Chemists International (AOAC International) or 2) by a scientific body based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three-tube Most Probable Number Definitions Pre-evisceration refers to the location early in the slaughter process prior to evisceration of the hog. Post-chill refers to a later point in the slaughter process after carcasses are chilled and all interventions have been applied prior to fabrication. 8", "(MPN) method; this type of method must also agree with the 95 percent upper and lower confidence

limits of the appropriate MPN index (9 CFR 310.25(a)(3). Performance criteria are those that represent the highest expected microbial loads on carcasses when the slaughter process is under control. The generic E. coli baseline results, using the surface swab sampling technique, can serve as support to establishments that slaughter swine in assessing the effectiveness of their process, using their own test results (70 FR 8058). An establishment may also choose to use the generic E. coli performance criteria defined in the Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule, also see Table 1 below, for samples collected using an excisional collection method. These generic E. coli performance criteria have been separated into three categories for process control verification: acceptable, marginal, and unacceptable. In the Pathogen Reduction\HACCP Regulation, \u201cm and M\u201d represent the 80th and 98th percentile of sample results, respectively, leaving 18 percent of the results in the marginal range based on the upper limits for the acceptable and marginal ranges. An establishment is considered to be operating within the criteria when the most recent generic E. coli test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

Table 1. Performance Criteria for Generic E. coli for Swine Carcasses Using Excisional Sampling	Lower limit of marginal range (m)	Upper limit of marginal range (M)
Number of Samples tested (n)	Maximum number permitted in the marginal range	10 CFU/cm <sup>2</sup>
10,000 CFU/cm <sup>2</sup>	13	Because each swine slaughter establishment will determine which microbial organism(s) will be most effective in assessing its process control when developing its sampling plan, additional indicator organism upper control limits are provided in Table 2. The upper control limits in Table 2, were determined from surface swab samples based on the FSIS Market Hog Baseline Study (MHBS) and may be used for all swine species; but establishments are not required to use this table. There may be some variability among swine classes. The information in Table 2 represents the 80th percentile limit for additional indicator organisms. Percentiles represent the percent of establishments that are below the associated number in the distribution of average bacteria indicators per establishment.
9", "APCs Enterobacteriaceae	9", "APCs Enterobacteriaceae	110
Total Colliforms	E.coli	Organism Average PrePostPrePostPre-evisceration PostPrePost-
CFU/cm <sup>2</sup>	evisceration	chill evisceration chill chill evisceration chill 4200000 790 8,300 110
5,500	35	3,800 30 Distribution 80% 80% 80% 80% Percentile Table 2. Indicator Organism
Optional Upper Control Limits for Market Hog Carcasses d FSIS MHBS, 2010 \u2013 2011. An establishment should aim for test results below those limits listed for its selected indicator organism at pre-evisceration and post-chill locations. Indicator organism results below the upper control limit shown in Table 2 indicate that the process is in control. FSIS recommends that the establishment plot its data on a control chart to evaluate its test results over time, and to evaluate process control and variability in its food safety system. Additionally, FSIS recommends that establishments monitor the log reduction between pre-evisceration and post-chill as an additional measure to evaluate process control. Example: If an establishment has APC test results above 790 CFU/cm <sup>2</sup> at post-chill, its process is most likely out of control and the establishment should take corrective action to bring its process back under control. (Compliance Guideline for Controlling Salmonella in Market Hogs, page 29). An establishment should evaluate its sampling data at a defined frequency and adjust its upper control limits to lower thresholds to reflect improved process control trends. It is not advisable that an establishment raise its upper control limits in response to upward trends in its sampling data		

since its upper control limits were initially calculated based on its process being in control. Random Selection and Sampling of Carcasses At a minimum, all swine slaughter establishments are required to collect carcass samples at the frequency specified in Table 3. Samples should be collected randomly at the frequency determined by the establishment as part of its sampling plan. If more than one shift is operating at the establishment, the samples can be taken on any shift. Variations have been found from samples collected on different shifts; therefore, it is important that the establishment ensure that all shifts have an equal opportunity to be selected for sampling. An establishment should use a method for selecting a carcass for sampling that 10", "includes the use of random numbers to ensure that sampling is not biased. Examples of methods include random number tables, calculator or computergenerated random numbers, or drawing cards. The sampled carcass should be selected at random. If there are multiple lines, the establishment should randomly select the line for sample collection for that interval. Each line should have an equal chance of being selected at each sampling interval within the relevant time frame. Carcasses should be selected at the identified points in the process. Official swine slaughter establishments, except for VLV establishments, must collect and analyze samples for microbial organisms at the preevisceration (i.e., the location early in the process prior to evisceration of the hog) and post-chill points in the process (i.e., the point in the slaughter process after all slaughter interventions are completed and the carcass has been chilled in the cooler). VLV establishments must collect and analyze samples for microbial organisms only at the post-chill point in the process. Establishments that bone their products before chilling (i.e., hot-boned products) must collect a pre-evisceration sample and a sample after the final wash instead of at post-chill, because these products are not chilled before further processing. All swine establishments must sponge or excise tissue from the ham, belly, and jowl areas.

Following the application of an antimicrobial prior to the point of sample collection, a drip time of at least 60 seconds should be observed before sample collection to reduce antimicrobial carryover in the collected sample. Definitions Hot-bone refers to the process where carcasses (e.g., larger hogs and sows) are immediately deboned after slaughter prior to chilling.

11", "Table 3. Requirements for Microbial Sampling for Indicator Organisms in Swine Slaughter Establishments Establishment Size Based on Volume Microbial Sampling Requirement Very low volume (VLV) (Establishments that annually slaughter no more than 20,000 swine, or a combination of swine and other livestock not exceeding 6,000 cattle and 20,000 total of all livestock.) Starting June 1 of every year, establishments will collect a minimum of one post-chill sample during each week of operation. The sampling plan may be modified after 13 consecutive weekly samples demonstrate effective process control. All other establishments Establishments must analyze 1 sample collected at preevisceration and 1 sample collected at post-chill per sampling event. Samples must be collected at each location and analyzed at a frequency of one per every 1,000 carcasses, with a minimum of one sampling event preevisceration and post-chill during each week of operation. Note that the pre-evisceration and post-chill samples for each sampling event do not need to be taken from the same carcass. As described in Table 3, under the final rule swine slaughter establishments, except for VLV establishments, are required to collect pre-evisceration and post-chill samples at a frequency of one sample each per every 1,000 carcasses. VLV establishments will be required to collect at least one post-chill sample during each week of operation, beginning June 1 each year. If, after collecting 13 consecutive weekly samples, VLV establishments can demonstrate that they are effectively maintaining

process control, they can modify their sampling plans to collect samples less frequently. Pre-Sampling Preparation and Aseptic Technique Extraneous organisms from hands, clothing, sampling equipment, or the processing environment can contaminate samples and lead to erroneous analytical results. Aseptic sampling techniques should be followed to ensure accurate test results that are representative of the product and process. 12", "Before beginning sample collection, it is important to assemble sampling supplies, such as sterile gloves, sterile sampling solutions, and sterile sampling sponges. Sterile sampling solutions, such as buffered peptone water (BPW) broth, should be stored according to the manufacturer\u2019s instructions; however, at least 1 day before sample collection, FSIS recommends that establishments check the solution\u2019s expiration date and other indicators of sterility based on the manufacturer\u2019s instructions. An area should be designated as a staging site for preparing the sampling supplies. An easily sanitized surface, such as a stainless-steel table or wheeled cart, can be used. A small plastic tote may also be useful for transporting sampling supplies to sample collection sites. Sterile gloves should be used when handling sterile sampling equipment (e.g., a sampling sponge) during the sample collection process. Care should be taken to prevent contamination of the external surface of the gloves prior to and during the sample collection process. Sample Analysis The establishment should ensure that the microbiological testing it conducts meets its food safety needs. An establishment needs to determine whether sample analysis will be performed by an outside laboratory or in its own microbiological testing laboratory on-site (if available). Because of the costs and the logistics involved with maintaining an onsite microbiological testing laboratory, an establishment may choose to have its samples analyzed by an outside laboratory. FSIS has made available guidance to aid in the selection of a testing laboratory, Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory. This guidance document can assist an establishment when selecting a commercial or private laboratory to analyze its microbiological samples, the method used to analyze samples, and how the results are reported. The establishment should clearly communicate its needs to the testing laboratory and direct it to any necessary testing protocols or other guidance, including this document, that are available on the FSIS website. If an establishment selects a testing laboratory that does not apply appropriate testing methods or effective Quality Control\Quality Assurance (QC/QA) practices, it may not receive reliable or useful testing results to be able to support decisions made in its hazard analysis. The establishment is responsible for ensuring the appropriate analytical methods are used and should convey this information to the laboratory. FSIS has also made available a list of Foodborne Pathogen Test Kits Validated by Independent Organizations for the detection of relevant foodborne pathogens (i.e., *Salmonella*, *Campylobacter*, Shiga toxin-producing *E. coli*, including *E. coli* O157:H7, and *Listeria* spp., including *L. monocytogenes*). This list is updated periodically and is intended to be informational only. The list does not serve as an Agency endorsement or approval of any method or test kit. 13", "FSIS recommends that an on-site microbiological testing laboratory be segregated from manufacturing areas and that access to the laboratory space be limited to prevent cross-contamination and assure the reliability of the test results. If the establishment tests for pathogens on-site, FSIS recommends that it have the following additional safeguards in place to ensure food safety and biosecurity: \u2022 Follow requirements for Biosafety Level II laboratory operations as outlined in Biosafety in Microbiological and Biomedical Laboratories (BMBL); \u2022 Restrict access to the laboratory

to trained staff; and \u2022 Ensure the laboratory is operating under the supervision of a qualified microbiologist or equivalent. To obtain the most accurate results, samples should be analyzed as soon after collection as possible. If samples must be transported to an off-site laboratory, they should be shipped to the laboratory under refrigeration on the same day they are collected, via an overnight delivery or courier service. Multiple samples collected on the same day can be shipped together to the laboratory in the sample shipping container and should be analyzed individually and not composited into one sample. To ensure sample integrity and an accurate bacterial count, a sample should arrive at the laboratory and the analysis initiated within 48 hours of collection. If the shipment and the initiation of the laboratory analysis cannot be accomplished within 48 hours of the sample collection, the carcass or product selected for sampling should be held under refrigeration and not sampled until the shipping and initiation of the sample analysis can be accomplished within 48 hours of sample collection. The same principle applies for samples that are analyzed in-plant: if the sample cannot be processed for testing within 48 hours of collection, the carcass selected for sampling should be held under refrigeration and sample collection delayed until the sample can be processed for testing within 48 hours of collection. FSIS recommends including the sample date and the date the laboratory started processing the sample to be included in the establishment records. Sponge or excised tissue samples should not be held for an extended period prior to analysis. They should be analyzed in-plant within 48 hours or shipped on the day of collection for overnight delivery to the laboratory that will conduct the analysis shortly after the sample arrives. Sponge or excised tissue samples should be held at refrigerated temperatures, not frozen, and shipped cold to the laboratory in an insulated shipping container with frozen gel packs. Lastly, the identity and security of all microbiological samples should be maintained during shipping and analysis to ensure the integrity of the test results.

Recordkeeping Under the final rule, swine slaughter establishments are required to maintain daily records sufficient to document the implementation and monitoring of the procedures to prevent fecal and microbiological contamination of product throughout the slaughter process. Records may be maintained on computers if the establishment implements appropriate controls to ensure the integrity of the electronic data. Records must be maintained for at least 1 year and must be accessible to FSIS upon request. To meet requirements, establishments need to maintain records sufficient to document the implementation and monitoring of sample collections; the testing procedures, including support for the adequacy of the testing frequency; and the test results. Records should include information, such as the: \u2022 Time, date, and location of the sample collection; \u2022 Sample collector's name; \u2022 Name or description of the product or sample source; and \u2022 Lot information and producer. All entries should be dated and initialed by the sample collector immediately upon completion of the entry. If an outside laboratory is used for testing, then these records should also include sample shipment information, including sample identification information, shipment date and time, courier or other delivery service used, and shipment tracking information. The outside laboratory should maintain chain of custody and document the: \u2022 Date the sample was received; \u2022 Condition of the sample upon receipt, including sample temperature, if applicable; \u2022 Date the analysis was started and completed; and the \u2022 Test result. Test results should also be recorded and linked to the sample collection records by a sample number, form number, or some other unique identifier.

These records should be maintained in a way that ensures the integrity of the data. As noted above, these records can be maintained in an electronic format, provided there are measures in place to ensure the integrity of the information. These records should be readily accessible for review by the establishment and FSIS inspection program personnel upon request. Using Statistical Process Control to Interpret Test Results from Carcass Sampling Statistical process control provides a powerful mechanism for establishments to assess and interpret the data collected for ongoing HACCP verification. Statistical process control can provide an establishment with an early warning that its process may not be functioning as designed. This warning can allow an establishment to take corrective actions or make other process modifications to bring its process back into control. Statistical process control can also provide an establishment with reasonable assurance that its HACCP system is functioning as designed.

15", "Establishments should consider available guidance and develop a statistically valid approach for interpreting sample results (Saini et al. 2011 and De Vries 2010). In cases where an establishment does not have the resources or capacity to develop its own statistical control limits or analytical procedures, establishments can utilize the results from the FSIS MHBS, provided in Table 2. The specific indicator organism limits for generic E. coli, APC, Enterobacteriaceae, and total coliforms correspond to the 80th percentile limit. FSIS compared the presence and levels of specific microbiological targets to determine whether significant differences existed between samples taken at pre-evisceration and post-chill. Percentiles represent the percent of establishments that are below the associated number in the distribution of average bacteria indicators per establishment. These indicator organism limits can be used by establishments to verify their process control. Given that samples collected per establishment in the FSIS MHBS were limited and the variation within individual establishments was high, the control limits in Table 2 are approximations. Charting and Interpreting Test Results for Carcass Sampling Specific techniques of statistical process control include the use of a control chart, which plots data over time but also displays an upper control limit for specific measurements and often a centerline, above and below which one would expect approximately an equal number of sample results, since the centerline is based on past sampling history. A sample result above the upper control limit would indicate the likely presence of a special cause of variation that should be addressed. Results within control limits indicate simply that the process is in control. Control charts are used to: A. Analyze and understand variables that affect the process; B. Determine process capabilities; and C. Assess effects of the variables on the difference between target and actual performance. Test results should be plotted and evaluated in a series over time. The test result chart should be updated at a regular interval, ideally within the next business day following the reporting of test results by the testing laboratory. Every time a new test result is recorded, the oldest test in the series should be dropped from the moving window. For example, an establishment may choose to evaluate its test results in a moving window of 13 tests. The establishment would use this series of 13 tests to evaluate its process control over the period represented by the series of 13 tests. The control chart would be updated with each new test result reported, adding the new test result and removing the oldest test result on the chart. Refer to Appendix 2 below for hypothetical examples of process control charts. 16", "Microbiological testing provides a measure of the extent of control at the step being evaluated and all preceding steps. By performing microbiological analyses at several points within a process it is relatively easy to identify the

segment of the process where control has been lost. In addition, sanitary dressing verification and end-product testing (though not required) can provide an integrated measure of the performance of the entire process. Pre-evisceration and post-chill test results could be charted on the same graph with separate, corresponding upper control limits to better correlate the samples and calculate the log reduction between the two samples. Actions in Response to Loss of Process Control As part of its process control procedures, an establishment should define the actions it will take if the test results obtained exceed the limits it has set. The establishment should delineate what its actions will be, who will take each action, how the outcome of these actions will be documented, and how the actions will be verified. FSIS has made available the Compliance Guideline for Controlling Salmonella in Market Hogs. The guideline summarizes potential control points for Salmonella in the pre-and post-harvest production process. Establishments should use this guide to improve management practices, to ensure effective sanitary dressing procedures and to assist in investigating events of apparent loss of process control. When an establishment makes changes at the appropriate locations in its process, process control should improve and result in the production of raw pork products that are within acceptable parameters, including indicator organisms and Salmonella. If an establishment determines that the trends in its test results indicate a loss of process control, the establishment should act to investigate the root cause(s). As discussed in the previous section on process control, an establishment should consider how the different parts of its food safety system work together and how they affect the entire food safety system. To do this, establishments should evaluate its process control procedures, sanitary dressing practices, and sanitation procedures to determine whether the root cause(s) can be identified, and subsequently, take steps to correct the problem. This evaluation should include a review of an establishment's process monitoring records and its processes during normal operations. The establishment should consider any implementation problems it has encountered or changes in procedures or practices, such as sanitary dressing procedures, including but not limited to: Procedures for routine cleaning and sanitizing of equipment, including hand tools used to remove contamination or to make cuts into the carcass; The design, configuration, and calibration of equipment to ensure proper function within operational parameters to prevent contact between carcasses and parts, and prevent contamination of carcasses; Employee hygiene practices, such as ensuring employees frequently wash hands, equipment, utensils, and aprons that come in contact with carcasses, and that employees are properly trained when there are new or substitute employees on the line; and The implementation of antimicrobial or mechanical intervention treatments, such as carcass washes, sprays, or brushes, in accordance with the limits selected and supported by the establishment, including effective application to ensure coverage of the entire carcass. Following its investigation, the establishment should respond to its findings by deploying appropriate decontamination procedures and antimicrobial intervention treatments, as necessary, to address contamination that may have occurred on carcasses or parts. The establishment should also take steps to initiate any necessary equipment repair or recalibration and employee training, when identified as a root cause for loss of process control.

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[https://www.fsis.usda.gov/wps/wcm/connect/d5c7c1d6-09b5-4dcc-93aef3e67ff045bb/Baseline\\_Data\\_Market\\_Hogs\\_2010-2011.pdf?MOD=AJPERES](https://www.fsis.usda.gov/wps/wcm/connect/d5c7c1d6-09b5-4dcc-93aef3e67ff045bb/Baseline_Data_Market_Hogs_2010-2011.pdf?MOD=AJPERES). Garrido V., S\u00f1\u00f1chez S., San Rom\u00f1n B., Zabalza-Barangu\u00f1 A., D\u00f1edaz-Tendero Y., de Frutos C., Mainar-Jaime R.C., Grill\u00f3 M.J. 2014. Simultaneous infections by different Salmonella strains in mesenteric lymph nodes of finishing pigs. BMC Vet Res. 2014 Mar 7;10:59. doi: 10.1186/1746-6148-10-59. NACMPI. 2010. \u2013 National Advisory Committee on Meat and Poultry Inspection\u2013 September 29, USDA South Building Cafeteria, Washington, D.C. O\u2019Connor, A.M., Wang B., Denagamage T., McKean J. 2012. Process Mapping the Prevalence of Salmonella Contamination on Pork Carcass from Slaughter to Chilling: a Systematic Review Approach. Foodborne Pathogens and Disease. 9(5): 386-95. doi: 10.1089/fpd.2011.1040. Saini, P.K., Marks H.M., Dreyfuss M.S., Evans P., Cook Jr. L.V., and Dessai U., 2011. Indicator Organisms in Meat and Poultry Slaughter Operations: Their Potential Use in Process Control and the Role of Emerging Technologies. Journal of Food Protection. 74 (8): 1387-94. doi:10.4315/0362-028X.JFP-10-433. van Hoek A.H., de Jonge R., van Overbeek W.M., Bouw E., Pielaat A., Smid J.H., Malorny B., Junker E., L\u00f1\u00f1ez C., Pedersen K., Aarts H.J., Heres L. A quantitative approach towards a better understanding of the dynamics of Salmonella spp. in a pork slaughter-line. Int. J. Food Microbiol. 153 (2012), pp. 45\u201352. 19", "Vieira-Pinto M., Temudo P., Martins C. 2005. Occurrence of Salmonella in the ileum, ileocolic lymph nodes, tonsils, mandibular lymph nodes and carcasses of pigs slaughtered for consumption. J Vet Med B Infect Dis Vet Public Health. Dec;52(10):47681. Williams M.S., Ebel E.D., and Allender H.D. 2015. Industry-level changes in microbial contamination on market hog and broiler chicken carcasses between two locations in the slaughter process. Food Control. May 51:361-370. doi:10.1016/j.foodcont.2014.11.039 Congressional Review Act Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this guideline is not a \u201cmajor rule,\u201d as defined by 5 U.S.C. 804(2). 20", "Appendix 1: Microbiological Sampling Plan Self-Assessment Tool The self-assessment tool below is designed to assist establishments in designing a sampling plan and selecting a testing laboratory. A regulated establishment should ensure that microbiological testing meets its food safety needs. Establishments should clearly communicate their needs to the testing laboratory and direct them to any necessary testing protocols or other guidance.

1. Written Microbiological Sampling Plan a. Sample Collection \uf071 Procedure for random selection of carcasses for sampling \uf071 Location within process where samples are collected \uf071 Pre-evisceration \uf071 Bleed Out \uf071 Other \uf071 Post-chill \uf071 Frequency of sample collection \uf071 Aseptic technique for gloving and sample collection \uf071 Description of sample collection procedure \uf071 Designated, trained employee to collect the sample \uf071 Date and time collected b. Sample Handling and Shipping \uf071 Proper sample



- Chart 3: Loss of Process Control Due to Gradual Process Failure 1.8 1.6 - Maximum \u2022 acceptable 1.4 level\* \u2022 \u2022 \u2022 1.2 --\u2022 \u2022 \u2022 \u2022 ~ 1.0 --- ~ \u2022 \u2022 u \_9 0.8 \u2022 0.6 0.4 0.2 0.0 0 5 10 15 20 25 Sample Number --\u00b7-----  
-----\u00b7-\u00b7-----\u00b7-----\u00b7-----\u00b7-----, Chart 3

depicts a situation where a component of the process is losing its effectiveness over time. This loss of process control is apparent by the upward trend in the data points toward the maximum acceptable level. ---\u00b7---

-----\u00b7 24","1.8 1.6 Maximum acceptable 1.4 level\u2022 1.2 .. ~ 1.0 ~ .9 0.8 0.6 0.4

0.2 0.0 1.8 1.6 Maximum acceptable level \u2022 1.2 CI : 5 1.0 .. ~ g' 0.8 .. J 0.6 0.4 0.2 0.0

Chart 4: Loss of Process Control Due to Abrupt Failure \u2022 \u2022 \u2022 \u2022 \u2022 --

\u000b7-\u000b7-\u000b7-----\u000b7-\u000b7-\u000b7-\u000b7-\u000b7-\u000b7-\u000b7-\u000b7-

catastrophic loss of process control. This pattern of test results would be encountered in a

situation such as an abrupt failure : i of a key piece of equipment, such as an antimicrobial wa

cabinet. i ! ----- : Chart 5: Lo

of Process Control Due to Recurring Transitory Failure --- \u2022 \u2022 \u2022 \u2022 \u2022

---\u2022 \u2022 \u2022 \u2022 0 5 10 15 20 Sample Number 25 r\u00b7-\u00b7-\u00b7-

\u00b7-\u00b7-\u00b7, i Chart 5 depicts conditions where there is an intermittent but

recurring problem i i within the process. Note the distinct periodicity of the test results over

time. An example of a situation where this pattern may be observed is the dripping of

condensation onto product as it travels down a conveyor belt. : ! i

25"}]}]},"file name":"FSIS GD 2019 0006","title":"Guideline for Training Establishment Sorters

under the New Swine Slaughter Inspection System", "num": "FSIS-GD-2019-0006", "id": "1d2aa8fdc48dd9c437675580e4ee160db39cc133c6b04e3d2cad7beb33510402", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/training-establishment-sorters-",

nsis.pdf", "type": "pdf", "n\_pages": 55, "word\_count": 10512, "text\_by\_page": ["Guideline for Training Establishment Sorters under the New Swine Slaughter Inspection System Food Safety and Inspection Service U.S. Department of Agriculture September 2019 This guideline is designed to help establishments that choose to operate under the New Swine Slaughter Inspection System (NSIS) train their employees to sort and remove animals affected with diseases or other conditions that would render them unfit for slaughter before FSIS ante-mortem inspection and to identify and remove defects on carcasses and parts before FSIS post-mortem inspection. 1 USDA-FSIS", "Guideline for Training Establishment Sorters under the New Swine Slaughter Inspection System (NSIS) Table of Contents I.

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Congressional Review Act 3 55", "I. PURPOSE This guideline can be used to assist swine	
slaughter establishments train their employees (hereafter referred to as sorters) to conduct the	
live animal and carcass sorting and trimming activities that are required for establishments that	
voluntarily adopt the New Swine Slaughter Inspection System (NSIS). II. BACKGROUND The	
Food Safety and Inspection Service (FSIS) has established a new voluntary inspection system for	
establishments that slaughter market hogs called the NSIS. Under the NSIS, establishments	
assume additional responsibilities for the sorting and removal of abnormal or unhealthy	
animals before FSIS ante-mortem inspection and adulterated carcasses and parts before FSIS	
post-mortem inspection. The Agency believes that training sorters in establishments that adopt	
NSIS is important to ensure that they are able to properly perform their sorting procedures	
before FSIS inspection. The content of this guideline is based on the same training that FSIS	
provides to its own inspection program personnel (IPP). The Agency is posting this guideline on	
the FSIS Web site at: <a href="http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guidesindex">http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guidesindex</a> . This guideline explains how establishments can meet	
FSIS requirements regarding sorting activities under the NSIS and represents FSIS\u2019s	
current thinking on this topic. FSIS encourages establishments planning to operate under the	
NSIS to use this guideline when developing their own training for their sorters. A. Does NSIS	
change how inspection program personnel (IPP) perform ante-mortem inspection? No. FSIS IPP	
will continue to inspect 100% of all market hogs presented for ante-mortem inspection by the	
establishment after the establishment has conducted sorting activities. FSIS IPP will continue to	
verify humane handling of all market hogs on premises. The NSIS will not affect the regulations	
that prescribe animal disposition procedures. Per FSIS Directive 6100.1, the FSIS Public Health	
Veterinarian (PHV) continues to make one of the following dispositions for market hogs	
presented for inspection: 1. Passed for normal slaughter; 2. Passed for slaughter but tagged as a	
U.S. Suspect animal (9 CFR 309.18 (a)). In addition, swine slaughtered in a dehairing operation	

must also have a tattoo applied when identified as a U.S. Suspect animal (9 CFR 309.18 (b)); or 3. Condemned and tagged as a U.S. Condemned animal (9 CFR 309.18 (c)). B. Does NSIS change FSIS humane handling verification or requirements? 4", "No. FSIS IPP will continue to verify the humane handling of all animals on the premises, including market hogs on the establishment\u2019s premises that are not presented for inspection. NSIS provides the opportunity for IPP to perform more humane handling verification. For information on humane slaughter, please refer to the FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock available at:

<https://www.fsis.usda.gov/wps/wcm/connect/da6cb63d-5818-4999-84f1-72e6dabb9501/CompGuide-Systematic-Approach-Humane-Handling-Livestock.pdf?MOD=AJPERES>

C. Does NSIS change how FSIS performs post-mortem inspection? No, as with traditional inspection, FSIS continues to perform 100% carcass-by-carcass inspection on each head, viscera, and carcass. After establishment sorters on the line have identified any conditions for carcass or parts removal or trimming, FSIS inspects each head, viscera, and carcass to ensure that they are fit to bear the mark of inspection and that establishment\u2019s sorting decisions meet regulatory requirements. FSIS continues to have the authority to retain carcasses and stop the line under NSIS. FSIS also continues to conduct offline inspection activities such as verifying compliance with sanitation and Hazard Analysis and Critical Control Point (HACCP) regulations, as well as humane handling requirements.

It\u2019s important to note that NSIS does allow FSIS inspectors to conduct more off-line verification activities. D. Questions Regarding Topics in this Guideline FSIS recommends that users who have questions regarding the information covered in this guideline search the publicly posted Questions & Answers (Q&As) in the askFSIS database or submit questions through askFSIS. Documenting these questions helps FSIS improve and refine present and future versions of the guideline and associated issuances. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided: Subject Field: Enter NSIS Sorting Guideline. Question Field: Enter question with as much detail as possible.

Product Field: Select General Inspection Policy from the drop-down menu. Category Field: Select Slaughter from the drop-down menu. Policy Area: Select Domestic (U.S.) Only from the drop-down menu. When all fields are complete, press Continue. III. GUIDANCE FOR

ESTABLISHMENT EMPLOYEE SORTER TRAINING PROGRAMS A. Training Program Elements This guideline recommends training elements and inspection standards that the Agency has found effective in training FSIS inspectors to identify live animals, carcasses and parts affected with defects and condemnable conditions. Market hog establishments may use this information to train establishment employees who will conduct sorting activities under the NSIS. 5", "Proper training is important to establishment sorters\u2019 ability to make sorting decisions on animals, carcasses, and parts. Under the NSIS, FSIS inspectors will continue to inspect all carcasses and parts and take regulatory control actions, if necessary. If establishment sorters do not make correct sorting decisions, IPP will continue to retain carcasses and parts for veterinary disposition; stop the production line; identify and verify restoration of contaminated carcasses or parts; and issue non-compliance records (NRs). Under the NSIS, the PHV will continue to have the authority to direct the establishment to reduce its line speed to maintain process control and assure that the FSIS online carcass inspectors are able to conduct a carcass-by-carcass inspection. A single training method or program may not be applicable to all

establishments. Individual establishments should design training programs consistent with the operational conditions in their establishment. FSIS recommends that each establishment develop a standardized training program for its sorters to properly identify unfit live animals and unwholesome carcasses and parts to ensure that such live animals, carcasses, and parts are not used as human food. FSIS recommends that sorter training programs include the components and content listed below: Classroom training refers to lecture style presentations that provide essential information for sorters that will assist them to: \u2022 Recognize and name common parts of market hog carcasses and organs; \u2022 Recognize and name common conditions affecting market hog carcasses and viscera; \u2022 Differentiate among normal, localized, and generalized conditions affecting market hog carcasses and viscera; \u2022 Determine the appropriate actions to take to ensure removal and disposal of unwholesome and unfit carcasses, parts, or viscera to ensure they cannot be used as human food; and \u2022 Create records documenting establishment sorting. NOTE: An exam or self-assessment for establishment sorter trainees following classroom and hands-on (i.e. wet lab) training may be helpful to measure and quantify understanding and comprehension of training. Hands-on (i.e. Wet Lab) Training is an activity that provides trainees with practical application of what they learn during classroom training. Features could include: \u2022 Using real examples of carcasses and parts \u2013 both normal and abnormal; \u2022 Performing hands-on practice prior to beginning normal duties online to identify carcass and parts conditions; \u2022 Assuring carcass and parts sorting decisions are correct and \u2022 Recording sorting and removal actions. On-the-Job Training is practicing what has been learned in the classroom and through wet labs in an establishment to an environment that simulates an establishment including: \u2022 Performing sorting activities at production rates; \u2022 Identifying defects on carcass, parts, and viscera; \u2022 Receiving real time feedback from supervisors; and \u2022 Taking appropriate actions (e.g., trimming contamination and identifying defects for removal or disposal) as determined necessary. Follow-up Sessions (referred to as correlations) are conducted to reinforce previous learning. Features include: \u2022 Conducting such sessions at a set regular frequency, \u2022 Discussing regularly standardized procedures for identifying and properly disposing of carcasses and parts on a continuous basis at production rates; and \u2022 Describing reasons for making decisions during sorting activities and appropriate actions. Continuous Monitoring of individual employee performance to maintain skill level.

**IV. COMPONENTS OF AN EFFECTIVE ANTE-MORTEM SORTING PROGRAM**

**A. Pre-Sorting Prior to Arrival:**

1. Pre-sorting on the farm:
  - a. Establishment purchase specifications
  - b. Treatment records
  - c. Animal health
  - d. Biosecurity procedures
2. On farm certification programs:
  - a. Pork Quality Assurance Program (PQAP)
  - b. Common Swine Industry Audit
  - c. Truckers Quality Assurance Programs

Under the NSIS, FSIS encourages establishments to begin their sorting activities by collecting and utilizing previous slaughter data for each supplier, and producer information including, in part: farm records, feeding programs, herd certification programs, and farm biosecurity programs, to ensure only healthy market hogs are delivered to the establishment. Systematic use of rigorous on farm sorting procedures, purchase specifications, and herd certifications will further ensure that animals with chemical, physical and biological hazards, including chemical hazards from violative residues, are not delivered to the slaughter establishment. On farm programs may be used by the establishment to support, in the establishment\u2019s HACCP system, ante-mortem and post-mortem sorting

procedures.

B. Sorting on Premises: How to Implement an Effective Ante-Mortem Sorting Program

1. Be familiar with the behavior of normal healthy market hogs.
2. Observe market hogs in motion; specifically look for:
  - a. Alertness: Healthy market hogs are aware of their surroundings and actively investigate the environment and their pen mates when initially unloaded or placed in pens. During lairage, market hogs will be recumbent and resting for most of the time.
  - b. Locomotion: Healthy market hogs bear weight equally on all four legs and walk freely.
  - c. Body condition: Healthy market hogs are full fleshed, with fat and muscle completely covering the ribs, backbone and hips.
  - d. Body functions: Healthy market hogs pass clear to pale yellow urine and formed yellow to greenish to brown stools, depending upon their diet. Market hogs may vomit due to motion sickness, so occasional vomiting in an otherwise healthy market hog should not be cause for concern.
3. Observe market hogs at rest; specifically look for:
  - a. Alertness: Healthy market hogs retain awareness of what is going on around them when resting and often vocalize when disturbed.
  - b. Respiration: Healthy market hogs display regular, rhythmic breathing.
  - c. Skin color: Healthy market hogs will have a white to pink uniformly colored skin (if not pigmented).

C. Ante-Mortem Conditions Requiring Removal and Identification for Disposal

1. Dead.
2. Moribund: Animals in the act of dying. Look for inactivity, loss of awareness of surroundings, abnormal skin color (blotchy or blue discolorations), irregular (gasping) respirations, frothy mouth and / or nasal discharge, unable to rise and walk.
3. Central nervous system (CNS) diseases. Look for seizures, convulsions, abnormal gait (circling, dizziness, loss of balance), difficulty swallowing, abnormally excited or aggressive behavior, head pressing or head tilt.
4. Febrile. Market hogs with an elevated body temperature are febrile. Normal body temperature of a pig is around 101.5°F - 102.5°F. Pyrexia is a febrile state when their body temperature is 106.0 F or higher. Look for loss of activity and awareness, reddish or bluish skin discoloration in white hogs, increased respirations, difficulty breathing, reluctance to get up from a recumbent position, and / or lameness.

NOTE: Establishment sorters must notify FSIS if they observe animals exhibiting signs of CNS diseases because these are reportable diseases. Establishment sorters must also notify FSIS if they observe an abnormal change in the amount of dead, moribund, or febrile animals because these could be signs of a reportable or foreign animal disease.

D. Ante-Mortem Conditions Requiring Sorting of Swine with Other Conditions; Holding Market Hogs in the \u201cSubject\u201d Pen; Further Sorting by the Establishment Lead Sorter; and Final Inspection by the FSIS PHV:

1. Fatigued or non-ambulatory market hogs. Fatigued market hogs appear normal at first but tire and become recumbent. Some fatigued market hogs suffer from muscle cramps and will vocalize and shake until they lay down. If isolated and allowed to rest, recovered fatigued market hogs are eligible for slaughter pending final sorting and FSIS inspection. If any market hogs become non-ambulatory disabled after ante-mortem inspection, establishments are required to move them to the \u201cSubject\u201d pens for reinspection by FSIS PHVs.
2. Overheated market hogs. Market hogs do not control their body temperatures well during warm weather and may overheat during inclement weather. Look for rapid, panting respirations, reddish skin discoloration, and lack of activity. These animals may be held for recovery and passing for slaughter, pending further sorting and final PHV inspection.

8", "3. Market hogs of uncertain status at the time of initial sorting. If establishment sorters are unsure about the health status of a market hog or its eligibility for production into human food, they should place the pigs in a pen that will be subject to further sorting by the

establishment's lead sorter (i.e., the establishment's designated offline sorter), and final inspection by the FSIS PHV. Conditions that sorters may question include abnormal body swellings, lameness, skin discolorations, scabs, wounds, coughing, sneezing, and abnormal body discharges (bloody urine, diarrhea, vaginal discharges, vomiting). Examples of Ante-Mortem Conditions Arthritis Signs: 1. Enlargement of one or more joints; 2. Abnormal locomotion; 3. Variable temperature depending upon stage of disease and ambient temperature. Temperature may range from very high to subnormal; each case will have to be independently assessed by the PHV; 4. Painful or abnormal stance and movement; 5. Reluctance to move or stand; 6. Depression; 7. Poor wasting condition; and/or 8. Infected navel in young animals. Special Note: Transport injury (i.e., sore feet) this also can result from market hogs being raised on concrete and must be distinguished from arthritis (See 9 CFR 309.2, 309.4, and 309.9). 9", "Moribund-Dying Condition Market hogs showing darkening of the abdomen or cyanosis of the belly and ears (see picture to the left); very depressed -typical of market hogs in a moribund or dying condition: Signs include: Depression, Reluctance to move, Cold dark ears, legs, belly, Reduced or elevated body temperature, Inability to rise, Paddling, Unaware of surroundings, Moribund, and Dehydration. Acute Erysipelas Signs: Fever; Reluctant to move; nonambulatory; Swollen joints; Sudden death; and/or Diffuse areas of purple raised, red diamond skin. Sorters must identify animals with signs of fever and signs of acute erysipelas for disposal. Market hogs with less severe signs suggesting a localized condition can move to the subject pen for closer evaluation and sorting. Eligible market hogs may be presented to the PHV for antemortem inspection. 10", "Abscess Signs: Swellings may be evident in various parts of the animal; Typically, abscesses of any size may be seen near the jowl, ham, hock, shoulder. Abscess/Hernia/Prolapse/Injury Depression or lethargy; Variable temperature from very high to subnormal; External wounds including Scirrhous cord (funiculitis), Umbilical abscess, tail-bite lesions, or infected open wounds; Swollen joints; Subcutaneous abscesses; and/or Poor wasting condition. E. Summary: Outcomes of Sorting 1. Normal healthy market hogs presented for FSIS ante-mortem inspection. 2. Market hogs identified for removal are humanely euthanized (if necessary), denatured, and disposed of. 3. Plant rejects (healthy animals that may be underweight, overweight, or do not meet other establishment purchase specifications) that are moved to another inspected establishment for slaughter only. 4. Market hogs that are held for further sorting in the Subject pen by establishment lead sorter and final inspection by the PHV. F. Foreign Animal Diseases (FADs) FSIS has a cooperative agreement with the Animal and Plant Health Inspection Service (APHIS) for conducting FAD surveillance during FSIS inspections. FADs of concern include Foot-and-Mouth Disease (FMD) (see picture on page 42), Hog Cholera, and African Swine Fever. As part of the NSIS, establishments are required to report any animal showing a condition suggestive of a FAD or other reportable conditions to the FSIS PHV (9 CFR 309.19(e)). The FSIS PHV will inspect for and make the final determination about whether the condition should be reported to APHIS. Early detection of FADs can help prevent spread of such diseases. Conditions associated with FADs and other reportable conditions include: 1. Sudden, unexplained death loss in a large number of market hogs upon arrival or that were previously observed as healthy; 2. Sudden, unexplained fever in a large number of market hogs; 3. Sudden, unexplained severe lameness in a large number of market hogs; 4. Vesicles (i.e. intact, ruptured, healing blisters or sores) on the nose and in between the toes; 5. Large numbers of market hogs with diarrhea; 6. Signs of

central nervous system disease (e.g. circling, head pressing, head tilt, staggering, tremors); and\or 7. Maggot infestations. Additional information about FADs and other reportable conditions may be found on the APHIS website at :<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animaldisease-information> or by calling the APHIS Area Veterinarian In Charge:  
[https://www.aphis.usda.gov/vs/nahss/swine/csf/CSF\\_PM\\_2007\\_AppendC\\_Directory.pdf](https://www.aphis.usda.gov/vs/nahss/swine/csf/CSF_PM_2007_AppendC_Directory.pdf)

G. Establishment Recordkeeping of Disposed Carcasses Sorted Before Ante-Mortem or Slaughter Under the NSIS, establishments are required to keep: 1. Records documenting the number of animals that were sorted and removed for disposal before ante-mortem inspection or slaughter. Establishments do not need to include the number of healthy animals that were diverted to another official establishment for slaughter. Establishment records must include reasons the animals or carcasses were removed. This information must be provided to FSIS to fulfill FSIS reporting obligations. 2. Records documenting sorting activities and disposal procedures. These records will vary depending upon how the establishment conducts its sorting activities and disposes of animals and carcasses (HACCP, Sanitation Standard Operating Procedures (Sanitation SOPs), or other pre-requisite programs) within its HACCP system.

H. Denaturing Requirements The NSIS requires establishments to have written procedures documenting that all dead and discarded market hogs are identified (using a tag, tattoo or other unique identification) and disposed of according to 9 CFR part 314 (9 CFR 309.19). Establishments have the option to render on-site or denature carcasses before disposed carcasses are transported offsite. Establishments can also continue to use denaturing by injection to help identify carcasses rendered on site. If rendered offsite, discarded carcasses are to be denatured with: (1) crude carbolic acid, (2) cresylic disinfectant; (3) a formula consisting of one part FD&C No. 3 green coloring, 40 parts water, 40 parts liquid detergent, and 40 parts oil of citronella; or (4) any other proprietary material approved by the Administrator in specific cases, during hours of operation and before transport from the establishment. When such carcasses are dressed (e.g. skinned), the carcass is to be denatured; carcasses that are dressed are required to be freely slashed before the denaturing agent is applied, except that, in the case of dead animals that have not been dressed, the denaturant may be applied by injection. The denaturant must be deposited in all portions of the carcass to the extent necessary to preclude the carcass from being used for food purposes.

12", "V. COMPONENTS OF AN EFFECTIVE POST-MORTEM SORTING PROGRAM

A. Preparation and Proper Presentation of Carcasses and Parts

Before FSIS inspection, establishment employees can remove surface contamination (e.g., feces, ingesta, or milk) on market hog carcasses in a sanitary manner, unless the carcasses are retained by IPP for PHV inspection. Trimming of carcass defects or blemishes (e.g., hair and minor bruises) is allowed for any defects not affecting disposition of the carcass or part. To operate at maximum efficiency, FSIS recommends that establishment employees present heads, viscera, and carcasses in a consistent and uniform manner to allow sorters to methodically examine and sort heads, viscera, or carcasses prior to FSIS inspection.

NOTE: Sorting of hearts and kidneys requires the opening or removal of the pericardial membrane and kidney capsule. Kidneys may be presented with the viscera or in the carcass.

B. Normal Carcass and Parts Photos

Establishment personnel should be familiar with normal market hog carcasses and parts.

Normal Head 13", "Normal lungs, aorta, and lymph nodes. Healthy hearts; slashed and washed. Healthy liver, gall bladder, stomach; spleen and intestines. 14", "Healthy viscera.

Healthy mesenteric lymph node chain draining the intestines. 15", "Carcass tracking system. Carcass tracking system: Carcass Number; Time; and\or Tattoo. 16", "LARGE INTESTINE CECUM SMALL INTESTINE RECTUM OR BUNG 7. SWINE VISCERA GALL BLADDER STOMACH DIAPHRAGM WEASAND LIVER HEART TRACHEA LUNGS 17", ". SWINE CARCASS -INSIDE HOCK JOINT (HIND LEG) STIFLE JOINT AITCH BONE PELVIC CANAL ABDOMINAL CAVITY -LINED WITH PERITONEUM Hilc:--l-+~:+-1:-----KIDNEY -POPPED OUT OF CAPSULE (MEMBRANE AND FAT) DIAPHRAGM (PILLARS BY KIDNEY) THORACIC CAVITY (LINED WITH PLEURA) KNEE (FRONT LEG) STERNUM (BREASTBONE) ..L.....JOWL CUT SURFACE OF SPINAL COLUMN (BACKBONE) 6 18", "Normal Healthy Market Hog Carcass (Left) Pre-evisceration carcass with head attached. (Right) Post evisceration carcass after removal of head and splitting of the carcass and kidneys exposed. 19", "Healthy market hog carcass showing pelvic canal, lower abdominal wall, leaf lard, and iliac lymph nodes. Healthy kidneys in split carcass with capsule removed. Thoracic inlet of healthy market hog split carcass showing ribs, vertebrae, sternum, and lymph nodes. 20", "VI. MAINTAINING IDENTITY OF CARCASSES AND PARTS A. Carcasses and Parts Intended for Food The establishment must maintain identity of the carcass and associated head and viscera until the carcass, head, and viscera receive final inspection by FSIS (9 CFR 310.2). The establishment must also continue to demonstrate that they are able to retrieve the associated head and viscera of any carcass up until the point of final carcass inspection, should the carcass be retained by IPP for PHV disposition (9 CFR 310.3). B. Carcasses and Parts Intended for Disposal (Not Food) Before FSIS post-mortem inspection, establishment sorters are required to identify carcasses and parts intended for disposal (9 CFR 310.26). Once carcasses or parts identified for disposal have been inspected by FSIS, the establishment is required to initiate steps to denature them as inedible (unless designated as naturally inedible (e.g., hides with hair, claws, etc.) or render them (see 9 CFR parts 325 and 314). Collection of inedible parts in suitably marked containers for animal food must comply with denaturing or other permitted identification procedures under 9 CFR parts 325 and 416. VII. SORTING FOOD SAFETY CONDITIONS AT SLAUGHTER Establishment sorters must identify, sort, and mark for disposal market hog carcasses and all associated parts with the following food safety conditions (9 CFR 310.26): 1. Septicemia, 2. Toxemia, 3. Pyemia, 4. Cysticercosis, 5. Feces, 6. Ingesta, and 7. Milk Contamination. A. Septicemia Septicemia is a food safety condition caused by the presence of pathogenic microorganisms spread through the entire carcass by way of blood or lymphatics (see 9 CFR 311.16). Not all signs listed below will be present in every animal with septicemia. Post-Mortem Signs: 1. Dark and blood filled (i.e., congestion) organs or organs with infected wounds or dark bruises; 2. Pinpoint to blotchy hemorrhages (most noticeable on kidneys, heart, lungs, spleen, and other internal organ membrane (i.e., serous) surfaces, typically 0.125 to 1.0201d or greater in dimension). 21", "3. Generalized lymphadenitis (multiple, congested, inflamed, or enlarged lymph nodes): lymph nodes tend to be less inflamed but more enlarged 1-2 weeks after infection develops. Multiple lymph nodes are enlarged and cut surface of lymph nodes may be reddened or pale with a rough surface; 4. Pale degeneration of tissues or organs; 5. thin, pale (anemic); organs are pale in color; 6. Blood fails to clot; 7. Yellow to bloody fluid in abdominal and\or thoracic cavities; 7. Injection sites (recent); 8. Edema or other evidence of acute generalized inflammation; and\or 9. Hemorrhages under the skin, organs, and body surfaces. Disposal: Sorters must identify carcasses showing signs of septicemia for disposal under FSIS inspection. Special Notes: (1) Generalized, acute lymphadenitis (hemorrhage and

early enlargement of lymph nodes) alone is enough for discarding a carcass for septicemia. (2) A carcass manifesting any degree or form of septicemia is never passed by FSIS. (3) Petechial ((i.e., pinpoint, less than 1 mm in size) hemorrhages on a normal kidney alone in a healthy carcass are not conclusive evidence of septicemia. Carcasses with true septicemia will show signs in multiple areas or systems. Hemorrhagic lymph node associated with septicemia; generalized lymphadenopathy may be hemorrhagic or enlarged or both. 22", "Carcass showing signs of septicemia involving multiple organs; note hemorrhages and swelling of membranes covering heart, and organs themselves. Swollen enlarged kidney with petechial and larger ecchymotic (i.e. patches 5-15 mm in size) hemorrhages and scars compatible with a septicemia.

B. Toxemia Related to septicemia, toxemia (i.e., toxins in the blood) is a food safety condition caused by the circulation of toxins produced by pathogenic microorganisms or resulting from the death of microorganisms or tissues by way of the blood or lymphatics (see 9 CFR 311.16 and 311.17). Not all signs listed below will be present in every animal with toxemia.

Post-Mortem Signs:

1. Petechial or ecchymotic hemorrhages. These hemorrhages are most noticeable in kidneys, epicardium, lungs, and serous surfaces;
2. Generalized, acute lymphadenitis;
3. Pale enlarged organs;
4. Large or shrunken spleen;
5. Pale degeneration of tissues or organs;
6. Pigmentation of fat;

23", "7. Slight icterus and\or anemia; 8. Presence of areas of tissue necrosis, red-brown to yellow color to tissues and organs and fat; and\or 9. Changes associated with decomposing tissue (e.g., splenic torsion, liver or lung necrosis, or dead autolyzing fetus.)

Disposal: Sorters must identify carcasses showing signs of toxemia for disposal under FSIS inspection.

Special Notes: Signs of toxemia can appear in varying degrees in carcasses with septicemia. Septicemia, toxemia, or both may simultaneously occur in cases of diseases like septic mastitis, metritis, or arthritis.

C. Pyemia Pyemia (i.e., pus forming bacteria in the blood) is a food safety condition. Pus forming bacteria from wounds or injuries enter the bloodstream and form abscesses in the lungs, joints, or throughout the body (see 9 CFR 311.16 and 311.17).

Post-Mortem Signs:

1. Infected wound;
2. Swollen joint or joints;
3. Multiple abscesses in lungs with changes in visceral organs;
4. Hemorrhages in lungs, and visceral organs;
5. small abscesses (i.e., 1mm in size) in lungs are recent and do not have capsules;

Degeneration of tissues or organs with multiple small abscesses in lungs; and\or 6. Multiple enlarged, inflamed, or swollen lymph nodes.

Disposal: Sorters must identify carcasses showing signs of pyemia for disposal under FSIS inspection.

Special Notes:

- (1) Neoplasia may appear as a large abscess with a thick capsule seen with old localized abscesses.
- (2) Tuberculosis (TB) may appear as a purulent gritty abscess in certain situations.
- (3) Although a pyemia may have caused them, multiple, localized, encapsulated abscesses throughout the body should not be confused with an active pyemia.

24", "25 Micro-abscesses in heart, joint; spleen, and kidney suggesting a pyemia.

D. Cysticercosis of Swine (Pork Measles) Cysticercosis (pork measles) is a public health concern because it is a parasitic condition transmissible to humans (see 9 CFR 311.24). Cysticercosis cysts are the larval form (i.e., cysts) of the tapeworm *Taenia soleum*. Cysticercosis is very rare in domestic market hogs raised under modern and hygienic animal production methods but could reappear at any time, depending on the supplier. Cysticercosis is a rare but reportable disease (i.e., requires notification to FSIS). Cysticercosis should be considered any time multiple small cysts are observed in large muscle cuts, heart, diaphragm, or weasand.

Post-Mortem Signs:

1. Muscle is edematous or discolored;
2. One to several dozen cysts in muscle of heart, tongue, esophagus (i.e., weasand), or carcass;
3. Grape-like clusters in

tissue underneath the tongue or attached to heart; and\or 4. Cysts may occasionally be found in fat and viscera. Disposal: Sorters must identify carcasses showing signs of cysticercosis for either disposal or further inspection by FSIS PHV (if going to cooking)(see 9 CFR 315.2). FSIS recommends that the lead establishment sorter contact the FSIS PHV for assistance whenever cysts are observed in any organ or muscles.", "Pork Measles (Cysticercosis) -Cysts in Muscle. Heart muscle showing live cysts. E. Contamination with Feces, Ingesta, or Milk Refer to descriptions in FSIS Directive 6420.2. VIII. OTHER CONDITIONS REQUIRING SORTING This section provides guidance relative to the most common abnormal conditions seen in market hogs that are not directly associated with food safety but require sorting, trimming, or disposal depending on the nature, degree, or extent of the condition. A. Abscess Abscesses in the lymph nodes must be differentiated from granulomas (e.g. TB) and tumors (e.g. malignant lymphomas) (see 9 CFR 311.14). Abscesses in the neck or jowl may originate from old injection sites. Abscesses in the spine may originate from previously infected tail-bite wounds. Abscesses in swine soft tissues typically have a thick wall surrounding a yellow creamy pus-filled center. Pus can be pinkish to white in color, depending on the agent. Abscesses may be found anywhere on the carcass, joint, bone, or visceral organ. Large abscesses in the lung are often the result of the body walling off a lung lobe destroyed by 26", "pneumonia. Multiple localized abscesses that are well encapsulated within the main limb joints (or ends of long bones) are not indicative of pyemia, unless there is the simultaneous appearance of small abscesses and systemic changes in organs (e.g. lungs, spleen, kidneys and liver) due to an active spread of pyogenic microorganisms in the blood. Post-mortem signs: 1. Abscesses in various parts of the carcass or organs; 2. Abscess capsules may be thin (active; recent) or thick (more chronic). Pus may have any texture and color is mostly yellow, rarely red-brown, greenish-white to white in color; 3. Enlarged lymph nodes identified as localized, acute or chronic, reactive, or edematous lymphadenitis draining the affected area. Disposal: Heads: Sorters are required to identify localized abscesses and associated lymph nodes for removal under FSIS inspection. Carcass: Sorters are required to identify localized abscesses for removal under FSIS inspection. Carcasses affected with multiple abscesses affecting the entire carcass are required to be identified for disposal under FSIS inspection. Special Notes: Proper disposition of the carcass is improved when findings of abscesses or TB in the head are marked on the carcass and visible to viscera sorters. Abscesses may be mistaken for other conditions including those listed below. (1)True abscesses in the head or jowl can be differentiated from other conditions by the presence of visible scar tissue surrounding the abscess or lymph node. An abscess in the head may extend to the jowl. Head sorters should look for contamination from abscesses in neck and identified for disposal under inspection. (2) Large old tumors may have a necrotic center. Old lymphomas in the head or neck may have a dry yellow center up to 1\u201d in diameter that may appear as an old chronic abscess. (3)Fungal granulomas and classic TB may appear as a thick or grainy (calcified) abscess of 13mm in size. Establishments are encouraged to review any carcass or thoracic granulomas found with the PHV (if not retained by FSIS IPP.). B. Arthritis Arthritis is the inflammation of joint tissues that may be traumatic (as evidenced by blood joint fluid) or infectious in origin (see 9 CFR 311.7). Post-Mortem Signs: 1. Enlarged joint; 2", "2. Reactive or congested regional lymph nodes that drain the affected joint; 3. Degeneration of tissues or organs; 4. Septic wounds or other infections may spread to the joints causing arthritis; 5. Proliferation of the joint lining occurs as the joint heals; 6. Character of exudate in joints: a.

Increased amount of joint fluid, b. Clear blood-tinged joint fluid (injury), c. Cloudy red to yellow orange joint fluid (inflammation, infection). Disposal: Sorters are required to identify localized arthritis for removal under FSIS inspection. Sorters are required to identify carcasses showing signs of acute, systemic, or generalized arthritis for disposal under FSIS inspection. Special Notes: (1)Normal joints have a small amount of clear viscous joint fluid. Increased amount of joint fluid is often associated with injury, such as being confined on concrete or being hauled long distances to market. Often this fluid is clear but may show signs of fresh blood when associated with trauma. Fresh watery bloody joint fluid without evidence of cloudy, fibrinous or purulent exudate would be more indicative of trauma than infection. (2)As far as carcass disposal is concerned, the type of exudate present in the joints is not the primary consideration, whether the condition is generalized (systemic) is of most public health importance. (3)Opening arthritic joints may result in contamination of the carcass and if not avoidable, requires removal under FSIS inspection. (4)The tarsal (hock) joints of market hog carcasses affected with localized arthritis may be removed on the pork cut if the joint is bone solid without evidence of pus or tracks. (5) Establishments dispose of carcasses because of the condition of the joints, not the number of affected joints. If the arthritis is localized and can be removed by trimming, the joint should be disposed of under FSIS inspection and removed with any draining lymph nodes, and the carcass passed for food. (6) Establishments should not open arthritic joints on carcasses to avoid inevitable contamination of edible product with joint exudate. 28", "29 C. Pericarditis Pericarditis is an inflammatory condition of the heart sac (pericardium) that is usually due to an infectious agent (see 9 CFR 311.16). Post-Mortem Signs: 1. Adhesions of pericardium and pleura covering ribs or lungs \u2013 normal to inflamed red in color; 2. Sero-fibrinous or fibrinous pericarditis or epicarditis (shaggy heart); Inflammation of Hock Bone or Joint-abscess or arthritis likely; pyemia possible. Normal heart next to an enlarged heart with a mild inflamed heart surface with epicarditis or pericarditis (multiple surfaces).", "3. Edema of body tissues and fluid accumulations (ascites, pleural effusion); and 4. Putrefactive odor of cut-surface of pericardial, abdominal, or thoracic lesion. Disposal: Sorters are required to identify localized defects for removal under FSIS inspection. Sorters are required to identify carcasses with reddened (inflamed) or bloody pus on heart sac associated with multiple other carcass changes for disposal under FSIS inspection. Special Notes: Inflammation of the heart valve(s) is \u201cdocarditis\u201d and may be associated with septicemia, pyemia, or previous pneumonia. D. Pleuritis Pleuritis is an inflammatory condition of the pleural (lung and ribs) lining due primarily to infectious agents. It is often associated with pleuritis (see 9 CFR 311.16). Notice normal and inflamed lungs attached to ribcage. Post-Mortem Signs: 1. Adhesions between lungs, heart and ribs; 2. Fluid in the chest cavity; and\or 3. Reddened to enlarged lymph nodes within the chest. Disposal: Sorters are required to identify carcasses with chronic, localized (i.e. healed) adhesions on the rib cage for removal under FSIS inspection. Sorters are required to identify carcasses showing the following signs of acute, systemic, or generalized pleuritis for disposal under FSIS inspection: 1. Extensive, reddened lungs and surface of the ribs; or 2. Reactive or congested (reddened) lymph nodes draining lungs; heart, and ribs and body. Special Notes: Pleuritis can be associated with pneumonia or be a separate disease. E. Pneumonia 30", "Pneumonia is an inflammatory condition of the lungs that may be caused by infectious agents, parasites, physical trauma, or foreign material inhalation (see 9 CFR 311.16). Pulmonary hemorrhage, edema -Check for signs of septicemia. Post-Mortem Signs: 1. Lungs

may be reddened to grayish in color; 2. Lymph nodes draining lungs may be swollen, hemorrhagic, or enlarged; 3. Changes in color, size, or shape of liver, spleen, and kidneys; 4. Hemorrhages (spots) on lungs, kidneys, viscera, or carcass; 5. Consolidation of lung lobe into a thick-walled abscess; and\or 6. Parasites. Disposal: Sorters are required to identify localized defects for removal under FSIS inspection. Sorters are required to identify carcasses showing the following signs of acute, systemic, or generalized pneumonia for disposal: 1. Heavy, red, inflamed lungs with reactive inflamed lymph nodes; 2. Red, inflamed adhesions on ribs; 3. Changes in color, size, shape of kidneys, spleen, or viscera; 4. Pale or anemic carcass; and\or 5. Marked pulmonary necrosis (abscess) with associated toxemic changes. F. Peritonitis 31", "Peritonitis is a common condition marked by inflammatory processes affecting the peritoneal lining that is usually caused by infectious agents; however, it can be initiated by intraperitoneal medications, ruptured bladder, or other irritants (see 9 CFR 311.16). Notice the discoloration of the leaf lard suggesting a peritonitis. Here is an inflamed and distended loop of intestine with congested mesenteric lymph nodes from a carcass that may have an associated peritonitis. Post-Mortem Signs: 1. Gastroenteritis -pathologic hemorrhage in stomach, intestines, abdominal organs, or walls; 2. Generalized, acute lymphadenitis; 32", "3. Degeneration of tissues or organs; and 4. Accumulation of fluid in abdominal cavity. Disposal: Sorters are required to identify localized defects for removal under FSIS inspection. Sorters are required to identify carcasses with the following signs of acute, systemic, or generalized peritonitis for disposal: 1. Acute diffuse peritonitis without generalized changes; or 2. Peritonitis associated with generalized changes. G. Gastroenteritis Gastroenteritis is inflammation of stomach or intestine (see 9 CFR 311.16). Notice the enlarged, darkened, blood filled loops of intestine and enlarged darkened spleen. Post-Mortem Signs: 1. Inflammation of stomach or intestine and draining lymph nodes; 2. Dark, blood-filled intestinal loops; 3. Gangrenous stomach or intestine; 33", "4. Intestinal emphysema (foamy intestines); and\or 5. Thickened \u201cgarden-hose\u201d intestine. Disposal: Sorters are required to identify localized defects for removal under FSIS inspection. Sorters are required to identify carcasses showing the following signs of acute, systemic, or generalized gastroenteritis for disposal under FSIS inspection: 1. Acute, extensive hemorrhagic or gangrenous enteritis; or 2. Any degree of gastroenteritis with generalized (systemic) changes. Special Notes: FSIS recommends that sorters notify the PHV when multiple carcasses from the same lot show signs of gastroenteritis because this could be a sign of a reportable animal disease. H. Nephritis Nephritis is an inflammatory condition of the kidneys (see 9 CFR 311.16). Proper presentation of the kidney for sorting and inspection requires removal of the kidney capsule. There are several types of conditions in kidneys that warrant disposal and closer examination of the carcass. Etiologies may include infectious agents, parasites, or toxins. Notice the raised pale plaques on the surface of the swollen edematous kidney. Notice the striations that run from the center to the outer cortex of the kidney. Kidneys have white spots raised or flattened and show up as white streaks on cut surface. To differentiate from lymphoma, look for evidence of lymphoma in other tissues. Laboratory assistance may be required. Establishments may review kidney dispositions with the PHV if they have questions. 34", "35 Acute interstitial nephritis \u2013 a type of inflammation of the kidneys from bacteria in blood or urinary tract. FSIS recommends that establishment sorters check for evidence of septicemia in the carcass. Notice the pale enlarged kidneys with hemorrhages on the surface. Look for changes in lymph nodes and other

organs in the carcass. Chronic interstitial nephritis \u2013 Look for anemia or uremia in carcass Carcasses with chronic interstitial nephritis\u2014white, firm, depressed, or pitted or scarred kidneys\u2014may be presented to an FSIS PHV, who will determine if the carcasses can be passed for food, if there are no generalized changes (anemia; uremia), after condemnation of and removal of abnormal tissues.", "Pyelonephritis \u2013 Chronic inflammation of the ureter and kidney. The kidney appears virtually destroyed; FSIS recommends that establishment sorters also check the carcass for odors or anemia. Benign Embryonal Nephroma -a congenital kidney tumor. Congenital kidney tumor in swine (i.e. embryonal nephroma). Establishment sorters are required to identify the defect for removal under FSIS inspection. 36", "Carcass with Cystic Kidneys and Normal Kidney Tissue Hydronephrosis. Cystic Kidneys -one or both kidneys literally appear as a \"bag of water\". Normal kidney tissue is replaced by a large fluid cyst. There is generally no effect upon the carcass. Affected kidneys are typically removed and disposed of. Post-Mortem Signs: 1. Inflammation, enlargement, pathological hemorrhage, or change of color in kidney; 2. Multiple abscesses of entire kidney; 3. Pyelonephritis-- accumulation of pus in the ureters and into the kidney; 4. Degeneration of tissues, organs, and lymph nodes; 5. Carcass and tissue edema from protein loss in blood; and\|or 6. Uremic odor of carcass, indicating uremia. Disposal: Sorters are required to identify localized defects for removal under FSIS inspection. Sorters are to identify carcasses with the following signs of acute, systemic, or generalized nephritis for disposal under FSIS inspection: 1.Nephritis (acute or chronic) associated with generalized lesions or disease; 2.Pyelonephritis (dilated ureter and kidney) associated with generalized changes; or 3.Uremia associated with any stage or type of nephritis. Special Notes: Certain conditions should not be confused with primary nephritis including: (1)Kidney worms; (2)Urinary obstructions (kidney or bladder stones); (3) Infarcts; (4)Neoplasms (See embryonal nephromas and malignant lymphomas); (5)Cystic water filled kidneys; (7)Traumatic injuries; or (8)Depressed white areas\u2014scars resulting from previous infarcts or nephritis. I. Uremia 37", "Uremia literally means urine in the blood (see 9 CFR 311.16 and 311.37). Uremia may occur when the kidneys acutely fail to remove nitrogen (ammonia) waste materials in the blood. This can occur after kidneys are temporarily or permanently damaged or after total destruction of the kidneys. This can occur rapidly or over time. Post-Mortem Signs: 1. Hydrothorax; 2. Ascites or edema in the abdominal cavity; 3. Fluid in all body tissues with lack of inflammatory process; 4. Nephritis or pyelonephritis; 5. Peritonitis; 6. Cystitis; 7. Kidney stones; 8. Hydronephrosis; 9. Carcass edema and reddening; 10.Uremic odor to muscles; and\|or 11.Ruptured urinary bladder with peritonitis. Disposal: Sorters are required to identify localized defects for removal under FSIS inspection. Sorters are required to identify carcasses showing signs of uremia associated with nephritis for disposal under FSIS inspection. Special Notes: (1)If there is evidence of a localized urine odor in tissues, establishments are required to trim the affected area. (2)It is possible that a ruptured bladder can result from faulty dressing procedures. Such contaminated areas are required to be thoroughly trimmed. J. Tuberculosis (TB) Swine TB is an increasingly rare condition associated with the ingestion of pathogenic acid-fast organisms, almost exclusively identified as *Mycobacterium avium* (see 9 CFR 311.2). *M. avium* is known to be ubiquitous in the environment. The most recent infections have been historically associated with exposure to organic bedding, contaminated feed, and birds. FSIS slaughter data have shown the prevalence of *M. avium* in market hogs has steadily decreased. It is believed this decrease can be attributed to improved biosecurity methods

associated with modern production practices and raising market hogs indoors. Establishment management, sorters, and IPP cannot make the same assumptions when market hogs are raised outdoors or under other circumstances (e.g., free range). Sorters should be aware that TB lesions are most likely to be found in one or more parts of the carcass referred to as the \u201cprimary seats\u201d. The primary seats of TB lesions in the market hog carcass are the mandibular (jaw), the mesenteric (intestines), and the bronchial (airway) lymph nodes. TB lesions (e.g. granulomas) in swine have historically been identified through the incision of the mandibular lymph nodes and palpation of mesenteric, portal, and bronchial lymph nodes. Post-Mortem Signs: 38", "1. Increasingly rare, TB granulomas typically appear in incised lymph nodes as small grains of sand or small abscesses 0.5-2 mm in diameter. 2. When found in the mesenteric lymph nodes, they may appear as small abscesses just below the surface of the mesentery along the mesenteric lymph node chain. Disposal: Sorters are required to identify heads with TB lesions in mandibular lymph nodes for disposal under FSIS inspection. Viscera sorters must then perform closer examinations of the mesenteric lymph nodes for evidence of TB. If lesions are found in the mesenteric lymph nodes, the sorters should identify the carcass and viscera for closer examination by the lead sorter. Carcasses with generalized TB lesions, as demonstrated with lesions in 3 primary seats or outside of the primary seats (e.g., in muscle, joint, or organ), are to be disposed of under FSIS inspection. If lesions are located in two or more primary seats, the carcass and viscera must be held by sorters for further sorting by the establishment\u2019s lead sorter. Sorters also may request that the FSIS PHV inspect a carcass to determine if it may be passed for cooking (i.e., Passed for Cooking only). A lymph node showing multiple diffuse TB lesions. K. Parasites Not Transmissible to Humans 1. Stephanuriasis (Swine Kidney Worms) Stephanuriasis is a rare parasitic condition caused by the presence of Stephanurus dentatus in carcass tissues (see 9 CFR 311.25). This condition is most likely seen in swine raised outdoors in the South Atlantic and South-Central parts of the United States. This parasite is not known to be transmissible to humans. 39", "Kidney Worms. Post-Mortem Signs: 1. Adult kidney worms; 2. Lesions can include: a. Pelvic inlet, pelvic and femoral canal, b. Abdominal lining, c. Muscle-primarily loin and ham muscles, d. Organs-primarily kidney, liver, pancreas, spleen, and lungs, and\or e. Brownish-lemon color of skin and fat. Disposal: Sorters are required to identify carcasses for disposal when a parasitic infestation is associated with generalized disease, such as uremia or septicemia. Carcasses with numerous or extensive lesions also must be identified for disposal. Sorters are required to identify moderate infestations for removal under FSIS inspection. Or, sorters may request that the PHV inspect the product to determine if it may be passed for cooking. Special Notes: (1)The larvae of Stephanurus dentatus migrate to tissues surrounding the kidneys, form cysts and abscesses, and develop to adulthood. The area around the kidneys often appears reddish-brown, and the cysts contain a creamy to reddish-brown colored substance. It is even possible to palpate cord-like masses in the kidney fat, which are tracts made during migration. (2)In the liver, there are sometimes multiple extensive orange-tan hemorrhagic areas, with the liver parenchyma later taking on a mahogany color. Usually abscessation occurs where the larvae have been trapped. In addition, severe scarring results where abscessation has occurred. 2. Ascarids (Roundworms) Adult roundworms, Ascaris suum, may be observed in the intestines, bile ducts, and gall bladders of market hogs (see 9 CFR 311.25). Larval migration of ascarids causes \u201cmilk spots\u201d on pork livers and damage to lungs. \"Slight\" scarring may be trimmed (spotting

the liver). Disposal: Sorters are required to identify localized defects for removal under FSIS inspection. Sorters may request that the PHV inspect the product to determine if it may be passed for cooking. Sorters are required to identify affected intestines with infestations of roundworms for disposal under FSIS inspection. 40", "L. Miscellaneous Skin Conditions; Vesicular Diseases Skin conditions are varied and many are very nonspecific, including conditions such as dermatitis, insect bites, erythema, urticaria, and photosensitization (see 9 CFR 311.21). Vesicles (blisters) on the head, snout, mouth, feet may indicate the presence of a reportable or FAD and must be reported to FSIS. Post-Mortem Signs: 1. Dermatitis; 2. Mange (sarcoptic), scabs with general areas of reddened, itchy or thickened skin; 3. Generalized lymphadenitis; 4. Tissue or organ degeneration; and\|or 5. Petechiae or ecchymotic hemorrhages in tissues, organs, or skin. Disposal: Sorters are required to identify localized defects for removal under FSIS inspection. Sorters are required to identify carcasses showing signs of extensive skin lesions and associated generalized or systemic changes for disposal under FSIS inspection. Special Notes: The following conditions might be confused with skin disease: (1)Market hogs over-scalded as a result of being in the scald vat for too long or at too high a temperature; (2)Erythema and bruising; (3) Frost-bite; (4) Hemophilic infection, fungal infections; (5)Vesicular diseases (e.g., FMD and Seneca Valley Virus (SVV)); and (6) Swine Circovirus. 41", "42 Ringworm (fungal dermatitis). Vesicles (Blisters). FMD is a vesicular disease, vesicles (blisters) are on snout; check tongue, feet, nipples. FMD is a foreign animal disease (FAD). M. Diamond Skin \u2013Skin Form of Swine Erysipelas Erysipelas is a disease of market hogs caused by the organism *Erysipelothrix rhusiopathiae*. A chronic form of erysipelas is recognized as \u201cdiamond skin\u201d disease (see 9 CFR 311.6).", "Diamond shaped skin lesions. Diamond shaped skin lesions on a scalded carcass after hair removal. Diamond shaped skin lesions at post-mortem. Post-Mortem Signs: 43", "1. Diamond shaped lesions, which may vary from acute to chronic; 2. Arthritis; 3. In acute disease, generalized lymphadenitis; 4. Petechial hemorrhage may be noticeable in lungs, kidneys, heart, or on outer surfaces; 5. Degeneration of tissues or organs; and\|or 6. Vegetative valvular endocarditis. Disposal: Sorters are required to identify localized defects for removal under FSIS inspection. Sorters are required to identify carcasses with the following signs of acute, systemic, or generalized diamond skin for disposal under FSIS inspection: 1. Numerous deep dark diamond skin lesions; 2. Petechial hemorrhages in the kidneys; 3. Hemorrhagic and congested lymph nodes; and\|or 4. Degeneration of organs. Special Note: \"Diamond skin\" is a common name for chronic stages of erysipelas in market hogs with chronic diamond skin lesions. When the lesions are limited to just the skin, as often the case, the sorter may identify skin lesions for removal under FSIS inspection. N. Fractures, Bruises, and Injuries, Septic and Non-Sepctic (See 9 CFR 311.14). Post-Mortem Signs: 1. Bruises, injuries, or fracture with hemorrhage into the tissues and involving regional or carcass lymph nodes; 2. Septic or toxic changes to organs; 3. Gangrene, strong odor; 4. Injection lesions; 5. Bruise showing hemorrhagic regional lymph nodes; 6. Brownish or dark discoloration of body tissues over whole carcass; or 7. Post-mortem rib fractures. Disposal: Sorters are required to identify localized defects for removal under FSIS inspection. Sorters are required to identify carcasses showing the following acute, systemic, or generalized defects for disposal under FSIS inspection: 1. Extensive, generalized bruising, discoloration that cannot be removed by trimming; or 2. Septic bruising or injuries that show associated systemic changes of septicemia or toxemia. Special Notes: Post-mortem fractures typically have no evidence of

hemorrhage near the fracture site. Post-mortem fractures, slight bruises, and healed rib fractures are quality defects that may be removed on the cut floor. O. Melanomas vs. Melanosis 44", "Melanin is a normal black pigment of the body (see 9 CFR 311.13). Melanosis is excessive melanin deposits or deposits in abnormal locations. Melanosis typically can be found in the lungs, spinal dura, skin, or lymph nodes draining other melanomas or melanin pockets. Such deposits must be removed from product for human food purposes. Melanomas are tumors consisting of melanin producing cells. Malignant tumors show evidence of metastasis in draining lymph nodes. Melanoma is a neoplasia of the naturally occurring melanocytes in the skin. Benign lesions (melanocytomas) and malignant lesions (malignant melanoma) occur, and these must be differentiated from melanosis. Laboratory analysis can be helpful in differentiating benign and malignant melanomas. Black tumors may be seen in the skin of any species. In market hogs these most often might be seen at the base of the ears, mid-back, tail-head and flanks. Certain breeds of market hogs are particularly prone to having melanosis and melanotic tumors. Melanosis (Pigmentation) of lung and liver tissue. 45", "Carcass with melanotic skin lesions. Sorters should check all draining lymph nodes. Melanoma (benign or malignant tumor). 46", "Pigmentation of lymph nodes; possible tumor. Notice melanotic patches of skin on the carcass. Check draining lymph nodes and viscera for evidence of melanosis or metastasis. Post-Mortem Signs: 1. Melanin pigment in lungs, liver, lymph nodes, or other organs; 2. Melanin in skin; 3. Melanin in sclera of eye; 4. Melanin associated with inflammation; 5. Metastasis (i.e., multiple tumors) to regional lymph nodes; 6. Metastasis to the lungs; and\or 7. Metastasis to the liver, spleen, and other internal organs. Disposal: Sorters are required to identify localized defects for removal under FSIS inspection. Sorters are required to identify carcasses with the following signs of acute, systemic, or generalized defects for disposal under FSIS inspection: 1. Generalized pigmentary deposits; 2. Melanin that cannot be removed or is impractical to remove, or that renders a carcass, organ, or part or the affected portion of a carcass, organ or part unfit for human food; 3. Evidence of abnormal tumor growth (i.e., metastasis-formation of multiple tumors); and 4. Tumors affecting the overall health or condition of the animal and carcass. Special Notes: Slight melanin deposits in spinal cord sheath (meninges) are normal. When including surface of the bones, the pigmented tissue must be removed when its appearance does not meet consumer expectations (9 CFR 311.1 and 311.13(b)). Slight or diffuse pigmentation of skin need not be removed unless tumorous or smearable. 47", "P. Icterus (Jaundice) Icterus represents an abnormal accumulation of yellowish bile pigments associated with the breakdown of blood that is stored in liver cells or the gall bladder (see 9 CFR 311.19). Post-Mortem Signs: 1. Degenerative changes in liver (e.g., pale, enlarged) and\or darkened spleen; 2. Lemon-yellow discoloration of connective tissues that are normally very white or pale including: a. Sclera (white part) of the eye, b. Tendons, c. Pleura (lining of the chest cavity), d. Peritoneum (lining of the abdominal cavity), e. Omentum (tissue that extends from the stomach to the adjacent organs in the abdominal cavity), f. Cut surface of abdominal wall fat, g. Joint surfaces, or h. Mesentery (fold of tissue attaching small intestines to the body wall). Disposal: Sorters are required to identify localized defects for removal under FSIS inspection. Sorters are required to identify carcasses that are icteric for disposal under FSIS inspection. Special Notes: Sorters should notify the PHV if they intend to hold icteric carcasses in the cooler pending final disposition. Q. Embryonal Nephroma Embryonal nephromas are rough, fibrous raised tumors of the kidney (see 9 CFR 311.11). Generally, they are benign

tumors and occur more commonly in young animals. Post-Mortem Signs: Presence of rough, fibrous tissue near the kidneys. 48","Benign Embryonal Nephroma. Embryonal Nephromas are typically benign (i.e. nonmalignant) congenital kidney tumors in swine. Disposal: Sorters are required to identify localized defects for removal under FSIS inspection. Sorters are required to identify carcasses showing signs of acute, systemic, or generalized embryonal nephroma for disposal under FSIS inspection. R. Malignant Lymphoma Lymphoma is a neoplastic condition of the lymphocytes and is considered malignant (see 9 CFR 311.11). There are many manifestations of lymphoma, so it can be confused with other diseases, such as granulomas, abscesses, or other types of neoplasia. Post-Mortem Signs: 1. Gross enlargement of one or more lymph nodes with uniformly pale moist surface; 2. Gross enlargement of lymph node with a large yellow necrotic center; (e.g., mandibular lymph nodes or lymph nodes of the thoracic inlet); 3. Gross enlargement of lymph nodes with a dark red center; 4. Gross enlargement of liver and spleen; and\or 5. Focal or diffuse neoplastic growth or plaques on pleural ribs wall or peritoneal (i.e., inside abdominal wall). Disposal: Sorters are required to identify any carcass showing signs of malignant lymphoma. Regardless of the extent and distribution of the lymphoma, any evidence, just one lesion, of lymphoma requires disposal of the entire carcass and viscera. 49","Notice large lymph nodes with smooth surface indicative of malignant lymphoma in the head. Some carcasses with malignant lymphoma may exhibit lymph nodes in the neck exhibiting a yellow necrotic center like a hardboiled egg. Check remainder of carcass. Carcasses with any evidence of malignant lymphoma are condemned. Enlarged malignant lymphoma in renal lymph nodes inside carcass. Malignant lymphoma in mesenteric lymph nodes. 50","Malignant lymphoma infiltrating kidney in several locations. Notice several raised bumps or plaques. Lesions are often found on the ribs, diaphragm, and abdominal organs. Notice the smooth appearance of malignant lymphoma on cut surface. The normal outer lymph node and center are obliterated with many tumor cells. Malignant lymphoma infiltration of enlarged liver 51","S. Odors; Undetermined; Sexual Odor of Swine The carcass of a barrow market hog with retained testicle can exhibit a characteristic sexual odor (see 9 CFR 311.20). Sexual odor is rarely seen in market hogs less than 6 months of age. When present, there is a distinct pungent odor to the tissues. NOTE: Because boars and stags are not market hogs, they are not eligible for slaughter under the NSIS without a waiver under the Salmonella Initiative Program. Post-Mortem Signs: 1. Any sex odor of carcass or viscera of any market hog; and\or 2. Chemical or medicinal odors. Disposal: Sorters are required to identify any carcass that exhibits a pronounced sexual odor for disposal under FSIS inspection. However, if the sexual odor is less than pronounced, sorters may request the PHV to inspect the carcass to determine if the carcass may be passed for use as human food, as either cooked comminuted product or for rendering as lard. Special Notes: (1)A warm carcass should be considered to have a pronounced odor if sorters can smell the odor when they are several inches away from the carcass. (2)If the odor is less than pronounced, sorters will have to get very close to the carcass to smell the odor. T. Pale Soft Exudative Pork (PSE) Extensive PSE is a form of muscular degeneration (See 9 CFR 311.35. Post-Mortem Signs: Affected muscle tissue appears pale soft and watery in appearance. Tissue may have a slight sour smell. Lesions may appear in one or more large muscles to varying degrees. Disposal: Mild forms of PSE are histologically normal and the carcasses and parts are suitable for further processing. Sorters are required to identify localized defects for removal under FSIS inspection. Sorters are required to identify carcasses

showing signs of acute, systemic, or generalized PSE for disposal under FSIS inspection. U. Over-Scald Post-Mortem Signs: Carcasses showing signs of being over-scalded will have a cooked appearance and will usually have varying degrees of mutilation and contamination of tissues with scald vat water. Disposal: Sorters are required to identify contaminated parts (e.g., broken skin) for removal under FSIS inspection. Sorters are required to identify carcasses that are severely over- 52", "scalded (e.g., the carcass has undergone thermal changes that may obscure other adulterating conditions like septicemia) for disposal under FSIS inspection. V. Classical Swine Fever (Hog Cholera) Classical Swine Fever (Hog Cholera) is a reportable FAD not found in the United States since 1978. Should hog cholera reappear, multiple signs of fever, illness, and inflammation will be seen at ante-mortem and post-mortem. Establishments are required to immediately notify FSIS inspectors if they identify, while conducting sorting activities, an animal or carcass that they suspect has a reportable or foreign animal disease (9 CFR 309.19(e)). Upon notification by the establishment, the PHV will notify APHIS. W. African Swine Fever African Swine Fever (ASF) is also a reportable FAD not found in the United States. ASF is currently affecting swine in other countries around the world. Notable signs include high death loss, fever, and illness. Establishments are required to immediately notify FSIS inspectors if they identify, while conducting sorting activities, an animal or carcass that they suspect has a reportable or foreign animal disease (9 CFR 309.19(e)). For more information on ASF, see the APHIS website: <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/swinedisease-information/african-swine-fever/african-swine-fever> X. Brucellosis in Feral or Other Swine Classes Swine brucellosis is a reportable disease rarely found in confinement raised market hogs. Swine brucellosis may be found in other classes of swine especially mature breeding swine or feral swine. Swine brucellosis is a potential disease of public health concern and occupational health. Human infections are associated with exposure to reproductive organs (e.g. uterus, testicles). Brucellosis in market hogs has few post mortem lesions. Establishments are required to immediately notify FSIS inspectors if they identify, while conducting sorting activities, an animal or carcass that they suspect has a reportable or foreign animal disease (9 CFR 309.19(e)). Special Notes: Should an establishment desire to slaughter other classes of swine (e.g. sows, boars, and feral swine) under the NSIS, a waiver would be required. 53" "IX. REFERENCES A. FSIS Online Inspection Training Information 1. FSIS Slaughter Inspection Training

<http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/regional-on-sitetraining/slaughter-inspection-training> 2. PHV Disposition Guide

[http://www.fsis.usda.gov/wps/wcm/connect/347a0e1f-d496-40c0-bf40-b505929ffb0e/PHVtMulti\\_Species\\_Disposition\\_93.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/347a0e1f-d496-40c0-bf40-b505929ffb0e/PHVtMulti_Species_Disposition_93.pdf?MOD=AJPERES) 3. FSIS Beginning PHV Inspection Training

<http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/workforce-training/regional-on-sitetraining/public-health-veterinarian/public-health-veterinarian> 4.

FSIS FAD training [[http://www.fsis.usda.gov/wps/wcm/connect/2afa4f5f-e7df-479c-905855aecc60d145/PHVt-Reportable\\_\\_Foreign\\_Animal\\_Diseases.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/2afa4f5f-e7df-479c-905855aecc60d145/PHVt-Reportable__Foreign_Animal_Diseases.pdf?MOD=AJPERES)] 5. FSIS Federal Code of Regulations, Sections 309-311 [9 CFR 309-311]

[http://www.ecfr.gov/cgi-bin/textidx?SID=4632a5415489f65b789aea7bbc069bea&mc=true&tpt=/ecfrbrowse/Title09/9cfrv2\\_02.t pl#300](http://www.ecfr.gov/cgi-bin/textidx?SID=4632a5415489f65b789aea7bbc069bea&mc=true&tpt=/ecfrbrowse/Title09/9cfrv2_02.t pl#300) 6. FSIS Directive 6000.1 -Responsibilities Related to Foreign Animal Diseases (FADs) and Reportable Conditions 7. FSIS Directive 6100.1 \u2013

Ante-mortem Directive 8. FSIS Directive 6100.2 -Post-mortem Directive 9. FSIS Directive 6420.2 -Livestock Zero Tolerance Directive 10.FSIS Directive 6240.1 -TB Directive and related materials 11.FSIS Directive 6100.8 -Instructions for Verification of IMPROVEST\u00ae Hogs [http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/6000-series] B. APHIS Online Information on Reportable and Foreign Animal Diseases 1. APHIS Animal Disease Training \u2022 <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information> 2. APHIS Veterinary Service Points of Contact \u2022 [https://www.aphis.usda.gov/animal\\_health/downloads/sprs\\_contact/field\\_office\\_contact\\_info.pdf](https://www.aphis.usda.gov/animal_health/downloads/sprs_contact/field_office_contact_info.pdf) C. Scientific or Academic Resources 54", "SMALL PLANT HELP DESK N~UU! \u2022 .!\" mIII rIII lII \u00b5lI-,; \u00b500b717\u2022~0J\u2022C\u2022 askFSIS USDA r--I -, ----- a policy-related question Office International des Epizooties (OIE) Sites \u2022 <http://www.oie.int/en/animal-health-in-the-world/animal-diseases/> Iowa State Center for Food Safety and Public Health \u2022 <http://www.cfsph.iastate.edu/Species/swine.php> \u2022 <http://www.cfsph.iastate.edu/pdf/foot-and-mouth-disease-pocket-guide-swine> <http://askfsis.custhelp.com/> FSIS/USDA www.fsis.usda.gov X. Congressional Review Act Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this guideline is not a \u201cmajor rule,\u201d as defined by 5 U.S.C. 804(2). 55"]}, {"file\_name": "FSIS\_GD\_2019\_0008", "title": "Foodborne Pathogen Test Kits Validated by Independent Organizations", "num": "FSIS-GD-2019-0008", "id": "d2cdf12d2569689048890f2bc07d552c3d7f8798fdda52818facdab17247aef1", "corp\_us": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/documents/Validated-Test-Kit.pdf", "type": "pdf", "n\_pages": 54, "word\_count": 21076, "text\_by\_page": ["Foodborne Pathogen Test Kits Validated by Independent Organizations FSIS is making available a list of test kits that have been validated for detection of relevant foodborne pathogens (i.e., *Salmonella*, *Campylobacter*, *Listeria* spp. including *L. monocytogenes*, *E. coli* O157:H7 and non-O157 STEC). The list is intended to be informational and is not an endorsement or approval of any specific test kit, regardless of its inclusion in the list. FSIS does not specifically endorse any of the mentioned test kits or products and acknowledges that equivalent test kits or products may be available for laboratory use. Likewise, FSIS does not require the use of any specific test kit, including those incorporated into FSIS\u2019s Microbiology Laboratory Guidebook methods. Instead, establishments and laboratories should choose test kits that are: 1)Validated for testing relevant foods by a: a) Recognized independent body (i.e., AOAC, AFNOR, MicroVal, NordVal), b) U.S. regulatory body (i.e., FSIS MLG or FDA BAM), or c) International Organization for Standardization (ISO) process 2)In addition, the validated method should be: a)Fit for the intended purpose and application (e.g., validated for the appropriate matrix and sample size to detect the appropriate foodborne pathogen), and b)Performed per the conditions of the validated protocol by a laboratory that assures the quality of the analytical results. The table below contains a list of foodborne pathogen test kits that are validated by recognized independent organizations (i.e., AOAC, AFNOR, MicroVal, NordVal) and therefore meet criterion 1a above. However, the test kits in this list are not necessarily equivalent or appropriate for all testing applications. FSIS intends to update validated test kit lists on a quarterly basis. # Method"]}]

Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test
Portion Size S001a	3M Molecular Detection Assay	Salmonella (MDA 2)	Salmonella spp.	3M	
Health Care AFNOR # 3M 01\16 - 11\16	All human food products (except spices, aromatic herbs, instant coffees and teas, bouillon cubes\concentrates, milk powders and cocoa powders) and environmental samples (except primary production stage environment)	25g			
S001c 3M\u2122 Molecular Detection Assay (MDA)	Salmonella Method	Salmonella spp.	3M		
Food Safety AOAC-OMA # 2013.09	Raw ground beef (25g, 325g, 375g), cooked breaded chicken (325g), liquid egg (100g), shrimp, fresh spinach, and wet dog food (375g), raw ground chicken (25g, 325g), pasteurized american cheese, peanut butter, dry dog food (25g, 375g), sprout irrigation water (375g), chicken carcass rinse (30ml), chicken carcass sponge, sealed\glazed ceramic tile, concrete, stainless steel 25g except where noted in \"Validated Matrices\" S005a				
ANSR for Salmonella	Salmonella enterica and Salmonella bongori	Neogen Corporation	AOAC-PTM # 061203	Raw ground beef, hot dogs (25g, 325g), chicken carcass rinse (30mL), raw ground turkey, oat cereal, surfaces (stainless steel, plastic, sealed concrete, ceramic tile rubber) 25g except where noted in \"Validated Matrices\" S005b	
Neogen Corporation AFNOR # NEO 35\02 - 05\13	Meat products, dairy products, seafood and vegetables 25g	S006a Assurance GDS for Salmonella Tq	Salmonella spp.	BioControl Systems, Inc.	
AFNOR # TRA 02\12 - 01\09	All human foodstuffs, animal feed and environmental samples 25g ** N\A = Not available", "# Method Name	Target Organism(s)	Manufacturer External Validation	Validated Matrices	Validated Test Portion Size S006b Assurance GDS\u00ae
Salmonella Salmonella spp.	BioControl Systems, Inc.	AOAC-OMA # 2009.03	Meats, poultry, poultry carcass rinse, seafood, dairy products, egg, pasta, peanut butter, fruits and vegetables, spices (curry powder, chili powder, and cumin powder), and environmental surfaces 25g	S006c Assurance GDS for Salmonella Salmonella spp.	BioControl Systems, Inc. AOAC-PTM # 050602
Raw beef, raw pork, ground turkey, chicken rinse, raw shrimp, nonfat dry milk, egg, and environmental surfaces (stainless steel, rubber, concrete) 25g	S007 Assurance Gold EIA				
Salmonella Salmonella spp.	BioControl Systems, Inc.	AOAC-OMA # 999.08	All foods 25g	S008 Assurance\u00ae Salmonella Enzyme Immunoassay (EIA) Test Kit	Salmonella spp. BioControl Systems, Inc. AOAC-OMA # 992.11 All foods 25g
Salmonella enterica subspecies: enterica, diarizonae, arizonae, houtenae, indica, salamae Roka Biosciences, Inc.	AOAC-PTM # 031201 Fresh raw ground beef (375g), frozen raw ground beef (375g), chicken carcass rinse, raw ground chicken, cooked deli turkey (325g), cooked deli chicken (325g), pasteurized dried whole egg (100g)), raw cod, creamy nonorganic peanut butter, romaine lettuce (375g), tomatoes, instant nonfat dry milk, string cheese (mozzarella), milk chocolate, cocoa powder (375g), raw cookie dough, dry pet food, dry pasta, shell eggs, nacho cheese seasoning, black pepper, soy flour, environmental surfaces (stainless steel, plastic, sealed 25g except where noted in \"Validated Matrices\" S010a BAX System PCR Assay for Salmonella PCR (Classic + Q7 Instruments) Salmonella spp. Oxitel, Thermo Fisher Scientific NordVal # 030 Dairy products, meat, fish, vegetables, pastries, egg products, ready to eat meals, animal feed, and environmental samples 25g	S009 Atlas Salmonella Detection Assay			
S010b BAX System PCR Assay for Salmonella 2 BAX System X5 PCR Assay for Salmonella (formerly known as Dupont BAX System PCR Assay for Salmonella 2 )	Salmonella spp. Qualicon Diagnostics LLC, a Hygiena Company AOAC-PTM # 100201 Milk (2%), custard, nonfat dry milk, liquid egg, chipped ham, cooked chicken, hot dogs, ground beef, cooked fish, prawns, frozen peas, orange juice, peanut butter,				

alfalfa sprouts, black pepper, dry pet food, chilled ready-meal, chocolate, elbow macaroni, pizza dough, isolated soy protein, spinach, lettuce, (4 x4 in sponge) concrete, ceramic tile, stainless steel, plastic, epoxy material affixed to a support matrix 25g S010c BAX\00ae System PCR Assay Salmonella spp. (automated) Salmonella spp. DuPont Qualicon AFNOR # QUA 18\03 - 11\02 All human food products, animal feed and environmental samples (excluding environment of primary production stage) 25g S010d BAX\00ae System Salmonella Salmonella spp. DuPont Qualicon (DuPont Nutrition & Health Diagnostics) AOAC-OMA # 2003.09 Frankfurters, raw ground beef, raw ground chicken, mozzarella cheese, raw frozen tilapia fish, and orange juice 25g \*\* N/A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size S011 BBL\2122 CHROMagar\2122 Salmonella Salmonella spp. Becton Dickinson and Company AOAC-PTM # 020502 (25 g samples) - raw chicken, raw ground beef, raw fish, lettuce, raw eggs N/A S012 BioControl 1-2 TEST Motile Salmonella spp. BioControl Systems, Inc. AOAC-OMA # 989.13 All foods 25g S014 Check&Trace Salmonella (previously marketed as PremiTTest Salmonella ) Salmonella spp. Check-Points AOAC-PTM # 121001 Pure cultures N/A S015 Colorimetric GENE-TRAK Salmonella Assay Salmonella spp. GENE-TRAK Systems\Neogen Corp. AOAC-OMA # 990.13 All foods 25g S016 foodproof Salmonella Detection Kit and foodproof StarPrep One Kit or foodproof Magnetic Preparation Kit IV for DNA extraction Salmonella spp. BIOTECON Diagnostics GmbH MicroVal # 2011LR39 Powdered infant formula, probiotic culture powders, ingredients Up to 100g S017b foodproof Salmonella Detection Kit (liquid and lyophilized) with foodproof ShortPrep I Kit, foodproof StarPrep One Kit, or foodproof Magnetic Preparation Kit I with the foodproof RoboPrep Series Salmonella spp. BIOTECON Diagnostics GmbH AOAC-PTM # 120301 milk powder, ice cream, egg powder, chicken breast, minced meat, sliced sausage, sausage, smoked fish, watermelon, sliced cabbage, coconut, white pepper, cumin, wet pet food, dry pet food, dough, food dye, milk chocolate, cocoa powder, pasta, custard, chocolate ice cream, raw ground beef, mayonnaise, primary production samples (boot socks with it it i l ) t f d 25g S018 GeneDisc Plate Pathogenic E. coli O157 & Salmonella spp. E. coli O157 & Salmonella spp. Pall GeneDisc Technologies AOAC-PTM # 021104 25 g, 375 g - fresh raw ground beef, fresh raw beef trim 25g, 375g S019 GeneDisc Plate STEC & Salmonella Shigatoxigenic E. coli & Salmonella spp. Pall GeneDisc Technologies AOAC-PTM # 021105 25 g, 375 g - fresh raw ground beef, fresh raw beef trim 25g, 375g S020a GeneDisc Salmonella spp. Salmonella spp. Pall GeneDisc Technologies AFNOR # GEN 25\05 -11\08 All human food products and animal feeding stuffs 25g S020b GeneDisc Plate Salmonella spp. V2 Salmonella spp. Pall GeneDisc Technologies AOAC-PTM # 021101 Raw ground beef (25g, 375g) and raw beef trim (25g, 375g), raw chicken breast (25g, 375g), raw ground turkey, (25g, 375g), chicken carcass rinsates (30ml), raw de-headed shrimp, fresh cut cantaloupe, whole cantaloupe, bagged ready to eat mixed lettuce, creamy nonorganic peanut butter, raw alfalfa sprouts, instant nonfat dry milk, cheddar cheese, vanilla ice cream, milk chocolate, dry dog food (25g, 375g), black pepper, shell eggs, spent sprout irrigation water (375g), stainless steel, 25g except where noted in \"Validated Matrices\" S021a GeneQuence\00ae Salmonella Salmonella spp. Neogen Corporation AOAC-OMA # 2007.02 Raw turkey, dried, liquid and liquid frozen pasteurized eggs, milk chocolate, and dry pet food See Manufacturer's guidance \*\* N/A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size S021b GeneQuence\00ae Salmonella Salmonella spp. Neogen

Corporation AOAC-PTM # 030201 Dried whole egg, nonfat dry milk, cheese powder, raw pooled shell egg, raw ground pork, beef franks, raw ground turkey, raw ground chicken, raw fish fillet, surimi, dried fruit, fresh mushrooms, frozen fruit, black pepper, dry pet food, dry cake mix, shelled walnuts, semi-sweet chocolate, refrigerated cookie dough, soy flour, egg noodles food dye 25g S025 Microbiologique E. coli O157, Stx-producing Stx-producing E. coli IEH Laboratories & AOAC-PTM # 100701 Raw ground beef (25g, 375g), raw beef 25g except where E. coli (STEC) with Intimin and Salmonella (STEC) (026, O45, Consulting Group trim (25g, 375g), raw poultry (25g, noted in Test System O103, O111, O121 & 375g), RTE turkey (omitted for STEC) & \"Validated O145) with intamin, Salmonella mixed leafy greens (25g, 125g) Matrices\" S026 InstantLabs\|u00ae Salmonella Species Food Safety Kit Salmonella spp. InstantLabs Medical Diagnostics Corporation AOAC-PTM # 031202 Raw ground beef (375g), raw chicken breast, raw ground chicken, lettuce, rolled oats (750g), oat flour (750g), wheat flour (750g) 25g except where noted in \"Validated Matrices\" S027a iQ-Check Salmonella II Kit Salmonella spp. Bio-Rad Laboratories AFNOR # BRD 07\|06 - 07\|04 All human and animal food products, production environment samples, and animal faeces and environmental samples from the primary production stage 25g S027b iQ-Check\|u2122 Salmonella II Kit Salmonella spp. Bio-Rad Laboratories AOAC-PTM # 010803 cantaloupe (25 g), eggs (25 g), raw chicken (25g), raw ground chicken (375 g), raw beef (25 g), fresh raw ground beef (375 g), fresh raw beef trim (375 g), peanut butter (25 g), raw pork (25g), fresh spinach (25 g), fresh baby spinach (375 g), nonfat dry milk (375 g), whey powder (375 g), white chocolate (375 g), chocolate liquor (375 g), cannabis flower (>0.3% delta 9-tetrahydrocannabinol [THC]), ceramic (1x1 in), concrete (1x1 in), plastic (4x4 in), stainless steel (4x4 in), stainless steel (1x1 in environmental swabs with HICap Neutralizing Broth), dry dog food (25 g and 375 g), wet cat food, (25 g), ready-to-eat deli ham (375 g), milk chocolate (375 g), raw milk cheese (375 g), chicken carcass rinse (30 ml) 25g except where noted in \"Validated Matrices\" S027c iQ-Check Salmonella II Kit Salmonella spp. Bio-Rad Laboratories NordVal # 038 Meat products, dairy products, fishbased and vegetable products, egg products, animal feed, and environmental samples 25g S027d iQ-Check\|u2122 S. Enteritidis S. Enteritidis Bio-Rad Laboratories AOAC-PTM # 081903 25 g - raw chicken breast with skin, raw chicken breast without skin, raw chicken breast without skin containing 2% w\|w salt, raw chicken thigh with skin, raw chicken thigh without skin, 25g \*\* N\|A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size S027e iQ-Check\|u2122 S. Typhimurium S. Typhimurium Bio-Rad Laboratories AOAC-PTM # 081904 25 g - raw chicken breast with skin, raw chicken breast without skin, raw chicken breast without skin containing 2% w\|w salt, raw chicken thigh with skin, raw chicken thigh without skin, 25g S028 IRIS Salmonella\|u00ae Salmonella spp. SOLABIA SAS AFNOR # BKR 23\|07 - 10\|11 All human food products, animal feeding stuffs and production environment samples (except primary production stage environment) 25g S029 LOCATE\|u00ae Salmonella Assay Kit Salmonella spp. Rhone-Poulenc AOAC-OMA # 997.16 All foods 25g S031 Microgen GNA ID Salmonella spp.& E. coli Microgen Bioproducts Limited AOAC-PTM # 061101 Pure culture N\|A S032a MicroSEQ\|u00ae Salmonella spp. Salmonella spp. Life Technologies Corporation, Part of Thermo Fisher Scientific AFNOR # ABI 29\|02 - 09\|10 All human food products (including meat products) and animal feeding stuffs, animal feces, and environmental samples from primary production stage 25g S032b MicroSEQ Salmonella species Detection Kit Salmonella spp. Thermo Fisher Scientific AOAC-PTM # 031001 Raw ground beef, raw chicken

wings, raw shrimp, cantaloupe, brie, dry infant formula, chocolate, dry pet food, shell eggs, black pepper, peanut butter (25 g); stainless steel, sealed concrete, plastic, ceramic tile, rubber; 10-pooling Salmonella spp. for fresh diced tomatoes, chocolate, and deli ham; dry pet food (375 g) 25g except where noted in \"Validated Matrices\" S035 PATHATRIX Pooling System for Salmonella species Salmonella spp. Life Technologies (Part of Thermo Fisher Scientific) AOAC-PTM # 090203C Raw ground chicken, pasteurized liquid egg, raw ground beef, cooked sliced ham, milk powder, orange juice, black ground pepper, chocolate, soft cheese, produce, raw fish, lasagna (ready meal), cooked ham, raw whole egg, chocolate, milk powder, frozen prawns See \"Validated Matrices\" S036 Pathotec Cytochrome Oxidase Test MICRO-ID\u00ae Identification Kit Salmonella spp., E. coli , and other Enterobacteriaceae Remel AOAC-OMA # 989.12 N\A N\A S037 PDX-SIB Salmonella spp. Paradigm Diagnostics, Inc. AOAC-PTM # 071102 ceramic tile, stainless steel, plastic, and sealed concrete N\A S038a RAPID'Salmonella Salmonella spp. Bio-Rad Laboratories AFNOR # BRD 07\11 - 12\05 All human and animal food products and environmental samples (excluding those from primary production environment) 25g \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size S038b RAPID'Salmonella Salmonella spp. Bio-Rad Laboratories AOAC-PTM # 050701 Raw chicken breast, eggs, cantaloupe, and peanut butter 25g S038c RAPID'Salmonella Salmonella spp. Bio-Rad Laboratories NordVal # 032 Foods, animal feeds, and environmental samples 25g S039b RapidChek SELECT Salmonella Test Salmonella spp. Romer Labs Technology, Inc. AOAC-PTM # 080601 Liquid eggs, raw ground beef, raw ground chicken, chicken carcass rinsates (30ml), sliced cooked turkey, and environmental surfaces painted concrete (1x1 in), plastic (4x4 in), rubber (4x4 in), stainless steel 4x4 in, 12x12 in), ground beef (375g) 25g except where noted in \"Validated Matrices\" S040 RapidChek SELECT Salmonella Enteritidis Test System & RapidChek CONFIRM Salmonella Enteritidis Immunomagnetic Separation (IMS) Kit Salmonella Enteritidis and other D1 serovars Romer Labs, Inc. AOAC-PTM # 111002 Poultry house environmental drag swabs, egg pools, chicken carcass rinsates N\A S043a Reveal Salmonella 2.0 Detection of Salmonella belonging to group A (except Salmonella Paratyphi A) through group E Neogen Corporation AFNOR # NEO 35\01 - 10\11 Meat products, dairy products (except milk powders, egg products, seafood and vegetables (except dehydrated products) 25g S043b Reveal 2.0 for Salmonella Test System Salmonella enterica of serogroups A-E Neogen Corporation AOAC-PTM # 960801 raw ground beef, raw ground chicken, raw ground sausage, raw ground pork, cooked chicken, beef skin, pork skin, chicken rinse water, pickled crab meat, shrimp, fishmeal, liquid eggs, poultry feed, powdered milk, soybean meal, frozen whole eggs, chicken carcass rinse, raw ground turkey, raw ground beef, hot dogs, raw shrimp, ready-to-eat meal product, dry pet food, icecream, spinach, cantaloupe, peanut butter, sprout irrigation water, stainless steel N\A S044a RIDASCREEN Salmonella Salmonella spp. R-Biopharm AG AFNOR # RBP 31\01 - 06\08 All human food products, animal feed and environmental samples (except samples of primary production) 25g S045 Salmonella detection method by real-time PCR Salmonella spp. Eurofins NordVal # 041 Raw meat and swabs from beef and pork carcasses 25g S048 Salmonella PRECIS\u2122 Salmonella spp. OXOID Ltd AFNOR # UNI 03\06 - 12\07 All human and animal food products and environmental samples (excluding breeding samples) 25g S049 Salmonella Rapid Culture Method using ONE Broth Salmonella & Brilliance Salmonella Salmonella spp. Thermo Fisher Scientific AOAC-PTM # 120802 Ground beef, ground chicken, lettuce, shrimp &

shell eggs 25g S050 Salmonella -Tek ELISA Test System Salmonella spp. Organon Teknika Corp. AOAC-OMA # 993.08 All foods 25g S051 Salmonella -Tek Screen Kit Salmonella spp. Organon Teknika Corp. AOAC-OMA # 986.35 All foods 25g S052 Salmonella -Tek Screen Kit Salmonella spp. Organon Teknika Corp. AOAC-OMA # 987.11 All foods other than raw foods or foods with a high microbial load 25g \*\* N/A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size S054 SESAME Salmonella Test Salmonella spp. SOLABIA SAS AFNOR # BKR 23\04 - 12\07 All human and animal food products and environmental samples (with the exception of environment of primary production stage) 25g S055 Simple Method for Salmonella (SMS\u2122) Salmonella spp. bioM\u00e9rieux AFNOR # AES 10\04 - 05\04 All food products, animal feed and environmental samples (excluding rearing environment) 25g S056 Singlepath\u00ae Salmonella Salmonella spp. Merck KGaA AOAC-PTM # 060401 Dried skimmed milk, black pepper, dry pet food, desiccated coconut, cooked peeled frozen prawns , raw ground beef, raw ground turkey 25g S057b SureFast Salmonella PLUS Salmonella spp. CONGEN Biotechnologie GmbH AOAC-PTM # 041103 25 g - salami, pork minced meat, bacon, fresh ground chicken, fresh chicken carcass, frozen marinated chicken fillets, semi-skim milk powder, raw goat milk cheese, chocolate ice cream, salad with mayonnaise, paella, cream-based pastry, dehydrated poultry proteins, wheat-based flour, pet food pellets, raw ground beef frozen poultry meat, raw milk, fresh spinach, pasteurized liquid whole egg, pet food pellets 25g S060a TRANSIA PLATE Salmonella Gold Salmonella spp. BioControl Systems, Inc. AFNOR # TRA 02\08 - 03\01 Food, animal feeding stuffs and environmental samples (excluding breeding samples) 25g S060c Transia\u00ae Plate Salmonella Gold Salmonella spp. BioControl Systems, Inc. AOAC-PTM # 010602 Cooked chicken, raw milk, cantaloupe, sausages, raw shrimps, yogurt, mayonnaise, shell eggs, frozen berries, currants, bean sprouts, raw ground beef, smoked fish (trout), fresh pasta, milk chocolate, ground black pepper, cake mix, dry milk-based infant formula, dry cat food, raw ground turkey, brie cheese 25g S062a VIDAS Easy Salmonella Salmonella spp. bioM\u00e9rieux, sa AFNOR # BIO 12\16 - 09\05 All human and animal food products and environmental samples (except stock farming environment) 25g S062b VIDAS Salmonella (VIDAS SLM) Dual selective enrichment Salmonella spp. bioM\u00e9rieux, sa AFNOR # BIO 12\01 - 04\94 All human food products and pet food 25g S062c VIDAS Salmonella (VIDAS SLM) Single selective enrichment Salmonella spp. bioM\u00e9rieux, sa AFNOR # BIO 12\10 - 09\02 All human food products and pet food 25g S062d VIDAS\u00ae Salmonella (SLM) Assay Kit Salmonella spp. bioM\u00e9rieux, Inc. AOAC-OMA # 2004.03 Foods 25g S062e VIDAS\u00ae Salmonella (SLM) Assay Salmonella spp. bioMerieux Vitek, Inc. AOAC-OMA # 996.08 All foods 25g \*\* N/A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size S062f VIDAS\u00ae Salmonella (SLM) Assay method Easy SLM with ChromID\u2122 Salmonella (SM2) Agar Salmonella spp. bioM\u00e9rieux, sa AOAC-PTM # 020901 Turkey, roast beef, raw ground pork, pork sausage, raw chicken breast, raw peeled shrimp, raw cod, cantaloupe, ground black pepper, bagged spinach, pecans, peanut butter, ice cream, liquid eggs, whole milk, non-fat dry milk, orange juice, dry pasta, cake mix, dry pet food, spent irrigation water, dog food, cat food, dark chocolate, rubber (4x4"), concrete (1x1"), ceramic (1x1"), plastic (4'x4"), stainless steel (4'x4") Sample preparation and enrichment as per FSIS MLG Ch. 4 for meat/poultry/egg and environmental samples S062g VIDAS\u00ae Salmonella (SLM) Easy Salmonella Salmonella spp.

bioM\u00e9rieux, sa AOAC-OMA # 2011.03 Liquid egg, vanilla ice cream, spinach (frozen and fresh), raw shrimp, peanut butter, deli turkey, roast beef, raw ground pork, turkey, pork sausage, raw chicken breast, dry pet food, moist pet food, whole milk, raw cod, spent irrigation water, pecans, dry pasta, cake mix, ground black pepper, non-fat dry milk, dried egg yolk, dark chocolate, cantaloupe, and orange juice Sample preparation and enrichment as per FSIS MLG Ch. 4 or FDA BAM Ch. 5 S063a VIDAS\u00ae Immuno-Concentration Salmonella (ICS) Kit

Salmonella spp. bioM\u00e9rieux, sa AOAC-OMA # 2001.07 All foods 25g S063b VIDAS\u00ae Immuno-Concentration Salmonella (ICS) Kit and Selective Plate (HE BS XLD) Screening

Salmonella spp. bioM\u00e9rieux, sa AOAC-OMA # 2001.08 All foods 25g S063c VIDAS\u00ae Immuno-Concentration Salmonella (ICS) Kit and Selective Plate (HE BS XLD) Screening

Salmonella (SLM) EnzymeLinked Immunofluorescent Assay (ELFA) Salmonella spp.

bioM\u00e9rieux, sa AOAC-OMA # 2001.09 All foods 25g S065a VIDAS Up Salmonella

Salmonella spp. bioM\u00e9rieux, sa AFNOR # BIO 12/32 - 10/11 All human food products (except raw milk cheese), animal feeding stuffs and production environmental samples 25g

S065b VIDAS\u00ae UP Salmonella (SPT) Salmonella spp. bioM\u00e9rieux, sa AOAC-PTM # 071101 Raw ground beef (25g, 375g, 675g), deli roast beef, liquid eggs (25 g), powdered 25g except where noted in S065c VIDAS\u00ae UP Salmonella (SPT) Salmonella spp.

bioM\u00e9rieux, sa AOAC-OMA # 2013.01 Raw ground beef (25 and 375 g), processed American cheese (25 g), deli roast beef (25 g), liquid egg (25 g), peanut butter (25 g), vanilla ice cream (25 g), cooked shrimp (25 g), raw cod (25 g), bagged lettuce (25 and 375 g), dark chocolate (375 g), powdered eggs (25 g), instant nonfat dry milk (25 and 375 g), ground black pepper (25 g), dry dog food (375 g), raw ground turkey (375 g), almonds (375 g), chicken carcass rinsates (30 mL), and stainless steel, plastic, and ceramic 25g except where noted in \"Validated Matrices\" S066 VIP Gold for Salmonella Assay Salmonella spp. BioControl Systems, Inc. AOAC-OMA # 999.09 All foods 25g \*\* N/A = Not available", "# Method Name Target Organism(s)

Manufacturer External Validation Validated Matrices Validated Test Portion Size S067 Vitek GNI+ Screening System Salmonella spp. and other Enterobacteriaceae bioM\u00e9rieux, sa AOAC-OMA # 991.13 N/A N/A S068 Vitek\u00ae 2 Gram-Negative (GN) Biochemical Identification System Gram-negative bacteria bioM\u00e9rieux, Inc. AOAC-OMA # 2011.17 N/A N/A S069 QIAGEN mericon Salmonella spp Salmonella spp. QIAGEN GmbH AFNOR # QIA 36/01 - 02/13 All human food products, animal feed and environmental samples (except primary production stage environment) 25g S070b Solus Scientific Salmonella ELISA Salmonella spp. Solus Scientific Ltd. AOAC-PTM # 051601 Raw chicken breast, raw salmon filet, bagged romaine lettuce, shredded cheddar cheese, instant non-fat dry milk, shell eggs, raw beef trim (375g), stainless steel environmental surface (swab, 1 x 1 in), polystyrene, environmental surface (sponge, 4 x 4 in) 25g except where noted in \"Validated Matrices\" S071 Atlas Salmonella G2 Detection Assay Salmonella enterica subspecies: enterica, diarizonae, arizonae, houtenae, indica, salamae Roka Biosciences, Inc. AOAC-PTM # 041303 Fresh raw ground beef (25g, 375g), fresh raw ground turkey (375g), cooked deli turkey (325g), romaine lettuce (375 g), oat cereal, environmental surfaces (stainless steel, plastic, sealed concrete), peanut butter, raw almonds, string cheese, milk chocolate, cocoa powder, raw cookie dough, soy flour, whey powder, tomatoes, instant non-fat dried milk, chicken carcass rinse, pasteurized dried whole egg 25g except where noted in \"Validated Matrices\" S072a Thermo Scientific SureTect Salmonella species PCR Assay Salmonella spp. Oxoid Ltd. Part of Thermo Fisher Scientific AOAC-

PTM # 051303 (25 g; 1:10) Raw, ground: beef, pork frankfurters, raw chicken breast, bagged lettuce, non-fat dried milk powder, cooked shrimp, chilled ready-to-eat dinner, pasteurized liquid whole egg and stainless steel (4in x 4in, sponge), wet cat food, dry dog food, pasteurized 2% milk, bean sprouts, cantaloupe, chilled pizza dough, black peppercorns, peanut butter, ice cream, plastic surface, dark chocolate (85% cocoa solids), 20% fat raw ground beef (375g) 25g except where noted in \"Validated Matrices\" S072b Thermo Scientific SureTect Salmonella species PCR Assay Salmonella spp. OXOID Ltd, Part of Thermo Fisher Scientific AFNOR # UNI 03\07 - 11\13 Non-seasoned raw ground beef meat 25g S073a 3M \u2122 Petrifilm\u2122 Salmonella Express (SALX) System Salmonella spp. 3M Company (3M Food Safety) AOAC-PTM # 061301 Raw ground beef, raw ground pork, raw ground chicken, cooked chicken nuggets (325g), pasteurized liquid whole egg (100g), frozen uncooked shrimp, fresh bunched spinach, dry dog food (375g), stainless steel (sponge) 25g except where noted in \"Validated Matrices\" \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size S073b 3M\u2122 Petrifilm\u2122 Salmonella Express System Salmonella spp. 3M Food Safety AOAC-OMA # 2014.01 Raw ground beef, raw ground chicken, pasteurized liquid whole egg (100g), raw ground pork, cooked chicken nuggets (325g), frozen uncooked shrimp, fresh bunched spinach, dry dog food (375g) and stainless steel 25g except where noted in \"Validated Matrices\" S074 mericon\u2122 Salmonella spp. Kit Salmonella spp. Qiagen GmbH AOAC-PTM # 071204 Fresh raw ground beef (25g), chicken carcass rinses, creamy non-organic 25g S075a BAX\u00ae System Real-Time PCR Assay for Salmonella Salmonella Hygiena AOAC-PTM # 081201 AOAC-OMA 2003.09 Raw ground beef (25g, 375g), chicken carcass rinse (30mL), cream cheese (25g), bagged lettuce (25g), raw comminuted chicken (325g), turkey (325g), dry pet food (375g), and stainless steel, dry pet food, milk chocolate, chocolate liquor, cocoa powder, shell egg, stainless steel, plastic 25g except where noted in \"Validated Matrices\" S075b BAX\u00ae System Real-Time PCR Assay for Salmonella Salmonella spp. DuPont Nutrition & Health Diagnostics AOAC-OMA # 2013.02 Raw ground beef (25g and 375g), ground beef with soy (25g and 325g), beef trim (25g and 325g), frankfurters (325g), shrimp, ground turkey, chicken wings, poultry rinse (30mL), whole powdered (dried) eggs, shell eggs (1000mL), fresh bagged lettuce, frozen peas, orange juice (pasteurized; 25mL), cream cheese, nonfat dry milk, ice cream, peanut butter, cocoa, white pepper, milk-based infant formula (25mL), dry pet food (375g), and on stainless steel, ceramic tile, and plastic 25g except where noted in \"Validated Matrices\" S075c BAX System Real-Time PCR Assay for Salmonella spp. Salmonella spp. DuPont Qualicon AFNOR # QUA 18\08 - 03\15 Meat products (including raw beef), egg products, vegetables, seafood, and pet food 25g S076 Pathatrix\u00ae Auto Salmonella spp Kit Linked to Selective Agar Detection Salmonella spp. Life Technologies Corporation, Part of Thermo Fisher Scientific AFNOR # ABI 29\06 - 11\13 Cooked meat products and raw beef meat, heat treated milk and dairy products N\A S077 Pathatrix Auto Salmonella spp. Kit Linked to MicroSEQ\u00ae Salmonella spp. Detection Kit Salmonella spp. Life Technologies Corporation, Part of Thermo Fisher Scientific AFNOR # ABI 29\07 - 11\13 Cooked meat products and raw beef meat, heat treated milk and dairy products See Manufacturer's guidance S078 ANSR\u00ae Salmonella Confirmation Test Salmonella spp. Neogen Corporation AOAC-OMA # 2013.14 N\A N\A S079 Actero\u2122 Salmonella \u2225 STEC Enrichment Media Salmonella spp.\u2225 STEC FoodChek System Inc. AOAC-PTM # 041403 Raw ground beef (325 g), liquid whole egg (100 g), raw ground chicken (25 g), raw frozen scallops

(25 g), sprouts (25 g), and Environmental surfaces (stainless steel (1 x 1 in), plastic, rubber (1 x 1 in), ceramic tiles(1 x 1 in), sealed concrete(1 x 1 in) See \"Validated Matrices\" \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size S082a foodproof Salmonella spp. method 5'Nuclease or hybridization probes (liquid and lyophilized), automated protocol Salmonella spp. BIOTECON Diagnostics Gm MicroVal # 2011LR40 Meat and Meat products (raw beef meat 375g), Milk and dairy products, Egg products, Feed samples Liquid kit: chocolate and bakery products, meat and meat products, milk and dairy products, egg products, raw beef meat 375 g and feed samples Lyophilized kit: broad range of foods (chocolate and bakery products, meat and meat products, milk and dairy products, egg products, fish and f d d t ) d f d l 25g except where noted in \"Validated Matrices\" S082b foodproof Salmonella spp method Manual protocol Salmonella spp. BIOTECON Diagnostics Gm MicroVal # 2011LR42 Food, feed and primary production samples, raw beef meat (375g) 25g except where noted in \"Validated Matrices\" S083 Veriflow Salmonella species Salmonella spp. Invisible Sentinel AOAC-PTM # 011404 beef hot dogs, raw ground beef (20% fat), chicken carcass rinse, pasteurized milk (2%), stainless steel, ceramic tile, sealed concrete, and plastic, peanut butter, ground black pepper (25 g), whey protein isolate powder (25 g) N\A S084 Hygiena Lateral Flow System for Salmonella AD (not sold in the US \u2013 international only) Salmonella spp. Qualicon Diagnostics LLC, a Hygiena Company AOAC-PTM # 021001 Raw ground beef, raw ground chicken, sliced cooked turkey, chicken carcass rinses, liquid eggs 25g S085b GENE-UP Salmonella Salmonella spp. bioM\u00e9rieux, sa AFNOR # BIO 12\38 - 06\16 All human food products, except raw milk products, by conducting validation assays on a broad range of food and environmental samples excluding environment of primary production stage 25g S086a BACGene Salmonella spp. Salmonella spp. Eurofins GeneScan GmbH AFNOR # EGS 38\01 - 03\15 All human food products, feed products, pet foods (375g), production environmental samples, milk powders and infant formula without probiotics (50g-375g) 25g except where noted in \"Validated Matrices\" \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size S086b BACGene Salmonella spp. Salmonella spp. Eurofins GeneScan GmbH AOAC-PTM # 121501 fresh raw ground beef (15% fat, 25 g), frozen spinach (25 g), pasteurized whole liquid egg (25 mL), frozen cod fillet (25 g), raw whole milk (25 mL), dog p\u00e9t\u00e9e (composed of beef meat and animal by-products, cereals, carrots and vegetable bi-products, 375 g), dry dog pellets (25 g), infant formula milk powder supplemented with probiotics (*Bifidus lactis*) (375 g), process water from scalding tank (25 ml), and stainless steel environmental surface (1\" x 1\" area), cocoa butter (375 g), cocoa liquor (375 g), cocoa powder (375 g), milk chocolate (375 g), raw ground beef (375 g), raw ground pork (250 g), marinated raw chicken with brine (250 g), cotton swabs for swabbing 100 cm<sup>2</sup> of pork carcasses, ice cream (25 g), dry pet food (375 g), ceramic tiles (4\"x4\"), 25g except where noted in \"Validated Matrices\" S087a 3M Molecular Detection Assay 2 (MDA 2) - Salmonella Salmonella 3M Food Safety AOAC-PTM # 091501 Raw ground beef (73% lean, 25g & 325g), raw ground chicken (25g & 325g), chicken carcass rinse (30mL), chicken carcass sponge, pasteurized liquid whole egg (100g), cooked breaded chicken (325g), instant non-fat dry milk (25 g), black pepper (25 g), cocoa powder (25 g), raw whole shrimp (25 g), raw bagged spinach (25 g), creamy peanut butter (25g & 375g), dry dog food (25g & 375g), pasteurized processed American cheese (25 g), spent sprout irrigation water (375mL), and environmental surfaces

sealed concrete (sponge, 225 mL enrichment broth), stainless steel (10 mL enrichment broth), and sealed ceramic tile (sponge, 50 mL enrichment broth), See \"Validated Matrices\" \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size S087b 3M Molecular Detection Assay 2 - Salmonella Method Salmonella spp. 3M Food Safety AOAC-OMA # 2016.01 Raw ground beef (73% lean, 25g & 325g), raw ground chicken (25g & 325g), chicken carcass rinse (30mL), chicken carcass sponge, pasteurized liquid whole egg (100g), cooked breaded chicken (325g), instant non-fat dry milk, black pepper, cocoa powder, raw whole shrimp, raw bagged spinach, creamy peanut butter (25g & 375g), dry dog food (25g & 375g), pasteurized processed American cheese, spent sprout irrigation water (375mL), and environmental surfaces (sealed concrete, stainless steel, and sealed ceramic tile) 25g except where noted in \"Validated Matrices\" S088 Salmonella ELISA Test OPTIMA Salmonella spp. Eurofins GeneScan GmbH AOAC-PTM # 960901 Contact Manufacturer 25g S090 Reveal 2.0 Group D1 Salmonella (including Salmonella Enteritidis) Group D1 Salmonella Neogen Corporation AOAC-PTM # 041602 Raw shell eggs (20 shells), poultry feed (25g), chicken carcass rinse (30ml) 25g S091 Crystal Diagnostics AutoXpress AXSLM Test Kit (formerly Xpress S) Salmonella spp. Crystal Diagnostics Corporation AOAC-PTM # 051602 whole raw tomatoes, whole chicken rinsate, raw ground beef (325 g), raw beef trim (325 g), liquid whole eggs (100 g) N\A S092 Salmonella Velox spp. And Salmonella Salmonella spp. DNA Diagnostic A\S NordVal # 046 raw meat (25-125g), chicken, fish and 25g except where Velox SE + ST seafood, minced meat (25-100g) noted in \"Validated Matrices\" S093 SALMA One Day Salmonella spp. bioM\u00e9rieux AFNOR # BIO 12\41 - 03\17 All human food products (by performing validation assays on a broad range of foods), feed products and production environmental samples and surface areas (excluding environment from primary production stage) 25g S094 3M\u2122 Molecular Detection Assay 2 - Salmonella Salmonella spp. 3M Health Care AFNOR # 3M 01\16 - 11\16 All human food products (by concluding validated assays on a broad range of foods) and production environmental samples (excluding primary production samples) 25g S096 Thermo Scientific RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit Salmonella species, Salmonella ser. Typhimurium and Salmonella ser. Enteritidis Oxoid Ltd. Part of Thermo Fisher Scientific AOAC-PTM # 081701 (25 g) Raw chicken thighs with skin, raw chicken wings with skin, chicken nuggets, raw pork sausage, stainless steel environmental surface (4in x 4in sponge), raw ground turkey (375g), chicken carcass rinse shell eggs 25g except where noted in \"Validated Matrices\" \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size S097 GDS Salmonella Tq detection Kit for the detection of Salmonella spp. Salmonella spp. Merck MiliporeSigma MicroVal # 2015LR50 Raw beef meats, delicatessen and heat treated meat products (with 25 g sampling), Dairy products (with 25 g sampling), Fruits and vegetables (with 25 g sampling), Environmental samples (with 25 g or surface sampling), Raw beef meats (with 375 g sampling), raw poultry meats (25g) See \"Validated Matrices\" S098 iQ-Check Salmonella II Real-Time PCR test kit Salmonella spp. Bio-Rad (Hercules, CA, USA AOAC-OMA # 2017.06 375 g test portions of raw ground chicken, ready-to-eat (RTE) deli ham, dry dog food, milk chocolate, raw milk cheese, to chicken carcass rinse (30 mL), to 25 g test portions of whole eggs, raw ground beef, raw ground chicken, cantaloupe, peanut butter, raw chicken breast, raw pork, fresh spinach, dry dog food, wet cat food, and to environmental samples from stainless steel, ceramic, plastic, and sealed t See \"Validated

Matrices\" S099 PDX-STEC Shiga toxin-producing E. coli (STEC) Salmonella spp. Paradigm Diagnostics, Inc. AOAC-PTM # 101705 Raw beef trim 325g 325 g S100 VereBeef Detection Kit (8-20 hr) Escherichia coli O157:H7, STEC virulence factors (stx1A or stx2A and eae) (10-20 hr) Escherichia coli O26, O45, O103, O111, O121, O145, Salmonella spp. Veredus Laboratories Pte, Ltd. AOAC-PTM # 011801 Raw beef trim (25 g, 325 g, 375 g) See \"Validated Matrices\" S102 VIP Gold Salmonella Salmonella spp. BioControl Systems, Inc. AOAC-PTM # 031801 raw spinach, raw fresh pasta noodles, raw almonds, stainless steel, plastic sealed concrete, chicken carcass rinsate, ready-to-eat poultry, roast beef N\A S103 PolySkope One Multiplex Detection Assay STECs, E. coli O157:H7 & Non-O157 STEC Big 6 (O26,O45,O103,O111,O 121,O145), Listeria monocytogenes, Salmonella species PolySkope Labs AOAC-PTM # 041801 (25g) Fresh raw ground beef (73% lean), deli turkey, fresh baby spinach, stainless steel (4x4 in sponge) See \"Validated Matrices\" S104 GENE-UP enviroPRO (formerly enviroPRO) Listeria species, Salmonella species Invisible Sentinel Inc. AOAC-PTM # 061801 Stainless steel environmental surfaces (4x4\" squares), whey powder; Salmonella 375 g, Listeria 125 g - pea powder, cookie dough raw ground turkey (100 g), chicken carcass rinsate (40 ml), raw beef trim (100 g) carcass sampling cloth N\A \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size S105 SureFast Salmonella ONE Salmonella species Congen Biotechnologie GmbH AOAC-PTM # 081803 25g - salami, pork minced meat, bacon, fresh ground chicken, fresh chicken carcass, frozen marinated chicken See \"Validated Matrices\" fillets, semi-skim milk powder, raw goat milk cheese, chocolate ice cream, salad with mayonnaise, paella, cream-based pastry, dehydrated poultry proteins, wheat-based flour, pet food pellets, raw ground beef, frozen poultry meat, raw milk, fresh spinach, pasteurized liquid whole egg, pet food pellets S106 Solus Salmonella ELISA Salmonella spp. Solus Scientific (part of PerkinElmer Inc.) AFNOR # SOL 37\01 - 06\13 All human and food products (by performing validation assays on a broad range of foods), feed products and production environmental samples(excluding primary production environmental samples ) N\A S107 MALDI Biotyper complete solution for the confirmation of Salmonella spp. Salmonella spp. Bruker Daltonik GmbH MicroVal # 2017LR73 Only pure cultures\isolates N\A S108 SureFast Salmonella ONE Salmonella spp. CONGEN Biotechnologie GMBH MicroVal # 2014LR43 A broad range of foods (poultry meat, meat products, dairy products, vegetables, (excluding sprouts) egg products, and feed) N\A S109 Bruker MALDI Biotyper Method Salmonella spp., Campylobacter spp. Bruker Daltonik GmbH, Bremen, Germany AOAC-OMA # 2017.09 Only pure cultures\isolates N\A S110 Solus One Salmonella Salmonella species (Salmonella enterica and Salmonella bongori, and Salmonella subspecies) Solus Scientific AOAC-PTM # 101801 Raw beef trim (>30% fat content, 375 g), pasteurized liquid egg (100 g), raw salmon (fillet, 25 g), cheddar cheese (shredded, 25 g), Romaine lettuce (bagged, 25 g), non-fat dry milk powder (NFDM, 375 g), stainless steel (18 gauge: 304 food grade with a brushed finish) and plastic (polystyrene) environmental surface,cocoa powder (375g), cocoa liquor (375g), milk chocolate bar (375g), honey mustard seasoning and flavored ranch seasoning, cinnanom powder, paprika powder, whole black peppercorns See \"Validated Matrices\" \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size S111 GENE-UP\u00ae Salmonella 2 (SLM 2) Salmonella spp. bioM\u00e9rieux, s.a. AOAC-PTM # 121802 liquid whole egg (25 g), cooked ham (25 g), raw ground beef (25 g), raw chicken (25 g), lettuce (25 g), chocolate (25 g), dry pet food (25 g, 375

g), Stainless steel (4 x 4 in sponge), Fresh raw ground beef 20% fat (25 g, 375 g), fresh raw chicken breast (25 g), fresh raw fish, creamy peanut butter (25 g, 375 g), vanilla ice cream (25 g), chicken carcass rinse (30 mL), raw ground chicken (25 g), Raw beef trim (375 g), raw ground pork (375 g), raw ground bison (375 g), pasteurized liquid egg (100 g), powdered egg (100 g), whey protein powder (375 g), dark chocolate (375 g), garlic powder (375 g), bulk bagged romaine lettuce (375 g), milk chocolate (NFDM with 0.1% brilliant green 25 g; 375 g), milk chocolate (NFDM, 25 g), dark chocolate (BPW at 36\u00b0C, 375g), dry dog kibble (375 g) turmeric powder (375 g), whole cannabis flower (10g 1g) whole hemp 25g except where noted in \"Validated Matrices\" S112 Clear Safety Salmonella Salmonella enterica Clear Labs, Inc.

AOAC-PTM # 111802 Raw ground chicken (375 g), ready-to-eat deli turkey breast (375 g), chicken carcass rinse (30 mL) dry pet food (375 g), stainless steel (sponge). See \"Validated Matrices\" S113 QFast Salmonella Salmonella spp. iMICROQ, S.L. AENOR # B59\|000001 Veterinary samples originating from the poultry industry. Samples of animal food.

Environmental samples originating from primary production (poultry industry). General Food: fruits and vegetables, dairy products and various products, including spices, mayonnaise and eggs; and meat 25 g S114 QFast Salmonella Easy Salmonella spp. iMICROQ, S.L. AENOR # B59\|000002 Animal feed samples, Veterinary samples (faeces, shoe covers, necks),

Environmental samples originating from primary production (poultry industry), General Food: fruits and vegetables, dairy products and various products, including spices, mayonnaise and eggs; and meat 25 g S115 Solus One Salmonella Salmonella spp. Solus Scientific (part of PerkinElmer Inc.) AFNOR # SOL 37\|04 - 12\|18 Ready-to-eat and ready-to-reheat (excluding smoked products), heat processed milk and dairy products, and egg products N\|A S116 Thermo Scientific\u2122 RapidFinder\u2122 Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit Salmonella spp., S. Typhimurium and S. Enteritidis Oxoid Ltd, Part of Thermo Fisher Scientific AFNOR # UNI 03\|12 - 01\|18 Raw pork and raw poultry meat, ready-to-eat and ready-to-reheat pork and poultry meats and production environmental samples (excluding environment from primary production) N\|A \*\* N\|A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size

S117 BACSpec Salmonella 2 Salmonella spp. Eurofins GeneScan Technologies GmbH AOAC-PTM # 111903 Mayonnaise-based vegetable salad, ground beef (fat content approx 20%), raw milk (fat content approx 4%), fresh spinach, pasteurized liquid egg, dry pet food, stainless steel (304L) surface (1\"x1\"), sealed ceramic tile surface (4'x4') 25g except where noted in

\"Validated Matrices\" S118 Simultaneous Multiplex Real Time PCR (SIMUL-qPCR) Salmonella Assay Salmonella spp. Applied Food Diagnostics AOAC-PTM # 042001 Raw beef trim (375g, 80% lean), raw ground beef (375g, 80% lean), raw ground poultry (375g), ready-to-eat cooked poultry (375g), pasteurized liquid eggs (100g), frankfurters\|sausages (25g), poultry carcass rinses, dry pet food (375g), peanut butter (25g), stainless steel (4\"x4\", 1\"x1\"), plastic (1\"x1\"), rubber (1\"x1\"), ceramic tile (1\"x1\"), and sealed t (1\" 1\") See \"Validated Matrices\" S119 Simultaneous Multiplex Real Time PCR Salmonella spp. Applied Food

Diagnostics AOAC-PTM # 042002 Stainless steel (1\"x1\"), plastic (1\"x1\"), See \"Validated (SIMUL-qPCR) Salmonella Assay rubber (1\"x1\"), ceramic tile (1\"x1\"), and Matrices\" sealed concrete (1\"x1\") S120 PhageDx Salmonella Assay Salmonella spp. Laboratory Corporation of America AOAC-PTM # 121904 Raw ground turkey, powdered infant formula (milk-based) See \"Validated Matrices\" S121 Salmonella species DNA Test Kit Salmonella spp. BioChek (UK) Ltd.

AFNOR # BCK 40\01 - 07\19 Ready to eat and ready to re-heat foods, meat products, ingredients and specific foods, feed products, production environmental samples and primary production samples N\A S122 GENE-UP\u00ae Salmonella (SLM) Test Method Salmonella spp. bioM\u00e9rieux, Inc. AOAC-OMA # 2020.02 25 g test portions of fresh raw ground chicken, fresh raw chicken breast, fresh See \"Validated Matrices\" raw ground beef (80% lean), cooked ham, liquid whole egg, fresh raw fish, lettuce, creamy peanut butter, vanilla ice cream, dry pet food and milk chocolate; for 30 mL test portions of chicken carcass rinse; for 100 g test portions of pasteurized liquid eggs and powdered egg; for 375 g test portions of fresh raw ground beef (80% lean), raw beef trim, raw ground pork, raw ground bison, whey protein powder, dry pet food, creamy peanut butter, garlic powder, bulk bagged Romaine lettuce, dark chocolate and milk chocolate; for stainless steel environmental sponges \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size S123 Solus One Salmonella Salmonella spp. Solus Scientific AOAC-OMA # 2020.03 Raw beef trim (375 g), instant nonfat dry milk powder (NFDM; 375 g), pasteurized liquid egg (100 g), raw salmon (25 g), cheddar cheese (25 g), romaine lettuce (25 g), honey mustard onion season (375 g), flavored ranch seasoning (375 g), cinnamon powder (25 g), paprika powder (25 g), and whole black peppercorns (25 g) and two environmental surfaces (stainless steel: sponges and polystyrene: swabs). See \"Validated Matrices\" S124 One Broth One Plate for Salmonella (OBOPS) Salmonella spp. Neogen Corporation MicroVal # 2019LR88 Environmental samples, Feed samples, A broad range of foods See \"Validated Matrices\" S125 One Broth One Plate Salmonella (OBOP Salmonella ) Salmonella enterica, bongori Neogen Corporation AOAC-PTM # 102002 Raw groud turkey (25 g) chicken carcass rinse (whole carcass), pasteurized liquid egg (100 g), queso fresco (25 g), smoked salmon (25 g), cantalope (25 g), dry pet food (25 g and 375 g), chocolate (25 g and 325 g), black pepper (25 g), chili powder (25 g), sponge samples from stainless steel surfaces (4in x 4in) See \"Validated Matrices\" S126 EnviroX-F Salmonella spp. PathogenDx AOAC-PTM # 092001 WorldBio PUR-BlueTM Swabs in 5 mL of Hi-Cap broth - Environmental Surface Swabs (4in x 4in): Stainless Steel, Plastic (polystyrene), Rubber, and Sealed Concrete See \"Validated Matrices\" S127 SMARTCHEK Salmonella spp. Detection Kit Salmonella spp. Genesystems Co. Ltd. AOAC-PTM # 032102 bagged romaine lettuce (25 g), smooth See \"Validated for GENECHECKER UF=300 Real-Time peanut butter (25 g), liquid whole egg Matrices\" PCR System (100 ml), chicken carcass rinse, raw ground chicken (25 g) S128 Salmonella CANARY Zephyr Salmonella enterica Smiths Detection AOAC-PTM # 042201 1\"x1\" test area - stainless steel, silicone rubber (FDS-grade), high density polyethylene (HDPE), and glazed See \"Validated Matrices\" S129 TAAG F41 VIP - Listeria monocytogenes , Salmonella spp., Escherichia coli and Staphylococcus aureus L. monocytogenes , Salmonella spp., S. aureus , and generic E. coli TAAG Genetics, S.A. AOAC-PTM # 072101 Environmental surface:18 GA 300 series, brushed finish, NSF certified stainless steel (100 cm<sup>2</sup> test area) and pasteurized 2% fat liquid milk (25 ml) See \"Validated Matrices\" S130 Pathatrix Salmonella spp. Kits Linked to Selective Agar Detection Salmonella spp. Life Technologies AFNOR # ABI 29\06 - 11\13 raw beef meats (fresh and frozen, seasoned or not), heat-treated milk and dairy products\u201d and \u201ccocoa and cocoa products N\A S131 3M Molecular Detection Assay Salmonella Salmonella spp. 3M Health Care AFNOR # 3M 01\11 - 11\12 All human food products and production environment samples (except primary production environment samples) N\A \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation

Validated Matrices Validated Test Portion Size S132 BACSpec Salmonella 2 Salmonella spp. Eurofins GeneScan Technologies AFNOR # EGS 38\07 - 12\20 All human food products (by performing validation assays on a broad range of foods), feed products and industrial production environmental samples N\A S133 foodproof Salmonella Genus plus Enteritidis and Typhimurium Detection LyoKit Salmonella spp., Salmonella Enteritidis and Salmonella Typhimurium BIOTECON Diagnostics GmbH NordVal # 055 raw and ready to cook meat and poultry products and environmental samples See \"Validated Matrices\" S134 Ancera PIPER\u2122 Salmonella Detection Kit Salmonella enterica spp. Ancera Inc. AOAC - PTM# 122203 Raw ground poultry (25 g), poultry carcass rinse (30 mL), poultry feed (25 ) N\A S135 BACGene Salmonella spp. PLUS Salmonella spp. Eurofins GeneScan Technologies GmbH AOAC-PTM # 102101 stainless steel (type 316L), plastic (polypropylene), creamy peanut butter, dry dog food, cocoa powder, cocoa liquor, cocoa butter, milk, chocolate, whole milk powder N\A S136 N-Light Salmonella Risk Salmonella spp. NEMIS Technologies AG AOAC-PTM # 072204 Stainless steel (AISI 304, grade 2b finish), plastic (polystyrene), ceramic (glazed earthen), 1\" x 1\" test areas N\A S137 3M Environmental Scrub Sampler with 10 mL Wide Spectrum Neutralizer Salmonella spp. and Listeria spp. 3M Food Safety AOAC-PTM # 022104 Stainless steel, sealed concrete and plastic environmental surfaces 4\"x4\" N\A S135 BAX System PCR Assay Salmonella spp. 2 Salmonella spp. Hygenia LLC. AFNOR # QUA 18\03-11\02 All human food products (by performing validation assays on a broad range of foods), feed products and industrial production environmental samples N\A \*\* N\A = Not available","Foodborne Pathogen Test Kits Validated by Independent Organizations FSIS is making available a list of test kits that have been validated for detection of relevant foodborne pathogens (i.e., Salmonella, Campylobacter, Listeria spp. including L. monocytogenes, E. coli O157:H7 and non-O157 STEC). The list is intended to be informational and is not an endorsement or approval of any specific test kit, regardless of its inclusion in the list. FSIS does not specifically endorse any of the mentioned test kits or products and acknowledges that equivalent test kits or products may be available for laboratory use. Likewise, FSIS does not require the use of any specific test kit, including those incorporated into FSIS\u2019s Microbiology Laboratory Guidebook methods. Instead, establishments and laboratories should choose test kits that are: 1)Validated for testing relevant foods by a: a) Recognized independent body (i.e., AOAC, AFNOR, MicroVal, NordVal), b) U.S. regulatory body (i.e., FSIS MLG or FDA BAM), or c) International Organization for Standardization (ISO) process 2)In addition, the validated method should be: a)Fit for the intended purpose and application (e.g., validated for the appropriate matrix and sample size to detect the appropriate foodborne pathogen), and b)Performed per the conditions of the validated protocol by a laboratory that assures the quality of the analytical results. The table below contains a list of foodborne pathogen test kits that are validated by recognized independent organizations (i.e., AOAC, AFNOR, MicroVal, NordVal) and therefore meet criterion 1a above. However, the test kits in this list are not necessarily equivalent or appropriate for all testing applications. FSIS intends to update validated test kit lists on a quarterly basis. # Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size C002 BAX System Real-Time PCR Assay for Campylobacter jejuni, coli, and lari Campylobacter jejuni; Campylobacter coli; Campylobacter lari Qualicon Diagnostics LLC, a Hygiena Company NordVal # 039 Faeces on cloacae swabs (levels above 100 cfu\g) N\A C003 BAX\u00ae System Real-Time PCR Assay for Campylobacter jejuni, coli, and lari Campylobacter

jejuni; *Campylobacter coli*; *Campylobacter lari* Qualicon Diagnostics LLC, a Hygiena Company AOAC-PTM # 040702 Ready-to-eat turkey product & chicken carcass rinses 25g, 30mL C004a *CampyFood Agar (CFA)* *Campylobacter* spp. bioM\u00e9rieux AFNOR # BIO 12\30 - 05\10 Meat products and production environment samples 25g C004b *CampyFood Agar (CFA)* *Campylobacter* spp. bioM\u00e9rieux, sa AOAC-PTM # 071201 fresh raw pork, raw chicken breast, processed chicken nuggets, chicken carcass rinsate, turkey carcass sampled with sponge 25g C004c *CampyFood*\u00ae agar method *Campylobacter* spp. bioM\u00e9rieux MicroVal # 2009LR28 Poultry products, meat products, environmental samples 25g C005 *Campylobacter* real-time PCR *Campylobacter* spp. Eurofins Genescan NordVal # 017 Chicken raw meat, faeces on cloacae swabs, disposal shoe covers with chicken feces N/A C007 iQ-Check *Campylobacter* Real-Time PCR *Campylobacter jejuni*; *Campylobacter coli*; *Campylobacter lari* Bio-Rad Laboratories AOAC-PTM # 031209 Chicken carcass rinse, turkey carcass sponge, raw ground chicken breast 25g, 30mL C008 Brilliance\u2122 *CampyCount Agar* *Campylobacter* spp. Thermo Fisher Scientific MicroVal # 2008LR12 Poultry products N/A \*\* N/A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size C009 Singlepath *Campylobacter* *Campylobacter jejuni*; *Campylobacter coli* Merck KGaA AOAC-PTM # 120401 25 g - raw ground chicken, raw ground turkey, pasteurized milk 25g C010 Veriflow *Campylobacter* *Campylobacter jejuni* and *Campylobacter coli* Invisible Sentinel, Inc. AOAC-PTM # 101201 Chicken carcass rinse N/A C011a VIDAS\u00ae *Campylobacter* (VIDAS CAM) *Campylobacter* spp. bioM\u00e9rieux AFNOR # BIO 12\29 - 05\10 Meat products and production environment samples 25g C011b VIDAS *Campylobacter* (CAM) *Campylobacter* spp. bioM\u00e9rieux, sa AOAC-PTM # 051201 fresh raw pork, raw chicken breast, processed chicken nuggets, chicken carcass rinsate, turkey carcass sampled with sponge 25g C012 RAPID' *Campylobacter* *Campylobacter* spp. Bio-Rad AFNOR # BRD 07\25 - 01\14 Meat and meat products Poultry and poultry products Environmental samples N/A C013 ANSR for *Campylobacter* *Campylobacter jejuni*; *Campylobacter coli*; *Campylobacter lari* Neogen Corporation AOAC-PTM # 071601 chicken carcass rinse and turkey carcass sponge N/A C015 Tadpole *Campylobacter* *Campylobacter jejuni* Real-Time PCR Identification Kit *Campylobacter* *Campylobacter jejuni* Suzhou Tadpole Biotechnology Co., Ltd. AOAC-PTM # 081804 Only pure cultures\isolates N/A C016 MALDI Biotyper\u00ae complete solution for the confirmation of *Campylobacter* spp. *Campylobacter* spp. Bruker Daltonik GmbH MicroVal # 2017LR74 Only pure cultures\isolates N/A C018 Bruker MALDI Biotyper Method *Salmonella* spp., *Campylobacter* spp. Bruker Daltonik GmbH, Bremen, Germany AOAC-OMA # 2017.09 Only pure cultures\isolates N/A C019 3M Molecular Detection Assay 2 *Campylobacter* (MDA2-CAM) *Campylobacter* *Campylobacter jejuni*, *C. lari* and *C. coli* 3M Food Safety AOAC-PTM # 111803 Chicken carcass rinse samples, poultry parts rinse samples, raw ground chicken (325g), turkey carcass sponge samples and ready-to-eat, breaded chicken nuggets (25g) See \"Validated Matrices\" C020 Tempo\u00ae Cam *Campylobacter* spp. bioM\u00e9rieux, sa AFNOR # BIO 12\43 - 04\20 Raw poultry, ready-to-eat poultry products N/A C020 Tempo CAM (*Campylobacter*) *Campylobacter* *Campylobacter jejuni*, *C. lari* and *C. coli* bioM\u00e9rieux, sa AOAC-PTM # 112002 raw ground chicken (325 g), raw chicken liver (325 g), raw ground turkey (25 g), chicken carcass rinse (30 ml), turkey carcass sponge See \"Validated Matrices\" C021 GENE-UP *Campylobacter* (CAM) *Campylobacter* *Campylobacter jejuni*, *C. lari* and *C. coli* Invisible Sentinel, Inc. AOAC-PTM # 012202 raw ground chicken (25 g), raw poultry parts rinse (30 ml), chicken carcass rinsate (30 ml), poultry carcass sponges See

\\"Validated Matrices\\" - \*\* N\\A = Not available", "I # Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size C022 Atlas Campylobacter Detection Assay Campylobacter jejuni, C. lari and C. coli RokaBio, Inc. AOAC-PTM # 032101 chicken carcass rinses, turkey carcass sponge, raw ground poultry (25 g, mix of ground chicken 50% and ground turkey 50%), ready to eat (RTE) meat samples (25 g, mix of RTE poultry 50% and RTE pork 50%) See \\\"Validated Matrices\\" C023 RapidCheck Campylobacter Test System Campylobacter jejuni, C. Romer Labs, Inc. AOAC-PTM # 052201 raw ground chicken (325 g), See \\\"Validated lari and C. coli chicken carcass rinses, and Matrices\\" turkey carcass sponges C024 Thermo Scientific SureTect Campylobacter jejuni , C. coli , and C. lari PCR Kit Campylobacter jejuni, C. lari and C. coli Oxoid Ltd. (part of Thermo Fisher Scientific) AOAC-PTM # 012101 raw ground turkey (325 g), raw chicken thigh with skin (325 g). ready-to-reheat chicken nuggets (25 g), chicken carcass rinse (30 ml), turkey carcass sponge (4'x4") See \\\"Validated Matrices\\" \*\* N\\A = Not available", "Foodborne Pathogen Test Kits Validated by Independent Organizations FSIS is making available a list of test kits that have been validated for detection of relevant foodborne pathogens (i.e., Salmonella, Campylobacter, Listeria spp. including L. monocytogenes, E. coli O157:H7 and non-O157 STEC). The list is intended to be informational and is not an endorsement or approval of any specific test kit, regardless of its inclusion in the list. FSIS does not specifically endorse any of the mentioned test kits or products and acknowledges that equivalent test kits or products may be available for laboratory use. Likewise, FSIS does not require the use of any specific test kit, including those incorporated into FSIS\\u2019s Microbiology Laboratory Guidebook methods. Instead, establishments and laboratories should choose test kits that are: 1)Validated for testing relevant foods by a: a)Recognized independent body (i.e., AOAC, AFNOR, MicroVal, NordVal), b) U.S. regulatory body (i.e., FSIS MLG or FDA BAM), or c) International Organization for Standardization (ISO) process 2)In addition, the validated method should be: a)Fit for the intended purpose and application (e.g., validated for the appropriate matrix and sample size to detect the appropriate foodborne pathogen), and b)Performed per the conditions of the validated protocol by a laboratory that assures the quality of the analytical results. The table below contains a list of foodborne pathogen test kits that are validated by recognized independent organizations (i.e., AOAC, AFNOR, MicroVal, NordVal) and therefore meet criterion 1a above. However, the test kits in this list are not necessarily equivalent or appropriate for all testing applications. FSIS intends to update validated test kit lists on a quarterly basis. # Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size L001 3M Petrifilm Environmental Listeria (EL) Plate Listeria monocytogenes, Listeria innocua, and Listeria welshimeri 3M Food Safety AOAC-PTM # 030601 (Environmental swabs or sponges enriched in 5mL of buffered peptone water) stainless steel, ceramic tile, N\\A sealed concrete L006 ACTERO Listeria Enrichment Media Listeria spp. FoodChek Systems, Inc AOAC-PTM # 111201 Frankfurters, smoked turkey breast (125 g), cured ham (125 g), raw frozen salmon, cold smoked salmon, frozen 25g except where noted in \\\"Validated Matrices\\" cooked shrimp, cooked shrimp, ice cream, pasteurized milk, pasteurized 2% milk, soft Mexican-style cheese, bagged spinach, soft fresh ricotta cheese, liquid whole eggs, ceramic tile, rubber, sealed concrete, stainless steel, plastic L010 AL\\Agar (Detection) Listeria monocytogenes and Listeria spp. BIO-RAD AFNOR # BRD 07\\16 -01\\09 All human food products (by performing validation assays on a broad range of foods) and industrial 25g L011 AL Enumeration Listeria

monocytogenes BIO-RAD AFNOR # BRD 07\17 -01\09 production environmental samples.  
N\A L012 ALOA Count Listeria monocytogenes bioM\u00e9trie AFNOR # AES 10\05 - 09\06  
All foodstuffs for human N\A and Listeria spp. consumption and environmental samples - - \*\*  
N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation  
Validated Matrices Validated Test Portion Size L013a ALOA One Day Listeria monocytogenes  
and Listeria spp. bioM\u00e9trie AFNOR # AES 10\03 \u2013 09\00 All foodstuffs for human  
consumption and environmental samples 25g L014a ANSR for Listeria Listeria spp. (L. grayi  
variable) Neogen Corporation AOAC-PTM # 101202 Pasteurized 2% milk, queso fresco, ice  
cream, smoked salmon, lettuce, cantaloupe, guacamole, pasteurized liquid egg, hot dog (125g),  
fermented sausage, deli turkey, stainless steel, plastic, ceramic tile, sealed concrete, rubber 25g  
except where noted in \"Validated Matrices\" L014b ANSR for Listeria Listeria monocytogenes  
and Listeria spp. NEOGEN Europe Ltd. AFNOR # NEO 35\03 - 01\16 All human food products  
and production environmental samples N\A L015a Assurance GDS for Listeria monocytogenes  
Listeria monocytogenes BioControl Systems, Inc. AOAC-PTM # 070702 Liquid pasteurized milk,  
Mexican soft cheese, frankfurter, deli turkey, raw fish, raw green beans, environmental surfaces  
(stainless steel, rubber, concrete plastic) 25g L015b Assurance GDS Listeria monocytogenes Tq  
Listeria monocytogenes BioControl Systems Inc. MicroVal # 2014LR32 All food products and  
environmental samples 25g L016a Assurance GDS for Listeria species Listeria species including  
L. monocytogenes , L. innocua , L. seeligeri , L. welshimeri , L. ivanovii and L. grayi BioControl  
Systems, Inc. AOAC-PTM # 070701 Liquid pasteurized milk, Mexican soft cheese, frankfurter,  
deli turkey, raw fish, raw green beans, environmental surfaces (stainless steel, rubber, concrete  
plastic) 25g L016b Assurance GDS Listeria spp. Tq Listeria spp. BioControl Systems Inc. MicroVal  
# 2010LR31 All food products and environmental samples 25g L017a Assurance\u00ae Listeria  
EIA Listeria monocytogenes and Listeria spp. BioControl Systems, Inc. AOAC-OMA # 996.14  
Dairy foods, red meats, pork, poultry and poultry products, seafood, fruits, vegetables,  
nutmeats, pasta, chocolate, eggs, bone meal, and from environmental surfaces 25g L017b  
TRANSIA AG Listeria L. monocytogenes , L. innocua , L. seeligeri , L. welshimeri , L. ivanovii , L.  
grayi BioControl Systems, Inc. AOAC-PTM # 060802 Liquid pasteurized milk, Mexican soft  
cheese, raw beef trim, ready to eat turkey, raw green beans, raw fish, environmental surfaces  
(stainless steel, rubber, plastic) N\A L018 BAX\u00ae system L. monocytogenes Listeria  
monocytogenes DuPont Qualicon (DuPont Nutrition & Health Diagnostics) AOAC-OMA #  
2003.12 Dairy products, fruits and vegetables (except radishes), seafoods, raw and processed  
meats and poultry 25g L019a BAX System PCR Assay for Genus Listeria 24E (formerly DuPont  
BAX System Real-Time PCR Assay for Genus Listeria 24E) Listeria spp. Qualicon Diagnostics LLC,  
a Hygiena Company AOAC-PTM # 050903 Bagged spinach, processed cheese, frankfurters,  
cooked shrimp, environmental surfaces (stainless steel) 25g - - - \*\* N\A = Not available", "#  
Method Name Target Organism(s) Manufacturer External Validation Validated Matrices  
Validated Test Portion Size L019b BAX System PCR Assay Genus Listeria 24E Listeria spp.  
excluding L. grayi Qualicon Diagnostics LLC AFNOR # QUA 18\06 - 07\08 All human food  
products (by performing validation assays on a broad range of foods) and industrial production  
environmental samples 25g L020a BAX\u00ae System PCR Assay for Listeria monocytogenes  
24E Listeria monocytogenes Qualicon Diagnostics LLC, a Hygiena Company AOAC-PTM # 080901  
Bagged spinach, processed cheese, frankfurters, cooked shrimp, stainless steel 25g L020b  
BAX\u00ae System PCR Assay for Listeria monocytogenes 24E Listeria monocytogenes Qualicon

Diagnostics LLC AFNOR # QUA 18\05 - 07\08 All human food products and production environmental samples 25g L021 BAX System PCR Assay for Listeria monocytogenes and BAX System X5 PCR Assay for Listeria monocytogenes (formerly DuPont BAX System Real-Time PCR Assay for Listeria monocytogenes ) Listeria monocytogenes Qualicon Diagnostics LLC, a Hygiena Company AOAC-PTM # 070202 Chocolate ice cream, milk (2%), vanilla yogurt, apple juice, cabbage slaw, fish sticks, frankfurters, langostinos, orange juice, peas, pepperoni, spinach strawberries, surimi, deli turkey, ground pork, queso fresco plastic (4\"x4\") 25g L022 BAX System PCR Assay for Genus Listeria BAX System X5 PCR Assay for Genus Listeria (formerly DuPont BAX System RealTime PCR Assay for Genus Listeria) Listeria species Qualicon Diagnostics LLC, a Hygiena Company AOAC-PTM # 030502 Processed cheese, frankfurters, smoked salmon, spinach, environmental surfaces (plastic ceramic, tile, rubber, painted wood surfaces, unpainted wood, sealed concrete, cast iron, air filter material & drain swabs, bagged spinach, queso h 25g L023 BBL\u2122 CHROMagar\u2122 Listeria Listeria monocytogenes , Listeria ivanovii Becton Dickinson and Company AOAC-PTM # 060501 25 g - raw ground beef, smoked salmon, lettuce, brie cheese N/A L027 ChromID Lmono Agar (LMO-F) for Listeria monocytogenes enumeration Listeria monocytogenes bioM\u00e9rieux MicroVal # 2010LR35 All food categories & environmental samples N/A L029a Compass Listeria Agar (Detection) Listeria monocytogenes and Listeria spp. SOLABIA SAS AFNOR # BKR 23\02-11\02 All human food products and production environment samples 25g L029b Compass\u00ae Listeria Agar (Enumeration) Listeria monocytogenes SOLABIA SAS AFNOR # BKR 23\05-12\07 All human food products and production environment samples N/A - - \*\* N/A = Not available","# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size L032a foodproof Listeria monocytogenes Detection Kit with foodproof ShortPrep II Kit foodproof Listeria monocytogenes Detection 5' Nuclease LyoKit with foodproof StarPrep Tow Kit; foodproof StarPrep Two Kit Protocol A; and foodproof StarPrep Two 8-Strip Kit foodproof Listeria monocytogenes Detection 5' Nuclease LyoKit with foodproof Magnetic Preparation II Kit with the Listeria monocytogenes BIOTECON Diagnostics GmbH AOAC-PTM # 070401 Dried whole eggs, dry whole milk, vanilla ice cream, Harzer cheese, sausage, raw ground chicken, raw ground pork, ham, gravlax, pollack fillet, melon cubes, white cabbage, bean sprouts, paprika emulsion dye, parsley flakes, dry pet food, peanut butter, milk chocolate, pizza, spaghetti, minced meat, raw fish, cantelope melon, cheese 25g L032b foodproof\u00ae Listeria monocytogenes Detection Kit, Hybridization Probes and foodproof\u00ae Listeria monocytogenes Detection Kit, 5' Nuclease in combination with foodproof\u00ae ShortPrep II Kit Listeria monocytogenes BIOTECON Diagnostics GmbH NordVal # 025 Foods and environmental samples 25g L033 GeneDisc Plate Listeria DUO Listeria monocytogenes Pall GeneDisc Technologies AOAC-PTM # 031206 Deli roast beef, hot dogs, deli turkey, raw shrimp, cold smoked salmon, romaine lettuce, pasteurized whole milk, vanilla ice cream, Brie cheese, liquid eggs, environmental surfaces (stainless steel, sealed concrete) N/A L034a GeneDisc\u00ae Listeria monocytogenes Listeria monocytogenes Pall GeneDisc Technologies AFNOR # GEN 25\08 - 07\10 All human food products and production environment samples 25g L034b GeneDisc Plate Listeria monocytogenes Listeria monocytogenes Pall GeneDisc Technologies AOAC-PTM # 031204 Deli roast beef, hot dogs, deli turkey, raw shrimp, cold smoked salmon, romaine lettuce, pasteurized whole milk, vanilla ice cream, Brie cheese, liquid eggs, environmental surfaces (stainless steel, sealed concrete) N/A

L035a GeneDisc Listeria DUO and GeneDisc Listeria spp. Listeria spp. Pall GeneDisc Technologies AFNOR # GEN 25\07 - 07\10 All human food products and production environment samples 25g L036 GeneDisc\u00ae Plate Listeria ID L. monocytogenes Pall GeneDisc Technologies AOAC-PTM # 031207 Deli roast beef, hot dogs, deli turkey, raw shrimp, cold smoked salmon, romaine N\A --- \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size L037 GeneQuence\u2122 Listeria Microwell Test Listeria spp. Neogen Corporation AOAC-PTM # 010403 Parmesan cheese, brie cheese, pasteurized milk, ice cream, cottage cheese, mayonnaise, ground beef, deli turkey, hot dogs, ground pork, deli ham, lettuce, mixed vegetables, alfalfa sprouts, raw shrimp, pasteurized crab meat, smoked salmon, environmental surfaces (stainless steel, ceramic, cast iron, plastic, concrete, painted 25g L038 GENE-TRAK Listeria Listeria spp. Neogen Corporation AOAC-OMA # 993.09 Dairy products, meats, and seafoods 25g L040 Microbiologique Listeria spp. and Listeria monocytogenes Test System Listeria spp. & Listeria monocytogenes IEH Laboratories & Consulting Group AOAC-PTM # 021201 375 g - raw beef trim, ready-toeat turkey swab\sponge - stainless steel, plastic 25-375g L041a iQ-Check\u2122 Listeria monocytogenes II Listeria monocytogenes BIO-RAD AFNOR # BRD 07\10 - 04\05 All human foodstuffs and environmental samples 25g L041b iQ-Check Listeria monocytogenes II Real Time PCR Listeria monocytogenes Bio-Rad Laboratories AOAC-PTM # 010802 Smoked salmon, cottage cheese, hot dogs, deli turkey, live pate, raw fermented sausage, deli ham, environmental surface ( t i l t l ) 25g L041c iQ-Check\u2122 Listeria monocytogenes II Listeria monocytogenes Bio-Rad Laboratories NordVal # 037 Foods and environmental samples 25g L042a iQ-Check Listeria species Listeria spp. BIO-RAD AFNOR # BRD 07\13 - 05\07 All human foodstuffs and environmental samples 25g L042b iQ-Check Listeria spp. Real-Time PCR Listeria spp. Bio-Rad Laboratories AOAC-PTM # 090701 sponge 4x4 in, swab 1x1 in stainless steel, plastic, ceramic, polystyrene sponge (1x1 in swab), and sealed concrete 25 g - liver pate, raw fermented sausage, deli ham, hot dogs, deli turkey, and stainless (1x1 in), stainless stell (swab 1x1 in with HiCap Neutralizing broth), sealed concrete (sponge 4x4 in with Lethen broth), natural 25g except where noted in \"Validated Matrices\" L044a Listeria Precis\u2122 (Detection) Listeria monocytogenes OXOID Ltd, Part of Thermo Fisher Scientific AFNOR # UNI 03\04 -04\05 All human food products and environmental samples 25g L044b Listeria Precis\u2122 (Enumeration) Listeria monocytogenes OXOID Ltd, Part of Thermo Fisher Scientific AFNOR # UNI 03\05 -09\06 All human food products and environmental samples N\A L045 Listeria - Tek ELISA Listeria monocytogenes Organon Teknika Corporation AOAC-OMA # 994.03 Meat, meat products, fish, dairy products 25g L046 LUMIprobe 24 Listeria monocytogenes Listeria monocytogenes EUROPROBE SA AFNOR # EUR 15\03 - 12\05 All human food products and environmental samples 25g \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size L047 Microgen Listeria-ID Listeria species (monocytogenes, innocua, welshimeri, seeligeri, ivanovii, grayi ) Microgen Bioproducts Ltd AOAC-PTM # 060402 Pure culture N\A L048 MICRO-ID Listeria Listeria spp. Organon Teknika Corporation AOAC-OMA # 992.18 Foods and environmental samples N\A L049a MicroSEQ Listeria monocytogenes Listeria monocytogenes Life Technologies Corporation, part of Thermo Fisher Scientific AFNOR # ABI 29\05 - 12\11 meat products, dairy products, fishery products, vegetables and environmental samples 25g L049b MicroSEQ Listeria monocytogenes Detection Kit Listeria monocytogenes Applied Biosystems

AOAC-PTM # 011002 25 g - pasteurized whole milk, dry infant formula, ice cream, roast beef, cured bacon, lox (cold-smoked salmon), lettuce, salad dressing, and mayonnaise 25g L050a MicroSEQ Listeria spp. Listeria spp. Life Technologies Corporation, part of Thermo Fisher Scientific AFNOR # ABI 29\04 - 12\11 meat products, dairy products, fishery products, vegetables, and environmental samples N\A L050b MicroSEQ Listeria species Detection Kit Listeria spp. Applied Biosystems AOAC-PTM # 021108 Pasteurized whole cows milk, dry infant formula, hot dogs, roast beef, lox (smoked salmon), environmental surfaces (stainless steel, plastic cutting board, ceramic tile, rubber sheets, concrete sealed with Seal Hard\u00ae) N\A L051b 3M\u2122 Molecular Detection Assay (MDA) Listeria Method Listeria spp. 3M Food Safety AOAC-OMA # 2014.06 Beef hot dogs (25g), deli turkey (25g), cold smoked salmon (25g), full-fat cottage cheese (25g), bagged raw spinach (25g), whole cantaloupe melone, sealed concrete (sponge in 100mL and sponge in 225mL enrichment volume), stainless steel (sponge in 225mL enrichment volume), and plastic (swab in 10ml enrichment volume) enriched in pre warmed Demi Fraser (DF) broth See \"Validated Matrices\" L053 PATHATRIX Pooling System for Listeria species Listeria spp. LifeTechnologies part of Thermo Fisher Scientific AOAC-PTM # 090201B Raw ground beef, cooked sliced ham, milk powder, orange juice, soft cheese, single cream, ground black pepper, chocolate, cooked chicken, lasagna ready meal, frozen pawns, soft cheese, cream cooked chicken 25g - - \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size L054 PDX-LIB Listeria species including L. monocytogenes, L. innocua, L. ivanovii, L. seeligeri, L. welshimeri, L. grayi, and L. marthii Paradigm Diagnostics, Inc. AOAC-PTM # 040501 4x4 in - ceramic tile, stainless steel (18-gauge, 304 foodgrade with a brushed finish), plastic (polypropylene), and sealed concrete) N\A L055a RAPID'L. mono (Detection) Listeria monocytogenes and Listeria spp. BIO-RAD AFNOR # BRD 07\04 - 09\98 All human food products and environmental samples 25g L055b RAPID'L. mono (Enumeration) Listeria monocytogenes BIO-RAD AFNOR # BRD 07\05 - 09\01 All human food products and environmental samples N\A L055c RAPID'L. mono Listeria monocytogenes Bio-Rad Laboratories AOAC-PTM # 030406 Brie cheese, surimi, mixed salad, & deli turkey N\A L055d RAPID'L. mono Listeria monocytogenes Bio-Rad Laboratories NordVal # 022 Foods and environmental samples 25g L056 RapidChek Listeria Listeria spp. Romer Labs Technology, Inc. AOAC-PTM # 020401 Ice cream, soft cheese, pasteurized whole milk, deli turkey, pepperoni, hot dogs, roast beef, cooked shrimp, smoked fish, potato salad, environmental surfaces (rubber, painted concrete, stainless steel) 25g L057a RAPID'Listeria spp. Listeria spp. Bio-Rad Laboratories AFNOR # BRD 07\12 - 12\06 All human food products and environmental samples 25g L057b RAPID'Listeria spp. Listeria spp. Bio-Rad Laboratories AOAC-PTM # 080701 stainless steel, plastic, ceramic, sealed concrete N\A L058 Reveal 2.0 Listeria Test System Listeria spp. excluding L. grayi Neogen Corporation AOAC-PTM # 041101 Pasteurized liquid egg, ice cream, parmesan cheese, 2% milk, deli turkey, hot dogs, frozen cooked hamburgers, pepperoni, pasteurized crab meat, smoked salmon, environmental surfaces (stainless steel, ceramic tile, plastic, concrete) 25g L059 Roka Listeria Detection Assay Listeria species: Listeria monocytogenes, L. innocua, L. welshimeri, L. ivanovii, L. seeligeri, L. grayi Roka Bioscience, Inc. AOAC-PTM # 011201 Pasteurized whole milk, ice cream, brie cheese, hot dogs, cured ham, deli chicken, chicken salad, cold-smoked salmon, romaine lettuce. Stainless steel, sealed concrete, plastic (swab or sponge enriched in 90mL) 25g - - - \*\* N\A = Not available", "# Method Name



vegetables, seafood, raw meats and poultry, and processed meats and poultry 25g L069 VIDAS\u00ae LMO2 Listeria monocytogenes bioM\u00e9rieux, sa AOAC-OMA # 2004.02 Dairy products, vegetables, seafood, raw meats and poultry, and processed meats and poultry 25g L070a VIDAS UP Listeria (LPT) Listeria spp. bioM\u00e9rieux AFNOR # BIO 12/33 - 05/12 Human food products and production environment samples N/A L070b VIDAS\u00ae UP Listeria (LPT) Listeria spp. bioM\u00e9rieux, sa AOAC-OMA # 2013.10 Deli ham (25 and 125 g), pepperoni (25 g), beef hot dogs (25 g), chicken nuggets (25 g), chicken liver p\u00e9t\u00e9 (25 g), ground beef (125 g), deli turkey (125 g), cooked shrimp (25 g), smoked salmon (25 g), whole cantaloupe melon, bagged mixed salad (25 g), peanut butter (25 g), black pepper (25 g), vanilla ice cream (25 g), queso fresco (25 and 125 g), stainless steel, plastic, ceramic and concrete environmental See \"Validated Matrices\" L071a VIP\u00ae Gold for Listeria Listeria monocytogenes and Listeria spp. BioControl Systems, Inc. AOAC-OMA # 997.03 Dairy foods, red meats, pork, poultry and poultry products, seafood, fruits, vegetables, nutmeats, pasta, chocolate, eggs, bone meal, and environmental surfaces 25g L071b VIP\u00ae for Listeria L. monocytogenes , L. seeligeri , L. welshimeri , L. ivanovii , L. grayi BioControl Systems, Inc. AOAC-PTM # 060801 Liquid pasteurized milk, Mexican soft cheese, raw beef trim, ready to eat turkey, raw green beans, raw fish, environmental surfaces (stainless steel, rubber, plastic) 25g L072 Vitek GPI and GNI+ Listeria spp. bioM\u00e9rieux, sa AOAC-OMA # 992.19 N/A N/A - \*\* N/A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size L073a Solus Listeria ELISA Listeria spp. Solus Scientific (part of PerkinElmer Inc.) AFNOR # SOL 37/02 - 06/13 Human food products and environmental samples N/A L073b Solus Scientific Listeria ELISA Listeria species (L. grayi, L. innocua, L. ivanovii, L. monocytogenes, L. seeligeri, L. welshimeri ) Solus Scientific Ltd. AOAC-PTM # 041601 Bagged romaine lettuce, hot dogs, frozen raw shrimp, smoked salmon, soft cheese (brie), stainless steel (swab, 1 x 1 in), polystyrene (sponge, 4 x 4 in) 25g L074 VITEK \u00ae 2 Gram Positive (GP) Gram-positive bacteria, including Listeria spp. and Staphylococcus spp. bioM\u00e9rieux, sa AOAC-OMA # 2012.02 N/A N/A L075 InstantLabs Listeria Species Food Safety Kit Listeria spp. InstantLabs Medical Diagnostics Corporation AOAC-PTM # 041304 hot dogs, raw shrimp, cheddar cheese, stainless steel, and sealed concrete 25g L076 InstantLabs Listeria monocytogenes Food Safety Kit Listeria monocytogenes InstantLabs Medical Diagnostics Corporation AOAC-PTM # 051302 Hot dogs, deli turkey, romaine lettuce, raw shrimp, cheddar cheese, vanilla ice cream, pasteurized whole milk, and environmental surfaces (stainless steel, sealed concrete) 25g L077 Veriflow Listeria monocytogenes (LM) Listeria monocytogenes Invisible Sentinel AOAC-PTM # 051304 hot dogs, deli turkey deli meat, stainless steel, sealed concrete, plastic, ceramic tile, 2% milk N/A L078a Thermo Scientific SureTect Listeria monocytogenes PCR Assay Listeria monocytogenes Oxoid Ltd. Part of Thermo Fisher Scientific AOAC-PTM # 061302 Raw ground beef, pork frankfurters, salami, cooked sliced turkey, fresh bagged spinach, ice cream, smoked salmon, cooked prawns, fresh cantaloupe, proceed cheese, raw ground turkey, raw ground pork, pasteurized 2% milk, raw pork sausage, raw cod, pasteurized brie cheese, cooked sliced ham, bagged lettuce, sliced deli turkey, bagged lettuce, pasturized 2% fat milk, plastic, (1x1 in swab) stainless steel 25g L078b Thermo Scientific\u2122 SureTect\u2122 Listeria monocytogenes PCR Assay Listeria monocytogenes OXOID Ltd, part of Thermo Fisher Scientific AFNOR # UNI 03/08 - 11/13 All human food products and production environmental samples N/A L079 Atlas Listeria monocytogenes LmG2

Detection Assay Listeria monocytogenes Roka Bioscience, Inc AOAC-PTM # 111301 Hot dogs, cured ham, deli turkey (125g), chicken salad, environmental surfaces (stainless steel), frozen chocolate cream pie, frozen cheese pizza, vanilla ice cream, queso fresco (125g), cut cantaloupe 25g except where noted in \"Validated Matrices\" - - - \*\* N/A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size L080 Sample6 DETECT\|L Test Listeria species (L. monocytogenes, L. innocua, L. ivanovii, L. seeligeri, L. welshimeri & L. marthii) Sample6 AOAC-PTM # 041401 Environmental surface (Stainless steel) N/A L081b mericon\u00ae Listeria monocytogenes Pathogen Detection Assay Listeria monocytogenes Qiagen GmbH AFNOR QIA 36\|02 - 05\|17 Meat and dairy products N/A L084a Thermo Scientific SureTect Listeria species PCR Assay Listeria spp. OXOID Ltd, part of Thermo Fisher Scientific AOAC-PTM # 071304 Raw ground beef, pork frankfurters, salami, ground pork, raw ground turkey, raw pork sausages, cooked sliced ham, cooked sliced turkey, pasteurized 2% milk, bagged lettuce, fresh bagged spinach, cantaloupe, processed cheese, smoked salmon, raw cod, cooked prawns, pasteurized brie cheese, ice cream, (sponge 4\" x 4\" enriched 225 mL of 24 LEB suplemented with 24 LEB selective supplement and 10 mL of LEB buffer supplement) stainless steel and plastic 25g except where noted in \"Validated Matrices\" L084b Thermo Scientific SureTect Listeria Species PCR Assay Listeria spp. OXOID Ltd, part of Thermo Fisher Scientific AFNOR # UNI 03\|09 - 11\|13 All human food products and production environmental samples N/A L086 BAX Systen Real-Time PCR Assay for Genus Listeria (formerly DuPont BAX System Real-Time PCR Assay for Genus Listeria) Listeria species (including L. monocytogenes, L. innocua, L. ivanovii, L. welshimeri, L. seeligeri, and L. grayi ) Qualicon Diagnostics LLC, a Hygiena Company AOAC-PTM # 081401 Frankfurters (beef), cooked shrimp, bagged lettuce, queso fresco (Mexican style cheese), and environmental surfaces (stainless steel, plastic, and concrete) 25g L087a 3M\u2122 Molecular Detection Assay (MDA) Listeria monocytogenes Method Listeria monocytogenes 3M Food Safety AOAC-OMA # 2014.07 Beef hot dogs (25g and 125g), deli turkey (25g and 125g), cold smoked salmon, full-fat cottage cheese, chocolate milk, bagged raw spinach, romaine lettuce, whole cantaloupe melon, sealed concrete (sponge in 100mL and sponge in 225mL) and stainless steel (sponge in 225 L) 25g except where noted in \"Validated Matrices\" L088 Atlas Listeria Environmental LE Detection Assay Listeria monocytogenes, Listeria innocua, L. welshimeri, L. ivanovii, L. seeligeri, and L. grayi Roka Bioscience, Inc AOAC-PTM # 061503 stainless steel, PVC, plastic, sealed concrete N/A - - - \*\* N/A = Not available", "- # Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size L089 BAX System Real-Time PCR Assay for L. monocytogenes (formerly DuPont BAX System Real-Time PCR Assay for L. monocytogenes) Listeria monocytogenes Qualicon Diagnostics LLC, a Hygiena Company AOAC-PTM # 121402 Beef frankfurters, bagged spinach, queso fresco, cooked shrimp, stainless steel, plastic & concrete 25g L090a ANSR for Listeria monocytogenes Listeria monocytogenes Neogen Corporation AOAC-PTM # 061506 25 g - queso fresco, cantaloupe, guacamole, pasteurized liquid egg, sprout irrigation water, stainless steel, hot doga (125 g), stainless steel (4x4 in) 25g except where noted in \"Validated Matrices\" L090b ANSR for Listeria monocytogenes Listeria monocytogenes NEOGEN Europe Ltd. AFNOR # NEO 35\|04 - 03\|16 All human food products and production environmental N/A L091a 3M Molecular Detection Assay 2 (MDA2) - Listeria species Listeria species (L. monocytogenes, L. seeligeri, L. inanovii, L. innocua, L. grayi, L. welshimeri, L. fleishmanii subsp. coloradensis, L.

cornellensis, L. grandensis, L. marthii, and L. riparia ) 3M Company (3M Food Safety) AOAC-PTM # 111501 Beef hot dogs, deli turkey (125g), raw chicken (leg pieces and fillets), cold smoked salmon, whole melon, romaine lettuce, queso fresco, vanilla ice cream, 4% milk fat cottage cheese, bagged raw spinach, sealed concrete (4"x 4" sponge enriched in 100mL), plastic (1" x 1" swab enriched in 10mL), stainless steel (4"x 4" sponge enriched in 225 25g except where noted in \"Validated Matrices\" L091b 3M\u2122 Molecular Detection Assay (MDA) 2 - Listeria Method Listeria spp. 3M Food Safety AOAC-OMA # 2016.07 hot dogs (25g, 125g), salmon, deli turkey (25g, 125g), cottage cheese, vanilla ice cream, queso fresco, spinach, melon (whole), raw chicken leg pieces, raw chicken fillet; concrete (3M\u2122 Hydrated Sponge Stick with D/E, 225mL, 100mL), stainless steel (3M\u2122 Hydrated Sponge Stick with D/E, 225mL), and plastic (3M\u2122 EnviroSwab with Letheen, 10mL) environmental samples 25g except where noted in \"Validated Matrices\" L091c 3M Molecular Detection Assay 2 -Listeria Listeria spp. 3M Health Care AFNOR # 3M 01\14 - 05\16 All human food products and production environmental samples N/A L092a 3M Molecular Detection Assay 2 -Listeria monocytogenes (MDA2-LMO) Listeria monocytogenes 3M Company (3M Food Safety) AOAC-PTM # 081501 Beef hot dogs, deli turkey (125g), raw chicken (leg pieces and fillets), cold smoked salmon, whole melon, romaine lettuce, queso fresco vanilla ice 25g except where noted in \"Validated Matrices\" -- \*\* N/A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size L092b 3M\u2122 Molecular Detection Assay (MDA) 2 - Listeria monocytogenes Method Listeria monocytogenes 3M Food Safety AOAC-OMA # 2016.08 hot dogs (25g, 125g), salmon, deli turkey (25g, 125g), cottage cheese, chocolate milk, vanilla ice cream, queso fresco romaine lettuce 25g except where noted in \"Validated Matrices\" L092c 3M\u2122 Molecular Detection Assay 2 -Listeria monocytogenes Listeria monocytogenes 3M Health Care AFNOR # 3M 01\15 - 09\16 All human food products and production environmental samples N/A L093 Veriflow Listeria spp. Listeria spp. Invisible Sentinel, Inc. AOAC-PTM # 121302 Deli Turkey (125g), beef hot dogs, whey protein isolate, and environmental surfaces (1" x 1" swab or 4" x 4" sponge; stainless steel, ceramic tile, sealed concrete, plastic) 25g except where noted in \"Validated Matrices\" L095 One Broth One Plate for Listeria (OBOP-L) Listeria spp. Neogen Europe Ltd. AFNOR # NEO 35\05 - 07\16 All human food products and production environmental samples N/A L096 ANSR for Listeria monocytogenes Listeria monocytogenes Neogen Europe Ltd. AFNOR # NEO 35\06 - 07\16 All human food products and production environmental samples N/A L097b GENE-UP Listeria spp. Listeria spp. bioM\u00e9rieux AFNOR # BIO 12\39 - 09\16 All human food products and production environmental samples 25g L098 Xpress LM Listeria monocytogenes Crystal Diagnostics Corporate AOAC-PTM # 071602 4"x4" - stainless steel, plastic, ceramic tile N/A L099b GENE-UP\u00ae Listeria monocytogenes 2 (LMO 2) Listeria monocytogenes bioM\u00e9rieux AFNOR # BIO 12\40 - 11\16 All human food products and production environmental samples 25g L100 BACSpec Listeria Listeria spp. (including L. monocytogenes , L. seeligeri , L. welshimeri , L. marthii , L. ivanovii , L. grayi , L. innocua , and L. recourtiae ) Eurofins GeneScan AOAC-PTM # 051703 25 g - vegetable salad, frozen cantaloupe, soft white cheese, raw whole milk, frankfurter sausages, process water, smoked salmon, frozen cooked shrimp, stainless steel (1x1 in), sealed ceramic tile (4x4 in) 25g L101 BACGene Listeria Multiplex Listeria monocytogenes & Listeria spp. Eurofins GeneScan GmbH AFNOR # EGS 38\05 - 03\17 All human food products (by performing validation assays on a broad range of

foods) and production environmental samples 25g - \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size L102 BACGene Listeria Multiplex Listeria spp. (including L. monocytogenes , L. seeligeri , L. welshimeri , L. marthii , L. ivanovii , L. grayi , L. innocua , and L. recourtiae ) and L. monocytogenes Eurofins GeneScan AOAC-PTM # 061701 Mayonnaise-based vegetable salad, frankfurters, raw whole milk, soft white cheese (Listeria spp. only), frozen cantaloupe balls, smoked salmon, frozen cooked shrimp (Listeria spp. only), stainless steel 304L (1x1 in swab), ceramic tile (4x4 in sponge), and process water, ice cream with chocolate inclusions, plastic surface samples with sponge (with and without background flora of 25g L103 BACGene Listeria spp. Listeria spp. Eurofins GeneScan GmbH AFNOR # EGS 38\02 - 01\17 All human food products (by performing validation assays on a broad range of foods) and production environmental samples 25g L104 BACGene Listeria spp. Listeria spp. (including L. monocytogenes , L. seeligeri , L. welshimeri , L. marthii , L. ivanovii , L. grayi , L. innocua , and L. recourtiae ) Eurofins GeneScan AOAC-PTM # 061702 Mayonnaise-based vegetable salad, frankfurters, raw whole milk, soft white cheese, frozen cantaloupe balls, smoked salmon, frozen cooked shrimp, stainless steel 304L (1x1 in swab), ceramic tile (4x4 in sponge), and process water (vegetable sausage production) 25g L105 BACGene Listeria monocytogenes Listeria monocytogenes Eurofins GeneScan GmbH AFNOR # EGS 38\03 - 01\17 All human food products (by performing validation assays on a broad range of foods) and production environmental samples 25g L106 BACGene Listeria monocytogenes Listeria monocytogenes Eurofins GeneScan AOAC-PTM # 061703 Mayonnaise-based vegetable salad, frankfurters, raw whole milk, frozen cantaloupe balls, smoked salmon, stainless steel 304L (1x1 in swab), ceramic tile (4x4 in sponge), and process water (vegetable sausage production) 25g L107 BACSpec Listeria Listeria spp. Eurofins GeneScan Technologies GmbH AFNOR # EGS 38\04 - 01\17 All human food products (by performing validation assays on a broad range of foods) and production environmental samples 25g L108 RapidChek Listeria monocytogenes Listeria monocytogenes Romer Labs, Inc. AOAC-PTM # 011805 25 g - hot dogs, cured ham, frozen cooked breaded chicken, frozen cooked shrimp, stainless steel (4x4 in sponge), and plastic (1x1 in swab) 25 ml ice cream 25g - - - \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size L109 RapidChek\u00ae Listeria monocytogenes Listeria monocytogenes Romer Labs, Inc. AOAC-OMA # 993.12 Ice cream, camembert, raw milk, skim milk powder, and Limburger 25mL L110 Sample6 DETECT HT\ L Kit Listeria species (L. monocytogenes, L. innocua, L. ivanovii, L. seeligeri, L. welshimeri, L. marthii) Sample6 AOAC-PTM # 101704 Stainless steel environmental surfaces (4x4 squares; 18 ga. 304 stainless steel, brushed finish, not mirror) N\A L113 PolySkope One Multiplex Detection Assay STECs, E. coli O157:H7 & Non-O157 STEC Big 6 (O26,O45,O103,O111,O 121,O145), Listeria monocytogenes, Salmonella species PolySkope Labs AOAC-PTM # 041801 (25g) Fresh raw ground beef (73% lean), deli turkey, fresh baby spinach, stainless steel (4x4 in sponge) See \"Validated Matrices\" L114 Solus One Listeria Listeria species (L. monocytogenes, L. innocua, L. ivanovii, L. seeligeri, L. welshimeri, L. grayi, L. marthii) Solus Scientific Ltd. AOAC-PTM # 051802 Stainless steel (18 guage: 304 food grade with a brush finish; 4x4 sponge), plastic (polystyrene; 1x1 swab) N\A L115 GENE-UP enviroPRO (formerly known as EnviroPRO) Listeria and Salmonella species Invisible Sentinel Inc. AOAC-PTM # 061801 Stainless steel environmental surfaces (4x4" squares) Salmonella 375 g; Listeria spp. 125

gwhey powder, pea N\A L116 InSite L. mono Glo Listeria monocytogenes and Listeria species (L. innocua, L. fleischmannii, L. welshimeri, L. weihenstephanensis, L. ivanovii, L. seeligeri) Hygiena LLC. AOAC-PTM # 061802 Stainless steel, ceramic, plastic (4x4\" swab) N\A L116b InSite Listeria ssp. Listeria species ( L. monocytogenes, innocua, fleischmanni, welshimeri, weihenstaphansis, ivanovii, and seeligeri) Hygiena LLC. AOAC-PTM # 121902 Stainless steel, ceramic, plastic (4x4\" swab) N\A L117 Listeria Right Now Listeria spp. (Listeria spp. rRNA) Neogen Corporation AOAC-PTM # 081802 swab, 1x1 in - stainless steel, sealed concrete, ceramic tile, plastic, rubber N\A L118 Solus Listeria ELISA Listeria spp. Solus Scientific (part of PerkinElmer Inc.) AFNOR # SOL 37\02 - 06\13 All human and food products and production environmental samples N\A L119 MALDI Biotyper\u00ae complete solution for the confirmation of Listeria spp. and Listeria monocytogenes Listeria spp. & Listeria monocytogenes Bruker Daltonik GmbH MicroVal # 2017LR75 Only pure cultures\isolates N\A L120 Bruker MALDI Biotyper Method Listeria spp. & Listeria monocytogenes Bruker Daltonik GmbH, Bremen, Germany AOAC-OMA # 2017.10 Only pure cultures\isolates N\A - - \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size L121 GENE-UP Listeria species (LIS) (formerly PTM 051603 GENE-UP Listeria species Detection Kit) Listeria species: L. innocua, L. ivanovii, Listeria monocytogenes, L. seeligeri and L. welshimeri bioM\u00e9trieux, s.a. AOAC-PTM # 121803 Deli ham (25 g, 125 g), Deli turkey (25 g), Beef hot dogs (25 g), Breaded chicken nuggets (25 g), Fresh bagged spinach (25 g), Fresh bagged lettuce (25 g), Cooked shrimp (25 g), Smoked salmon (25 g, 125 g), Stainless steel (4 x 4 in sponge), Whole liquid egg (100 g), Whey powder (375 g), Vanilla ice cream (25 g), Mexican soft cheese (25 g) See \"Validated Matrices\" L122 GENE-UP Listeria monocytogenes (LMO) (formerly GENE-UP Listeria monocytogenes Detection System ) Listeria monocytogenes bioM\u00e9trieux, s.a. AOAC-PTM # 121804 Deli ham (25 g, 125 g), Deli roast beef (25 g), Deli turkey (25 g), Turkey hot dogs (25 g), Smoked salmon (25 g), Cooked shrimp (25 g), Fresh spinach (25 g), Mixed bagged salad (25 g), Liquid whole egg (100 g), Whey powder (375 g), Vanilla ice cream (25 g), Mexican soft cheese (25 g, 125 g), Stainless steel (sponge 4x4 in) See \"Validated Matrices\" L124 Clear Safety Listeria Listeria monocytogenes & Listeria spp. (L. monocytogenes, L. innocua, L. ivanovii, L. marthii, L. grayi, L. welshimeri, L. seeligeri ) Clear Labs, Inc. AOAC-PTM # 091901 Hot dogs (125 g), stainless steel (4x4 in sponge), plastic (4x4 in sponge), ceramic (4x4 in sponge), sealed concrete (4x4 in sponge) See \"Validated Matrices\" L125 GENE-UP\u00ae Listeria spp. 2 (LIS 2) Listeria spp. (monocytogenes, innocua, ivanovii, seeligeri, and welshimeri) bioM\u00e9trieux, s.a. AOAC-OMA # 2019.10 25 g test portions of pork rillettes, raw milk, salmon offcuts, mixed precooked vegetables, mixed salad and process water, deli ham, deli turkey, beef hot dogs, breaded chicken nuggets, fresh bagged spinach, fresh bagged lettuce, cooked shrimp, smoked salmon, vanilla ice cream, Mexican soft cheese; 100 g test portions of whole liquid egg; 125 g test portions of deli ham and smoked salmon; 375 g test portions of whey powder; stainless steel See \"Validated Matrices\" - - \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size L126 GENE-UP\u00ae Listeria monocytogenes 2 (LMO 2) Listeria monocytogenes bioM\u00e9trieux, s.a. AOAC-OMA # 2019.11 25 g test portions of pork rillettes, raw milk, salmon offcuts, mixed precooked vegetables, mixed salad and process water, deli ham, deli roast beef, deli turkey, turkey hot dogs, fresh spinach, mixed bagged salad, cooked shrimp, smoked salmon, vanilla ice cream, Mexican soft cheese; 100 g test portions of

whole liquid egg; 125 g test portions of deli ham and Mexican soft cheese; 375 g test portions of whey powder; stainless steel See \"Validated Matrices\" L127 BAX System Real-Time PCR Assay for Genus Listeria Listeria spp. Qualicon Diagnostics LLC AFNOR # QUA 18\|09 - 01\|19 All human food products, and production environmental samples N\|A L128 BAX\u00ae System Real-Time PCR Assay for Genus Listeria monocytogenes Listeria monocytogenes Qualicon Diagnostics LLC AFNOR # QUA 18\|10 - 01\|19 All human food products, and production environmental samples N\|A L129 Molecular Environmental Monitoring Program (MEMP) Listeria Assay Listeria species Applied Food Diagnostics Inc. AOAC-PTM # 052003 Stainless steel (1\"x1\"), plastic(1\"x1\"), rubber (1\"x1\"), ceramic tile (1\"x1\"), and sealed concrete (1\"x1\") N\|A L130 Solus Listeria monocytogenes ELISA Listeria spp. Solus Scientific Solutions Ltd. AOAC-PTM # 082001 Beef hot dogs (25g, 125g), sliced deli ham (25g, 125g), raw ground beef (~70% lean (25g), bagged romaine lettuce (25g, 125g), pasteurized brie cheese (25g, 125g), frozen raw shrimp (25g), stainless steel (18 guage 304 food grade with brushed finish 4x4 sponge) and plastic (polystyrene, 1\"x1\" swab) environmental surfaces See \"Validated Matrices\" L131 One Broth One Plate for Listeria (OBOP-L) Listeria spp. NEOGEN Europe Ltd AFNOR # NEO 35\|05 - 07\|16 In all human food products N\|A L132 One Broth One Plate for Listeria monocytogenes (OBOP-LMO) Listeria monocytogenes NEOGEN Europe Ltd AFNOR # NEO 35\|06 - 07\|16 In all human food products and industrial production environmental samples N\|A L133 RiboFlow Listeria Twin Detection Kit Listeria monocytogenes SY-LAB Ger\u00e4te GmbH MicroVal # 2015LR53 Raw milk and dairy products, heat-processed milk and dairy products, ready-to-eat, ready-to-reheat meat products and ready-to-eat, ready-to-reheat fishery products N\|A - \*\* N\|A = Not available", "- # Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size L134 EnviroX-F Listeria spp., L. monocytogenes and Salmonella spp. PathogenDx AOAC-PTM # 092001 WorldBio PUR-Blue Swabs in 5 mL of Hi-Cap broth Environmental Surface Swabs (4in x 4in): stainless Steel, plastic (polystyrene), rubber, and sealed concrete See \"Validated Matrices\" L135 Simultaneous Multiplex Real Time PCR (SIMUL-qPCR) Listeria species and monocytogenes Assay Listeria species and Listeria monocytogenes Applied Food Diagnostics Inc. AOAC-PTM # 062001 Frankfurters (125 g), ready to eat (RTE) sliced turkey (125 g) cooked eggs (25 g), soft fresh raw cheese (25 g) chicken salad (25 g), ice cream (25 g), pasteurized milk (25 g), frozen\cooked shrimp (25 g), stainless steel (4\"x4\", 1\"x1\"), plastic (1\"x1\"), rubber (1\"x1\") ceramic tile See \"Validated Matrices\" L136 SMARTCHEK Listeria monocytogenes Detection Kit for GENECHECKER UF-300 Real-Time PCR System Listeria monocytogenes Genesystems Co., Ltd. AOAC-PTM # 042101 uncured ready-to-eat deli turkey (25 g), ready-to-eat deli ham (25 g), cooked shrimp, spinach, and environmental 18 GA 300 series, brush finish NSF certified steel (sponge 4\"x4\") See \"Validated Matrices\" L137 PhageDX Listeria Assay Listeria spp. [L. monocytogenes (1\|2a, 1\|2b, 1\|2c, 3a, 4a, 4b, 4c, 4d, 4e), L. innocua, L. ivanovii, L. seeligeri, L. welshimeri, L. grayi ] Laboratory Corporation of America AOAC-PTM # 102005 4 in x 4 in - stainless steel and ceramic environmental surfaces See \"Validated Matrices\" L138 N-Light L. monocytogenes Listeria monocytogenes NEMIS Technologies AG AOAC-PTM # 122002 Environmental surface swabs (1\" x 1\") - stainless steel [AISI 304 (1.4301), grade 2b finish], plastic (polystyrene), and ceramic (glazed earthen) See \"Validated Matrices\" L139 Listeria CANARY Zephyr Listeria species (Listeria aquatica, L. booriae, L. cornellensis, L. fleischmannii, L. floridensis, L. innocua, L. ivanovii, L. marthii, L. monocytogenes, L. newyorkensis, L. riparia, L. seeligeri, L. welshimeri )

Smiths Detection AOAC-PTM # 122005 stainless steel (type 304 #4 finish, 1\'' x 1\'' swab), stainless steel (18 GA 300 series, brush finish, NSF certified, 1\'' x 1\'' swab), plastic (HDPE, 1\'' x 1\'' swab), rubber (silicone FDA-grade, 1\'' x 1\'' swab), and sprout irrigation water (25 ml) See \"Validated Matrices\" L140 TAAG F41 VIP - Listeria monocytogenes , Salmonella spp., Escherichia coli and Staphylococcus aureus L. monocytogenes , Salmonella spp., S. aureus , and generic E. coli TAAG Genetics S.A. AOAC-PTM # 072101 Environmental surface: 18 GA 300 series, brushed finish, NSF certified stainless steel (100 cm<sup>2</sup> test area) and pasteurized 2% fat liquid milk (25 ml) See \"Validated Matrices\" L141 Compact Dry LM (enumeration) Listeria monocytogenes Nissui Pharmaceutical Co. Ltd. MicroVal # 2020LR91a Environmental samples, A broad range of foods N/A L142 One Plate Listeria (OP-L) Listeria monocytogenes ; Listeria spp. Neogen Corporation MicroVal # 2019LR89 A broad range of foods N/A \*\* N/A = Not available","# Method Name Target Organism(s) Manufacturer External Validation Validated Matrices Validated Test Portion Size L143 foodproof Listeria plus L. monocytogenes Listeria monocytogenes BIOTECON Diagnostics NordVal # 054 food products and production N/A Detection LyoKit \u2013 5\u2019Nuclease and Listeria spp. GmbH environmental samples L144 3M Environmental Scrub Sampler with 10 Salmonella spp. and 3M Food Safety AOAC-PTM # 022104 Stainless steel, sealed N/A mL Wide Spectrum Neutralizer Listeria spp. concrete and plastic environmental surfaces 4\''x4\'' \*\* N/A = Not available","Foodborne Pathogen Test Kits Validated by Independent Organizations FSIS is making available a list of test kits that have been validated for detection of relevant foodborne pathogens (i.e., Salmonella, Campylobacter, Listeria spp. including L. monocytogenes, E. coli O157:H7 and non-O157 STEC). The list is intended to be informational and is not an endorsement or approval of any specific test kit, regardless of its inclusion in the list. FSIS does not specifically endorse any of the mentioned test kits or products and acknowledges that equivalent test kits or products may be available for laboratory use. Likewise, FSIS does not require the use of any specific test kit, including those incorporated into FSIS\u2019s Microbiology Laboratory Guidebook methods. Instead, establishments and laboratories should choose test kits that are: 1)Validated for testing relevant foods by a: a)Recognized independent body (i.e., AOAC, AFNOR, MicroVal, NordVal), b)U.S. regulatory body (i.e., FSIS MLG or FDA BAM), or c) International Organization for Standardization (ISO) process 2)In addition, the validated method should be: a)Fit for the intended purpose and application (e.g., validated for the appropriate matrix and sample size to detect the appropriate foodborne pathogen), and b)Performed per the conditions of the validated protocol by a laboratory that assures the quality of the analytical results. The table below contains a list of foodborne pathogen test kits that are validated by recognized independent organizations (i.e., AOAC, AFNOR, MicroVal, NordVal) and therefore meet criterion 1a above. However, the test kits in this list are not necessarily equivalent or appropriate for all testing applications. FSIS intends to update validated test kit lists on a quarterly basis. # Method Name Target Organism(s) Manufacturer External Validation Validated matrices Validated Test Portion Size EC003 Assurance GDS for E. coli O157:H7 E. coli O157:H7 BioControl Systems AOAC-OMA # 2005.04 Raw ground beef, beef trim, orange juice, apple juice, fresh 25g EC004 Assurance GDS Shigatoxin Genes E. coli O157:H7 and E. coli O157:H7 nonmotile (NM) BioControl Systems AOAC-OMA # 2005.05 Raw ground beef, beef trim, orange juice, apple juice, fresh vegetables, and sprout process water 25g EC005 Assurance\u00ae Enzyme Immunoassay (EIA) E. coli O157:H7 (EHEC) BioControl Systems AOAC-OMA # 996.10 Dairy

foods, meats, poultry products, fruits, nutmeats, seafood pasta liquid eggs 25g EC006a BAX System Real-Time PCR Assay E. coli O157:H7 E. coli O157 DuPont Qualicon (DuPont Nutrition & Health Diagnostics) AFNOR # QUA 18\07 - 07\10 Raw beef and raw vegetables 25g EC006b BAX System Real-Time PCR Assay for E. coli O157:H7 E. coli O157:H7 Hygiena AOAC-PTM # 031002 lettuce (25 g), spinach (25 g), beef trim (375 g) & ground beef (65 g) 25g except where noted in \"Validated Matrices\" EC007a BAX System PCR Assay for E. coli O157:H7 MP E. coli O157 DuPont Qualicon (DuPont Nutrition & Health Diagnostics) AFNOR # QUA 18\04 - 03\08 Raw beef meat, raw milk, fruits, vegetables, Ready-to-Eat meals, raw pork meat, raw 25g EC007b BAX System PCR Assay for E. coli O157:H7 MP BAX System X5 PCR Assay for E. coli O157:H7 (formerly DuPont BAX System PCR E. coli O157:H7 Hygiena AOAC-PTM # 050501 raw ground beef (25 g, 65 g), beef trim (65 g, 325 g, 375 g), spinach (25 g), lettuce (25 g), red leaf lettuce (200 g, 375 g) 25g except where noted in \"Validated Matrices\" \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated matrices Validated Test Portion Size EC010 BBL CHROMagar O157 E. coli O157:H7 Becton Dickinson and Company AOAC-PTM # 090501 25 g - raw ground beef and unpasteurized apple cider N\A EC015b foodproof E. coli O157 Detection Kits (5'Nuclease and Hybridization Probes) with foodproof ShortPrep II Kit E. coli O157 BIOTECON Diagnostics GmbH AOAC-PTM # 100601 Camembert cheese, egg salad, raw milk, mayonnaise, hamburger meat, brockwurst sausage, coalfish, fresh salmon, apple juice, raw vegetables 25g EC016a GeneDisc E. coli O157:H7 E. coli O157 Pall GeneDisc Technologies AFNOR # GEN 25\06 - 11\08 Raw beef meats (including frozen, seasoned), dairy products and vegetables 25g EC016b GeneDisc Plate Pathogenic E. coli O157 E. coli O157 Pall GeneDisc Technologies AOAC-PTM # 021102 fresh raw ground beef and fresh raw beef trim 25g, 375g EC017 GeneDisc Plate Pathogenic E. coli O157 & Salmonella E. coli O157 & Salmonella spp. Pall GeneDisc Technologies AOAC-PTM # 021104 Fresh raw ground beef, fresh raw beef trim 25g, 375g EC019 Microbiologique E. coli O157, Stx- producing E. coli (STEC) with Intimin and Salmonella Test System E. coli O157, Stx-producing E. coli (STEC, specifically O26, O45, O103, O111, O121 & O145) with intimin & Salmonella IEH Laboratories & Consulting Group AOAC-PTM # 100701 raw ground beef (25 g, 375 g), raw beef trim (25 g, 375 g), raw poultry (25 g), RTE turkey (25 g), mixed leafy greens, (25 g, 125g) 25g except where noted in \"Validated Matrices\" EC020a iQ-Check E. coli O157:H7 Real Time PCR E. coli O157:H7 Bio-Rad Laboratories AOAC-PTM # 020801 Ground beef, apple cider, fresh spinach (25 g), raw ground beef (83% lean), raw beef trim, fresh spinach (375 g), raw chicken breast without skin, raw chicken thigh with skin, mechanically separated chicken, raw ground pork (25 g) 25g except where noted in \"Validated Matrices\" EC020b iQ-Check E. coli O157:H7 Kit E. coli O157 BIO-RAD AFNOR # BRD 07\15 - 06\08 Raw beef 25g EC021b MicroSEQ E. coli O157:H7 Detection Kit E. coli O157:H7 Life Technologies AOAC-PTM # 071001 raw ground beef (25 g, 375 g), raw beef trim (25 g, 375 g); spinach, orange juice, apple juice 25g except where noted in \"Validated Matrices\" EC022b 3M Molecular Detection Assay E. coli O157 (including H7) E. coli O157 3M Health Care AFNOR # 3M 01\12 - 03\13 Raw beef meats, raw dairy products, raw fruits and 25g EC023 PATHATRIX Pooling System for E. coli O157 E. coli O157 (including H7) Life Technologies (Thermo Scientific) AOAC-PTM # 030202 Raw ground beef (25 g) 25g EC024 RapidChek E. coli O157 (including H7) Lateral Flow Test Assay E. coli O157 (including H7) Romer Labs Technology, Inc. AOAC-PTM # 070801 Raw ground beef & boneless beef trim 25g, 375g - - \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation

Validated matrices Validated Test Portion Size EC025a RAPID'E. coli O157:H7 E. coli O157:H7 Bio-Rad Laboratories AOAC-PTM # 060701 25 g - raw ground beef and fresh spinach Sample preparation, enrichment, and IMS as per FSIS MLG Ch 5 EC025b RAPID'E. coli O157:H7\Agar E. coli O157:H7 BIO-RAD AFNOR # BRD 07\14 - 09\07 Meat products, dairy products, fruits and vegetables, composite foods 25g\25mL EC026a Reveal for E. coli O157:H7 Test in Selected Foods and Environmental Swabs E. coli O157:H7 Neogen Corporation AOAC-OMA # 2000.14 Raw ground beef, raw beef cubes, apple cider, iceberg lettuce rinse, environmental swabs of stainless steel 25g, 375g (20hr enrichments) EC026b Reveal for E. coli O157:H7 Test System in Selected Foods E. coli O157:H7 Neogen Corporation AOAC-OMA # 2000.13 Raw ground beef, raw beef cubes, iceberg lettuce rinse 25g (8hr enrichments), 375g (12hr enrichments) EC027 Reveal 2.0 E. coli O157:H7 Test System Escherichia coli serotypes O157:H7 & O157:NM Neogen Corporation AOAC-PTM # 011103 Raw beef trim, raw ground beef 65g, 375g EC029 Singlepath E. coli O157 E. coli O157 (including H7) Merck KGaA AOAC-PTM # 010407 Raw ground beef & pasteurized milk 25g EC031a VIDAS UP E. coli O157 (including H7) (ECPT) coliform bioM\u00e9rieux, sa AOAC-PTM # 060903 Ground beef, beef trimmings (with sample sizes: 25 g, 75 g & 375 g composite & wet pooled samples 75 g & 375 g), bagged lettuce, fresh spinach & irrigation water 25g except where noted in \"Validated Matrices\" EC031b VIDAS UP E. coli O157 including H7 (VIDAS ECPT) E. coli O157 bioM\u00e9rieux AFNOR # BIO 12\25 - 05\09 Raw meat products, raw milk and raw milk products, raw vegetables, and environmental samples 25g EC032 Visual Immunoprecipitate Assay (VIP\u00ae) Assay E. coli O157:H7 BioControl Systems AOAC-OMA # 996.09 Dairy products, meats, poultry, fruits, nutmeats, seafood, pasta, liquid eggs, vegetables, raw beef, cooked beef 25g EC033 Crystal Diagnostics AutoXpress AXECO157 kit for E. coli O157 (formerly MultiPath System E for Detection of Escherichia coli O157) E. coli O157 Crystal Diagnostics Corporation AOAC-PTM # 041301 375 - raw ground beef, raw beef trim, 200 g - fresh raw spinach See \"Validated Matrices\" EC034 GeneDisc\u00ae Plate STEC Shigatoxigenic E. coli Pall GeneDisc Technologies AOAC-PTM # 021103 fresh ground beef (25 g, 375 g), fresh beef trim (25 g, 375 g) 25g, 375g - \*\* N/A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated matrices Validated Test Portion Size EC035 iQ-Check STEC VirX Stx1, Stx2, eae , O26, O45, Bio-Rad Laboratories AOAC-PTM # 121203 375 g - raw ground beef, raw 25g iQ-Check STEC SerO O103, O111, O121, O145, beef trim, fresh spinach, beef iQ-Check STEC SerO II O157:H7, and STEC carcass sampling cloth (4\" x 4\" MicroTally Cloth) EC036 GeneDisc Plate STEC & Salmonella spp. Salmonella spp. Pall GeneDisc Technologies AOAC-PTM # 021105 Fresh raw ground beef (25 g, 375 g), fresh raw beef trim (25 g, 375 g) 25g, 375g EC038 Atlas STEC EG2 Combo Detection Assay E. coli O26:H11, E. coli O157:H7 and E. coli O45:H2 ROKA Bioscience, Inc AOAC-PTM # 011402 Fresh raw ground beef (73% lean), fresh raw beef trim, romaine lettuce 375g EC039 InstantLabs E. coli O157 (including H7) Food Safety Kit E. coli O157 (including H7) InstantLabs Medical Diagnostics Corp AOAC-PTM # 011403 Fresh raw ground beef (27% fat, 375 g), fresh raw beef trim (375 g), fresh raw ground chicken, Romaine lettuce, pasteurized apple juice 25g except where noted in \"Validated Matrices\" EC040 GeneDisc Plate STEC Top 7 E. coli O157:H7, O26, O45, O103, O111, O121, O145 Pall GeneDisc Technologies AOAC-PTM # 031401 375 g - fresh raw ground beef (20%), fresh raw beef trim (20%) 375g EC041 Actero Salmonella \STECEnrichment Media Salmonella spp. and STEC FoodChek System Inc. AOAC-PTM # 041403 raw ground beef (25 g, 325 g, 375 g) liquid whole egg (100 g) raw

ground chicken (25 g) raw frozen scallops (25 g), sprouts (25 g), stainless steel (1x1 in, 4x4), plastic, rubber (1x1 in, 4x4), and ceramic tiles (1x1 in), dry pet food (25 g, 375 g), milk chocolate (25 g), chocolate liquor (25 g), cocoa powder (25 g), shell (20-egg), chicken carcass rinse, dried whole egg (100 g), raw almonds (375 g), peanut butter (25 g), dried parsley (25 g), whole black pepper (25 g), dried raisins (25 g) Contact Manufacturer EC042 NH Immunochromato O157 Test Kit E. coli O157:H7 and O157:NM NH Foods Ltd. AOAC-PTM # 091403 25 g - raw ground beef (15% fat) 25g EC043a Thermo Scientific SureTect Escherichia coli O157:H7 PCR Assay E.coli O157:H7 Oxoid Ltd. Part of Thermo Fisher Scientific AOAC-PTM # 021501 Raw ground beef (375 g, 1:4 and 1:5 ratios); raw beef trim (375 g, 1:4 and 1:5 ratios); bagged spinach, (1:10 ratio) 25 g and apple juice 25g except where noted in \"Validated Matrices\" EC043b Thermo Scientific SureTect Escherichia coli O157:H7 PCR Assay Escherichia coli O157:H7 OXOID Ltd., part of Thermo Fisher Scientific AFNOR # UNI 03\|10 - 03\|15 raw beef meats 25g - \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated matrices Validated Test Portion Size EC047 ANSR for E. coli O157:H7 E. coli O157:H7 Neogen Corporation AOAC-PTM # 111502 Ground beef (80% lean, 325 g), beef trim (~20% fat, 375 g and 325 g), spinach (200 g), sprout irrigation water (125 mL) See \"Validated Matrices\" EC048 Solus E. coli O157 ELISA E. coli O157 Solus Scientific (part of PerkinElmer, Inc.) AFNOR # SOL 37\|03 -10\|15 Raw beef meat products (seasoned or not), raw milks and dairy products, vegetables, and production environmental samples N\A EC049 Veriflow O157:H7 E. coli O157:H7 Invisible Sentinel, Inc. AOAC-PTM # 121401 2% fat milk (25 ml), 20% fat raw ground beef (325 g), raw spinach (200 g), whey protein powder (25g), 20% raw ground beef (375g) Contact Manufacturer EC050 PhageDX E. coli O157:H7 Assay E. coli O157:H7 Laboratory Corporation of AOAC-PTM # 081601 25 g - fresh raw ground beef See \"Validated America (80% lean), fresh raw ground Matrices\" beef (70% lean), raw beef trim (containing >30% fat content, 375g) EC052 Assurance GDS for E. coli O157:H7 Tq Detection Kit Escherichia coli O157:H7 BioControl Systems, Inc MicroVal # 2015LR49 Raw beef meats (25 g, 375 g), dairy products (25 g), fruits and vegetables (25 g), environmental samples (25 g or surface sample) See \"Validated Matrices\" EC053 Veriflow STEC Escherichia coli with Stx1 or Stx2 and Eae virulence factors Invisible Sentinel Inc. AOAC-PTM # 111601 Raw beef trim 375g EC054 3M Molecular Detection Assay 2 -E. coli O157 (including H7) E. coli O157 3M Health Care AFNOR # 3M 01\|18 - 05\|17 Raw beef meats, raw dairy products, raw fruits and vegetables 25g EC055 3M\u2122 Molecular Detection Assay (MDA) Escherichia coli O157:H7 3M Food Safety AOAC-OMA # 2017.01 Raw ground beef (73% lean), 25g 2\u2013E. coli O157 (Including H7) frozen blueberries, fresh bean sprouts, and fresh baby spinach EC056 QIAGEN mericon\u00ae E. coli O157 Screen Plus and mericon\u00ae E. coli STEC O-Type Pathogen Detection Assays Escherichia coli O157:H7 and Escherichia coli nonO157 STEC Qiagen Germantown, MD AOAC-OMA # 2017.05 Fresh spinach (25 g), raw ground beef (70% lean) (325 g), raw beef trim (325 g) See \"Validated Matrices\" EC057 GENE-UP E. coli O157:H7 Escherichia coli O157:H7 bioM\u00e9rieux MicroVal # 2015LR59 Fresh and frozen raw meats, cured and fermented meats, vegetables, raw dairy products using a specific protocol and raw meats (except poultry) using a short protocol (25 g and 375 g sample size), and production environmental samples See \"Validated Matrices\" \*\* N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated matrices Validated Test Portion Size EC058 VereBeef Detection Kit (8-20 hr) Escherichia coli O157:H7, STEC virulence factors (stx1A or stx2A and eae) (10-20 hr) Escherichia

coli O26, O45, O103, O111, O121, O145, Salmonella spp Veredus Laboratories Pte, Ltd. AOAC-PTM # 011801 Raw beef trim 25 g, 325 g, 375 g See \"Validated Matrices\" EC059 PolySkope One Multiplex Detection Assay STECs, E. coli O157:H7 & Non-O157 STEC Big 6 (O26, O45, O103, O111, O121, O145), Listeria monocytogenes, Salmonella species PolySkope Labs AOAC-PTM # 041801 (25g) Fresh raw ground beef (73% lean), deli turkey, fresh baby spinach, stainless steel (4x4 in sponge) See \"Validated Matrices\" EC060 GENE-UP E. coli O157:H7 2 (ECO 2) E. coli O157:H7 bioM\u00e9rieux, s.a. AOAC-PTM # 121805 Ground beef (25 g, 375 g), raw spinach (200 g), beef trim (375 g), raw ground pork (375 g), raw ground chicken (25 g) See \"Validated Matrices\" EC061 GENE-UP\u00ae E. coli O157:H7 2 (ECO 2) E. coli O157:H7 bioM\u00e9rieux, s.a. AOAC-OMA # 2019.03 Raw ground beef (73% lean; 25 g and 375 g), fresh spinach (200 g), raw milk cheese (25 g), raw ground chicken (25 g), See \"Validated Matrices\" EC062 NeoSeek STEC EHEC Escherichia coli O26, O45, O103, O111, O121, O145, and O157 Neogen Corporation AOAC-PTM # 081901 raw beef trim (325 g), pure bacterial cultures, raw ground beef (325 g) See \"Validated Matrices\" EC063 Assurance GDS EHEC ID for E. coli O157:H7 Tq Escherichia coli O157:H7, E. coli O157:NM BioControl Systems, Inc. \u2221 MilliporeSigma AOAC-PTM # 101901 Raw ground beef (375 g, ~85% lean), raw beef trim (375 g, ~85% lean), frozen finely textured beef (375 g, 97% lean) carcass cloths See \"Validated Matrices\" EC064 BACGene E. coli O157:H7 Workflow E. coli O157:H7 Eurofins GeneScan Technologies, GmbH AOAC-PTM # 022002 fresh raw ground beef (375 g), fresh raw beef trim (375 g), beef carcass sampling cloth (4\" x 4\"), romaine lettuce (375 g), all-purpose flour (25 g), stainless steel (4\" x 4\", 18gauge 300 series, brush finish, NSF-certified), unglazed ceramic tile (1\" x 1\") See \"Validated Matrices\" EC065 BACGene E. coli O157:H7 E. coli O157:H7 Eurofins GeneScan Technologies, GmbH AFNOR # EGS 38/06 - 11/19 Raw meat, ready-to-eat and ready-to-reheat meat (except poultry), raw milk and raw milk based products, fresh 25g EC066 BAX System Real-Time PCR Assays for STEC Suite and BAX System RealTime PCR Assays for E.coli O157:H7 Shiga toxin-producing Escherichia coli (O26, O103,O111, O145, O121 and O157:H7) serogroups Qualicon Diagnostics LLC. AFNOR # QUA 18/11 - 12/20 Raw beef meat, raw dairy products and vegetables products 25g - \*\* N/A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation  
Validated matrices Validated Test Portion Size EC067 GENE-UP\u00ae EHEC Detection Method E. coli (O26, O45, O103, O111, O121, O145, O157) bioM\u00e9rieux Inc. AOAC-OMA # 2020.06 Raw beef trim, raw ground beef (73 and 80% lean), raw veal, raw milk, and raw milk cheese; 200 g test portions of spinach; 375 g test portions of raw ground beef (73% lean), 25g except where noted in \"Validated Matrices\" EC068 BAX System Real-Time PCR Assay for E. coli O157:H7 Exact E. coli O157:H7 Hygiena AOAC-PTM # 102003 fresh raw ground beef (25 and 375 g, 73% lean), fresh raw beef trim (325 g and 375 g), leafy greens (375 g), raw fluid milk (25 g), dried cannabis flower [>0.3% delta 9tetrahydrocannabinol (THC)] and dried hemp flower (\u22210.3% THC) See \"Validated Matrices\" EC069 Simultaneous Multiplex Real Time PCR (SIMUL-qPCR) Top7 STEC Assay Collection Shiga toxin (stx) genes (eae), E. coli serotypes O157, O26, O45, O103, O111, O121. and O145 Applied Food Diagnostics AOAC-PTM # 022001 Fresh raw ground beef (~75% lean), fresh raw beef trim (~75%), and beef carcass sampling sheets (spun bonded polyolefin sampling sheet), leafy greens (200g), hemp flower (10g, <0.3% delta 9THC) See \"Validated Matrices\" EC070 GENE-UP EHEC Series Escherichia coli O157:H7 and non-O157 STEC Top 6 bioM\u00e9rieux, s.a. AOAC-PTM # 121806 spinach (200 g with enrichment 10-24 h), raw beef trim (375 g with enrichment 1024 h), raw ground beef (25 g with enrichment 10-24 h)

enrichment 8-24 h and 375 g with enrichment 10-24 h), whole cannabis flower (10 g, 1 g) and whole hemp flower (10 g, 1 g) See \"Validated Matrices\" EC071 foodproof STEC Screening LyoKit and foodproof STEC Identification LyoKit with foodproof StarPrep Three Kit stx1 , stx2 , eae , Escherichia coli serogroups O157, O26, O45, 103, O111, O121, O145, O104 BIOTECON Diagnostics GmbH AOAC-PTM # 102004 25 g and 375 g - fresh raw ground beef (~25% fat content), fresh raw beef trim) See \"Validated Matrices\" EC072 SUPREME Real Time Detection Kit E. coli E. coli O157, E. coli O111, E. coli O26, E. coli O103, E. coli O145 serotypes containing stx1 and\|or stx2 and eae genes BPMR (BioPremier SA) AOAC-PTM # 081902 25 g - raw ground beef, cream cheese, mixed lettuce, can orange juice See \"Validated Matrices\" EC073 Crystal Diagnostics AutoXpress AXSTEC Test Kit E. coli serogroups O26, O45, O103, O111, O121, O145, and O157 Crystal Diagnostics Corporation AOAC-PTM # 011502 325 g - raw ground beef, raw beef trim 200 g - raw spinach, Romaine lettuce, and spring mix greens See \"Validated Matrices\" \*\* N\|A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated matrices Validated Test Portion Size EC074 BACGene STEC Top7 Workflow STEC Top 7 Escherichia coli O157:H7 and non-O157 STEC E. coli O26, O45, O103, O111, O121, O145 Eurofins GeneScan Technologies, GmbH AOAC-PTM # 022003 fresh raw ground beef (375 g), fresh raw beef trim (375 g), beef carcass sampling cloth (4\" x 4\"), romaine lettuce (375 g), all-purpose flour (25 g), stainless steel (4\" x 4\"), 18gauge 300 series, brush finish, NSF-certified), unglazed ceramic tile (1\" x 1\") N\|A EC075 Solus One E. coli O157 Escherichia coli O157, including H7 Solus Scientific Solutions AOAC-PTM # 112001 fresh raw ground beef (~75% lean, 375 g) and fresh raw beef trim (~75% lean, 375 g) 375 g EC076 Applied Biosystems RapidFinder STEC Detection Workflow E. coli O157:H7 and \"Big Six\" non-E. coli STEC serotypes (O26, O45, O103, O111, O121, and O145) Life Technologies part of Thermo Fisher Scientific AOAC-PTM # 061602 fresh raw ground beef (73% lean, 375 g) fresh raw beef trim (375 g) 375 g EC077 Thermo Scientific SureTect Escherichia coli O157:H7 and STEC Screening PCR Assay Thermo Scientific SureTect Escherichia coli STEC Identification PCR Assay Shiga-toxin producing Escherichia coli (E. coli ): E. coli O157:H7, E. coli O26, E. coli O45, E. coli O103, E. coli O111, E. coli O121, E. coli O145 Oxoid Ltd part of Thermo Fisher Scientific AOAC-PTM # 012102 fresh raw spinach (25 g up to 375 g), fresh baby leaves (25 g) fresh cut tomatoes (25 g) frozen raw beef (25 g) raw beef trim (25 g up to 375 g), and beef carcass sponge See \"Validated Matrices\" EC078 GENE-UP Pathogenic E. coli (PEC) Shiga toxin-producing Escherichia coli containing highly correlated co-localized virulence genes stx and eae bioM\|u00e9rieux, s.a. AOAC-PTM # 022203 raw ground beef (80% lean, 375 g) raw beef trim (375 g) Romaine lettuce (375 g), and carcass sampling cloths (MicroTally) See \"Validated Matrices\" EC079 RAPID\|u2019E.coli 2 Agar E.coli and total coliforms Bio-Rad Laboratories NordVal # 020 broad range of foods See \"Validated Matrices\" EC080 TEMPO EC (E. coli) Test E. coli bioM\|u00e9rieux, s.a. AOAC-PTM # 080603 raw fresh ground pork, raw fresh ground veal, frozen ground beef, frozen chicken nuggets, raw fresh ground turkey, frozen turkey breast, raw white fish fillet, raw salmon steak, frozen cooked white fish, iceberg lettuce, fresh strawberries, dry pet food, raw milk, mozzarella cheese, yogurt, pasteurized eggs, dried cannabis flower [delta 9-tetrahydrocannabinol See \"Validated Matrices\" EC081 Assurance GDS MPX ID for Top STEC Top 6 Shiga Toxin-producing Escherichia coli (STEC), serotypes O26,O45,O103,O111,O121, O145 BioControl Systems, Inc. \|\ MilliporeSigma AOAC-PTM # 101502 Raw beef trim (375g), raw ground beef (375g), raw spinach (25g), stainless steel surface

spones (4\"x4\") N\A EC082 PDX\_STX Shiga toxin-producing Escherichia coli (STEC), Salmonella spp. Paradigm Diagnostics AOAC-PTM # 101705 raw ground beef 325 g N\A \*\* N\A = Not available", "Foodborne Pathogen Test Kits Validated by Independent Organizations FSIS is making available a list of test kits that have been validated for detection of relevant foodborne pathogens (i.e., Salmonella, Campylobacter, Listeria spp. including L. monocytogenes, E. coli O157:H7 and non-O157 STEC). The list is intended to be informational and is not an endorsement or approval of any specific test kit, regardless of its inclusion in the list. FSIS does not specifically endorse any of the mentioned test kits or products and acknowledges that equivalent test kits or products may be available for laboratory use. Likewise, FSIS does not require the use of any specific test kit, including those incorporated into FSIS\u2019s Microbiology Laboratory Guidebook methods. Instead, establishments and laboratories should choose test kits that are: 1)Validated for testing relevant foods by a: a)Recognized independent body (i.e., AOAC, AFNOR, MicroVal, NordVal), b)U.S. regulatory body (i.e., FSIS MLG or FDA BAM), or c) International Organization for Standardization (ISO) process 2)In addition, the validated method should be: a)Fit for the intended purpose and application (e.g., validated for the appropriate matrix and sample size to detect the appropriate foodborne pathogen), and b)Performed per the conditions of the validated protocol by a laboratory that assures the quality of the analytical results. The table below contains a list of foodborne pathogen test kits that are validated by recognized independent organizations (i.e., AOAC, AFNOR, MicroVal, NordVal) and therefore meet criterion 1a above. However, the test kits in this list are not necessarily equivalent or appropriate for all testing applications. FSIS intends to update validated test kit lists on a quarterly basis.

# Method Name	Target Organism(s)	Manufacturer	External Validation	Validated matrices	Validated Test Portion Size
STEC001	GeneDisc Plate STEC	Pall GeneDisc Technologies	AOAC-PTM # 021103	Shigatoxigenic Escherichia coli	fresh ground beef (25 g, 375 g), fresh beef trim (25 g, 375 g) See \"Validated Matrices\" STEC003 iQ-Check STEC VirX iQ-Check STEC SerO iQ-Check STEC SerO II Stx1, Stx2, eae, O26, O45, O103, O11, O121, O145, O157:H7, and STEC Bio-Rad Laboratories AOAC-PTM # 121203 raw beef trim, raw ground beef, fresh spinach, beef carcass sampling cloth (4\" x 4\", MicroTally Cloth) 375g
STEC004	GeneDisc Plate STEC & Salmonella spp.	Pall GeneDisc Technologies	AOAC-PTM # 021105	Shigatoxigenic E. coli and Salmonella spp.	Fresh raw ground beef, fresh raw beef trim 25g, 375g
STEC005	Microbiologique E. coli O157, Stx-producing E. coli (STEC) with Intimin and Salmonella Test System	E. coli O157, Stx-producing E. coli (STEC, specifically O26, O45, O103, O111, O121 & O145) with intimin and Salmonella IEH Laboratories & Consulting Group	AOAC-PTM # 100701	AOAC-PTM # 100701 Raw ground beef (25 g,375 g), raw beef trim (25 g, 375 g), raw poultry (25 g, 375 g), RTE turkey & mixed leafy greens (25g, 125g) 25 g except where noted in \"Validated Matrices\" ** N\A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated matrices Validated Test Portion Size STEC006 BAX System Real-Time PCR Assay Suite for STEC (formerly DuPont BAX System Real-Time PCR Assay Suite for STEC) STEC Screening Assay -stx and eae virulence genes STEC Panel 1 assay -E. coli O26, O111, O121 STEC Panel 2 assay -E. coli O45, O103, O146 Hygiena AOAC-PTM # 091301 raw beef trim (375 g), raw ground beef (325 g, 375 g), raw ground beef plus soy (325 g), raw ground beef (25 g), and all-purpose flour (25 g), dried cannabis flower [>0.3% delta 0-tetrahydrocannabinol (THC)] and dried hemp flower (\u22640.3% THC) See \"Validated Matrices\" STEC007 Assurance GDS for MPX Top 7 STEC STECs including: O26, O45, O103, O111, O121, O145, & O157	

BioControl Systems, Inc. AOAC-PTM # 071301 raw beef trim (375 g), raw ground beef (375 g), spinach (375 g), leafy greens (25 g), spinach (25 g), stainless steel (4\" x 4\" sponge) See \"Validated Matrices\" STEC008 Atlas STEC EG2 Combo Detection Assay E. coli O26:H11, E. coli O157:H7 and E. coli O45:H2 ROKA Bioscience, Inc AOAC-PTM # 011402 375 g - fresh raw ground beef (73% lean), fresh raw beef trim, romaine lettuce See \"Validated Matrices\" STEC009 GeneDisc Plate STEC Top 7 Escherichia coli O157:H7, O26, O45, O103, O111, O121, O145 Pall GeneDisc Technologies AOAC-PTM # 031401 375 g - fresh raw ground beef (20% fat), fresh raw beef trim (20% fat) See \"Validated Matrices\" STEC010 Actero Salmonella \/STEC Enrichment Media Salmonella spp. and STEC FoodChek Systems Inc. AOAC-PTM # 041403 Raw ground beef (25, 325 g), raw ground chicken (25 g), chicken carcass rinse, dried whole egg (100 g) whole liquid egg (100 g), raw frozen scallops (25 g), sprouts (25 g), raw almonds (375 g), peanut butter (25 g), dried parsley (25 g), whole black pepper (25 g), dried raisins (25 g) and Environmental surfaces: stainless steel (1x1 in), plastic, rubber (1x1 in), ceramic tiles (1x1 in), sealed concrete (1x1 in), dry pet food (25, 275 g), milk chocolate (25 g), chocolate liquor (25 g), cocoa powder (25 g), shell egg See \"Validated Matrices\" STEC011 Assurance GDS Top 7 STEC (eae ) Tq with Assurance GDS Shiga Toxin Genes (Top 7) Tq Top 7 Shiga toxin-producing Escherichia coli (STEC) serotypes O26, O45, O103, O111, O121, O145, and O157 BioControl Systems, Inc. AOAC-PTM # 071303 375 g - raw beef trim, raw ground beef 25 g - mixed greens and spinach (25 g) Contact Manufacturer \*\* N/A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation Validated matrices Validated Test Portion Size STEC012 Crystal Diagnostics AutoXpress AXSTEC Test Kit (formerly Xpress E7 STEC) E. coli serogroups O26, O45, O103, O111, O121, O145, and O157 Crystal Diagnostics Corporation AOAC-PTM # 011502 325 g - raw ground beef, raw beef trim 200 g - raw spinach, Romaine lettuce and spring mix greens See \"Validated Matrices\" STEC014 Assurance GDS MPX ID for Top STEC (MPX ID) Top 6 Shiga toxin-producing Escherichia coli (STEC) serotypes O26, O45, O103, O111, O121, O145 BioControl Systems, Inc. AOAC-PTM # 101502 Raw ground beef 20% fat (375 g), raw beef trim 45% fat (375 g), raw spinach (375 g), stainless steel (4\" x 4\" sponge) See \"Validated Matrices\" STEC017 Applied BioSystems RapidFinder STEC Detection Workflow E. coli O157:H7 and \"Big Six\" non-E. coli STEC serotypes (O26, O45, O103, O111, O121, O145) Life Technologies part of Thermo Fisher Scientific AOAC-PTM # 061602 375 g - fresh raw ground beef (73% lean), fresh raw beef trim See \"Validated Matrices\" STEC019 Veriflow STEC Escherichia coli with Stx1 or Stx2 and Eae virulence factors Invisible Sentinel Inc. AOAC-PTM # 111601 Raw beef trim (325 g) N/A STEC020 QIAGEN mericon\u00ae E. coli O157 Screen Plus and mericon\u00ae E. coli STEC O-Type Pathogen Detection Assays Escherichia coli O157:H7 and Escherichia coli nonO157 STEC Qiagen Germantown, MD AOAC-OMA # 2017.05 Fresh spinach (25 g), raw ground beef (70% lean; 325 g), raw beef trim (325 g) See \"Validated Matrices\" STEC021 VereBeef Detection Kit (8-20 hr) Escherichia coli O157:H7, STEC virulence factors (stx1A , stx2A and eae ) (10-20 hr) Escherichia coli O26, O45, O103, O111, O121, O145, Salmonella spp. Veredus Laboratories Pte, Ltd. AOAC-PTM # 011801 (Raw beef trim 25 g, 325 g, 375 g) See \"Validated Matrices\" STEC022 PDX-STEC Shiga toxin-producing E. coli (STEC), Salmonella spp. Paradigm Diagnostics, Inc. AOAC-PTM # 101705 Raw ground beef (325 g) N/A STEC023 PolySkope 1.0 Multiplex Detection Assay STECs, E. coli O157:H7 & Non-O157 STEC Big 6 ( O26, O45, O103, O111, O121, O145), Listeria monocytogenes, Salmonella spp. PolySkope Labs AOAC-PTM # 041801 (25 g) Fresh raw ground beef (73% lean), deli turkey, fresh baby spinach, stainless steel (4x4 in sponge) See \"Validated

Matrices\" STEC024 GENE-UP EHEC Series (formerly GENE-UP EHEC Series PTM 031701)  
Escherichia coli O157:H7 & non-O157 STEC Top 6 bioM\u00e9rieux, s.a. AOAC-PTM # 121806  
Raw beef trim (375 g with enrichment 10-24h), raw ground beef (25 g with enrichment 8-24h  
and 375 g with enrichment 10-24h), spinach (200 g with enrichment 10-24h), spinach (200 g),  
whole cannabis flower (10 g, 1 g), whole hemp flower (10 g 1 g) See \"Validated Matrices\" \*\*  
N/A = Not available", "# Method Name Target Organism(s) Manufacturer External Validation  
Validated matrices Validated Test Portion Size STEC025 NeoSeek STEC EHEC Escherichia coli of  
serogroups O26, O45, O103, O111, O121, O145, and O157 Neogen Corporation AOAC-PTM #  
081901 325 g - raw beef trim, raw ground beef, pure bacterial cultures Contact Manufacturer  
STEC026 GeneDisc STEC Shiga toxin-producing Escherichia coli (O26, O103,O111, O145, O157)  
Pall GeneDisc Technologies AFNOR # GEN 25\09 -03\19 Raw beef meat, raw dairy products  
and vegetables 25g STEC027 3M Molecular Detection Assay 2 -STEC Gene Screen (MDA2-  
STXEAE) STEC\Shiga-toxin producing enterohemorrhagic E. coli ( E. coli strains containing  
Escherichia coli genes stx1 (codes for Shiga toxin type 1) and\or stx2 (codes for Shiga toxin  
type 2), and eae gene (codes for intimin) 3M Food Safety AOAC-PTM # 071902 Fresh raw beef  
trim (375 g,~75% lean) fresh raw ground beef (375 g,~73% lean), fresh raw spinach (200 g),  
fresh raw ground beef (25 g, ~75% lean), fresh raw ground pork (375 g, ~70% lean), fresh raw  
poultry parts (375 g), sprouts (25 g) See \"Validated Matrices\" STEC028 3M Molecular  
Detection Assay 2 -STEC Gene Screen (MDA2-STX) Shiga-toxin producing E. coli (E. coli strains  
containing Escherichia coli genes stx1 codes for Shiga-toxin type 1) and\or stx2 (codes for  
Shigatoxin type 2) 3M Food Safety AOAC-PTM # 071903 Fresh raw ground beef (375 g,~73%  
lean), fresh raw spinach (200 g), fresh raw ground beef (25 g, ~75% lean), fresh raw beef trim  
(25 g,~75% lean), fresh raw ground pork (375 g, ~70% lean), fresh raw poultry parts (375 g)  
sprouts (25 g) See \"Validated Matrices\" STEC029 BACGene STEC Top7 Workflow STEC Top 7  
(Escherichia coli O157:H7 & non-O157 STEC E. coli O26, O45, O103, O111, O121, O145) Eurofins  
GeneScan Technologies, GmbH AOAC-PTM # 022003 Fresh raw ground beef (375 g), fresh raw  
beef trim (375 g), beef carcass sampling cloth (4\" x 4\" cloth), romaine lettuce (375 g), all-  
purpose flour (25 g) stainless steel (4\" x 4\") See \"Validated Matrices\" STEC030 SUPREME Real  
Time Detection Kit E. coli E.coli O157, O111, O26, O103, O145 serotypes containing stx1  
and\or stx2 and eae genes BPMR - Produ\u00e7\u00e3o e Desenvolvimento, Lda AOAC-PTM #  
081902 raw ground beef, cream cheese, mixed lettuce, can orange juice 25g STEC031 Thermo  
Scientific SureTect STEC Screening PCR Assay and Thermo Scientific SureTect Identification PCR  
Assay Shiga toxin-producing Escherichia coli (O26, O103,O111, O145, O157 ) serogroups Oxoid  
Ltd. Thermo Fisher Scientific AFNOR # UNI 03\13 - 10\20 Raw meats (including poultry  
meats), dairy products and vegetables including fruits 25g STEC032 BAX System Real-Time PCR  
Assays for STEC Suite and BAX System Real-Time PCR Assays for E.coli O157:H7 Shiga toxin-  
producing Escherichia coli (O26, O103,O111, O145, O121 and O157:H7) serogroups Qualicon  
Diagnostics LLC. AFNOR # QUA 18\11 -12\20 Raw beef meat, raw dairy products and  
vegetables products 25g STEC033 GENE-UP EHEC Detection Method STEC bioM\u00e9rieux  
MicroVal # 2018LR84 Raw meat, except poultry (25g and 375g), raw milk, and raw milk cheeses  
and production environmental samples See \"Validated Matrices\" \*\* N/A = Not available", "#  
Method Name Target Organism(s) Manufacturer External Validation Validated matrices  
Validated Test Portion Size STEC034 GENE-UP Pathogenic E. coli (PEC) Shiga toxin producing E.  
coli (STEC) containing highly correlated co-localized virulence genes stx and eae

bioM\u00e9rieux AOAC-PTM # 022203 375 g - raw ground beef (80% lean), raw beef trim, Romaine lettuce, and carcass sampling cloths (MicroTally) See \"Validated Matrices\" STEC035 Assurance GDS MPX for Top 7 STEC, MPX ID for Top STEC and EHEC ID for E. coli O157:H7 detection of Shiga toxinproducing Escherichia coli (STEC) and the determination of O26, O45, O103, O111, O121, O145, O157 serogroups Millipore Sigma AFNOR # TRA 02\13 - 04\22 Raw beef meat (excluding seasoned meat), raw milk and dairy products 375 g STEC036 Simultaneous Multiplex Real Time PCR (SIMUL-qPCR) Top 7 STEC Assay Collection Shiga toxin (stx) genes, Intimin genes (eae), E. coli Serotypes: O157, O26, O45, O103, O111, O121, O145 Applied Food Diagnostics, Inc. AOAC-PTM # 022001 Hemp flower, Leafy greens, Fresh raw ground beef (~75% lean), Fresh raw beef trim (~75%), beef carcass sampling sheets (spunbonded polyolefin sampling sheet) N\A \*\* N\A = Not available"]}, {"file\_name": "FSIS\_GD\_2019\_0009", "title": "Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submissions (2019)", "num": "FSIS-GD-2019-0009", "id": "6b7a4bdf745ee34dc1cb9beb9c28bd7b86fa0e550e0fd82f88e66541f95b86d0", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-02/RaisingClaims.pdf", "type": "pdf", "n\_pages": 18, "word\_count": 6118, "text\_by\_page": ["1 This guideline is designed to help establishments determine: \u2022The supporting documentation needed when submitting labels that bear an animal raising claim. \u2022Whether a modified label with an animal raising claim that has been approved is required to come back for approval or can be changed generically. \u2022How to add additional suppliers to a label with an animal raising claim that has been approved. This guideline is designed to help establishments determine: \u2022The supporting documentation needed when submitting labels that bear an animal raising claim. \u2022How to add additional suppliers to a label with an animal raising claim that has been approved. Food Safety and Inspection Service Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submissions December 2019", "2 FSIS Compliance Guideline for Label Approval Table of Contents Preface"]}]

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Use\... 13  
Source\Traceability\... 14 Third-Party  
Certification\... 15  
Organic\... 15 Adding a New  
Supplier\... 16 Label  
Example\... 17 Additional Resources

..... 18", "3 Preface What is the purpose of this Compliance Guideline? The purpose of this compliance guideline is to outline the documentation that establishments need to submit in support of label applications for products that bear animal raising claims. The Food Safety and Inspection Service (FSIS) is the Agency in USDA with the responsibility for ensuring that the labeling of meat and poultry products is truthful and not misleading. Labeling bearing claims referring to the way that the source animal for a meat or poultry product was raised need to be evaluated and approved by FSIS prior to use. For the past 25 years, FSIS has evaluated animal raising claims by considering information on animal raising practices submitted by companies as part of their label approval requests. The Agency has approved such claims if the animal raising information submitted with the label application supported the claim being made and the claim is truthful and not misleading. FSIS developed this guideline to respond to numerous requests to the Labeling Program and Delivery Staff (LPDS) through phone calls, askFSIS questions, and other correspondence regarding the type of information needed to support the approval of labels bearing animal raising claims. This guideline is intended to facilitate the approval process for labels bearing animal raising claims. The information in this guideline is provided as guidance to assist meat and poultry establishments and is not legally binding from a regulatory perspective. Who is this guideline designed for? This guideline is for establishments that are designing or modifying meat or poultry product labels with animal raising claims. The establishment must determine what supporting documentation is required for the various types of animal raising claims. This guideline will assist the establishment in making this determination. How will FSIS verify whether establishments meet requirements related to this guideline? FSIS in-plant personnel verify that establishments comply with labeling regulations, when performing the General Labeling task assigned through the Public Health Information System (PHIS). For product bearing animal raising claims, in-plant personnel verify whether establishments maintain an FSIS approved label on file. Animal raising claims are special statements and claims

that establishments are Key Points The following are examples of animal raising claims that are required to be approved by FSIS prior to use in commerce: 1. Raised Without Antibiotics 2. Organic 3. Grass Fed 4. Raised Without the Use of Hormones", "4 required to submit to FSIS for approval for compliance with 9 CFR 412.1, USDA\ufe0f's Label Approval Regulations. Changes made to the guideline from the previous version After reviewing the comments received, FSIS has revised the guideline by section as follows: \u2022 Product Labeling: Use of Animal-Raising Claims on the Labels of Meat or Poultry Products o Added information about labeling needed for products bearing claims certified by third-party organization, including when products certified as \u201corganic\u201d need to disclose the certifying entity\ufe0f's website address on the product label. o Added information about carrying claims forward on additional products. o Removed age claims section because establishments are not using these claims. o Animal Welfare and Environmental Stewardship Claims: o Added descriptive language or information (terminology) that should accompany these claims to explain the meaning of the claim to consumers, including the type of information that needs to appear on the label when the product is certified by a third-party organization. o Breed claims: o Added information about carrying these claims forward to other products. o Living- or Raising-Condition Claims: o Reorganized section for clarity regarding labeling terminology and recommended documentation for approval. o Added information about additional terminology that typically accompanies these claims to explain the meaning of the claim to consumers, including where the information must appear on the label. o Added information on the use of \u201cFree Range\u201d and synonymous claims (\u201cFree Roaming,\u201d \u201cPasture Fed,\u201d Pasture Grown,\u201d \u201cPasture Raised,\u201d and \u201cMeadow Raised\u201d) on labels of poultry products and the documentation needed to substantiate these claims. o Raised Without Antibiotics \u2013 Livestock\Red Meat or Poultry: o Added \u201cRaised Antibiotic Free\u201d and \u201cNo added antibiotics\u201d as examples of claims that may be used to disclose the fact that animals were not administered antibiotics at any point in the animal production process. o Added information on claims that include the term \u201csub-therapeutic antibiotics\u201d to ensure that consumers understand that the claim means that antibiotics may only be administered in the event of an illness and includes the circumstances for which FSIS will approve labels bearing these claims. o Raised Without Hormones (No Hormones Administered or No Steroids Administered): o Updated information to clarify that FSIS will no longer require a qualifying statement on pork products labeled with \u201ca raised without hormones\u201d claim because Federal law permits the use of certain hormones in swine, e.g., for gestation.", "5 o Added new examples of this type of claim. o Updated information to clarify why a qualifying statement is necessary for products made from a kind or species for which Federal law prohibits hormone use and to emphasize that this information must be displayed on the label in a manner that is likely to be read and understood by the ordinary individual for FSIS to approve the claim.. o Third-Party Certification: o Added information about documentation needed to support labels bearing animal raising claims that have been \u201cverified\u201d or \u201ccertified\u201d by third-party organizations. o Added information about \u201corganic\u201d claims, including other claims that could be substantiated with an Organic Certificate. o Added section on procedures for adding an additional supplier for a label with animal-raising claims that was previously approved by FSIS. The updated guideline is posted at:

<https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/complianceguides-index/>. FSIS will update this document, as necessary. What if I still have questions after I read this guideline? If the desired information cannot be found within the Compliance Guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the askFSIS database or submit questions through askFSIS. Documenting the questions helps FSIS improve and refine present and future versions of the Compliance Guideline and associated issuances. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided: SubjectField: \u201cDocumentation Needed to Substantiate Animal Raising Claims\u201d QuestionField: Enter question with as much detail as possible. ProductField: Select Labeling from the drop-down menu. CategoryField: Select Labeling Regulations, Policies and Claims from the dropdown menu. Policy Arena: Select Domestic (U.S.) only from the drop-down menu. When all fields are complete, press Continue. Congressional Review Act Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this guideline is not a \u201cmajor rule,\u201d as defined by 5 U.S.C. 804(2).", "6 Product Labeling: Use of the Animal Raising Claims on the Labels of Meat and Poultry Products A Federal establishment is required to use labels that are in compliance with the Federal Meat Inspection Act (FMIA; 21 U.S.C. \u00a7 601, 607) and the Poultry Products Inspection Act (PPIA; 21 U.S.C. \u00a7 451, 457) (the Acts), and the implementing regulations. Requirements include all mandatory labeling requirements as prescribed in Title 9 of the Code of Federal Regulations (CFR) section 317.2 and Part 381 Subpart N. Although FSIS does not exercise its authority of prior label approval to point of purchase materials (e.g., pamphlets and placards) displayed in conjunction with products sold at retail and bearing animal raising claims, FSIS does require these materials be neither false or misleading, in compliance with the Acts and Federal regulations. As stated in 9 CFR 412.1, labels with special statements and claims are required to be approved by FSIS prior to use in commerce. Labels bearing animal raising claims are required to be submitted to LPDS with specific documentation to support all animal raising claims that appear on that label. Examples of animal raising claims include, but are not limited to: Raised Without Antibiotics, Grass Fed, Free-Range, and Raised Without the Use of Hormones. For most animal raising claims, the documentation typically needed to support these claims is: 1. A detailed written description explaining the controls used for ensuring that the raising claim is valid from birth to harvest or the period of raising being referenced by the claim; 2. A signed and dated document describing how the animals are raised which may include feed formulations (e.g., vegetarian fed, raised without antibiotics, grass fed), to support that the specific claim made is truthful and not misleading; 3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution; 4. A written description for the identification, control, and segregation of nonconforming animals\product; and 5. If a third-party certifies a claim, a current copy of the certificate from the certifying organization. NOTE: If the claim was certified by a third-party certifying organization, FSIS will not approve the label bearing the claim if it does not include the certifying entities name, website address,<sup>1</sup> and logo, when the organization has a logo. An asterisk or other symbol must connect the claim to this information.  
1 Products certified as \u201corganic\u201d would not need to disclose a website address on the label, except when the address is required under 7 CFR Part 205.", "7 In general, a

purchased product bearing an approved animal raising claim may be used to support the claim in lieu of numbers 1 \u2013 3 above. If a company purchases product bearing animal raising claims and would like to carry forward those claims onto its labeled product, the company needs to provide a copy of the purchased product label and segregation procedures when entering their federal establishment. However, companies cannot carry forward certified claims, logos and\or websites from purchased products that are certified by a third-party entity unless the companies that are carrying the claim forward are also under that same certification. Companies cannot carry forward USDA organic claims, logos and\or websites without being certified organic themselves. Types of Animal Raising Claims and Guideline on the Documentation Needed to Substantiate the Claims Animal Welfare and Environmental Stewardship These claims describe how animals are raised based on the care they receive by the producer or how the producer maintains the land and replenishes the environment. FSIS has not defined these claims in regulations or policy guidelines. For animal welfare claims, such as \u201cRaised with Care,\u201d or environmental stewardship claims, such as \u201cSustainably Raised,\u201d FSIS will only approve a claim if a statement is provided on the label showing the name of the entity that established the standard and includes additional terminology explaining the meaning of the claim for consumers, e.g., \"TMB Ranch Defines Raised with Care\Sustainably Raised as [explain the meaning of the claim on the label].\" If the entity has a website that describes the standards used to define the claim, the label may provide the website address instead of explaining what the claim means on the product label, e.g., \u201cRaised with Care as defined by TMB Ranch at: [website address].\u201d As an alternative, animal welfare and environmental stewardship claims can be certified by a third-party certifying organization that posts the standards used to define the claim on its website. If the claim is certified by a third-party certifying organization, FSIS will not approve the label bearing the claim if it does not include the certifying entities name, website address, and logo, when the organization has a logo. The claims may appear on any panel of the package. The additional terminology that explains the meaning of the claim may appear with the claim or may be connected to the claim by an asterisk or another symbol and placed elsewhere on the same panel that bears the claim. For example, if a claim is made on the principal display panel (PDP), the part of the label most likely to be seen by consumers when offered for retail sale, the explanation of the claim\u2019s meaning may be placed with the claim or placed elsewhere on the PDP provided the claim and explanation are connected by a symbol. If the claim is certified by a third-party certifying organization, an asterisk or other symbol must connect the claim to the certifying entities name, website address, and\or logo, when the organization has a logo, for FSIS to be able to approve the label. Examples of these types of claims include, but are not limited to: Humanely Raised\*, Sustainably Farmed\*, and Raised with Environmental Stewardship\*.,"8 \*TMB Ranch defines \u201cHumanely Raised\u201d\|\u201dSustainably Farmed\Raised with Environmental Stewardship\u201d as [insert description of standards used to define the claim] Documentation needed: 1. A detailed written description explaining the meaning of the animal welfare or environmental stewardship claim and the controls used for ensuring that the raising claim is valid from birth to harvest; or the period of raising being referenced by the claim; 2. A signed and dated document describing how the animals are raised to support that the claims are not false or misleading; 3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through

packaging and wholesale or retail distribution; and 4. A written description for the identification, control, and segregation of nonconforming animals\product (e.g., how animals not raised in accordance with the specific animal welfare guidelines or stewardship program are segregated from animals eligible to bear the claim). Breed Breed claims refer to the declaration of a specific breed of livestock or poultry. Examples of this type of claim include, but are not limited to: Angus, Wagyu (American Kobe), Hereford, Berkshire, Duroc, Muscovy, Silkie, and heritage poultry, pork or beef breeds. Documentation needed: 1. A signed and dated document that substantiates the breed claim, e.g., under a Agricultural Marketing Service (AMS) Certified Meat and Poultry Program or a certificate from a breed organization; 2. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution; 3. Documentation to support the breed by phenotype (for example, hide color) or genotype (traceable to one registered parent or two registered grandparents with a breed association); and 4. A written description for the identification, control, and segregation of nonconforming animals\product. Alternatively, a purchased product label may be used in lieu of numbers 1 \u2013 3 above. If a company purchases product bearing a breed claim and would like to carry forward the claim on to their product, the company needs to provide a copy of the purchased label and segregation procedures for product entering the federal establishment when submitting for label approval.

NOTE: See label example", "9 Diet Diet claims refer to what animals are fed prior to harvest and processing. These claims require that the animals only eat the diet claimed for the lifetime of the animal, with the exception of milk consumed prior to weaning. FSIS considers Grassfed, Grass Fed and Grass-Fed synonymous terms. \u201cGrass Fed\u201d or \u201c100% Grass Fed\u201d claims may only be applied to meat and meat product labels derived from cattle that were only (100%) fed grass (forage) after being weaned from their mother\u2019s milk. The diet must be derived solely from forage, and animals cannot be fed grain or grain by-products and must have continuous access to pasture during the growing season until slaughter. This means 100% grass-fed animals are never confined to a feedlot. Forage consists of grass (annual and perennial), forbs (e.g., legumes, Brassica), browse, or cereal grain crops in the vegetative (pre-grain) state. Hay, haylage, baleage, silage, crop residue without grain, and other roughage sources may also be included as acceptable feed sources. Routine mineral and vitamin supplementation may also be included in the feeding regimen. If incidental supplementation occurs due to inadvertent exposure to non-forage feedstuffs or to ensure the animal\u2019s wellbeing at all times during adverse environmental or physical conditions, the producer should provide a signed and dated document to the establishment attesting the above incident is not a routine occurrence. The establishment should include this information as part of the labeling documentation verifying the product qualifies for a grass fed claim. When animals have less than 100-percent access to grass or forage the partial \u201cgrass fed\u201d claim must accurately reflect the circumstances of raising, e.g., \u201cMade from cows fed 85% grass and 15% corn.\u201d The claim \u201cGrass Finished\u201d is not the same as \u201cGrass Fed\u201d because animals that are \u201cgrass finished\u201d can be fed grain, in which case the claim \u201cGrain Fed, Grass Finished\u201d would be truthful and not misleading. Historically, the AMS Grass (Forage) Fed Marketing Claim Standard was considered one form of proof to FSIS that the claim \u201cgrass fed\u201d was truthful and not misleading. In January 2016, AMS withdrew the standard. This change did not change

FSIS\u2019s documentation requirements for companies wishing to label their products as \u201cGrass Fed.\u201d Examples of this type of claim include, but are not limited to: Grass (Forage) Fed, Grain Fed, Vegetarian Feed, Raised Using Vegetarian Feeds [This means all vegetable feeds and no animal products (e.g., whey) are fed to the animal.], Raised Using Vegetarian Feeds (with a disclaimer to clarify animal products are fed to the animal for a certain period of time, e.g., \u201cexcept for dairy products fed from birth to eight weeks\u201d or \u201cafter 8 weeks\u201d), and Fed No Animal By-Products. Documentation needed: 1. A detailed written description explaining controls for ensuring that the raising claim is valid from birth to harvest or the period of raising being referenced by the ", "10 claim; (e.g., controls to ensure cattle that are supposed to be raised 100% grass fed are not fed grains); 2. A signed and dated document describing the diet of the animals to support that the claims are not false or misleading; 3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution; and 4. A written description for the identification, control, and segregation of nonconforming animals\product. As an alternative, a producer may use the USDA Process Verified Program (PVP) (carried out by AMS) to verify their product meets their own grass-fed standard in lieu of documentation needed for 1-4 above. The USDA PVP is a voluntary, user-fee verification service that offers applicants a unique way to market their products to customers using clearly defined, implemented, and transparent process points. An applicant\u2019s program may include one or more agricultural processes or portions of processes independently verified by a qualified AMS auditor. Examples of process points include, but are not limited to: adherence to a recognized standard or one created by a company or organization; definitions included within this guidance; a production, raising and\or handling practice that provides specific information to consumers to enable them to make informed decisions on the products that they buy; or a characteristic, practice, or requirement that is specifically requested by a customer or consumer. AMS auditors conduct a comprehensive review of a company\u2019s program, which includes an on-site audit of all facilities and phases of the operation that impact process verified points. Additional information about the USDA PVP service, shield, certificate, and official listing are available at [www.ams.usda.gov/services/auditing/process-verified-programs](http://www.ams.usda.gov/services/auditing/process-verified-programs). There are a number of private third-party certification programs that accomplish the same objectives. If the claim is certified by a third-party organization, an asterisk or other symbol must connect the claim to the certifying entities name, website address, and\or logo, when the organization has a logo. NOTE: See label example Living\Raising\Raising Conditions These claims refer to the environment in which the animals or birds were raised during their lifespan. Examples of this type of claim include but are not limited to: Cage or Crate Free, Free Range\*\*, Not Confined, Free Roaming, Pasture Fed, Pasture Grown, Meadow Raised, and Pasture Raised. NOTE: For all of the above claims, additional terminology is necessary on the label to define its meaning on livestock products and to convey that the animals were never confined to a feedlot. Because FSIS has not defined these claims in the regulations or policy guidelines, nearly all living\raising conditions claims need to describe the standards used to define", "11 that claim as applied to that particular product, e.g., \u201cCage free. Chickens were never confined to cages during raising.\u201d The information must appear with the claim or be connected by a symbol on the same panel on which the claim appears. As an alternative, these living\raising claims can be certified by a third-party certifying organization

that posts its standards for defining the claim on its website. If the claim is certified by a third-party certifying organization, FSIS will not approve the label bearing the claim if it does not include the certifying entity's name, website address, and logo, when the organization has a logo. An asterisk or other symbol must connect the claim to this information. \*\*Based on consultations with AMS, FSIS determined that additional terminology is not needed on the label for the claim Free Range or synonymous claims (\u201cFree Roaming,\u201d \u201cPasture Fed,\u201d Pasture Grown,\u201d \u201cPasture Raised,\u201d and \u201cMeadow Raised\u201d) on poultry products. However, for FSIS to approve these claims, additional documentation must be submitted to substantiate the claim. Specific details about what additional information is needed is provided below. Documentation needed: 1. A detailed written description explaining controls for ensuring that the animals are raised in a manner consistent with the meaning of the raising claim that is valid from birth to harvest or the period of raising being referenced by the claim. 2. A signed and dated document describing how the animals are raised to support that the claims are not false or misleading; 3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution; and 4. A written description of the identification, control, and segregation of nonconforming animals\product. As part of 1 or 2 above, for the claim Free Range on poultry products, the documentation must describe the housing conditions for the birds and demonstrate continuous, free access to the outside throughout their normal growing cycle. During the winter months in a northern climate, birds are not free range if they stay in poultry housing or coops all winter. Producer documentation to support the use of the claim for birds raised in a northern climate during winter months would also need to describe the housing conditions for the birds and demonstrate continuous, free access to the outside throughout their normal growing cycle. As part of 1 or 2 above, for the claims Free Roaming, Pasture Fed, Pasture Grown, Pasture Raised, and Meadow Raised on meat or poultry products, documentation that will typically substantiate these claims will show that the animals or birds have continuous, free access to the outdoors throughout their usual grow-out period. For ruminants, this means the entire grazing season for the geographical area.

NOTE: See label example", "12 Negative Antibiotics Use \u2013 Livestock\Red Meat Raised Without Antibiotics: To use this claim, source animals cannot be administered antibiotics in their feed, water or by injections at any point in the production process. This includes ionophores which are recognized as antibiotics by FSIS. Examples of this type of claim include, but are not limited to: Raised Without Antibiotics, No Antibiotics Administered, No Added Antibiotics, No Antibiotics Ever and Raised Antibiotic Free. No Sub-Therapeutic Antibiotics: FSIS will approve a claim that states that animals have not been administered subtherapeutic antibiotics if the claim is part of a complete claim that explain what the term \u201bsub-therapeutic\u201d means, e.g., \u201cNo sub-therapeutic antibiotics. Animals do not receive antibiotics on a daily basis; animals only receive antibiotics in the case of illness.\u201d Other examples of this claim that FSIS is likely to find to be truthful and not misleading include: \u201cBeef Raised with No Sub-Therapeutic Antibiotics Ever, animals may be given antibiotics for the treatment of illness\u201d or \u201cBeef Raised with No Sub-Therapeutic Antibiotics, Animal do not receive antibiotics on a daily basis only in the case of illness.\u201d Documentation needed: 1. A detailed written description explaining controls for ensuring that the animals are not given antibiotics from birth to harvest or the period of raising being

referenced by the claim including feed formulation; 2. A signed and dated document describing how the animals are raised to support that the claims are not false or misleading; 3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution; and 4. A written description for the identification, control, and segregation of nonconforming animals\product (e.g., if beef raised without the use of antibiotics need to be treated with antibiotics due to illness). NOTE: See label example Negative Antibiotics Use \u2013 Poultry Raised Without Antibiotics For FSIS to find this claim to be truthful and not misleading, source animals cannot be administered antibiotics in their feed, water, or by injections. Animals cannot be administered ionophores, which are recognized as antibiotics by FSIS. Examples of this type of claim include: Raised Without Antibiotics, No Antibiotics Administered, No Added Antibiotics, No Antibiotics Ever, and Antibiotics Free. No Sub-Therapeutic Antibiotics:","13 This claim requires additional explanation on the label to ensure consumers understand antibiotics will be administered to the animals in the event of illness. Examples of this claim include: \u201cTurkey Raised with No Sub-Therapeutic Antibiotics Ever, birds may be given antibiotics for the treatment of illness\u201d or \u201cChicken Raised with No SubTherapeutic Antibiotics, birds do not receive antibiotics on a daily basis only in the case of illness.\u201d Documentation needed: 1. A detailed written description explaining controls for ensuring that the raising claim is valid from birth to harvest; or the period of raising being referenced by the claim; 2. A signed and dated document describing how the animals are raised without antibiotics to support that the claims are not false or misleading; 3. A written description of product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution; and 4. A written description for the identification, control, and segregation of nonconforming animals\product (e.g., if chicken raised without the use of antibiotics need to be treated with antibiotics due to illness). In addition to the documentation listed above, the establishment needs to submit a company letter (signed and on company letterhead) answering the following questions: 1. Do you use antibiotics pre-hatch in any way with respect to the eggs that you hatch for the poultry that will bear the claim? If so, please describe how you use antibiotics? 2. Do you inject any vaccines in ovo? If so, please state whether any of the vaccines includes an antibiotic. If any of them does, please state what antibiotics are used, what the antibiotics are used for, and in what amount they are used. 3. Do you inject any antibiotics in ovo? If so, please state what antibiotics are used, what the antibiotics are used for, and in what amount they are used. What is the withdrawal time for the antibiotics? 4. Have you verified that the poultry that you use to produce your products was not derived from eggs or poultry that were injected or otherwise treated in any way with antibiotics? If so, how have you verified these conclusions? NOTE: See label example Negative Hormones Use Under Federal law, hormones are only approved for use in beef cattle, swine\*\*\*, and lamb production. There are no hormones approved for use in the production of poultry, goat, veal calves, mature sheep, or exotic, non-amenable species (such as bison, buffalo, elk, and venison). Thus, additional terminology is necessary on these labels to convey that Federal law prohibits hormone use in these species.", "14 FSIS will only approve a negative hormone claim on products made from a kind or species for which Federal law prohibits hormone use when it is accompanied by the qualifying statement: \u201cThere are no hormones approved for use in (kind or species [poultry, goat, veal, mature sheep, or exotic, non-amenable]) by Federal

Regulations.\u201d The qualifying statement must be prominently and conspicuously displayed on the label, e.g., it appears adjacent to the claim or is in type at least one-third the height, in accordance with 9 CFR 317.2(b) for meat products or 9 CFR 381.116(b) for poultry products. As for any labeling claim, FSIS confirms compliance with these regulations during the label approval process. \*\*\*NOTE: In the previous draft of this guideline, FSIS stated that no hormones had been approved for use in the production of swine. After additional research, FSIS has found that there are several hormones approved by the Food and Drug Administration and marketed by drug makers to be used in swine in the United States for various reasons (e.g., gestation). Establishments do not need to resubmit their labels for approval to remove the previously required disclaimer statement from pork product labels. The change can be made generically under 9 CFR 412.1. Examples of this type of claim include: Raised Without Added Hormones, No Added Hormones Administered, Raised Without Steroids. Documentation needed: 1. A detailed written description explaining controls for ensuring the animals are raised without hormones or steroids to support the claim is valid from birth to harvest; or the period of raising being referenced by the claim; 2. A signed and dated document describing how the animals are raised (e.g., without the use of hormones) to support that the claims are not false or misleading; 3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution; and 4. A written description for the identification, control, and segregation of nonconforming animals\product. NOTE: See label example Source\Traceability This type of claim demonstrates how the animal can be traced back to its farm of origin from birth to slaughter\harvest. Examples of this type of claim include: Source Verified and Traceable to [Name of Farm of Origin]. Documentation needed: 1. A detailed written description explaining controls for ensuring the source of the animal can be verified from birth to harvest or the period of raising being referenced by the claim; 2. A signed and dated document describing how the animals are raised to support that the claims are not false or misleading;","15 3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution; and 4. A written description for the identification, control, and segregation of nonconforming animals\product; and 5. Live animal raising records demonstrating how individual animals or a group of animals are identifiable and traceable to their farm or ranch of birth, and if verified, the individual or entity verifying the claim. NOTE: See label example Third-Party Certification Generally, FSIS accepts animal raising claims verified by a third-party auditing or certifying program. The standards for acceptance of the third-party certifier need to be credible and reliable. FSIS evaluates certifiers\u2019 acceptance standards as necessary to assess suitability for animal raising claims on labels. The label bearing the claim needs to include the certifying entity\u2019s name, website address, and logo, when the organization has a logo. An asterisk or other symbol must connect the claim to this information. Examples of this type of claim include but are not limited to: USDA PVP (administered by AMS), Animal Welfare Approved (AWA), or GAP Step ratings (Global Animal Partnership (GAP)). Documentation needed: 1. A current copy of the certificate; and 2. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution. NOTE: If used in conjunction with any other animal raising claim(s) that are not covered by the third-party organization certification, refer to the documentation needed for the particular

claim(s). However, third-party certification cannot be carried over to other products unless the company has the same certification. NOTE: See label example Organic USDA organic regulations describe the specific standards required for a company to use the word \u201corganic\u201d or the USDA organic seal on food, feed, or fiber products. See <https://www.ams.usda.gov/services/organic-certification-and/or> <https://www.ams.usda.gov/rules-regulation/organic/labeling>. The USDA organic regulations are administered by AMS\u2019s National Organic Program (NOP) and described at 7 CFR Part 205. For animal products to be labeled as organic, livestock producers must be certified organic and any operations that subsequently handle the organic product must be certified organic (e.g., slaughter plants, meat", "16 packing facilities). Organic operations are inspected annually by USDA-accredited certifying agents. The label bearing the claim needs to include the certifying entity\u2019s name, website address, and logo, when the organization has a logo. 1. FSIS accepts current organic certificates to substantiate certain animal raising claims such as: \u201craised without antibiotics,\u201d \u201cno added hormones,\u201d \u201cvegetarian diet,\u201d \u201cno animal-by-products,\u201d \u201cNON-GMO\u201d and \u201chumanely raised\u201d with company\u2019s description and qualifier [\u201cThese are consistent with the USDA organic regulations\u201d]. 2. As referenced previously in this document, organic claims, logos and\or websites from purchased products cannot be carried over to other products unless the company has the same certification. 3. If an establishment produces meat or poultry products that qualify for an organic claim under the NOP, the establishment would not need to provide a written description of the product tracing and segregation mechanism because these activities are a condition of NOP certification. NOTE: See label example Requesting approval for the addition of new suppliers to the documentation for a product with a previously approved label bearing animal raising claims LPDS has procedures in place that allow for an establishment to add a new supplier to the documentation of a previously approved label and not have to resubmit the label for another sketch approval. For the purposes of this section, a supplier is a producer, farmer, or even another establishment that provides animals or products to another establishment to use in its products that bear the same animal raising claims. Examples would include but not limited to suppliers added for an approved product label bearing animal raising claims, meat or poultry cuts for specific breeds. Additional suppliers must be approved by LPDS and upon approval the labeling record must be updated to reflect the new supplier(s). To obtain approval, the producing establishment would need to submit a signed and dated request to LPDS by email or letter that includes the following: 1. The product name; 2. The producing establishment\u2019s name, address, and establishment number; the prior label approval number; and a copy of the previously approved label application; 3. The specific claim(s) that will be used on the product label containing source materials from the new supplier; 4. The new supplier\u2019s name, address, and one copy of any labels with the same claim(s) previously approved by LPDS associated with the supplier or documentation to support why the claim(s) also applies to the new supplier; and 5. Finally, for claims certified by a third-party, include a copy of the current certificate(s). Due to the fact that most certifications expire after one year, FSIS will consider a certificate current based on a one-year time span unless the certificate states otherwise.", "17 Once all the documentation above is evaluated, LPDS will notify the applicant in writing of its final determination. As mentioned above, this letter needs to be included as part of the

supporting documentation in the producing establishment's official labeling record. Label Example The above label contains the following types of claims: - Breed (Angus); - Diet (Grass-fed); - Living\Raising\Raising Conditions (Free-Range); - Raised Without Antibiotics \u2013 Livestock\Red Meat (No Added Antibiotics); - Raised Without Added Hormones (No Added Hormones Administered); - Source\Traceability (Source Verified and Traceable to TMB Ranch); - Third-Party Certification (LPDS True 2 Earth); and - Organic (USDA Organic)", "18 http:\askfsis.custhelp.com\ FSIS\USDA www.fsis.usda.gov 2019"]}, {"file\_name": "FSIS\_GD\_2019\_0010", "title": "FSIS Product Categorization (Import)", "num": "FSIS-GD-2019-0010", "id": "41349f1c1feb7f785d5687f2c1b12b4b243c5cbf9f25b806a974de01ebd06cf9", "corp\_us": "fsis\_guidelines", "source\_page\_url": "https:\www.fsis.usda.gov\policy\fsis-guidelines", "url": "https:\www.fsis.usda.gov\sites\default\files\media\_file\2021-05\Product-Categorization\_0.pdf", "type": "pdf", "n\_pages": 16, "word\_count": 3479, "text\_by\_page": ["FSIS Product Categorization FSIS has developed this document to assist with accurate identification of the meat, poultry, and egg products certified for export to the United States. Process Category: There are nine (9) process categories identified in 9CFR 417.2(b). Of the nine (9) listed, Slaughter is considered an internal process that occurs in establishments where the animals or birds are slaughtered. This category is not used for imported products. An additional process category that is not contained in 9CFR 417.2(b) is Egg Products. Note that FSIS has recently renamed two process categories: Raw Product -Ground and Raw Product -Not Ground are now referred to as Raw Product -Non-Intact and Raw Product -Intact, respectively. However, use of either terminology will be acceptable to FSIS. Note that official foreign inspection certificates should reflect the process category name, rather than the obsolete coding previously used by FSIS (e.g. 03B, 03C, etc.). These codes have been included in the table as some countries previously certified the process categories on the inspection certificates with this coding. Raw Product -Non-Intact: This process category applies to establishments that further process by using processing steps such as grinding, comminuting, injecting product with solutions, or mechanical tenderization by needling, cubing, pounding devices or other means of creating non-intact product. Examples of finished products in this category include raw products reconstructed into formed entrees, mechanically separated species, and advanced meat recovery product. If the establishment produces bench trim or pieces of meat produced from non-intact meat, then the bench trim or pieces are also considered non-intact. Raw Product -Intact: FSIS considers raw products to be intact unless they have undergone any of the processes associated with the Raw Product -Non-Intact process category. Thermally Processed -Commercially Sterile: This process category applies to establishments that use a thermal processing step. Thermally processed, commercially sterile finished products are products in cans or flexible containers such as pouches, or semi-rigid, as in lunch bowls. Thermally processed, commercially sterile products are addressed in 9 CFR 431. Not Heat Treated -Shelf Stable: This process category applies to establishments that further process by curing, drying, or fermenting processing step as the sole means by which product achieves food safety. Establishments in this process category may apply a low-level heat treatment as long as the heat treatment is not used as means to achieve food safety. The finished products produced under this Process Categories are shelf stable. FSIS does not require

shelf stable products to be frozen or refrigerated for food safety purposes. Heat Treated -Shelf Stable: This process category applies to establishments that further process by using a heat treatment processing step to achieve food safety in combination with curing, drying, or fermenting processing step to achieve food safety. The finished products produced under this process category are shelf stable. FSIS does not require shelf stable products to be frozen or refrigerated for food safety purposes. If the establishment produces using the processing steps applicable under this process category and the product is not shelf stable, then establishment is producing product under the process category Fully Cooked -Not Shelf Stable. Fully Cooked - Not Shelf Stable: This process category applies to establishments that further process products by using primarily a full lethality heat process step (e.g. cooking) to achieve food safety. The finished products that establishments produce under this process category are not shelf stable. FSIS requires the products to be frozen or refrigerated for food safety purposes. These products also meet the definition of Ready to Eat (RTE) as defined in 9 CFR 430.1." "Heat Treated but Not Fully Cooked -Not Shelf Stable: This process category applies to an establishment that further processes products that are (1) not ready-to-eat products (NRTE) or (2) raw otherwise processed products that are refrigerated or frozen throughout the product's shelf life. Meat and poultry products are produced using a heat process that meets one of the following criteria: a. The heat-processing step is not adequate to achieve food safety. Products may be partially cooked or heated to set batter on a raw product. b. The heat processing step applied to meat or poultry component was adequate to achieve food safety, however product is further processed, assembled, or packaged so that cooked meat or poultry products contacts nonready to-eat product ingredients. In this case, the final product is in a form that is not edible without additional preparing to achieve food safety. An example of this product is pot pie product that contains cooked chicken and raw dough. NOTE: This category may also include products that receive a full lethality treatment but there is no standard of identity defining them as fully cooked (e.g., hotdogs or barbecue) or a common or usual name that consumers understand to refer to RTE product (e.g., pates). Products with Secondary Inhibitors -Not Shelf Stable: This process category applies to establishments that further process by using a curing processing step or a processing step using other ingredients that inhibit bacterial growth. These products are generally refrigerated or frozen throughout the product's shelf life. Depending on the process and ingredients, these products may or may not meet the definition of RTE as defined in 9 CFR 430.1. Eggs\Egg Products: This process category applies to dried, pasteurized, and unpasteurized egg products. Product Category: (with Applicable Species) The Product Categories are shown in the FSIS Product Categorization table with the appropriate species indicated for each. The Species designations FSIS is using for PHIS are: for Meat: Beef, Veal, Pork, Lamb, Mutton, and Goat; for Poultry: Chicken, Turkey, Duck, Goose, Guinea, and Squab, including for Ratites: Emu, Ostrich, and Rhea; for Eggs: Chicken, Turkey, Duck, Goose and Guinea; for Siluriformes: Siluriformes -Ictaluridae (Catfish), Siluriformes \u2013 Other; and for Egg Products: Chicken, Turkey, Duck, Goose, and Guinea. For each product, the certification must indicate which species is predominant in the product to assure the appropriate regulations are applied to the product when applicable. Product Group: The product group defines the product down to a level that FSIS can program appropriate types of inspections (TOI) for examinations and laboratory sampling. While these appear to be self-explanatory, for Raw Product -Intact, Cuts are cuts of meat that are below the Primal and Subprimal level (e.g.,

food service\retail cuts such as steaks, or chops).", "The following table displays the process categories and the types of finished products that can be present in a process category.

Finished Product Types by Process Category

Process Categories	Finished Products	Raw Product
NRTE Product	RTE Products	Thermally Processed Product
(Raw Ground)	Slaughter	\u2022 Raw -Non Intact
\u2022 Raw -Intact (Raw Not Ground)	\u2022 Thermally Processed -	
Commercially Sterile	-Shelf Stable	\u2022 \u2022 HeatTreated-ShelfStable
\u2022 Fully Cooked -Not Shelf Stable	\u2022 Heat Treated but Not Fully Cooked -Not Shelf Stable	\u2022
\u2022 Product with Secondary Inhibitors -Not Shelf Stable	\u2022	\u2022
\u2022 Eggs\Egg Products	Not Applicable Ready to Eat applies to any product intended for human consumption without further preparation steps. Note: Products that appear fully cooked or are customarily consumed without further preparation, but the label does not include cooking instructions, are by default considered RTE. RTE fully cooked means that the products have been sufficiently cooked so that they are safe to eat as they are, with no further preparation required by the consumer. Note: Many of these products are customarily eaten hot, and heating instructions may be included on the label. Some frozen RTE products require reheating for palatability. These frozen products are still safe to eat without this further preparation by the consumer and are therefore still considered RTE. Some examples include: fully cooked hams, cooked beef, roast beef, pastrami, corned beef, hot dogs, meat loaves, meat and poultry salads, sliced luncheon meats, baked chicken, frozen entrees, and poultry rolls.	
Fresh or frozen entrees with fully cooked meat or poultry portions combined with fully cooked sauces, vegetables, pasta, or other ingredients	are RTE products. These products are designed to be re-heated by the consumer, and may include instructions for re-heating. Not Ready to Eat applies to products with cooking instructions or labeled with statements on the principal display panel such as \"Cook Thoroughly, Cook and Serve, Not Ready to Eat, or For Safety and Quality-follow these cooking instructions.\\" These products are considered NRTE. Certain NRTE products are required to bear safe handling instructions (SHI).", "Some NRTE finished products are heat treated but are not fully cooked. These NRTE products should have sufficient labeling information to inform the consumer that the product must be cooked for safety. This information may be contained within the product name on the principal display panel, and may contain cooking instructions that refer to cooking the product for safety rather than heating the product for best quality. The product often times may bear a safe handling instruction. Some NRTE finished products are prepared with both meat\poultry components that have received a lethality treatment in combination with non-meat\poultry components that need to receive a lethality treatment. These multi- component products, e.g., meals, dinners, and entrees, have labeling features which are conspicuous so that intended users are fully aware that the product must be cooked for safety. The principle display panel on the label defines these products, e.g., \"Cook and Serve, \"Must be thoroughly cooked,\\" \"Cook before eating\", and the product should include cooking instructions when required. Processors should refer to <a href="http://www.fsis.usda.gov/wp/cm/connect/ebb99e17-40f9-4528-ac0f-0b733fd87fd6/Resource_1.pdf?MOD=AJPERES">http://www.fsis.usda.gov/wp/cm/connect/ebb99e17-40f9-4528-ac0f-0b733fd87fd6/Resource_1.pdf?MOD=AJPERES</a> for guidance on the labeling of NRTE products.", "Raw Product -Non-Intact [HACCP] Process Category [Finished] Product Category Species Product Group Raw -Non Intact Raw ground comminuted or otherwise non-intact Siluriformes Siluriformes -Ictaluridae (Catfish), Siluriformes -Other \u2022 Ground Product \u2022 Non-Intact Cuts \u2022 Other Non-Intact Raw ground, comminuted, or Beef, Veal \u2022 Advanced	

Meat Recovery Product (AMR) otherwise non-intact beef \u2022 Beef Patty Product \u2022 Bench Trim from non-intact \u2022 Finely Textured Beef \u2022 Formed Steaks \u2022 Ground Beef \u2022 Hamburger \u2022 Low Temperature Rendered Product \u2022 Non-Intact Cuts \u2022 Other Non-Intact \u2022 Other Non-Intact Products \u2022 Partially Defatted Beef Fatty Tissue (PDBFT) \u2022 Partially Defatted Chopped Beef (PDCB) \u2022 Sausage \u2022 Trimmings from Non-Intact Raw ground, comminuted, or Chicken \u2022 Ground Product otherwise non-intact chicken \u2022 Mechanically Separated (Species) \u2022 Other Non-Intact \u2022 Sausage Raw ground, comminuted, or Goat, Lamb, Mutton \u2022 Advanced Meat Recovery Product (AMR) otherwise non-intact meat -other \u2022 Ground Product (sheep, goat) \u2022 Mechanically Separated \u2022 Other Non-Intact \u2022 Sausage Raw ground, comminuted, or Pork \u2022 Advanced Meat Recovery Product (AMR) otherwise non-intact pork \u2022 Ground Product \u2022 Mechanically Separated \u2022 Other Non-Intact \u2022 Sausage Raw ground, comminuted, or Duck, Goose, Guinea, Squab, \u2022 Ground Product otherwise non-intact poultry -other (ducks, geese, squab) Emu, Ostrich, Rhea \u2022 Mechanically Separated (Species) \u2022 Other Non-Intact \u2022 Sausage Raw ground, comminuted, or Turkey \u2022 Ground Product otherwise non-intact turkey \u2022 Mechanically Separated (Species) \u2022 Other Non-Intact \u2022 Sausage", "Raw Product - Intact [HACCP] Process Category [Finished] Product Category Species Product Group Raw -Intact Raw intact beef Beef, Veal \u2022 Boneless Manufacturing Trimmings \u2022 Carcass (including carcass halves or quarters) \u2022 Cheek Meat \u2022 Cuts \u2022 Edible Offal \u2022 Head Meat \u2022 Heart Meat \u2022 Other Intact \u2022 Primals and Subprimals \u2022 Weasand Meat Raw intact chicken Chicken \u2022 Boneless and\or Skinless Parts \u2022 Boneless Manufacturing Trimmings \u2022 Poultry parts (including necks\feet & giblets) \u2022 Whole Bird Raw intact meat -other Siluriformes -Ictaluridae (Catfish), Siluriformes -Other \u2022 Cuts \u2022 Other Intact \u2022 Whole Fish Raw intact meat -other (sheep, goat) Goat, Lamb, Mutton \u2022 Boneless Manufacturing Trimmings \u2022 Carcass (including carcass halves or quarters) \u2022 Cuts \u2022 Edible Offal \u2022 Other Intact \u2022 Primals and Subprimals Raw intact pork Pork \u2022 Boneless Manufacturing Trimmings \u2022 Carcass (including carcass halves or quarters) \u2022 Cuts \u2022 Edible Offal \u2022 Other Intact \u2022 Primals and Subprimals Raw intact poultry -other (ducks, geese, squab) Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea \u2022 Boneless and\or Skinless Parts \u2022 Boneless Manufacturing Trimmings \u2022 Poultry parts (including necks\feet & giblets) \u2022 Whole Bird Raw intact turkey Turkey \u2022 Boneless and\or Skinless Parts \u2022 Boneless Manufacturing Trimmings \u2022 Poultry parts (including necks\feet & giblets) \u2022 Whole Bird", "Thermally Processed -Commercially Sterile [HACCP] Process Category [Finished] Product Category Species Product Group Thermally Processed\Commercially Sterile Thermally processed, commercially sterile Beef, Veal, Chicken, Duck, Goat, Goose, Guinea, Squab, Emu, Ostrich, Rhea, Lamb, Mutton, Turkey \u2022 Corned (species) \u2022 Other \u2022 Sausage \u2022 Soups Siluriformes -Ictaluridae (Catfish), Siluriformes -Other \u2022 Other Pork \u2022 Corned (species) \u2022 Ham \u2022 Other \u2022 Sausage \u2022 Soups", "Not Heat Treated -Shelf Stable [HACCP] Process Category [Finished] Product Category Species Product Group Not Heat Treated -Shelf Stable NRTE otherwise processed meat Beef, Veal, Goat, Lamb, Mutton, Pork \u2022 Bacon \u2022 Meals\Dinners\Entrees \u2022 Other \u2022 Pies\Pot Pies \u2022 Rendered Fats, Oils

\u2022 Sandwiches\Filled Rolls\Wraps \u2022 Sauces \u2022 Sausage Products \u2022 Smoked Parts \u2022 Soups Siluriformes -Ictaluridae (Catfish), Siluriformes -Other \u2022 Meals\Dinners\Entrees \u2022 Other NRTE otherwise processed poultry Chicken, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea, Turkey \u2022 Bacon \u2022 Meals\Dinners\Entrees \u2022 Other \u2022 Pies\Pot Pies \u2022 Rendered Fats, Oils \u2022 Sandwiches\Filled Rolls\Wraps \u2022 Sauces \u2022 Sausages \u2022 Smoked Parts \u2022 Soups RTE acidified \u2022 fermented meat (without cooking) Beef, Veal, Goat, Lamb, Mutton, Pork \u2022 Other -Not sliced \u2022 Other -Sliced \u2022 Sausage\Salami -Not sliced \u2022 Sausage\Salami -Sliced Siluriformes -Ictaluridae (Catfish), Siluriformes -Other \u2022 Sausage\Salami RTE acidified \u2022 fermented poultry Chicken, Duck, Goose, Guinea, \u2022 Other -Not sliced (without cooking) Squab, Emu, Ostrich, Rhea, Turkey \u2022 Other -Sliced \u2022 Sausage\Salami -Not sliced \u2022 Sausage\Salami -Sliced", "Not Heat Treated -Shelf Stable (Con't) [HACCP] Process Category [Finished] Product Category Species Product Group Not Heat Treated -Shelf Stable RTE dried meat Beef, Veal, Goat, Lamb, Mutton \u2022 Jerky \u2022 Other -Not sliced \u2022 Other -Sliced Siluriformes -Ictaluridae (Catfish), Siluriformes -Other \u2022 Other Pork \u2022 Ham -Not sliced \u2022 Ham -Sliced \u2022 Jerky \u2022 Other -Not sliced \u2022 Other -Sliced RTE dried poultry Chicken, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea, Turkey \u2022 Jerky \u2022 Other -Not sliced \u2022 Other -Sliced RTE salt-cured meat Beef, Veal, Goat, Lamb, Mutton, Pork \u2022 Not-sliced \u2022 Sliced Siluriformes -Ictaluridae (Catfish), Siluriformes -Other \u2022 Other RTE salt-cured poultry Chicken, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea, Turkey \u2022 Not-sliced \u2022 Sliced", "Heat Treated -Shelf Stable [HACCP] Process Category [Finished] Product Category Species Product Group Heat Treated -Shelf Stable NRTE otherwise processed meat Beef, Veal, Goat, Lamb, Mutton, Pork \u2022 Bacon \u2022 Meals\Dinners\Entrees \u2022 Other \u2022 Pies\Pot Pies \u2022 Rendered Fats, Oils \u2022 Sandwiches\Filled Rolls\Wraps \u2022 Sauces \u2022 Sausage Products \u2022 Smoked Parts \u2022 Soups Siluriformes -Ictaluridae (Catfish), Siluriformes -Other \u2022 Meals\Dinners\Entrees \u2022 Other NRTE otherwise processed poultry Chicken, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea, Turkey \u2022 Bacon \u2022 Meals\Dinners\Entrees \u2022 Other \u2022 Pies\Pot Pies \u2022 Rendered Fats, Oils \u2022 Sandwiches\Filled Rolls\Wraps \u2022 Sauces \u2022 Sausages \u2022 Smoked Parts \u2022 Soups RTE acidified \u2022 fermented meat (without cooking) Beef, Veal, Goat, Lamb, Mutton, Pork \u2022 Other -Not sliced \u2022 Other -Sliced \u2022 Sausage\Salami -Not sliced \u2022 Sausage\Salami -Sliced Siluriformes -Ictaluridae (Catfish), Siluriformes -Other \u2022 Sausage\Salami RTE acidified \u2022 fermented poultry Chicken, Duck, Goose, Guinea, \u2022 Other -Not sliced (without cooking) Squab, Emu, Ostrich, Rhea, Turkey \u2022 Other -Sliced \u2022 Sausage\Salami -Not sliced \u2022 Sausage\Salami -Sliced", "Not Heat Treated -Shelf Stable (Con't) [HACCP] Process Category [Finished] Product Category Species Product Group Heat Treated -Shelf Stable RTE dried poultry Chicken, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea, Turkey \u2022 Jerky \u2022 Other -Not sliced \u2022 Other -Sliced Siluriformes -Ictaluridae (Catfish), Siluriformes -Other \u2022 Other Pork \u2022 Ham -Not sliced \u2022 Ham -Sliced \u2022 Jerky \u2022 Other -Not sliced \u2022 Other -Sliced", "Heat Treated -Shelf Stable (Con't) [HACCP] Process Category [Finished] Product Category Species Product Group Heat Treated -Shelf Stable RTE dried poultry Chicken, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea, Turkey \u2022 Jerky \u2022 Other -Not sliced \u2022 Other -Sliced RTE salt-cured meat Beef, Veal, Goat, Lamb, Mutton, Pork \u2022 Not-sliced \u2022 Sliced Siluriformes -Ictaluridae (Catfish), Siluriformes -Other \u2022 Other RTE

salt-cured poultry Chicken, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea, Turkey \u2022 Not-sliced \u2022 Sliced", "Fully Cooked -Not Shelf Stable [HACCP] Process Category [Finished] Product Category Species Product Group Fully Cooked -Not Shelf Stable RTE fully-cooked meat Beef, Veal, Goat, Lamb, Mutton \u2022 Diced\Shredded \u2022 Hot Dog Products \u2022 Meat + Nonmeat Component \u2022 Nuggets \u2022 Other Fully cooked not sliced product \u2022 Other Fully cooked sliced product \u2022 Parts \u2022 Patties \u2022 Salad\Spread\Pate \u2022 Sausage Products Siluriformes -Ictaluridae (Catfish), Siluriformes -Other \u2022 Diced\Shredded \u2022 Nugget \u2022 Other Pork \u2022 Diced\Shredded \u2022 Ham Patties \u2022 Ham, Not Sliced (Includes: Shoulders, Picnics, Butts and Loins; chopped ham, pressed ham, spiced ham, etc.) \u2022 Ham, Sliced \u2022 Hot Dog Products \u2022 Meat + Nonmeat Component \u2022 Nuggets \u2022 Other Fully cooked not sliced product \u2022 Other Fully cooked sliced product \u2022 Parts \u2022 Patties \u2022 Salad\Spread\Pate \u2022 Sausage Products RTE fully-cooked poultry Chicken, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea, Turkey \u2022 Diced\Shredded \u2022 Hot Dog Products \u2022 Other Fully cooked not sliced product \u2022 Other Fully cooked sliced product \u2022 Parts \u2022 Patties\Nuggets \u2022 Poultry + Nonpoultry Component \u2022 Salad\Spread\Pate \u2022 Sausage Products", "Fully Cooked -Not Shelf Stable (Con\u2019t) [HACCP] Process Category [Finished] Product Category Species Product Group Fully Cooked -Not Shelf Stable RTE meat fully-cooked without subsequent exposure to the environment Beef, Veal, Goat, Lamb, Mutton \u2022 Diced\Shredded \u2022 Hot Dog Products \u2022 Meat + Nonmeat Component \u2022 Nuggets \u2022 Other Fully cooked not sliced product \u2022 Other Fully cooked sliced product \u2022 Parts \u2022 Patties \u2022 Salad\Spread\Pate \u2022 Sausage Products RTE meat fully-cooked without subsequent exposure to the environment Siluriformes -Ictaluridae (Catfish), Siluriformes -Other \u2022 Diced\Shredded \u2022 Nuggets \u2022 Other Pork \u2022 Diced\Shredded \u2022 Ham Patties \u2022 Ham, Not Sliced (Includes: Shoulders, Picnics, Butts and Loins; chopped ham, pressed ham, spiced ham, etc.) \u2022 Ham, Sliced \u2022 Hot Dog Products \u2022 Meat + Nonmeat Component \u2022 Nuggets \u2022 Other Fully cooked not sliced product \u2022 Other Fully cooked sliced product \u2022 Parts \u2022 Patties \u2022 Salad\Spread\Pate \u2022 Sausage Products RTE poultry fully-cooked without subsequent exposure to the environment Chicken, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea, Turkey \u2022 Diced\Shredded \u2022 Hot Dog Products \u2022 Other Fully cooked not sliced product \u2022 Other Fully cooked sliced product \u2022 Parts \u2022 Patties\Nuggets \u2022 Poultry + Nonpoultry Component \u2022 Salad\Spread\Pate \u2022 Sausage Products", "Heat Treated -Not Fully Cooked -Not Shelf Stable [HACCP] Process Category [Finished] Product Category Species Product Group Heat Treated -Not Fully Cooked -Not Shelf Stable NRTE otherwise processed meat Beef, Veal, Goat, Lamb, Mutton, Pork \u2022 Bacon \u2022 Meals\Dinners\Entrees \u2022 Other \u2022 Pies\Pot Pies \u2022 Rendered Fats, Oils \u2022 Sandwiches\Filled Rolls\Wraps \u2022 Sauces \u2022 Sausage Products \u2022 Smoked Parts \u2022 Soups Siluriformes -Ictaluridae (Catfish), Siluriformes -Other \u2022 Other NRTE otherwise processed poultry Chicken, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea, Turkey \u2022 Bacon \u2022 Meals\Dinners\Entrees \u2022 Other \u2022 Pies\Pot Pies \u2022 Rendered Fats, Oils \u2022 Sandwiches\Filled Rolls\Wraps \u2022 Sauces \u2022 Sausages \u2022 Smoked Parts \u2022 Soups", "Product with Secondary Inhibitors -Not Shelf Stable [HACCP] Process Category

[Finished] Product Category Species Product Group Product with Secondary Inhibitors -Not Shelf Stable NRTE otherwise processed meat Beef, Veal, Goat, Lamb, Mutton, Pork \u2022 Bacon \u2022 Meals\Dinners\Entrees \u2022 Other \u2022 Pies\Pot Pies \u2022 Rendered Fats, Oils \u2022 Sandwiches\Filled Rolls\Wraps \u2022 Sauces \u2022 Sausage Products \u2022 Smoked Parts \u2022 Soups Siluriformes -Ictaluridae (Catfish), Siluriformes -Other \u2022 Other NRTE otherwise processed poultry Chicken, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea, Turkey \u2022 Bacon \u2022 Meals\Dinners\Entrees \u2022 Other \u2022 Pies\Pot Pies \u2022 Rendered Fats, Oils \u2022 Sandwiches\Filled Rolls\Wraps \u2022 Sauces \u2022 Sausages \u2022 Smoked Parts \u2022 Soups RTE salt-cured meat Beef, Veal, Goat, Lamb, Mutton, Pork \u2022 Not-sliced \u2022 Sliced Siluriformes -Ictaluridae (Catfish), Siluriformes -Other \u2022 Other RTE salt-cured poultry Chicken, Duck, Goose, Guinea, Squab, Emu, Ostrich, Rhea, Turkey \u2022 Not-sliced \u2022 Sliced","Eggs\Egg Products [HACCP]

Process Category [Finished] Product Category Species Product Group Eggs\Egg Products Egg Products Chicken, Duck, Goose, Guinea and Turkey \u2022 Dried -Egg products (blends of whole egg, egg whites, and\or yolks, w\wo added ingredients) \u2022 Dried -Egg whites (with or w\o added ingredients) \u2022 Dried -Whole egg (w\wo added ingredients) \u2022 Dried -Yolk (w\wo added ingredients) \u2022 Pasteurized (Frozen or Liquid) -Egg products (blends of whole egg, egg whites, and\or yolks, w\wo added ingredients) \u2022 Pasteurized (Frozen or Liquid) -Egg whites (w\wo added ingredients) \u2022 Pasteurized (Frozen or Liquid) -Whole egg (w\wo added ingredients) \u2022 Pasteurized (Tanker\Large Totes) -Egg products (blends of whole egg, egg whites, and\or yolks, w\wo added ingredients) \u2022 Pasteurized (Tanker\Large Totes) -Egg whites (w\wo added ingredients) \u2022 Pasteurized (Tanker\Large Totes) -Whole egg (w\wo added ingredients) \u2022 Pasteurized (Tanker\Large Totes) -Yolk (w\wo added ingredients) \u2022 Unpasteurized (Frozen or Liquid) -Egg products (blends of whole egg, egg whites, and\or yolks, w\wo added ingredients) \u2022 Unpasteurized (Frozen or Liquid) -Egg whites (w\wo added ingredients) \u2022 Unpasteurized (Frozen or Liquid) -Whole egg (w\wo added ingredients) \u2022 Unpasteurized (Frozen or Liquid) -Yolk (w\wo added ingredients) \u2022 Unpasteurized (Tanker\Large Totes) -Egg products (blends of whole egg, egg whites, and\or yolks, w\wo added ingredients) \u2022 Unpasteurized (Tanker\Large Totes) -Egg whites (w\wo added ingredients) \u2022 Unpasteurized (Tanker\Large Totes) -Whole egg (w\wo added ingredients) \u2022 Unpasteurized (Tanker\Large Totes) -Yolk (w\wo added ingredients)"]}, {"file\_name": "FSIS\_GD\_2019\_0011", "title": "The FSIS Equivalence Process: Presentation", "num": "FSIS-GD-2019-0011", "id": "ba8cddce07b75fcfd8227b0c4567ea91c8fea06e1020656fb9ddde4aac091d820", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/FSIS-Equivalence-Process-PPT.pdf", "type": "pdf", "n\_pages": 31, "word\_count": 2851, "text\_by\_page": ["USDA - United States Department of Agriculture 1", "Thank you for your interest in learning about the Food Safety and Inspection Service\u2019s (FSIS) equivalence determination processes. In this presentation I will first explain what equivalence is. Then I\u2019ll discuss the origin of equivalence and FSIS\u2019s requirements. Following that, I\u2019ll discuss the four (4) types of FSIS\u2019s equivalence determinations, which includes initial, ongoing, reinstatement, and individual sanitary measure, and the process steps involved for each type of equivalence"]}

determination. 2","In order to understand FSIS\u2019s equivalence determination processes, let\u2019s first start out by clarify what equivalence means. 3","Equivalence is the process of determining whether a country\u2019s food safety inspection system achieves FSIS\u2019s appropriate level of protection for public health as applied domestically in the United States (US). 4","The country\u2019s food safety inspection system is to provide standards equivalent to FSIS to ensure other non-food safety requirements are met, such as humane handling, accurate labeling, and assurance that meat, poultry, or egg products are not economically adulterated. 5","Equivalence does not mean that the country is required to develop and implement the same procedures that the US does, but rather the country must objectively demonstrate how its procedures meets the US level of protection. Countries wishing to become eligible to export meat, poultry, or egg products to the US must demonstrate that they have a regulatory food safety inspection system that is equivalent to that of the US. 6","FSIS is the US Central Competent Authority (CCA) responsible for regulating and inspecting meat, poultry, and egg products. The CCA is a country\u2019s national government authority that is responsible for ensuring the safety and truthful labeling of the food supply. FSIS implements an equivalence determination process to ensure that US treaty obligations under the World Trade Organization\u2019s (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) are met. 7","The World Trade Organization\u2019s (WTO)\u2019Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) sets out the basic international rules for food safety, animal, and plant health standards. FSIS ensures during the equivalence process that SPS Agreement principals are implemented. 8","To ensure that meat, poultry, or egg products (including imported products) do not pose any public health risks to US consumers, FSIS implements the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), Egg Products Inspection Act (EPIA), Humane Methods of Slaughter Act (HMSA), and regulations under Title 9 Code of Federal Regulations (CFR) Parts 300-590. FSIS ensures that a country\u2019s food safety inspection system addresses FSIS\u2019s food safety regulatory-based objectives. Food safety regulatory-based objectives are food safety goals for preventing the occurrence of an identified food safety hazard. The criteria by which FSIS assesses the equivalence of a country\u2019s food safety inspection system can be found under Title 9 CFR \u00a77327.2 (for meat products), \u00a77557.2 (for fish of the order Siluriformes products), \u00a77381.196 (for poultry products), and \u00a77590.910 (for egg products). 9","Determining equivalence of a country\u2019s food safety inspection system is important because it protects public health and facilitates trade. An equivalence determination of an exporting country\u2019s regulatory food safety inspection system for meat, poultry, or egg products is a prerequisite for trade for the United States Department of Agriculture\u2019s (USDA) FSIS. 10","Now that we have a better understanding of what equivalence is and FSIS\u2019s statutory and regulatory requirements associated with equivalence determinations, let\u2019s discuss FSIS\u2019s different equivalence determinations and the process steps. 11","There are four (4) types of equivalence determinations: (1) Initial Equivalence, (2) Ongoing Equivalence Verification, (3) Reinstatement of Equivalence, and (4) Individual Sanitary Measure. 12","Initial Equivalence Process is undertaken when countries want to export meat, poultry, or egg products to the US for the first time. FSIS evaluates a country\u2019s food safety inspection system to make an initial equivalence determination before the country can export products to the US. This process is for

countries that are not listed in the CFR as eligible to export meat, poultry, or egg products. 1. To start the initial equivalence process, countries are to have their CCA contact FSIS\u2019s Office of International Coordination (OIC) by sending a formal written request to start the initial equivalence process. 2. In response to a country\u2019s request, FSIS will send the country a packet of information that includes guidance and a Self-Reporting Tool (SRT). We will discuss what the SRT is on the next slide. 3. After FSIS receives an SRT with all referenced supporting documentation, FSIS reviews and decides whether the country\u2019s food regulatory system meets all US import requirements in an equivalent manner and cumulatively provides the level of public health protection as that attained domestically. 4. An on-site verification audit is an audit of the country\u2019s food safety inspection system with the goal of verifying, through objective evidence, that the country\u2019s inspection system has an equivalent level of public health protection as applied domestically in the US. 13", "5. Based on the outcome of FSIS\u2019s SRT and supporting documentation review and the on-site audit, FSIS initiates rulemaking to propose that the country be listed in the CFR as eligible to export meat, poultry, or egg products to the US. 6. FSIS analyzes any received comments and publishes a final rule to list the country in the CFR as eligible to export meat, poultry, or egg products to the US. FSIS sends the country a notification letter about the published rule. The letter includes instructions about exporting meat, poultry, or egg products to the US. 13", "The SRT is a questionnaire that provides an organized means for the country\u2019s government to demonstrate that its inspection system achieves an equivalent level of protection as applied domestically in the US. The SRT is arranged into six (6) components: 1. Government Oversight (e.g., Organization and Administration) 2. Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling) 3. Government Sanitation 4. Government Hazard Analysis and Critical Control Point (HACCP) System 5. Government Chemical Residues Testing Programs 6. Government Microbiological Testing Programs Please refer to the SRT and the presentation on How to Complete and Submit the SRT Using the Public Health Information System (PHIS) for additional information on how a country should categorize its food safety inspection system, respond to the SRT, and submit a completed SRT to FSIS for review. 14", "An on-site verification audit is an audit of the country\u2019s food safety inspection system with the goal of verifying, through objective evidence, that the country\u2019s inspection system has an equivalent level of public health protection as applied domestically in the US. If FSIS determines that a country\u2019s food safety inspection system is tentatively equivalent based on the SRT document review process, OIC will work with the country\u2019s CCA to arrange an on-site verification audit of the country\u2019s food safety inspection system. Initial equivalence audits are conducted FSIS International Auditors. The audit scope includes visual observations of all aspects of the country\u2019s food safety inspection system. 15", "During the on-site audit, International Auditors verify that the CCA implements, monitors, and verifies all of the procedures in the country\u2019s food safety inspection system. Typically, International Auditors will need to visit multiple sites that may include the following: \u2022 Central, regional, and local government offices; \u2022 Exporting establishments (slaughter and processing establishments) and warehouses (including cold storage); and \u2022 Laboratories. After the on-site audit, FSIS sends a draft audit report to the country applying for equivalence for the country\u2019s review and comment. FSIS then takes the country\u2019s comments

into account and generates the final audit report. 16","In order for FSIS to make an initial equivalence determination, the CCA should show through documentation, which includes SRT responses and supporting documentation, that the design of its food safety inspection system achieves an equivalent level of public health protection. Once the CCA can show through documentation that its food safety inspection system is equivalent, the CCA is to show FSIS that it can implement the inspection system as documented in the submitted SRT responses and supporting documentation. Equivalent documentation and acceptable audit results will support FSIS to initiate rulemaking by publishing a proposed rule in a Federal Register. 17","Based on the outcome of FSIS\u2019s SRT and supporting documentation review and the on-site audit, FSIS initiates rulemaking to propose that the country be listed in the CFR as eligible to export meat, poultry, or egg products to the US. To initiate rulemaking, the country will need to provide 5 years of projected economic analysis information. Upon publication, the public can submit comments (generally up to 60 days after publication) to FSIS about the proposed rule. FSIS analyzes any received comments and publishes a final rule to list the country in the CFR as eligible to export meat, poultry, or egg products to the US. FSIS sends the country a letter notifying it of the published rule. After the rule becomes effective, the country then certifies establishments as being eligible to export meat, poultry, or egg products to the US. After a country has compiled a list of eligible certified establishments, the country sends the completed list to OIC. A certified establishment is an establishment that the CCA determines as meeting US requirements and, therefore, eligible to export meat, poultry, or egg products to the US. Additionally, countries are to submit to OIC a sample of the health certificate they propose to use for exported meat, poultry, or egg product shipments to the US. Each eligible country\u2019s CCA is responsible for the certification of shipments of meat, poultry, or egg products to the US. Please refer to Title 9 CFR \u00a7327.4 (for meat), \u00a7557.4 (for fish of the order Siluriformes), \u00a7381.197 (for 18","poultry), and \u00a7590.915 (for egg products). 18","It is important to note that FSIS only determines whether a country\u2019s meat, poultry, or egg products food safety inspection system is equivalent. Countries should be aware that animal diseases are regulated by the USDA\u2019s Animal and Plant Health Inspection Service (APHIS) (Title 9 CFR Parts 92 through 95), and a country\u2019s animal disease status can impact what products the country can export to the US. For a list of USDA-recognized animal health status of countries, please visit APHIS\u2019s Animal Disease Status webpage ([https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animalproduct-import-information/ct\\_animal\\_disease\\_status](https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animalproduct-import-information/ct_animal_disease_status)). 19","Countries are to contact OIC for: 1. All questions and requests for technical assistance, 2. To submit formal equivalence requests, 3. To submit a paper copy of an SRT and supporting documentation for review, or 4. To notify FSIS that an SRT was submitted in PHIS. Please submit all written equivalence requests to OIC by e-mail (preferred), mail, or fax. 20","Ongoing equivalence is applicable to countries that are listed in the CFR as eligible to export to the US and are actively shipping meat, poultry, or egg products to the US. FSIS will continuously evaluate and verify the equivalence of an exporting country\u2019s food safety inspection system through a three (3) part process: (1) on-site audits, (2) document reviews, and (3) point-of-entry (POE) reinspection of meat, poultry, and egg products. FSIS will periodically conduct an on-site audit of every eligible country\u2019s food safety inspection system. These audits will be performed by FSIS International Auditors and are similar to the on-site verification audits that FSIS does as part of

the initial equivalence process. Countries are to submit the following for review at least annually by May 18th:

1. Either (1) updated SRT responses, or (2) communicate to FSIS that the Central Competent Authority (CCA) has verified its SRT responses, as recorded in FSIS's Public Health Information System (PHIS) (i.e., by reviewing the SRT electronically in PHIS) or by mailed hard copy of the version of SRT responses FSIS has entered for the CCA, are accurate and complete.
2. An up-to-date list of all certified establishments eligible to export meat, poultry, or egg products to the US.
3. An updated government residue control program, including the previous year's residue test results and reactions to residue findings.
4. Updated government microbiological sampling and testing programs, including the previous year's test results and reactions to (A) indicator organism results for intestinal or fecal contamination; (B) *Salmonella* and *Campylobacter* results for raw meat and poultry products; (C) *Listeria monocytogenes*, *Salmonella*, or other pathogens of public health concern in ready-to-eat (RTE) meat and poultry products and all lots of pasteurized egg products; and (D) shiga toxin-producing *Escherichia coli* (STEC) in raw beef products.

All imported shipments of meat, poultry, and egg products that enter the US are presented to FSIS for reinspection. If a POE violation is identified, FSIS notifies the countries, and requests and reviews corrective action responses.

"Countries wishing to reinstate previous equivalence determinations to start exporting meat, poultry, or egg products to the US again are to send a formal written request to OIC. Reinstatement of equivalence is only applicable to countries who are listed in the CFR as eligible to export to the US, but have not shipped meat, poultry, or egg products to the US for an extended period of time. A possible reason for a country to request a reinstatement of equivalence determination includes the lifting of a trade ban after an extended period of time due to a change in animal disease status allowing the export of certain animal products to the US. A reinstatement of equivalence process follows the same process as the initial equivalence process, except that the country may be subjected to a verification audit, and will not be subjected to the rulemaking steps. The rulemaking steps are not applicable for a reinstatement of equivalence determination because the country's food safety inspection system has already been determined to be equivalent. After FSIS completes its document review and, as needed, an on-site verification audit, OIC will notify the country of FSIS's decision through a formal written letter. The letter will discuss FSIS's basis for its decision to reinstate equivalence. If FSIS does not perform an audit as part of the reinstatement of equivalence process, then FSIS will verify the reinstated process during the next scheduled audit."

"Countries wishing to change a procedure (sanitary measure) that the US has previously determined to be equivalent in their food safety inspection system are to send a formal written request to OIC. An individual sanitary measure is only applicable to countries who are listed in the CFR as eligible to export to the US, but want to change a previously determined equivalent procedure in their food safety inspection system. An example of an individual sanitary measure equivalence determination request is when a country wants to change its postmortem inspection procedures for livestock from traditional (hands-on) inspection to visual assessment. An eligible country is to request an individual sanitary measure equivalence determination before the country implements the new procedure on products destined for export to the US. Countries are to submit a formal written request for an individual sanitary measure to FSIS's OIC. If a country does not notify FSIS of changes in its food safety procedures, a possible disruption of trade could result. FSIS will evaluate a request for an

individual sanitary measure equivalence determination to ensure that the new procedure: \u2022 Is equivalent to FSIS\u2019s relevant food safety regulatory objective-based criteria, and \u2022 Achieves an appropriate level of protection from identified food safety hazards. Countries that request an individual sanitary measure will need to update their SRT and submit supporting documentation to FSIS for review. The submitted 23","documentation should demonstrate that the measure provides an equivalent level of public health protection. After FSIS completes its review, OIC will notify the country of FSIS\u2019s decision through a formal written letter. The letter will discuss FSIS\u2019s basis for its decision to either accept or reject the proposed individual sanitary measure. If FSIS accepts the individual sanitary measure, FSIS will verify the application of the individual sanitary measure during the next scheduled on-site verification audit. 23","FSIS has a food safety objective-based criterion that requires the CCA to ensure that raw beef products are free of STEC at the end of the production process. In the US, beef slaughter and processing establishments use a combination of antimicrobial treatments and sanitary dressing procedures to control STEC. 24","However, other countries prohibit the use of antimicrobial treatments and have submitted requirements that raw beef establishments are to implement robust sanitary dressing procedures with additional controls and government verification procedures to prevent STEC. In this situation, the CCA has verification procedures (including rigorous microbial sampling) that demonstrate sanitary dressing procedures ensure that raw beef products are free of STEC at the end of the production process. Additionally, the CCA\u2019s controls include a focus on carcasses as well as other conditions (high event periods) and classes of raw products that collectively increase the likelihood of detecting STEC if present. Based upon the evaluation of the CCA\u2019s verification procedures, controls, and receipt and evaluation of ongoing microbial results from the CCA, FSIS has determined this approach to be equivalent because the CCA demonstrates that it meets the food safety criterion. 25","For all questions, including technical and equivalence questions, please contact OIC through methods listed above. 26","27

27"]},{"file\_name":"FSIS\_GD\_2019\_0012","title":"How to Complete and Submit the SRT Using the PHIS (Presentation)","num":"FSIS-GD-2019-0012","id":"c7e8ec25c61e68a51d1b199b716dcea67f0223a45f9c2cbfcf771982d99393b7","corp\_us":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/import/Submit-SRT-Using-PHIS-

PPT.pdf","type":"pdf","n\_pages":70,"word\_count":4950,"text\_by\_page":["1","Thank you for your interest in learning how to complete the Self\u2010Reporting Tool, or SRT, for initial, reinstatement, and ongoing equivalence. In this presentation I will first explain what the SRT is. Then I\u2019ll discuss recent improvements to the SRT. I\u2019ll next discuss how to complete and update the SRT. Following that, I\u2019ll discuss the Food Safety and Inspection Service\u2019s (FSIS) procedures for translating submitted SRT responses, programs, or supporting documentation into English and how it affects the review time. Next, I\u2019ll walk through how to become e\u2010authenticated and gain access to the Public Health Information System (PHIS). Finally, I\u2019ll show you how to submit the SRT through PHIS. 2","For countries that have not exported meat, poultry, or egg products to the United States (US) before, you are probably wondering what the SRT is. 3","The SRT is a questionnaire that provides an organized means for the country\u2019s government, or Central Competent

Authority (CCA), to demonstrate that its inspection system achieves an equivalent level of public health protection as applied domestically in the US. The CCA is the country's national government authority that is responsible for ensuring the safety and truthful labeling of the food supply. The CCA is expected to answer all component questions in the SRT in order for an effective determination of equivalence.

4", "The SRT is arranged into six components that define a food safety inspection system. The six (6) defined components are:

1. Government Oversight (e.g., Organization and Administration)
2. Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)
3. Government Sanitation
4. Government Hazard Analysis and Critical Control Point (HACCP) System
5. Government Chemical Residues Testing Programs
6. Government Microbiological Testing Programs

The questions under these six components are called component questions. The component questions are the food safety objective-based criteria that FSIS uses to determine equivalence in the form of a question. The food safety objective-based criteria are based off of FSIS' laws and regulations. This includes FSIS' Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), Egg Products Inspection Act (EPIA), Humane Methods of Slaughter Act (HSMA), and Title 9 Code of Federal Regulations (CFR) Parts 300 through 590. The CCA is expected to answer all component questions in the SRT in order for effective determination of equivalence.

5", "6", "Countries wishing to export meat, poultry, or egg products are to send a formal written request to FSIS' Office of International Coordination (OIC) to start the equivalence determination process. FSIS will then provide the country with a packet of information that includes a copy of the SRT and guidance materials to assist you with the equivalence process. Countries wishing to reinstate previous equivalence determinations, or that want to change a procedure that the US has previously determined to be equivalent are to send a formal written request to OIC. Written requests need to include the type of equivalence determination process (for example, initial or reinstatement), as well as the specific commodity (or commodities) the equivalence request is for. For example, reinstatement of equivalence for raw beef, or initial equivalence for heat treated and thermally processed poultry.

7", "As a result of helpful feedback from CCAs, FSIS has significantly improved the current version of the SRT.

8", "Specifically, FSIS significantly reduced the number of questions by revising the questions to focus on the food safety objective-based criteria to be achieved. Food safety objective-based criteria are the standards that FSIS uses to determine whether the country's food safety inspection system is equivalent. The component questions, that is, the questions listed under the six components in the SRT, are the food safety objective-based criteria that FSIS uses to determine equivalence in the form of a question. These changes are designed to help countries better understand the food safety objective-based criteria that FSIS uses to evaluate whether the country's food safety inspection system is equivalent. These changes have also greatly reduced redundancy and make the questions more understandable. The revised SRT is available in PHIS for countries to use. We will discuss later in this presentation how to gain access to PHIS, and the steps on how to complete and submit the SRT in PHIS.

9", "So, you have sent a formal request to FSIS' Office of International Coordination, and received a copy of the SRT to complete. How do you respond to the SRT?

10", "The questions under the six components are called component questions. The CCA is expected to answer all component questions in the SRT in order for an

effective determination of equivalence. The CCA should provide complete responses to SRT questions. Complete responses include a short narrative, accompanied by supporting documentation, to characterize how a country's food safety inspection system is implemented. Responses should include references to where in the supporting documentation the answer to the question is found. For example, answers should include the page number, section number, or chapter from the relevant supporting documentation.

11", "The CCA should submit all supporting documentation concerning its food safety inspection system in the SRT. The following list identifies types of supporting documentation that the CCA should provide in the SRT to show how its food safety inspection system is equivalent to the US domestic food safety inspection system.

12", "To submit the SRT with all applicable programs and supporting documentation, the CCA can either use the Microsoft Word version of the SRT or upload the information into the webbased PHIS. FSIS encourages countries to submit the information through PHIS by inserting the responses directly. If the Microsoft Word version is submitted to FSIS, FSIS then extracts the information and places it into an SRT in PHIS. Consequently, this extra handling may contribute to added error or missing information. In addition, to extract and upload the SRT responses and supporting documentation into PHIS, will delay the review process up to a couple of weeks if submitted in English. The benefits for using PHIS to submit the information includes an expedited SRT review, transparency, and security. To ensure an expedited review of a submitted SRT, particularly an SRT submitted in PHIS, FSIS encourages countries to submit SRT responses and supporting documentation in English.

13", "FSIS acknowledges that most countries' native language is not English. However, to expedite the equivalence review process, FSIS encourages countries to submit SRT responses and supporting documentation in English through PHIS. If you submit an SRT and supporting documentation in a language in other than English, FSIS will have to have the information translated and then have the country verify that the translations are accurate. This can result in significant delays and possible errors.

14", "The following steps describe the process FSIS follows to ensure that translations are accurate.

1. First, the CCA submits the SRT and documents to FSIS in a language other than English.
2. Next, FSIS sends the SRT and documents for translation into English.
3. Upon receiving the translated SRT and documents, FSIS inserts the English translated SRT responses into the SRT in PHIS.
4. Next, FSIS provides the CCA the opportunity to verify the accuracy of the English translated SRT responses and documents.
5. Finally, the CCA responds to FSIS concerning the accuracy of the translated SRT and documents. If the CCA provides corrections to the translated SRT in a language other than English, FSIS will send the corrections for translation, and the process will start over until the CCA agrees with the translations.

FSIS maintains all countries SRT responses and submitted supporting documentation in PHIS. Through PHIS the CCA will have the opportunity to verify that the translated responses are accurately captured by FSIS in PHIS. For countries that submitted paper SRT

15", "responses, the CCA will be provided an opportunity to verify a paper copy of the English translated SRT responses entered into PHIS. Note that by not communicating the SRT responses in English and by using a paper copy rather than PHIS for inputting SRT information by the CCA, the equivalence review process could be delayed by weeks and possibly months. Importantly, regardless of how the CCA manages the SRT, FSIS relies upon the PHIS English version of the SRT responses when making equivalence decisions. Countries are encouraged to gain access to PHIS in order to ensure completeness of documentation of the SRT.

15","I\u2019ll next discuss how to become e\u2019authenticated and how to access PHIS which is available 24\7. As I said earlier, FSIS recommends that countries enter their SRT responses and upload documentation into PHIS to expedite the review process. However, even if countries do not enter their SRT responses into PHIS, FSIS relies upon the PHIS SRT responses for its equivalence evaluation. Thus, countries can view the information in PHIS 24\7. 16","The benefits for using PHIS include an expedited SRT review, transparency, and security. Countries that use PHIS to submit their SRT only need to review and affirm SRT responses or revise certain questions to reflect changes in their inspection system in order meet the annual deadline of May 18th to update the SRT. Also, participating countries will be able to log into PHIS at any time to view their SRT and its status. Please refer to the Federal Register for more information about country access to PHIS

(<http://www.fsis.usda.gov/wps/wcm/connect/3d648d9c\u20104498\u201049ae\u20108a958adc4526deff/2014\u20100039.pdf?MOD=AJPERES>). 17","Countries that do not already have access to PHIS and level 2 eAuthentication credentialing need to complete the following steps in order to start using PHIS to complete the SRT. It is important to understand that the level 2 eAuthentication credentialing and PHIS enrollment are two separate processes. It is important to note that when the designated CCA official becomes level 2 eAuthentication credentialed, the PHIS enrollment process is not automatically initiated. As these processes are independent from one another, it will take time to complete both of these processes. To start the level 2 eAuthentication credentialing process, a country first needs to identify a designated CCA official. This identified official will be responsible for entering the SRT responses and uploading supporting documents into PHIS. This official is responsible for first obtaining level 2 eAuthentication credentials, and then requesting to be enrolled in PHIS to complete the SRT.

18","To begin the process for obtaining level 2 eAuthentication credentialing, the country\u2019s designated CCA official first needs to complete the registration form at <http://1.usa.gov/1rbeFcL>. After completing the form, the designated CCA official will receive a confirmation e\u2010mail. Typically, this happens within an hour after submitting a complete form. The official MUST respond to the e\u2010mail within 7 days of receiving the confirmation e\u2010mail. The designated CCA official will be asked to create a username and password. It is important to remember this username and password in order to log into PHIS. 19","Once your designated CCA official receives a confirmation e\u2010mail and has responded to the confirmation e\u2010mail, please contact Ms. Monica Marcelli with the Office of Policy and Program Development at [monica.marcelli@fsis.usda.gov](mailto:monica.marcelli@fsis.usda.gov) or 1 (202) 720\u20100473. Ms. Marcelli will help the designated CCA official to schedule the appointment with the LRA to verify his or her government issued photo identification. If the designated CCA official is based at an embassy in Washington DC, or visiting Washington DC, he or she can meet with the LRA at the United States Department of Agriculture building to complete the eAuthentication credentialing process. If the designated CCA official is not in the US, FSIS can make arrangements to complete the credentialing process while in country. If your designated CCA official does not receive a confirmation e\u2010mail within 24 hours after submitting the complete registration form, please contact Ms. Marcelli. 20","Once your designated CCA official receives an e\u2010mail confirming his or her level 2 eAuthentication credentials, he or she is now able to enroll in PHIS. To begin the PHIS enrollment process, open a web browser and go to <https://phis.fsis.usda.gov>. The eAuthentication login page will appear. Enter your level 2

eAuthentication username and password that the designated CCA official created while completing the level 2 eAuthentication form. 21", "On the Welcome to the FSIS Enrollment Application page, click Submit Enrollment Request. 22", "On the FSIS Enrollment Request Wizard (Step 1) page, click Next. 23", "On the FSIS Enrollment Request Wizard (Step 2) page, for the Account Type field, select Foreign Country from the drop\u2010down list and click Next. 24", "On the FSIS Enrollment Request Wizard (Step 3) page, for the Role field, select Central Competent Authority from the drop\u2010down list and click Next. 25", "On the FSIS Enrollment Request Wizard (Step 4) page, for the Country field, select your country from the drop\u2010down list and click Next. 26", "On the FSIS Enrollment Request Wizard (Step 5) page, complete any of the optional fields and click Next. 27", "On the FSIS Enrollment Request Wizard (Step 6) page, for the Comments field, type any additional information and click Next. 28", "Once you have completed the Enrollment Request Wizard, steps 1 through 6, you are taken to an Enrollment Request Summary page. Review the information. If you need to edit the information, click Previous until you get to the desired page and edit the information. Otherwise, click Finish and then click Logout eAuth. After you have submitted your enrollment request for PHIS, it will be reviewed by FSIS. You will receive a confirmation e\u2010mail once your request has been approved. This typically happens within an hour. Upon receiving your confirmation e\u2010mail, you can log in and begin using PHIS at https:\u2010\phis.fsis.usda.gov. If you do not receive a confirmation e\u2010mail 24 hours after submitting your request, please contact Ms. Marcelli for assistance. 29", "Please check junk e\u2010mail for confirmation e\u2010mails regarding level 2 eAuthentication credentialing and PHIS enrollment. Log in to PHIS at least every 60 days to prevent your account from being disabled. If your designated CCA official\u2019s PHIS account becomes disabled, he or she must make sure that his or her level 2 eAuthentication password is up\u2010to\u2010date, and then contact Ms. Marcelli for further assistance. For designated CCA officials that are enrolled in PHIS, FSIS will send reminder e\u2010mails to log into PHIS. For security reasons, eAuthentication will occasionally prompt you to change your password. If it is time to change your password, the system will prompt you to change your password. Failure to log into PHIS at least annually may result in loss of level 2 eAuthentication credentials. If the designated CCA official loses their level 2 eAuthentication credentials, they will need to complete the level 2 eAuthentication registration process again. If the designated CCA official is not able to log into PHIS because he or she has locked the level 2 eAuthentication account by trying to enter his or her password too many times, please contact the eAuthentication Help Desk at 1\u2010800\u2010457\u20103642, and select Option 1 or email eAuthHelpDesk@ftc.usda.gov. Your designated official may be prompted to answer security questions that he or she set up while completing the eAuthentication registration form. 30", "Lastly, the USDA does not permit sharing accounts or passwords. 30", "Now that you (meaning the designated CCA official) have successfully received level 2 eAuthentication credentialing and are enrolled in PHIS, you can now log into PHIS and start to complete the SRT. 31", "To log into PHIS, open a web browser and go to https:\u2010\phis.fsis.usda.gov. Log into PHIS with your Level 2 eAuthentication user ID and password that you created while completing the level 2 eAuthentication registration form. 32", "Once you\u2019re logged into PHIS, the first page you see is the Homepage. I\u2019ll refer to this as your Dashboard. 33", "Your dashboard contains a menu on the left side of the page and status notifications in the center. All designated officials are to have a PHIS user role of a Central Competent Authority. My

Dashboard displays a history of all SRT Notifications for initial, or ongoing SRTs. PHIS tracks the status of each country's SRT at the following points: Sent Request FSIS has created a new version of an SRT for a country, but you have not made any edits yet.

With Country You have opened the SRT and answered at least one question or uploaded at least one document. Submitted You have clicked Submit, but FSIS has not started the review process. You can continue to edit your SRT or upload additional documents during this phase. Under Review FSIS has started reviewing the SRT. You can continue to edit your SRT or upload additional documents during this phase.

Under Review Locked FSIS is reviewing the SRT and has locked the SRT. When an SRT is locked, you cannot make any changes to the SRT. Archived FSIS has completed its review of the SRT and has archived the SRT. After an SRT is archived, you can no longer make any changes to the SRT. All new status notifications are in bold. Once you have read a notification, you can mark it with a check mark. At that point, the status notification will no longer be in bold, so you can differentiate between read and unread notifications.

Notifications appear on your dashboard for 180 days before they are removed. NOTE: Blurred items on example screen shots are done to protect private information and will not appear when you view PHIS. Next I will discuss how to respond to the SRT questions using PHIS. Once FSIS receives a country's formal written initial equivalence request, an SRT will be generated in PHIS. FSIS will notify the country after the SRT has been created in PHIS. Countries that already have equivalence for a specific commodity and are either wishing to update their SRT information or requesting initial equivalence for another commodity are to verify that the responses and the selected supporting documents in PHIS for the specific SRT questions are correct. If the responses or supporting documents no longer reflect the country's current food safety inspection system practices, then the country needs to update the responses and supporting documents. To answer SRT questions, from the left menu, select SRT Survey. Clicking SRT Survey from your Dashboard (Homepage), you are brought to the SRT Survey page. Select the info icon for each SRT to add commodity specific information. Select the view icon for each SRT to complete or make changes to the SRT questions. When the info icon is selected, the SRT Information window appears. Here you are to provide information related to the products and process categories relevant to the selected SRT. To begin, select products to be exported and select process categories applicable to the SRT and add Additional Product Description, if necessary. For more information about the process categories and types of meat, poultry, or egg products that would fall under each process category, please review the Product Categorization guide which can be found on FSIS' website at

<http://www.fsis.usda.gov/wps/wcm/connect/abbf595d/u20107fc7/u20104170b7be/u201037f812882388/Product/u2010Categorization.pdf?MOD=AJPERES>. If information needs to be added or changed, do so and click Save. If you do not need to make any changes, click the X button in the top right corner and go to the next step. Clicking Save brings you back to the SRT Survey page. NOTE: The options on this page vary based on the selected inspection system (meat, poultry, or egg products). When you select the view icon for an SRT, the SRT Survey Details page appears. The SRT Survey Details page is a table of contents for the SRT. Expand the survey tree until you find the question you want to answer. The survey tree is organized by the Equivalence Component Level (Government Oversight, Government Statutory

Authority and Food Safety and Other Consumer Protection Regulations, Government Sanitation, Government Hazard Analysis and Critical Control Point (HACCP) Systems, Government Chemical Residues Testing Programs, and Government Microbiological Testing Programs). Within each component is the Equivalence Criteria Level that contains instructions on whether the SRT questions within that component are required or voluntary and the SRT Question Level. The SRT Question Level includes the questions that contain the criteria FSIS uses to evaluate the equivalence of a country\u2019s SRT response. Pictured here is an example of an expanded survey tree with all the levels expanded and the questions visible. Answered SRT questions will display a green checked circle next to Select in front of the question. Click Select next to the SRT question that you want to answer, review, or update.

40", "Scroll down to the Answer section and answer the question. NOTE: The system is only able to save responses in languages with a letter based alphabet. At this time, the system is not able to save responses in languages that use a symbol\u2010based script. To respond to an SRT question in a language other than English, you need to reference a word or pdf document. I will discuss later how to upload and reference documentation. If you intend to reference a document that contains your SRT question response, please type in the textbox in English \u201cSee attached response.\u201d 41", "There are two categories of questions: 1. Required questions are marked with a red asterisk (\*). If left unanswered, the system will not go to the next page until you answer all the required questions on the page. 2. Level of Advancement (LOA) are optional questions and are marked with the phrase \u201cThis is a scoreable question. It is an optional question. Select all that apply.\u201d Although these LOA questions are voluntary, a complete response by the CCA to these questions provides FSIS with more context as to how the design of the country\u2019s inspection system functions beyond the minimum expectations to ensure food safety. 42", "If you try to move onto the next page in the SRT without answering all required SRT questions, an error message appears. 43", "To return to a specific question at a later time, select the Mark for Review checkbox. For required questions, Mark for Review must have something entered into the text box in order to move to the next page of the SRT. See example placeholder. If you want to jump to the top of the page, select \u2191Top. 44", "At the top of each SRT questionnaire page is the following: Questionnaire \u2013the SRT Questionnaire version. Document \u2013a system generated document title. Status \u2013a progress tracker that identifies the percentage of SRT questions that have been responded to. Started on \u2013the date when the SRT was started (meaning when FSIS assigned the SRT to the country). Completed on \u2013the date when the SRT was completed (meaning submitted in PHIS). 45", "Once you are in the SRT survey, there are several different ways to navigate through the SRT survey. At the bottom of each SRT survey page, the following navigation options appear. Click Next to go the next page of the SRT questionnaire. Clicking Next moves you to the next page in the survey and saves your answers on the current page. Click Previous to move to the previous page. Click the blue arrows to go to either the very first page, or the last page of the SRT with unanswered SRT questions. Type in a page number in the designated Page No. box, then click Go to jump to a specific page in the SRT questionnaire. Click the pdf Reports symbol to view a pdf copy of the SRT questionnaire and the populated responses to each SRT question that you have completed thus far. Click Cancel, then SRT Import on the left side to return to the FSIS equivalence component and question survey tree. When you are ready to exit, click Save & Close to save your SRT question responses and return to the

Home page. 46", "If you clicked the pdf Reports symbol to view a pdf copy of the SRT questionnaire, this page appears. To return to the SRT Questionnaire, click Go Back to Questionnaire at the bottom left corner of the page. 47", "When you click Cancel or Submit your SRT questionnaire, this page appears. To return to the SRT questionnaire that you were working on, click Requested Questionnaire. To view and open \u201cin\u2010progress\u201d SRT questionnaires (meaning SRT questionnaires that have not been submitted for review), click My Questionnaires. To return to the SRT questionnaire equivalence component and question survey tree that you were currently working on, click SRT Import. To return to your homepage, click on FSIS Dashboard. All in\u2010progress SRT questionnaires are listed in the center of your screen under My InProgress Questionnaires. To access the first page of an In\u2010Progress SRT questionnaire, select Open on the right hand side. 48", "A complete response to an SRT question should reference programs and supporting documentation. If a country does not provide all relevant programs and supporting documentation in its SRT submission, the review process takes longer. To expedite the review process, it is important that the country upload all programs and supporting documentation into PHIS and reference the supporting documentation as part of its answer to the relevant SRT question. The following steps demonstrate how to upload and reference programs and supporting documentation.

49", "You\u2019ll first need to upload programs and supporting documentation in order to be able to reference them as part of your answer to an SRT question. To upload programs and supporting documentation, select Documents located on the left side on your dashboard.

50", "This brings you to the Country Documents page. To add a document, preferably in Microsoft Word, Microsoft Excel, or pdf, click Add Attachment. From this page, you can also download, view, or delete listed documents on the Country Documents page by selecting either the download icon or trash can icon next to the document. NOTE: Example screen shots are intentionally blurred to protect private information. Screens will not appear blurry when you view PHIS. 51", "To add a document, scroll to the bottom of the page. In the File Name field, click Browse. Locate the file you want to upload and click Open. For the Document Title field, type a meaningful title. Click Upload. It may take a few minutes for the document to upload. The page refreshes with the newly attached file in the grid. If the document does not appear after the page finishes loading, click Refresh and the document should appear. If a document does not appear after clicking Upload, or you receive an error message, the file may be too large. Therefore, you may need to break up files over 5 MB into smaller files to be able to upload them into PHIS. 52", "After you have uploaded all documents, click on SRT Survey on the left to return to the SRT. You\u2019re now ready for the second step, add a reference to the supporting documentation. 53", "This brings you to the SRT Survey page. Select the View icon next to the SRT that you want to add, update, or remove references to programs and supporting documentation. 54", "Clicking the View icon brings you to the SRT Survey Details page. Expand the survey tree until you find the question you want to add, update, or remove referenced programs and supporting documentation. Then click Select to go to that specific question in the SRT. 55", "After your question loads, click Add Reference below the answer field. A grid appears with a list of all uploaded programs and supporting documents. 56", "Locate the document that you wish to reference. 57", "Next, if applicable, select a Category that best describes the associated document. NOTE: Countries can only add categories to documents that are referenced to an SRT question. 58", "After clicking Select, the grid disappears and the

Questionnaire page refreshes with the document appearing in the reference grid. The bookmark name for a selected bookmark appears after the file name. The category, if selected, appears in parentheses to the right of the file name in the grid. To delete a referenced document, click the red X next to the document from this grid. This does not remove the document from PHIS. This action only deletes the reference between the document and that specific question. 59","After you have responded to each question and referenced all relevant programs and supporting documentation in the SRT, you are now ready to submit the SRT to FSIS for review. 60","Navigate to the last page of questions in the SRT questionnaire and click Next. If you have marked questions for review, PHIS displays the Questions Marked for Review page with a grid of all the questions that were marked for review. If you do not have any questions marked for review, proceed. 61","To review a question, click Review in the far right column. PHIS opens the SRT on the page that contains the question under review. Review your answer and make any necessary changes. Then uncheck the Mark for Review checkbox and click Next. PHIS opens the SRT at the next question that was marked for review. Repeat these steps until all checkmarks have been removed. If you do not wish to review checked Mark for Review questions, then click Remove All Marks on this page. After you have addressed all questions marked for review, click Continue. 62","On the Submit Questionnaire page, click Submit. 63","Congratulations! You have successfully submitted the SRT in PHIS. At this point, the SRT is submitted to FSIS for review. Please notify OIC after you have submitted the SRT. You can monitor the status notification changes made to your SRT during the review process on your dashboard. Clicking Submit brings you to the My Questionnaires page. 64","65","Countries are to contact FSIS\u2019s Office of International Coordination for: 1. All questions and requests for technical assistance, 2. To submit formal equivalence requests, 3. To submit a paper copy of an SRT and supporting documentation for review, or 4. To notify FSIS that an SRT was submitted in PHIS. 66","67"]},{"file\_name":"FSIS\_GD\_2019\_0014","title":"FSIS Guidance for Suggested Reporting Tables of the Government Chemical Residue Control Program","num":"FSIS-GD-2019-0014","id":"09cdcb2ad3ed72006d7cda8cdc2c7e4c66eec6f842f2a38b5a968a9a6ba54344","corpus":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/import/Suggested-Reporting-Tables-Government-Chemical-Residue-Control-Program.pdf","type":"pdf","n\_pages":2,"word\_count":850,"text\_by\_page":["FSIS Guidance for Suggested Reporting Tables of the Government Chemical Residue Control Program NOTE: This document is updated from the 2018 version but does not contain substantive changes to the suggested reporting format. FSIS requests that all eligible countries submit their 2019 Chemical Residue Control Program Plan and 2018 Residue Control Program Results. The tables included in this guidance are to assist Central Competent Authorities (CCAs) provide FSIS with the information requested in FSIS\u2019s Self-Reporting Tool (SRT) question, Government Chemical Residues Testing Programs. FSIS is providing suggested reporting table formats for the annual data submissions of the 2019 Residue Control Program Plan and 2018 Residue Control Program Results that are due to FSIS by May 18, 2019. The use of these reporting table formats is optional; FSIS will review information submitted in other formats. The information that should be submitted includes: \u2022 2019 FSIS Residue Control Plan (Table 1 \u2013 suggested reporting format) 1) Names of individual compounds for each slaughter class or, if

providing a method, then a list of individual compounds for each method 2) Proposed tissue (e.g., muscle, liver, kidney) for sample collection 3) Analytical methodology used to evaluate each compound for regulatory decision making 4) Established tolerance or action level, (e.g., maximum residue limit (MRL) 5) Proposed number of samples for each production class for each chemical compound 6) Criteria used to determine the proposed sampling number (e.g., statistical basis, etc.) 7) Criteria used to determine whether a compound is included or removed from the testing program 8) Processes for reassessing the yearly chemical residue plan and for reviewing the data and identifying specific violations or violation trends 9) Indicate whether livestock (beef, pork, goat, sheep) carcasses are held pending negative laboratory test results before exported to the US \u2022 2018 FSIS Residue Control Program Results (Table 2 \u2013 suggested reporting format) 1) Actual number of samples analyzed for each production class for each chemical compound and number of violative results 2) Description of the CCA\u2019s enforcement strategy in response to violative results Countries testing applicable processed products should include this information in their submission. Regarding the 2019 FSIS Residue Control Annual Plan, FSIS is including the attachment, FSIS Government Residue Control Program, as a reference. This attachment includes sampling and testing frequencies for FSIS government testing programs. The 2019 FSIS Residue Control Annual Plan and the 2018 Residue Control Program Annual Results can be submitted to FSIS by either uploading it into our Public Health Information System (PHIS) under SRT question, Government Chemical Residues Testing Programs, or by submitting it to our International Coordination Executive at: US Department of Agriculture Food Safety and Inspection Service Office of International Coordination Room 3143, South Building 1400 Independence Ave SW Washington D.C. 20250-3700 Fax: 1-202-690-3856 E-mail: InternationalCoordination@fsis.usda.gov", "FSIS Guidance for Suggested Reporting Tables of the Government Chemical Residue Control Program NOTE: This document is updated from the 2018 version but does not contain substantive changes to the suggested reporting format. For your reference, please see the links below for FSIS\u2019s Residue Sampling Plan and Results: \u2022 FSIS Residue Sampling Plans (Blue Book) \u2022 FSIS Residue Sample Results (Red Book) \u2022 FSIS Directive 10,800.11, Residue Sampling, Testing and Other Verification Procedures under the National Residue Program for Meat and Poultry Products

Table 1: Suggested Reporting Table for the 2019 Government Residue Control Program Annual Plan. Please include the following information below for the product categories for which the CCA is currently equivalent or seeking equivalence. (The information provided in the table is for illustrative purposes only)

Species (subspecies)	Compound class	Sampling location (e.g., farm/\ establishment)	Tissue (e.g., kidney, liver, muscle)	Analytical methodology for regulatory decision making	Limit of confirmation (with units)	Action Level or Maximum Residue Level (with units)	Number of samples planned	Bovine (veal, cattle)	Aminoglycosides Neomycin Farm Kidney LC MS\MS
					10 ppb	15 ppb	300		10 ppb

Table 2: Suggested Reporting Table for the 2018 Government Residue Control Program Annual Results. Please include the following information below for the product categories for which the CCA is currently equivalent or if the data exists, seeking equivalence. (The information provided in the table is for illustrative purposes only)

Species (subspecies)	Compound Analyzed	Tissue (e.g., kidney, liver, muscle)	Number of samples analyzed	Number of samples above tolerance or MRL	Violative levels
Bovine (veal, cattle)	Neomycin	Kidney	300	1	50 ppb

Follow-Up Actions Bovine (veal, cattle) Neomycin Kidney 300 1 50 ppb Briefly describe the CCA\u2019s enforcement strategy in response to violative results (e.g., investigation, trace

back, corrective action (root cause), punitive\legal sanctions, etc.) Ex: All suspect carcasses declared unfit for human consumption and destroyed. Full on farm investigations including examination of medicines on farm and animal remedies record were carried out in each case. As appropriate, advice is given to the farmer and follow-up visits take place. 1 FSIS Directive 10,800.1 also available in Arabic, Chinese, Spanish, and Vietnamese translations. 2 Include the compound class for the chemical compound being analyzed. 3 Include the name of the individual chemical compound being analyzed. Please note that compound class alone is not sufficient. 4 Include the regulatory limit for the compound. This may be an \u201caction level\u201d or a \u201cmaximum residue level\u201d.]}, {"file\_name": "FSIS\_GD\_2019\_0016", "title": "Summary of FSIS Government Microbiological Sampling Programs Frequencies", "num": "FSIS-GD-2019-0016", "id": "9dff984e43841f43449dc86b583bc82a3e545c2590746b486de427389b8bcfc1", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Microbiological-Frequencies.pdf", "type": "pdf", "n\_pages": 5, "word\_count": 1408, "text\_by\_page": ["Summary of FSIS Government Microbiological Sampling Programs Frequencies NOTE: This document is updated from the 2018 version. It includes revised footnotes. FSIS microbiological sampling and testing programs are implemented to ensure that establishments maintain control of their production processes and adhere to FSIS regulations, policies and pathogen performance standards. Ongoing government sampling in FSIS-regulated domestic establishments allows FSIS to assess the effectiveness of industry process controls, compliance with performance standards, and other efforts to control the presence of pathogens in FSIS-regulated meat, poultry, and processed egg products. These microbiological sampling and testing programs are an important component of the FSIS mission to protect the health and welfare of consumers by regulating the meat, poultry, and egg products produced in federally-inspected establishments and to prevent the distribution into commerce of any such products that are adulterated or misbranded. FSIS conducts routine microbiological sampling and testing for *Salmonella*, *Campylobacter*, *Listeria monocytogenes*, and *Shiga toxin-producing Escherichia coli* (STEC), including *E. coli* O157:H7 and six non-O157 STEC (O26, O45, O103, O111, O121, and O145). The analyses for these pathogens are conducted using methods as outlined in the FSIS Microbiology Laboratory Guidebook (MLG). In this attachment, FSIS is providing a summary (Tables 1-3) of the frequency of government sampling and the microbiological analyses performed by FSIS. Central competent authorities (CCAs) can use this information as a reference when implementing government microbiological testing. The tables also include test portions analyzed by FSIS for each of these sampling programs. For your reference, please see additional helpful links below: \u2022 FSIS Annual Sampling Program Plan, Fiscal Year 2019 \u2022 FSIS Sampling Results for FSIS Regulated Products \u2022 FSIS Directive 10,010.11, Sampling Verification Activities for *Shiga Toxin-Producing Escherichia coli* (STEC) in Raw Beef Products \u2022 FSIS Directive 10,250.12, *Salmonella* and *Campylobacter* Verification Program for Raw Meat and Poultry Products \u2022 FSIS Directive 10,240.43, Verification Activities for the *Listeria monocytogenes* (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program 1 FSIS Directive 10,010.1 also available in Arabic, Chinese, Spanish, and Vietnamese translations. 2 FSIS Directive 10,250.1 also available in Arabic, Chinese, Spanish, and Vietnamese translations. 3 FSIS Directive 10,240.4 also available in Arabic, Chinese, Spanish, and Vietnamese"]}]}

Microbiological Sampling Programs Frequencies", "num": "FSIS-GD-2019-0016", "id": "9dff984e43841f43449dc86b583bc82a3e545c2590746b486de427389b8bcfc1", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/Microbiological-Frequencies.pdf", "type": "pdf", "n\_pages": 5, "word\_count": 1408, "text\_by\_page": ["Summary of FSIS Government Microbiological Sampling Programs Frequencies NOTE: This document is updated from the 2018 version. It includes revised footnotes. FSIS microbiological sampling and testing programs are implemented to ensure that establishments maintain control of their production processes and adhere to FSIS regulations, policies and pathogen performance standards. Ongoing government sampling in FSIS-regulated domestic establishments allows FSIS to assess the effectiveness of industry process controls, compliance with performance standards, and other efforts to control the presence of pathogens in FSIS-regulated meat, poultry, and processed egg products. These microbiological sampling and testing programs are an important component of the FSIS mission to protect the health and welfare of consumers by regulating the meat, poultry, and egg products produced in federally-inspected establishments and to prevent the distribution into commerce of any such products that are adulterated or misbranded. FSIS conducts routine microbiological sampling and testing for *Salmonella*, *Campylobacter*, *Listeria monocytogenes*, and *Shiga toxin-producing Escherichia coli* (STEC), including *E. coli* O157:H7 and six non-O157 STEC (O26, O45, O103, O111, O121, and O145). The analyses for these pathogens are conducted using methods as outlined in the FSIS Microbiology Laboratory Guidebook (MLG). In this attachment, FSIS is providing a summary (Tables 1-3) of the frequency of government sampling and the microbiological analyses performed by FSIS. Central competent authorities (CCAs) can use this information as a reference when implementing government microbiological testing. The tables also include test portions analyzed by FSIS for each of these sampling programs. For your reference, please see additional helpful links below: \u2022 FSIS Annual Sampling Program Plan, Fiscal Year 2019 \u2022 FSIS Sampling Results for FSIS Regulated Products \u2022 FSIS Directive 10,010.11, Sampling Verification Activities for *Shiga Toxin-Producing Escherichia coli* (STEC) in Raw Beef Products \u2022 FSIS Directive 10,250.12, *Salmonella* and *Campylobacter* Verification Program for Raw Meat and Poultry Products \u2022 FSIS Directive 10,240.43, Verification Activities for the *Listeria monocytogenes* (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program 1 FSIS Directive 10,010.1 also available in Arabic, Chinese, Spanish, and Vietnamese translations. 2 FSIS Directive 10,250.1 also available in Arabic, Chinese, Spanish, and Vietnamese translations. 3 FSIS Directive 10,240.4 also available in Arabic, Chinese, Spanish, and Vietnamese"]}]}

translations.", "Summary of FSIS Government Microbiological Sampling Programs Frequencies NOTE: This document is updated from the 2018 version. It includes revised footnotes. Table 1: Frequency of FSIS Government Microbiological Sampling and Testing for Raw Meat and Poultry Products Product Type or Production Class Pathogen Target(s) Test Portion Frequency (# of samples per establishment)4 Very Small Est (<1,000 lbs./day) Small Est (1,001-50,000 lbs./day) Medium Est (50,001-250,000 lbs./day) Large Est (>250,000 lbs./day) Steer/heifer/cow/bull 5 carcass Salmonella 3-site sponge (300 cm 2 total); with hydrate See footnote 5 See footnote 5 See footnote 5 Raw ground beef/veal E. coli O157:H7 325 grams 1/month 2/month 3/month 4/month Salmonella 325 grams 1/month 2/month 3/month 4/month Raw beef/veal manufacturing trimmings E. coli O157:H7 Entire N60 sample (~325-375grams) 1/month 2/month 3/month 4/month Salmonella Entire N60 sample (~325-375grams) 1/month 2/month 3/month 4/month Non-O157 STEC (O26, O45, O103, O111, O121, and O145) Entire N60 sample (~325-375grams) 1/month 2/month 3/month 4/month Raw beef/veal bench trimmings E. coli O157:H7 Entire N60 sample (~325-375grams) 1/month 2/month 3/month 4/month Raw beef/veal components other than trim (e.g., head meat, cheek meat, weasands, hearts) E. coli O157:H7 325 grams 1/month 2/month 3/month 4/month Salmonella 325 grams 1/month 2/month 3/month 4/month The volume production ranges listed are based on pounds of a specific product type or process category produced per day by a single establishment. Alternatively, the CCA may choose to use the volume of products that are exported to the US to categorize establishments eligible to export in order to determine the appropriate frequency for testing. If the frequency of sampling is based on volume of products exported to the US, the corresponding volume ranges would be: Very Small Est (<20,000 lbs./month exported to the US), Small Est (20,001-100,000 lbs./month exported to the US), Medium Est (100,001-5,000,000 lbs./month exported to the US), Large Est (>5,000,000 lbs./month exported to the US). 5 FSIS suspended official government verification of compliance with the Salmonella performance standards in beef (steers/heifers and cows/bulls) and swine (market hog) carcasses (2011), as well as in raw ground beef (2014), because the percentage of positive findings was very low in carcasses and because of methods changes in ground beef. CCAs need to provide their performance standard criteria for evaluation of Salmonella results, including how the CCA assesses on an ongoing basis whether certified establishments meet performance standards for carcasses (cow/bull, steer/heifer, and swine) and raw ground beef. Alternatively, if the CCA has been following the FSIS standards but wants to make changes to its program, CCAs can request an individual sanitary measure (ISM) determination and submit data to support that their measure provides an equivalent level of public health protection.", "Summary of FSIS Government Microbiological Sampling Programs Frequencies NOTE: This document is updated from the 2018 version. It includes revised footnotes. Product Type or Production Class Pathogen Target(s) Test Portion Frequency (# of samples per establishment)4 Very Small Est (<1,000 lbs./day) Small Est (1,001-50,000 lbs./day) Medium Est (50,001-250,000 lbs./day) Large Est (>250,000 lbs./day) Market swine 5 carcass Salmonella 3-site sponge (300 cm 2 total); with hydrate See footnote 5 See footnote 5 See footnote 5 Broiler carcasses Salmonella 30mL of 400mL rinsate 1/month 2/month 2/month 5/month Campylobacter6 30mL of 400mL rinsate 1/month 2/month 2/month 5/month Turkey carcasses Salmonella 2-site sponge (100 cm 2 total); with hydrate 1/month

3\month 5\month 5\month Campylobacter6 2-site sponge (100 cm<sup>2</sup> total); with hydrate  
1\month 3\month 5\month 5\month Raw comminuted chicken Salmonella 325 grams  
5\month 5\month 5\month Campylobacter6 30mL of 325 gram resuspension in 1625 mL  
BPW 5\month 5\month 5\month Raw comminuted turkey Salmonella 325 grams 3\month  
5\month 5\month Campylobacter6 30mL of 325 gram resuspension in 1625 mL BPW  
3\month 5\month 5\month Raw chicken parts Salmonella 30mL of 400mL rinsate 1\month  
1\month 4\month Campylobacter6 30mL of rinsate 1\month 1\month 4\month 6 In  
August 2018, FSIS began using an enrichment-based method to analyze poultry samples for  
Campylobacter due to the low sensitivity of the direct plating analytical method. Therefore, at  
this time, FSIS is not currently assessing Campylobacter performance in poultry establishments  
and is currently revising the Campylobacter performance standards based on the enrichment  
method.", "Summary of FSIS Government Microbiological Sampling Programs Frequencies  
NOTE: This document is updated from the 2018 version. It includes revised footnotes. Table 2:  
Frequency of FSIS Government Microbiological Sampling and Testing for Ready-to-eat (RTE)  
Meat and Poultry Products Type of Sample Collected Pathogen Target(s) Test portion  
Frequency7 (# of samples per establishment per year) Post-lethality Exposed Products Not Post-  
lethality Exposed Products RTE Products Listeria monocytogenes 25 gram 7 3 Salmonella 325  
gram 7 3 Food Contact Surface and NonFood Contact Environmental Surface Listeria  
monocytogenes Entire sponge (with hydrate) Once every 4 years and should include a  
minimum of: -3 units8 in large establishments (>500 employees) -2 units in small  
establishments (10-500 employees) -1 unit in very small establishments (<10 employees) 7 If an  
establishment produces both post-lethality exposed and not post-lethality exposed ready-to-  
eat products, sampling frequency should be in accordance with post-lethality exposed RTE  
products. 8 1 unit consists of 5 product samples, 10 food contact surface samples, and 5 non-  
food-contact surface samples", "Summary of FSIS Government Microbiological Sampling  
Programs Frequencies NOTE: This document is updated from the 2018 version. It includes  
revised footnotes. Table 3: Frequency of FSIS Government Microbiological Sampling and Testing  
for Pasteurized Liquid or Dried Egg Products Product Type Pathogen Target(s) Test Portion  
Frequency (# of samples per establishment) Liquid\frozen egg whites with or without added  
ingredients Listeria monocytogenes 25 mL or 25grams 1 sample\month Salmonella 100 mL or  
100 grams 1 sample\month Liquid\frozen whole eggs or yolks (<2% or no added ingredients)  
Listeria monocytogenes 25 mL or 25grams 1 sample\month Salmonella 100 mL or 100 grams 1  
sample\month Liquid\frozen whole eggs, yolks, or whole egg\yolk blends (>2% added  
ingredients other than salt\sugar) Listeria monocytogenes 25 mL or 25grams 1 sample\month  
Salmonella 100 mL or 100 grams 1 sample\month Liquid\frozen whole eggs, yolks, or whole  
egg\yolk blends (>2% added salt or sugar) Listeria monocytogenes 25 mL or 25grams 1  
sample\month Salmonella 100 mL or 100 grams 1 sample\month Dried yellow egg products  
Listeria monocytogenes 25grams 1 sample\month Salmonella 100 grams 1 sample\month  
Spray-dried egg whites with or without added ingredients Listeria monocytogenes 25grams 1  
sample\month Salmonella 100 grams 1 sample\month Pan-dried egg whites Listeria  
monocytogenes 25grams 1 sample\month Salmonella 100 grams 1  
sample\month"]}, {"file\_name": "FSIS\_GD\_2019\_0017", "title": "FSIS Responses to the SRT  
(v2019-001): United States (U.S.) Department of Agriculture Food Safety and Inspection Service  
(FSIS) Responses to the Self-Reporting Tool (SRT)", "num": "FSIS-GD-2019-"}]

0017","id":"cdbd52a9d4c5331e100bb6d97e4a4203085fa5145d7a7daf76e7148f708e415a","corpus":"fsis\_guidelines","source\_page\_url":"https:\V\www.fsis.usda.gov\policy\fsis-guidelines","url":"https:\V\www.fsis.usda.gov\sites\default\files\import\srt-responses.pdf","type":"pdf","n\_pages":45,"word\_count":27759,"text\_by\_page":["FSIS Responses to the SRT (v2019-001) 1 United States (U.S.) Department of Agriculture Food Safety and Inspection Service (FSIS) Responses to the Self-Reporting Tool (SRT) What is the purpose of this document? This document is designed to demonstrate to the Central Competent Authority (CCA) that intends to submit answers to SRT questions the level of detail FSIS needs in those answers for FSIS to determine whether the country\u2019s documented food safety inspection system achieves a level of sanitary protection equivalent to the U.S. system. In this document, FSIS provides answers to the SRT based on our documented national food safety inspection system governing meat, poultry, and egg products. In addition, FSIS has included links to our supporting documentation (i.e., laws, regulations, inspection procedures, sampling plans, and sampling results) within each SRT answer. Furthermore, FSIS altered some answers to SRT questions to provide a more applicable response. For example, SRT question #2, \u201cHow does the CCA ensure that no meat, poultry, or egg products intended for export to the U.S. are adulterated or misbranded (i.e., properly labeled and packaged), and only eligible meat, poultry, and egg products are certified for export to the U.S.? \u201d was answered from the standpoint of ensuring that no meat, poultry, or egg products intended for export from the U.S. are adulterated or misbranded, and only eligible products are certified for export. Information on ensuring that only eligible products are received for importation was provided in a subsequent question (SRT question #3). Who is this document designed for? This document is designed for all countries to use as a reference when providing SRT answers as part of their required annual documentation submission for ongoing equivalence. In addition, this document is a useful tool for countries requesting a reinstatement of equivalence, initial equivalence, or expansion of initial equivalence to demonstrate the type of information that they will need to provide in their SRT submission. How is this document structured? This document was structured to provide the U.S. laws, regulations, and inspection procedures applicable to each SRT answer. The primary issuances noted throughout this document are as follows: \u2022 U.S. laws- Federal Meat Inspection Act, Poultry Products Inspection Act, and Egg Products Inspection Act \u2022 U.S. regulations- Title 9 of the Code of Federal Regulations (9 CFR) chapters 300 to 590 \u2022 FSIS inspection procedures- FSIS Directives In addition, this document provides SRT answers to all commodities (meat, poultry, and egg products) produced under various processing categories. Therefore, not all SRT questions and answers will apply to every country. The following chart identifies which SRT questions the CCA needs to provide answers and supporting documentation for based on the specific products the country is eligible to export or interested in exporting to the U.S. To view which products your country is currently eligible to export to the U.S., refer to FSIS Import Library- Eligible Countries and Products. For more information on HACCP product categorization, please refer to the FSIS Product Categorization Guide. Products SRT Question Numbers Standard SRT questions to be answered for all products 1, 2, 3, 4, 5, 7, 9, 13, 14, 15, 16, 18, 23, 24, 26 Raw-Intact and Raw-Non Intact Beef and Veal 6, 10, 11, 12, 17, 22, 25, 27, 28, 29", "FSIS Responses to the SRT (v2019-001) 2 Raw-Intact and Raw-Non Intact Pork 6, 10, 11, 12, 22, 25, 27, 28 Raw-Intact and Raw-Non Intact Lamb, Mutton, or Goat 6, 10, 11, 12, 17, 22, 25, 27, 28 Raw-Intact and Raw-Non Intact Poultry and Ratites 6,

10, 11, 12, 22, 25, 27, 28 Raw-Intact and Raw-Non Intact Siluriformes Fish 6, 20, 21, 25 Thermally Processed-Commercially Sterile Meat and Poultry Products 6, 25, 33 Not Heat Treated-Shelf Stable Meat and Poultry Products 6, 25, 30, 31, 32 Heat Treated-Shelf Stable Meat and Poultry Products 6, 25, 30, 31, 32 Fully Cooked-Not Shelf Stable Meat and Poultry Products 6, 25, 30 Heat Treated-Not Fully Cooked-Not Shelf Stable Meat and Poultry Products 6, 25, 32 Product with Secondary Inhibitors-Not Shelf Stable Meat and Poultry Products 6, 25, 30, 32 Egg Products 8, 19, 30 Lastly, in this document, the term \u201cestablishments\u201d refers to all official establishments under FSIS inspection eligible to produce meat, poultry, and egg products for domestic commerce and for export (i.e., certified to export product to foreign countries).", "FSIS Responses to the SRT (v2019-001) 3 Component 1 Government Oversight 1. How does the CCA ensure that the laws and regulations governing meat (including beef, veal, pork, sheep, goat, and Siluriformes fish), poultry (including chickens, turkeys, ducks, geese, guineas, ratites, or squabs), and egg products inspection are enforced? The Central Competent Authority (CCA) of the United States (U.S.) is the Food Safety and Inspection Service (FSIS), part of the U.S. Department of Agriculture (USDA), and it is organized and administered as part of the national government. FSIS is the public health regulatory agency responsible for ensuring that domestic and imported meat, poultry, and egg products are safe, wholesome, and correctly labeled and packaged. FSIS inspects domestic and imported meat, poultry, and egg products under the authority of the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA). On December 2, 2015, FSIS published the Final Rule \u201cMandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish\u201d (80 FR 75590). This rule amended the Agency\u2019s regulations to establish a mandatory inspection program for fish of the order Siluriformes, both farm-raised and wild-caught, and for products derived from these fish. Further, the rule explains that, because these fish are amenable to the FMIA (21 U.S.C. 601(w)(2)), the Siluriformes inspection program is part of FSIS\u2019s meat inspection program, and is governed by FSIS under the authority of the FMIA. (NOTE: Throughout this SRT, regulatory citations to FSIS\u2019s inspection requirements for Siluriformes fish and fish products are provided. In most cases, these regulations reference the existing regulations for meat and meat food products as applying to Siluriformes products). The authority to enforce these Acts, and maintain a regulatory program aimed at protecting the health and welfare of consumers, is delegated from the Secretary of Agriculture, who is appointed by the President of the United States. In turn, the Secretary of Agriculture appoints a FSIS Administrator to oversee all FSIS activities and program areas, including but not limited to, inspection services, laboratory services and technical support, and training and education. FSIS comprises several program areas (FSIS Organizational Chart), including the Office of Field Operations (OFO), which manages regulatory oversight and inspection of establishments that slaughter, process, import and export meat, poultry and egg products. Inspection services are provided by ten (10) OFO district offices spanning across the U.S. The district offices are responsible for coordinating the activities of local inspection circuits, as well as certifying establishments. FSIS inspection program personnel (IPP) ensure that all provisions in the aforementioned Acts are met and followed by verifying and enforcing that official establishments meet all applicable regulatory requirements in Title 9 of the Code of Federal Regulations (9 CFR) chapters 300 to 590. Among other provisions, these Acts give FSIS the authority and ability to require corrective actions in

establishments and to take additional enforcement measures as necessary when regulatory requirements are not met. FSIS IPP require and verify that establishments implement corrective actions, including measures to prevent recurrence, when the establishment fails to prevent direct contamination or adulteration of product (9 CFR 416.15), or when a deviation from a critical limit occurs (9 CFR 417.3). Furthermore, if an establishment fails to take appropriate corrective actions, FSIS has the authority and ability to take additional enforcement measures. These measures include, but are not limited to, retaining product or rejecting equipment; refusing to allow the marks of inspection to be applied to product; and suspending or withdrawing inspection (9 CFR 500 (meat and poultry), 590.160 (eggs)). (NOTE: The Rules of Practice in 9 CFR 500 apply to fish inspection activities per 9 CFR 561. Throughout this SRT, answers referring to the Rules of Practice in 9 CFR 500 apply to meat and poultry products, including", "FSIS Responses to the SRT (v2019-001) 4 Siluriformes.) Other circumstances under which FSIS would take enforcement measures (e.g., failure to have or maintain a Hazard Analysis and Critical Control Point (HACCP) plan, failure to have or maintain Sanitation Standard Operating Procedures (Sanitation SOPs), or handling or slaughtering livestock inhumanely) are provided in 9 CFR 500 (meat and poultry) and 590.160 (egg products). Instructions to FSIS personnel on the types of enforcement actions that may be taken under 9 CFR 500, and the enforcement methodology to use when taking enforcement actions, are provided in FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology. For example, when a FSIS OFO district office decides to pursue an enforcement action under 9 CFR 500.3 Withholding or suspension without prior notification, it issues a Notice of Suspension letter. When a FSIS OFO district office decides to pursue an enforcement action under 9 CFR 500.4 Withholding action or suspension with prior notification, it issues a Notice of Intended Enforcement letter. In connection with these enforcement actions, the FSIS OFO district office prepares an Administrative Enforcement Report case file to include establishment documentation, FSIS and establishment communications, supporting documents, evidence collected (as described in FSIS Directive 8010.3 Procedures for Evidence Collection, Safeguarding and Disposal), and verification plans. Additionally, FSIS conducts public health risk evaluations to determine if risk-based, targeted reviews of establishment food safety systems (i.e., food safety assessments) are necessary. These food safety assessments are conducted by FSIS personnel (i.e., Enforcement Investigation and Analysis Officers- EIAOs) who have received advanced training in the assessment and analysis of establishment food safety systems. Some examples of when a FSA may be conducted include, but are not limited to, when an establishment produces adulterated product, or when an establishment produces product associated with an outbreak. FSIS EIAOs follow instructions outlined in FSIS Directive 5100.4 Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology when conducting a public health risk evaluation to determine whether a food safety assessment is necessary, and FSIS Directive 5100.1 Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology when performing food safety assessments. Furthermore, the Acts provide FSIS with the authority to seize and condemn adulterated or misbranded meat, poultry, and egg products in commerce or being transported in commerce (21 U.S.C. 673 (meat), 467(b) (poultry), and 1049 (egg products)). FSIS\u2019s Office of Investigation, Enforcement and Audit (OIEA) is responsible for the enforcement of FSIS criminal, civil, and administrative sanctions and authorities. FSIS OIEA

compliance officers follow instructions outlined in FSIS Directives (8000 series) when performing procedures including, but not limited to, conducting in-commerce surveillance activities (FSIS Directive 8010.1 Methodology for Conducting In-Commerce Surveillance Activities); collecting, safeguarding, and disposing evidence (FSIS Directive 8010.3 Procedures for Evidence Collection, Safeguarding and Disposal); detention and seizure (FSIS Directive 8410.1 Detention and Seizure); determining appropriate action and referring enforcement matters (FSIS Directive 8010.5 Case Referral and Disposition); and writing an investigation report (FSIS Directive 8010.4 Report of Investigation). 2. How does the CCA ensure that no meat, poultry, or egg products intended for export to the U.S. are adulterated or misbranded (i.e., properly labeled and packaged), and only eligible meat, poultry, and egg products are certified for export to the U.S.? FSIS ensures that all meat, poultry, or egg products exported from the U.S. are certified, and not adulterated or misbranded, by enforcing the same laws and regulations for all products produced under FSIS inspection, and by certifying that all products eligible for export adhere to both FSIS requirements and the requirements of the importing country. The FMIA, PPIA, and EPIA provide FSIS with the authority and responsibility to enforce the laws and regulations governing meat, poultry, and egg products inspection, and to certify these products for", "FSIS Responses to the SRT (v2019-001) 5 export. Furthermore, 9 CFR 322.1-322.2 (meat), 381.106 (poultry), 552.1 (Siluriformes) and 590.407 (egg products) list the requirements that must be met prior to FSIS IPP signing an export certificate. These requirements include, but are not limited to, verifying that the product to be exported is \u201cU.S. inspected and passed,\u201d determining that the product is neither adulterated or misbranded, and verifying that the outside container contains an official USDA mark or a mark containing a unique identifier linking the consignment to the export certificate. FSIS IPP verify that any product tested for adulterants by FSIS receives acceptable testing results prior to receiving the mark of inspection and being eligible for distribution in commerce (both domestically and for export). This includes the confirmation of acceptable official government testing results for the following sampled products: raw non-intact beef product or raw intact beef product intended for raw non-intact use that is tested for Shiga toxinproducing Escherichia coli (STEC); RTE products tested for Listeria monocytogenes (Lm), Salmonella, or STEC (RTE beef products); RTE product that passed over food contact surfaces that have been tested for the presence of Lm and Salmonella; and livestock carcasses subject to FSIS testing for veterinary drugs (e.g., antibiotics, sulfonamides, avermectins). When performing export verification activities, FSIS IPP follow instructions provided in FSIS Directive 13,000.5 Public Health Information System Export Certification (for countries active in PHIS) or FSIS Directive 9000.1 Export Certification (for countries not active in PHIS). This export verification activity includes consulting the FSIS Export Library, which lists export requirements by country for meat, poultry, and egg products, to determine the eligibility of shipments for export. This library is updated when a country notifies FSIS of a change in its requirements, and includes information such as certificate requirements, eligible and ineligible products, facility requirements, and labeling requirements. Further, FSIS IPP perform the following activities during export verification: verify that the export application is accurate and complete, and, if necessary, request additional documentation from the applicant (e.g., laboratory testing results, bill of lading, livestock country of origin, Agricultural Marketing Service (AMS) grading certificate, etc.); verify that the correct export mark number is applied; verify that labels meet the requirements of the

receiving country; and, if required, conduct product re-inspection. When not in use, export certificates, official export stamps, and certificate inventory records must be kept under official lock or seal, and any unused export stickers must be returned to FSIS and destroyed. Additional information on IPP export inspection procedures are provided in FSIS Directives 9000.2 Inspection and Export Certification of Livestock Intestines or Casings; 9000.6 Export Certification of Egg Products from Other than Official Egg Products Plants; and 9010.1 Export Products Returned to the United States. The FMIA, PPIA, and EPIA all provide statutory definitions for adulterated or misbranded product (21 U.S.C. 453, 601, and 1033). The circumstances under which FSIS considers product to be adulterated include, but are not limited to, product that bears or contains any poisonous or deleterious substance which may render it injurious to health; product that consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food; or product that has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. FSIS considers product to be misbranded if it contains false or misleading labeling. To ensure product is wholesome, unadulterated, and correctly labeled and packaged, FSIS IPP perform routine verification activities in all establishments and enter their inspection results into the Public Health Information System (PHIS), which is a web-based comprehensive data analytic system used to collect, consolidate, and analyze data in order to improve public health. These verification activities include Sanitation SOPs and Sanitation Performance Standards (SPS) verification, HACCP verification, economic adulteration, and labeling verification. The priority and frequency for these verification activities is based on the expected impact on public health. For example, routine verification activities, such as HACCP verification, sanitation verification, and labeling verification are performed by FSIS IPP at least twice per week. For establishments with multiple HACCP process categories (e.g., raw-", "FSIS Responses to the SRT (v2019-001) 6 intact, raw-non intact, fully cooked-shelf stable), routine HACCP verification activities are performed at least twice per week per process category. PHIS distributes the appropriate number of verification activities, including sampling activities, to each inspector\u2019s PHIS verification task list. In addition to the verification activities generated by PHIS at an expected frequency, FSIS IPP can also perform \u201casneeded\u201d verification activities. These are known as \u201cdirected\u201d verification activities and are initiated in response to inspection findings, sample results, or other available information. For example, when FSIS IPP record a noncompliance record in PHIS, PHIS initiates a directed instance of the same verification activity that resulted in the noncompliance. FSIS IPP are also able to initiate directed instances of routine verification activities based on conditions they observe in establishments. Instructions to FSIS IPP on how to schedule and complete verification activities in PHIS are provided in FSIS Directives 13,000.1 Scheduling In-Plant Inspection Tasks in the Public Health Information System (PHIS); 13,000.2 Performing Sampling Tasks in Official Establishments Using the Public Health Information System; and 13,000.5 Public Health Information System Export Certification. If FSIS IPP determine that product may be adulterated or misbranded (as per the definitions provided in the Acts), and the product is not in commerce, FSIS IPP can take a regulatory control action, such as retaining the product, to ensure the product does not enter commerce. This product will remain under FSIS control until the establishment determines product disposition and FSIS

verifies that the product disposition is appropriate. Instructions to FSIS IPP on how and when to take a regulatory control action are provided in FSIS Directive 5000.1 Verifying an Establishment's Food Safety System. Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology. Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in FSIS Directive 8010.5 Case Referral and Disposition. In the event that adulterated or misbranded product enters commerce, meat and poultry establishments (including both the receiving and producing establishment) are required to notify the appropriate district office within 24 hours and provide information such as the type, amount, origin, and destination of the adulterated or misbranded product (9 CFR 418.2). In addition, meat and poultry establishments are required to maintain written recall procedures describing their decision making process in determining whether to conduct a product recall, and the method and procedures that will be used to carry out the recall (9 CFR 418.3). Instructions to FSIS IPP on the actions to take when a meat or poultry establishment produces or receives adulterated product are provided in FSIS Directive 8140.1 Notice of Receipt of Adulterated or Misbranded Product. Instructions to FSIS IPP on how to verify that establishments have prepared and are maintaining required written recall procedures, including how and when to document noncompliance, are provided in FSIS Directive 5000.8 Verifying Compliance with Requirements for Written Recall Procedures. Recalls are voluntary and are performed by the establishment responsible for shipping the adulterated or misbranded product into commerce. Although it is an establishment's decision to recall product, FSIS coordinates with the establishment to verify it has properly identified and removed recalled product from commerce by verifying the effectiveness of the establishment's recall activities. FSIS also notifies the public about product recalls. If an establishment refuses to recall adulterated or misbranded product from commerce, or if the recall is inadequate, the Acts provide FSIS with the authority to detain or seize this product (21 U.S.C. 467, 673, and 1049). When there is reason to believe that the products are adulterated, misbranded, or otherwise in violation of the Acts, FSIS personnel follow instructions in FSIS Directive 8410.1 Detention and Seizure when detaining, or preparing a recommendation to seize, meat, poultry, and egg products found in commerce. FSIS's role in voluntary recalls is further described in FSIS Directive 8080.1 Recall of Meat and Poultry Products.

3. How does the CCA ensure that source meat, poultry, or egg products used in processing", "FSIS Responses to the SRT (v2019-001) 7 operations originate from certified establishments in countries that the U.S. has determined have an equivalent meat, poultry, or egg products inspection system (i.e., eligible countries)? The Acts require that imported meat, poultry, and egg products originate from eligible countries and from establishments that are certified to export to the U.S. (21 U.S.C. 466, 620, and 1046). A country becomes eligible following an equivalence determination process completed by FSIS in coordination with the country's CCA. Foreign establishments become eligible when FSIS determines that a country's food safety inspection system achieves a level of sanitary protection equivalent to the level achieved by FSIS, and the foreign country's CCA certifies the foreign establishment as meeting U.S. requirements. The requirements that a foreign inspection system must demonstrate are provided in 9 CFR 327.2 (meat), 381.196 (poultry), 557.2

(Siluriformes), and 590.910 (egg products). Prior to being presented to FSIS for reinspection, importers into the U.S. must file a customs entry form with the appropriate U.S. Customs and Border Protection (CBP) port director and are subject to inspection at the port-of-entry by CBP. CBP verifies that the imported products are permitted entry into the U.S., are represented by the proper paperwork, and comply with USDA Animal and Plant Health Inspection Service (APHIS) regulations, which restrict some products from entering the U.S. due to animal disease conditions in the country of origin. FSIS IPP perform reinspection on all imported product for appearance, condition, certification, and label compliance before the product is allowed entry into the U.S. (9 CFR 327.6 (meat), 381.199 (poultry), 557.6 (Siluriformes), and 590.925 (egg products). In addition, FSIS IPP also perform sampling verification on imported products. FSIS IPP follow instructions outlined in FSIS Directives (9900 series) when performing import reinspection procedures including, but not limited to, performing document review and verifying proper presentation of shipments of imported meat, poultry, and egg products (FSIS Directive 9900.1 Imported Product Shipment Presentation); prioritizing and performing assigned reinspections (FSIS Directive 9900.2 Import Reinspection of Meat, Poultry, and Egg Products); label verification (FSIS Directive 9900.5 Label Verification of Imported Meat, Poultry, and Egg Products); and sampling and testing imported products for adulterants recognized by FSIS (including withholding the mark of inspection pending acceptable test results) (FSIS Directive 9900.6 Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products and FSIS Directive 14,100.1 Speciation, Residue, and Salmonella Testing of Fish of the Order Siluriformes at Official Import Inspection Establishments). Instructions to FSIS IPP on how to perform import reinspection on Siluriformes fish and fish products are provided in FSIS Directive 14,950.1 Inspection Program Personnel Responsibilities at Official Import Inspection Establishments That Receive Shipments of Siluriformes Fish and Fish Products. Once inspected and passed, imported product is stamped with a USDA inspection legend and enters domestic commerce. All meat, poultry, and egg products entering official establishments are required to be inspected and passed and contain a USDA inspection legend per 9 CFR 318.1 (meat), 381.145 (poultry) and 590.424 (egg products). FSIS IPP verify that meat, poultry, and egg products source material meet this regulatory requirement when performing routine government verification activities.

4. How does the CCA ensure that the same set of laws, regulations, and policies are applied consistently to all establishments certified to export meat, poultry, or egg products to the U.S.? FSIS ensures that the same set of laws, regulations, and policies are applied consistently to all establishments through a uniform system of conducting government verification activities to ensure that these establishments adhere to all statutory provisions and regulatory requirements. In addition, 9 CFR 302 (meat), 9 CFR 381 subpart D (poultry), 9 CFR 532 (Siluriformes) and 9 CFR 590 (egg products) require that all establishments, producing product for sale or transportation in domestic commerce, apply for and receive inspection services unless operating under one of the exemptions defined in the "FSIS Responses to the SRT (v2019-001) 8 regulations. (NOTE: FSIS does not allow product produced under an exemption to be exported.) FSIS district office personnel are responsible for overseeing and managing the establishment certification process. Prior to granting FSIS inspection services at an establishment, FSIS district office personnel review the establishment's submitted application for completeness. In addition, 9 CFR 304.3 (meat), 9 CFR 381.22 (poultry), and 9 CFR 532.2 (Siluriformes) list the requirements an establishment must demonstrate prior to being

granted Federal inspection and include written Sanitation SOP\u2019s, written recall procedures, a hazard analysis, and a validated HACCP plan. The requirements that an egg products establishment must demonstrate prior to receiving inspection are listed in 9 CFR 590.146, and include an initial survey by FSIS IPP to verify adequate facilities and the submission of drawings\specifications. (NOTE: Egg products establishments are also required to submit updated drawings\specifications when making significant modifications to the interior of their facilities.) FSIS supervisory personnel conduct on-site visits to verify these requirements are met prior to granting an establishment Federal inspection. Instructions to FSIS supervisory personnel on how to verify the appropriate regulatory requirements are met prior to granting Federal inspection are provided in FSIS Directive 5220.1 Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection under PHIS (meat and poultry) and FSIS Directive 5030.5 Review of Egg Products Plants Drawings and Specifications (egg products). Once an establishment is granted Federal inspection, it is considered an official establishment and is certified to produce meat, poultry, or egg products for domestic commerce and export. FSIS maintains a list of all official establishments in its Meat, Poultry, and Egg Product Inspection Directory (MPI). Furthermore, FSIS has the authority and ability to withdraw a meat or poultry establishment\u2019s grant of inspection under certain circumstances, such as failure to maintain a HACCP plan or Sanitation SOP\u2019s (9 CFR 500.6). Likewise, FSIS has the authority and ability to withdraw an egg products establishment\u2019s grant of inspection under certain circumstances, such as failure to maintain premises, facilities, and equipment in a satisfactory state of repair (9 CFR 590.160). Instructions to FSIS personnel on the methodology to use when determining whether to refuse, deny, suspend, or withdraw inspection services are provided in FSIS Directive 8010.5 Case Referral and Disposition. FSIS disseminates information regarding FSIS requirements from FSIS headquarters to FSIS IPP through written issuances, webinars, classroom training, and supervisory visits. In addition to the rules and regulations published in the Federal Register and Code of Federal Regulations (9 CFR), FSIS disseminates information to FSIS IPP on current FSIS requirements and policies through the issuance of FSIS Directives and FSIS Notices. FSIS Directives provide official communications and instructions to FSIS IPP in carrying out their functions. FSIS Notices are time sensitive materials issued to provide instruction in support of workplace policies, procedures and food safety regulations and expire one year from the date of publication. If the information provided in the FSIS Notice is still applicable after one year, the FSIS Notice is reissued or the information is incorporated into a FSIS Directive. Furthermore, FSIS IPP often perform verification activities in response to the issuance of a FSIS Directive or FSIS Notice to verify the regulatory requirements (described in the issuance) are met. These are typically \u201cdirected\u201d PHIS verification activities, which are in addition to the routine verification activities generated by PHIS. In addition, FSIS provides administrative and technical support on meeting FSIS requirements to FSIS IPP and establishments through various resources, including askFSIS, and various education and training materials. AskFSIS is a web-based application that allows customers to submit policy-related and technical questions to specific policy staffs (e.g., labeling, sampling, import\export). Furthermore, FSIS publishes compliance guidelines to aid industry in understanding and complying with FSIS policies. The compliance guidelines are intended to be guidance documents and are not regulatory requirements. These guidelines can be found under the Compliance Guides Index on the FSIS

website.", "FSIS Responses to the SRT (v2019-001) 9 For information on exports, FSIS provides an export certification checklist on the FSIS website, which offers an overview of the steps necessary when an establishment wants to export meat, poultry, or processed egg products from the U.S. FSIS also offers an electronic mail subscription service, which allows interested parties to sign up to receive notifications on any information or policy changes regarding exports. 5. How does the CCA ensure that government inspection personnel assigned to certified establishments exporting meat, poultry, or egg products to the U.S. are employees of and paid by the government? FSIS IPP are employed directly by the U.S. government on a permanent or intermittent basis, and are eligible to perform all applicable inspection duties, including: the ante-mortem inspection of livestock and poultry; the post-mortem inspection of each and every livestock carcass, head, and viscera and poultry carcass and viscera<sup>1</sup>; sanitation and HACCP verification activities in all meat and poultry establishments; the continuous inspection of egg products; and the official government verification sample collection activities in meat, poultry, and egg products establishments. The FMIA (21 U.S.C.) affords the Secretary of Agriculture the authority to \u201cappoint\u201d inspectors to examine and inspect all meat food products prepared for commerce in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment (\u00a7 606). This includes inspectors examining and inspecting all amenable species (e.g., cattle, sheep, swine, and goats) before slaughter (\u00a7 603), performing post-mortem examination on each and every carcass and its parts (\u00a7 604), and assessing sanitary conditions (\u00a7 608). The PPIA (21 U.S.C. 453(k)) defines an inspector as an employee or official of the U.S. Government authorized by the Secretary of Agriculture to inspect poultry and poultry products. Authorized inspectors shall perform ante-mortem inspection (\u00a7455(a)), post-mortem inspection of each carcass (\u00a7455(b)), and inspect the sanitary practices of the premises, facilities, and equipment (\u00a7456(a)). The EPIA (21 U.S.C. 1033(k)) defines an inspector as any employee or official of the U.S. Government authorized to inspect eggs or egg products. FSIS\u2019s regulatory definition for an inspector is found in 9 CFR 300.4. Further, all FSIS employees are paid directly by the national government through payments deposited directly into their bank accounts (Public Law 104-134). Lastly, to avoid conflict of interest, FSIS maintains prescriptive requirements in 9 CFR 306.4. These requirements include prohibiting FSIS IPP (including supervisory personnel) from working at an establishment where a member of his or her family is employed by the operator of the establishment; and prohibiting FSIS IPP from acquiring product from any establishment unless the product is purchased from a store or outlet open to the general public, and at a price paid by the general public. 6. How does the CCA ensure that government inspection occurs continuously during slaughter operations, and at least once per production shift during the processing of meat or poultry intended for export to the U.S.? The Acts require that FSIS provide government inspection in all meat and poultry slaughter and processing (i.e., non-slaughter) establishments, and egg products establishments. Both the FMIA and 1 Under FSIS\u2019s New Poultry Inspection System (NPIS), the government inspector\u2019s visual inspection of each carcass also serves as the inspection of the viscera if the inspector\u2019s condemnation of a carcass also requires condemnation of the corresponding viscera.", "FSIS Responses to the SRT (v2019-001) 10 PPIA require that government inspection personnel conduct ante-mortem and post-mortem inspection in meat and poultry slaughter establishments (21 U.S.C. 455, 603, and 604). The regulatory requirements for government

inspection during ante-mortem inspection are provided in 9 CFR 309 (meat) and 9 CFR 381.70 (poultry). The regulatory requirements for government inspection during post-mortem inspection are provided in 9 CFR 310 (meat) and 381.76 (poultry). Furthermore, the regulations require that post-mortem inspection be conducted on each and every carcass, or bird, and its parts. In addition, FSIS requires that FSIS IPP in all meat and poultry processing establishments conduct inspection activities at least once per shift (21 U.S.C. 455 and 606). These provisions are codified in 9 CFR 307.4, which requires that any operation requiring inspection be conducted under the supervision of a FSIS employee, meaning a government inspector conducts verification activities at least once per shift, during meat and poultry processing operations. FSIS identifies a \u201cshift\u201d as eight (8) consecutive hours (9 CFR 307.4). To ensure that all establishments receive and maintain adequate inspection coverage, establishments are required to submit work schedules to FSIS for review and approval prior to being granted Federal inspection. If an establishment wishes to operate outside of its approved work schedule, including during overtime periods, the proposed change must be submitted for FSIS approval (9 CFR 307.4). Furthermore, FSIS IPP must receive supervisory approval prior to scheduled absences to ensure adequate inspection coverage. In the case of an unscheduled absence, FSIS supervisory personnel will assign IPP to provide inspection coverage at the establishment.

7. How does the CCA ensure that government inspection personnel have appropriate educational credentials, disciplinary backgrounds, and training to carry out their inspection tasks? FSIS hires FSIS IPP through the Federal Government\u2019s official employment site, USAJOBS. Each job posting on this site contains basic qualifications, such as specific experience or education requirements, that must be demonstrated in the applicant\u2019s submission for an FSIS IPP position. Further, all FSIS veterinarians are required to possess a Doctor of Veterinary Medicine professional degree. All FSIS employees are also subject to a background investigation and screening assessment prior to being hired. Additional information on the requirements for FSIS IPP positions can be found under Careers on the FSIS website. In addition, FSIS conducts classroom training and on-the-job training to ensure that inspection personnel have the appropriate training to carry out their inspection tasks. All FSIS IPP responsible for conducting government verification activities in establishments attend a month long training session on essential FSIS verification activities prior to beginning their assignments. Topics discussed during this initial training session include, but are not limited to, HACCP verification, Sanitation SOP and SPS verification, and labeling verification. At the completion of the month long training session, FSIS IPP must demonstrate a competent knowledge of all course material by passing a written examination. Other training sessions include Slaughter Inspection, Public Health Veterinarian (PHV) training, and Egg Products training. In addition to classroom training, FSIS IPP also take courses on various topics, such as export verification, through an online system called AgLearn. Additional information on the various training opportunities available to FSIS IPP can be found under Workforce Training on the FSIS website.

8. How does the CCA ensure continuous government inspection during the processing of egg products designated for export to the U.S.? Continuous government inspection during the processing of egg products is mandated in the EPIA (21 U.S.C. 1034) and implemented through the regulatory requirement in 9 CFR 590.24. In addition, "FSIS Responses to the SRT (v2019-001) 11 \u201cprocessing\u201d is defined in 9 CFR 590.5 as the \u201cmanufacturing of egg products, including breaking eggs or filtering, mixing, blending,

pasteurizing, stabilizing, cooling, freezing or drying, or packaging egg products at official plants.\u201d The labeling of egg products and final product examinations are also considered processing activities. FSIS IPP are on the premises during operations, and conduct inspection activities (both observations and records review) that include, but are not limited to, sanitation verification, food safety and operational verification, review of monitoring records, and verification of time\temperature at critical points in the operation. Furthermore, FSIS has determined that continuous inspection is not required during the entirety of the stabilization processing step and the heat treatment of dried egg whites. In these situations, the inspector is required to be present at the beginning and end of these processing steps.

9. How does the CCA ensure adequate oversight of laboratories that perform analyses for official government sampling and testing programs for meat, poultry, or egg products that are exported to the U.S., including oversight to ensure that laboratories conducting official government analyses comply with the general quality assurance and control criteria provided in International Organization for Standardization (ISO)\International Electrotechnical Commission (IEC) Guide 17025? FSIS ensures that every establishment producing products for domestic commerce or for export is included in official government chemical residue and microbiological sampling and testing programs by assigning official government verification sampling activities to FSIS IPP through PHIS. FSIS ensures that every product for which there is a pathogen performance standard is considered for official government microbiological verification testing. In addition, official government verification testing for chemical residues is assigned to FSIS IPP in establishments producing product eligible for residue testing. The frequency of official government verification sampling and testing is typically determined by the amount of eligible product type (e.g., beef manufacturing trimmings tested for STEC) being produced (production volume). FSIS collects product volume information through PHIS. In all establishments, FSIS IPP routinely verify that establishment profiles in PHIS are up-to-date and accurately reflect which product groups the establishment is producing, and the average daily volumes of the product groups being produced. Instructions to FSIS IPP on how to maintain accurate establishment profiles in PHIS, including instructions on how to enter accurate production volume information, are provided in FSIS Directive 5300.1 Managing the Establishment Profile in the Public Health Information System (meat and poultry) and FSIS Directive 5030.2 Managing the Establishment Profile in the Public Health Information System (PHIS) for Egg Products Inspection. For imported products, the type of inspection verification PHIS assigns to the imported product informs IPP when samples are to be collected and sent for laboratory analysis. Additional information on the laboratory types of inspections assigned to FSIS IPP in import establishments can be found in FSIS Directive 9900.6 Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products. FSIS oversees three (3) national FSIS Field Service Laboratories, which are responsible for coordinating and conducting laboratory analytical services for official microbiological and chemical samples. FSIS\u2019s Office of Public Health Science (OPHS) maintains direct oversight over all three national laboratories, and provides scientific technical support to other FSIS program areas. In addition, FSIS administers the Accredited Laboratory Program (ALP), which accredits nonfederal analytical chemistry laboratories to analyze official government samples of meat and poultry food products for moisture, protein, fat, and salt content and\or certain classes of chemical residues. Currently, the specific chemical residues included in analyses conducted by ALP laboratories are chlorinated hydrocarbons, polychlorinated

biphenyls, sulfonamides, nitrosamines, and arsenic.", "FSIS Responses to the SRT (v2019-001) 12 All FSIS Field Service laboratories that conduct analyses for official government samples of meat, poultry, or egg products are ISO 17025 accredited, and have established and implemented quality control procedures. The ISO 17025 accreditation certificates for FSIS\u2019s three Field Service laboratories are available via the following links: FSIS Western Laboratory, FSIS Eastern Laboratory, and FSIS Midwestern Laboratory. Within OPHS, the Laboratory Quality Assurance Staff (LQAS) is responsible for laboratory quality management system oversight, and maintaining and distributing system policy and procedures. LQAS managers within each of the three laboratories verify that quality control procedures for laboratories are established, effective, and followed by conducting internal audits of each Field Service Laboratory at least three times per year to verify compliance with ISO 17025 requirements, accreditation body requirements (i.e., American Association for Laboratory Accreditation (A2LA) Food Testing Program Requirements), and quality management system requirements. Regarding external laboratory audits, the A2LA evaluates and assesses each FSIS Field Service laboratory for on-going compliance with ISO\IEC 17025:2005 requirements by performing annual audits of the laboratory system. In addition to the annual A2LA audit, OPHS LQAS auditors also conduct external audits. FSIS\u2019s national laboratories maintain quality control procedures that are consistent with the requirements in ISO 17025 including: monitoring the validity of tests and calibrations, implementing and documenting quality control procedures for each batch of samples; verifying that testing, calibration, and sampling methods are fit for purpose; requiring non-standard methods to be validated; ensuring that samples tested meet the acceptance criteria for releasing batches; and taking corrective actions for all samples outside the acceptance criteria. In addition, FSIS laboratories participate in proficiency testing for all accredited test methods. FSIS laboratories also perform duplicate analysis, and calibration of instruments and media. Furthermore, quality control samples are tracked to ensure the validity of the results. To ensure sample integrity, reliability, and chain of custody is maintained in all official samples collected and tested under FSIS\u2019s sampling programs, samples remain under direct FSIS control while in the establishment and in the FSIS laboratories, and under FSIS seal during transport from the establishment to the laboratory. Instructions to FSIS IPP on how to use sample seals and identity labels to ensure sample integrity and identity are provided in FSIS Directive 7355.1 Use of Sample Seals for Laboratory Samples and Other Applications. In addition, sample status and sample analysis result information are reported electronically to FSIS personnel and establishments through the Laboratory Information System-Direct (LIMS-Direct), which updates data every 15 minutes. Instructions to FSIS IPP on how to access the LIMS-Direct system are provided in FSIS Directive 10,210.5 FSIS Sampling Data Reporting Through Laboratory Information Management System - Direct. Furthermore, FSIS provides quarterly letters to establishments to summarize official government sampling results covering a 12-month window. Lastly, in the event of a positive or violative result for an official government sample, FSIS does not re-test the sample. Component 2 Government Verification of Food Safety and Other Consumer Protection Requirements 10. How does the CCA ensure that animals are handled and slaughtered humanely? The FMIA (21 U.S.C. 603b, 610) and the Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, 1902, and 1906) both mandate that the handling and slaughter of livestock be carried out by humane methods. Further, 7 U.S.C. 1902 provides the two acceptable livestock slaughter methods that

FSIS", "FSIS Responses to the SRT (v2019-001) 13 considers to be humane. These methods include rendering the livestock insensible to pain by a single blow or gunshot, or electrical, chemical, or other means that is rapid and effective, prior to shackling, hoisting, and cutting the animal; or the simultaneous and instantaneous severance of the carotid arteries causing a loss of consciousness. For livestock, the statutory provisions are implemented through FSIS IPP enforcing and verifying compliance with 9 CFR 313. These prescriptive requirements include, but are not limited to, maintaining pens, driveways, and ramps in good repair and free from sharp or protruding objects; slip resistant or waffled flooring; providing water in all holding pens and, if held longer than 24 hours, access to feed; and the prohibition against dragging disabled animals while conscious. 9 CFR 313 also prescribes the requirements for using carbon dioxide, captive bolt, gunshot, and electric current during livestock slaughter. FSIS IPP perform verification of the establishment's humane handling activities for livestock during each shift that animals are slaughtered, or when animals are on site, and record the results in PHIS. Furthermore, 9 CFR 313.50 lists the regulatory control actions that IPP can take if they observe an incident of inhumane slaughter or handling. Examples of noncompliance with humane handling requirements include, vehicles or ramps not properly positioned leading to the injury of animals, animals slipping and falling because of poor footing or lack of slip resistant flooring, holding pens lacking access to water, or animals regaining consciousness after stunning.

Instructions to FSIS IPP, including how and when to document noncompliance and take enforcement actions, are provided in FSIS Directive 6900.2 Humane Handling and Slaughter of Livestock. Instructions to District Veterinary Medical Specialists conducting humane handling verification visits are provided in FSIS Directive 6910.1 District Veterinary Medical Specialist (DVMS) Work Methods. Furthermore, establishments in violation of the statutory provisions and regulatory requirements, requiring the handling and slaughter of livestock to be carried out through humane methods, are subject to the enforcement actions in 9 CFR 500, such as suspension and withdrawal of inspection. Regarding poultry establishments, 9 CFR 381.65(b) requires that poultry be slaughtered in accordance with good commercial practices in a manner that will result in thorough bleeding of the carcasses and ensure that breathing has stopped prior to scalding. Also, any poultry carcass showing evidence of having died from causes other than slaughter is considered adulterated and must be condemned (21 U.S.C. 453(g)(5), 9 CFR 381.90). FSIS IPP perform verification activities during each shift that poultry is slaughtered to verify compliance with good commercial practices. Examples of noncompliance with the requirement for good commercial practices include, establishment employees mistreating birds or handling them in a way that will cause death or injury, prevent thorough bleeding, or result in excessive bruising; stunning or bleeding equipment that is not functioning properly; or an increased number of bruised wings or legs. Instructions to FSIS IPP on how to verify good commercial practices in poultry establishments, including how and when to document noncompliance, are provided in FSIS Directive 6110.1 Verification of Poultry Good Commercial Practices. 11. How does the CCA ensure that government inspection personnel perform ante-mortem inspection of livestock and poultry prior to slaughter? The FMIA and PPIA both mandate that government inspectors perform ante-mortem inspection of all livestock (21 U.S.C. 603) and poultry (21 U.S.C. 455(a)) in establishments. These statutory provisions are codified in 9 CFR 309.1(livestock) and 9 CFR 381.70 (poultry). 9 CFR 309.1 requires that all livestock receive ante-mortem inspection on the

day of slaughter, prior to entering an establishment. Therefore, if an establishment does not present animals for ante-mortem inspection in accordance with 21 U.S.C. 603 and 9 CFR 309.1, FSIS IPP are not able to determine that carcasses are not adulterated and, therefore, cannot permit the carcasses to be marked as \u201cinspected and passed.\u201d Carcasses from animals that did not receive ante-mortem inspection are condemned in", "FSIS Responses to the SRT (v2019-001) 14 accordance with procedures in 9 CFR 314. Furthermore, FSIS does not allow for the emergency slaughter of cattle that did not receive ante-mortem inspection (9 CFR 309.12). 9 CFR 309.2-309.18 provide the requirements for the proper disposition of certain conditions. For example, 9 CFR 309.2 provides the conditions under which livestock would be determined to be \u201cU.S. Suspect\u201d (e.g., livestock that reacted to a tuberculin test). \u201cU.S. Suspect\u201d livestock are set apart and slaughtered separately from other livestock, and identified with a \u201cU.S. Suspect\u201d metal ear tag that can only be removed by FSIS personnel. In addition, any livestock found to be dead, dying, or diseased (per the conditions listed in 9 CFR 311) are identified with a metal ear tag as \u201cU.S.

Condemned\u201d and disposed of per the requirements in 9 CFR 309.13 and 314. Other conditions requiring a disposition of \u201cU.S. Condemned\u201d include, but are not limited to, all non-ambulatory disabled cattle, including nonambulatory veal calves; and livestock showing symptoms of certain metabolic, toxic, nervous or circulatory disturbances, nutritional imbalances, or infectious or parasitic diseases. After determining that livestock is \u201cU.S. Condemned,\u201d FSIS Public Health Veterinarians (PHVs) verify that the establishment disposes the condemned livestock in accordance with 9 CFR 314 and maintains the required records (9 CFR 320). During ante-mortem livestock inspection, FSIS IPP observe the animals at rest and in motion (from both sides) to assess the overall condition of each animal; the degree of alertness, mobility, and breathing; and whether there are any unusual swellings or any other abnormalities. In addition, FSIS IPP routinely verify that only livestock that have passed ante-mortem inspection are moved to slaughter, and that the number of livestock receiving ante-mortem inspection is equal to the number of livestock slaughtered. FSIS IPP then enter ante-mortem disposition data into PHIS. Instructions to FSIS IPP on conducting ante-mortem livestock inspection are provided in FSIS Directive 6100.1 Antemortem Livestock Inspection. Regarding poultry establishments, 9 CFR 381.70(a) requires that poultry receive ante-mortem inspection on the day of slaughter. 9 CFR 381.71-381.75 lists the conditions under which a bird would be condemned, segregated, or quarantined and identified as either \u201cU.S. Suspect\u201d or \u201cU.S. Condemned.\u201d \u201cU.S. Suspect\u201d birds are set apart and slaughtered separately from other birds, and all birds found to be \u201cU.S.

\u201cU.S. Suspect\u201d or \u201cU.S. Condemned\u201d are identified with a tag that can only be removed by FSIS personnel. Further, the list of diseases or conditions that would render a bird \u201cU.S. Condemned\u201d are provided in 9 CFR 381.80-381.93 and include, but are not limited to, avian leucosis, septicemia or toxemia, and cadavers. Condemned birds are disposed of in accordance with procedures in 9 CFR 381.95. During ante-mortem poultry inspection, FSIS IPP observe the overall condition of the birds, and determine whether there are any unusual swellings or any other abnormalities on the birds, such as edema of the wattles, gasping and sneezing, off-colored feces, diarrhea, skin lesions, lameness, torticollis (e.g., wry neck), or bone or joint enlargement. After completing ante-mortem inspection, FSIS IPP enter ante-mortem disposition data into PHIS. Instructions to FSIS IPP on how to perform ante-mortem poultry

inspection are provided in FSIS Directive 6100.3 Ante-mortem and Post- mortem Poultry Inspection. Instructions to FSIS IPP on how to perform ante-mortem inspection of ratites (e.g., ostrich, emu) are provided in FSIS Directive 6170.1. 12. How does the CCA ensure that government inspection personnel perform post-mortem inspection of each and every livestock carcass, head, and viscera and each and every poultry carcass and viscera during and after the slaughter of livestock and poultry? NOTE: In this SRT answer, the term \u201conline\u201d FSIS IPP refers to government inspectors working on the production line and performing post-mortem inspection procedures on each and every livestock carcass," "FSIS Responses to the SRT (v2019-001) 15 head, and viscera and each and every poultry carcass and viscera2. The term \u201coffline\u201d FSIS IPP refers to government inspectors performing verification activities throughout the establishment (e.g., HACCP, sanitation, zero tolerance). Offline FSIS IPP do not remain on the production line performing inspection activities throughout the day. Offline FSIS IPP are also referenced in SRT question #22. Post-mortem inspection of each and every livestock carcass, head, and viscera and poultry carcass and viscera3 by government inspectors during and after slaughter is provided for in the FMIA (21 U.S.C. 604) and PPIA (21 U.S.C. 455(b)). These statutory provisions are codified in 9 CFR 310.1(livestock) and 9 CFR 381.76 (poultry). Livestock establishments are required to use an identifying device (e.g., ear tag, back tag) identifying all carcass parts (e.g., head, tongue, viscera) to the rest of the carcass (9 CFR 310.2) until post-mortem inspection by FSIS IPP is complete. Further, any carcass or part identified as either unfit for food purposes or adulterated, and requiring subsequent inspection, is marked with a \u201cU.S. Retained\u201d tag and retained by FSIS IPP pending final inspection by a FSIS PHV. If, at final inspection, the FSIS PHV then determines that the carcass or part is unsound, unhealthful, unwholesome, or otherwise adulterated, the carcass or part is marked as \u201cU.S. Inspected and Condemned\u201d and disposed of in accordance with the requirements in 9 CFR 314. 9 CFR 310.1 prescribes livestock government inspection staffing standards detailing how many inspectors must be present at each station dependent on maximum slaughter line speed. 9 CFR 310 also contains the requirements for presentation (9 CFR 310.12); the procedures for the disposition of thyroid glands, laryngeal muscle tissue, and lungs; and the procedures for the inspection of kidneys and mammary glands. The requirements for identifying and handling carcasses or components with certain disease conditions (e.g., tuberculosis, actinomycosis, melanosis) are provided in 9 CFR 311. In addition, FSIS recognizes fecal material, ingesta, and milk on livestock carcasses or carcass parts as common vehicles for microbial pathogens that cause foodborne illness and requires adequate removal of the contamination prior to passing inspection (9 CFR 310.17-310.18). Online FSIS IPP perform post-mortem inspection procedures on each and every livestock carcass, head, and viscera to verify that the carcasses and parts are wholesome and not adulterated, including inspection procedures to ensure that each and every livestock carcass, head, and viscera are free of visible fecal material, ingesta, and milk. FSIS Directive 6100.2 Post-mortem Livestock Inspection provides instructions to online FSIS IPP on how to perform livestock post-mortem inspection on each and every carcass and carcass part (e.g., procedures for examining the head, carcass, and viscera of cattle, calves, swine, sheep, and lamb), and instructions to offline FSIS IPP on how and when to document noncompliance. For example, when examining cattle heads presented with the tongue inside the head, online FSIS IPP are instructed to observe the head's surfaces and eyes, and incise and observe the mandibular, parotid, medial, and lateral

retropharyngeal lymph nodes. Further, FSIS Directive 6100.2 Post-mortem Livestock Inspection provides instructions to online FSIS IPP on the procedures to take if they observe fecal, ingesta, or milk contamination on a livestock carcass, head, or viscera during post-mortem inspection procedures. For example, when online FSIS IPP observe fecal, ingesta, or milk contamination at the final carcass inspection, they are to stop the slaughter line (unless the establishment has a rail-out loop) to allow establishment personnel to trim the contaminated carcass. Online FSIS IPP then re-inspect the trimmed carcass to verify that the contamination was removed in a sanitary manner (9 CFR 310.18(a)). If online FSIS IPP at the final carcass station believe that the establishment's rail-out procedure is inadequate to prevent carcass accumulation or cross-contamination of other carcasses; or the establishment's slaughter or dressing processes are not under control based on repeated presentation of contaminated carcasses for post-mortem inspection, the online FSIS IPP notify 2 Under FSIS' New Poultry Inspection System (NPIS), the government inspector's visual inspection of each carcass also serves as the inspection of the viscera if the inspector's condemnation of a carcass also requires condemnation of the corresponding viscera. 3 See Footnote 2,"FSIS Responses to the SRT (v2019-001) 16 the FSIS inspector-in-charge (IIC). The IIC will perform additional verification activities, such as a livestock zero tolerance verification activity, to verify the adequacy of the establishment's procedures. Instructions to offline FSIS IPP on how to perform livestock verification activities are provided in FSIS Directive 6420.2 Verification of Procedures for Controlling Fecal Material, Ingesta and Milk in Slaughter Operations. Instructions to FSIS PHVs on how to make post-mortem livestock dispositions for select diseases and conditions are provided in FSIS Directive 6100.6 Post-mortem Dispositions for Public Health Veterinarians. After completing post-mortem livestock inspection, FSIS IPP record their inspection findings, along with daily slaughter data, in PHIS. Regarding poultry establishments, 9 CFR 381.76(a) requires post-mortem inspection for each and every poultry carcass and viscera4. The specific post-mortem inspection procedures depend on the type of post-mortem inspection system used by the establishment. 9 CFR 381.76 lists the six (6) types of postmortem inspection systems and the requirements for each system (i.e., Traditional Inspection, Streamlined Inspection System (SIS), New Line Speed (NELS) Inspection System, New Poultry Inspection System (NPIS), New Turkey Inspection System (NTI), and Ratite Inspection). Maximum line speeds for each inspection system are provided in 9 CFR 381.67 (traditional), 381.68 (NTI), 381.69 (NPIS), and 381.76 (NELS and SIS). Under all poultry post-mortem inspection systems, FSIS IPP conduct post-mortem inspection for each and every poultry carcass and look for condemnable conditions (e.g., septicemia, toxemia), as specified in 9 CFR 381.80-381.94. Under every poultry postmortem inspection system except NPIS, FSIS IPP conduct post-mortem inspection for each and every poultry viscera and look for condemnable conditions (e.g., tumor, inflammatory process). Adulterated product that cannot be reprocessed or reconditioned (i.e., by means of online antimicrobial intervention; offline vacuuming, washing, or trimming) is condemned under the supervision of a government inspector and disposed of in accordance with the requirements in 9 CFR 381.95. Examples of condemnable conditions in poultry carcasses include, but are not limited to, tuberculosis (9 CFR 381.81), septicemia or toxemia (9 CFR 381.83), and cadavers (9 CFR 381.90). In establishments operating under NPIS, offline FSIS government inspectors perform hourly verification checks to verify that carcasses are free of visible fecal material and septicemia or toxemia before the carcasses are presented to the

online FSIS government inspector for inspection. In addition, online FSIS government inspectors performing verification activities at establishments operating under NPIS continually verify that the establishment has properly trimmed, sorted (i.e., identified and disposed of poultry carcasses or parts exhibiting condemnable conditions), and reprocessed all carcasses; and carcasses are free from visible fecal material (as required per 381.65(f)) and septicemia or toxemia, before the carcasses enter the chiller. Furthermore, FSIS requires NPIS establishments slaughtering young chicken to notify FSIS IPP prior to the slaughter of each new flock to allow the government inspection of viscera for avian visceral leukosis (9 CFR 381.76(b)(6)(iv)). Instructions to online FSIS IPP on how to perform post-mortem poultry inspection, including dispositions for certain diseases, are provided in FSIS Directive 6100.3 Ante-mortem and Post-mortem Poultry Inspection. For example, when performing online post-mortem inspection, FSIS IPP are instructed to observe the inner surfaces of the carcass for yellow scabbed areas between the skin and subcutaneous tissue of the flaps that could indicate inflammatory process. Instructions to FSIS IPP on how to perform online and offline post-mortem inspection procedures at poultry slaughter establishments operating under NPIS are provided in FSIS Directive 6500.1 New Poultry Inspection System: Post-Mortem Inspection and Verification of Ready-To-Cook Requirement. Instructions to FSIS IPP on how to perform post-mortem inspection of ratites are provided in FSIS Directive 6170.1. After completing post-mortem poultry inspection, FSIS IPP record their inspection findings, along with daily slaughter data, in PHIS.

4 See Footnote 2", "FSIS Responses to the SRT (v2019-001) 17 13. How does the CCA ensure that a representative of the government inspection system makes periodic supervisory visits to each certified establishment to evaluate the performance of inspection personnel? FSIS ensures that FSIS supervisory personnel make periodic supervisory visits to each establishment for the purpose of evaluating the performance of FSIS IPP by requiring that FSIS supervisors conduct at least two (2) in-plant performance reviews for each and every inspector per year. These reviews consist of firsthand, onsite observations to assess FSIS IPP's demonstrated knowledge of job requirements, appropriate regulatory decision making, and ability to execute inspection and verification procedures. Specifically, FSIS supervisory personnel assess FSIS IPP performance in the following areas: antemortem inspection; post-mortem inspection; humane handling and good commercial practices; Sanitation SOPs and Sanitation Performance Standards (SPS) verification; HACCP verification; food defense; economic adulteration and labeling verification; sampling methodology and collection procedures; export certification; import inspection; complete separation of official establishments; and official control over condemned material. Furthermore, supervisory IPP (i.e., PHVs) receive at least one in-plant performance review per year from the FSIS area supervisor to evaluate their performance in conducting and overseeing the performance of FSIS IPP in establishments. FSIS EIAOs also receive at least one in-person assessment per year from FSIS supervisory personnel to evaluate their performance in conducting food safety assessments, public health risk evaluations, recall effectiveness checks, and outreach activities. In addition to the in-plant performance reviews of FSIS IPP, FSIS also maintains a performance management system, as required in 5 U.S.C. 43, which identifies and sets performance expectations and monitors performance. All FSIS IPP receive a midyear progress review and an annual performance rating. FSIS IPP who do not receive an acceptable rating are put on a Performance Improvement Plan with clearly defined expectations and a timeline, and failure to improve can lead to reassignment or removal.

Instructions to FSIS supervisory personnel on how to conduct in-plant performance reviews are provided in FSIS Directive 4430.3 In-Plant Performance System (IPPS) and FSIS Directive 4430.5 Supervisory Tool for Assessment Results. Instructions to FSIS supervisory personnel on how to conduct in-person performance reviews for FSIS EIAOs are provided in FSIS Directive 4440.1 Enforcement Investigation and Analysis Officer Assessments.

14. How does the CCA ensure complete separation of certified meat, poultry, or eggs products from non-certified meat, poultry, or egg products? FSIS ensures complete separation of official from unofficial establishments by verifying compliance, during routine government verification activities and supervisory visits, with 9 CFR 305.2 (meat), 381.26 (poultry), and 533.1 (Siluriformes). These regulations require that official establishments be \u201cseparate and distinct\u201d from other establishments. When official establishments produce non-FSIS amenable product (e.g., product produced under the jurisdiction of the U.S. Food and Drug Administration (FDA)), FSIS IPP routinely verify that the FSIS amenable product is produced separately, by time or space, from the non-FSIS amenable product. In addition, FSIS IPP consult the Export Library to verify that establishments producing product for export are meeting the specific requirements of the importing country, including any requirements necessitating producing product for export separately from domestic product (e.g., product produced without antimicrobial rinses).

15. How does the CCA ensure that meat, poultry, and egg products intended for export to the U.S. meet U.S. labeling requirements?", "FSIS Responses to the SRT (v2019-001) 18 FSIS ensures that meat, poultry, and egg products produced for domestic commerce or export comply with the labeling requirements in 9 CFR 317 and 319 (livestock), 9 CFR 541 (Siluriformes), 9 CFR 381 subpart N (poultry), and 9 CFR 590.410- 590.419 (egg products). These regulations implement the statutory provisions in 21 U.S.C. 607 (meat), 457 (poultry), and 1036 (egg products). The FMIA and PPIA both require establishments to obtain prior approval for labels of meat and poultry products before the products enter commerce. Prior approval is granted in one of two ways: sketch approval which is approved by the FSIS Labeling and Program Delivery Staff (LPDS), or generic approval which is approved by FSIS IPP verifying compliance with 9 CFR 412.2. In addition, FSIS requires that establishments maintain records of all labeling (9 CFR 320.1(b)(11), 381.175(b)(6), 412.1, and 550), to include: the final label applied to the product; product formulation; processing procedures; and supporting documentation, including prior sketch approval from LPDS (if applicable). The labeling requirements for imported meat and poultry products are provided in 9 CFR 327.14 - 327.15 (meat), 381.204 - 381.206 (poultry), and 557.14 \u2013 557.15 (Siluriformes). For egg products establishments, 9 CFR 590.411 requires prior label approval for all egg products before the products enter commerce. Further, 9 CFR 590.950 and 590.955 list the labeling requirements for imported egg products. FSIS IPP perform routine labeling verification activities (i.e., no less than two labeling verification activities per week in meat and poultry establishments, and no less than one labeling verification activity per week in egg products establishments) to verify that all regulatory labeling requirements are being met and followed, and all labels are accurate and truthful. When performing the general labeling verification activity, FSIS IPP verify that the label contains all required information; the ingredients statement is accurate, (i.e., that all ingredients are listed in descending order of predominance); the label declares any proteinaceous substances used in the ingredients statement; the establishment used restricted ingredients as per regulatory requirements (e.g., sodium nitrite in bacon) the label is used on appropriate product; and a label approval is on file.

Further, during general labeling verification, FSIS IPP review a sample of labels generically approved by the establishment to determine compliance with generic labeling requirements (9 CFR 412.2). Instructions to FSIS IPP for performing the general labeling verification activity, including how and when to document noncompliance, are provided in FSIS Directive 7221.1 Prior Labeling Approval. Instructions to FSIS IPP for performing labeling verification activities on imported products are provided in FSIS Directive 9900.5 Label Verification of Imported Meat, Poultry, and Egg Products. In addition to verifying general labeling requirements, FSIS IPP also routinely verify that products are labeled with accurate net weights and not economically adulterated (9 CFR 442); and that labeled products meet regulatory standards through reviewing formulation records, or observing the preparation of products and comparing the findings to the appropriate regulatory standards (e.g., verifying that labeled products meet the standards of identity in 9 CFR 319 (meat) and 9 CFR 381 Subpart P (poultry)). Instructions to FSIS IPP on how to verify that products are labeled accurately and not economically adulterated (e.g., inaccurate net weight), including how and when to document noncompliance, are provided in FSIS Directive 7000.1, Verification of Non-Food Safety Consumer Protection Regulatory Requirements. FSIS IPP also verify that ingredients used in the production of meat, poultry, and egg products are safe and suitable and approved per 21 CFR. These approved ingredients are listed in FSIS Directive 7120.1 Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products, and 9 CFR 424.21. In addition to routine labeling verification activities, FSIS IPP also perform a monthly verification activity to verify that establishments are accurately controlling and labeling the eight most common food allergens (i.e., wheat; crustacean shellfish (e.g., crab, lobster, shrimp); eggs; fish; peanuts; milk;,"FSIS Responses to the SRT (v2019-001) 19 tree nuts (e.g., almonds, pecans, walnuts); and soybeans). Instructions to FSIS IPP on how to perform this allergen verification activity, including how and when to document noncompliance, are provided in FSIS Directive 7230.1. If an establishment ships product into commerce containing an undeclared allergen, the product is considered adulterated and misbranded (as defined in 21 U.S.C. 601 (meat), 453 (poultry), or 1033 (egg products)), and the establishment is subject to enforcement actions per 9 CFR 500 (meat and poultry) or 9 CFR 590.160 (egg products). Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology. Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in FSIS Directive 8010.5 Case Referral and Disposition. Lastly, FSIS conducts \u201cfor cause\u201d species verification testing on both domestic and imported product. Instructions to FSIS IPP on how to collect samples for species verification testing are provided in FSIS Directives 7000.1. Instructions to FSIS IPP on how to collect samples for species verification testing in domestic establishments producing Siluriformes products are provided in FSIS Directive 14,010.1 Speciation, Residue, and Salmonella Testing of Fish of the Order Siluriformes from Domestic Establishments, and instructions for collecting samples for species verification testing on imported Siluriformes products are provided in FSIS Directive 14,100.1 Speciation, Residue, and Salmonella Testing of Fish of the Order Siluriformes at Official Import Inspection Establishments.

16. How does the CCA ensure that meat and poultry products designated for export to the U.S. are not restricted by the USDA Animal and Plant Health Inspection Service

(APHIS)? FSIS ensures that its imported meat and poultry originate from regions not currently restricted by APHIS by only importing meat, poultry, and egg products from countries where FSIS has determined, through documentation review and an on-site audit that the country\u2019s food safety inspection system provides a level of sanitary protection equivalent to the level achieved by FSIS. Part of the equivalency process involves determining that the foreign country and establishments are not using source material from a currently restricted region (as identified on the APHIS website) to produce product for export to the U.S. Countries that fail to demonstrate that its source material is from an unrestricted region are deemed not equivalent and, thus, ineligible to export that commodity to the U.S. Furthermore, CBP verifies that the imported products are permitted entry into the U.S. and comply with USDA APHIS regulations prior to the products being received for FSIS reinspection. In addition, APHIS restrictions are programmed into PHIS and alert FSIS IPP if a shipment intended for importation is restricted by APHIS. During import reinspection, FSIS IPP verify that imported product originates from an eligible country with no current APHIS restrictions for that product, and if a violation or defect is observed upon reinspection, FSIS IPP document the finding in PHIS and refuse entry of the product. Instructions to FSIS IPP on how to identify, control, document, and dispose of imported meat, poultry, or egg products that are refused entry into the U.S. are provided in FSIS Directive 9900.8 Meat, Poultry, and Egg Products Refused Entry Into The United States (U.S.). Furthermore, FSIS IPP verify during ante-mortem inspection that animals presented for slaughter do not display symptoms of foreign animal diseases and reportable conditions. Instructions to FSIS IPP on the conditions to look for when suspecting an animal may have a foreign animal disease or reportable condition, including the actions to take when a condition is suspected (i.e., contact APHIS), are provided in FSIS Directive 6000.1

#### Responsibilities Related to Foreign Animal Diseases (FADs) and Reportable Conditions.

Jurisdiction over imported shell eggs is shared by FDA, APHIS, and USDA Agricultural Marketing Service (AMS). Each individual farm that produces shell eggs for export to the U.S. must register with FDA and comply with the regulatory requirements in 21 CFR 118. In addition, APHIS verifies that all", "FSIS Responses to the SRT (v2019-001) 20 imported agricultural products shipped to the U.S. from abroad, including shell eggs and egg products, meet APHIS entry requirements to exclude pests and diseases of agriculture. (Note: APHIS will allow for the importation of shell eggs from regions with Newcastle disease or Highly Pathogenic Avian influenza provided that the requirements in 9 CFR 94.6 are met (i.e., the shipment is accompanied by a certificate signed by an official veterinarian from that region, the eggs are moved under USDA seal directly from the port of arrival to an official breaking and pasteurization establishment)). Furthermore, AMS is responsible for checking imported shell eggs and ensuring that imported eggs originate from foreign farms registered with FDA. Further information can be found on the FSIS website under Sourcing Egg Products and Shell Eggs from Foreign Countries. 17. How does the CCA ensure that all beef products are free of infectious materials associated with bovine spongiform encephalopathy (BSE), and all small ruminants (i.e., sheep and goats) are free of infectious materials associated with transmissible spongiform encephalopathy (TSE)? FSIS ensures that all beef products are free of infectious materials associated with BSE by requiring and verifying that specified risk materials (SRMs) be removed from the carcasses of cattle, segregated from edible materials, and disposed of in accordance with the provisions in 9 CFR 314.1 or 9 CFR 314.3. 9 CFR 310.22 identifies the following

materials from cattle 30 months of age and older as SRMs: brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia. In addition, the distal ileum of the small intestine and the tonsils are recognized as SRMs in cattle of all ages. Further, 9 CFR 310.22(d)(1) lists the conditions under which the small intestine from all cattle may be used for human food. 9 CFR 310.22 also identifies prescriptive procedures for the removal, segregation, and disposition of SRMs. Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle are required to develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. Furthermore, these procedures must address potential contamination of edible materials with SRMs before, during, and after entry into the establishment, and be incorporated into the establishment\u2019s HACCP plan, Sanitation SOPs, or other prerequisite program. If either the establishment or FSIS determines that the establishment\u2019s SRM procedures failed to effectively remove, segregate, or dispose of SRM material, the establishment is required to take corrective actions. In addition, the establishment must maintain daily records sufficient to demonstrate adequate implementation and monitoring of the SRM procedures and any corrective actions taken. Lastly, 9 CFR 310.22 describes the sanitation requirements for equipment used to cut through SRMs. Instructions to FSIS IPP on how to verify the adequate removal, segregation, and disposition of SRMs, including instructions on documenting noncompliance and enforcement actions, are provided in FSIS Directive 6100.3 Ante-mortem and Post- mortem Poultry Inspection. In addition to FSIS IPP verifying the adequate removal, segregation, and disposition of SRMs through routine government in-plant verification activities, USDA APHIS administers a national BSE surveillance program where FSIS IPP collect and submit brain tissue samples from cattle condemned on ante-mortem inspection for central nervous system conditions. Instructions to FSIS IPP on how to collect and submit samples for this program are provided in FSIS Directive 10,400.1 Sample Collection from Cattle under the Bovine Spongiform Encephalopathy (BSE) Ongoing Surveillance Program. Lastly, FSIS does not require or verify the removal of SRMs from small ruminants because TSE has not been determined to be a public health risk in the U.S. USDA APHIS conducts a Scrapie Flock Certification Program to certify scrapie-free herds and a Scrapie Eradication Program to accelerate the eradication of scrapie from the U.S." , "FSIS Responses to the SRT (v2019-001) 21 18. How does the CCA ensure control over condemned animals, which can include portions of inspected carcasses and parts, and inedible material, until destroyed or otherwise denatured? The FMIA (21 U.S.C. 603, 604, 606, 641), PPIA (21 U.S.C. 455, 460), and EPIA (21 U.S.C. 1034(c), 1039) all contain provisions requiring control over condemned animals or inedible material until destroyed for food purposes in the presence of an inspector, or otherwise denatured. These statutory provisions are codified in 9 CFR 311 and 314 (meat), 381.95 (poultry), 540 (Siluriformes), and 590.422 (egg products). In addition, the requirements for denaturing products and acceptable denaturing procedures are provided in 9 CFR 325.11, 325.13 (meat), 381.95 (poultry), and 540.3 (Siluriformes). During both ante-mortem and post-mortem livestock and poultry inspection activities, FSIS IPP verify that adulterated and condemned materials are properly identified and controlled. FSIS IPP verify that any carcass or part affected with a disease or condition listed in 9 CFR 311 (meat) or 9 CFR 381.80381.94 (poultry) is disposed of in accordance with the requirements in 9 CFR 314 (meat) or 9 CFR

381.95 (poultry). Furthermore, FSIS IPP verify that SRM and inedible materials are properly identified, controlled, and disposed of, and that all inedible materials are denatured prior to leaving the establishment. During routine inspector verification of SPS requirements, FSIS IPP verify that establishments comply with 9 CFR 416.3(c), which requires that containers used for storing inedible material be clearly marked for that purpose and cannot be used for storing edible product. Additionally, FSIS maintains the authority and ability to suspend any establishment that fails to destroy a condemned meat or poultry carcass or its components (9 CFR 500.3). Regarding egg product establishments, FSIS IPP verify that eggs ineligible for breaking and adulterated egg products are condemned and destroyed for human food purposes under the supervision of an inspector (9 CFR 590.422); and that all loss or inedible eggs or egg products are placed in a container clearly labeled \u201cinedible,\u201d and sufficiently denatured per the requirement in 9 CFR 590.504(c). 19. How does the CCA ensure the implementation and maintenance of an egg products food safety inspection system that prevents food safety hazards that arise before, during, and after the intake of shell eggs for processing; and that only shell eggs determined to be fit for human food are used to produce processed egg products designated for export to the U.S.? FSIS\u2019s regulatory oversight of egg products establishments ensures that food safety hazards are being prevented before, during, and after receiving shell eggs for processing by providing continuous government inspection to verify compliance with the statutory provisions in the EPIA and all regulatory requirements in 9 CFR 590. Examples of regulatory requirements that FSIS IPP verify compliance with include operating requirements for the following: candling and transfer room facilities and equipment (9 CFR 590.506, 590.508); proper sorting and identification of shell eggs to ensure that ineligible eggs as listed in 590.510 are not used to produce FSIS-inspected egg products; washing shell eggs with a continuous cleaning method (9 CFR 590.515); sanitizing (with potable water containing 100-200 ppm of available chlorine) and drying prior to breaking ( 9 CFR 590.516); and breaking rooms, freezing rooms, defrosting tanks or vats, spray process and albumen flake process dryers, blending and packaging equipment, air flow filtration, and heat treatment rooms (9 CFR 590.520-590.548). In addition, FSIS IPP verify that liquid egg products are properly pasteurized per the minimum temperature and holding time requirements in 9 CFR 590.570, or are heat-treated per the methods in 9 CFR 590.575; and meet the minimum cooling and freezing temperature requirements listed in 9 CFR 590.530 and 590.536. FSIS IPP verify that only shell eggs determined to be fit for human food are used to produce FSIS-inspected egg products by verifying that shell eggs are properly classified and sorted so only eligible","FSIS Responses to the SRT (v2019-001) 22 eggs are presented for breaking (9 CFR 590.510). FSIS IPP follow instructions in FSIS Directive 5030.1 Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants to verify that egg products establishments are meeting all food safety regulatory requirements in 9 CFR 590, including the requirement that shell eggs, when presented for breaking, be of edible interior quality and the shell be sound and free of adhering dirt and foreign material (9 CFR 590.510(c)). Instructions to FSIS IPP on how to verify that egg products establishments meet all applicable regulatory requirements, including how and when to document noncompliance and take additional enforcement actions, are provided in FSIS Directive 5030.1 Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants . Additional instructions to

FSIS IPP on performing egg products verification activities are provided in FSIS Directives 5020.1 Verification Activities for the Use of New Technology in Meat and Poultry Establishments and Egg Products Plants, 5030.5 Review of Egg Products Plants Drawings and Specifications, and 5040.1 Uses of FSIS Form PY-200 Egg Products Inspection Certificate. Component 3

Government Sanitation Verification 20. How does the CCA ensure that Siluriformes fish and fish products are raised and transported under sanitary conditions? FSIS IPP verify that Siluriformes fish and fish products are raised and transported under sanitary conditions by verifying compliance with the regulatory requirements in 9 CFR 534. These requirements include, but are not limited to, ensuring that Siluriformes fish harvested for use as human food have grown and lived under conditions that will not render the Siluriformes fish or their products unsound, unwholesome, unhealthful, or otherwise unfit for human food (9 CFR 534.1); and vats or containers used to transport the Siluriformes fish from the producer to the processor are maintained in a sanitary condition (9 CFR 534.4). FSIS IPP verify compliance with the regulatory requirements in 9 CFR 534 during a weekly verification activity by reviewing establishment records pertaining to pre-harvest standards and transportation to the processing establishment, such as water quality records for ponds and other waters where the Siluriformes fish are harvested. After reviewing the establishment records, if FSIS IPP have concerns that the Siluriformes fish may have been raised under insanitary conditions that may lead to adulterated or unwholesome product (e.g., evidence of heavy metals, pesticides, fertilizers, industrial chemicals, or drugs), FSIS IPP perform a HACCP verification activity to verify whether the establishment took appropriate corrective actions according to its HACCP system, adequately addressed chemical hazards in its hazard analysis, and implemented controls for the identified chemical hazards. In addition, Siluriformes fish arriving at the establishment that are dead, dying, diseased, or contaminated with substances that may adulterate fish products, are condemned (NOTE: FSIS does not require that wildcaught Siluriformes fish that die on the way to the establishment be condemned unless they are in a diseased or spoiled state). Instructions to FSIS IPP on how to verify compliance with 9 CFR 534 are provided in FSIS Directive 14,000.1 Consumer Safety Inspector Responsibilities at Fish Establishments. Instructions to FSIS IPP on how to verify HACCP regulatory requirements are provided in FSIS Directive 5000.1 Verifying an Establishment\u2019s Food Safety System. Instructions to FSIS IPP on how to verify that establishments adequately address hazards in their HACCP system are provided in FSIS Directive 5000.6 Performance of the Hazard Analysis Verification (HAV) Task. Furthermore, if FSIS suspects that Siluriformes fish are being raised under insanitary conditions, 9 CFR 534.2 provides FSIS with the authority to collect samples of feed, fish, and water from producers for the purpose of verifying that the Siluriformes fish are being raised under conditions that will yield safe, wholesome products.", "FSIS Responses to the SRT (v2019-001) 23 Lastly, if an establishment produces and ships adulterated Siluriformes products, FSIS has the authority and ability to suspend or withdraw inspection per 9 CFR 500. Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology. Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in FSIS Directive 8010.5 Case Referral and Disposition. 21. How does the CCA ensure that Siluriformes fish that have died from circumstances other than

under the controlled circumstances of commercial fishing are separated from eligible Siluriformes fish and fish products? FSIS IPP verify that Siluriformes fish that have died from circumstances other than under the controlled circumstances of commercial fishing are separated from eligible Siluriformes fish and fish products by verifying compliance with the regulatory requirements in 9 CFR 539.1 and 540.1. The types of conditions that would preclude a fish or fish part from being eligible for further processing include, but are not limited to, abscesses; lesions; parasites; flukes; spoilage or decomposition; and gross deformities caused by disease or chemical contamination. FSIS IPP verify compliance with the regulatory requirements in 9 CFR 539.1 and 540.1 during a monthly verification task by observing points in the process where the establishment examines whole fish and fish products for quality or acceptability (e.g., initial sorting of live fish; after evisceration of whole fish; or after the fillet, trim, and cutup processes). In addition, FSIS IPP verify establishment control for various conditions including, but not limited to, abscesses; sores; ulcers; evidence of spoilage or decomposition in whole fish or processed product; unusual gross deformities caused by disease or chemical contamination; and disease, spoilage or decomposition of dead fish arriving at the establishment. (NOTE: FSIS does not require that wildcaught Siluriformes fish that die on the way to the establishment be condemned unless they are in a diseased or spoiled state).

Instructions to FSIS IPP on how to verify compliance with the regulatory requirements in 9 CFR 539.1 and 540.1, including how and when to document noncompliance, are provided in FSIS Directive 14,000.1 Consumer Safety Inspector Responsibilities at Fish Establishments. Further, if an establishment produces and ships adulterated Siluriformes products, FSIS has the authority and ability to suspend or withdraw inspection per 9 CFR 500. Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology. Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in FSIS Directive 8010.5 Case Referral and Disposition.

How does the CCA ensure that livestock and poultry are slaughtered and processed in a sanitary manner? FSIS ensures that livestock are slaughtered and processed in a sanitary manner by verifying that establishments implement adequate sanitary dressing and process control procedures to prevent carcass contamination and comply with the regulatory requirements in 9 CFR 310.3, 310.17(a), 310.18(a), 318.2(b) and (d), 318.4(b), 416, and 417. Furthermore, the presence of visible fecal material, ingesta, or milk on livestock carcasses or carcass parts is considered an adulterant by FSIS per 21 U.S.C. 601(m)(3). "FSIS Responses to the SRT (v2019-001) 24 FSIS utilizes a system wide approach and verifies that the design of the establishment\u2019s slaughter operation includes a means to measure how well the sanitary dressing and process control procedures accomplish this purpose, and that the establishment responds if the measure shows that carcasses are adulterated and exposed to food safety hazards. The requirements concerning sanitary dressing include, but are not limited to, the removal of lactating and diseased mammary glands in livestock (9 CFR 310.17(a)); handling livestock in a sanitary manner to prevent contamination with fecal material, urine, hair, bile, dirt, or foreign material (9 CFR 310.18(a)); and ensuring that all livestock products are available for government reinspection as often as necessary for FSIS IPP to verify that products are not adulterated or misbranded at the time they enter or leave establishments (9 CFR 318.2(b)). In

beef slaughter establishments , FSIS IPP perform a sanitary dressing verification activity at least once per month to verify that establishments are implementing effective sanitary dressing and process control procedures to prevent contamination of carcasses (as required per 310.18(a)), and properly applying decontamination and antimicrobial intervention treatments to carcasses and parts to address any contamination that may occur. FSIS IPP perform this monthly sanitary dressing verification activity prior to the carcass receiving final inspection. Furthermore, FSIS IPP verify that establishments are properly assessing any microbial testing results, including results for indicators of process control, at any point during slaughter and at subsequent trim fabrication and grinding operations. Examples of microorganisms used as indicators of process control in raw beef operations include Enterobacteriaceae, generic Escherichia coli (E. coli), E. coli O157:H7, non-O157 STECs, and Salmonella. Instructions to FSIS IPP on how to verify sanitary dressing and process control procedures in beef slaughter establishments, including how and when to document noncompliance, are provided in FSIS Directive 6410.1 Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age. In addition to the monthly sanitary dressing verification activity in beef slaughter establishments, FSIS IPP also perform weekly SPS verification activities to verify that establishments maintain sanitary conditions in compliance with 9 CFR 416.1-416.5. Furthermore, in livestock establishments that incorporate written sanitary dressing and process control procedures as part of their HACCP Plan, Sanitation SOP, Good Manufacturing Practices (GMP), or other pre-requisite programs, FSIS IPP perform routine HACCP and sanitation verification activities to verify that establishments are implementing and following their procedures as written. Instructions to FSIS IPP on how to verify compliance with HACCP, Sanitation SOP, and SPS requirements, including how and when to document noncompliance, are provided in FSIS Directive 5000.1 Verifying an Establishment\u2019s Food Safety System. Furthermore, offline FSIS IPP perform livestock zero tolerance verification activities at least once per shift in livestock slaughter establishments. This activity includes verifying that livestock carcasses are free of visible fecal material, ingesta, and milk at or immediately after the final rail and before the final wash; and head, cheek, and weasand meat are free of visible fecal material, ingesta, and milk at the end of the harvesting process (e.g., at the packaging step or when the product is placed into a container for storage). Additionally, FSIS IPP verify that establishments implement controls (i.e., Critical Control Points) to prevent contamination of carcasses with fecal contamination, ingesta, and milk. Instructions to FSIS IPP on how to perform the livestock zero tolerance verification activity, including how and when to document noncompliance, verify appropriate corrective actions (as required per 9 CFR 417.3), and take enforcement measures, are provided in FSIS Directive 6420.2 Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Livestock Slaughter Operations and FSIS Directive 5000.1 Verifying an Establishment\u2019s Food Safety System. Regarding poultry establishments, 9 CFR 381.65(f) requires all establishments that slaughter poultry (other than ratites) to develop, implement, and maintain written procedures to ensure that poultry", "FSIS Responses to the SRT (v2019-001) 25 carcasses contaminated with visible fecal material do not enter the chiller (as fecal material on poultry carcasses entering the chiller is considered by FSIS to be an adulterant per 21 USC 453(g)(3)). 9 CFR 381.65(g) requires establishments that slaughter poultry (other than ratites) to develop, implement, and maintain written procedures to prevent contamination with enteric pathogens and feces throughout the slaughter process. 9

CFR 381.65(g) also requires poultry slaughter establishments to determine which microbial organisms will be effective in monitoring process control and implement their own sampling plans, specifically for enteric pathogens and indicators of fecal contamination (e.g., generic E. coli). Further, 9 CFR 381.65 (f) and 381.65(g) require poultry slaughter establishments to incorporate the above written procedures into their HACCP plan, Sanitation SOP, or other prerequisite program. Lastly, 9 CFR 381.145(b) requires that all poultry products be available for government reinspection as often as necessary for FSIS IPP to verify that the products are not adulterated or misbranded at the time they enter or leave official establishments (9 CFR 381.145(b)). In establishments operating under poultry inspection systems other than NPIS (e.g., traditional, streamlined inspection system (SIS), new line speed (NELS) inspection system), offline FSIS IPP perform zero tolerance verification activities to verify that establishments are preventing carcasses with fecal material from entering the chiller. This activity is performed at least two times per production line on each shift that poultry is slaughtered, and consists of selecting and examining 10 poultry carcasses after the final wash and before the chilling tank, to verify that the establishment complies with 9 CFR 381.65(f). In establishments operating under NPIS, the zero tolerance verification activity is performed at an increased frequency of at least 8 times per production line on each shift that poultry is slaughtered (i.e., at least once per hour, offline FSIS IPP select and examine 10 carcass samples prior to the chiller to verify compliance with 9 CFR 381.65(f)). FSIS IPP perform routine HACCP and sanitation verification activities to verify that poultry establishments are maintaining and implementing written procedures for preventing contamination with feces throughout the slaughter process. For example, if a poultry slaughter establishment produces giblets (i.e., edible livers, hearts, or gizzards) and maintains a procedure in its Sanitation SOP plan to prevent fecal contamination on giblets, FSIS IPP perform a sanitation verification activity to verify that the establishment is following its written procedures and giblets are free from fecal contamination. Instructions to offline FSIS IPP on how to verify poultry slaughter establishments maintain adequate procedures for preventing contamination with feces and enteric pathogens throughout the slaughter process, including how and when to document noncompliance, verify appropriate corrective actions (as required per 9 CFR 417.3), and take enforcement measures, are provided in FSIS Directive 6420.5 Verifying Poultry Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination with Feces and Enteric Pathogens. Additional instructions to FSIS IPP on how to perform verification activities in establishments operating under NPIS, including how and when to document noncompliance, verify appropriate corrective actions (as required per 9 CFR 417.3), and take enforcement measures, are provided in FSIS Directive 6500.1 New Poultry Inspection System: Postmortem Inspection and Verification of Ready-To-Cook Requirement. Instructions to FSIS IPP on how to verify compliance with HACCP, Sanitation SOP, and SPS requirements, including how and when to document noncompliance, are provided in FSIS Directive 5000.1 Verifying an Establishment's Food Safety System. Lastly, FSIS has the authority under 9 CFR 500 to implement enforcement measures including, but not limited to, suspension of inspection if sanitary conditions are such that products in the establishment are or would be rendered adulterated (9 CFR 500.3), and withdrawal of inspection for failure to maintain sanitary conditions (9 CFR 500.6(d)). Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions

are provided in FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology. Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in FSIS Directive", "FSIS Responses to the SRT (v2019-001) 26 8010.5 Case Referral and Disposition. 23. How does the CCA ensure that the condition of certified establishments\u2019 construction, facilities, and equipment is adequate to prevent the contamination or adulteration of meat, poultry, or egg products designated for export to the U.S.? FSIS ensures that establishments\u2019 construction, facilities, and equipment are maintained in a sanitary manner to prevent the contamination or adulteration of meat, poultry, or egg products by FSIS IPP verifying compliance with the SPS requirements in 9 CFR 416.1-416.6 (meat and poultry), and the sanitation requirements in 9 CFR 590.500-590.575 (egg products) at least once per week. These regulations implement the statutory provisions in 21 U.S.C. 608 (meat), 456 (poultry), and 1035 (egg products), which require that all establishments maintain sanitary conditions in their premises, facilities, and equipment, or FSIS will refuse to provide inspection. Prior to granting a meat or poultry establishment Federal inspection, FSIS surveys each establishment to determine whether the construction and facilities of the establishment are in accordance with the SPS regulations (9 CFR 304.2 (meat), 381.20 (poultry), and 532.2 (Siluriformes). Once an establishment is granted Federal inspection, FSIS verifies ongoing compliance with these regulations through routine verification activities and on-site supervisory reviews. If FSIS determines that a meat or poultry establishment\u2019s construction and facilities are creating insanitary conditions, FSIS can take an enforcement action, such as a regulatory control action or suspension, per 9 CFR 500. Instructions to FSIS personnel on granting, refusing, suspending or withdrawing inspection are provided in FSIS Directive 5220.1 Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection under PHIS. Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology. Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in FSIS Directive 8010.5 Case Referral and Disposition. Examples of the SPS regulatory requirements that FSIS IPP verify compliance with include, but are not limited to, maintaining a pest management program; separate and distinct rooms for the handling and processing of edible and inedible products; adequate lighting and ventilation; a potable water supply with adequate pressure; and cleaning and sanitizing both food contact surfaces and non-food contact surfaces, as frequently as necessary, to prevent the creation of insanitary conditions and the adulteration of product (9 CFR 416.2-416.4). Instructions to FSIS IPP on how to verify compliance with the SPS regulatory requirements, including how and when to document noncompliance and how to verify appropriate establishment corrective actions after instances of noncompliance, are provided in FSIS Directive 5000.1 Verifying an Establishment's Food Safety System. Prior to receiving continuous government inspection in egg product establishments, the establishment must demonstrate compliance with the sanitation requirements in 9 CFR 590, including requirements for equipment and facilities (9 CFR 590.146). The regulatory requirements for facilities\u2019/sanitation in egg products establishments are provided in 9 CFR 590.500-590.575. Examples of these requirements include, but are not limited to, maintaining buildings in sound construction and good repair to

prevent the entrance of vermin; efficient drainage and plumbing; a potable water supply with adequate pressure; and separate and enclosed refuse rooms (9 CFR 590.500). Instructions to FSIS IPP on how to verify construction, facility, and equipment requirements in egg processing establishments, including how and when to document noncompliance, are provided in FSIS Directive 5030.1 Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants. Furthermore, FSIS maintains the authority and ability to suspend inspection at egg product establishments that fail to maintain their premises, facilities, and equipment in a "FSIS Responses to the SRT (v2019-001) 27 satisfactory state of repair (9 CFR 590.160). 24. How does the CCA ensure that certified establishments develop, implement, and maintain daily pre-operational and operational sanitation procedures sufficient to prevent the direct contamination or adulteration of meat, poultry, and egg products designated for export to the U.S.? FSIS ensures that each establishment develops, implements, and maintains daily pre-operational and operational sanitation procedures sufficient to prevent the direct contamination or adulteration of meat, poultry, and egg products by verifying compliance with the Sanitation SOP requirements in 9 CFR 416.11-416.17 (meat and poultry) and 9 CFR 537.1 (Siluriformes), and the sanitation requirements in 9 CFR 590.500-590.575 (egg products). These regulations implement the statutory provisions in 21 U.S.C. 608 (meat), 456 (poultry), 1035 (egg products), which require that all establishments comply with the sanitation regulations to prevent adulterated product from entering commerce, or FSIS will refuse to render inspection. Furthermore, these regulations were created with the enactment of the Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems Final Rule (61 FR 38806) in 1996 which requires that each meat and poultry establishment develop and implement written Sanitation SOPs. As previously mentioned, meat and poultry establishments are required to develop written Sanitation SOPs prior to receiving Federal inspection (9 CFR 304.3 (meat), 381.22 (poultry), and 532.2 (Siluriformes)). Instructions to FSIS personnel on how to verify these regulatory requirements are met prior to granting Federal inspection, and how to refuse, suspend or withdraw inspection when the requirements are not met, are provided in FSIS Directive 5220.1 Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection under PHIS. In addition, the regulatory requirement to develop, implement, and maintain written Sanitation SOPs is verified through both routine in-plant verification activities and on-site supervisory visits. During Sanitation SOP verification activities, FSIS IPP routinely perform both observational and recordkeeping verification activities (i.e., at least twice per week) to verify that establishments meet all the regulatory requirements in 9 CFR 416.11-416.17, such as, describing the procedures and frequencies of all Sanitation SOPs; identifying the establishment personnel responsible for the implementation and maintenance of the procedures; identifying pre-operational cleaning procedures to include the cleaning of food contact surfaces; performing corrective actions when the Sanitation SOPs failed to prevent direct contamination or adulteration of product; and maintaining daily records documenting the implementation and monitoring of the Sanitation SOPs, and any corrective actions taken. Instructions to FSIS IPP on how to perform both operational and pre-operational sanitation verification activities, including enforcement measures and how and when to document noncompliance, are provided in FSIS Directives 5000.1 Verifying an Establishment's

Food Safety System and 5000.4 Performing The PreOperational Sanitation Standard Operating Procedures Verification Task. FSIS Directive 5000.1 also provides instructions to FSIS IPP on how to verify that establishments meet all the requirements in 9 CFR 416.15 when taking corrective actions, including how and when to take a regulatory control action when the establishment does not comply with the corrective action requirements in 9 CFR 416.15. Furthermore, if a meat or poultry establishment fails to implement or maintain written Sanitation SOP\u2019s, FSIS has the authority and ability to suspend or withdraw inspection per 9 CFR 500. Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology. Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in FSIS Directive 8010.5 Case Referral and Disposition. In addition to verification during routine in-plant sanitation verification activities, FSIS supervisory personnel conduct on-site visits to verify that FSIS IPP are adequately performing sanitation", "FSIS Responses to the SRT (v2019-001) 28 verification activities and the establishment in meeting the requirements in 9 CFR 416. Furthermore, FSIS EIAOs verify compliance with sanitation regulatory requirements during food safety assessments. During these assessments, EIAOs verify that the design and implementation of the establishment\u2019s Sanitation SOPs is adequate to prevent insanitary conditions and product adulteration. Instructions to FSIS EIAOs on how to perform this activity are described in FSIS Directive 5100.1 Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology. Egg products establishments must also demonstrate compliance with sanitation requirements prior to receiving continuous government inspection (9 CFR 590.146). On-going compliance with the egg products sanitation regulations (9 CFR 590.500-590.575) is verified through both in-plant verification activities and on-site supervisory reviews. During government verification activities, FSIS IPP routinely perform both observational and recordkeeping verification activities to verify that the establishment is meeting all sanitation requirements. These requirements include cleaning and sanitizing utensils and equipment prior to operations, and maintaining equipment and utensils in clean and sanitary conditions during all processing operations (9 CFR 590.504(n)). Instructions to FSIS IPP on how to perform sanitation verification activities in egg products establishments, including how and when to document noncompliance and take enforcement measures, are provided in FSIS Directive 5030.1 Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants. In addition, if an egg products establishment fails to maintain sanitary conditions, FSIS has the authority and ability to refuse, suspend, or withdraw inspection per 9 CFR 590.160. Component 4 Government HACCP System Verification 25. How does the CCA ensure that certified establishments develop, implement, and maintain a HACCP system to ensure that food safety hazards are identified, and prevented or controlled when producing meat or poultry products for export to the U.S.? FSIS ensures that meat and poultry establishments identify food safety hazards and control identified food safety hazards by verifying compliance with all HACCP regulatory requirements in 9 CFR 417. These regulations were created with the enactment of the \u201cPathogen Reduction; Hazard Analysis and Critical Control Point (PR)\u201c/HACCP) Systems\u201d Final Rule (61 FR 38806) in 1996 which requires that all meat and poultry

establishments develop and implement a HACCP system for the purpose of reducing the occurrence and numbers of pathogenic microorganisms on meat and poultry products, and reducing the incidence of foodborne illness associated with the consumption of those products. Prior to receiving a grant of Federal inspection, or producing a new product for distribution in commerce, meat and poultry establishments are required to conduct a hazard analysis, and develop and validate a HACCP plan (if it is determined in the hazard analysis that one or more food safety hazards are likely to occur in the production process) as required by 9 CFR 304.3 (meat), 381.22 (poultry), and 532.2 (Siluriformes). In order to validate their HACCP plan under actual processing conditions, FSIS provides establishments seeking a grant of Federal inspection, or establishments producing new product, a 90-day conditional grant. Further, any establishment that produces product without a HACCP plan is subject to enforcement actions, such as suspension or withdrawal of inspection, per 9 CFR 500. Instructions to FSIS personnel on how to verify these regulatory requirements are met prior to granting Federal inspection, and how to refuse, suspend or withdraw inspection when the requirements are not met, are provided in FSIS Directive 5220.1 Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection under PHIS. To verify regulatory compliance with all 9 CFR 417 requirements (and 9 CFR 537 requirements in establishments producing Siluriformes products), FSIS IPP routinely perform both observational and recordkeeping verification activities (i.e., at least twice per week per process category). During the "FSIS Responses to the SRT (v2019-001)" 29 observational and recordkeeping components of the HACCP verification activity, FSIS IPP verify that the establishment meets all HACCP regulatory requirements for all critical control points (CCP\u2019s), including monitoring, verification, recordkeeping, and corrective actions. These requirements include, but are not limited to, establishing critical limits; listing the procedures and frequencies used to monitor CCP\u2019s; performing and documenting on-going verification activities (i.e., the calibration of process monitoring instruments, direct observations of monitoring activities and corrective actions, and records review); maintaining CCP monitoring records that record the actual time, temperature, or other quantifiable value; reassessing the HACCP plan at least annually, or whenever any changes occur (e.g., a change in raw or source material, a change in product formulation); performing pre-shipment review; and developing and implementing corrective actions that will ensure that the cause of the deviation is identified and eliminated, the CCP will be under control after the corrective action is taken, measures to prevent recurrence are established, and no product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce (9 CFR 417.2-417.5). Furthermore, when performing routine HACCP verification activities, FSIS IPP verify that establishments review all records associated with the HACCP system and tied to the specific production lot being shipped prior to signing the preshipment review record. This includes verifying that establishments receive acceptable establishment testing results (for establishment testing performed to support a decision made in the hazard analysis) and perform adequate corrective actions (9 CFR 417.3); and verifying that establishments receive and confirm acceptable official government testing results (from all official government samples taken from the specific production lot being shipped) prior to completing and signing the preshipment review record. As outlined in 76 FR 19955 \u201cNot Applying the Mark of Inspection Pending Certain Test Results\u201d, \u201cthe pre-shipment review of records associated with the production lot will not be complete without the pending

[official government] test results.\u201d This applies to confirmation of acceptable government verification testing results for the following sampled products: raw non-intact beef product or raw intact beef product intended for raw non-intact use that is tested for STEC; RTE products tested for Lm, Salmonella, or STEC (RTE beef products); RTE product that passed over food contact surfaces that have been tested for the presence of Lm and Salmonella; and livestock carcasses subject to FSIS testing for veterinary drugs (e.g., antibiotics, sulfonamides, avermectins). In addition to verification during routine in-plant HACCP verification activities, FSIS supervisory personnel also verify compliance with the HACCP requirements during supervisory visits. FSIS supervisory personnel conduct on-site visits to verify that FSIS IPP are adequately performing HACCP verification activities and the establishment in meeting the requirements in 9 CFR 417. Furthermore, FSIS EIAOs verify compliance with HACCP regulatory requirements during food safety assessments. During these assessments, EIAOs analyze and document whether the establishment\u2019s HACCP system has identified and prevented or controlled all hazards that are reasonable likely to occur in the production process, and whether the establishment maintains adequate supporting documentation to support its decisions regarding the identified hazards. Instructions to FSIS EIAOs on how to perform this analysis are described in FSIS Directive 5100.1 Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology. Lastly, FSIS IPP perform quarterly hazard analysis verification activities in all establishments to verify that establishments have conducted a hazard analysis identifying all food safety hazards in their process, and implemented preventive measures to control these hazards. When performing the hazard analysis verification activity, FSIS IPP refer to the FSIS Meat and Poultry Hazards and Controls Guide, which lists potential biological, physical, and chemical hazards and frequently used controls and preventive measures for each step. FSIS IPP also verify that establishments maintain adequate support for all decisions made in their hazard analyses, including support for both CCPs and prerequisite programs. This also includes verifying that establishments maintain both components for HACCP validation: scientific and technical data, and in-plant (implementation) data." "FSIS Responses to the SRT (v2019-001) 30 Instructions to FSIS IPP on how to verify that an establishment is meeting all HACCP regulatory requirements and effectively implementing its HACCP plan, including how and when to document noncompliance and take enforcement measures, are provided in FSIS Directive 5000.1 Verifying an Establishment's Food Safety System. Instructions to FSIS IPP on how to verify that an establishment\u2019s hazard analysis meets all 9 CFR 417 regulatory requirements, including how and when to document noncompliance and take enforcement measures, are provided in FSIS Directives 5000.1 and 5000.6 Performance of the Hazard Analysis Verification (HAV) Task. Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology. Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in FSIS Directive 8010.5 Case Referral and Disposition. Component 5 Government Chemical Residue Program 26. How does the CCA ensure the implementation and maintenance of an official government chemical residue control program that prevents and controls all specific compounds of concern in the foreign country and in the U.S.? FSIS considers meat, poultry, and egg products to be

adulterated under the FMIA (21 U.S.C. 601(m)(1)), PPIA (21 USC 453(g)(1)), and EPIA (21 USC 1033(a)(1)) if the product contains a chemical compound at a level in excess of an established tolerance or action level, or if the residue detected has no approved tolerance. Under the authority of the FMIA, PPIA, and EPIA, FSIS administers the U.S. National Residue Program (NRP) for Meat, Poultry, and Egg Products, which is an interagency program designed to identify, rank, and analyze for chemical contaminants in meat, poultry, and egg products. FSIS publishes the NRP Residue Sampling Plans (known as the Blue Book) each year to provide information on the process of sampling meat, poultry, and egg products for chemical contaminants of public health concern. The Blue Book includes information on FSIS\u2019s chemical residue sampling plans, a summary of changes from the previous year\u2019s NRP, and a list of chemical residues by class\method. The NRP is developed in consultation with the Surveillance Advisory Team (SAT) which is comprised of technical experts from the following three principal U.S. government agencies: FSIS, FDA, and the Environmental Protection Agency (EPA). The SAT meets annually to decide which compounds represent a public health concern and warrant inclusion in the NRP scheduled sampling plans. In addition, the SAT may propose, based on professional judgment and reliable field information, the initiation of exploratory assessments for directed sampling on a production class or region of the country. These agencies work together to create the annual sampling plan, based on the following: prior NRP findings of chemical residues in meat, poultry, and egg products; FDA veterinary drug inventories completed during on-farm visits and investigation information; and pesticides and environmental contaminants of current importance to EPA. FSIS\u2019s 2018 NRP includes an overview of domestic and import reinspection sampling plans, as well as the policy and procedures for holding or controlling product under the NRP. Chemical compounds analyzed in the program include approved and unapproved veterinary drugs, pesticides, and environmental compounds. The NRP is designed to: (1) provide a structured process for identifying and evaluating chemical compounds used in animal foods, (2) analyze chemical compounds of concern, (3) collect, analyze, and report results, and (4) identify the need for regulatory follow-up subsequent to the identification of violative levels of chemical residues.", "FSIS Responses to the SRT (v2019-001) 31 FSIS uses novel multi-residue methods for the detection and confirmation of veterinary drugs, pesticides, and environmental contaminants. Appendix I of the NRP lists the names of the chemical residues by class\method. The analytical methods used for screening and confirmation are provided in the FSIS Chemistry Laboratory Guidebook. Furthermore, the tolerances for veterinary drugs and action levels for environmental contaminants are established by FDA, and listed under Title 21 CFR. Tolerances for registered pesticides are established by the EPA, and listed under Title 40 CFR. The NRP consists of three separate, but interrelated, chemical residue testing programs: scheduled sampling (Tier 1), targeted sampling at the production or compound class level (Tier 2), and targeted sampling at the herd\flock or compound class level. The NRP also contains the number of analyses per production class by compound class, and the statistical basis for the sampling number (about 800 samples for each of the nine major production classes tested under Tier 1). Furthermore, FSIS laboratory personnel enter detailed residue violation information into an FSIS\FDA interagency database, and post a weekly Residue Repeat Violator\u2019s List on the FSIS website. When a violative result is identified, FSIS notifies the establishment, FSIS IPP, and the producer, of the analysis results. In addition, FSIS shares the violation data with EPA and FDA.

FDA has on-farm jurisdiction and works with cooperating State agencies to investigate producers linked to residue violations and, if conditions leading to residue violations are not corrected, can enforce legal action. FSIS IPP collect and submit official government chemical residue samples through either the scheduled (directed) sampling program or inspector generated sampling. Inspector generated sampling is conducted whenever FSIS IPP suspect, through either herd history or ante-mortem or post-mortem inspection findings, that a carcass may contain a violative residue finding (e.g., FSIS IPP observe mastitis or an injection site when performing ante-mortem inspection) or on any carcass exhibiting signs of systemic conditions (e.g., septicemia, peritonitis, pyemia). Inspector generated sampling is performed through an in-plant screening test known as the Kidney Inhibition Swab (KIS\u2122), which is an antibiotic screen test for kidney tissue; and through the collection and submission of tissue samples. Other examples of when inspector generated sampling is performed include, but are not limited to, when FSIS PHVs suspect nonsteroidal anti-inflammatory drugs (NSAID) or beta-agonist use in livestock. In addition, FSIS IPP also collect and submit samples for laboratory analyses on imported meat and poultry products. When a KIS\u2122 test and any other inspector-generated sampling is performed, FSIS IPP maintain control of the carcass and its parts pending non-violative test results. If a KIS\u2122 test is positive, FSIS IPP send liver, muscle, and kidney tissue to the laboratory for further analysis. Under the directed sampling program, FSIS IPP send kidney, liver, and muscle tissues to the laboratory for analysis; and verify the appropriate disposition of the livestock carcass pending violative test results.

Directed samples are assigned to FSIS IPP through PHIS based on the frequency noted in the NRP. Instructions to FSIS IPP on how and when to collect and submit residue samples; retain livestock carcasses pending non-violative test results (for samples taken under the inspector generated sampling program) or verify establishments are retaining carcasses pending nonviolative test results (for samples taken under the inspector generated sampling program); verify corrective actions; document noncompliance; and take enforcement actions are provided in FSIS Directive 10,800.1, Residue Sampling, Testing and Other Verification Procedures under the National Residue Program for Meat and Poultry Products and FSIS Directive 14,010.1 Speciation, Residue, and Salmonella Testing of Fish of the Order Siluriformes from Domestic Establishments. Instructions to FSIS IPP on how to collect KIS\u2122 samples are provided in KISTM Test Instructions. Lastly, instructions to FSIS IPP on how to collect and submit residue samples for imported meat, poultry, and egg products are provided in FSIS Directive 9900.6 and FSIS Directive 14,100.1 Speciation, Residue, and Salmonella Testing of Fish of the Order Siluriformes at Official Import Inspection Establishments. In addition, FSIS IPP withhold the mark of inspection on all livestock carcasses subject to FSIS testing (e.g., veterinary drugs, such as antibiotics, sulfonamides, or avermectins or the feed additive carbadox) pending non-violative testing results (77 FR 73401); and verify that establishments maintain control of "FSIS Responses to the SRT (v2019-001) 32 the livestock carcasses and parts and not allow those carcasses and parts to enter commerce until receipt and confirmation of non-violative official government testing results (76 FR 19955). If an establishment does not maintain control of a livestock carcass tested by FSIS for chemical residues (under the directed sampling program) and found to be violative, and the product enters commerce, FSIS has the authority and ability to take additional enforcement measures per 9 CFR 500. Accompanying the NRP is a detailed spreadsheet of the previous year\u2019s residue sampling results (known as the Red Book).

This sheet provides detailed information regarding samples taken by FSIS for both the domestic scheduled and inspector-generated sampling programs, in addition to the import sampling program results. The detailed results include sample collection and review dates, the project code, the animal class, tissue type, chemical residue name, concentration value, sample results (whether positive non-violative or positive violative), chemical concentration values (if any) and the CFR reference per chemical listed in the data sheet. Further information on FSIS\u2019s NRP, including a link to the Residue Repeat Violator\u2019s List and Residue Quarterly Reports, can be found under Residue Chemistry on the FSIS website. Component 6 Government Microbiological Pathogen and Process Control Programs 27. How does the CCA ensure that a slaughter establishment\u2019s microbiological sampling and testing program for meat and poultry verifies process control using microbiological analyses for indicators of intestinal and fecal contamination? Under \u201cPathogen Reduction; Hazard Analysis and Critical Control Point (PR)\u201c(HACCP) Systems\u201d (61 FR 38806), FSIS requires that slaughter establishments conduct routine microbiological testing to verify the adequacy of their slaughter and sanitary dressing process controls for the prevention of contamination with fecal material and other intestinal contents and associated bacteria. In livestock and ratite slaughter establishments, establishment testing for generic E.coli as an indicator organism allows the establishment to assess process capability and process control. More recently, FSIS implemented \u201cModernization of Poultry Slaughter Inspection\u201d (79 FR 49566) which specifies the requirements for how poultry slaughter establishments (excluding ratites) are to monitor process control through analyses for microbiological organisms, including sampling location and sampling frequency requirements. Requirements for process control verification criteria and testing can be found in 9 CFR 310.25 (meat), 381.65(g) (poultry) and 381.94 (ratites). 9 CFR 310.25 requires that all livestock slaughter establishments test for generic E.coli, and provides the sampling techniques, methodology, and frequency requirements for testing. These requirements include, developing and maintaining written specimen collection procedures that identify the employees designated to collect samples, the locations of sampling, how randomness is achieved, and measures to ensure sample integrity. Sample collection procedures include sponging or excising tissue from the flank, brisket, and rump for cattle (excluding hide-on calves); and sponging or excising tissue from the ham, belly, and jowl areas for swine. Further, this regulation requires that establishments analyze results using an Association of Official Analytical Chemists (AOAC) approved quantitative method or equivalent method, and maintain records of the analytic results (to be made available for FSIS review). FSIS IPP perform a weekly verification activity to verify that establishments implement effective control measures for relevant pathogens by reviewing establishment records for trend analysis of testing results and for responses to deviations resulting in food safety hazards. In addition, FSIS IPP perform routine verification activities to verify that establishments are implementing adequate control measures through either their HACCP system, Sanitation SOP\u2019s, or other prerequisite programs to control pathogens (e.g., antimicrobial intervention, sanitary dressing). Furthermore, FSIS IPP supervisory personnel verify that establishments maintain adequate control measures for relevant microbiological pathogens during supervisory reviews. Instructions to FSIS IPP on how to verify compliance with the "FSIS Responses to the SRT (v2019-001) 33 regulatory requirements in 9 CFR 310.25, including how and when to document noncompliance and how to identify trends of noncompliance, are provided in FSIS Directive

5000.1 Verifying an Establishment\u2019s Food Safety System. Instructions to FSIS IPP on how to review establishment testing data are provided in FSIS Directive 5000.2 Review of Establishment Data by Inspection Personnel. Additionally, 9 CFR 381.65(g) requires that all official poultry establishments (except those that slaughter ratites) develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens (e.g., *Salmonella* and *Campylobacter*) and fecal material throughout the entire slaughter and dressing operation. At a minimum, these procedures must include sampling and analysis for microbial organisms. Further, each establishment must incorporate these written procedures, including their microbiological sampling plans, into their HACCP plan, Sanitation SOPs, or other prerequisite programs; and maintain daily records documenting the implementation and monitoring of these procedures (also required to be made available for FSIS review). This regulation also specifies that samples are to be collected and analyzed for microbial organisms at the pre-chill and post-chill points in the process (unless a very small or very low volume establishment operating under Traditional Inspection), and that the required sampling frequency is proportional to the establishment\u2019s production volume (e.g., once per 22,000 carcasses for chicken, once per 3,000 carcasses for turkeys, ducks, geese, guineas, and squabs). Instructions to FSIS IPP on how to verify compliance with the regulatory requirements in 9 CFR 381.65(g), including how and when to document noncompliance, are provided in FSIS Directives 5000.1 Verifying an Establishment\u2019s Food Safety System and 6420.5 Verifying Poultry Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination with Feces and Enteric Pathogens. Official establishments that slaughter ratites must also test for generic *E. coli* (9 CFR 381.94). These requirements mirror the requirements for generic *E. coli* testing in livestock establishments. Lastly, if a meat, poultry, or ratite establishment fails to meet the regulatory requirements in 9 CFR 310.25, 381.65(g), or 381.94, FSIS can take enforcement actions per 9 CFR 500, including suspension or withdrawal of inspection.

28. How does the CCA ensure the reduction of *Salmonella* in raw meat and poultry products, and *Campylobacter* in raw poultry products through sampling and other verification activities? FSIS ensures that raw meat and poultry products are produced safely and that pathogen levels are reduced or eliminated during slaughter and processing operations by implementing official government sampling and testing programs (i.e., routine, follow-up, and import sampling) for *Salmonella* and *Campylobacter* and performing non-sampling government verification activities (i.e., HACCP, Sanitation SOP, sanitary dressing verification) in establishments. FSIS IPP perform routine HACCP, Sanitation SOP, and sanitary dressing verification activities in all raw meat and poultry establishments to determine whether an establishment has procedures in place designed to address the control or monitoring of *Salmonella* or *Campylobacter* (e.g., interventions to reduce or eliminate *Salmonella* or *Campylobacter*, pre-harvest practices or purchase specification programs intended to reduce *Salmonella* or *Campylobacter* in live animals or raw materials received at the establishment). FSIS IPP also perform quarterly hazard analysis verification activities to verify that establishments are identifying and adequately addressing *Salmonella* and *Campylobacter* in their hazard analyses. In addition, FSIS IPP review establishment testing data and results at least once per production week for trend analysis. When reviewing establishment testing data, FSIS IPP verify that establishments perform adequate corrective actions in response to positive establishment testing results. Further, FSIS IPP in official poultry establishments verify that

establishments meet the chilling performance standards in 9 CFR 381.66(b) for poultry (excluding ratites) which include, chilling all poultry carcasses, parts, and giblets immediately after slaughter operations to prevent pathogen outgrowth (9 CFR 381.66(b)(1)(i)); and developing, implementing, and maintaining written procedures", "FSIS Responses to the SRT (v2019-001) 34 for chilling that addresses the potential for pathogen outgrowth, the conditions affecting carcass chilling, and the length of time necessary for adequate chilling (9 CFR 381.66(b)(3)). These procedures are required to be incorporated into the establishment\u2019s HACCP plan, Sanitation SOPs, or other prerequisite programs. In addition, 9 CFR 381.91(b)(1) and 381.91(b)(2) contain requirements for online and offline poultry reprocessing and require official establishments to incorporate procedures for the use of approved online antimicrobial intervention systems or offline reprocessing into their HACCP plans, Sanitation SOPs, or other prerequisite programs (see List of Approved On Line Reprocessing (OLR) and Off Line Reprocessing (OFLR) List of Approved On Line Reprocessing (OLR) and Off Line Reprocessing (OFLR) Antimicrobial Systems for Poultry). Instructions to FSIS IPP on how to verify establishment Salmonella and Campylobacter control programs are provided in FSIS Directive 10,250.1 Salmonella and Campylobacter Verification Program for Raw Meat and Poultry Products. Instructions to FSIS IPP on how to verify compliance with HACCP and sanitation regulatory requirements, including how and when to document noncompliance and take enforcement measures, are provided in FSIS Directive 5000.1 Verifying an Establishment\u2019s Food Safety System. Instructions to FSIS IPP on how to review establishment testing data are provided in FSIS Directive 5000.2 Review of Establishment Data by Inspection Personnel. The FSIS Salmonella sampling verification program formally began with the issuance of FSIS\u2019s final rule, \u201cPathogen Reduction; Hazard Analysis and Critical Control Point (PR)\u201c/HACCP) Systems\u201d (61 FR 38805-38989), published on July 25, 2006. Among other things, the PR\u201c/HACCP rule set Salmonella performance standards for establishments producing selected classes of raw meat and poultry products. As stated in the PR\u201c/HACCP rule (at 61 FR 38835), FSIS selected Salmonella for the performance standard because it is the most common cause of foodborne illness associated with meat and poultry products; it is present to varying degrees in all major species; and the interventions targeted at reducing Salmonella may help reduce contamination by other enteric pathogens. FSIS continues to use pathogen reduction performance standards to ensure that eligible establishments are consistently controlling or reducing harmful bacteria on raw meat and poultry products. FSIS has pathogen reduction performance standards listed in 9 CFR for the following products and is currently enforcing compliance with these performance standards: \u2022 Raw chicken and turkey o Carcasses (76 FR 15282) o Chicken parts (81 FR 7285)5 o Comminated products (81 FR 7285)6 FSIS has pathogen reduction performance standards listed in 9 CFR for the following products; however, these performance standards are not currently enforced by FSIS (see additional information below for information on why FSIS suspended its official government sampling verification program for these products): \u2022 Raw bovine products (9 CFR 310.25) o Steer and heifer carcasses o Cow and bull carcasses o Ground beef, bulk or patties \u2022 Market hog carcasses (9 CFR 310.25) To that end, FSIS has implemented official government sampling verification programs for Salmonella and Campylobacter in the following raw poultry products: chicken carcasses, turkey carcasses, chicken 5 On November 9, 2018, FSIS published Federal Register Notice \u201cChanges to the Salmonella and Campylobacter Verification

Testing Program: Revised Categorization and Follow-Up Sampling Procedure\u201d (83 FR 56046) 6 See Footnote 5","FSIS Responses to the SRT (v2019-001) 35 parts (e.g., legs, breasts, wings), comminuted chicken (i.e., product that has been ground, or hand- or mechanically deboned and further chopped, flaked, minced or otherwise processed to reduce particle size), and comminuted turkey. For clarification, \u201ccominuted\u201d means product that is ground, flaked, minced, or otherwise significantly reduced in particle size to less than \u00be inch (1.9 cm)). FSIS also tests the following raw beef products for Salmonella: raw ground beef, bench trim (purchased) and manufacturing trimmings, and other raw ground beef components such as head meat, cheek meat, weasand meat, heart meat, and product from advanced meat recovery systems (AMR). The methods for developing the pathogen reduction performance standards and predictions for the public health effect of those standards are described in the 2015 Public Health Effects of Raw Chicken Parts and Comminuted Chicken and Turkey Performance Standards. FSIS used the same methodology to estimate the public health effects for the chicken and turkey carcass performance standards in 2011. FSIS used a common analytical framework to estimate the improvements in public health (illnesses averted) associated with six separate pathogen reduction performance standards discussed as options. Based on the risk assessment predictions, FSIS estimated the reductions in salmonellosis and campylobacteriosis cases that would result if establishments made changes in their processes. Do note, in August 2018, FSIS began using an enrichment-based method to analyze poultry samples for Campylobacter due to the low sensitivity of the direct plating analytical method. Therefore, at this time, FSIS is not currently assessing Campylobacter performance in poultry establishments and is currently revising the Campylobacter performance standards based on the enrichment method. Regarding official government verification sampling for Salmonella in raw beef and swine, FSIS suspended official government verification of compliance with the Salmonella performance standards in beef (steers\heifers and cows\bulls) and swine (market hog) carcasses (2011), as well as in raw ground beef (2014), because the percentage of positive findings was very low. However, regulatory requirements in 9 CFR 310.25 remain in place for cow\bull\steer\heifer and market swine, and establishments that slaughter these livestock are expected to meet these criteria. Although these official government sampling verifications programs were suspended, FSIS continues to monitor the reduction of Salmonella by co-analyzing official government samples of raw ground beef, beef manufacturing trimmings, bench trim, and other raw ground beef components collected for STEC analysis for the presence of Salmonella (see 79 FR 32436, \u201cChanges to Salmonella Verification Sampling Program: Analysis of Raw Beef for Shiga Toxin-Producing Escherichia coli and Salmonella\u201d). In addition, FSIS samples raw ground beef products at retail stores, and imported ground beef, trim, and other raw ground beef components for Salmonella. For raw pork products, FSIS has initiated sampling and analysis of raw pork cuts and raw comminuted pork to determine the prevalence of Salmonella in these products (Raw Pork Products Exploratory Sampling Program). FSIS will use the data collected from these raw beef and pork products sampling programs to support future policy development, which could include new or updated Salmonella performance standards. In addition, FSIS has initiated sampling and analysis of raw Siluriformes fish products to determine the prevalence of Salmonella in these products to inform future policy development. The frequency of routine government verification sample assignment is dependent on slaughter volume data (e.g., higher volume-

producing establishments are sampled more frequently (maximum 4-5 samples per month per product type) than lower volume-producing establishments (minimum 1 sample\month per product type)). Additional information can be found in FSIS Establishment Eligibility Criteria for the Salmonella and Campylobacter Verification Sampling Program and FSIS Scheduling Algorithm for the Salmonella and Campylobacter Verification Sampling Programs for Raw Poultry. Instructions to FSIS IPP on how to choose and collect carcass\parts rinses (chicken) and carcass sponge (turkey) samples for Salmonella and Campylobacter testing, and the actions to take in the event an establishment fails to meet FSIS performance standard criteria (i.e., follow-up sampling) are provided in FSIS Directive 10,250.1 Salmonella and Campylobacter Verification Program for Raw", "FSIS Responses to the SRT (v2019-001) 36 Meat and Poultry Products. Additional information and instructions to FSIS IPP can be found under the Raw Chicken Parts Sampling Program and Raw Chicken Parts Sampling Supplies and \u201cHow to\u201d Guidance; and the Not Ready-to-Eat Commminated Poultry Sampling Program and Commminated Poultry Sampling Supplies and \u201cHow-to\u201d Guidance. In addition, FSIS monitors relevant databases (e.g., those maintained by the Centers for Disease Control and Prevention and the National Institutes of Health) for clinical isolates that match food isolates obtained by FSIS in its sampling of products produced by official establishments. When not ready-to-eat (NRTE) poultry or meat products are associated with an illness outbreak and contain pathogens that are not considered adulterants, FSIS likely will consider the product linked to the illness outbreak to be adulterated under 21 U.S.C. 453(g)(3) or 21 U.S.C. 601(m)(3) because the product is \u2018unsound, unhealthful, unwholesome, or otherwise unfit for human food.\u2019 In such cases, FSIS would request that the establishment recall the product if it is still in commerce. FSIS may also perform follow-up sampling and conduct a public health risk evaluation, to analyze the establishment\u2019s food safety system and determine if a food safety assessment is necessary. If deemed necessary, FSIS will schedule a food safety assessment (FSA) and verify whether the establishment is able to produce safe and wholesome poultry products in accordance with FSIS statutory and regulatory requirements. During the FSA, FSIS EIAOs review the establishment\u2019s food safety system as a whole, including the design of the establishment\u2019s HACCP system, supporting documentation for decisions made in the hazard analysis (e.g., validation documents), the design and implementation of the establishment\u2019s sampling and testing programs, and the establishment\u2019s reaction to sampling results. Instructions to FSIS EIAOs on how to conduct public health risk evaluations and perform food safety assessments are provided in FSIS Directive 5100.4 Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology and FSIS Directive 5100.1 Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology. FSIS\u2019s methods of analysis for official government Salmonella and Campylobacter verification testing programs are included in the MLG (Chapter 4 and Chapter 41, respectively). The proposed number of Salmonella (and Campylobacter in poultry) official government verification samples for raw beef and raw poultry products for the 2017 fiscal year (FY17), the actual number of samples for FY17, and the proposed number of samples for the FY18 can be found in the FSIS Annual Sampling Program Plan. Information on FSIS\u2019s Salmonella and Campylobacter sampling program for imported products can also be found in the FSIS Annual Sampling Program Plan. Lastly, additional information on FSIS\u2019s Salmonella and Campylobacter

verification testing program for raw meat and poultry, including monthly, quarterly, and annual reports, can be found under Microbiology on the FSIS website.

29. How does the CCA ensure through sampling and other verification activities that raw beef products are free of STEC at the end of the production process? FSIS considers all raw non-intact beef and raw intact beef intended for use in raw non-intact product to be adulterated under the FMIA (21 U.S.C. 601(m)(1)) if contaminated with E. coli O157:H7 or one of six non-O157 STEC (O26, O45, O103, O111, O121, and O145). To ensure that raw beef products are free of STEC, FSIS implements official government verification sampling and testing programs (i.e., routine, follow-up, and import sampling) and performs routine non-sampling government verification activities (i.e., HACCP, Sanitation SOP, sanitary dressing verification). FSIS IPP conduct routine HACCP verification activities, through review of records and observations, and a quarterly hazard analysis verification activity to verify that the establishment is meeting all 9 CFR 417 PR\HACCP regulatory requirements including, identifying STEC as a hazard in the hazard analysis; maintaining support for decisions made in the hazard analysis and HACCP plan, including prerequisite programs; adequately validating their HACCP plan; reassessment; and conducting monitoring, "FSIS Responses to the SRT (v2019-001) 37 verification, recordkeeping, corrective actions, and preshipment review per the regulatory requirements. FSIS IPP also verify that establishments identify the product\u2019s intended use (e.g., intact beef primal and subprimal cuts are intended for intact use) per the requirement in 9 CFR 417.2(a)(2) and have supporting documentation to support the product\u2019s intended use per 9 CFR 417.5(a)(1). FSIS IPP verify that establishments and retail stores that grind raw beef for sale in commerce maintain specific information about their grinding activities as required per 9 CFR 320.1(b)(4). Furthermore, FSIS IPP verify that establishments perform ongoing verification activities to ensure their food safety system is functioning as intended and continues to support decisions made in their hazard analysis, such as conducting establishment testing for STEC on an ongoing basis to demonstrate that their HACCP systems are working effectively to eliminate or reduce STEC to a non-detectable level. FSIS IPP review establishment testing data and results at least once per production week for trend analysis. When reviewing establishment testing data, FSIS IPP verify that establishments that received positive STEC results from their establishment testing program identify the sampled lot as adulterated per 21 USC 601(m)(1) and perform adequate corrective actions per 9 CFR 417.3. If an establishment fails to perform adequate corrective actions on product that tested positive for STEC (through establishment testing), and the product is shipped into commerce, FSIS can take enforcement actions per 9 CFR 500. Instructions to FSIS IPP on how to perform inspection verification activities other than official government verification sampling (e.g., HACCP verification), including how and when to document noncompliance and take enforcement measures, are provided in FSIS Directive 10,010.2 Verification Activities for Shiga Toxin-Producing Escherichia Coli (STEC) in Raw Beef Products. Instructions to FSIS IPP on how to review establishment testing data are provided in FSIS Directive 5000.2 Review of Establishment Data by Inspection Personnel. Instructions to FSIS IPP on how to verify whether official establishments are maintaining required records concerning suppliers and source materials for raw beef ground at the establishment are provided in FSIS Directive 5000.10 Verifying that Records are Kept by Official Establishments that Grind Beef. In addition to inspection verification activities, FSIS conducts official government verification sampling of raw ground beef products and raw intact beef products

intended for non-intact use, or when the intended use is unclear as described in FSIS Directive 10.010.1 Sampling Verification Activities for Shiga Toxin-Producing Escherichia Coli (STEC) in Raw Beef Products. FSIS collects and analyzes raw beef samples for both E. coli O157:H7 and Salmonella under four routine sampling programs which are categorized based on the product group (i.e., beef manufacturing trimmings; bench trim; other raw ground beef components, such as head meat, cheek meat, weasand meat, heart meat and product from advanced meat recovery systems (AMR); and raw ground beef products in establishments that grind or form patties). Beef manufacturing trimmings are also analyzed for presence of the six non-O157 STECs (i.e., O26, O45, O103, O111, O121, and O145), in addition to E. coli O157:H7 and Salmonella. These product samples are collected and submitted by FSIS IPP under the STEC sampling program. FSIS bases the frequency of its domestic sampling program primarily on production volume for each product group. The proposed number of official government verification samples for STEC in raw non-intact beef and raw intact beef intended for use in raw non-intact product for the 2017 fiscal year (FY17), the actual number of samples collected and analyzed for FY17, and the proposed number of samples for the FY18 can be found in the FSIS Annual Sampling Program Plan. Information on FSIS\u2019s STEC sampling program for imported beef products can also be found in the FSIS Annual Sampling Program Plan.

FSIS\u2019s methods of analysis for official Salmonella and STEC verification testing programs are included in the MLG (Chapter 4 and Chapter 5C respectively). Instructions to FSIS IPP on how to collect and submit official government STEC samples, including the actions to take when a test result is positive for STEC, are provided in FSIS Directive 10.010.1 Sampling Verification Activities for Shiga ToxinProducing Escherichia Coli (STEC) in Raw Beef Products . FSIS requires establishments to hold or maintain control of raw beef products that FSIS has tested for STEC pending negative FSIS results (76 FR 19955). In addition, FSIS IPP verify that establishments maintain a supportable basis for their lotting definition. For sampling purposes, lots should be defined","FSIS Responses to the SRT (v2019-001) 38 so that they are microbiologically independent; meaning that if a positive result is found in one lot, the product from the other lot would not be implicated. Factors that FSIS IPP look for when determining if the lot is microbiologically independent include, scientific, statistically-based sampling programs for STEC used to distinguish between segments of production; Sanitation SOP\u2019s or other prerequisite programs used to control the spread of STEC cross-contamination between raw beef components during production; co-mingling of products; and processing interventions that limit or control STEC contamination. Product that is implicated with a positive official government test result (i.e., product that is not microbiologically independent from the sample) and was not held would be subject to voluntary recall. 76 FR 19955 stipulates that if the establishment has completed preshipment review prior to receiving official government test results, and the official government test results are positive, the establishment has produced and shipped adulterated product into commerce (21 USC 601(m)(1)). Under these circumstances, FSIS will take an appropriate enforcement action per 9 CFR 500 (e.g., immediately suspending inspection or issuing a Notice of Intended Enforcement Action). In addition, FSIS will request a voluntary recall of product, detain the product in commerce, or institute other product control actions if necessary. Instructions to FSIS IPP on how to verify that establishments hold or retain control of product pending negative FSIS test results for STEC, and maintain support for lot definitions are provided in FSIS Directive 10,010.1 Sampling

Verification Activities for Shiga ToxinProducing Escherichia Coli (STEC) in Raw Beef Products.

When a routine official government verification sample tests positive for STEC, the sampled lot is considered adulterated as per the statutory definition in 21 U.S.C. 601(m)(1). FSIS IPP conduct followup sampling and perform HACCP, Sanitation SOP, and sanitary dressing verification activities, in both the producing and supplying establishments, to determine whether the establishments effectively address control of STEC and implement corrective actions per 9 CFR 417.3. Instructions to FSIS IPP on how to perform follow-up sampling when an official government test result is positive for STEC are provided in FSIS Directive 10,010.1 Sampling Verification Activities for Shiga Toxin-Producing Escherichia Coli (STEC) in Raw Beef Products. In addition, when a routine official government sample tests positive for STEC, FSIS EIAOs perform traceback investigations to verify all source materials and potential suppliers of source materials were identified, and any products not microbiologically independent from the adulterated lot are removed from commerce (when applicable). As part of traceback investigations, FSIS IPP review slaughter establishment test results to determine whether the establishment has experienced a high-event period. A high-event period is a high rate of positive STEC sample results over a relatively short period of time, indicating the establishment did not maintain adequate process control over STEC. FSIS IPP use this information to determine whether the establishment has a supportable basis for microbiological independence and can support its decision concerning which products are held from entering commerce. Instructions to FSIS personnel on how to perform traceback investigations, and determine whether the establishment has experienced a high-event period, are provided in FSIS Directive 10,010.3 Traceback Methodology for Escherichia Coli (E. coli) O157:H7 in Raw Ground Beef Products and Bench Trim. Furthermore, if an official government test result is confirmed positive for STEC, FSIS will conduct a public health risk evaluation to assess and analyze the establishment\u2019s food safety system and determine if an immediate enforcement action or food safety assessment is necessary. If necessary, FSIS will schedule a food safety assessment and verify whether the establishment is able to produce safe and wholesome beef products in accordance with FSIS statutory and regulatory requirements.

During the food safety assessment, FSIS EIAOs review the establishment\u2019s food safety system as a whole, including the design of the establishment\u2019s HACCP system, supporting documentation for decisions made in the hazard analysis (e.g., validation documents), the design and implementation of the establishment\u2019s sampling and testing programs, and the establishment\u2019s reaction to sampling results. Instructions to FSIS EIAOs on how to conduct public health risk evaluations and perform food safety assessments are provided in FSIS Directive 5100.4 Enforcement, Investigations and Analysis Officer", "FSIS Responses to the SRT (v2019-001) 39 (EIAO) Public Health Risk Evaluation (PHRE) Methodology and FSIS Directive 5100.1 Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology. Lastly, if an establishment ships STEC positive product into commerce (determined through either establishment testing or official government verification testing), FSIS can take enforcement actions per 9 CFR 500. Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology. Instructions to FSIS OIEA compliance officers on the procedures to follow when taking

enforcement actions are provided in FSIS Directive 8010.5 Case Referral and Disposition. 30. How does the CCA ensure through sampling and other verification activities that RTE meat and poultry products and all lots of pasteurized egg products are not contaminated with microbiological pathogens or their toxins, including Lm and Salmonella? FSIS considers all RTE meat, poultry products, and pasteurized egg products to be adulterated under the FMIA (21 U.S.C. 601(m)(1)), PPIA (21 U.S.C. 453(g)(1)), and EPIA (21 U.S.C. 1033(a)(1)) if contaminated with any level of Lm or Salmonella. Further, FSIS identifies RTE product as adulterated if it passes over a food contact surface that has tested positive for Lm or Salmonella. To ensure that RTE products are free of Lm and Salmonella, FSIS implements official government verification sampling and testing programs (i.e., routine, follow-up, and import sampling) and performs routine nonsampling government verification activities (e.g., HACCP, sanitation, labeling). The regulations requiring control of Lm in post-lethality exposed RTE products are contained in 9 CFR 430.4 (also known as the Listeria Rule), and state that Lm is a hazard that establishments producing post-lethality exposed RTE meat or poultry products must control through their HACCP plans, or prevent in their processing environment through the implementation of Sanitation SOP\u2019s or other prerequisite programs. (NOTE: Establishments producing RTE Siluriformes products are subject to the requirements of the Listeria rule as specified in 9 CFR 548.5.) In order to maintain the sanitary conditions necessary to meet this requirement, establishments are required to comply with the requirements of one of three Listeria alternatives listed in 9 CFR 430.4. For example, Alternative 1 uses a post-lethality treatment (PLT) and an antimicrobial agent or process (AMAP) to control Lm and requires that the PLT be included in the HACCP plan. Alternative 2b (AMAP alone) and Alternative 3 (sanitation alone) both require establishment testing of food contact surfaces in the post-lethality processing environment for Lm or an appropriate indicator organism. Establishments with processes falling in Alternatives 2b or 3 are also required to identify the size, site location, frequency of testing, and conditions under which the establishment will hold and test the product following a positive test for Listeria spp. on a food contact surface. FSIS IPP perform routine verification activities (i.e., HACCP, sanitation, and labeling) to verify that the design and execution of the establishment\u2019s programs meet the requirements of 9 CFR 430.4. For example, FSIS IPP perform sanitation verification activities at least twice per production week in RTE establishments to verify that establishments design and execute their Sanitation SOPs to prevent contamination of food contact surfaces or adulteration of RTE products with Lm and other pathogens prior to and during operations in the post-lethality environment. FSIS IPP also perform routine HACCP verification activities at least twice per production week to verify that establishments design and execute their HACCP plan effectively to control contamination of food contact surfaces or adulteration of RTE products with Lm and other pathogens. This includes verifying that establishments that use post-lethality treatments to reduce or eliminate microorganisms on the product include the post-lethality treatment in their HACCP plan (as required per 9 CFR 430.4). FSIS IPP also perform quarterly hazard analysis verification activities to verify that establishments producing RTE products are identifying and", "FSIS Responses to the SRT (v2019-001) 40 adequately addressing Lm and other pathogens in their hazard analyses. In addition, FSIS IPP perform at least one general labeling verification activity per production week to verify that product that is labeled as RTE product meets the requirements in 9 CFR 318.17, 318.23, or 381.150. Additional information on the routine verification activities

used by FSIS IPP to verify establishment compliance with 9 CFR 430.4, including instructions to FSIS IPP on how and when to document noncompliance and take enforcement actions, can be found in FSIS Directive 10,240.4 Verification Activities for the Listeria monocytogenes (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program. Instructions to FSIS IPP on how to review establishment testing data are provided in FSIS Directive 5000.2 Review of Establishment Data by Inspection Personnel. Furthermore, as part of these routine HACCP verification activities, FSIS IPP verify that establishments perform ongoing verification activities to ensure their food safety inspection system is functioning as intended and continues to support decisions made in their hazard analysis, such as conducting ongoing establishment testing for Lm (or an indicator organism) on food contact surfaces in the post-lethality processing environment (as required by certain Listeria alternatives) to demonstrate that their HACCP and sanitation systems are working effectively to eliminate or reduce Lm to a non-detectable level. FSIS IPP review establishment testing data and results at least once per production week for trend analysis. When reviewing establishment testing data, FSIS IPP verify that establishments that received positive Lm (or an indicator organism) results from their establishment testing program for food contact surfaces perform corrective actions per 9 CFR 416.15 or 9 CFR 417.3. For example, in establishments producing RTE products under Alternative 3, FSIS IPP verify that establishments perform follow-up sampling on food contact surfaces for Lm or an indicator organism in accordance with 9 CFR 430.4(b)(3)(ii)(A). FSIS considers post-lethality exposed RTE product that passed over the food contact surface that tested positive for Lm through establishment testing, or the product that tested positive for Lm through establishment testing, to be adulterated per 21 USC 601(m)(1). If the establishment fails to perform adequate corrective actions in response to positive Lm establishment test results, and the product is shipped into commerce, FSIS can take enforcement actions per (9 CFR 500). Instructions to FSIS IPP on how to review establishment testing data are provided in FSIS Directive 5000.2 Review of Establishment Data by Inspection Personnel. Instructions to FSIS IPP on how to verify adequate corrective actions in the event of positive establishment test results are provided in FSIS Directive 10,240.4 Verification Activities for the Listeria monocytogenes (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program. In addition to verifying compliance with the Lm requirements in 9 CFR 430.4 for RTE products, FSIS IPP perform HACCP verification activities to verify that establishments employ adequate lethality and stabilization procedures to meet the lethality performance standards for Salmonella in 9 CFR 318.17(a)(1) (meat) and 9 CFR 381.150(a)(1) (poultry). FSIS IPP also verify that establishments comply with the stabilization requirements (to prevent the growth of Clostridium botulinum (C. botulinum) and limit the growth of Clostridium perfringens (C. perfringens) in RTE products) in 9 CFR 318.17(a)(2) and 318.23(c)(1)(meat), and 9 CFR 381.150(a)(2)(poultry). Additionally, FSIS recommends a 5.0-log<sub>10</sub> reduction of E. coli O157:H7 in RTE fermented products containing beef. Instructions to FSIS IPP on how to verify that an establishment's lethality and stabilization procedures meet regulatory requirements, including the actions to take in the event of a heating or cooling deviation, are provided in FSIS Directive 7111.1 Verification Procedures for Lethality and Stabilization. Furthermore, if FSIS determines that an establishment produced and shipped adulterated RTE products containing pathogens that are injurious to health due to inadequate lethality or stabilization procedures (21 USC 601(m)(1) and 453(g)(1)), or that an establishment has shipped products that were

prepared, packed, or held under insanitary conditions (21 U.S.C. 601(m)(4) and 453(g)(4)), FSIS can take enforcement actions per 9 CFR 500. Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology. Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in "FSIS Responses to the SRT (v2019-001) 41 FSIS Directive 8010.5 Case Referral and Disposition. FSIS performs government verification testing for Lm and Salmonella in both post-lethality exposed and non-post-lethality exposed RTE products. These product samples are collected and submitted by FSIS IPP under the RTE routine sampling program. Additional information on the scheduling criteria FSIS uses to assign samples under the RTE routine sampling program can be found under Updates to Random and Risk-based Scheduling Criteria for the Ready-to-Eat (RTE) Product Routine Sampling Program. In addition, FSIS performs verification testing for Lm in product, and on food contact surfaces and environmental (non-food contact) surfaces under its routine risk-based Lm (RLm) sampling program; and verification testing for Lm and Salmonella on product, food contact surfaces, and environmental surfaces, in response to positive government verification results or a documented change in an establishment's production process that may impact public health, under its Intensified Verification Testing (IVT) program. Further, when performing government verification testing for Lm and Salmonella in RTE products, FSIS considers the sampled lot to be the product produced from clean-up to clean-up (i.e., a product lot separated by complete cleaning and sanitizing), unless the establishment has another supportable lot definition. Additionally, FSIS requires establishments to hold or control RTE product tested by FSIS for Lm or Salmonella, and RTE product that has passed over food contact surfaces tested by FSIS for Lm or Salmonella, pending acceptable FSIS test results (76 FRN 19955). (NOTE: FSIS discontinued testing RTE samples for the presence of E. coli O157:H7 in dried/semi-dried, fermented sausages and cooked meat patties after an analysis showed that testing over 10,000 such products over a nine-year period yielded no E. coli O157:H7 positive samples.) Instructions to FSIS IPP on how to collect and submit official government verification samples for Lm and Salmonella in RTE products, including verifying that the establishment holds or retains control of the RTE product pending acceptable FSIS test results, can be found in FSIS Directive 10,240.4 Verification Activities for the Listeria monocytogenes (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program. Furthermore, if an official government verification test result is confirmed positive for Lm or Salmonella in RTE product, FSIS IPP verify that establishments take adequate corrective actions per 9 CFR 416.15 or 417.3. In addition, FSIS will conduct a public health risk evaluation, to assess and analyze the establishment's food safety system and determine if an immediate enforcement action or food safety assessment (including sampling under the IVT testing program) is necessary. If necessary, FSIS will schedule a food safety assessment and verify whether the establishment is able to produce safe and wholesome RTE meat or poultry products in accordance with FSIS statutory and regulatory requirements. During the food safety assessment, FSIS EIAOs review the establishment's food safety system as a whole, including the design of the establishment's HACCP system, supporting documentation for decisions made in the hazard analysis (e.g., validation documents), the design and implementation of the establishment's sampling and testing programs, and

the establishment's reaction to sampling results. Further, during food safety assessments, FSIS EIAOs conduct routine RLm sampling and IVT sampling (in response to a positive government verification results for Lm or Salmonella or a documented change in an establishment's production process that may impact public health). FSIS EIAOs also verify that establishments take adequate corrective actions in the event of a positive official government test result for Lm and Salmonella (either food contact surface or product). If an establishment does not perform adequate corrective actions in the event of a positive official government test result for Lm or Salmonella on food contact surfaces or in product, and the postlethality exposed RTE product that passed over the food contact surface that tested positive for Lm or Salmonella enters commerce, or the product that tested positive for Lm or Salmonella enters commerce, FSIS can take enforcement actions (9 CFR 500). Instructions to FSIS EIAOs on how to conduct public health risk evaluations and perform food safety assessments are provided in FSIS Directive 5100.4 Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology and FSIS Directive 5100.1 Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology. Instructions to FSIS EIAOs on how to collect and submit samples under the RLm testing program are provided under FSIS Directive 10,240.5", "FSIS Responses to the SRT (v2019-001) 42 Verification Procedures for Enforcement, Investigations and Analysis Officers (EIAOs) for the Listeria monocytogenes (Lm) Regulation and Routine Risk-Based Listeria monocytogenes (RLm) Sampling Program. Instructions to FSIS EIAOs on how to collect and submit samples under the IVT testing program are provided under FSIS Directive 10,300.1 Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces and Environmental Surfaces for Listeria Monocytogenes. In egg products establishments, FSIS collects and tests dried, frozen, and liquid pasteurized egg products for Lm and Salmonella under its egg monitoring (EM) sampling program as described in FSIS Directive 10,210.1 Unified Sampling Form. In addition, egg products establishments are required to submit pasteurized egg products and all lots of dried egg products to an FSIS approved laboratory for Salmonella testing and analysis. Any product found to be Salmonella positive is required to either be reprocessed, pasteurized, and analyzed for the presence of Salmonella, or denatured (9 CFR 590.420(c), 590.422, 590.504(o)(1), and 590.580). Instructions to FSIS IPP on how to verify that establishments are complying with their Salmonella surveillance program are provided in FSIS Directive 10,230.4 Salmonella Surveillance Program for Liquid and Frozen Egg Products. Instructions to FSIS IPP on how to perform routine verification activities (e.g., sanitation, labeling) in egg products establishments can be found in FSIS Directive 5030.1 Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants. Information on the proposed number of Lm and Salmonella official government verification samples for FY17 for RTE meat and poultry products and egg products, food contact surfaces, and environmental surfaces, the actual number of samples collected and analyzed for FY17, and the proposed number of samples for FY18 can be found in the FSIS Annual Sampling Program Plan. Information on FSIS's Lm and Salmonella sampling program for imported RTE meat and poultry products and egg products can also be found in the FSIS Annual Sampling Program Plan. FSIS's validated analytical methods for isolating and identifying Lm (Chapter 8) and Salmonella (Chapter 4) in RTE meat and poultry products and egg products are contained in the MLG. Lastly, further information on

FSIS's sampling program for Lm and Salmonella in RTE meat and poultry products, including results for 2017, can be found under Testing Program for RTE Meat and Poultry on the FSIS website; and further information on FSIS's EM sampling program for egg products, including results for 2017, can be found under Testing Program for Pasteurized Egg Products on the FSIS website.

31. How does the CCA ensure that RTE shelf-stable meat and poultry products that do not rely on cooking alone to achieve lethality, such as fermented, acidified, salt-cured or dried meat and poultry products, achieve adequate lethality and shelf-stability to prevent contamination with microbiological pathogens or their toxins (e.g., Salmonella, Lm and STEC (in beef products), C. perfringens, C. botulinum, and Staphylococcus aureus (S. aureus))? FSIS maintains lethality performance standards for Salmonella in RTE products in 9 CFR 318.17(a)(1) (meat) and 9 CFR 381.150(a)(1) (poultry); and stabilization performance standards to prevent the growth of C. botulinum and limit the growth of C. perfringens in RTE products in 9 CFR 318.17(a)(2) and 318.23(c)(1)(meat), and 9 CFR 381.150(a)(2)(poultry). In RTE shelf-stable meat and poultry products, FSIS considers achieving at least a 5-log reduction in Salmonella and STEC (in beef products) to be a sufficient pathogen reduction target in protecting public health.

Further, FSIS requires all establishments to conduct a hazard analysis to identify any food safety hazards that are reasonably likely to occur during the production process (9 CFR 417.2). In establishments producing RTE shelf-stable meat and poultry products that do not rely on cooking alone to achieve lethality, such as fermented, acidified, salt-cured or dried meat and poultry products, FSIS IPP perform routine HACCP verification activities (both recordkeeping and observation) and quarterly hazard analysis verification activities to verify that establishments are effectively implementing their HACCP system to control pathogens during the lethality and stabilization processes.", "FSIS Responses to the SRT (v2019-001) 43 In particular, FSIS IPP verify during routine HACCP verification activities that establishments have included in their HACCP plan the overall performance standard or pathogen reduction target in the multiple processing steps (e.g., a 2-log reduction of Salmonella on source materials through antimicrobial intervention, 2-log reduction of Salmonella by marinating product in a low pH marinade, and 2-log reduction of Salmonella through drying achieve the pathogen reduction target of at least a 5log reduction in Salmonella in shelf-stable meat and poultry products). FSIS IPP also verify during the quarterly hazard analysis verification activity that establishments maintain adequate scientific support that the lethality steps combined achieve the performance standard or target. For stabilization, FSIS IPP verify during the quarterly hazard analysis verification activity that establishments have identified and maintain supporting documentation for the amount of growth of S. aureus they will allow during processing (e.g., during fermentation\acidification, salt-curing, or drying) and during storage under ambient conditions (e.g., up to 2-logs growth during processing and no growth during storage). In addition, FSIS IPP verify during routine HACCP verification activities that establishments continue to meet the critical operational parameters identified in their HACCP plans to prevent the growth of spore-formers during the stabilization process (e.g., a pH \u2264 4.6 before cooling or water activity (aw) <0.93 before cooling to prevent the growth of C. perfringens and C. botulinum). Instructions to FSIS IPP on how to perform HACCP verification activities in establishments that achieve lethality and stabilization by processes, such as fermentation\acidification, salt-curing, and drying, including how and when to document noncompliance and take enforcement measures, can be found in FSIS Directive 7111.1

Verification Procedures for Lethality and Stabilization. 32. How does the CCA ensure that heat-treated not ready-to-eat (NRTE) meat and poultry products are properly stabilized to prevent outgrowth of microbiological pathogens or their toxins (i.e., *C. perfringens* and *C. botulinum*), and properly labeled to ensure adequate cooking by the consumer? FSIS maintains stabilization performance standards for NRTE partially cooked and char-marked meat patties in 9 CFR 318.23(c)(1) and partially cooked poultry breakfast strips (e.g. turkey bacon) in 9 CFR 381.150(b). In establishments producing other NRTE, heat-treated, not fully-cooked products, FSIS verifies that establishments consider the food safety hazards that are reasonably likely to occur in their stabilization processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level (9 CFR 417.2). In establishments producing heat-treated NRTE meat and poultry products, FSIS IPP perform routine HACCP verification activities (both recordkeeping and observation) and quarterly hazard analysis verification activities to verify that establishments are effectively implementing their HACCP system to control pathogens during the stabilization processes. Instructions to FSIS IPP on how to verify that establishments are preventing the outgrowth of microbiological pathogens or their toxins during the stabilization of NRTE meat and poultry products, including how to verify adequate corrective actions in the event of a cooling deviation and how and when to document noncompliance, can be found in FSIS Directive 7111.1 Verification Procedures for Lethality and Stabilization. If FSIS determines that the establishment did not take adequate corrective actions and shipped heat-treated NRTE products that were prepared, packed, or held under insanitary conditions (21 U.S.C. 601(m)(4) and 453(g)(4)), FSIS can take enforcement actions per 9 CFR 500. Furthermore, FSIS IPP perform routine labeling verification activities to verify the following: NRTE products are labeled with safe handling instructions as required per 9 CFR 317.2(l) (meat) and 9 CFR 381.125(b) (poultry); and NRTE products that are not shelf-stable are labeled with special handling statements, such as keep refrigerated or keep frozen as required per 9 CFR 317.2(k) (meat) and 381.125(b) (poultry). Instructions to FSIS IPP on how to perform labeling verification activities for NRTE meat and poultry products, including how and when to document noncompliance and take", "FSIS Responses to the SRT (v2019-001) 44 enforcement measures, are provided in FSIS Directive 7221.1 Prior Labeling Approval. 33. How does the CCA ensure that the processing of canned meat and poultry products addresses *C. botulinum* and the finished products are commercially sterile? FSIS ensures that thermally processed\commercially sterile meat and poultry products are free of microorganisms capable of growing in non-refrigerated conditions in storage and distribution (over 50\u00b0F or 10\u00b0C) by verifying that establishments employ either HACCP to control microbiological food safety hazards (9 CFR 417), or follow the regulatory \u201ccanning\u201d requirements in 9 CFR 431 to prevent microbiological contamination from occurring during the thermal process. (NOTE: FSIS recently consolidated its canning regulations for meat (9 CFR 318, Subpart G) and poultry (9 CFR 381, Subpart X) into one section in 9 CFR. These regulations are now located in 9 CFR 431 as outlined in 83 FR 25302 \u201cElimination of Trichinae Control Regulations and Consolidation of Thermally Processed, Commercially Sterile Regulations\u201d.) In establishments that choose to address the microbiological food safety hazards in the thermal process through their HACCP system, FSIS IPP perform routine HACCP verification activities to verify compliance with all 9 CFR 417 regulatory requirements. Instructions to FSIS IPP on how to verify HACCP regulatory compliance, including how and when to document noncompliance and take enforcement

measures, are provided in FSIS Directive 5000.1 Verifying an Establishment's Food Safety System. 9 CFR 431.1 provides the regulatory definitions for thermal process, a canned product, and an abnormal container. Thermal process is defined as the heat treatment necessary to achieve shelf stability as determined by the establishment's processing authority. It is quantified in terms of time and temperature, or minimum product temperature. Canned product is defined as a meat or poultry product with a water activity above 0.85 that receives a thermal process either before or after being packed in a hermetically sealed container. An abnormal container is defined as a container with any sign of swelling or product leakage or any evidence that the contents of the unopened container may be spoiled. When establishments follow the regulatory requirements in 9 CFR 431, this can be used to support that a microbiological hazard is not reasonably likely to occur (9 CFR 417.5(a)(1)). Thus, establishments are not required to address microbiological hazards in their HACCP plan (9 CFR 417.2(b)(3)). However, establishments are still required to conduct a hazard analysis per 9 CFR 417.2 to address any chemical or physical food safety hazards that could occur during their process. FSIS IPP verify that establishments continue to support their decision in the hazard analysis that microbiological contamination is not reasonably likely to occur, by performing routine verification activities to verify compliance with all FSIS canning requirements, including, but not limited to, the following: posting the process schedules in a location visible to the operator and the government inspector; maintaining a process schedule appropriate for the product and type of container being used; no unauthorized change in product formulation, equipment, or treatment that was not already incorporated in the process schedule; initial temperature was measured and recorded by the establishment; all critical factors associated with the production lot were met; required processing and production information was correctly recorded; any process deviation was handled appropriately; only normal containers were selected for incubation (if applicable), and only normal appearing containers were shipped from the establishment, as determined by an appropriate finished product inspection program; and the establishment reviewed all processing and production records no later than one working day after the actual process, to verify the completeness of the records and to determine whether all products received the process schedule. All records including the temperature/time recorder charts and critical factor control records are signed or initialed and dated by the person conducting the review. The 9 CFR 431 regulations also specify the corrective actions to be taken whenever there is a deviation", "FSIS Responses to the SRT (v2019-001) 45 from the process schedule (9 CFR 431.9). Instructions to FSIS IPP on how to verify compliance with 9 CFR 431 canning regulations, including how and when to document noncompliance and verify appropriate corrective actions, are provided in FSIS Directive 7530.2 Verification Activities in Canning Operations that Choose to Follow the Canning Regulations. Instructions to IPP on how to handle a process deviation or abnormal container of thermally processed/ commercially sterile product are provided in FSIS Directive 7530.1 Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile Canned Product. Instructions to FSIS IPP on how to examine the condition of canned product containers are provided in FSIS Directive 7520.2 Procedures for Condition of Canned Product Container Examination. Lastly, if FSIS determines that an establishment has shipped adulterated thermally processed/commercially sterile products into commerce, FSIS can take enforcement actions per 9 CFR 500. Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS

OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology. Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in FSIS Directive 8010.5 Case Referral and Disposition."]}, {"file\_name": "FSIS\_GD\_2019\_0018", "title": "FSIS Guidance for a Suggested Reporting Table for the Certified Establishment List", "num": "FSIS-GD-2019-0018", "id": "b4902b84b851946a1129e9a8bfb677d1b678137bbd3eba1d18f4b41fa8ca3c78", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-03/Suggested%20Reporting%20Table%20Certified%20Establishment%20List.pdf", "type": "pdf", "n\_pages": 2, "word\_count": 1290, "text\_by\_page": ["1 FSIS Guidance for a Suggested Reporting Table for the Certified Establishment List By May 18th of each year, the Central Competent Authorities (CCAs) of countries wishing to maintain on-going equivalence and continue actively exporting meat, poultry, or egg products to the United States (U.S.) are required to provide the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) an up-to-date list of all certified establishments used in the production of products eligible for export to the U.S. Therefore, if the production chain involves more than one establishment (e.g., beef is slaughtered at one establishment, further processed at a different establishment, packaged and labeled at yet another establishment, and then exported to the U.S. from a different establishment), each establishment in the production chain, including the establishment providing the raw source material and the storage facility from where the product is exported, must be listed on the certified establishment list. Furthermore, countries that are not eligible to export raw product directly to the U.S. (e.g., due to USDA Animal and Plant Health Inspection Service (APHIS) animal disease requirements), but are eligible to use their own raw source materials to produce processed products are required to certify and list the establishments providing the raw source materials. Lastly, when listing an establishment that provides raw source material, please clearly identify the establishment as a source establishment on the certified establishment list. The reporting table below may be used to assist CCAs with providing the required information to FSIS by May 18th of each year. The format of the table is optional; however, the information noted with an asterisk (\*) is required to be sent to FSIS annually. For each certified establishment, CCAs should only include products that the country is currently eligible to export to the U.S., including raw source materials for further processing. In addition, if your country is prevented from exporting certain meat, poultry, or egg products to the U.S. due to an APHIS animal disease requirement, FSIS requests that the CCA clearly identify the product categories and product groups that each certified establishment intends to export to the U.S. To view which products your country is currently eligible to export to the U.S., refer to FSIS Import Library- Eligible Countries and Products. For a list of product categories and product groups, please refer to the FSIS Product Categorization Guide. Certified establishments that are no longer eligible to export products to the U.S. must be identified as delisted on the list provided to FSIS. Furthermore, FSIS requests that CCAs inform FSIS of any establishment delisting within 90 days. CCAs can submit the required information to FSIS by either uploading it into our Public Health Information System (PHIS) under question 4 of the 2019 self-reporting tool (SRT), or by submitting it to our International"]}]

Coordination Executive at: US Department of Agriculture Food Safety and Inspection Service, Office of International Coordination, Room 3143 South Building, 1400 Independence Ave SW, Washington D.C. 20250-3700 E-mail: InternationalCoordination@usda.gov Date \u00b9\*

Eligibility Status \u00b2\* Establishment Number\* Establishment Name\* Establishment Address\* Type(s) of Operation\u00b3\* Process Category\u2074\* Species\u2075 \* Product Category Product Group MMI\DD\YYYY 1. Date \u2013 The date of an establishment\u2019s initial certification, delisting, or relisting. 2. Eligibility Status \u2013 If an establishment listed on the previous year\u2019s certified establishment list remains eligible to export products to the U.S., please leave this field blank. \u2022 New - Establishments that are newly certified as eligible to export products to the U.S. that were not previously certified as eligible to export products to the U.S. \u2022 Delisted \u2013 Establishments that were previously certified as eligible to export products to the U.S. and are no longer eligible to export products to the U.S. \u2022 Relisted \u2013 Establishments that were previously delisted and have been relisted as certified as eligible to export products to the U.S. 3. Type(s) of Operation \u2013 Slaughterhouse, Non-Slaughter Processing, Egg Processing, Cold Storage, Exporting Warehouse, or Source Establishment. \u2022 Slaughterhouse \u2013 Establishments where healthy, live animals are humanely slaughtered under sanitary conditions to produce meat or poultry products for human consumption. \u2022 In slaughter operations, FSIS requires continuous government inspection during slaughter activities to ensure that each and every livestock carcass, head, and viscera and each and every poultry carcass and viscera are inspected. \u2022 Non-Slaughter Processing - Operations include all non-slaughter activities, including but not limited to, boning, cutting, slicing, grinding, injecting, pumping, filleting, breading, adding ingredients through other mechanical means, formulating, cooking, smoking, cooling, assembling, and packaging.", "FSIS Guidance for a Suggested Reporting Table for the Certified Establishment List 2 \u2022 In processing operations (i.e., non-slaughter), FSIS requires that a government inspector be on the premises and performing inspection activities at least once per production shift during processing operations. The requirement for government inspection once per production shift during processing operations is not the same as inspection once daily; therefore, if an establishment has more than one production shift per day during which it produces product for export to the U.S., a government inspector must be present at least once during each production shift. \u2022 Egg Processing - Manufacturing of egg products, including breaking eggs, filtering, mixing, blending, pasteurizing, stabilizing, cooling, freezing, drying, or packaging egg products at certified establishments. \u2022 Cold Storage \u2013 Facility that receives and stores meat, poultry, or egg products from certified establishments and maintains products under refrigeration until export to the U.S. \u2022 Exporting Warehouse \u2013 Facility that receives and stores meat, poultry, or egg products from certified establishments until export to the U.S. Additionally, the facility where export verification and certification services for exports are provided. \u2022 Source Establishment - Slaughter establishment that provides raw source materials to certified establishments for the production of processed products intended for export to the U.S. Source establishments are not eligible to export product directly to the U.S. due to disease restrictions, regionalization, product ineligibility, or other reasons. However, source establishments must meet all U.S. requirements, be certified by the CCA, and be identified as a source establishment on the certified establishment list. 4. Process Category \u2013 1. Raw \u2013 Non Intact 4. Not Heat Treated - Shelf Stable 7. Heat

Treated - Not Fully Cooked - Not Shelf Stable 2. Raw - Intact 5. Heat Treated - Shelf Stable 8. Product with Secondary Inhibitors - Not Shelf Stable 3. Thermally Processed - Commercially Sterile 6. Fully Cooked - Not Shelf Stable 9. Eggs\Egg Products For the purposes of this document the term \u201cprocessed\u201d refers to raw meat or poultry product that has been modified through an additional processing step. Methods of processing meat and poultry products include, but are not limited to, cooking, salting, curing, aging, fermentation, and smoking. Simple mechanical processes (sometimes referred to as further processing) such as cutting, grinding, or mixing of raw meat or poultry product are not included in this definition. \u2022 Raw meat and poultry products may be produced and certified under the following FSIS Process Categories: \u2022 Raw Product - Non-Intact and \u2022 Raw Product \u2013 Intact. \u2022 Processed meat and poultry products may be produced and certified under the following FSIS Process Categories: \u2022 Thermally Processed - Commercially Sterile, \u2022 Not Heat Treated - Shelf Stable, \u2022 Heat Treated - Shelf Stable, \u2022 Fully Cooked - Not Shelf Stable, \u2022 Heat Treated - Not Fully Cooked -Not Shelf Stable, and \u2022 Products with Secondary Inhibitors - Not Shelf Stable. The term \"egg products\" refers to eggs that are removed from their shells for processing. 5. Species \u2013 F: fish of the order Siluriformes O: lamb\mutton (ovine) SQ: squab B: beef (bovine) P: pork (porcine) EM: emu V: veal D: duck OS: ostrich CH: chicken GO: goose R: rhea C: goat (caprine) GU: guinea T: turkey

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Signature

Official Title Date"]},{"file\_name":"FSIS\_GD\_2019\_0019","title":"FSIS Guidance on Suggested Reporting Tables of the Government Microbiological Sampling and Testing Program","num":"FSIS-GD-2019-0019","id":"e194732cd45c567525e5e3f6384dbe375b457b1c1f0011116f066a7ab3474bfe","corpus":"fsis\_guidelines","source\_page\_url":"https:\Vwww.fsis.usda.gov\policy\fsis-guidelines","url":"https:\Vwww.fsis.usda.gov\sites\default\files\import\Suggested-Reporting-Tables-Government-Microbiological-Sampling-Testing-Program.pdf","type":"pdf","n\_pages":4,"word\_count":1954,"text\_by\_page":["FSIS Guidance on Suggested Reporting Tables of the Government Microbiological Sampling and Testing Program  
NOTE: This document is updated from the 2018 version but does not contain substantive changes to the suggested reporting format. FSIS requests that all eligible countries submit their 2019 Microbiological Sampling and Testing Program Plan and 2018 Microbiological Sampling and Testing Program Results. The tables included in this guidance are intended to assist Central Competent Authorities (CCAs) in providing FSIS with the information requested in FSIS\u2019s SelfReporting Tool (SRT) question, Government Microbiological Testing Programs. FSIS is providing suggested reporting table formats for the annual data submissions of the 2019 Microbiological Sampling and Testing Program Plan and 2018 Microbiological Sampling and Testing Program Results that are due to FSIS by May 18, 2019. The use of these reporting table formats is optional; FSIS will review information submitted in other formats that incorporate the necessary information. The information that should be submitted includes: \u2022 2019 Microbiological Sampling and Testing Program Plan (Tables 1 and 2 \u2013 suggested reporting format) 1) The types of products or production classes and the types of microbiological analyses that are included in government verification sampling programs for those products or production classes 2) The method\type of sample collection 3) The test portion that is

analyzed for each type of sample that is collected 4) The microbiological methodology used to analyze the sample, including the screening method used as part of detection, if applicable 5) Planned frequency of testing for eligible establishments for each of the products or process categories \u2022 2018 Microbiological Sampling and Testing Program Results (Table 3 \u2013 suggested reporting format) 1) The actual number of samples analyzed for each product type or production class for each pathogen 2) The established criteria by which the analysis result is evaluated for compliance (e.g., number of allowed positives) 3) Regarding follow-up to unacceptable test results from government testing, submit a list of eligible establishments with unacceptable sampling results, including the number of samples analyzed, the number of unacceptable results, and the CCA\u2019s enforcement strategy in response to unacceptable results. Regarding the 2019 Microbiological Sampling and Testing Program Plan, FSIS is including the attachment, FSIS Government Microbiological Sampling and Testing Program, as a reference. This attachment includes sampling and testing frequencies for FSIS government testing programs. The 2019 Microbiological Sampling and Testing Program Plan and the 2018 Microbiological Sampling and Testing Program Results can be submitted to FSIS by either uploading it into our Public Health Information System (PHIS) under SRT question, Government Microbiological Testing Programs, or by submitting it to our International Coordination Executive at: US Department of Agriculture Food Safety and Inspection Service Office of International Coordination Room 3143, South Building 1400 Independence Ave SW Washington D.C. 20250-3700 Fax: 1-202-690-3856 E-mail: InternationalCoordination@fsis.usda.gov", "FSIS Guidance on Suggested Reporting Tables for the Government Microbiological Sampling and Testing Program NOTE: This document is updated from the 2018 version but does not contain substantive changes to the suggested reporting format. Table 1: Suggested Reporting Table for the 2019 Government Microbiological Sampling and Testing Program Annual Plan. Please include the list of products or process categories for which the CCA is currently equivalent or seeking equivalence and include a description of the method of sample collection, the test portion of the collected sample that is analyzed by the laboratory, and the analytical methods that are used by the laboratory for analysis of the samples, including reference to the screening method, if applicable. (The information provided in the table is for illustrative purposes only)

Product\ Process Categories	Pathogen(s)	Targeted Sampling Procedure	Test Portion
Criteria	1	3	4
3	4	5	1
4	5	2	3
5	1	3	4
1	2	4	5
2	3	5	1
3	4	1	2
4	5	2	3
5	1	3	4

Product\ Process Categories1 Pathogen(s) Targeted Sampling Procedure Test Portion2 Criteria3 Analytical Detection Methods4 Analytical Screen Methods5 Raw chicken Salmonella Rinsate collected 30 mL N=51 MLG Chapter 4.10 provides MLG Chapter 4.10 includes a rapid carcass from 1 carcass with 400 mL neutralizing buffered peptone water rinsate c=5 instructions for sample preparation, enrichment, isolation, and confirmation of Salmonella in raw chicken carcass rinsates. molecular screen test (3M\u2122 Molecular Detection Assay 2 \u2013 Salmonella kit) that is used in combination with a culture confirmation method for detection of Salmonella in raw chicken carcass rinsates. Pasteurized Salmonella Randomly collect an 100 mL N=1 MLG Chapter 4.10 provides MLG Chapter 4.10 includes a rapid liquid and dried intact final package (liquid) c=0 instructions for sample preparation, molecular screen test (3M\u2122 Molecular egg products or at least 150 grams of each egg product category manufactured by the establishment or 100 grams (dried) enrichment, isolation, and confirmation of Salmonella in pasteurized liquid and dried egg products. Detection Assay 2 \u2013 Salmonella kit) that is used in combination with a culture confirmation method for detection of Salmonella in pasteurized liquid and dried egg products. Ready-to-Eat Listeria Randomly collect at 25 grams N=1 MLG

Chapter 8.11 provides MLG Chapter 8.11 includes a rapid (RTE) meat and moncytogenes least two pounds of c=0 instructions for sample preparation, molecular screen test (3M\u2122 Molecular poultry products finished product in an intact package enrichment, isolation, and confirmation of Listeria moncytogenes in RTE meat and poultry products. Detection Assay 2 \u2013 Listeria moncytogenes kit) that is used in combination with a culture confirmation method for detection of Listeria moncytogenes in RTE meat and poultry products. Raw beef\veal E. coli O157:H7 N60 sample (60 Entire N=1 MLG Chapter 5C.00 provides MLG Chapter 5C.00 includes a rapid (raw beef and non-O157 pieces trimmed from N60 c=0 instructions for sample preparation, molecular screen test (Bio-Rad iQ-Check\u2122 manufacturing STEC, including external tissue sample enrichment, isolation, and VirX kit and SerO kits) that is used in trimmings) O26, O45, O103, O111, O121, O145 collected throughout production lot) (~325375 grams) confirmation of Escherichia coli O157:H7 and non-O157 Shiga toxinproducing E. coli (non-O157 STEC) in raw beef and veal products. combination with culture confirmation methods for detection of E. coli O157:H7 and non-O157 STEC in raw beef and veal products. 1 List the product categories: (1) beef\veal; (2) lamb\mutton; (3) goat; (4) pork; (5) poultry\ratites; (6) egg products; (7) Siluriformes fish and process categories: (a) raw (e.g., intact and non-intact raw products); (b) processed (e.g., ready-to-eat, which may include shelf stable, not-shelf stable, and commercially sterile products) 2 Enter the portion of the collected sample that is tested (e.g., 30 mL rinsate, 325 grams), or sampling method (e.g., sponge, swab) 3 Please describe standard in terms of (c) number of allowable positive results when (N) number of samples are analyzed. 4 List the validated laboratory procedure (e.g., MLG Chapter 4.10) that is used by analysts in the laboratory to detect microbiological targets, including procedures for sample preparation, enrichment when appropriate, isolation and culture-based confirmation. 5 If a screen method is used as part of the detection method, please include reference to a manufacturer name (e.g., 3M\u2122 Molecular Detection Assay 2 \u2013 Salmonella kit ), validation approval (e.g., Association of Analytical Communities (AOAC) Performance Tested Method #091501) and\or validated laboratory procedure (e.g., MLG Chapter 4.10) that is used by analysts in the laboratory.", "FSIS Guidance on Suggested Reporting Tables for the Government Microbiological Sampling and Testing Program NOTE: This document is updated from the 2018 version but does not contain substantive changes to the suggested reporting format. Table 2: Suggested Reporting Table for the 2019 Government Microbiological Sampling and Testing Program Annual Plan. The data reported each year should include the number of samples planned for analysis for each product type\process category and for each of the different pathogen analyses that are conducted. Additionally, the information should include the number of eligible establishments (by production volume or by volume of products exported to the US) and the total number of samples planned for those establishments in each of those categories. (The information provided in the table is for illustrative purposes only) Product Type\Process Category Pathogen Target(s) 2019 Planned Microbiological Sampling Frequency6 Very Small Est (<1,000 lbs.\day) Small Est (1,001-50,000 lbs.\day) Medium Est (50,001-250,000 lbs.\day) Large Est (>250,000 lbs.\day) # establishments exporting to US # samples\yr Raw ground beef\veal E. coli O157:H7 10 120 10 240 10 360 10 480 Salmonella 10 120 10 240 10 360 10 480 Raw beef\veal (raw beef manufacturing trimmings) E. coli O157:H7 10 120 10

240 10 360 10 480 Salmonella 10 120 10 240 10 360 10 480 Non-O157 STEC, including O26, O45, O103, O111, O121, O145 10 120 10 240 10 360 10 480 6 The volume production ranges listed are based on pounds of a specific product type or process category produced per day by a single establishment. Alternatively, the CCA may choose to use the volume of products that are exported to the US to categorize establishments eligible to export in order to determine the appropriate frequency for testing. If the frequency of sampling is based on volume of products exported to the US, the corresponding volume ranges would be: Very Small Est (<20,000 lbs./month exported to the US), Small Est (20,001-100,000 lbs./month exported to the US), Medium Est (100,001-5,000,000 lbs./month exported to the US), Large Est (>5,000,000 lbs./month exported to the US)." , "FSIS Guidance on Suggested Reporting Tables for the Government Microbiological Sampling and Testing Program NOTE: This document is updated from the 2018 version but does not contain substantive changes to the suggested reporting format. Table 3: Suggested Reporting Table for the 2018 Government Microbiological Sampling and Testing Program Annual Results. This information can be formatted similarly to the current year\u2019s proposed sampling plan (Table 2) but should include actual sampling numbers for the previous year\u2019s Government Microbiological Sampling and Testing Program. The data reported each year should include the actual number of samples analyzed for each product type\process category and for each of the different pathogen analyses that are conducted. Additionally, the information should include the number of establishments that were sampled, preferably grouped by production volume, or by volume of products exported to the US, and the total number of samples collected and analyzed at each of those establishments in the previous year. If there were positives that exceeded the criteria as outlined in the Government Microbiological Sampling and Testing Program Annual Plan (Table 1), a list of eligible establishments that failed to meet the criteria and a description of the CCA\u2019s enforcement strategy in response to unacceptable results should also be included. (The information provided in the table is for illustrative purposes only) Product Type\Process Category Pathogen Target(s) 2018 Microbiological Sampling Results7 Very Small Est (<1,000 lbs./day) Small Est (1,001-50,000 lbs./day) Medium Est (50,001-250,000 lbs./day) Large Est (>250,000 lbs./day) # establishments exporting to US # samples\yr. # establishments exporting to US # samples\yr. # establishments exporting to US # samples\yr # establishments exporting to US # samples\yr Raw ground beef\veal E. coli O157:H7 9 105 4 96 10 360 7 335 Salmonella 9 105 4 96 10 360 7 335 Raw beef\veal (raw beef manufacturing trimmings) E. coli O157:H7 10 120 10 240 5 180 10 480 Salmonella 10 120 10 240 5 180 10 480 Non-O157 STEC, including O26, O45, O103, O111, O121, O145 10 120 10 240 5 180 10 480 7 The volume production ranges listed are based on pounds of a specific product type or process category produced per day by a single establishment. Alternatively, the CCA may choose to use the volume of products that are exported to the US to categorize establishments eligible to export in order to determine the appropriate frequency for testing. If the frequency of sampling is based on volume of products exported to the US, the corresponding volume ranges would be: Very Small Est (<20,000 lbs./month exported to the US), Small Est (20,001-100,000 lbs./month exported to the US), Medium Est (100,001-5,000,000 lbs./month exported to the US), Large Est (>5,000,000 lbs./month exported to the US)." ]}, {"file\_name": "FSIS\_GD\_2019\_0020", "title": "Modernization of Swine Slaughter Inspection Webinar", "num": "FSIS-GD-2019-

0020","id":"a26c1870b93d1181a028c562c7510f066cab7c9e8b62ea04ab29265a5899a2a8","corpus":"fsis\_guidelines","source\_page\_url":"https:\V\www.fsis.usda.gov\policy\fsis-guidelines","url":"https:\V\www.fsis.usda.gov\sites\default\files\media\_file\2021-02\FSIS-GD-2019-0020\_1.pdf","type":"pdf","n\_pages":48,"word\_count":2291,"text\_by\_page":["OneUSDA\u201c Do right and feed everyone\u201d",""\uf071Welcome & Introductions to Panel \uf071Swine Modernization & HACCP followed by open question session \uf071Monitoring Process Controls followed by open question session \uf071New Swine Slaughter Inspection System followed by open question session \uf071Implementation followed by open question session Modernization of Swine Slaughter Inspection Food Safety and Inspection Service:  
Modernization of Swine Slaughter Inspection","Modernization of Swine Slaughter Inspection Food Safety and Inspection Service:","\u2022 On February 1, 2018, proposed to create a new optional inspection system for market hog slaughter establishments, the New Swine Slaughter Inspection System (NSIS), informed by the Agency\u2019s experiences under the Hazard Analysis and Critical Control Point (HACCP)-Based Inspection Models Project (HIMP).  
\u2013Market hog slaughter establishments that do not choose to operate under the new swine inspection system may continue to operate under traditional inspection. \u2022 FSIS also proposed several changes to the regulations that allow swine slaughter establishments to develop sampling plans that are more tailored to their specific operations, and thus more effective in monitoring their specific process control. \u2022 On October 1, 2019, FSIS published the final rule in the Federal Register. Food Safety and Inspection Service:  
Modernization of Swine Slaughter Inspection 4","\uf071Establishments must have an effective HACCP system \uf071HACCP is science-based control approach to food safety \uf071Focus is on preventing food safety hazards \uf071Responsibility belongs to the establishment with verification conducted by FSIS Food Safety and Inspection Service: HACCP Approach and HIMP HACCP 5","Hazard Analysis and Critical Control Point (HACCP) Systems Overview Food Safety and Inspection Service: HACCP","1.Conduct a Hazard Analysis 2.Determine Critical Control Points 3.Establish Critical Limits 4.Establish Monitoring Procedures 5.Establish Corrective Actions 6.Establish Recordkeeping & Documentation 7.Establish Verification Procedures HACCP Seven Principles 7",""\uf071Identify Reasonably Likely To Occur (RLTO) hazards at each process step \u2013Biological \u2013Chemical \u2013Physical \uf071Identify preventive measures \u2013 forms the basis for CCPs \uf071Unique to each establishment Conducting a Hazard Analysis 8",""\uf071Is there a potential hazard at this step? \u2013Biological? Chemical? Physical? \uf071Is it reasonably likely to occur? \u2013Yes\u2013CCP \u2013No \u2013What basis for this decision? \u2022Supporting documentation \u2022Prerequisite program \V other supporting program Thought Process for Hazard Analysis 9",""\uf071 Procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. \uf071 Become part of the HACCP system if used to support a decision in the hazard analysis. \uf071 Common examples \u2013Temperature control programs \u2013Sanitation SOPs \u2013Purchase specifications \u2013Allergen control programs \u2013Sanitary dressing programs \u2013Antimicrobial interventions \u2013Establishment sorting procedures Prerequisite Programs 10 Prerequisite Programs",""\uf071Validation \u2013Element 1: Scientific and Technical Support \u2013Element 2: In-plant Validation Data (90 calendar days ) \uf071Ongoing verification

\uf071Reassessment \uf071Government verification Verification Procedures 11","Questions & Discussion Food Safety and Inspection Service:","Monitoring Process Control Food Safety and Inspection Service:","G 14 Food Safety and Inspection Service: Generic E. coli","\\uf071 Under the 1996 PR\\HACCP final rule, FSIS set a Salmonella performance standard for market hog carcasses. \\uf071 Until 2011, FSIS routinely tested market hog carcasses for Salmonella to verify process control using the codified performance standard; sampling discontinued after low Salmonella recovery. \\uf071 With the final rule, FSIS is eliminating these performance standards \\u2013FSIS intends to propose new performance standards for raw pork products in 2020 Food Safety and Inspection Service: Salmonella Performance Standards 15","Food Safety and Inspection Service: Changes for All Swine Slaughter Establishments: Requirements for Written Sanitary Dressing Plans and Sampling \\u2022Develop, implement, and maintain written procedures to prevent contamination \\u2022These procedures must include microbiological sampling and analysis to assess ability to maintain process control \\u2022Incorporate written procedures into HACCP\\Sanitation SOP\\Prerequisite Program \\u2022Maintain records 16","Food Safety and Inspection Service: Mandatory Changes for All Swine Slaughter Establishments: Requirements for Written Sanitary Dressing Plans and Sampling Establishments: Collect 2 samples: 1 Pre-evisceration and 1 post-chill sample 1 per 1,000 carcasses Minimum of once per week Random Selection and Sampling of Carcasses Very Low Volume Establishments: Collect 1 post-chill sample Starting June 1 of every year Minimum of 13 samples Random Selection and Sampling of Carcasses 17","Food Safety and Inspection Service: Sampling Guideline to Assist Establishments 18 The guideline does not impose new regulatory requirements","Food Safety and Inspection Service: Sampling Guideline Types of Indicator Organisms \\uf0fc\*Aerobic Plate Counts\* \\uf0fcEnterobacteriaceae \\uf0fcGeneric E. coli \\uf0fcTotal coliforms Generic E. coli is a \\u2018Safe Harbor\\u2019 \\u2022 Establishments can continue to use generic E. coli 19","Food Safety and Inspection Service: Loss of Process Control Example 20","Food Safety and Inspection Service: Actions in Response to Loss of Process Control \\u2022Establishments must define actions to take in response if the test results exceed the limit \\u2022Delineate actions, who will take them, how they will be documented, and how verified \\u2022Investigate root cause and deploy corrective actions 21","Questions & Discussion Food Safety and Inspection Service:","The New Swine Slaughter Inspection System Food Safety and Inspection Service:","(1) Requires establishment personnel to sort and remove unfit animals before FSIS ante-mortem inspection and to trim and identify defects on carcasses and parts before FSIS post-mortem inspection; (2) Requires establishment personnel to identify animals or carcasses, that they have sorted and removed for disposal before FSIS inspection, with a unique tag, tattoo, or similar device, and to develop, implement, and maintain written procedures in their HACCP system to ensure that animals and carcasses sorted and removed for disposal do not enter the human food supply and are properly disposed of according to 9 CFR part 314; (3) Requires establishments to maintain records to document the total number of animals and carcasses sorted and removed per day and the reasons for their removal; Food Safety and Inspection Service: Key Elements of NSIS 24","(4) Requires establishment personnel to immediately notify FSIS inspectors if they identify, while conducting sorting activities, an animal or carcass that they suspect has a reportable or foreign animal disease (e.g., African swine fever, classical swine fever, or Nipahvirus encephalitis); (5) Shifts Agency resources to conduct more offline inspection activities that are more effective in ensuring food safety, which

allows for up to two offline verification inspectors per line per shift and reduces the number of online inspectors to a maximum of three per line per shift; (6) requiring establishments to maintain records documenting that products resulting from their slaughter operations meet the new definition of ready-to-cook (RTC) pork product, which is any slaughtered pork product sufficiently free from bile, hair, scurf, dirt, hooves, toe nails, claws, bruises, edema, scabs, skin lesions, icterus, foreign material, and odor which is suitable for cooking without need of further processing; and (7) Revokes maximum line speeds. Food Safety and Inspection Service: Key Elements of NSIS 25", "Food Safety and Inspection Service: NSIS: Ante-Mortem 26", "Food Safety and Inspection Service: Traditional: Post-Mortem 27", "Food Safety and Inspection Service: NSIS: Post-Mortem 28", "\u2022 Ante-mortem \u2013Food Safety Conditions removed and identified for disposal: Dead, Moribund (Dying), Central Nervous System (CNS) Disorders, Pyrexia (Body Temp. > 106 degrees F) \u2013Other ante-mortem abnormalities are sorted to \u201cSubject\u201d Pen for inspection by FSIS Public Health Veterinarian. \u2022 Post-mortem \u2013Food Safety Conditions marked for disposal of carcass and parts: Septicemia, Toxemia, Pyemia, Cysticercosis. \u2013All other diseases or abnormal conditions marked for trimming and disposal of affected parts or carcass depending on nature, degree, or extent. \u2022 Foreign Animal Diseases \u2013Establishments are required to report animals showing signs of foreign or reportable animal diseases to FSIS PHV for examination. For example: Foot and Mouth Disease, Hog Cholera, African Swine Fever. Food Safety and Inspection Service: Establishment Sorting 29", "Food Safety and Inspection Service: Sorter Guideline 30", "\u2022 Under NSIS, establishments will have the flexibility to design and implement measures to \u2022 address OCP defects that are best suited to their operations. \u2022 They will also be responsible for determining the type of records that will best document that they are meeting the RTC pork product definition. \u2022 The records will be subject to review and evaluation by FSIS offline inspectors (9 CFR 310.26(d)(1)). Food Safety and Inspection Service: RTC Pork Product 31", "Food Safety and Inspection Service: RTC Pork Product 32", "Questions & Discussion Food Safety and Inspection Service:", "Implementation Food Safety and Inspection Service:", "\u2022 The final rule will become effective on December 2, 2019. \u2022 The portion of the final rule that requires all hog slaughter establishments to develop and implement written sanitary dressing plans and sampling programs to monitor process control for enteric pathogens by establishment size will be applicable as follows: \u2022 In large establishments, defined as all establishments with 500 or more employees, on Dec. 30, 2019; \u2022 In small establishments, defined as all establishments with 10 or more employees but fewer than 500 employees, on Jan. 29, 2020; and \u2022 In very small establishments, defined as all establishments with fewer than 10 employees or annual sales of less than \$2.5 million: 180 days, on March 30, 2020. Food Safety and Inspection Service: Dates 35", "\u2022 All market hog establishments will initially have until March 30, 2020 to notify FSIS of their intent to operate under the NSIS. Establishments that do not notify FSIS of their intent within that period will be deemed to have chosen to continue operating under traditional inspection. Food Safety and Inspection Service: Dates 36", "Waiver Status Market Hog line speed, decreased numbers of inspectors, generic E. coli testing, 9 CFR 310.25(a) and (b) for OCP defects Establishments operating under HIMP or HIMP like system must choose to convert to NSIS or Traditional inspection system by 3/30/2020. May continue to use the sampling frequency and location in their generic E. coli sampling waiver until FSIS announces new criteria. Waivers for line speed,

decreased numbers of inspectors, and OCP defects evaluation end on 3\30\2020. Market Hog generic E. coli testing (9 CFR 310.25(a)) Establishments with waivers for alternative sampling frequency and location in their generic E. coli sampling program may continue until FSIS announces new criteria. Food Safety and Inspection Service: Current Waiver Status 37", "Waiver Status Market Hog alternative kidney presentation for increased line speed and generic E. coli testing (9 CFR 310.1(b)(3) and 310.25(a) Establishment with waiver for line speed associated with alternative kidney presentation ends on 12\31\2020. However, may continue to use the sampling frequency and location in their generic E. coli sampling waiver until FSIS announces new criteria. Market Hog handling of bruised parts and generic E. coli testing waivers (9 CFR 310.14 and 310.25(a)) Establishments with waiver for handling bruised parts ends on 12\31\2020. However, may continue to use the sampling frequency and location in their generic E. coli sampling waiver until FSIS announces new criteria. Food Safety and Inspection Service: Current Waiver Status 38", "Food Safety and Inspection Service: Waivers As described in the final rule, FSIS will consider possible waivers in the future \u2022HOLD -Do not apply for a waiver now \u2022FSIS will issue a Federal Register Notice announcing the criteria for waivers 39", "Food Safety and Inspection Service: Salmonella Initiative Program Waivers Possible Waivers to Inform Future Rulemaking: \u2022 Sampling Frequency \u2022 Alternative Carcass Sampling Sites (alternative to ham, belly, jowl) \u2022 Alternative Sampling Locations (pre-evisceration, post-chill) \u2022 Lymph Node Incision Salmonella Initiative Program participation required 40", "Food Safety and Inspection Service: Food Safety and Inspection Service: NSIS Opt-in Requests To opt-in, establishments must submit a request in writing to the District Office with an estimated date that they expect to be operational. District management will begin a dialogue with establishment management to ensure they understand their responsibilities under NSIS including: \u2022Sorting and removing unfit animals before FSIS antemortem inspection and to trim and identify defects on carcasses and parts before FSIS post-mortem inspection \u2022Identifying animals that they have sorted and removed for disposal and to ensure that animals sorted and removed for disposal are properly disposed of", "Food Safety and Inspection Service: Food Safety and Inspection Service: NSIS Opt-in Requests (cont.) \u2022Maintaining records to document the total number of animals and carcasses sorted and removed per day \u2022Submitting annual worker safety attestations The FSIS in-plant supervisor will monitor establishment progress in meeting its estimated operational date by ensuring: \u2022The establishment is in compliance with facilities requirements \u2022Establishment personnel have been trained in carcass sorting and disposition \u2022Has processes in place to maintain records to document animals and carcasses sorted and removed", "Food Safety and Inspection Service: Food Safety and Inspection Service: NSIS Opt-in Requests (cont.) \u2022The opt-in period for priority conversion for establishments closes on March 30, 2020 \u2022Establishments who opt-in subsequent to March 30, 2020 will be \u201clower\u201d priority for conversion by Districts than establishments that notified of conversion by March 30, 2020", "Food Safety and Inspection Service: Food Safety and Inspection Service: Staffing Analysis Once the District Office receives the opt-in request, District management will need to: \u2022Assess DO resources \u2013Verify current in-plant staffing \u2013Determine new staffing under NSIS based on new line configurations \u2022Coordinate with HR on recruitment and hiring announcements, as needed", "Food Safety and Inspection Service: Food Safety and Inspection Service: Training \u2022Schedule NSIS training for CSIs and

PHVs \u2013Review leave schedules to ensure staffing coverage \u2013Ensure district train the trainer is available to deliver training \u2022Schedule IM training (4 weeks) for inspection program personnel, as needed \u2022Track training and completion", "Food Safety and Inspection Service: Food Safety and Inspection Service: NSIS Plant Conversion Complete Once an establishment is staffed with trained employees and the establishment has met all requirements for sorting, record-keeping, etc., implementation\conversion is complete. The District Offices will: \u2022Update internal tracking documents with the conversion date \u2022Provide notification to HQ of establishment conversion date \u2022Make any necessary changes in the Public Health Information System for assignments and for inspection verification purposes \u2022Verify HACCP program reassessments for termination of redundant waivers issued prior to the publication of the final rule", "Questions & Discussion Food Safety and Inspection Service:", "Thank you. Food Safety and Inspection Service:"}], {"file\_name": "FSIS\_GD\_2020\_0002", "title": "PHIS Viewing Waivers and No Objection Letters: Quick Reference Guide (Industry)", "num": "FSIS-GD-2020-0002", "id": "68808bf6417294ca839fcf6a7b4decfb8f923b1d3ce1374fe455dc11228c16b", "corp\_us": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/import/phis-waivers-letters-qrg-industry.pdf", "type": "pdf", "n\_pages": 3, "word\_count": 590, "text\_by\_page": ["Food Safety and Inspection Service (FSIS) United States Department of Agriculture (USDA) Viewing Waivers and No Objection Letters Quick Reference Guide (Industry) Version 5.2 Public Health Information System PHIS 11.0", "Plant Management You are here: Home > Domestic Profile > Waivers & Letters My Establishments B .Establishment Profile ~ Waivers & Letters Select Establishment t:\\"1 \u00a3profile Summary - Waivers & Letters I Waivers Reset Filt Slaughter i', nimal Disposition B 'iew Report Log# Issue Date Regulations Status Summary I All 03-XX-402 11\06\2019 9 CFR 310.1 Active 11\19\2019 This is a sample summary for .. - Letters Reset Filte 10 Log# Issue Date Status Status Date Summary View I All ... I XX-2233 11\12\2019 Active 11\12\2019 This is a sample letter summa ... PHIS Quick Reference Guide: Viewing Waivers and No Objection Letters This guide explains how to view Waivers and No Objection Letters and any associated attachments. This guide is for an industry user with the role of Plant Management. Figure 1 -Waivers & Letters landing page Waivers & Letters Landing Page This page consists of a grid for Waivers and a second grid for No Objection Letters. 1. Role -Displays the selected role. 2. Menu -Displays the selected menu option. 3. Header -Displays the selected establishment name and number. For technical assistance, contact the FSIS Service Desk at 1-800-473-9135, 4. Log # -Displays the log number of the waiver or no objection letter. 24 hours a day. 5. Issue Date -Displays the date the waiver or no objection letter was issued. If calling from outside of the United States, please dial +1-929-279-8190. 6. Regulations -Displays regulations if applicable. Regulations apply only to waivers. 7. Status -Displays the current status of the waiver or no objection letter. 8. Status Date -Displays the date when that status went into effect. 9. Summary -Displays a short summary. 10. One action column: \u2022View -Displays View icon to view the record in read-only mode. 1 PHIS Quick Reference Guide: Viewing Waivers and No Objection Letters (Industry)", "USDA..\_.:. .... \_ \_....., - = Food Safety and Inspection Service Yt:1u 111\u2022 hat'\u25a0: Mama Dom-.tk Proflla > WM11\u2022n. & l.alt.-. > ~l\u2022 W.IOvan; 11nd I.Jltt-. My Establishments Establishment Profile ~elect Establishment frofile Summary Slaughter Animal Disposition ~te'W Report View Waiver Issue"]}

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for the appropriate record to be directed to the View Waiver page. See Figure 2. 2. If there is an  
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the attachment. Viewing No Objection Letter Records 1. From the Waivers & Letters landing  
page, select View icon for the appropriate record to be directed to the View No Objection  
Letter page. See Figure 3. 2. If there is an attachment that you want to view, select the file  
name of the attachment to open or download the attachment. PHIS Quick Reference Guide:  
Viewing Waivers and No Objection Letters (Industry) Figure 2: Viewing Waiver Records Figure 3:  
Viewing No Objection Letter Records 1"]],{"file\_name":"FSIS\_GD\_2020\_0005","title":"FSIS Food  
Safety Guideline for Egg Products","num":"FSIS-GD-2020-  
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us":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-  
guidelines","url":"https://www.fsis.usda.gov/sites/default/files/media\_file/2021-  
05/FSIS-GD-2020-  
0005.pdf","type":"pdf","n\_pages":42,"word\_count":15801,"text\_by\_page":["This guideline is  
designed to help small and very small plants producing egg products meet the new regulatory  
requirements under the Egg Products Inspection Regulations Final Rule. This guideline covers:  
\u2022 Regulatory requirements associated with the safe production of egg products; \u2022  
Hazard Analysis and Critical Control Point (HACCP) requirements; \u2022 Options to achieve  
lethality and/or safe cooling and freezing; and \u2022 Recommendations for meeting the  
sampling and testing requirements for detection and identification of *Salmonella* spp. in egg  
products. FSIS Food Safety Guideline for Egg Products September 9, 2020", "2 FSIS Food Safety  
Guideline for Egg Products Table of Contents Preface

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	42","4

Preface This is a revised version of the FSIS Guideline for Small and Very Small Plants that Produce Ready-to-Eat (RTE) Egg Products. It has been updated in response to comments received on the previous version and renamed. In addition, the guideline now includes updates for hazards related to Listeria monocytogenes (Lm) and residues, updates concerning amendments to the regulations, former regulatory parameters for defrosting, and changes to improve its readability. This guideline represents FSIS's current thinking on these topics and should be considered usable when applicable provisions in the egg products rule becomes effective. The information in this guideline is provided to assist egg products plants in meeting the regulatory requirements. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to industry regarding existing requirements under the regulations. Under the regulations, plants may choose to implement different procedures than those outlined in this guideline, but they would need to validate and support how those procedures are effective. This guideline is focused on small and very small plants in support of the Small Business Administration's initiative to provide small businesses with compliance assistance under the Small Business Regulatory Enforcement Fairness Act (SBREFA). However, all egg products plants may apply the recommendations in this guideline. It is important that small and very small plants have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective HACCP systems. Although large plants can benefit from the information, focusing the guideline on the needs of small and very small plants provides them with assistance that may be otherwise unavailable to them. Under the final rule, (Egg Products Inspection Regulations) egg products plants will be required to meet HACCP and sanitation requirements consistent with meat and poultry product regulations. This rule removes the prescriptive time and temperature parameters for egg products pasteurization, heat treatment, freezing, and cooling procedures. Instead, FSIS requires that plants support and validate procedures for lethality treatments, cooling, and freezing in its HACCP system and develop written Sanitation Standard Operating Procedures (Sanitation SOPs). In addition, egg products are required to be edible without additional preparation to achieve food safety and

are, therefore, considered ready-to-eat (RTE). Purpose of this Guideline This guideline contains information to assist plants producing egg products that undergo pasteurization, heat treatment, cooling, and freezing in complying with the new regulatory requirements in the final rule. Under 9 Code of Federal Regulations (CFR) 591.1(a), all egg products plants have to comply with the requirements contained in 9 CFR 416, Sanitation (one year after the final rule issues), 9 CFR 417, "5 Hazards Analysis and Critical Control Point Systems (HACCP) (two years after the final rule issues), and 9 CFR 500, Rules of Practice (60 days after the final rule issues). This guideline includes information on: \u2022 Regulatory requirements associated with the safe production of egg products; \u2022 HACCP requirements; \u2022 Options to achieve lethality and/or safe cooling and freezing; and \u2022 Recommendations for meeting the sampling requirements for detection of *Salmonella* spp. in egg products. Plants can always seek guidance from State university extension service specialists and HACCP Coordinators on developing programs and plans not provided in this guideline to comply with new regulatory requirements. Plants that follow the recommendations in this guideline are likely to meet the regulatory requirements. Changes from the Previous Version This guideline, dated September 9, 2020, is final. FSIS will update this guideline as necessary should new information become available. FSIS made the following change to this guideline to reflect the comments received on the previous version during the comment period for the proposed rule and to include additional scientific information: \u2022 Revised the section Pasteurization of Liquid Egg Whites (9 CFR 590.570) to state why the former regulatory time and temperature requirements for pasteurization of liquid egg whites was not included in Table 1 and to explain under what circumstances these combinations could be used; \u2022 Added Lm as a potential hazard in egg products, such as 10% salted egg products, and FSIS time and temperature pasteurization recommendations to destroy Lm; \u2022 Added the section Defrosting Operations (9 CFR 590.539) for frozen egg products that need to be defrosted or tempered; \u2022 Included egg substitutes and freeze-dried egg products; \u2022 Added acceptable culture testing methods for *Salmonella*; \u2022 Reorganized the Food Safety Systems and the HACCP Framework, Microbiological Testing Method, and New Technologies sections to improve clarity and make it more streamlined.", "6 Questions Regarding Topics in this Guideline If the desired information cannot be found within the guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the askFSIS database or submit questions through askFSIS. Documenting these questions helps FSIS improve and refine present and future versions of the guidance and associated issuances. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided: Subject Field: Enter Egg Products Guideline. Question Field: Enter question with as much detail as possible. Product Field: Select General Inspection Policy from the drop-down menu. Category Field: Select Sampling from the drop-down menu. Policy Arena: Select Domestic (U.S.) Only from the drop-down menu. When all fields are complete, press Continue.", "7 FSIS Food Safety Guideline for Egg Products Background Bacteria and viruses are common causes of foodborne illness and may be present in the environment, in live animals and on raw food. Eggs have been identified as important reservoirs for pathogens. Pathogens can be transferred to eggs during formation inside the hen; laying; and egg breaking, handling, and other processing steps. Previous FSIS regulations included prescriptive requirements for egg products plants to address contamination and did not allow flexibility for egg products plants to innovate. Under this final

rule, FSIS has adopted HACCP as the organizing structure for its egg products food safety program, consistent with current requirements in the meat and poultry products inspection regulations. Egg Products Final Rule: Amendments to the Regulations In the final rule, FSIS amended the egg products inspection regulations to require all federallyinspected egg products plants to develop and implement HACCP systems, Sanitation SOPs, and Sanitation Performance Standards (SPS) to design and support the food safety system (9 CFR 416 and 9 CFR 417). Implementation of HACCP, Sanitation SOPs, and SPS provides greater flexibility and incentives for innovation. This final rule also aligns egg products regulations with the meat and poultry products regulations. The amendments include the following (this guideline addresses the items bolded below): \u2022 Eliminate the current regulations that are inconsistent with HACCP, Sanitation SOPs, and SPS requirements; \u2022 Specify that egg products are required to be edible without additional preparation to achieve food safety; \u2022 Assert FSIS jurisdiction over egg substitutes and freeze-dried egg products; \u2022 Allow for the use of irradiated shell eggs in the production of egg products, provided the egg product subsequently undergoes pasteurization or another lethality treatment; \u2022 Provide for generic approval as part of the prior label approval system for egg products under 9 CFR 412.2; \u2022 Make changes to labeling requirements for shell eggs that are consistent with the Food and Drug Administration (FDA) regulations; ", "8 \u2022 Require special handling instructions on egg products that require special handling to maintain their wholesome condition; \u2022 Eliminate the requirements for prior approval by FSIS of egg products plant drawings, specifications, and equipment; \u2022 Incorporate egg products plants under 9 CFR 500, Rules of Practice that the Agency follows when initiating administrative enforcement actions; \u2022 Change the Agency\u2019s interpretation of the requirement for continuous inspection. The information contained within this guideline is applicable to egg products, including egg substitutes and freezedried egg products. Egg substitutes are low-cholesterol egg products. They are characterized as egg whites with nonegg yolk replacers such as vegetable oil, nonfat dry milk, soy protein, gums, food coloring, artificial flavors, and vitamins and minerals (for nutritional fortification). Freeze-dried egg products consist of an egg product that is flash frozen and placed in a vacuum chamber to remove ice particles. Known Pathogens of Concern in Egg Products While egg products can be contaminated by several pathogens, the two most common pathogens are *Salmonella* and Lm. *SALMONELLA* *Salmonella* spp. are bacterial pathogens that cause foodborne illnesses. The most common symptoms of salmonellosis are diarrhea, abdominal cramps, and fever within 12 to 72 hours after eating the contaminated food. The illness usually lasts 4 to 7 days. Salmonellosis may result in *Salmonella*-induced chronic conditions such as aseptic reactive arthritis and Reiter\u2019s syndrome (a combination of urethritis, conjunctivitis, and arthritis). Older adults, infants, and persons with weakened immune systems are more likely to develop a severe illness. The Centers for Disease Control and Prevention (CDC) reported that nontyphoidal *Salmonella* spp. are one of the leading causes of foodborne illness, with an estimated 1 million illnesses, 19,300 hospitalizations, and 380 deaths annually in the United States (Scallan, et.al., 2011). *Salmonella* spp. contamination in the final egg products can be due to underprocessing by not meeting the time and temperature parameters to achieve full lethality. Contamination can also occur Egg substitutes Egg whites with added color, mineral, or vitamin, and sold as a low-cholesterol alternative to whole egg products. Freeze-dried egg products Egg product that is flash frozen

and placed in a vacuum chamber. Egg products Broken shell eggs that are processed into liquid, frozen, or dried egg white, egg yolk, or whole egg products. Full definition may be found in 9 CFR 590.5.,"9 in the post-processing environment through contact with contaminated food contact surfaces, improper handling, addition of ingredients, and insect or animal vectors. If plants do not address pathogen reduction in their HACCP systems or do not have a process that is validated to achieve the necessary level of pathogen reduction, adulterated products may be released into commerce. Egg products found positive for *Salmonella* spp. or other pathogens are adulterated. FSIS requires plants to maintain control of products until test results (either plant testing or FSIS testing) confirm the product does not contain pathogens, such as *Salmonella* spp. (9 CFR 590.504(e)). *LISTERIA MONOCYTOGENES* (Lm) Lm is a bacterium that is found in moist environments, soil, and decaying vegetation and can persist along the food continuum. Listeriosis is a serious infection usually caused by eating food contaminated with Lm. The CDC estimates that infection with Lm causes about 1,600 illnesses, 1,500 hospitalizations, and 260 deaths in the United States each year. Listeriosis is rare, but its fatality rate is very high (about 20 percent, compared with 0.5 percent for *Salmonella* or *Escherichia coli* (*E. coli*)). It primarily affects older adults, pregnant women, newborns, and people with weakened immune systems (Scallan, et.al., 2011). Transfer of Lm from the environment or employees is a hazard of concern in RTE foods, including egg products. Lm can survive and grow at cool temperatures (as low as just above freezing). Because of Lm growth and survival characteristics, Lm is usually persistent in the environment and is commonly referred to as a harborage organism (i.e., it can form biofilms, which is a community of organisms firmly attached to a surface, that allow Lm to grow to high numbers in the environment and protect it from sanitizers). Lm can cross-contaminate food contact surfaces and foods. Improper sanitation, improper equipment maintenance, product handling, and employee practices post-lethality can lead to the transfer of Lm to egg products, causing them to become adulterated. Egg products contaminated with Lm are considered adulterated. FSIS requires plants to maintain control of products until test results confirm the product does not contain pathogens, such as Lm (9 CFR 590.504(e)). While Lm is a hazard of concern in egg products, FSIS recommends that plants continue to use *Salmonella* as an indicator of effective pasteurization in egg products because the thermal destruction of *Salmonella* in cooked products would indicate the destruction of most other pathogens (64 FR 733). Refer to the section Liquid Egg Yolks for reprocessing recommendations of egg products that test positive for Lm. Food Safety Systems and the HACCP Framework The statutory provisions require that egg products are pasteurized and not adulterated before shipping into commerce (21 U.S.C. 1036(a)). Because egg products undergo a lethality step to destroy pathogens of concern in the finished product, they can be safely consumed \u201cas is,\u201d Key Point Plants are required to process egg products to be edible without additional preparation to achieve food safety.,"10 meaning without any additional cooking or food safety interventions. Consistent with HACCP, under the final rule, the former 9 CFR 590.570 regulation was replaced by a new regulation specifying that egg products must be produced to be edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. Hazards such as *Salmonella* and Lm can be prevented, eliminated, or reduced through developing a food safety system. FSIS uses the HACCP framework as its food safety system. HACCP has multiple components that together form the

HACCP system. HACCP Requirements The HACCP system is defined as the food safety system in operation, including the HACCP plan. The HACCP plan includes the hazard analysis, supporting documentation, and all HACCP records. The first step in developing a HACCP plan is to conduct a hazard analysis (9 CFR 417.2(a)). The hazard analysis must include all biological, physical, and chemical food safety hazards that can occur before entry into the plant and throughout the processing and storage. The plant would then identify the points in each of its processes at which control is necessary to prevent, eliminate, or reduce each hazard (9 CFR 417.2(c)(2)). Plants implement measures to address those hazards identified in the hazard analysis into their HACCP system, such as at the lethality treatment, cooling, and freezing process steps. For each hazard identified in the hazard analysis, the plant determines if the hazard is reasonably likely to occur (RTLO) or not reasonably likely to occur (NRLTO). For any RLTO hazard, plants are required to develop a critical control point (CCP) in their HACCP plan. Plants may also determine that a prerequisite program effectively prevents the occurrence of certain food safety hazards, so they are NRLTO, for which a CCP is not required. Prerequisite programs to HACCP may include Sanitation SOPs (9 CFR 416.11-17), as well as other prerequisite programs, such as purchase specifications. Prerequisite programs to prevent hazards should be designed and monitored to ensure they are working as intended. Written validated HACCP plans (9 CFR 417.2(b)) may include, but are not limited to, items in the list below in order to meet the 9 CFR 417 regulatory requirements: \u2022 Identification of hazards RLTO in the production process, such as *Salmonella* spp. and Lm; \u2022 Identification and description of the CCP for each identified hazard in the HACCP plan; \u2022 Specification of the critical limit that must be met at each CCP, and, if appropriate, a target limit, such as identifying time and temperature parameters for the lethality, cooling, and Definition The HACCP system is defined as the food safety system in operation, including the HACCP plan, to prevent, eliminate, or reduce food safety hazards. The HACCP plan includes the hazard analysis, supporting documentation, including prerequisite programs and scientific documentation used to support decisions, and all HACCP records.", "11 freezing procedures; \u2022 Description of the monitoring procedure, frequency, and monitoring device to be used, such as a calibrated thermometer to monitor the temperature at lethality and cooling process steps; \u2022 Description of the corrective action to be taken if the critical limit has not been met; \u2022 Description of the records that would be generated and maintained at each CCP; and \u2022 Description of the verification activities (e.g., direct observation, records review, calibration) and the frequency at which they are to be conducted along with support for these procedures and frequencies. In addition to developing a hazard analysis and HACCP plan, processors are required to develop and maintain written Sanitation SOPs to minimize the risk of direct product contamination and adulteration (9 CFR 416.11-17). The regulations require that the plant\u2019s Sanitation SOPs specify the cleaning and sanitizing procedures for all equipment and facilities involved in the production of every egg product. As part of the Sanitation SOPs, a plant employee is required to record results of sanitation checks at the frequencies stated in the Sanitation SOPs. All the records generated from monitoring CCPs, Sanitation SOPs, and other prerequisite programs become part of the HACCP system records. When conducting a pre-shipment review, the HACCP records must be reviewed and signed by a plant employee. When practicable, the review should be conducted by an employee other than the one who produced the record before the product is distributed in commerce, and preferably by someone trained in HACCP or the responsible plant official (9

CFR 417.5(c)). Lastly, HACCP records must be retained in accordance with 9 CFR 417.5(e), for at least 1 year for refrigerated products and 2 years for frozen, preserved, or shelf-stable products. HACCP Plan to Control Hazards Pasteurized egg products must be free of detectable pathogens (*Salmonella* and *Lm*) and have no violative levels of residues (pesticides, heavy metals, persistent organic pollutants) or detectable toxins or levels of toxin-producing organisms that would be a public health concern. Egg products plants produce safe product by controlling, eliminating, and reducing microbiological, physical, and chemical hazards, where identified, throughout their HACCP system. During completion of the hazard analysis, plants are required to consider and account for hazards that could occur at the farm (*Salmonella*, residues), during transportation to the plant (checking seals on trucks, performing organoleptic examinations on incoming products), and during processing at the plant (lethality, cooling, and freezing procedures, storage conditions). Plants need to verify on an ongoing basis that they are addressing the hazards identified in the hazard analysis and that the HACCP plan is functioning to ensure food safety (9 CFR 417.4(a)). Consistent with the former regulations, the amended regulations require plant-performed microbiological sampling and testing to", "12 verify the absence of *Salmonella* spp. in the finished product. Plants are required to maintain control of the egg products until the testing results are received (9 CFR 590.504(e)). Egg products may be moved from a plant before the plant receives laboratory results only if the plant retains control of the product. In the hazard analysis, the plant determines if a hazard is RLTO (addressed through a CCP) or NRLTO (typically addressed through Sanitation SOPs or other prerequisite programs). Process deviations may occur despite the best efforts of a plant to maintain process control. Heating and cooling deviations occur when the plant fails to meet its heating (i.e., pasteurization, heat treatment) or cooling process schedule. Failure to meet the time and temperature combination is a common cause of heating deviations and can result in underprocessing. Common causes for cooling deviations include inadequate chilling due to large volumes, improper agitation of the product, power failures, or refrigeration equipment breakdowns. When processing deviations occur, a plant is required to take corrective action to bring the process back in control (9 CFR 417.3). \u2022 When the identified hazards are addressed through CCPs, plants are required to determine the cause of all critical limit deviations (9 CFR 417.3(a)(1)), regain control of the CCP (9 CFR 417.3(a)(2)), and ensure measures are established to prevent recurrence (9 CFR 417.3(a)(3)). Recurring deviations constitute an unacceptable risk within the HACCP system. In addition, the plant would be required to initiate measures to ensure that no product potentially injurious to health or otherwise adulterated because of the deviation enters commerce (9 CFR 417.3(a)(4)). \u2022 When the identified hazards are addressed through a prerequisite program, plants are required to reassess their HACCP plan to determine whether the newly identified deviation (i.e., unforeseen hazard) should be incorporated into the HACCP plan (9 CFR 417.3(b)(4)). In addition, the plant may not be able to continue to support the decisions in its hazard analysis that the identified hazard is NRLTO if it has continual or repetitive deviations from its prerequisite program (9 CFR 417.5(a)(1)). If a plant fails to support decisions made in the hazard analysis or demonstrates ongoing or repetitive CCP or prerequisite program deviations, there could be an imminent food safety concern that may have an impact on public health. Producing product with potential food safety concerns can result in a regulatory control action or an enforcement action by FSIS, according to the Rules of Practice (9 CFR 500). Validation,

Verification, Reassessment Validation is the process of demonstrating that the HACCP system as designed can adequately control potential hazards to produce a safe, unadulterated product. Validation is a key step to determine if a HACCP system is effective (9 CFR 417.4(a)(1)). Key Point FSIS recommends that egg product plants use the Compliance Guideline HACCP Systems Validation document to ensure that the HACCP systems are properly validated.", "13 Validation ensures that the HACCP system is designed and functioning appropriately. Validation has two elements as described in the Compliance Guideline HACCP Systems Validation. Element 1 involves supporting the decisions made in the hazard analysis (hazards as RLTO or NRLTO) and in the HACCP plan (critical operating parameters, such as time and temperature). Examples of support are provided in the section Scientific Support Availability for Lethality Requirements in Egg Products. Plants can meet the new requirements by implementing the former regulatory time and temperature parameters in 9 CFR 590.530, 9 CFR 590.536, 9 CFR 590.539, 9 CFR 590.570, and 9 CFR 590.575 or any of the other time and temperature parameters included in this guideline. FSIS considers these parameters to be safe harbors. Safe harbors are recognized procedures that can be employed without any further validation studies. Plants will not have to gather additional scientific support for their process if they choose to use these safe harbors. Plants that choose to use the former regulations must incorporate these procedures into their HACCP system (i.e., HACCP plan, prerequisite programs, Sanitation SOPs). Element 2 involves collecting 90 calendar days of in-plant data to demonstrate that the system is capable of meeting the critical operating parameters. The in-plant validation may include in-plant observations, measurements, microbiological test results, or other information demonstrating that the control measures (CCPs and prerequisite programs), as written into a HACCP system, can be executed within a particular plant to achieve the process\u2019s intended result. Plants using existing HACCP systems developed before the issuance of this document that do not have the documents from its initial validation on file would need to gather the necessary data. Plants using safe harbors to satisfy Element 1 are still required to meet Element 2 of the validation process. Once the HACCP system is validated, the plant will need to perform on-going verification and continue to monitor those operating parameters, review records generated by the HACCP system, and maintain documentation verifying that they are following these procedures (9 CFR 417.4(a)(2)). At least annually, and anytime a process is changed, the plant must reassess their HACCP system to ensure the decisions made in the hazard analysis and HACCP plan are still valid (9 CFR 417.4(a)(3)).

Scientific Support Available for Lethality Requirements for Egg Products There are generally six types of information that can be used to demonstrate compliance with the new scientific support regulatory requirements in the final rule on Egg Products Inspection Regulations: (1) published processing guidelines, (2) challenge studies, (3) peer-reviewed scientific or technical data or information, (4) pathogen modeling programs, (5) expert advice from processing authorities, and (6) former egg products regulations. Finished product sampling results alone cannot be used to validate lethality procedures because they do not provide information on the incoming pathogen load and, consequently, the level of pathogen reduction achieved. FSIS recommends that plants refer to the guidance provided in the FSIS Compliance Guideline HACCP Systems Validation to ensure that their HACCP systems are properly validated.", "14 (1) Published Processing Guidance This guideline, as well as other guidance available on FSIS\u2019s Guidance Website, are examples of Published Processing Guidance. This Egg Products Guideline contains safe harbors from

former egg products regulations, options from approved New Technology waivers, and the mathematical time and temperature combinations for pasteurization. Figure 1 illustrates the options that plants may use to comply with the new regulatory requirements in the final rule. Appendix II, New Technology Pasteurization and Freezing Time and Temperature Tables, provides tables of validated pasteurization and freezing time and temperature parameters from historical FSIS New Technology waivers and No Objection Letters (NOLs). These tables can be used as resources to meet the proposed regulations. Appendix III, Pasteurization Time and Temperature Tables, provides tables of pasteurization time and temperature combinations that are calculated to achieve the lethality performance standard for specific egg products based on data and models that are presently available to FSIS. FSIS considers these to be scientifically validated processes and safe harbors to meet regulatory requirements. Figure 1. Overview of Options Available to Meet the New Regulatory Requirements Options available to assist plants in meeting the Egg Product Regulations for: 9 CFR 590.570 for pasteurization; 9 CFR 590.530 for cooling; 9 CFR 590.536 for freezing; and 9 CFR 590.539 for defrosting Develop your own alternative time and temperature parameters for pasteurization, heat-treatment, cooling and\or freezing. Refer to HACCP Systems Validation Compliance Guidelineto ensure proper HACCP system validation. Use the Pasteurization Time and Temperatures Tables in Appendix III. Refer to Tables III.A-III.Cto determine which time and temperature combinations are suitable for your egg operation. Refer to Table III.C for Liquid Egg Yolk Products. Refer to Table III.B for Liquid Whole Egg Products. Refer to Table III.A for Liquid Egg Whites products. Use the New Technology Pasteurization and Freezing Time and Temperature Tables in Appendix II. Refer to Tables II.A -II.Dfor new technology waivers for pasteurization time and temperatures combinations for liquid egg products Refer to Table II.E for freezing temperature parameters. Use the safe harbor former prescriptive regulationsfor pasteurization, heat treatment, cooling, freezing, and defrosting to meet the new requirements. Refer to Table 1for pasteurization time and temperature parameters. Refer to Table 2for cooling parameters. Refer to Table 3 for defrosting parameters.", "15 (2) Challenge Studies One of the most definitive validation tools available is the inoculated pack or challenge study of the time and temperature used by the plant for egg products pasteurization. Challenge studies involve inoculating the product with a known amount of a pathogen and calculating the level of reduction or elimination that is achieved. Since challenge studies introduce hazards to the product, they should be conducted in a testing laboratory and not in the processing plant environment. Such studies should be undertaken by individuals who have a thorough knowledge of laboratory methods used in lethality research for *Salmonella* spp. in liquid or dried egg products. The challenge study design, including a description of the process and all critical operating parameters affecting the reduction or elimination, and the achieved level of pathogen reduction or elimination should be documented and maintained as part of the HACCP system. Challenge studies should be based on a sound statistical design that ensures confidence in the data and employs positive and negative controls. The statistical design should include the number of samples collected at each time interval and the number of study replicates needed to ensure the validity of the study. Quantitative methods such as power analysis may be used to assess the statistical quality of a study. For more information on conducting challenge studies, please review the article published by the National Advisory Committee on Microbiological Criteria for Foods in the Journal of Food Protection in 2010. (3) Peer-Reviewed Journal Articles Published studies, such

as peer-reviewed research studies on the pasteurization of egg products, can serve as initial validation of pasteurization time and temperature parameters. Published studies should include the time and temperature requirements to achieve a specific log reduction and type of product and formulation (e.g., whole egg; whole egg with citric acid). Additional parameters could include viscosity and pH of the egg product used. To be used as part of initial validation, the study selected should describe products and processes similar to those used by the plant. The plant should not use published studies whose study parameters do not represent the plant's process and products. For example, a study on the pasteurization time and temperature for liquid egg whites is not adequate supporting documentation for the pasteurization of whole eggs. (4) Pathogen Modeling Programs FSIS is not presently aware of any publicly available computerized software available on lethality models for the inactivation of *Salmonella* spp. in liquid or dried egg products. However, such models might be developed without FSIS awareness and could be used for demonstrating compliance if the model is applicable and validated for the plant's product. Individual plants can develop their own computer models using data from published literature, provided that the assumptions used for developing the models are scientifically sound. Predictive food microbiology uses models (i.e., mathematical equations) to describe the growth, survival, or inactivation of microbes in food systems. Listed below are peer-reviewed studies using various mathematical equations to determine inactivation of heat-resistant *Salmonella* spp. strains.", "16 \u2022 Jordan, S.S., Gurtler, J.B., Marks, H.M., Jones, D.R. and Shaw, W.K. 2011. A mathematical model of inactivation kinetics for a four-strain composite of *Salmonella Enteritidis* and *Oranienburg* in commercial liquid egg yolk. *Food Microbiology*. 28:67-75. \u2022 Gurtler, J.B., Marks, H.M., Bailey, R.B, Juneja, V. and Jones, D.R. 2013. Kinetics Model Comparison for the inactivation of *Salmonella Enteritidis* and *Oranienburg* in 10% salted liquid whole egg. *Foodborne Pathogens and Disease*. 10:492-499. \u2022 Gurtler, J.B., Marks, H.M., Jones, D.R, Bailey, R.B, and Bauer, N.E. 2011. Modeling the thermal inactivation kinetics of heat-resistant *Salmonella Enteritidis* and *Oranienburg* in 10 percent salted liquid egg yolk. *Journal of Food Protection*. 74:882-892. \u2022 Gurtler, J. B., V. K. Juneja, D. R. Jones, and A. Purohit. 2019. Thermal inactivation kinetics of three heat-resistant *Salmonella* strains in whole liquid egg. *Journal of Food Protection*. 82(9):1465-1471. (5) Expert Advice from Processing Authority Expert advice from processing authorities may be used as scientific or technical support. Such expert advice should include reference to established scientific principles as well as reference to peer-reviewed scientific data. Expert advice from processing authorities should not rely on expert opinion alone. The scientific principles and data should relate to the plant's product and process as well as the hazard identified in the hazard analysis. One example of how expert advice may be used is a processing authority's justification for why a different limit of a critical operational parameter from the one studied in the scientific support should not impact the effectiveness of an intervention. As part of the justification, in addition to their own expert opinion, the processing authority should cite one or more peer-reviewed scientific data sets or documents that provide a science-based rationale for why the different limit of the critical operational parameter should be at least equally as effective from the one in the scientific support. (6) Former Egg Products Regulations The former regulations for pasteurization, heat treatment of dried egg whites, cooling, freezing, and defrosting operations could be used by a plant to meet new regulatory requirements. The former regulations are recognized as safe

harbors and are considered validated processes. Pasteurization Operations (9 CFR 590.570) Table 1 provides the former pasteurization requirements for liquid egg products. It should be noted that the time and temperature parameter for the pasteurization of liquid egg whites under the former regulations are not included here as it does not achieve the same level of lethality as for other liquid egg products and can only be used under certain conditions. In general, FSIS considers a 5-log10 reduction of Salmonella to be safe in products that are edible without additional preparation to achieve food safety, including egg products. This will eliminate up to 100,000 Colony Forming Units", "17 per gram (CFU/g) pathogenic organisms before the number of bacteria overwhelms the lethality treatment. The conditions under which liquid egg whites may be processed using the former regulatory time and temperature pasteurization combination are described in the \u201cPasteurization of Liquid Egg Whites\u201d section. Table 1. Former Pasteurization Requirements for Liquid Egg Products That Could Be Used as Safe Harbors Liquid Egg Products Minimum Temperature Requirements (\u00b0F) Minimum Holding Time Requirements (Minutes) Whole egg 140 3.5 Whole egg blends (less than 2% added nonegg ingredients) 142 140 3.5 6.2 Fortified whole egg and blends (24\u201338% egg solids, 2\u201312 percent added nonegg ingredients) 144 142 3.5 6.2 Salt whole egg (with 2% or more salt added) 146 144 3.5 6.2 Sugar whole egg (2\u201312% sugar added) 142 140 3.5 6.2 Plain yolk 142 140 3.5 6.2 Sugar yolk (2% or more sugar added) 146 144 3.5 6.2 Salt yolk (2\u201312% salt added) 146 144 3.5 6.2 Pasteurization of Liquid Egg Whites (9 CFR 590.570) Based on the scientific literature, the former regulatory pasteurization time and temperature for liquid egg whites (134\u00b0F for 3.5 minutes) did not achieve a 5-log10 reduction (International Egg Pasteurization Manual, USDA FSIS 1998 Risk Assessment) of Salmonella. This time and temperature combination may be used as a safe harbor if the eggs did not originate from a farm that is positive for Salmonella Enteritidis. The time and temperature requirements of the former pasteurization regulations were based on a pH of about 9 for egg whites, as described in the USDA FSIS 1998 Risk Assessment. At the time the regulations were written, it would take eggs 3 to 5 days to arrive at the processing plant. During this time, the pH of the albumen would rise from about 7.8 to 9.4. However, current practice allows for the eggs to arrive at the processing plant much sooner, when the pH is closer to 7.8. The pH of albumen, or the egg white, has a significant effect on the reduction of Salmonella Enteritidis when liquid egg white is pasteurized. Salmonella Enteritidis is more sensitive to heat at higher pH levels, thus making egg pasteurization more effective. Egg whites have natural antimicrobial properties that limit Salmonella growth. These properties include lysozyme, ovotransferrin, vitamin chelating proteins, and proteinase inhibitors (Baron et. al., 2016). With these inherent properties, it is possible that egg whites may not require a process that achieves a 5-log10 reduction of Salmonella under certain conditions (refrigerated within 36 hours of lay; not originating from a farm that has Salmonella Enteritidis-positive eggs). These antimicrobial properties would limit the growth of Salmonella cells present in the egg white, thus allowing for", "18 greater effectiveness of the former pasteurization time and temperature combination before the lethality treatment is overwhelmed. Available studies examined Salmonella in eggs from chickens infected with Salmonella. Humphrey et. al., (1989, 1991) enumerated Salmonella from the egg, but also looked at Salmonella growth when inoculated into different parts of the egg (albumen versus yolk). Garibaldi et. al., (1969) enumerated Salmonella from whole egg and from the albumen while Gast and Beard (1992) enumerated the Salmonella from the whole

egg. Their studies demonstrated that most eggs had less than 1-log10 of Salmonella per egg while a few eggs had 2.1-log10 of Salmonella. Humphrey et. al., (1991) determined that Salmonella inoculated into the outer edge of the albumen was less likely to grow than when inoculated next to the yolk membrane, fresh eggs were less likely to support Salmonella growth regardless of its position in the albumen, and that Salmonella positive eggs contained less than 1.3log10 of Salmonella when stored at room temperature for less than three weeks. Gast and Beard (1992) studied the effect of storage temperature on frequency of isolation and concentration of Salmonella in eggs from experimentally infected hens and determined that eggs stored at 45\u00b0F for 7 days had 0.75-log10 of Salmonella. Since that time, the industry has continued to lower Salmonella levels in egg products. FSIS performed a Salmonella baseline survey from 2012 to 2013. Results of that baseline indicate that raw liquid whole egg samples had -0.60-log10 to -0.31-log10 (95% confidence interval) Salmonella, meaning that there was 1 Salmonella organism per 2 to 4 mL. Raw liquid egg whites had -0.92-log10 to -0.24-log10 Salmonella, meaning that there was 1 Salmonella organism per 2 to 8 mL. In addition, FSIS sampling indicated that pasteurized egg whites had a Salmonella prevalence of 0.61% from 1995 to 1999. That prevalence decreased to 0.19% from 2013 to 2018. However, the FDA Final Rule: Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation (74 FR 33030, July 9, 2009) requires all eggs diverted from a farm that has Salmonella Enteritidis be treated using a technology or process that achieves a 5-log10 destruction of Salmonella Enteritidis. Since the former regulatory pasteurization time and temperature for liquid egg whites does not achieve a 5-log10 reduction, it was not included in Table 1. Considering this, egg products plants could use the former regulatory pasteurization time and temperature of 134\u00b0F for 3.5 minutes as a safe harbor, provided that the eggs are not diverted from a farm that has Salmonella Enteritidis. If plants are using the former pasteurization time and temperature combination and receive multiple positive Salmonella results, then they will be required to reassess their hazard analysis and make appropriate corrective actions. Plants pasteurizing liquid egg whites that require a 5-log10 reduction of Salmonella may refer to the section Liquid Egg Whites for acceptable time and temperature combinations. Heat Treatment of Dried Egg Whites (9 CFR 590.575) Heat treatment of dried whites is an approved method of pasteurization. The product should be heated throughout for the necessary time and temperature that will result in a reduction of Salmonella spp. to undetectable levels. The product for heat treatment should be in closed containers to prevent post-lethality exposure. The containers should be placed in a heat treatment room with adequate spacing between the containers", "19 to assure heat penetration and air circulation so that all product reaches the desired time and temperature combination. Each container should include information on the product type (spray or pan dried) and the production lot number or production code. Former regulatory times and temperatures for heat treatment of spray or pan dried albumen are as follows: \u2022 Spray dried albumen should be heated throughout to a temperature not less than 130\u00b0F and held continuously at such temperature for a minimum of 7 days; or \u2022 Pan dried albumen should be heated throughout to a temperature of not less than 125\u00b0F and held continuously at such temperature for a minimum of 5 days. Cooling Operations (9 CFR 590.530) Table 2 provides the former cooling requirements for liquid egg products. Liquid egg products would be considered satisfactorily cooled only when the entire mass reaches the required temperature. The temperature of

previously cooled product may rise because of further processing operations such as blending, homogenizing, or reconstituting dried products. The temperature must be reduced again to meet the safe harbors. Prior to pasteurization, the liquid egg products listed in Table 2 would need to be brought to the respective temperature within two hours of breaking. Table 2.

Former Cooling and Temperature Requirements for Liquid Egg Products That Could Be Used as Safe Harbors Product Non-Salted Liquid Product to be held 8 hours or less Non-Salted Liquid Product to be held more than 8 hours Salted Liquid Product Temperatures within 2 hours after Pasteurization Temperatures within 3 hours after Stabilization White (not to be stabilized)

55\u00b0F or lower 45\u00b0F or lower \_\_\_\_\_ 45\u00b0F or lower \_\_\_\_\_ Whites (to be stabilized) 70\u00b0F or lower 55\u00b0F or lower \_\_\_\_\_ 55\u00b0F or lower 1 All other product with less than 10% added salt 45\u00b0F or lower 40\u00b0F or lower \_\_\_\_\_

45\u00b0F or lower if to be held 8 hours or less 40\u00b0F or lower if to be held more than 8 hours 45\u00b0F or lower if to be held 8 hours or less 40\u00b0F or lower if to be held more than 8 hours All other product with 10% or more added salt \_\_\_\_\_ 65\u00b0F or

lower if to be held for 30 hours or less 45\u00b0F or lower if to be held more than 30 hours 65\u00b0F or lower 2 Stabilized liquid whites should be dried as soon as possible after removal of glucose. The storage of stabilized liquid whites should be limited to that necessary to provide a continuous operation. 2 The cooling process should be continued to assure that any salt product to be held more than 24 hours is cooled and maintained at 45\u00b0F or

lower. Freezing Operations (9 CFR 590.536) Freezing rooms should be kept clean and free from objectionable odors.", "20 \u2022 Non-pasteurized egg products intended for freezing should be solidly frozen or reduced to a temperature of 10\u00b0F or lower within 60 hours from time of breaking. Non-pasteurized frozen egg product would need to be defrosted or tempered (see Defrosting Operations) prior to pasteurization. \u2022 Pasteurized egg products intended for freezing should be solidly frozen or reduced to a temperature of 10\u00b0F or lower within 60 hours from time of pasteurization. The temperature of products not solidly frozen should be taken at the center of the container. Containers should be stacked to allow sufficient air circulation around the containers. The outside of liquid egg containers should be clean and free from evidence of liquid egg, shell, or debris. Frozen egg products should be examined

organoleptically after freezing to determine their fitness for human food. Defrosting Operations (9 CFR 590.539) Frozen egg products which are to be defrosted must be defrosted in a sanitary manner. Frozen egg products should be examined organoleptically prior to defrosting to determine their fitness for human food. Table 3 provides acceptable tempering and defrosting operations for frozen egg products. Table 3. Former Defrosting Requirements for Liquid Egg Products That Could Be Used as Safe Harbors Product Type Temper \u2219 Defrost Option

Temperature Time Special Considerations Dried Albumen Ambient - - For production of dried albumen Egg Products Ambient 40\u00b0F or lower 48 hours or less Liquid product maintained at 50\u00b0F or lower Egg Products Ambient Greater than 40\u00b0F 24 hours or less Egg Products Running Water 70\u00b0F or lower - Plastic or metal container Once the product has been defrosted, it should be maintained at 40\u00b0F or less, unless it is to be pasteurized or stabilized by glucose removal. Defrosted liquid product shall not be held more than 16 hours prior to processing or drying. Control of Pathogens in Egg Products The times and temperatures for destroying Salmonella spp. are dependent upon the type of egg product being produced: egg white, whole egg, or egg yolk, as well as product formulations such as added salt or sugar.

In addition to the former regulatory pasteurization time and temperatures already provided in Pasteurization Operations (9 CFR 590.570), Appendix II and Appendix III provide pasteurization time and temperature tables. Along with eliminating and reducing pathogens during the lethality step, plants also need to control for pathogens after the lethality step by limiting the cross-contamination potential. The subsequent sections provide detailed information for the control of pathogens in each specific product type as well as at the post-lethality step." , "21

Liquid Egg Products Liquid egg products include whites, yolks, whole eggs, blends of whole eggs and yolks, and egg substitutes. Some egg products, such as those containing salt and sugar, may require higher pasteurization times and temperatures. Appendix III includes Tables III.A through III.C that provide different combinations of times and temperatures for 14 different types of liquid egg products, including: plain egg white at four different pH values (7.8, 8.2, 8.8, and 9.3); plain whole egg and plain egg yolk; 10% added sugar or 10% added salt to liquid plain whole egg or to liquid plain egg yolk; and five formulated liquid egg products. Plants should select the option that will allow them to meet the requirements for their specific processes.

Liquid Egg Whites Pasteurization can adversely affect the functional properties of liquid egg whites depending on the time and temperature used. Egg white proteins are particularly susceptible to heat damage and, therefore, require lower heating temperatures (International Egg Pasteurization Manual) to preserve functionality. A 5-log<sub>10</sub> reduction of *Salmonella* spp. in liquid egg whites with lower pasteurization times and temperatures can be achieved by raising the pH. The higher pH values work to reduce the heat resistance of *Salmonella* spp. A recognized bactericidal agent can also be added to liquid egg whites to reduce microbial contamination. It allows for the pasteurization of egg whites at relatively low temperatures (Eskin and Shahidi, 2012). Appendix III, Table III.A provides different combinations of times and temperatures at four different pH values (7.8, 8.2, 8.8, and 9.3) that achieve a 5-log<sub>10</sub> reduction of *Salmonella* and, thus, may be used for egg whites originating from farms that have positive *Salmonella Enteritidis* eggs. Plants can select which time and temperature combination is suitable for their egg products processing operation. For example, a pH of 7.8 at a pasteurization temperature of 140°F and holding time of 21 seconds is needed to ensure adequate pasteurization and that pathogens are non-detectable in *Salmonella Enteritidis*-diverted eggs. For liquid egg products with a lower pH, additional ingredients may be added to improve lethality while preserving the functionality. Chemical reagents and metal ions are commonly added to stabilize the proteins that contribute to the egg white's functionality in cooking and baking. Hydrogen peroxide, a recognized bactericidal agent, can also be added to liquid egg whites to reduce microbial contamination. It allows for the pasteurization of egg whites at relatively low temperatures (Eskin and Shahidi, 2012).

Liquid Whole Eggs Liquid whole eggs often consist of blended non-egg ingredients, including salt, sugar, or corn syrup. These are added to whole eggs to prevent egg yolk gelation during freezing or impart functional properties to the liquid whole egg product. Liquid whole eggs that do not contain blended ingredients may be pasteurized at times and temperatures lower than egg yolks. To use the time and temperature combinations for liquid whole egg products without added ingredients, the plant should refer to Table III.B in Appendix III. For example, 10% salt whole egg at a pasteurization temperature of 150°F requires a holding time of 78 seconds to ensure adequate pasteurization and that pathogens are non-detectable." , "22

Liquid Egg Yolks Liquid egg yolk has a higher viscosity (due to higher fat and protein content) than egg whites, thus

decreasing the lethality of *Salmonella* to heat (Li, et.al., 2005). In addition, *Salmonella* spp. are the most heat resistant at near neutral pH, similar to the conditions of the egg yolk (Eskin and Shahidi, 2012). As a result of the higher viscosity and near neutral pH, *Salmonella* spp. may acquire greater heat-resistance more readily in egg yolk than in egg whites. Hence, the pasteurization for egg yolk is higher and longer than egg whites. Sugar, salt, glycerol, or other similar ingredients are often added at levels of 10 to 15% to reduce the gelation that can occur when freezing liquid egg yolk (Carter, 1968). *Salmonella* spp. are more resistant when salt is added due to lowering of the water activity. Consequently, salted egg yolk requires increased time and temperature for effective pasteurization than non-salted egg yolk (Palumbo, et.al., 1995). Scientific studies have also identified that Lm has a much higher heat resistance in salted egg yolk products (Palumbo et al., 1995; Michalski et al., 2000; Huang, 2019). FSIS has determined that a pasteurization temperature of 155°F with a minimum holding time of 12 to 13 minutes is needed in order to achieve a 5-log<sub>10</sub> reduction of Lm in the 10% salted egg yolk, based on the D-values from three published thermal death time studies (Palumbo et. al., 1995; Michalski et. al., 2000; Huang, 2019). In the past, *Salmonella* has been used as the indicator of lethality because of the association of *Salmonella Enteritidis* foodborne illnesses with eggs and because *Salmonella Enteritidis* can infect the egg during the developmental process inside the chicken (FSIS Risk Assessment, 1998; FSIS Risk Assessment, 2005). FSIS recommends that plants continue to use *Salmonella* as an indicator of effective pasteurization in egg products because the thermal destruction of *Salmonella* in cooked products would indicate the destruction of most other pathogens (64 FR 733). If the plant's scientific support demonstrates that its lethality treatment achieves sufficient reduction in *Salmonella*, it does not need to provide additional support that adequate reduction in other pathogens is achieved. However, if a sample tests positive for Lm, the plant should verify that inadequate lethality was not the root cause as part of its corrective actions (9 CFR 417.3(b)). If reprocessing the adulterated product, the plant would need to repasteurize at 155°F for 12 to 13 minutes or provide alternate scientific support for the pasteurization time and temperature required to achieve a 5-log<sub>10</sub> reduction of Lm. To use the time and temperature combinations for egg yolk products, plants should refer to Table III.C in Appendix III. For example, 10% sugar egg yolk at a pasteurization temperature of 155°F requires a holding time of 17 seconds to ensure adequate pasteurization and that *Salmonella* spp. are non-detectable. Alternatively, plants may choose not to use the tables in Appendix III and implement a customized process that is designed to ensure egg products are edible without additional preparation to achieve food safety. Plants would need to provide adequate scientific support for any processes not provided in this guideline. See the section Scientific Support Available for Lethality Requirements for Egg Products for examples of scientific support." , "23 Dried Egg Products Dried or dehydrated egg products are known as egg solids and typically are spray dried to remove most of the moisture. Dried product that is not subjected to a pasteurization treatment (i.e., dried egg white products) in a liquid state must be subjected to a heat treatment in the dried state that will impart a lethality necessary to ensure pathogens are non-detectable. This section discusses the processing of dried egg white products. Since dried egg yellows are pasteurized first prior to drying, control of pathogens in dried egg yellows is discussed in the sections Liquid Whole Eggs, Liquid Egg Yolks, and Post-Lethality Handling and Sanitation. Lethality models for *Salmonella* were constructed based on a Weibull inactivation

curve using the measured levels reported in the Jung and Beuchat (1999) paper for Salmonella and the USDA Agricultural Research Service. For Salmonella, it was estimated that a product containing 5% moisture requires more than 21 days at  $54^{\circ}\text{C}/129.2^{\circ}\text{F}$  to achieve lethality of  $5.7 \log_{10}$ ; a product containing 8% moisture requires more than 12 days. Other models predicted that even more time would be required to achieve a lethality of  $5.7 \log_{10}$ . Table 4 provides estimates of the minimum number of days at  $54^{\circ}\text{C}/129.2^{\circ}\text{F}$  that would be required to obtain a minimum lethality of  $5.7 \log_{10}$ . The percent moisture described in Table 4 refers to the moisture content at the initial state, at the beginning of pasteurization. For example, a plant places one lot of dried egg whites into the hot room, with the initial percent moisture ranging from 6% to 8%. The dried egg whites would have to be held for the number of days associated with the lowest initial percent moisture level (6%) to meet the minimum lethality of  $5.7 \log_{10}$ ; the lot would have to be held for a minimum of 18 days. Table 4. Estimated Minimum Number of Days at  $54^{\circ}\text{C} / 129.2^{\circ}\text{F}$  to obtain at least a lethality of  $5.7\log_{10}$  for Salmonella spp. in Dried Egg White Product, Based on the Percent Moisture of product before pasteurization.

Percent (%)	Moisture	4	5	6	7	8
Days at $54^{\circ}\text{C}/129.2^{\circ}\text{F}$	26	22	18	15	13	

Likewise, as with liquid egg products, information from challenge studies, published studies, and computer modeling can be used to demonstrate that a process complies with the lethality performance requirements. Plants can also develop alternative lethality protocols for dried egg products based on yield-equivalent-weight (grams) sample which is the specific dried product yield to the liquid product. For example, if 100 mL of liquid egg white product produced approximately 13 grams of dried product, the alternative lethality value would be determined with respect to the 13 grams of dried product rather than 100 mL of liquid product. Post-Lethality Handling and Sanitation Eliminating and reducing pathogens during the lethality step is just part of controlling pathogens. After lethality, plants need to control their processing environment to prevent contamination of product with pathogens from product handling. Although Salmonella contamination in eggs is typically due to", "24 under processing it may also occur due to cross-contamination in the post-lethality environment. Lm contamination can also be a concern if products are exposed post-lethality. Although liquid egg product processes tend to have limited contact with food contact surfaces post-lethality, any opportunity for contact could result in the potential for post-lethality contamination. In one previous case of an Lm positive in a liquid egg product, the investigation identified that there was a leak in the closed pasteurization system that likely led to cross-contamination. In addition, liquid egg products may be exposed post-lethality during the drying process, such as with spray-dried or pan-dried egg product. Sanitary conditions in drying rooms need to be maintained to prevent contamination of the product during drying and collection. Furthermore, plants producing egg substitutes may add color additives to pasteurized egg whites. If this is the case, then the egg substitute product will need to be repasteurized. The addition of an ingredient post-pasteurization presents a hazard in which contamination could occur. Microbiological Sampling and Testing Program Egg product plants are required to conduct pathogen sampling to ensure their HACCP system is functioning adequately and that the products are free from the presence of Salmonella spp. and Lm. The amended 9 CFR 590.580 pathogen reduction standards testing regulation requires that: \u2022 Plants must test to determine that the production of egg products is in compliance with the Egg Products Inspection Act (EPIA) and the egg products inspection regulations. Egg products plants

are required to hold and maintain control of egg products that have been sampled and tested for public health hazards (e.g., *Salmonella* spp.) until the test results become available in accordance with 9 CFR 590.504. \u2022 To verify adequate pasteurization: \u2013 Pasteurized liquid, frozen, and dried egg products, and heat-treated dried egg whites must be sampled and analyzed for the presence of *Salmonella* spp.; \u2013 Testing must be performed in a manner sufficient to verify that the HACCP system is capable of eliminating *Salmonella* spp. and that the system is working; \u2013 As a safe harbor, the frequency of sampling and testing liquid and frozen egg products can be supported by skip lot testing, which is described in Appendix I: Safe Harbor Sampling Rates for *Salmonella* spp. Verification Testing for Liquid and Frozen Egg Products; \u2013 Samples must be analyzed for the presence of *Salmonella* spp. at a frequency and using a laboratory method (see section Microbiological Testing Method) that will ensure that the product is not adulterated (9 CFR 590.580(b)(2)); and \u2013 Samples must be collected from the final packaged form (9 CFR 590.580(b)(3)). \u2022 Plants are not required to analyze for the presence of Lm.", "25 Written Microbiological Sampling Program To meet the regulatory requirements, the plant must develop and implement a written microbiological sampling and testing program. At a minimum, the written sampling program must include: \u2022 A description of the sample collection procedures, including how random sampling is achieved, how the sample is collected, and how samples are handled to ensure sample integrity, and the name or title of the plant employees designated to collect the samples for testing; \u2022 A description of the analytical method used to test the samples and the name and location of the microbiology testing laboratory performing the analysis. The method used should be validated by a recognized independent testing body. Further information can be found in the FSIS Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory; \u2022 The microbiological organisms (e.g., *Salmonella* spp.) that the plant will test its samples for to monitor the effectiveness of its process control; \u2022 The locations within the plant\u2019s production process where samples are collected; \u2022 The frequency of sample collection; and \u2022 Scientific and technical documentation to support the design of the sampling program. Further information on scientific and technical documentation can be found in the FSIS Compliance Guideline HACCP Systems Validation.

Microbiological Testing Method Egg products plants should ensure that microbiological testing meets its food safety needs. A plant needs to determine whether sample analysis will be performed by an outside laboratory or in its own laboratory onsite (if available). The test method used should be validated for the target organisms and for the sample matrix being analyzed to ensure accuracy of the results. It should also be a method validated by a recognized independent body, such as the Association of Official Analytical Chemists (AOAC) Official Method of Analysis or International Organization for Standardization (ISO). FSIS has made available a list of Foodborne Pathogen Test Kits Validated by Independent Organizations for the detection of relevant foodborne pathogens (i.e., *Salmonella* spp., *Campylobacter*, Shiga toxin-producing *E. coli*, and *Listeria* spp., including Lm). These lists are intended to be informational and are not an endorsement or approval of any particular method, regardless of its inclusion in the list. A rapid screening method may be used if that method is validated for egg products and is approved by a recognized independent body or the FSIS Rapid Screening Method as described in the Microbiological Laboratory Guidebook. Presumptive positives from the rapid screening methods may", "26 be confirmed using an accepted culture method. If the rapid

screening method is not used, plants may use an accepted cultural method. Accepted culture methods include: \u2022 FSIS Microbiology Laboratory Guidebook, Chapter 4 \u2013 Identification of Salmonella from Meat, Poultry, Pasteurized Egg Products, and Siluriformes Products and Carcass and Environmental Sponges; or \u2022 FDA Bacteriological Analytical Method, Chapter 5 \u2013 Salmonella. For plants electing to use an outside laboratory, FSIS has made available the guidance, Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory. This guidance document should be particularly useful to plants when they are selecting a commercial or private laboratory to analyze microbiological samples. Plants should clearly communicate their needs to the testing laboratory and direct them to any necessary testing protocols or other guidance, including this document, on the FSIS Guidance Website. Plants that select a laboratory that does not apply appropriate testing methods or effective Quality Control\Quality Assurance (QC\QA) practices may not receive reliable or useful testing results. For plants electing to maintain their own microbiological testing laboratory, FSIS recommends that the laboratory be segregated from manufacturing areas and that access to the laboratory space be limited to prevent cross-contamination. If the plant will be testing for pathogens onsite, then they should follow requirements for Biosafety Level II laboratory operation as outlined in to ensure food safety and security. Recordkeeping Upon implementation of the sampling program, the plant must maintain records sufficient to document the implementation and monitoring of sample collection to comply with 9 CFR 590.580. It is recommended that records include the testing procedures, including support for the adequacy of the testing frequency, the test results, and other information, such as the: \u2022 Time, date, and location of the sample collection; \u2022 Sample collector\u2019s name; \u2022 Name or description of the product or sample source; and \u2022 Lot information and producer. All entries should be dated and initialed by the sample collector immediately upon completion of the entry. If an outside laboratory is used for testing, then these records should also include information, such as the date the sample was shipped to the laboratory for analysis. The outside laboratory should document the:","27 \u2022 Date received; \u2022 Condition of the sample upon receipt, including sample temperature, if applicable; \u2022 Date the analysis was started and completed; and \u2022 Analytical result. Test results should also be recorded and linked to the sample collection records by a sample number, form number, or some other unique identifier. The testing records: \u2022 Should be maintained in a way that ensures the integrity of the data; \u2022 May be maintained in an electronic format<sup>1</sup>, provided there are measures in place to ensure the security of the information; and \u2022 Should be readily accessible for review by the plant and FSIS IPP upon request<sup>2</sup>. Actions in Response to Test Results Plants are required to test egg products for the presence of Salmonella. In addition, FSIS will collect samples to analyze for Salmonella, Lm, and violative residues<sup>3</sup>. Plants are required to hold or maintain control of lots samples for Salmonella or Lm (meaning, hold the product at the plant or move the product to another location but keep the product under plant control). FSIS recommends but does not require that the plant hold or maintain control of lots sampled for violative residues. If a sample of an egg product tests positive for Salmonella spp., Lm, or a violative residue, FSIS considers the lot adulterated. The section Lotting Practices provides FSIS\u2019s guidance on defining lots. The plant is required to take corrective actions according to 9 CFR 417.3(a) or (b), depending on whether the plant controls the applicable hazard through its HACCP plan or

prevents it through a prerequisite program. \u2022 If product is positive for Salmonella spp. or Lm and the plant does not want to destroy the product, it can be reprocessed with the assurance that the egg product will be rendered free of detectable pathogens. 1 Acceptable electronic formats include scanned images of the original paper records, saved email attachments of laboratory results, etc. It is not acceptable to transcribe original official records to an alternate format, such as Excel, and then discarding the official record. 2 Accessibility of records for IPP review does not mean that plants are required to grant IPP access to the plant computer. 3 On September 21, 2016, FSIS began analyzing all domestic and imported pasteurized egg products that it analyzes for Salmonella spp. and for Lm (as a measure of environmental cleanliness). On September 27, 2018, FSIS began analyzing egg products for residues, such as pesticides.", "28 \u2022 If the product contains a violative residue, the product must be destroyed as reprocessing of the product will not remove the violative residue.

**Lotting Practices**

If either a plant sample or an FSIS sample is found positive for Salmonella or Lm, or found to contain violative levels of residues, the lot representing that sample (henceforth, sampled lot) is considered adulterated. When a sampled lot is found adulterated, multiple lots may be implicated. Proper lotting may be instrumental in reducing the impact of reprocessing product (for Salmonella or Lm positive product) or product recalls (for product that was not held). Lots should be designed so that if the sampled lot was found adulterated, the product in other lots can be deemed independent and not implicated. The sampled lot definition will differ based on microbiological versus chemical analyses. For microbiological analyses, a typical lot can be defined as one day\u2019s production (physically separated pasteurization run) of each type of product. A physically separated pasteurization run means that product has been separated from other production lots by cleaning and sanitizing, such that there is no potential contamination between separate lots of product. This may include cleaning the entire system (pasteurizer, clean-in-place (CIP) lines to packaging room, final packing\filling equipment). The following factors may be considered when FSIS determines what additional lots may be implicated if the sampled lot is found adulterated:

\u2022 Egg products plants are not required to perform a CIP procedure between each lot production. However, if egg products are stored or packaged using common pipelines and equipment that have not been cleaned and sanitized prior to establishing another individual lot, FSIS cannot recognize the product subsequently produced as a separated product lot;

\u2022 Plants may store multiple lots in a common area. The plant must maintain sanitary conditions to prevent contamination of the product(s) during storage and consider possible crosscontamination if products from different lots are stored in the same cooler, freezer, or dry egg products cool storage;

\u2022 Plants may define a lot differently based on the product group. For example, dried egg whites undergo a heat treatment, rather than a pasteurization run. In this case, the sampled lot would be all products present in the same heat treatment room at the same time;

\u2022 Because Salmonella can contaminate final egg products as a result of underprocessing, if one lot of egg product tests positive by FSIS and another lot of product received the same lethality treatment, scientific support is necessary to justify why the later lot should not be implicated; and

\u2022 In addition, some plants may store more than one lot of pasteurized product in one pasteurized egg product silo without conducting a cleanup between lots. When this occurs, FSIS would consider the sampled lot to consist of all co-mingled pasteurized runs.", "29 A plant may reduce its lot size when collecting a microbiological sample, or when FSIS is collecting a microbiological

sample, to facilitate holding the product, as long as the change does not interfere with collecting a representative sample. A reduction of lot size may be accomplished by breaking fewer eggs or pasteurizing smaller amounts of liquid eggs. FSIS is not aware of a mechanism to reduce the lot size of dried egg whites, as fewer boxes in the room would alter heat distribution and no longer reflect normal operations. For chemical analyses, FSIS generally considers the sampled lot to be all products originating from the same poultry farm. In general, poultry management practices result in the entire flock being treated at the same time rather than individually. Most plants may combine egg products from shell eggs coming from multiple poultry farms into a single production run. If this is the case, then all poultry farms represented in a violative-positive production run would be implicated unless the plant can supportably justify the exclusion of certain farms. Plants may reduce the number of farms representing the sampled lot when FSIS is collecting a residue sample. By reducing the number of farms comprising a lot, fewer farms would be implicated if the sample was found violative. In addition, plants may reduce implicated lots by using the sampled lot in only one product type and not combining the sampled lot with egg products from other farms until the results are received. It is up to the plant to determine the size of the lot. New Technologies The amended regulations provide more flexibility for plants to innovate with new technologies that can improve efficiency and food safety. However, there may still be occasion for plants to request a waiver or No Objection Letter (NOL) for certain innovations. Plants may submit a new technology notification and protocol through AskFSIS. In the request, plants should provide data to justify the new technology request. In addition, egg products plants may only use sanitizers and color additives that are recognized as safe and suitable under the conditions of its intended use (such as those listed in FSIS Directive 7120.1, Safe and Suitable Ingredients in Meat, Poultry, and Egg Products and those that are listed in 9 CFR 424.21(c)). If a plant chooses to develop and implement applications that incorporate such substances or ingredients that are not recognized as safe and suitable, then it must apply for an NOL through the new technology notification process. Key Point FSIS recommends that plants use the FSIS Compliance Guideline Procedures for New Technology Notifications and Protocol document, which provides guidance concerning the procedures for preparing and submitting a new technology notification and protocol to FSIS." "30 References 21 U.S.C. 1036 - Pasteurization and labeling of egg products at official plants. Retrieved from: <https://www.gpo.gov/fdsys/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21-chap15-sec1036.pdf> Baron, F., Nau, F., Gu\u00e9rin-Dubiard, C., Bonnassie, S., Gautier, M., Andrews, S., and Jan, S. 2016. Egg white versus *Salmonella Enteritidis*! A harsh medium meets a resilient pathogen. *Food Microbiology*. 53:82-93. Carter, T.C. 1968. Egg Quality: A Study of the Hen\u2019s Egg. National Academics. [CDC] Centers for Disease and Control. Listeria (Listeriosis). Retrieved from: <https://www.cdc.gov/listeria/faq.html> [CDC] Centers for Disease and Control. Salmonella. Retrieved from: <https://www.cdc.gov/salmonella/general/index.html> [CDC] Centers for Disease and Control. National Enteric Disease Surveillance: STEC Surveillance Overview. Retrieved from: <https://www.cdc.gov/ncezid/dfwed/PDFs/national-stec-surveillance-overview-508c.pdf> Eskin, N.A.M. and Shahidi, F. 2012. Biochemistry of Foods. Academic Press. [FDA] Food and Drug Administration. 2009. Final Rule: Prevention of *Salmonella Enteritidis* in Shell Eggs During Production, Storage, and Transportation (74 FRN 33030). Retrieved from: <https://www.gpo.gov/fdsys/pkg/FR-2009-07-09/pdf/E9-16119.pdf> [FSIS] Food Safety and

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"32 Appendix I: Safe Harbor Sampling Rates for *Salmonella* spp. Verification Testing for Liquid and Frozen Egg Products Liquid and Frozen Egg Products Sampling of lots for each product category will begin at the 100 percent frequency level unless or until a history of compliance has been established (60 consecutive lots are *Salmonella* spp. negative). For each category, one type of product will be identified for sampling each production day on a rotation basis. (Each product within a category does not need to be sampled every day). \u2022 100 percent sampling (No history of compliance for a category) \u2013 every lot must be sampled until 60 consecutive lots are found to be *Salmonella* spp. negative. \u2022 Level 1 \u2013 1 lot sampled for every 2 lots produced. \u2022 Level 2 \u2013 1 lot sampled for every 4 lots produced. \u2022 Level 3 \u2013 1 lot sampled for every 8 lots produced. Reducing the Sampling Frequency To reduce the sampling frequency:

1. From 100 percent to Level 1: 60 consecutive lots within a product category must be *Salmonella* spp. negative.
2. From Level 1 to Level 2: 60 sampled lots within the product category must be *Salmonella* spp. negative.
3. From Level 2 to Level 3: 60 sampled lots within the product category must be *Salmonella* spp. negative.

NOTE: Plants currently sampling under one of the three reduced sampling levels may maintain that level until sampling results indicate that an increase in sampling frequency is required or that the sampling frequency may be further reduced.

Action Required for *Salmonella* spp. Positive Lots

1. If a *Salmonella* spp. positive4 lot is found at any of the 3 reduced sampling levels, the plant must immediately begin sampling the entire product category at 100 percent.
2. See the section, titled \u201cMicrobiological Testing Methods\u201d for information on the expectations of test method choices.
3. Once 60 consecutive lots of that product are *Salmonella* spp. negative, sampling frequency may resume at the level attained before the positive was found.

However, if the product initially identified as *Salmonella* spp. positive is not sampled during those 60 consecutive lots, the next lot produced of that product must be sampled.

3. If 2 lots within the same category are found to be *Salmonella* spp. positive within a 12-month period, the plant must return to the 100 percent sampling level for that category.
- Once 60 consecutive lots are *Salmonella* spp. free, the plant must then satisfy the requirements for both Level 1 and Level 2 before moving to Level 3.

Required Records

The egg products inspection regulations require a plant to maintain records for each lot of product produced. Records must be maintained for at least 1 year for refrigerated products and 2 years for frozen, preserved, or shelf-stable products and must be available to FSIS program employees upon request. Records must contain the following information:

- \u2022 Type of product, category, and lot number of each product lot;
- \u2022 Number, net weight, and type of containers in each lot, (e.g., 125 30-pound can; 250 30-pound cases (6 5-pound cartons));
- \u2022 For each lot sampled, the lot

number, date sampled, number of samples collected, portion of the lot from which the sample(s) was taken (i.e., container number, pallet number, etc.) and the sampling level for that category of product; \u2022 Individual sample results; and the \u2022 Name and location of the recognized laboratory performing the analyses.", "34 Figure I.A. Egg Products Sampling Flow Diagram NOTE: Plants without a sampling history or plants producing a new product category begin sampling at the 100% sampling frequency. Plants currently at one of the three reduced frequencies may maintain that frequency until sampling results indicate that an increase in sampling frequency is required, or that the sampling frequency may be further reduced. 100% Sampling 60 Consecutive Lots Plants with no sampling history or that receive 2 or more positive results Level 1 - 1 of 2 Lots 60 Consecutive Lots 100% Sampling of 60 Consecutive Lots Level 2 - 1 of 4 Lots 60 Consecutive Lots 100% Sampling of 60 Consecutive Lots Level 3 - 1 of 8 Lots All Sampled Lots 100% Sampling of 60 Consecutive Lots Any Positive Any Positive Any Positive Second Positive Second Positive Second Positive", "35 Appendix II: New Technology Pasteurization and Freezing Time and Temperature Tables Under the former regulations, plants had submitted protocols to implement alternate procedures and waive the prescriptive regulatory requirement. The protocols from those waivers and NOLs have been incorporated in the tables below as additional options for plants to use as safe harbors. The following tables include various product formulations for egg whites, whole egg, egg yolk, and enzyme modified egg products and their respective approved pasteurization time and temperature parameters, as well as alternate freezing parameters.", "36 Table II.A. Acceptable Safe Harbor Pasteurization Time and Temperature Combinations for Achieving Minimal Lethality Performance for Salmonella spp. Derived from New Technology Waivers That Can Be Used for Various Egg White Products Liquid Egg White Formulations (11-13% Solids) Pasteurization Temperature \ Time Egg Whites 99.96%; Anti-foam 0.04% 135\u00b0F \ 3.5 min Egg Whites 99.7-99.9%; Non-Egg Ingredients 0.1-0.3% (e.g., Solvent; Thickener, Stabilizer) 134\u00b0F \ 3.5 min or 126\u00b0F \ 3.6 min, with hydrogen peroxide Egg Whites 99.3-99.4%; Non-Egg Ingredients 0.6-0.7% (e.g., Emulsifier; Defoamer; Flavor; Vitamin) 135\u00b0F \ 3.5 min Table II.B. Acceptable Safe Harbor Pasteurization Time and Temperature Combinations for Achieving Minimal Lethality Performance for Salmonella spp. Derived from New Technology Waivers That Can Be Used for Various Whole Egg or Yolk with Added Egg Whites or Other Ingredients Liquid Whole Egg \ Yolk with Added Egg Whites or Other Ingredients (14-22% Egg Solids) Pasteurization Temperature \ Time Whole Egg 16%; Egg Whites 64.4%; Water 16.5%; Non-Fat Dairy 2%; Other Non-Egg Ingredients <1.1% (e.g., Thickener\Stabilizer, Preservative; pH Buffer; Colorant) 149\u00b0F \ 3.5 min Whole Egg 46-53%; Egg Whites 47-53% 140\u00b0F \ 3.5 min Whole Egg 21-77%; Egg Whites 3.7-77.4%; Water 0-12.14%; Other Non-Egg Ingredients <1-5.13 (e.g., Thickener\Stabilizer; Solvent; pH Buffer\Preservative; Dairy; Salt; Colorant; Lipid, Vitamin\Colorant) 142\u00b0F to 144\u00b0F \ 3.5 min Whole Egg 78-95%; Egg Whites 0-2.58%; Water 0-18%; Non-Egg Ingredients 3-4% (e.g., Non-Fat Dairy; pH Buffer\Preservative; Salt; Solvent; Thickener\Stabilizer; Vitamin) 149\u00b0F \ 2.5 minutes Whole Egg 78-80%; Water 19-21%; Non-Egg Ingredients 0.56-0.85% (e.g., Salt; Thickener\Stabilizer; Solvent; pH Buffer\Preservative; Colorant, Flavor) 142\u00b0F \ 3.5 min Egg Yolk 19-20%; Egg Whites 79-81% 140\u00b0F \ 3.5 min", "37 Table II.C. Acceptable Safe Harbor Pasteurization Time and Temperature Combinations for Achieving Minimal Lethality Performance for Salmonella spp. Derived from New Technology Waivers That Can Be Used for Various Whole Egg Products Liquid

Whole Egg Formulations (23-28% Solids) Pasteurization Temperature \ Time Pasteurized Whole Egg 66.54%; Sugar 32.66%; Other Non-Egg Ingredients 0.8% (e.g., Thickener\Stabilizer; Solvent\Preservative\Sweetener; pH Buffer; Binder) Re-Pasteurize at 155\u00b0F for 4 minutes Whole Egg 67-69%; Egg Whites 11-27%; Water 0-19%; Other Non-Egg Ingredients 0.5-6% (e.g., Lipid; Thickener\Stabilizer; Emulsifier; Dairy; Salt; pH Buffer; Preservative; Stabilizer; Flavor) 144\u00b0F \ 3.5 minutes Whole Egg 94-99%; Non-Egg Ingredients 1-6% (e.g., Water; Non-Fat Dairy; pH Buffer\Preservative; Thickener\Stabilizer; Emulsifier; pH Buffer\Stabilizer; Vitamin) 144\u00b0F to 149\u00b0F \ 3.5 minutes Table II.D. Acceptable Safe Harbor Pasteurization Time and Temperature Combinations for Achieving Minimal Lethality Performance for Salmonella spp. Derived from New Technology Waivers That Can Be Used for Various Egg Yolk Products Liquid Egg Yolk Product Formulations (43-47% Egg Solids) Pasteurization Temperature \ Time Egg Yolk 99.95%; Enzyme 0.05% 152\u00b0F \ 3.5 minutes Egg Yolk 99.67%; Peroxide 0.22%; Glucose Oxidase 0.11% 142\u00b0F\3.5 minutes for liquid, 157\u00b0F \ 2 hours in hot room Egg Yolk 95-99.99%; Non-Egg Ingredients 0-5% (e.g., Salt, Binder; Enzyme) 134.6\u00b0F \ minimum of 5 hours; not to exceed 24 hours Egg Yolk 93-99.5%; Salt 2.5-4.1%; Non-Egg Ingredients 2% (e.g., Thickener\Stabilizer, Enzyme) 151\u00b0F to 152\u00b0F \ 3.5 minutes Egg Yolk 90.83%; Salt 2.5%; Other Non-Egg Ingredients 2% (e.g., Sweetener\Thickener; Enzyme) 149F\u00b0/\ 3.5 minutes Egg Yolk 89.95%; Salt 10%; Enzyme 0.05% 150\u00b0F \ 3.5 minutes Pasteurized Whole Egg 73-74%; Non-Egg Ingredients 26-27% (Thickener\Emulsifier; Binder; Salt; Water) \*This product is only 38% solids due to the difference between egg product and the replacement solids Re-Pasteurize at 148\u00b0F \ 3.5 minutes Egg Yolk 80%; Salt or Sugar 20% 146\u00b0F \ 3.5 minutes or 144\u00b0F \ 6.2 minutes", "38 Table II.E. Acceptable Safe Harbor Pasteurization Time and Temperature Combination for Achieving Minimal Lethality Performance for Salmonella spp. Derived from New Technology Waivers That Can Be Used for Enzyme Modified Egg Products Egg Product Pasteurization Time \ Temperature Enzyme Modified Egg Products Product is held at a minimum temperature of 130\u00b0F and not over a maximum of 140\u00b0F during batch pasteurization for a minimum of 5 hours Table II.F. Acceptable Safe Harbor Time and Temperature Combinations for Freezing Derived from New Technology Waivers That Can Be Used for All Liquid Egg Products Method Time \ Temperature Requirement Freezing\* Extends the freezing requirement of 60 hours or reduced to a temperature of 10\u00b0F from the time of pasteurization to 144 hours for liquid egg products \*Product shall not be stored in the pasteurized silo more than 36 hours Freezing Extends the freezing requirement of 60 hours from the time of pasteurization to 144 hours for liquid egg products Freezing Allows for non-pasteurized egg products which are to be frozen to be solidly frozen or reduced to a temperature of 10\u00b0F or lower within 144 hours from time of breaking", "39 Appendix III: Pasteurization Time and Temperature Tables To provide additional safe harbors for the pasteurization of egg products, FSIS calculated time and temperature combinations to achieve a specific log reduction in egg whites at four different pH, five different whole egg formulations, and five different egg yolk formulations. Table III.A. Time and Temperature Combinations for Achieving Minimal Lethality Performance for Salmonella spp. That Can Be Used for Various Liquid Egg Whites to Obtain a 5.7-log<sub>10</sub> Lethality Degrees Fahrenheit (\u00b0F) Degrees Celsius (\u00b0C) Plain Egg White, pH = 7.8 Plain Egg White, pH = 8.2 Plain Egg White, pH = 8.8 Plain Egg White, pH = 9.3 127.5 53.1 --- 36.45 minutes 128.0 53.3 --- 31.26 minutes 128.5

53.6 --- --- 26.81 minutes 129.0 53.9 --- --- 23.00 minutes 129.5 54.2 --- --- 19.72  
minutes 130.0 54.4 --- --- 38.32 minutes 16.92 minutes 130.5 54.7 --- --- 33.27 minutes 14.91  
minutes 131.0 55.0 --- 36.70 minutes 28.72 minutes 12.45 minutes 131.5 55.3 --- 31.07 minutes  
24.62 minutes 10.68 minutes 132.0 55.6 32.16 minutes 26.12 minutes 20.95 minutes 9.16  
minutes 132.5 55.8 27.02 minutes 21.80 minutes 17.69 minutes 7.85 minutes 133.0 56.1 22.56  
minutes 18.08 minutes 14.82 minutes 6.74 minutes 133.5 56.4 18.71 minutes 14.88 minutes  
12.33 minutes 5.78 minutes 134.0 56.7 15.43 minutes 12.18 minutes 10.19 minutes 4.96  
minutes 134.5 56.9 12.64 minutes 9.90 minutes 8.36 minutes 4.25 minutes 135.0 57.2 10.30  
minutes 8.00 minutes 6.81 minutes 3.65 minutes 135.5 57.5 7.11 minutes 6.42 minutes 5.52  
minutes 3.13 minutes 136.0 57.8 5.65 minutes 5.13 minutes 4.44 minutes 2.68 minutes 136.5  
58.1 4.47 minutes 4.08 minutes 3.56 minutes 2.30 minutes 137.0 58.3 3.51 minutes 3.22  
minutes 2.83 minutes 1.98 minutes 137.5 58.6 2.75 minutes 2.54 minutes 2.24 minutes 1.69  
minutes 138.0 58.9 2.15 minutes 1.99 minutes 1.77 minutes 87 seconds 138.5 59.2 1.67  
minutes 93 seconds 84 seconds 75 seconds 139.0 59.4 78 seconds 72 seconds 65 seconds 65  
seconds 139.5 59.7 60 seconds 56 seconds 51 seconds 56 seconds 140.0 60.0 47 seconds 44  
seconds 39 seconds 48 seconds 140.5 60.3 36 seconds 33 seconds 31 seconds 41 seconds 141.0  
60.6 27 seconds 26 seconds 24 seconds 35 seconds 141.5 60.8 21 seconds 20 seconds 18  
seconds 30 seconds 142.0 61.1 --- --- 26 seconds 142.5 61.4 --- --- 23 seconds 143.0 61.7 ---  
--- 19 seconds 143.5 61.9 --- --- 17 seconds 144.0 62.2 --- --- 14 seconds 144.5 62.5 ---  
--- 145.0 62.8 --- --- 145.5 63.1 --- --- No applicable time and temperature  
combination to meet desired lethality performance standard for liquid egg white  
products", "Table III.B. Time and Temperature Combinations for Achieving Minimal Lethality  
Performance for *Salmonella* spp. That Can Be Used for Various Liquid Whole Egg to Obtain 6.0-  
 $\log_{10}$  Lethality Degrees Fahrenheit (\u00b0F) Degree s Celsius (\u00b0C) Plain Whole Egg  
Scrambled Egg Mix USDA (30.27% Solids) 1 Scrambled Egg Mix USDA (22.43% Solids) 2  
Comments Degrees Fahrenheit (\u00b0F) Degrees Celsius (\u00b0C) 10% Salt Whole Egg 10%  
Sugar Whole Egg 133.0 56.1 --- 29.42 minutes 1 Scrambled Egg Mix USDA (30.27% Solids)  
Ingredients: Whole egg \u2013 24.2% solids; nonfat dry milk \u2013 95% solid; vegetable oil,  
salt, and water 2 Scrambled Egg Mix USDA (22.43% Solids) \ Scrambled egg mix, pH 6.5 to 6.8  
Ingredients: Whole egg \u2013 24.2% solids; nonfat dry milk \u2013 95% solid; xanthan gum,  
citric acid, and water --- No applicable time and temperature combination to meet desired  
lethality performance for whole egg products 136.0 57.8 --- 26.43 minutes 133.5 56.4 ---  
25.04 minutes 136.5 58.1 --- 21.13 minutes 134.0 56.7 --- 13.91 minutes 21.32 minutes 137.0  
58.3 --- 16.99 minutes 134.5 56.9 --- 12.45 minutes 18.15 minutes 137.5 58.6 --- 13.74 minutes  
135.0 57.2 28.82 minutes 11.15 minutes 15.47 minutes 138.0 58.9 --- 11.18 minutes 135.5 57.5  
25.22 minutes 10.00 minutes 13.18 minutes 138.5 59.2 --- 9.15 minutes 136.0 57.8 22.07  
minutes 8.97 minutes 11.23 minutes 139.0 59.4 --- 7.53 minutes 136.5 58.1 19.32 minutes 8.05  
minutes 9.58 minutes 139.5 59.7 --- 6.23 minutes 137.0 58.3 16.91 minutes 7.23 minutes 8.17  
minutes 140.0 60.0 --- 5.18 minutes 137.5 58.6 14.80 minutes 6.50 minutes 6.98 minutes 140.5  
60.3 --- 4.33 minutes 138.0 58.9 12.95 minutes 5.84 minutes 5.96 minutes 141.0 60.6 25.67  
minutes 3.64 minutes 138.5 59.2 11.34 minutes 5.26 minutes 5.09 minutes 141.5 60.8 19.06  
minutes 3.07 minutes 139.0 59.4 9.92 minutes 4.73 minutes 4.35 minutes 142.0 61.1 14.64  
minutes 2.60 minutes 139.5 59.7 8.69 minutes 4.26 minutes 3.72 minutes 142.5 61.4 11.56  
minutes 2.22 minutes 140.0 60.0 7.60 minutes 3.84 minutes 3.18 minutes 143.0 61.7 9.34

minutes 1.90 minutes 140.5 60.3 6.65 minutes 3.46 minutes 2.73 minutes 143.5 61.9 7.69  
minutes 1.63 minutes 141.0 60.6 5.82 minutes 3.12 minutes 2.34 minutes 144.0 62.2 6.43  
minutes 85 seconds 141.5 60.8 5.10 minutes 2.82 minutes 2.00 minutes 144.5 62.5 5.44  
minutes 74 seconds 142.0 61.1 4.46 minutes 2.55 minutes 1.72 minutes 145.0 62.8 4.65  
minutes 65 seconds 142.5 61.4 3.90 minutes 2.30 minutes 89 seconds 145.5 63.1 4.01 minutes  
56 seconds 143.0 61.7 3.42 minutes 2.08 minutes 77 seconds 146.0 63.3 3.49 minutes 50  
seconds 143.5 61.9 2.99 minutes 1.88 minutes 66 seconds 146.5 63.6 3.05 minutes 44 seconds  
144.0 62.2 2.62 minutes 1.70 minutes 57 seconds 147.0 63.9 2.67 minutes 39 seconds 144.5  
62.5 2.29 minutes 93 seconds 49 seconds 147.5 64.2 2.36 minutes 35 seconds 145.0 62.8 2.01  
minutes 84 seconds 42 seconds 148.0 64.4 2.08 minutes 30 seconds 145.5 63.1 1.76 minutes 76  
seconds 36 seconds 148.5 64.7 1.84 minutes 27 seconds 146.0 63.3 93 seconds 69 seconds 32  
seconds 149.0 65.0 1.63 minutes 24 seconds 146.5 63.6 81 seconds 62 seconds 27 seconds  
149.5 65.3 87 seconds 22 seconds 147.0 63.9 71 seconds 57 seconds 24 seconds 150.0 65.6 78  
seconds 20 seconds 147.5 64.2 62 seconds 51 seconds 21 seconds 150.5 65.8 69 seconds 18  
seconds 148.0 64.4 54 seconds 47 seconds 18 seconds 151.0 66.1 62 seconds 17 seconds 148.5  
64.7 48 seconds 42 seconds 16 seconds 151.5 66.4 55 seconds --- 149.0 65.0 42 seconds 38  
seconds --- 152.0 66.7 49 seconds --- 149.5 65.3 36 seconds 35 seconds --- 152.5 66.9 44  
seconds --- 150.0 65.6 32 seconds 32 seconds --- 153.0 67.2 39 seconds --- 150.5 65.8 28  
seconds 29 seconds --- 153.5 67.5 35 seconds --- 151.0 66.1 25 seconds 26 seconds --- 154.0  
67.8 31 seconds --- 151.5 66.4 21 seconds 24 seconds --- 154.5 68.1 27 seconds --- 152.0 66.7 19  
seconds 22 seconds --- 155.0 68.3 24 seconds --- 152.5 66.9 17 seconds 20 seconds --- 155.5  
68.6 22 seconds --- 153.0 67.2 --- 18 seconds --- 156.0 68.9 20 seconds --- 156.5 69.2 18 seconds  
--- 157.0 69.4 16 seconds --- 157.5 69.7 15 seconds --- 158.0 70.0 13 seconds ---", "Table III.C.

Time and Temperature Combinations for Achieving Minimal Lethality Performance for  
Salmonella spp. That Can Be Used for Various Liquid Egg Yolk to Obtain a 6.2-log<sub>10</sub> Lethality  
Degrees Fahrenheit (\u00b0F) Degrees Celsius (\u00b0C) Plain Egg Yolk 10% Salt Egg Yolk 10%  
Sugar Egg Yolk Degrees Fahrenheit (\u00b0F) Degrees Celsius (\u00b0C) Fortified Egg Yolk  
\u201cTex\u201d (48.84% Solids)1 Fortified Egg Yolk \u201cTex\u201d (32.49% Solids)2  
Comments 138.0 58.9 --- 22.77 minutes 132.5 55.8 --- 25.56 minutes 1 Fortified Egg Yolk  
\u201cTex\u201d (48.84% Solids) Ingredients: Egg yolk \u2013 43% solid; 80% solid corn syrup,  
salt, and water 2 Fortified Egg Yolk \u201cTex\u201d (32.49% Solids) Ingredients: Whole egg  
\u2013 24.2% solids; egg yolk \u2013 43% solid; 36 DE corn syrup solids, salt, and water --- No  
existing time and temperature combination to meet desired lethality performance standard for  
egg yolk products 138.5 59.2 --- 18.57 minutes 133.0 56.1 --- 22.74 minutes 139.0 59.4 17.81  
minutes --- 15.24 minutes 133.5 56.4 --- 20.07 minutes 139.5 59.7 16.31 minutes --- 12.57  
minutes 134.0 56.7 --- 17.71 minutes 140.0 60.0 14.93 minutes 20.62 minutes 10.43 minutes  
134.5 56.9 --- 15.63 minutes 140.5 60.3 13.66 minutes 17.87 minutes 8.70 minutes 135.0 57.2 --  
- 13.79 minutes 141.0 60.6 12.51 minutes 15.53 minutes 7.29 minutes 135.5 57.5 --- 12.17  
minutes 141.5 60.8 11.45 minutes 13.53 minutes 6.14 minutes 136.0 57.8 --- 10.74 minutes  
142.0 61.1 10.48 minutes 11.81 minutes 5.20 minutes 136.5 58.1 --- 9.48 minutes 142.5 61.4  
9.60 minutes 10.34 minutes 4.41 minutes 137.0 58.3 --- 8.37 minutes 143.0 61.7 8.78 minutes  
9.07 minutes 3.77 minutes 137.5 58.6 --- 7.39 minutes 143.5 61.9 8.04 minutes 7.97 minutes  
3.23 minutes 138.0 58.9 --- 6.53 minutes 144.0 62.2 7.36 minutes 7.02 minutes 2.78 minutes  
138.5 59.2 --- 5.76 minutes 144.5 62.5 6.74 minutes 6.19 minutes 2.40 minutes 139.0 59.4 ---

5.09 minutes 145.0 62.8 6.17 minutes 5.47 minutes 2.08 minutes 139.5 59.7 --- 4.49 minutes  
145.5 63.1 5.65 minutes 4.84 minutes 1.81 minutes 140.0 60.0 23.66 minutes 3.97 minutes  
146.0 63.3 5.17 minutes 4.29 minutes 95 seconds 140.5 60.3 20.48 minutes 3.51 minutes 146.5  
63.6 4.73 minutes 3.81 minutes 83 seconds 141.0 60.6 17.73 minutes 3.10 minutes 147.0 63.9  
4.33 minutes 3.39 minutes 74 seconds 141.5 60.8 15.35 minutes 2.73 minutes 147.5 64.2 3.96  
minutes 3.01 minutes 65 seconds 142.0 61.1 13.28 minutes 2.42 minutes 148.0 64.4 3.63  
minutes 2.69 minutes 57 seconds 142.5 61.4 11.50 minutes 2.13 minutes 148.5 64.7 3.32  
minutes 2.40 minutes 51 seconds 143.0 61.7 9.95 minutes 1.89 minutes 149.0 65.0 3.04  
minutes 2.14 minutes 46 seconds 143.5 61.9 8.61 minutes 1.67 minutes 149.5 65.3 2.78  
minutes 1.91 minutes 41 seconds 144.0 62.2 7.46 minutes 89 seconds 150.0 65.6 2.55 minutes  
1.71 minutes 37 seconds 144.5 62.5 6.45 minutes 78 seconds 150.5 65.8 2.33 minutes 93  
seconds 33 seconds 145.0 62.8 5.59 minutes 69 seconds 151.0 66.1 2.14 minutes 83 seconds 30  
seconds 145.5 63.1 4.84 minutes 62 seconds 151.5 66.4 1.95 minutes 75 seconds 28 seconds  
146.0 63.3 4.19 minutes 54 seconds 152.0 66.7 1.79 minutes 67 seconds 26 seconds 146.5 63.6  
3.62 minutes 48 seconds 152.5 66.9 1.64 minutes 60 seconds 24 seconds 147.0 63.9 3.14  
minutes 42 seconds 153.0 67.2 90 seconds 54 seconds 22 seconds 147.5 64.2 2.71 minutes 38  
seconds 153.5 67.5 83 seconds 49 seconds 21 seconds 148.0 64.4 2.35 minutes 33 seconds  
154.0 67.8 76 seconds 44 seconds 19 seconds 148.5 64.7 2.03 minutes 30 seconds 154.5 68.1  
69 seconds 40 seconds 18 seconds 149.0 65.0 1.76 minutes 26 seconds 155.0 68.3 63 seconds  
36 seconds 17 seconds 149.5 65.3 92 seconds 23 seconds 155.5 68.6 58 seconds 33 seconds 16  
seconds 150.0 65.6 80 seconds 21 seconds 156.0 68.9 53 seconds 29 seconds 16 seconds 150.5  
65.8 69 seconds 18 seconds 156.5 69.2 49 seconds 27 seconds --- 151.0 66.1 60 seconds 16  
seconds 157.0 69.4 45 seconds 24 seconds --- 151.5 66.4 52 seconds --- 157.5 69.7 41 seconds  
22 seconds --- 152.0 66.7 45 seconds --- 158.0 70.0 38 seconds 20 seconds --- 152.5 66.9 39  
seconds --- 158.5 70.3 35 seconds 18 seconds --- 153.0 67.2 33 seconds --- 159.0 70.6 32  
seconds 17 seconds --- 153.5 67.5 29 seconds --- 159.5 70.8 29 seconds 15 seconds --- 154.0  
67.8 26 seconds --- 160.0 71.1 27 seconds 14 seconds --- 154.5 68.1 22 seconds --- 160.5 71.4 24  
seconds --- --- 155.0 68.3 19 seconds --- 155.5 68.6 17 seconds --- 156.0 68.9 14 seconds ---","42  
http:\askfsis.custhelp.com\ FSIS\USDA  
www.fsis.usda.gov"]},{"file\_name":"FSIS\_GD\_2020\_0006","title":"Egg Products Hazards and  
Controls Guide","num":"FSIS-GD-2020-  
0006","id":"d302b52facababd0bbb400b5e29482d1401073d45e5a418d1801f2a017cc537b","co  
rpus":"fsis\_guidelines","source\_page\_url":"https:\www.fsis.usda.gov\policy\fsis-  
guidelines","url":"https:\www.fsis.usda.gov\sites\default\files\media\_file\2021-  
01\egg-products-hazards-controls-  
guide.pdf","type":"pdf","n\_pages":26,"word\_count":4462,"text\_by\_page":[{"Egg Products  
Hazards and Controls Guide Food Safety and Inspection Service United States Department of  
Agriculture September 9, 2020","Table of Contents  
Introduction.....1  
Quick Reference Table of Process Steps in Alphabetical Order by Product Category.....2  
Suggested General VerificationQuestions for Most Process Steps.....3  
Process Steps, Potential Hazards, and Frequently Used Controls.....4  
i","Introduction FSIS developed this Guide to help FSIS personnel conduct a systematic  
evaluation of processes used in the production of egg products. The Guide identifies relevant

process steps, lists potential hazards for each of these process steps, and cites controls frequently used by processors to address these hazards. Using this Guide, FSIS personnel should be able to verify more effectively that an egg products plant's food safety system is adequately identifying and controlling the hazards associated with its operations. This Guide should be used with the following principles in mind:

- This Guide is not intended to suggest where Critical Control Points (CCPs) should be incorporated in a plant's HACCP system.
- The statement "common hazard" in the Guide is based on the information that is currently available and may change based on research or outbreak and recall investigations.
- Unforeseen hazards and the results of HACCP system reassessments may also identify a possible hazard in a process step where none was previously identified.
- The potential hazards listed may not be the only possible hazards for a particular process step.
- The entries in the "Frequently Used Controls" column are not the only valid controls that plants may include in their HACCP systems for a particular hazard.
- A set of suggested general and process-specific verification questions are included in this Guide after each process step listed. These questions are intended to guide FSIS personnel when evaluating a plant's HACCP system and specifically its process steps and to trigger additional questions. It is important for FSIS personnel to realize that these questions are not meant to be all-inclusive, but to provide examples of the types of questions that may arise when verifying the adequacy of a plant's HACCP system and regulatory compliance.
- This Guide should also be useful to plant personnel, particularly those in small and very small plants. However, the potential hazards and frequently used controls listed in this Guide are neither the only possible hazards nor the only applicable process controls available to a plant operator. Each plant must design its HACCP system to address those hazards that are reasonably likely to occur in its own specific production processes.

The Guide consists of the following major sections:

- Quick reference table of process steps in alphabetical order for the most common process steps in the production of egg products;
- General verification questions for most process steps; and
- A listing of individual process steps with currently identified potential hazards and frequently used controls.

1", "Quick Reference Table of Process Steps in Alphabetical Order by Product Category Process Steps Page No. Raw\NRTE RTE Not Shelf Stable RTE Shelf Stable Blending of dry ingredients into dried egg product 19 \u2022 Breaking and separating of eggs 10 \u2022 Classification and sorting, handling, and transfer of shell eggs 8 \u2022 Defrosting 12 \u2022 \u2022 Desugaring\fermentation 15 \u2022 \u2022 Egg washing\sanitizer 9 \u2022 Formulation\mixing\homogenization\reconstitution of dried product 13 \u2022 \u2022 Freezing 20 \u2022 \u2022 Heat treatment of dried egg whites 17 \u2022 Liquid egg cooling and holding 11 \u2022 \u2022 Packaging\repackaging 22 \u2022 \u2022 \u2022 Pasteurization 14 \u2022 Receiving and storage of packaging materials and non-egg ingredients 7 \u2022 \u2022 \u2022 Receiving and storage of raw\NRTE liquid egg products 5 \u2022 Receiving and storage of RTE egg products (liquid\dried) 6 \u2022 \u2022 Receiving and storage of shell eggs prior to use 4 \u2022 Rework 18 \u2022 \u2022 \u2022 Shipping 24 \u2022 \u2022 \u2022 Sifting of dried egg products 21 \u2022 \u2022 Spray\pan drying (yellow\white) 16 \u2022 Storage, handling and loading of egg product after packaging and prior to shipping 23 \u2022 \u2022 \u2022 2", "Suggested General Verification Questions for Most Process Steps The following set of general questions should be used by FSIS personnel when evaluating and assessing the adequacy of a plant's hazard analysis and its decision

making for each process step relative to potential hazards, controls for identified hazards, monitoring and recordkeeping. This Guide also includes more specific questions for each process step under the Process Steps, Potential Hazards, and Frequently Used Controls section that FSIS personnel can use to assist with their evaluation of the adequacy of a plant's HACCP system. Has the plant included this process step in its flow chart and hazard analysis? Does the plant have a prerequisite program that addresses this process step? Has the plant identified any hazards associated with this process step? Is this process step a CCP? Is the plant following procedures to eliminate or reduce any identified hazard? Can the plant support that the hazard is not reasonably likely to occur (NRLTO)? Did the plant validate the control methods, including preventive measures and prerequisite programs, for this hazard? Does the plant have in-plant validation data for 90 calendar days to support that the control is working as intended? (NOTE: The documentation for in-plant validation from small and very small establishments may contain data from greater than 90 calendar days if a request is granted in writing by the district office for additional calendar days to gather records to cover at least 13 production days.)

Is the plant following all procedures (i.e., prerequisite or other programs) identified in its hazard analysis? Does the plant maintain records associated with this process step? Do records contain information that indicates a reassessment of the hazard analysis necessary? Are records made available to FSIS? Is the equipment used clean, sanitary, and well maintained?

**3", "Process Steps, Potential Hazards, and Frequently Used Controls Process Step Potential Hazards Frequently Used Controls Receiving and storage of shell eggs prior to use Note:** Shells eggs intended for breaking must be transported and stored at or below 45°F ambient temperature beginning 36 hours after time of lay (21 CFR 118.4(e)).

**Biological\u2014Presence and outgrowth of Salmonella (interior and exterior of egg)**

**Pre-harvest:** Eggs handled by the source plant or farm in a manner that minimizes the possibility of pathogen contamination or outgrowth prior to acceptance (e.g., quality assurance programs, letters of guarantee, product temperature tracking, and delivery verification systems). Proper sanitation of equipment (e.g., egg conveyor systems or containers/flats) for in or off-line systems to reduce contamination. Shell eggs held at temperatures for durations that will minimize pathogen growth if contamination is present. This includes the time and temperature held prior to receipt by the processor.

**Chemical\u2014Residues (e.g., pesticides, antibiotics)**

**Physical\u2014No common hazard Suggested verification questions:** 1. Are shell eggs received held under refrigeration? 2. Are the shell eggs stored in a manner that protects them from environmental contamination? 3. How does the plant ensure residues are not present in shell eggs above legal tolerances?

**4", "Process Step Potential Hazards Frequently Used Controls Receiving and storage of raw\NRTE liquid egg products**

**Biological\u2014Presence and outgrowth of Salmonella**

**Product properly handled prior to acceptance (e.g., letters of guarantee, product temperature records).**

**\u2022 Proper receiving temperatures that will minimize pathogen growth.**

**\u2022 Maintain package and product integrity.**

**Chemical\u2014Allergens, residues (e.g., Letters of guarantee; approved pesticides, antibiotics) supplier program.**

**\u2022 Proper storage to prevent crosscontamination of allergen-free products.**

**\u2022 Separate equipment.**

**\u2022 Allergens properly identified in the ingredients statement on the finished product label.**

Physical\u2014Foreign material (e.g., metal, plastic, rubber) \u2022 Visual inspection; proper storage; sieves, filters. Suggested verification questions: 1. Are raw\NRTE liquid egg products received and held under refrigeration to preclude the growth of pathogens? 2. Is container integrity maintained to protect the raw\NRTE liquid egg products from environmental contamination such as dust, moisture, or other physical contaminants? 3. Does the plant address foreign material in its HACCP system? 4. Does the plant receive inedible egg products? If yes, are they handled in a manner that ensures adequate segregation and are inventory controls maintained? 5. Does the plant maintain communication with its suppliers concerning formulation changes or its suppliers\u2019 allergen control programs? 6. If the finished product contains non-egg allergens, does the final product label declare these allergens? 7. How does the plant ensure residues are not present in raw\NRTE liquid egg products above legal tolerances? 5", "Process Step Potential Hazards Frequently Used Controls Receiving and storage of RTE egg products (liquid\dried) Biological\u2014Potential for contamination with Listeria monocytogenes and Salmonella in post-lethality exposed RTE egg products \u2022 Proper sanitation (e.g., separation of raw and RTE product, product or environmental testing). \u2022 Product handled in a sanitary manner during storage and processing (e.g., product temperature, minimize cross-contamination). \u2022 Keep product at time\temperature combinations that will minimize pathogen growth. \u2022 Maintain package and product integrity; letters of guarantee. Chemical\u2014Allergens, residues (e.g., \u2022 Letters of guarantee; approved pesticides, antibiotics) supplier program. \u2022 Proper storage to prevent cross-contamination of allergen-free products. \u2022 Separate equipment. \u2022 Allergens properly identified in the ingredients statement on the finished product label.

Physical\u2014Foreign material (e.g., metal, plastic, rubber) \u2022 Visual inspection; proper storage; sieves, filters. Suggested verification questions: 1. Are the RTE egg products (liquid) received held under refrigeration or frozen to preclude the growth of pathogens? 2. Is container integrity maintained to protect these types of egg products from environmental contamination such as dust, moisture, or other physical contaminants? 3. Does the plant have a sanitation program to address Listeria monocytogenes and Salmonella in the post-lethality exposed environment? 4. If the product contains non-egg allergens, does the final product label declare all allergens? 5. Does the plant address foreign material in its HACCP system? 6. Does the plant have controls to prevent cross-contamination of RTE egg products with raw (i.e., unpasteurized) product? 7. Does the plant maintain communication with its suppliers concerning formulation changes or its suppliers\u2019 allergen control programs? 8. How does the plant ensure residues are not present in RTE egg products above legal tolerances? 6", "Process Step Potential Hazards Frequently Used Controls Receiving and storage of packaging materials and non-egg ingredients Biological\u2014Contamination with pathogens (e.g., Salmonella or Listeria monocytogenes) \u2022 Letters of guarantee. \u2022 Packing materials and non-egg ingredients are transported and stored in a manner that ensures product integrity and proper conditions are maintained. \u2022 Dry goods are protected from pests and environmental contamination. Chemical\u2014Allergens \u2022 Letters of guarantee; approved supplier program. \u2022 Proper storage to prevent cross-contamination of allergen-free products. \u2022 Separate equipment\tools (e.g., shovels) for products containing allergens. \u2022 Allergens properly identified in the ingredients statement on the finished product label.

Physical\u2014Foreign material (e.g., \u2022 Visual inspection for foreign metal, plastic)

material. \u2022 Protect packaging materials from environment. Suggested verification questions: 1. Are materials and ingredients guaranteed by the manufacturer? 2. Are materials and ingredients protected from environmental contamination, e.g., are containers kept closed, properly identified and properly stored in acceptable storage areas? 3. Does the plant maintain communication with its suppliers concerning formulation changes or its suppliers\u2019 allergen control programs? 4. If the finished product contains non-egg allergens, does the final product label declare all allergens? 5. For non-egg ingredients added post-lethality, can the plant support the safetyof these ingredients(i.e., free of pathogens and unintended allergens)foreach lot of product? 7", "Process Step Potential Hazards Frequently Used Controls Classification and sorting, candling, and transfer of shell eggs Biological\u2014Presence of Salmonella \u2022 Restricted orineligible eggs are properly segregated; eggs with strong odors are candled and broken separately, and then assessed for acceptability. \u2022 Soiled eggs are segregated for resorting and rewashing. \u2022 Proper cleaningof the transfer room equipmentand effective Sanitation Standard Operating Procedures (Sanitation SOPs). \u2022 Protections from environment. Chemical\u2014No common hazard Physical\u2014No common hazard Suggested verification questions: 1. Are shell eggs sorted andclassified into categoriesas requiredin9 CFR 590.510? 2. Are shell eggs having strong odors or eggs received in cases having strong odors candled and broken separately to determine acceptability? 3. Are ineligile and restricted shell eggs properly segregated? 4. Are candling devices designed to adequately determine the interior condition of shell eggs? 5. Are containers, shell egg conveyors, and floors constructed in a manner to allow thorough cleaning and disinfection? 8", "Process Step Potential Hazards Frequently Used Controls Egg washing\u2014sanitizer Biological\u2014Salmonellasurvival \u2022 pH of wash water\u2014concentration of sanitizer is monitored, recorded, and maintained at a level to maximize bactericidal effect on exterior of shell. \u2022 High-temperature wash water, maintain temperature differential between wash water and internal shell egg temperature. \u2022 Wash waterqualitymaintainedto minimize cross contamination of product. \u2022 Equipment operatingproperly (e.g., spray nozzles, brushes, pumping system, continuous reservoir over flow). \u2022 Proper personalhygiene in place. Chemical\u2014Inappropriate use ofegg \u2022 Egg washing compounds are safe washing or sanitizingagent and effective under the conditions of use; used according to the intended use specified in FSIS Directive 7120.1. \u2022 Equipment is operatingproperly (e.g., sanitizer spray nozzles, pumping system). \u2022 Sanitizers are used according to the intended use specified in FSIS Directive 7120.1. Physical\u2014No common hazard \u2022 Protections from environment are in place. Suggested verification questions: 1. Is egg washing equipment kept in good repair and operated in a manner to ensure eggs are free of visible contaminants after washing? 2. Are cleaning compounds used in the wash wateror egg shell sanitizers,safe and effective, under the conditions of use per FSIS Directive 7120.1, Safe and Suitable Ingredients Used in the Production of Meat, Poultry and Egg Products? 3. Does the plant have supporting documentation for the critical operating parameters1(to include pH, temperature, concentration, and duration of contact) of the wash water or egg shell sanitizer? 4. Is there a functional, adequate exhaust systemin use to reduce odors? 1 Critical operational parameters are the specific conditions that the intervention must operate under in order for it to be effective. For more information see FSIS Compliance Guideline HACCP SystemsValidation. 9", "Process Step Potential Hazards Frequently Used Controls Breaking and separatingof eggs

Biological\u2014Presence and outgrowth of Salmonella \u2022 Sanitation SOPs address proper cleaning and sanitation of room and equipment. \u2022 Proper personalhygiene and practices are in place. \u2022 Proper air movement to allow for organoleptic inspection of broken eggs for wholesomeness. \u2022 Use of sanitizers, frequency of equipment cleaning, and control of room temperature adequate to inhibit growth of pathogenic bacteria on food contact surfaces. \u2022 Ineligible eggs are prevented from entering the breaking room; line speed is adjusted to maintain process control. Chemical\u2014Cleaning chemicals and sanitizers \u2022 Sanitation SOPs address proper cleaning, sanitation, and use of cleaning chemicals\ compounds.

Physical\u2014Foreign material (e.g., \u2022 Liquid egg pumps and shell filters egg shell fragments) workingproperly. \u2022 Breaking equipment is properly adjusted to minimize shell fragmentation. Suggested verification questions: 1. Does theegg breaking roomhave adequate lightingfor visual inspection? 2. Is ventilation in the egg breaking room adequate to prevent product adulteration, control odors, and control condensation to provide for adequate organoleptic inspection? 3. Are eggsthat are ineligible for breaking (e.g., dirty, rots, moldy eggs, etc.) prevented from entering the breaking room? 10", "Process Step Potential Hazards Frequently Used Controls Liquid egg cooling and holding Biological\u2014Raw\NRTE products\outgrowth of Salmonella; RTE products\cross-contamination from raw products andoutgrowth of pa thogens (Salmonella and Listeria monocytogenes) \u2022 Maintain product at time\temperature combinations tha t minimize pathogen growth.

Chemical\u2014No common hazard \u2022 Maintain protection from environment.

Physical\u2014No common hazard Suggested verification questions: 1. Do liquid cooling units have sufficient capacity to cool all liquid eggs? 2. Are liquid egg holding tanks or vats equipped with suitable thermometers and agitators? 3. Are RTE liquid holding silos only vented back into a processing room for RTE product? 11", "Process Step Potential Hazards Frequently Used Controls Defrosting Biological\u2014Raw\NRTE products\outgrowth ofSalmonella; RTE products\cross-contamination from raw products and outgrowth of pathogens (Salmonella and Listeria monocytogenes) \u2022 Control environment. \u2022 Time and temperature. Chemical\u2014No common hazard \u2022 Maintain protection from environment. Physical\u2014No common hazard Suggested verification questions: 1. Are defrosting tankskept in good repair and constructedof material(s) thatfacilitate thorough cleaning? 2. Iseach container of frozen eggs checked for condition and odor just prior to being emptied into crusher or receiving tank? 3. Are crushers and other equipment used in the defrosting operation dismantled at the end of each shift and washed, rinsed, and sanitized? 4. Is the process performed at temperatures that preclude pathogen growth? 12", "Process Step Potential Hazards Frequently Used Controls Formulation\mixing\ homogenization\reconstitution of dried product Biological\u2014Outgrowth of pathogens in rawproducts (e.g., Salmonella); contamination from equipment or ingredientsin RTE products \u2022 Maintain product at time\temperature combinations that minimizepathogenoutgrowth in raw products. \u2022 Sanitation SOPs address proper cleaning and sanitation of room and equipment. \u2022 Ingredients are acceptable under conditions of use (e.g., letters of guarantee). \u2022 Proper personalhygiene. \u2022 Good manufacturing practices and proper processing procedures (e.g., ingredients are properly weighed,labeled, andstored). \u2022 Dusting of dried productis minimized. Chemical\u2014Cross-contamination \u2022 Allergens properly identified in with allergens the ingredients statement on the finished

product label. Products containing allergens are processed and stored separately from allergen-free products. Physical No common hazard Suggested verification questions: 1. Does the plant's Sanitation SOPs or other program address the potential for crosscontamination of pathogens in RTE products? 2. Are ingredients being used in the actual formulation in amounts that agree with the plant's documented formulation for the particular product? 3. Is reworked product included in product formulations? If yes, see rework process step. 4. Are all ingredients being used in actual formulation included in product formula and listed in descending order of predominance that agrees with the ingredient statement on the approved label for the product? 5. Are products that contain allergens processed and stored in a manner to prevent crosscontamination of allergen-free products? 13", "Process Step Potential Hazards Frequently Used Controls Pasteurization Biological Survival of pathogens (e.g., *Salmonella* or *Listeria monocytogenes*), due to insufficient time\temperature lethality treatment \u2022 Effective and validated time\temperature combinations to destroy pathogens. (Note: *Listeria* may become heat-resistant in some products and require an increased time\temperature combination to achieve lethality). \u2022 pH of product maintained to maximize efficacy of lethality treatment. \u2022 Processing aids (e.g., hydrogen peroxide) are used in accordance with approved methodology. \u2022 Equipment maintained and operating properly. \u2022 Proper cleaning procedures in Sanitation SOPs. Chemical No common hazard \u2022 Protection from environment.

Physical No common hazard Suggested verification questions: 1. Is the temperature of liquid egg product continuously and automatically recorded during process? 2. Are holding times and temperatures adequate? 3. If ready-to-eat (RTE) pasteurized egg products are processed using a validated process, are verification activities included as part of the permanent record? 4. Are pasteurized products sampled and analyzed for the presence of pathogens per 9 CFR 590.570? Are records of pathogen testing maintained for the products? 14", "Process Step Potential Hazards Frequently Used Controls Desugaring\fermentation Biological Outgrowth of *Salmonella* and other bacteria during fermentation due to elevated processing temperatures \u2022 Proper cleaning procedures, visual inspection, and effective Sanitation SOPs. \u2022 Proper incubation temperature. \u2022 Letters of guarantee from suppliers of culture. Chemical No common hazard \u2022 Sanitation SOPs address proper cleaning, sanitation, and chemical use. Physical No common hazard \u2022 Equipment maintained and operating properly. Suggested verification questions: 1. Does the plant conduct microbiological testing of ingredients? 2. Does the plant conduct microbiological testing of finished products? 3. Are cultures used at manufacturer's recommended levels? 4. Are product temperatures monitored throughout the process? 15", "Process Step Potential Hazards Frequently Used Controls Spray drying o Yellow (RTE) o White (raw\NRTE) Note: egg whites can be spray or pan dried Biological Potential for contamination with *Listeria monocytogenes* in RTE products \u2022 Continuous discharge to prevent accumulation of powder in dryer. \u2022 Spray or pan-dry parameters are within specifications (e.g., vacuum, temperature, humidity). \u2022 Proper cleaning procedures, visual inspection, and effective Sanitation SOPs. \u2022 Proper maintenance of equipment. Chemical No common hazard Physical Foreign material contamination (e.g., metal) Suggested verification questions: 1. Are drying room facilities and equipment sufficient to preclude adulteration of product? 2. Does the plant control\prevent the buildup of product residues inside the dryer

chambers? 3. Does the plant's Sanitation SOPs or other program address the potential for crosscontamination of pathogens in RTE products? 16", "Process Step Potential Hazards Frequently Used Controls Heat treatment of dried egg whites Biological\u2014Survival of Salmonella \u2022 Effective and validated time\temperature combinations to destroy pathogens. \u2022 Adequate spacing of product to allow heat penetration and air circulation. Chemical\u2014No common hazard Physical\u2014No common hazard Suggested verification questions: 1. Are dried egg whites that have been heat treated in the dry form sampled and analyzed for the presence of Salmonella? Is the sample collected from the center of the package? 2. Does the plant have a valid method for ensuring that the location for monitoring accurately reflects all product in the room? 3. Are records of pathogen testing maintained for the products? 17", "Process Step Potential Hazards Frequently Used Controls Rework Biological\u2014Raw\NRTE products\u2014outgrowth of Salmonella; RTE products\u2014cross-contamination from raw products and outgrowth of pathogens (Salmonella and Listeria monocytogenes) \u2022 Maintain product at appropriate temperatures to control growth of microorganisms. \u2022 Lotting program; effective Sanitation SOPs. \u2022 Proper personal hygiene and adherence to established processing procedures. Chemical\u2014Allergens \u2022 Proper cleaning procedures, visual inspection, and effective Sanitation SOPs. \u2022 Separate equipment. \u2022 Allergens are properly declared on the finished product label. Physical\u2014Foreign material contamination (e.g., metal and other physical contaminants) \u2022 Proper maintenance of equipment. \u2022 An appropriate screening procedure. Suggested verification questions: 1. Are egg products to be used for rework properly stored to preclude pathogen growth and contamination? 2. Are there any hazards associated with rework that are different than hazards associated with the product it is being added to? 3. Does the plant have any additional controls for reworked product (i.e., length of time in storage, results of examination when received)? 4. Does the plant conduct microbiological testing of reworked product? 5. Are all ingredients of the reworked product declared on the label of the finished product, and are they listed in the correct order of predominance? 6. If the finished product contains non-egg allergens, does the final product label declare all allergens? 7. Does the reworked product include returned product (e.g., rejected tanker loads), and if so, does the establishment have a procedure for ensuring the safety of the product? 18", "Process Step Potential Hazards Frequently Used Controls Blending of dry ingredients into dried egg product Biological\u2014Contamination with pathogens from ingredients (e.g., Salmonella and Listeria monocytogenes) \u2022 Letters of guarantee. \u2022 Non-egg ingredients are acceptable for intended use. \u2022 Proper cleaning procedures and effective Sanitation SOPs. Chemical\u2014Allergens \u2022 Established formulation and mixing procedures for restricted ingredients (e.g., silicon dioxide, silicoaluminate, monosodium phosphate). \u2022 Ingredients and chemicals separated, properly labeled, and stored in designated areas. \u2022 Allergens are properly declared on the finished product label. Physical\u2014Foreign material (e.g., equipment parts\pieces) \u2022 Proper maintenance of equipment for proper functioning (e.g., flow meters, pumps, scales). Suggested verification questions: 1. Is blending done in a room separate from other processing operations to prevent crosscontamination of other processing areas? 2. Is all blending and packaging equipment constructed without open seams and of materials that can be kept clean and that will have no deleterious effect on the product? 3. Are blending facilities sufficient to preclude adulteration of

productto include post-lethality contamination, if applicable? 4. If thefinished product contains non-egg allergens, does the final product label declare all allergens? 19", "Process Step Potential Hazards Frequently Used Controls Freezing(liquid products) Biological\u2014No common hazard \u2022 Product is frozen (i.e., time\temperature). \u2022 Freezer equipmentkept in good condition and properly functioning. Chemical\u2014No common hazard \u2022 Proper maintenance of equipment (e.g., pipes, valves maintained to prevent ammonia leak).

Physical\u2014No common hazard Suggested verification questions: 1. Are freezing rooms clean and free of objectionable odors? 2. Are containers stacked so as to permit circulation of air around the containers? 3. Are the egg products stored in a manner that protects them from environmental contamination? 20", "Process Step Potential Hazards Frequently Used Controls Siftingof dried egg products Biological\u2014Contamination with Listeria monocytogenes in RTE products \u2022 Proper cleaning proceduresand effective Sanitation SOPs. Chemical\u2014No common hazard Physical\u2014Foreign material (e.g., screens or parts of broken equipment) \u2022 Maintenance and proper functioningof equipment (e.g., sifter screens are in place and in good repair). Suggested verification questions: 1. Are sifters of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing to include post-lethality contamination, if applicable? 21", "Process Step Potential Hazards Frequently Used Controls Packaging\repackaging Biological\u2014Contamination with Salmonella and Listeria monocytogenes in post lethality exposedRTE products at time of packaging \u2022 Adequate packaging material. \u2022 Good employee hygiene and product handling procedures. \u2022 Use of HEPA filters and UV lights on packaging equipment. \u2022 Maintenance of packaging equipment andproper sealing of finished product containers. \u2022 Proper sanitationof packaging equipment (e.g., spray nozzles) and implementation of Sanitation SOPs. \u2022 Package integritymaintained.

Chemical\u2014Allergens; packaging not \u2022 Letters of guarantee from appropriate for direct product manufacturer. contact \u2022 Proper cleaning procedures, visual inspection, and effective Sanitation SOPs. \u2022 Separate equipment to prevent cross-contamination by allergens from another formulation. \u2022 Allergens are properly declared on product labeling. Physical\u2014No common hazard Suggested verification questions: 1. Are direct contact packaging materials backed by the supplier\u2019s letter of guarantee? 2. Are packaging materials properly stored and protected from environmental contamination? 3. Are the plant\u2019s SanitationSOPs sufficient to prevent direct contamination and adulteration of egg product in the post-lethality environment? 4. Are egg products handled in a manner that prevents contamination with pathogens and allergens? 5. Does the plant conduct microbial testing of repackaged lots? 6. If the finished product contains non-egg allergens, does the final product label declare these allergens? 22", "Process Step Potential Hazards Frequently Used Controls Storage, handlingand loadingof egg productprior to shipping o Liquid\Refrigerated o Frozen o Dried Biological\u2014Contamination and outgrowth of pathogens during storage and loadingof tankers (e.g., Salmonella and Listeria monocytogenes) \u2022 Maintenance ofproduct at appropriate temperatures to control growth of microorganisms. \u2022 Maintenance ofrefrigeration and freezer equipment and rooms. \u2022 Sanitation SOPs address cleaning and sanitizingof bulk containers (i.e., tankers). \u2022 Separate equipment used for RTE and raw\NRTE liquid egg products. Chemical\u2014No common hazard \u2022 Maintenance ofpackage integrity. \u2022 Sanitation SOPs address finished product handling (e.g., cleaning

and sanitizing tankers and transport vehicles). Physical\ufe0fNo common hazard Suggested verification questions: 1. Are egg products properly refrigerated and not held in areas without refrigeration? If the product is held in areas without refrigeration, does the plant provide supporting documentation for the time and temperature that the product is held? 2. Are liquid-refrigerated\frozen\dried egg products protected from environmental contamination such as dust, moisture, or other physical contaminants? 3. Does the plant address cleaning and sanitizing of tankers in their Sanitation SOPs? 4. Does the plant\ufe0f Sanitation SOPs or other program address the potential for crosscontamination in post-lethality exposed RTE egg products? 23","Process Step Potential Hazards Frequently Used Controls Shipping Biological\ufe0fOutgrowth of pathogens during transport (e.g.,Salmonella and Listeria monocytogenes) \ufe0f Monitor product temperatures during transport. \ufe0f Ensure refrigeration units in transport vehicles, if present,are working properly. Chemical\ufe0fNo common hazard \ufe0f Maintain package integrity. Physical\ufe0fNo common hazard Suggested verification questions: 1. Are egg products properly refrigerated and not held in areas without refrigeration? If the product is held in areas without refrigeration, does the plant provide supporting documentation for the time and temperature that the product is held? 2. Are egg products protected from environmental contamination such as dust, moisture, or other physical contaminants? 24"]},{"file\_name":"FSIS\_GD\_2020\_0009","title":"A Sanitation Standard Operating Procedure Model","num":"FSIS-GD-2020-0009","id":"4e922606a33a958b527ac109609e3419ffe28fc6080c5deba699f2fb5a4f8886","corp\_us":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/media\_file/2021-03/Sanitation-SOP-Guide.pdf","type":"pdf","n\_pages":16,"word\_count":4119,"text\_by\_page":["Sanitation Standard Operating Procedures Sanitation Standard Operating Procedures (Sanitation SOPs) are written procedures that an establishment develops and implements to prevent direct contamination or adulteration of product. The establishment is required to maintain these written procedures on file, and they must be available to FSIS upon request. The establishment is required to implement the procedures as written in the Sanitation SOPs. The establishment must maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective action taken. When the establishment or FSIS determines that the Sanitation SOPs may have failed to prevent direct contamination or adulteration of product, the establishment must implement corrective actions that include the appropriate disposition of product, restore sanitary conditions, and develop measures to prevent recurrence. These written Sanitation SOPs must contain the procedures the establishment will conduct before and during operation; the frequency with which each procedure is to be conducted; the establishment employee or position responsible and be signed and dated by the individual with overall authority. FSIS developed the Sanitation SOP model for establishments to use as a reference when developing Sanitation SOPs. The model was designed to assist establishments in applying the sanitation requirements to their operations and to meet the regulatory requirements of Part 416\ufe0fSanitation. The sanitation model is not intended to be used \ufe0fcas is\ufe0fd for industry Sanitation SOPs. Sanitation SOPs will vary from one establishment to another because each facility will have its own processes that likely differ from that of another. An establishment must tailor the model to suit the specific

circumstances of its own products, production processes and facilities. All elements of the model (e.g., frequencies, monitoring activities, corrective actions, and forms) must be modified (elements added or removed) to reflect the establishment's products, production systems and facilities. This Sanitation SOP is for illustrative purposes only. Page 1 of 16", "A Sanitation Standard Operating Procedure Model This document provides an overview of the Sanitation Standard Operating Procedures (Sanitation SOPs) requirements, a Sanitation SOP model (Attachment 1), and the complete text of the regulations cited in the document (Attachment 2). This information is to assist small and very small official establishments<sup>2</sup> in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Parts 416.11  
416.17.3 The Sanitation SOP model is for demonstration purposes only. The model demonstrates how an establishment might develop Sanitation SOPs to meet the regulatory requirements of 9 CFR 416.11  
416.17. The text and formatting used in the model do not represent requirements that must be met. The use of headings, numbered lists, and tables (forms) are not requirements that must be met. Establishments are required to develop Sanitation SOPs specific to their facilities, production practices, and products.<sup>4</sup>

Sanitation SOPs (9 CFR 416416.14 Sanitation) Sanitation SOPs are written procedures that an establishment develops and implements to prevent direct contamination or adulteration of product (9 CFR 416.11 General Rules). The establishment is required to maintain these written procedures on file, and they must be available to Food Safety and Inspection Service (FSIS) personnel upon request. The establishment is required to implement the procedures as written in their Sanitation SOPs. The establishment must maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs as well as any corrective action taken. When the establishment or FSIS determines that the Sanitation SOPs may have failed to prevent direct contamination or adulteration of product, the establishment must implement corrective actions that include the appropriate disposition of product, restore sanitary conditions, and develop measures to prevent recurrence.

Development of Sanitation SOPs The establishment is required to develop written Sanitation SOPs that clearly describe procedures the establishment will implement to prevent direct contamination or adulteration of product. The Sanitation SOPs cover the entire establishment and all shifts of operation. These written procedures<sup>5</sup> must:

- 1. contain all the procedures the establishment will conduct daily, before and during operation, sufficient to prevent direct contamination or adulteration of product(s) (9 CFR 416.12(a));
- 2. The model presents Sanitation SOPs for Establishment Grounds and Facilities (9 CFR 416.2), Equipment and Utensils (9 CFR 416.3), Sanitary operations (9 CFR 416.4) and Employee hygiene (9 CFR 416.5).

As stated in the HACCP rule, small establishments are defined as all establishments with 10 or more employees but fewer than 500 employees. Very small establishments are defined as all establishments with fewer than 10 employees or annual sales of less than \$2.5 million.

The links to the CFR on pages 1, 2 and 3 take the user to Attachment 2.

To ask questions or find posted Qs and As on these topics, see these external links: askFSIS Q&As and the Small Plant Help Desk.

See public askFSIS Q&As on 9 CFR Part 416.12 requirements. Page 2 of 16", "2 identify the procedures to be conducted prior to operations (pre-operational) and address, at a minimum, the cleaning of food contact surfaces off facilities, equipment, and utensils (9 CFR 416.12(c)); 2 specify the frequency with which each procedure in the Sanitation SOP is to be conducted and identify the establishment employee or position responsible for the implementation and maintenance of the procedures

(9 CFR 416.12(d)); and \u2022 be signed and dated by the individual with overall authority on-site or a higher-level official of the establishment. This signature signifies that the establishment will implement the Sanitation SOPs as written and will maintain the Sanitation SOPs in accordance with the requirements of this part of the regulation (9 CFR 416.12(b)).

**Implementation and Monitoring the Sanitation SOPs** Establishments are required to develop written procedures that are sufficient to prevent direct contamination or adulteration of product. The establishment is also required to implement the procedures in its written Sanitation SOPs (9 CFR 416.13). The pre-operational procedures in the Sanitation SOPs are conducted before the start of operations (9 CFR 416.13(a)). All other written procedures are conducted at the frequencies specified in the Sanitation SOPs (9 CFR 416.13(b)). In addition, establishments are required to monitor daily the implementation of the procedures in the Sanitation SOPs (9 CFR 416.13(c)). If the establishment writes a procedure in its Sanitation SOP, the regulations require that it implement that procedure at the stated frequency and monitor its implementation. **Maintenance of the Sanitation SOPs** Each establishment must meet two obligations to comply with the requirements for Sanitation SOP maintenance (9 CFR 416.14). First, the establishment is required to routinely evaluate the effectiveness of all Sanitation SOPs that have been implemented in their production operations. Second, the establishment is required to revise its Sanitation SOPs as needed to maintain effectiveness and to address any changes that have occurred including changes in facilities, equipment, utensils, operations, or personnel.<sup>6</sup> Establishments are not required to record the methods used to evaluate their Sanitation SOPs and determine their effectiveness. If the establishment determines the Sanitation SOPs are no longer effective and current, they must be modified, signed, and dated. This regulatory requirement encourages establishments to develop a system for the evaluation of their written Sanitation SOPs to prevent direct contamination or adulteration of product. Establishments must identify the employees who are responsible for the implementation and maintenance of their Sanitation SOP procedures (9 CFR 416.12(d)). The establishment is required to identify the frequency with which each procedure is conducted by those employees. The establishment must sign and date the Sanitation SOPs when first created and any time modifications are made (9 CFR 416.12(b)). There are no regulatory requirements for establishment personnel to notify FSIS of any change to their SOPs. <sup>6</sup> See askFSIS Q&As for information on maintenance of Sanitation SOPs. Page 3 of 16", "Corrective Actions The regulations require establishments to take corrective actions when either the establishment or FSIS determines that the Sanitation SOPs failed to prevent direct contamination or adulteration of product (9 CFR 416.15(b)). Regardless of the type or cause of the failure, corrective actions must be taken, including appropriate disposition of product.<sup>7</sup> There are three parts to corrective action, and all three of these requirements must be met and recorded each time product contamination occurs (9 CFR 416.15). One common exception to recording corrective actions individually for each incident of product contamination is when the establishment has an effective product reconditioning program in the operational Sanitation SOP. With such a reconditioning program, they do not need to document each incident of direct contamination of product individually. Inspection personnel will verify that the establishment implements these overarching procedures effectively, including the use of effective<sup>8</sup> procedures to restore products to wholesome, unadulterated conditions. The establishment is not required to notify inspection personnel when product contamination occurs. The establishment is required to

implement corrective actions that will meet the requirements (9 CFR 416.15(b)). Corrective action requirements under these regulations are: \u2022 Appropriate disposition of products that may be contaminated; \u2022 Restoration of sanitary conditions; and \u2022 Prevention of recurrence of direct contamination or adulteration of products. Re-evaluating and modifying the Sanitation SOPs and the specific procedures to which they refer is considered a corrective action. Improvements relating to the implementation of the Sanitation SOPs or the procedures to which they refer are also considered corrective actions. Recordkeeping The regulations require the establishment to maintain daily records (9 CFR 416.16(a)) sufficient to document the implementation and monitoring of the Sanitation SOPs as well as any corrective actions taken.<sup>9</sup> To meet these requirements, the establishment must have records documenting that monitoring has been conducted daily for each of the procedures specified in the Sanitation SOPs. When Sanitation SOP monitoring frequencies are more than once per day, the monitoring activities must be documented at the specified frequencies. The regulations require that the establishment follow the specified monitoring frequency established in the Sanitation SOP. The establishment employee specified in the Sanitation SOPs as being responsible for the implementation and monitoring of the procedures is required to authenticate these records with initials or signature and the date (9 CFR 416.16(a)). Records may be maintained on a computer system provided the establishment implements <sup>7</sup>See askFSIS Q&As for information on Corrective Actions. <sup>8</sup>Establishments must provide supporting information when a prerequisite program becomes part of the HACCP system. See page 16 of the FSIS Compliance Guideline HACCP Systems Validation guide for how to identify support for prerequisite programs. <sup>9</sup> See askFSIS Q&As for information on Recordkeeping. Page 4 of 16", "appropriate controls to ensure the integrity of the electronic data (9 CFR 416.16(b)). Records regarding the implementation of any corrective action must be kept on-site for a period of 48 hours once completed. After 48 hours, the records may be kept off-site but must be made readily available to FSIS within 24 hours of original request. Sanitation SOP records must be maintained for at least 6 months.<sup>10</sup> (9 CFR 416.16(c)). <sup>11</sup> Electronic records may be kept on an in-house computer or remote server for the first 48 hours. The electronic records must be readily available to FSIS during the 48 hour period. Page 5 of 16", "Attachment 1 FSIS developed the Sanitation SOP model for establishments to use as a reference when developing their own Sanitation SOPs. Sanitation SOPs will vary from one establishment to another because each facility will have its own processes that likely differ from that of another. The Sanitation SOP model addresses the sanitation concerns for a fictional company. An establishment must tailor the model to suit the specific circumstances of its own products, production processes and facilities. All elements of the model (e.g., frequencies, monitoring activities, corrective actions, and forms) must be modified (elements added or removed) to reflect the establishment's actual products, production systems and facilities. This Sanitation SOP is for illustrative purposes only. Model \u2013 Sanitation SOP XYZ Meat Packers, Inc. is a red meat processing establishment. This plant receives beef and pork for further processing. This facility cuts, grinds, and packages product. Owner \u2013 Signature: \_\_\_\_\_ Date: \_\_\_\_\_ Plant Manager - Team Captains \u2013 The Team Captains or their designees are responsible for implementing and daily monitoring of Sanitation SOPs and recording the findings and any corrective actions. The Team Captains are responsible for training and assigning specific duties to other employees and monitoring the employees' performance within the Sanitation

SOPs. All records, data, checklists, and other information pertaining to the Sanitation SOPs is maintained on file and made available to inspection personnel.

Pre-operational Sanitation \u2013 Equipment and Facility Cleaning Objective

All equipment is disassembled, cleaned, and sanitized before starting production

Establishment sanitary procedure for cleaning and sanitizing equipment

a. Product debris is removed from all equipment.

b. Equipment is rinsed with water to remove remaining debris.

c. An approved cleaner is applied to equipment and properly cleaned.

d. The equipment is reassembled.

e. Equipment is sanitized with approved sanitizer and rinsed with potable water if appropriate.

Implementing, Monitoring and Recordkeeping Team Captains perform daily organoleptic sanitation examination after preoperational equipment cleaning and just before sanitizing and before operations

11This information is to assist small and very small establishments in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Parts 416.11 \u2013 416.17.

The Sanitation SOP model is for demonstration purposes only.

Establishments are required to develop Sanitation SOPs specific to their facilities, production practices, and products.

Page 6 of 16", "begin.

The results are recorded on the establishment's Pre-operational Sanitation Form.

If found to be acceptable, the appropriate line is checked on the form.

If found unacceptable, actions taken to restore sanitary conditions are documented on the Preoperational Sanitation Form.

Corrective Actions

When the Team Captains determine that the equipment does not pass organoleptic examination, the cleaning procedure and inspections are repeated.

The Team Captains monitor the cleaning of the equipment and retrain employees if necessary.

Corrective actions are recorded on the establishment's Corrective Action Log.

Cleaning of Facilities including floors, walls, and ceilings

Cleaning procedures

1. Debris is swept up and discarded.

2. Facilities are rinsed with potable water.

3. Facilities are cleaned with approved cleaner.

4. Facilities are rinsed with potable water.

Cleaning of floors, ceilings, and walls is done at the end of each production day and when needed to maintain sanitary conditions.

Establishment monitoring

The Team Captain performs daily organoleptic examination before operations begin.

Results are recorded on the establishment's Pre-operational Sanitation Form.

Corrective action

When the Team Captain finds that the facilities do not pass organoleptic examination, the cleaning procedures and inspections are repeated.

The Team Captain examines the cleaning of the facilities and retrains employees as needed.

Corrective actions to prevent direct product contamination or adulteration are recorded on a Corrective Action Log.

Operational Sanitation \u2013 Equipment and Facility Cleaning Objective

Processing is performed under sanitary conditions to prevent direct and cross-contamination of the product

Sanitary procedures for processing

1. Employees clean and sanitize hands, gloves, knives, other hand tools, cutting boards, etc., as necessary during processing to prevent the creation of insanitary conditions and the contamination of products.

2. All equipment tables and other product contact surfaces are cleaned and sanitized throughout the day as needed to maintain sanitary conditions and protect the product.

Page 7 of 16", "3.

Outer garments such as aprons, boots, and gloves are hung in designated areas when employees leave processing areas.

Outer garments are maintained in a clean and sanitary manner and are changed at least daily and more often if necessary.

4. At the midday break: major solids are physically removed from floors, equipment, and food contact surfaces.

Equipment is disassembled as required for adequate cleaning.

All surfaces are rinsed with cold water.

Equipment is sanitized with approved sanitizer and rinsed with potable water as appropriate.

5. At the end of the shift: major solids are physically removed

from floors, equipment, and food contact surfaces. Equipment is disassembled as required for adequate cleaning. All surfaces are rinsed with cold water. 6. Administrative personnel wear smocks and waterproof boots when in processing areas. Smocks are laundered in-house as needed. Maintenance workers wear gray uniforms and waterproof boots. Maintenance uniforms are laundered in-house as needed. 7. Prevention of cross-contamination: clothing and personal belongings are not stored in production areas. Workers do not eat food, chew gum, drink beverages, or use tobacco in production areas. Workers sanitize their boots in boot baths. Waste is removed from processing areas every four hours during production. Coolers are cleaned weekly or more often if needed. Cooler evaporators are cleaned every six months or more often if needed. 8. Allergen control: allergen free products are reprocessed first, followed by products containing allergens. 9. Condensation: drip or condensate does not contaminate food or packaging materials. The finished product cooler is monitored twice a day. Condensation is removed in a sanitary manner. 10. Packaging materials are protected from contamination during storage and use. 11. Cleaning compounds, sanitizers and lubricants used in processing and packaging areas are food-grade. Non-food-grade chemicals and lubricants are stored separately outside processing and packaging areas. 12. Product reconditioning: an employee removes product from the floor in a timely manner, trim contaminants from the product surface area, wash the product at a product wash station, and examines it before returning it to production. This procedure is used for occasional instances of product contamination. 13. Employee health: employees are instructed to report to their supervisor any health condition that might result in food contamination. Monitoring and Recordkeeping The Team Captains are responsible for ensuring that employees' hygiene practices, sanitary handling procedures, and cleaning procedures are maintained. The Team Captains monitor the sanitation procedures during the day. Results are recorded on the establishment's Operational Sanitation Form daily. Page 8 of 16", "Corrective Action The Team Captains identify sanitation problems, stop production if necessary, and notify processing employees to take appropriate action to correct sanitation problems. If necessary, processing employees are retrained, and corrective actions are recorded on a Corrective Action Log. Establishment Grounds and Facilities Grounds and Pest Control Each day, after operations have ended, the Team Captain directs an employee to examine: 1. The area around the building for trash, debris, and garbage. All items found are disposed of in an appropriate waste container; 2. The area around the building for evidence of rodents, flies, and birds (nesting/feeding); 3. The rodent glue traps to ensure they are free of captured rodents and are properly placed and maintained; and, 4. The use and storage of pest control substances to ensure they are used according to manufacturer's instructions and stored securely and away from food production and storage areas. Facilities Each Wednesday, during operations, the Team Captain examines: 5. The structure, rooms, and compartments to verify they are of sound construction and in good repair; 6. The walls, floors, and ceilings to verify they are impervious to moisture and can be cleaned and sanitized; 7. The walls, floors, ceilings, doors, windows, and other outside openings to verify they prevent the entrance of vermin (flies, birds, rats, and mice); 8. The room where edible product is processed, handled, or stored to verify the room and edible products are separate from inedible product storage; 9. The lighting in the product handling and storage rooms, equipment and utensil cleaning area, the hand washing area, the locker room, and the toilet to ensure there is sufficient lighting; 10. The ventilation to verify it controls odors,

vapors, and condensation; 11.The plumbing systemto verify sufficientcity suppliedwateris available where needed in the building, and all floor and sink drains, and the toilet and shower basin remove waste from the building as intended (no backflow or standing water). 12.The supply of running water to verify there is sufficient pressure and temperature in Page 9of 16","the processing room, the cleaning room, hand washing sinks, toilet, and shower. 13. The locker room, toilet and sinks to verify they are maintained in a sanitary condition and in good repair Page 10 of 16","Pre-operational Sanitation Form Area and Equipment Results Accept Reject Equipment disassembled, cleaned, and sanitized before starting production Cleaning of facilities including floors, walls, and ceilings Notes Date: \_\_\_V\_\_\_V\_\_\_ Initials \_\_\_\_\_ (passes examination) Page 11 of 16","Operational Sanitation Form Results Observed? Yes or No Mid-Morning Mid-Afternoon Accept Reject Accept Reject Employees clean and sanitize equipment Food contact areas cleaned and sanitized as necessary Outer garments handled appropriately Food contact and equipment cleanup Administrative personnel in food processing departments Prevention of cross-contamination Allergen Control Condensation Packaging materials Cleaning compounds Employee health Product reconditioning Notes Date: \_\_\_V\_\_\_V\_\_\_ Initials \_\_\_\_\_ Page 12 of 16","v v Corrective Action Log Sanitary Procedures Found Unacceptable (Recorded on the Operational Sanitation Form) Employees clean and sanitize equipment Allergen Control Food contact areas cleaned and sanitized as necessary Condensation Outer garments handled appropriately Packaging materials Food contact and equipment cleanup Cleaning compounds Administrative personnel in food processing departments Employee health Prevention of cross-contamination Product reconditioning Measures taken to ensure the appropriate disposition of any contaminated product Measures taken to restore sanitary conditions Measures taken to prevent recurrence, including appropriate re-evaluation and modification of the Sanitation SOP Notes Date: \_\_\_V\_\_\_V\_\_\_ Initials \_\_\_\_\_ Page 13 of 16","Establishment Grounds and Pest Control M A\R T A\R W A\R T A\R F A\R Trash, Debris, and Garbage Evidence of Rodents, Flies, and Birds Rodent Glue Traps Use and Storage of Pest Control Substances Initials Notes Date: \_\_\_V\_\_\_V\_\_\_ Initials \_\_\_\_\_ (passes examination) Establishment Facilities Results Accept or Reject Construction and Repair Walls, Floors and Ceilings Openings to the Outside Edible and Inedible Product Lighting Ventilation Plumbing Water Supply Locker Room and Toilet Notes Date: \_\_\_V\_\_\_V\_\_\_ Initials \_\_\_\_\_ (passes examination) Page 14 of 16","----- Attachment 2 Code of Federal Regulations TITLE 9--ANIMALS AND ANIMAL PRODUCTS CHAPTER III--FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE PART 416--SANITATION12 Sec. 416.11 General rules. Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOPs) in accordance with the requirements of this part of the regulation. Sec. 416.12 Development of Sanitation SOPs. \u2022 The Sanitation SOPs shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s). \u2022 The Sanitation SOPs shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOPs as specified and will maintain the Sanitation SOPs in accordance with the requirements of this part. The Sanitation SOPs shall be signed and dated upon initially implementing the Sanitation SOPs and upon any modification to the Sanitation SOPs. \u2022 Procedures in the

Sanitation SOPs that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils. \u2022 The Sanitation SOPs shall specify the frequency with which each procedure in the Sanitation SOPs is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s). Sec. 416.13 Implementation of SOPs. (a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOPs before the start of operations. (b) Each official establishment shall conduct all other procedures in the Sanitation SOPs at the frequencies specified. (c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOPs. Sec. 416.14 Maintenance of Sanitation SOPs. Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOPs and the 12 This is an external link which directs the user to the govinfo.gov site. Page 15 of 16", "procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel. Sec. 416.15 Corrective Actions. (a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOPs or the procedures specified therein, or the implementation or maintenance of the Sanitation SOPs, may have failed to prevent direct contamination or adulteration of product(s). (b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOPs and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOPs or the procedures specified therein. Sec. 416.16 Recordkeeping requirements. (a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOPs as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOPs shall authenticate these records with his or her initials and the date. (b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data. (c) Records required by this part shall be maintained for at least 6 months and made available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request. Sec. 416.17 Agency verification. FSIS shall verify the adequacy and effectiveness of the Sanitation SOPs and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include: (a) Reviewing the Sanitation SOPs; (b) Reviewing the daily records documenting the implementation of the Sanitation SOPs and the procedures specified therein and any corrective actions taken or required to be taken; (c) Direct observation of the implementation of the Sanitation SOPs and the procedures specified therein and any corrective actions taken or required to be taken; and (d) Direct observation or testing to assess the sanitary conditions in the establishment. Page 16 of 16"]}, {"file\_name": "FSIS\_GD\_2020\_0010", "title": "HACCP Model for Raw Non-Intact Fresh Ground Pork Sausage Patties", "num": "FSIS-GD-2020-0010", "id": "65a55d0ec064091577c9c157bd9f4c9dafb8ce8e5e1a3b971dafe61684756bbe", "cor

pus":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/media\_file/2021-03/HACCP-Model-Non-Intact-Fresh-Ground-Pork-Sausage-Patties.pdf","type":"pdf","n\_pages":12,"word\_count":2823,"text\_by\_page":["A Generic HACCP Model for Fresh Ground Pork Sausage Patties The United States Department of Agriculture (USDA) published the Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) Systems Final Rule in July 1996. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to address safety hazards reasonably likely to occur in their production process. Therefore, this HACCP model's focus, and the focus of the other HACCP models, is on product safety, not product quality characteristics. With the rule, FSIS made available a guidebook for the preparation of HACCP plans and a generic model for each food processing category defined in the regulation (9 CFR 417.2(b)(1)). The guidebook and the generic models have been updated since their initial publication to be consistent with current science and policy. FSIS recommends you use of the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan. Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used as is. FSIS recommends that establishments tailor the model(s) to fit the establishment's operation. The model's critical control points (CCPs) do not necessarily apply to all operations or products in the product category. Products or operations may require fewer or more CCPs depending on the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. The food safety critical limits selected must come from scientific documents or other reliable sources to meet regulatory validation requirements. Each model includes references for guidance on the selection of critical limits. To select the model that will be most useful for the products produced, consider the production activity occurring (slaughter, cutting, grinding, smoking, cooking, etc.), the product (beef, pork, chicken, etc.), and the food safety characteristics of the final product produced (intact or non-intact, raw or ready-to-eat, requires refrigeration or is shelf-stable, etc.). Examine the list of processing categories (9 CFR 417.2(b)(1)) and group similar products according to the categories. Many similar products may be grouped under the same category and HACCP plan. Selection of the processing categories reveal which of the generic models might be useful. Selecting the most appropriate model to work from will save the establishment time and personnel resources. Deciding on a generic model is an important achievement for your establishment. The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis are HACCP records (CFR 417.5(a)). The selection of processing categories and HACCP models are preliminary steps to completing a hazard analysis. The documents produced during the selection process are HACCP records. Ensure you maintain the documents produced while developing a HACCP plan. For further assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP webpage. Page 1 of 12", "EXAMPLE PRODUCT DESCRIPTION1 Process \ Product Name: Fresh Ground Pork Sausage Patties Process \ Product Name Non-intact pork product (sausage

patties) Important product characteristics (Aw, pH, preservatives, etc.) None How it is to be used Intended to be thoroughly cooked. Packaging (durability and storage conditions) Tray packs Shelf-life and at what temperature 3 °C 6 months at 0°F or below; 7 days at 40°F Where it will be sold (specify intended consumers, especially at-risk populations)2 Sold to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI). Labeling instructions Product name, inspection legend and establishment number, handling statement, net weight statement, ingredients statement, address line, nutrition facts, the statement "Cook to an internal temperature of 160 degrees Fahrenheit as measured by a food thermometer" on the principle display panel, and safe handling instructions. Special distribution control Keep frozen, keep refrigerated DATE: APPROVED BY: 1Prior to developing the HACCP plan please read the FSIS Guidebook for the Preparation of HACCP Plans for detailed descriptions of the worksheets and hazard analysis. This information is best suited for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations(9 CFR)Part 417. The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products. 2At risk populations include young children, elderly and immunocompromised persons. Page 2 of 12","EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL3 Process ✓ Product Name: Fresh Ground Pork Sausage Patties Meat and meat by-products Fresh or frozen raw pork trimmings from in-house production. Purchased fresh or frozen raw pork trimmings. Non-meat food ingredients Sugar, Salt, Spices Antimicrobial interventions4 and processing aids None Packaging material Tray packs and shrink wrap Restricted ingredients or allergens None Other None DATE:

APPROVED BY: 3List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), antimicrobials, processing aids, and packaging material used in production of this product. This step is important to help identify special ingredients or processes to address in the HACCP plan. 4FSIS and the Food and Drug Administration (FDA) have a memorandum of understanding (MOU) that establishes the working relationship followed when responding to notifications for the use of food additives intended for use in the production of FSIS regulated products. FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDA on the requirements under the FD&C Act and its implementing regulations. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat Poultry and Egg Products for the list of suitable ingredients. Page 3 of 12","EXAMPLE PROCESS FLOW DIAGRAM5 Fresh Ground Pork Sausage Patties 1b. Receiving and Storage 1. Receiving Fresh or Frozen Raw 1a. Receiving and Storage of Packaging and Labeling Pork of Non-Meat Ingredients 2. Storage Fresh or Frozen Raw Meat 3. Tempering Frozen Meat 4. Weighing Meat and Non-Meat Ingredients 5. Combine Ingredients ✓ Chopping ✓ Grinding CCP 1 6. Forming 9. Rework and Work in Progress 7. Packaging and Labeling | 11 11111111'1111111 10. Returned Product 6. Finished Products Storage and Distribution 5This is an example flow diagram. Establishments\u2019 flow diagrams for the same product may be different. Establishments determine which steps are included in their process. The steps must represent all relevant hazards in the hazard analysis. 6 The Returned Product step(10) is shown as not connected to another process step. Returned product may re-enter the production system at different process steps depending on

condition or problem. Returned product may be relabeled, reground, discarded, tempered, etc.

Page 4 of 12", "EXAMPLE HAZARD ANALYSIS7 Fresh Ground Pork Sausage Patties Column 1

Column 2 Column 3 Column 4 Column 5 Column 6 Ingredient \ Process Step Potential Hazards (introduced or controlled) at this Step8 Is the Potential Food Safety Hazard Reasonably Likely to Occur (NRLTO)? (Yes or No)9 Justification \ Basis for Decision in Column 310 If yes in Column 3 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels11 Is this Step a Critical Control Point (CCP)?12 This is an example hazard analysis. Establishments\u2019 hazard analyses for the same product may be different. Establishments determine which hazards are applicable to their process. 8 Hazards are grouped into three categories: Biological(B), Chemical (C), and Physical(P). Biological hazards are living organisms. Chemical hazards maybe naturally occurring in foods, used, or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification. 9 Place the justification for your decision in column 4. Include control measures in column 4 for hazards not reasonably likely to occur and place them in column 5 for hazards reasonably likely to occur. If a hazard is reasonable likely to occur, then a CCP must be addressed at this step or a later step. See FSIS Meat and Poultry Hazards and Controls Guide for a list of frequently used controls. 10 Scientific references are important in making decisions and providing justifications. When scientific references are used for decisions, the referenced article must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from an FSIS program, then scientific or technical support is needed, and these non-FSIS supporting documents must be kept for the life of the HACCP plan.

11 Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation, page 5).

12 To determine the best CCP to control, reduce, or eliminate a hazard, see FSIS Guidebook for the Preparation of HACCP Plans.

Page 5 of 12", "Step Hazard RLTO Justification \ Basis Controls CCP 1. Receiving Fresh B:

Pathogens: No Pathogens known to be present and likely to or Frozen Raw Pork Salmonella outgrowth Trichinella spiralis13 No cause illness if not controlled. Pork trimmings are either sourced from in-house production or purchased. Pork trimmings may be processed fresh or placed in frozen storage for later use. Written Temperature Control SOP for maintaining product temperatures to prevent outgrowth of micro-organisms (The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50\u00b0F (Tompkin, R.B. 1996)). Letter of Guarantee is on file from the originating slaughter facility of

purchased product. The blanket LOG is updated annually. Not ready-to-eat pork products, including all forms of fresh pork, do not need to be treated to destroy *Trichinella* because they are customarily wellcooked in the home or elsewhere before being served to the consumer. Product label principle display panel includes the statement \u201cCook to an internal temperature of 160 degrees Fahrenheit as measured by a food thermometer\u201d to clearly indicate the products require additional treatment by the consumer. C: Allergens No Letter of Guarantee is on file from the originating slaughter facility of purchased product. The blanket LOG is updated annually. 13 This HACCP model uses option 3 Label NRTE pork products, including all forms of fresh pork to clearly indicate the products require additional treatment by the consumer described in the FSIS Compliance Guideline for the Prevention and Control of *Trichinella* and Other Parasitic Hazards in Pork and Products Containing Pork. Page 6of 12", "Step Hazard RLTO Justification \ Basis Controls CCP P: Foreign material No Written Foreign Material SOP14 for visual inspection of product in containers at receiving. Records generated from the Foreign Material SOP demonstrate no incidents of foreign materials detected in products received. 1a. Receiving and Storage of NonMeat Ingredients B: Pathogens: *Salmonella* No Spices and flavorings may introduce pathogens. Written Incoming Material SOP include procedures used to examine materials including temperature and sanitary conditions. Written Sanitation SOP for procedures used to protect ingredients from environmental contamination. Letters of Guarantee from suppliers describing quality controls and prevention procedures. Only irradiated spices are purchased. C: Allergens No Written Incoming Material SOP for procedures to examine incoming materials including allergen declarations. P: Extraneous materials No Letters of Guarantee from suppliers describing quality controls and prevention procedures. Written Incoming Material SOP includes procedures to examine integrity of packaging material. 1b. Receiving and Storage of Packaging and Labeling B: None 14 ThisForeign Materials SOP(prerequisite program) should have details on how this procedure is preventing the hazard from occurring (such as metal prevention controls) as well as the on-going verification procedures. These controls should be evident within the written document upon review. The Foreign Material SOP and plant data related to on-going verification activities then become part of recordkeeping and historic data. Page 7of 12", "Step Hazard RLTO Justification \ Basis Controls CCP C: Allergens and No Written Sanitation SOP for procedures used to pesticides protect packaging materials from environmental contamination. Letter of Guarantee for all packaging materials describing quality controls and prevention procedures. P: None No Written Sanitation SOP for procedures used to protect packing materials from physical contamination and debris. 2. Storage Fresh or B: Outgrowth of No Written Sanitation SOP for refrigerated or frozen Frozen Raw Meat Pathogens: *Salmonella* product storage to maintain sanitary environment. Written Temperature Control SOP for maintaining product temperatures in refrigerated and frozen product storage to prevent outgrowth of microorganisms. (Tompkin, R.B. 1996) C: None P: None 3. Tempering Frozen Meat B: Outgrowth of Pathogens: *Salmonella* No Written Tempering SOP to maintain time and temperature to prevent outgrowth of pathogens (Tompkin, R.B. 1996). C: None P: None 4. Weighing Meat and Non-Meat Ingredients B: None C: CrossNo Written Good Manufacturing Practices (GMPs) to contamination of prevent and minimize the likelihood of crossallergens or contamination with allergens and chemicals. chemicals Page 8of 12", "Step Hazard RLTO Justification \ Basis Controls CCP P: None 5. Combine B: Outgrowth of Yes Pathogen outgrowth may occur during processing CCP 1 is a

measure of the Yes Ingredients \ Chopping \ Pathogens: Salmonella procedures due to equipment generated heating of product. product temperature as it emerges from the grinder. CCP 1 Grinding Ingredients Temperature Control SOP is for monitoring the temperatures of ingredients batched for grinding (Tompkin, R.B. 1996) Temperature Control SOP for production room temperature control. C: CrossNo Equipment Maintenance SOP to ensure contamination with equipment used for processing products allergens containing allergens are properly labeled and not used for non-allergen containing product. P: Metal No No history of findings from daily equipment pre- contamination operational inspections (Sanitation SOPs). No history of consumer complaints. Equipment Inspection SOP. Metal Detector Prerequisite Program. 6. Forming B: Outgrowth of Pathogens: Salmonella No Pathogen outgrowth is a potential during processing procedures. Temperature Control SOP for production room temperature control. Proper employee handling through Sanitation SOP C: None Page 9of 12", "Step Hazard RLTO Justification \ Basis Controls CCP P: None 7. Packaging and B: Outgrowth of No Pathogen outgrowth is a potential during Labeling Pathogens: Salmonella processing procedures.

Temperature Control SOP for production room temperature control. Proper employee handling through Sanitation SOP. C: None P: None 8. Finished B: Outgrowth of No Written Sanitation SOP for product holding Products Storage Pathogens: coolers to maintain sanitary environment. and Distribution Salmonella Written Temperature Control SOP for maintaining cooler and product temperatures to prevent outgrowth of micro-organisms. Written Final Product SOP for procedures to examine outgoing products including sanitary condition of trucks, functioning transport refrigeration unit, and package integrity. C: None P: None 9. Rework and B: Outgrowth of No Temperature Control SOP for production room Work in Progress pathogens: Salmonella. temperature control. Written Sanitation SOP for product holding coolers to maintain sanitary environment. Written Temperature Control SOP for maintaining cooler and product temperatures to prevent outgrowth of micro-organisms. Proper employee handling through Sanitation SOP Page 10 of 12", "Step Hazard RLTO Justification \ Basis Controls CCP C: None P: None 10. Returned Product Reinspection SOP implemented before accepting returned product. Product enters the appropriate step of the production system based on findings of product evaluation. Opened packages are not accepted. Notify FSIS personnel when product has been returned.

DATE: APPROVED By: \_\_\_\_\_ Page 11 of 12" "EXAMPLE HACCP PLAN15 Fresh Ground Pork Sausage Patties Critical Critical Limits Monitoring Procedures Corrective Action Verification Records Control Point (CCP) Significant Hazard(s) for Each Control Measure What How Frequency Who CCP 1 Combine Ingredients \ Chopping \ Grinding Pathogen: Salmonella Temperature of product as it emerges from the grinder will measure at 40\u00b0F or less. Measure ground product temperature Calibrated handheld thermometer Once per hour during grinding operations. Quality Control Technician or designee If a deviation from the critical limit occurs, the supervisor will: 1.Hold all affected product until appropriate disposition taken (no product injurious to health will be sold); 2.Determine and eliminate the cause of the deviation; 3.Bring the CCP under control; 4.Take measures to prevent recurrence 9 CFR 417.3 Once per shift, supervisor will observe technician measure product temperature. Once per shift, supervisor will review records. Once per week, supervisor will calibrate thermometer per manufacturer\u2019s procedures. Preshipment Records Review Form Product Temperature Form Thermometer Calibration Form DATE: APPROVED By:

very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products. Page 12 of 12"]}, {"file\_name": "FSIS\_GD\_2020\_0011", "title": "HACCP Model for Traditional Swine Slaughter", "num": "FSIS-GD-2020-0011", "id": "e3a986f0da9ca4b6bf07a14e372a529ed433746c93e4e641927247bec8d842d3", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-03/HACCP-Model-for-Traditional-Swine-Slaughter.pdf", "type": "pdf", "n\_pages": 17, "word\_count": 5076, "text\_by\_page": ["HACCP Model for Traditional Swine Slaughter The United States Department of Agriculture (USDA) published the Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) Systems Final Rule in July 1996 mandating all USDA inspected meat and poultry establishments implement a HACCP system. Hazard Analysis Critical Control Point (HACCP) is a systematic and scientific method of process control for the production of safe food products. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to improve the safety of their products. The HACCP models' focus is on product safety, not product quality characteristics. With the rule, FSIS made available a guidebook for the preparation of HACCP plans and a generic model for each food processing category defined in the regulation (9 CFR 417.2(b)(1)). The guidebook and the generic models have been revised since their initial publication to be consistent with current science and policy. FSIS recommends you use of the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan. Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used as is. Establishments are to tailor the model(s) to fit the establishment's operation. The model's critical control points (CCPs) do not necessarily apply to all operations or products. Products or operations may require fewer or more CCPs depending on the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. The food safety critical limits selected must come from scientific documents or other reliable sources. Each model includes references for guidance on the selection of critical limits. To select the model that will be most useful for the products produced, consider the production activity occurring (slaughter, cutting, grinding, smoking, cooking, etc.), the product (beef, pork, chicken, etc.), and the food safety characteristics of the final product produced (intact or non-intact, raw or ready-to-eat, requires refrigeration or is shelf-stable, etc.). Examine the list of processing categories (9 CFR 417.2(b)(1)) and group similar products according to the categories. It is common for many products to be grouped under the same category and HACCP plan. Selection of the processing categories reveals which of the generic models might be useful. Selecting the most appropriate model to work from will save the establishment time and personnel resources. Deciding on a generic model is an important achievement for your establishment. The records produced while documenting a"]}

HACCP plan, including all documentation used to support the hazard analysis are HACCP records (CFR 417.5(a)). The selection of processing categories and HACCP models are preliminary steps to completing a hazard analysis. The documents produced during the selection process are HACCP records. Ensure you maintain the documents produced while developing a HACCP plan. For further assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP webpage. Page 1 of 17", "EXAMPLE PRODUCT DESCRIPTION1 Process \ Product Name: Market Hog Slaughter, Raw Intact (cuts) Process \ product type name Raw Intact (carcasses, sides, quarters, primals, subprimals, variety meats (offal) and head meat) Important product characteristics (Aw, pH, Preservatives, etc.) Not Applicable How it is to be used For further processing at this facility or another establishment or Intended for cooking by end consumer. Packaging (durability and storage conditions) Protective cover butcher paper, vacuum packaged, bagged, or boxed Shelf Life and at what temperature Refrigerated -15 days at 40 \u2109 Frozen \u2013 180 Days at <10\u2109 Where it will be sold (specify intended consumers, especially atrisk populations2) Sold direct to another establishment or to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI). Labeling instructions Product name, inspection legend and establishment number, handling statement, net weight statement, address line, nutrition facts, and safe handling instructions. What special distribution controls are required? Keep refrigerated <40\u2109 Keep frozen <10 \u2109 DATE: APPROVED BY: 1 Prior to developingthe HACCPplan read theFSIS Guidebook for the Preparation of HACCPPlans for detailed descriptions of theworksheets and hazard analysis. Thisworksheet helps describe the products. 2At-risk populations include young children, elderly and immunocompromised persons. Page 2 of 17", "EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL3 Process \ Product Name: Market Hog Slaughter, Raw Intact (Cuts) Meat and meat by-products Market hogs Non-Meat food ingredients None Antimicrobials4 or processing aids Scald agents, Organic acid5 Packaging material Butcher paper and tape, foam bone protectors, cardboard boxes, self-adhesive labels, plastic vacuum bags Restricted ingredients or allergens None Other None DATE: APPROVED BY: 3Listall meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, packaging material used in the production of this product. This is important to help identify any special ingredients or processes to address in the HACCPplan. 4FSIS and the Food and Drug Administration (FDA) have amemorandum of understanding (MOU) that establishes the working relationship followed when responding to notifications for the use of food additives intended for use in the production of FSIS regulated products. FSISdetermines the suitability of theuseoffood ingredients used in the production of meat, poultry, and egg products. FSISconsults, as necessary, with FDA on therequirements under the Food Drug&CosmeticAct and its implementing regulations. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat Poultry and Egg Products for the list of suitable ingredients. 5Antimicrobial interventions, even if considered processing aids,must be addressed in the HACCP system. Page 3 of 17", "EXAMPLE PROCESS FLOW DIAGRAM6 Process \ Product Name: Market Hog Slaughter7, Raw Intact (Cuts) 1. Live Hog Receiving 1a. Live Animal Wash: for heavy contamination 2. S t unni ng \ S ti c ki ng \ B leedi ng 3. S cal d i ng 4. D ehai ri ng \ Gam brel l ing \ S i ng ei ng \ Pol i shi ng \ S hav i ng \ K nife Tri m m i ng 4a. S k i nni ng (as needed duri ng hard hai r s eason) 4b. A ll Carc as es S k i nned 1b. Non-Meat Receiving (Processing Aids, Antimicrobials, Packaging Material) 5.

Pre-Evisceration Wash 7. Variety 6. . Head Was hi ng \ Ro dding t he E s o phagus \ Head Droppi ng \ B ung Rem o v al \ Carc ass Opening \ E vi sc erati on 8. Carc as s S p li t ti ng 11. P roduct (Carc ass and V ari et y M eat s) Chilling 10. F i nal Was h Org ani c Ac id S pray on Carc as es and V ari et y M eats CCP 2 M eat s (o ff al ) Tri m \ Was h 9. Z ero To leranc e E x ami nati on (c arcass , head s , and v ariet y m eats ) CCP 1 12. F ab ri c at i on, \ P ac k ag ing \ Lab eli ng 13. Co l d S t orage 14. P roduct S hippi ng I f II ~ \ I . It ~---\u2022=--, t 1 15. Returned Product8 DATE: APPROVED BY: 6Note: This is an example chart. Each establishment\u2019s flow chart maybe different. An establishment can determine what steps are included in the overall process as long as all of the hazards are considered in the hazard analysis. 7This model demonstrates two approaches to carcass preparation, either all carcasses are skinned (proceed from step 2 directly to step 4b), or carcasses are scalded (step 2 through steps 3, 4, and 4a). 8 The Returned Productstep (15)is shown as notconnectedto another process step. Returned product may re-enter the production system at different process stepsdepending on conditionor problem. Returned product may be relabeled, reprocessed, discarded, etc. Page 4of 17", "EXAMPLE MARKET HOG SLAUGHTER HAZARD ANALYSIS9 Column 1 Column 2 Column 3 Column 4 Column 5 Column 6 Ingredient, Process Step Potential Hazards (Introduced or Controlled) at this Step10 Is the Potential Food Safety Hazard Reasonably Likely to Occur (RLTO)? (Yes or No)11 Justification \ Basis for Decision12 If yes in Column 3 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels13 Is this Step a Critical Control Point (CCP)?14 9 See FSIS Compliance Guideline for Controlling Salmonella in Market Hogs, FSISCompliance Guideline for the Prevention and Controlof Trichinella and Other Parasitic Hazards in Pork and Products Containing Pork, and FSISCompliance Guide: Modernization of Swine Inspection System for suggested slaughter best practices and a list of scientific and technical references. 10 Hazards are grouped into threecategories:Biological(B), Chemical (C), and Physical(P). Biological hazardsarelivingorganisms. Chemical hazardsmaybe naturallyoccurringin foods, used, or added duringthe processingoffoods, or administered to live animals. Physical hazards areacomponent ofafood that is unexpected, such asplastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification. 11Place thejustification for your decision in column 4. Include control measures in column 4 forhazards not reasonably likely to occurand place them in column 5 forhazards reasonably likely to occur. If a hazard is reasonable likely to occur,then a CCP must beaddressed at this step or a later step. See FSISMeat and Poultry Hazards and Controls Guide for a list of frequently used controls. 12Scientificreferences are important in making decisions, providing justifications, and validating the HACCPsystem. When scientific references are used for decisions, the referencedarticle must be part ofthe HACCP records. If the scientificjustification isfromFSIS, then list the document name. If justificationis not from an FSISprogram, then HACCP system design must be supported by documentary evidence \u2013that is,documents depictingthe theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan. 13Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishmentis required to maintain records

associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation, page 5). 14 To determine whether a CCP is necessary, see Guidebook for the Preparation of HACCP Plans for decision tree to evaluate the areas of control (column 5) to determine the best CCP to control, reduce, or eliminate a hazard. Page 5 of 17", "Step Hazard RLTO Justification \ Basis Controls CCP 1. Live Hog Receiving B: Pathogens, Salmonella Trichinella 15 Yes No Live hogs may have pathogens on hair, skin, feet, and in the digestive tract. APHIS 16 validated Trichinella pre-harvest safety program. Therefore, the hazard is not reasonable likely to occur and treatment of such products for the destruction of Trichinæ is not necessary. Controlled at Subsequent CCP in process: CCP 1: Zero Tolerance Examination, CCP 2: Organic Acid Spray. Maintain adequate sanitation in holding pens, Good Manufacturing Practices. Documented pre-harvest farm management measures to reduce Salmonella. Transportation controls to reduce stress and fecal shedding, as well as crosscontamination. No C: Drug No Low risk per USDA Residue Monitoring residues Program, Compliance Guide for Residue Prevention. Residue certifications for live animals. Written Drug Residue Control SOP (Standard Operating Procedure). P: Foreign material, metal No Recorded historical data from written Foreign Material SOP 17 indicates low 15 See , FSIS Compliance Guideline for Controlling Salmonella in Market Hogs for guidance on controlling Salmonella and FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork and Products Containing Pork for options used to prevent the control of Trichinella in pork and pork products. 16 USDA Animal and Plant Health Inspection Service 17 Example: This Foreign Material SOP (prerequisite program) should have details on how this procedure is preventing the hazard from occurring (metal prevention controls) as well as the on-going verification procedures. These controls should be evident within the written document upon review. The Foreign Material SOP and plant data related to validation and on-going verification activities then become part of recordkeeping and historic data. Page 6 of 17", "Step Hazard RLTO Justification \ Basis Controls CCP (needles, likelihood at this establishment and from wire) suppliers. 18 Written Visual Ante-mortem Examination of Swine SOP for observation of live hogs in holding pens, carcasses during dressing, and parts, viscera, and equipment during processing make this hazard not reasonably likely to occur. 1a. Live Animal B: Pathogens Yes Skin and hair from swine are a significant Controlled at Subsequent CCP in process: No Wash: for Salmonella source of contaminants in slaughter CCP 1: Zero Tolerance Examination, CCP 2: heavy operations. Organic Acid Spray. Contamination 19 Written Live Animal Wash SOP with conditions for use (processing conditions, suppliers, customer specifications, etc.) and wash parameters to decrease pathogens and prevent cross-contamination. C: None P: None 1b. Non-Meat Receiving (Processing Aids \ Antimicrobials , Packaging Material) B: None 18 Note: this \u201chistorical

data must be supported with evidence from the establishment through the establishment's history or validation data with reference to the actual SOP or prerequisite program. When historical data is not available (for example, a HACCP plan for a new process or product), then system design must be supported by other documentary evidence, such as the FSIS Meat and Poultry Hazards and Controls Guide which states "visual examination of carcass for foreign material during slaughter" is a frequently used control for foreign material hazards in swine slaughter.<sup>19</sup> The criteria for use of the live animal wash should be clearly established in the prerequisite program. Page 7 of 17", "Step Hazard RLTO Justification √ Basis Controls CCP C: Incorrect chemical concentration received No Letters of Guarantee from suppliers. Written Chemical Receiving, Storage and Use SOP describing procedures for receiving, storage, mixing, use, and operational parameters verification procedures. Safety Data Sheets P: None 2. Stunning, Sticking, Bleeding B: Pathogens Salmonella Yes Live hogs may have pathogens on hair, skin, feet, and in the digestive tract. Contaminants on swine hair and skin could transfer to product during dressing procedures. Controlled at Subsequent CCP in process: CCP 1: Zero Tolerance Examination, CCP 2: Organic Acid Spray. Written Slaughter SOP describing the removal (trimming) of visible contaminants in the area where sticking occurs and the sanitation (heat or chemical) of the sticking knife prior to each procedure. No C: None P: None 3. Scalding B: Pathogens Salmonella Yes Potential for cross-contamination through stick wound as well as scalding process. Controlled at Subsequent CCP in process: CCP 1: Zero Tolerance Examination, CCP 2: Organic Acid Spray. Written Scalding SOP for procedures to minimize cross-contamination during scalding and use of processing aids, scald agent, antifoam, and carcass holding time and solution temperature parameters used in scalding process to decrease pathogen load, and maintenance of scalding sanitary condition (easy to clean and in good repair). No Page 8 of 17", "Step Hazard RLTO Justification √ Basis Controls CCP Immediate trimming of stick wound after scalding. C: No Letters of Guarantee from suppliers. Inappropriate Safety Data Sheets on file. chemical or concentration of scald agent used Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer's instructions and is within the allowable limits identified in Directive 7120.1 (FCN# [insert number]) P: None 4. Dehairing, B: Pathogens Yes Pathogens may be present on hog's skin. Controlled at Subsequent CCP in process: No Gambrelling, Salmonella Potential for cross-contamination during CCP 1: Zero Tolerance Examination, CCP 2: Singeing, dehairing operation. Organic Acid Spray Polishing, Shaving, Knife Trimming Singeing may reduce pathogens but is not a means to eliminate pathogens on skin. Written Sanitation SOP to maintain equipment sanitary conditions to minimize cross-contamination. Written Sanitary Dressing SOP. C: None P: None 4a. Skinning B: Yes Pathogens may be present on hog's skin. Controlled at Subsequent CCP in process: No (as needed Pathogens Potential for cross-contamination during CCP 1: Zero Tolerance Examination, CCP 2: during hard Salmonella skinning operation. Organic Acid Spray. hair season) Written Sanitation SOP to maintain equipment sanitary conditions to minimize cross-contamination. Written Sanitary Dressing SOP. C: None Page 9 of 17", "Step Hazard RLTO Justification √ Basis Controls CCP P: None 4b. All B: Yes Pathogens may be present on hog's skin. Controlled at Subsequent CCP in process: No Carcasses Pathogens Potential for cross-contamination during CCP 1: Zero Tolerance Examination, CCP 2: Skinned Salmonella skinning operation. Organic Acid Spray. Written Sanitation SOP to maintain

equipment sanitary conditions to minimize cross-contamination. Written Sanitary Dressing SOP. C: None P: None 5. PreB: Yes Pathogens may be present on hog's skin. Controlled at Subsequent CCP in process: No Evisceration Pathogens Washing may reduce pathogens but is not CCP 1: Zero Tolerance Examination, CCP 2: Wash20 Salmonella a means to eliminate pathogens on skin. Organic Acid Spray. Written Pre-evisceration Carcass Wash SOP. Process Control SOP (prerequisite program) for sampling of microbial organisms to monitor the establishment's ability to maintain process control (9 CFR 310.18). C: No Letters of Guarantee from suppliers. Inappropriate Safety Data Sheets on file. antimicrobial use and concentration Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals in scald water to ensure it meets manufacturer's instructions and Directive 7120.1 approval (FCN# [insert number]). 20 Pre-evisceration wash can be a control step where application parameters are monitored and documented in a prerequisite program (as listed). If a hazard at a step is considered reasonably likely to occur, a CCP needs to be assigned either at that step or at a later step. FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products lists suitable compounds for pre-evisceration wash. Concentrations and control parameters in prerequisite programs need to be validated to ensure they work as intended in the establishment (see FSIS Compliance Guide HACCP Systems Validation). Page 10 of 17", "Step Hazard RLTO Justification \ Basis Controls CCP P: None 6. Head B: Pathogens Yes Live hogs may have pathogens on hair, Controlled at Subsequent CCP in process: No Washing, Salmonella skin, feet, and in the digestive tract. CCP 1: Zero Tolerance Examination, CCP 2: Rodding the Contaminants could transfer to product Organic Acid Spray. Esophagus, during dressing procedures. Documentation of properly trained Head Dropping, Bung Removal, Carcass Opening, Evisceration Cross-contamination from insanitary dressing procedures and employee handling. employees. 21 Written Sanitation SOP for procedures and verification of equipment sanitized between each carcass processed to minimize cross-contamination. Written Sanitary Dressing Procedures which include tying the esophagus to prevent contamination from stomach contents. Written Pre-evisceration Wash SOP to minimize overspray from cabinet. C: None P: None 7. Variety B: Yes Live hogs may have pathogens on hair, Controlled at Subsequent CCP in process: No Meats (Offal) Pathogens skin, feet, and in the digestive tract. CCP 1: Zero Tolerance Examination, CCP 2: Trim \ Wash Salmonella Contaminants could transfer to product Organic Acid Spray. during dressing procedures. Properly trained employees to examine variety meats (offal). Written Sanitation SOPs to prevent cross-contamination and to minimize outgrowth of pathogens. 22 21 FSIS recommends that slaughter operations focus on their sanitary dressing procedures on preventing carcass contamination and the creation of insanitary conditions. Document the training of employees and training material used. Poor sanitary dressing procedures result in carcass contamination (visible or invisible, for example, microbial contamination) and limit the effectiveness of antimicrobial interventions. 22 Reference can be used to justify temperature and time during processing (for example, The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50°F (Tompkin, R.B. 1996). Page 11 of 17", "Step Hazard RLTO Justification \ Basis Controls CCP C: None P: None 8. Carcass B: Pathogens Yes Meat can become contaminated with Controlled at Subsequent CCP in process: No Splitting Salmonella pathogens during dressing procedures and processing. Splitting saw can transfer contaminants from carcass to carcass. CCP 1: Zero Tolerance Examination, CCP 2:

Organic Acid Spray. Recorded historical data from written Sanitation SOP Check to address splitting saw sanitation between carcasses to prevent cross-contamination indicates low likelihood of occurrence.<sup>23</sup> Written Sanitary Dressing SOP for monitoring the time required to move carcasses through the slaughter process to reduce exposure to contaminants. C: None P: None 9. Zero B: Pathogens Yes It is widely accepted that carcasses and Yes Tolerance Salmonella organs are to be handled in a sanitary CCP 124 Examination manner to prevent contamination with feces (Carcass or ingesta. heads, and FSIS enforces a zero tolerance standard for Variety Meats visible fecal material, ingesta, or milk on (Offal)) carcasses and parts (Livestock Carcasses and Poultry Carcasses Contaminated With Visible Fecal Material). If contamination 23 Documentation to support this statement using in-plant data collected from prerequisite program (Sanitation SOP) validation and on-going verification check. When historical data is not available (for example, a HACCPplan for a newprocess or product),then system design must be supported by other documentary evidence, such as the FSIS Meat and Poultry Hazards and Controls Guide which states \u201cmimimize cross-contamination through sanitary dressing procedures; Sanitation SOPs\u201d is a frequently used control for biological hazards in swine slaughter. <sup>24</sup> The CCP to reduce,control, or eliminate the previous hazards associated with zerotolerance for milk, fecalmaterial and ingesta as designated by \u201cyes\u201d in column 6. Page 12 of 17", "Step Hazard RLTO Justification \u201c Basis Controls CCP occurs, it is removed by trimming (9 CFR 310.18(a)). C: None P: None 10. Final wash and Organic Acid Spray on Carcass and Variety Meats B: Pathogens Salmonella Yes Live hogs may have pathogens on hair, skin, feet, and in the digestive tract. Contaminants could transfer to product during dressing procedures. Organic Acid sprays documented<sup>25</sup> to reduce contaminants on carcasses, variety meats (offal), and meat.<sup>26</sup> Written Carcass Wash SOP to minimize overspray from cabinet and ensure complete coverage. Yes CCP 2 C: Inappropriate concentration of organic acid No Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer\u2019s instructions and is within the allowable limits identified in Directive 7120.1 (FCN# [insert number]) P: None 11. Product (Carcass and B: Pathogen outgrowth Salmonella No Written Product Chilling SOP to address carcass and variety meats chilling and 25 Provide reference for scientific support and validation for effective concentrations and support for critical operational parameters that reduce biological hazards. FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat,Poultry and Egg Products contains the list of substances that maybe used in the production of meat and poultry products. The list contains the allowable amounts and the intended use of the approved antimicrobials. The list (Directive 7120.1) can be usedas supporting documentationfor chemical hazard controls(safety and suitability). Directive 7120.1 cannot be usedas supportforthe control ofbiological hazards because the antimicrobialconcentrationneeded to controlbacteria is different from the concentrationsrequired for safety and suitability. <sup>26</sup> If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support containsmicrobiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. However,if an establishment implements different critical

operational parameters in the process from the scientific support, or the scientific support identified does not contain microbiological data, then the establishment should collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological validation data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameter (FSIS Compliance Guideline HACCP Systems Validation, page 27). Page 13 of 17, "Step Hazard RLTO Justification \ Basis Controls CCP Variety Meats) holding cooler temperature to reduce Chilling pathogen growth<sup>27</sup> Tompkin, R.B. 1996. Written Sanitation SOP to address cooler sanitation and sanitary handling of products held in the cooler. Process Control prerequisite program for sampling of microbial organisms to monitor the establishment's ability to maintain process control (9 CFR 310.18). C: None P: None 12. B: Pathogen No Written Fabrication SOP to address Fabrication, outgrowth temperature control for the processing room Packaging, Salmonella to reduce pathogen outgrowth (Tompkin, Labeling R.B. 1996). Written Sanitation SOP includes procedures for sanitary handling of product. C: None P: None 13. Cold B: Pathogen No Written Cooler Storage SOP for proper Storage outgrowth Salmonella cooler storage temperature (Tompkin, R.B. 1996). Written Sanitation SOP to address cooler sanitation. C: None P: None 27 References can be used to justify temperature and time during processing (for example, The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50°F (Tompkin, R.B. 1996). Page 14 of 17, "Step Hazard RLTO Justification \ Basis Controls CCP 14. Product Shipping B: Pathogen Outgrowth Salmonella No Written Final Product SOP for procedures to examine outgoing products including sanitary condition of trucks, functioning transport refrigeration unit, and package integrity. C: None P: None 15. Returned Product Reinspection SOP implemented before accepting returned product. Product enters the appropriate step of the production system based on findings of product evaluation. Opened packages are not accepted. Notify FSIS personnel when product has been returned. DATE: APPROVED BY: Page 15 of 17, "Market Hog Slaughter (Raw Intact) HACCP PLAN<sup>28</sup> Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 1 Zero Tolerance Examination B: Pathogen: Salmonella No (Zero) visibly detected Examine carcasses, heads, and Observe all surfaces of 2 carcasses Once per shift for carcasses. Designated employee. Any visible fecal material, ingesta, or milk contaminants are knife Once per day a QA Tech or designated employee will examine for contaminants 2 Zero Tolerance Check Form<sup>30</sup> fecal material, milk, or ingesta contaminants on carcasses, heads, or variety meats. variety meats for contaminants. at the USDA final rail inspection station. Observe all surfaces of 2 heads after dressing at head processing station. Observe all Once per shift for variety meats and heads. trimmed immediately from carcasses, heads, or variety meats.<sup>29</sup> If a deviation from the critical limit occurs, the production supervisor will per 9 CFR 417.3: 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will be randomly selected carcass sides from those held in the cooler. Once per week at a randomly chosen time, a QA Tech will examine for contaminants 2 randomly selected dressed heads and 2 randomly selected pieces of variety meats. Once per week at a randomly chosen time, a QA Tech will observe the Corrective Action Log Preshipment Records Review Form Verification Records surfaces of 2 pieces of variety meats. sold); 2. Determine and eliminate the

cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence. designated employee perform zero tolerance monitoring on carcasses, variety meats, and heads. Weekly, the QA Tech will review the Zero Tolerance Check Form completed by designated employee. Records Review (9 CFR 417.4(a)(2)(iii)) 28 This informationis to help small and very small establishments in understanding the requirements in Title 9 Code ofFederal Regulations (9 CFR)Part 417. The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. 29 For example, an SOP describing the monitoring procedures might include this statement \u201each head, carcassand variety meat with a deviation will be shown to the supervisor. The supervisor willdetermine the cause ofthe deviation, take whatever measures are necessary to restore the CCPto control, and document the corrective actions in the Corrective Actions Log.\u201d 30One form for all monitoring and verification activities. Page 16 of 17","Critical Critical Limits for Monitoring Procedures

Corrective Action Verification Records Control Point (CCP) Significant Hazard(s) Each Control Measure What How Frequency Who CCP 2 Organic Acid Spray B: Pathogens, Salmonella Mix solution31 per manufacturer\u2019s instructions to achieve 2-5% solution of organic acid. Temperature of the solution in the tank is not to exceed 55oC. The solution is sprayed directly onto carcasses, head meat, and variety meats. The solution will be applied to each carcass side for 15 seconds and each whole carcass for 25 seconds or until all surfaces are dripping wet and some of the solution drips off. The solution will be applied to head meat and variety meats until all surfaces are wet and some of the solution drips off. Monitor the mixing of the organic acid solution, measure the temperature of the solution in the pressure tank, and check the application of the solution. Check the volumes of the ingredients used to make the solution. Check the temperature of the solution in the tank with a handheld thermometer. Monitor the application of the solution to carcasses, variety meats, and head meat pieces. Check the volumes of the ingredients and solution temperature once per shift. The application of the solution is monitored twice per shift. QA Tech or designee If the organic wash is outside the solution range, not applied to all surfaces or exceeds 55oC then the critical limits are not met. If a deviation from the critical limit occurs, the production supervisor will per 9 CFR 417.3: 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will be sold); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence. Randomly, once per week, QA Manager observes QA Tech performing monitoring functions; Once per week, QA Manager will calibrate thermometer per manufacturer\u2019s procedures. Once per week, the QA Manager will use a test kit to measure the solution concentration. Daily, QA Tech will review the Organic Acid Spray Form completed by designated employee. Records Review 9 CFR 417.4(a)(2)(iii) Organic Acid Spray Form Corrective Action Log Preshipment Records Review Form Verification Records 31 This is an example HACCP plan. See Directive 7120.1 for a complete list ofantimicrobials that FSISverifies as safe and suitable. Page 17 of 17"]},{"file\_name":"FSIS\_GD\_2020\_0012","title":"HACCP Model for New Poultry Inspection System (NPIS) Poultry Slaughter","num":"FSIS-GD-2020-0012","id":"3fdcdd07f8bd716a69d617077785f22112b9535700946a394b9ae46e469ee16b","content\_type":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/media\_file/2021-03/HACCP-Model-NPIS-Poultry-"}]

Slaughter.pdf", "type": "pdf", "n\_pages": 23, "word\_count": 5948, "text\_by\_page": ["A Generic HACCP Model for New Poultry Inspection System (NPIS) The United States Department of Agriculture (USDA) published the Pathogen Reduction\Hazard Analysis Critical Control Point (HACCP) Systems Final Rule in July 1996. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to address safety hazards reasonably likely to occur in their production process. Therefore, this HACCP model\u2019s focus, and the focus of the other HACCP models, is on product safety, not product quality characteristics. With the rule, FSIS made available a guidebook for the preparation of HACCP plans and a generic modelfor each food processing category defined inregulation (9 CFR 417.2(b)(1)). The guidebook and the generic models have been updated since their initial publication to be consistent with current science and policy. FSIS recommends you use of the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan. Generic models serve as usefulexamples ofhow to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used \u201cas is\u201d. FSIS recommends that establishments tailor the model(s) to fit the establishment\u2019s operation. The model\u2019s critical control points (CCPs) do not necessarily apply to all operations or products in the product category. Products or operations may require fewer or more CCPs depending on the operation. The flowdiagram demonstrates a general production process and should be modified toreflecttheprocesses used at theestablishment. The food safety criticallimits selected must come from scientific documents or other reliable sourcesto meet regulatory validation requirements. Each modelincludes references for guidance on the selection of critical limits. To select the model that will be most useful for the products produced, consider the production activity occurring (slaughter, cutting, grinding, smoking, cooking, etc.), the product (beef, pork, chicken, etc.), and the food safety characteristics of the final product produced (intact or nonintact, raw or ready-to-eat, requires refrigeration or is shelf-stable, etc.). Examine the list of processing categories (9 CFR 417.2(b)(1)) and group similar products according to the categories. Many similar products may be grouped under the same category and HACCP plan. Selection of the processing categories reveal which of the generic models might be useful. Selecting the most appropriate model to work from will save the establishment time and personnel resources. Deciding on a generic model is an important achievement for your establishment. The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis are HACCP records ((CFR 417.5(a)). The selection of processing categories and HACCP models are preliminary steps to completing a hazard analysis. The documents produced during the selection process are HACCP records. Ensure you maintain the documents produced while documenting a HACCP plan For further assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP webpage. Page 1of 23", "EXAMPLE PRODUCT DESCRIPTION1 Process \ Product Name: New Poultry Inspection System (NPIS) Poultry Slaughter \ Whole Carcasses, Parts, Other Intact Poultry Products Process \ product type name Young Ready-to-Cook chicken, other types of whole dressed poultry carcasses (turkeys, ducks, geese), single ingredient intact poultry products, such as

parts, giblets2, paws, and turkey fries Important product characteristics (Aw, pH, preservatives, etc.) Not Applicable How it is to be used For further processing at this facility or another establishment or intended for cooking by end consumer Packaging (durability and storage conditions) Vacuum packaged, tray packs, giblets in plastic sealed containers, bulk pack boxes with liners. Shelf life and at what temperature3 Refrigerated -10 Days at 40\u00baF Frozen \u2013 180 Days at <10\u00b0OF Where it will be sold (specify intended consumers, especially at-risk populations4) Sold direct to another establishment or to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI). Labeling instructions Product name, inspection legend and establishment number, handling statement, net weight statement, address line, nutrition facts, and safe handling instructions. What special distribution controls are required? Keep Refrigerated < 40\u00b0OF Keep Frozen < 10\u00b0OF DATE: APPROVED BY: 1Prior to developing the HACCPplan please read the FSIS Guidebook for the Preparation of HACCPPlans for detailed descriptions of the worksheets and hazard analysis. This information is best suited for establishments seeking assistance in understanding the requirements in Title 9 Code ofFederal Regulations (9 CFR)Part 417. The HACCP model is for demonstrationpurposes only. The model does not represent requirements that mustbe met. Establishments are required to develop HACCPplans specific to their facilities, production practices, and products. 2For thepurpose ofthismodel, giblets refers to poultry hearts, livers and gizzards. 3Each establishment may have their own defined shelf life. 4At-risk populations includeyoung children, elderly, and immunocompromised persons. Page 2of 23", "EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL5 Process \u2013 Product Name: NPIS Poultry Slaughter Whole Carcasses, Parts, Other Intact Poultry Products Poultry and poultry by-products Live birds Non-meat food ingredients None Antimicrobials6 and processing aids Chlorine, Organic acid7 Packaging material Plastic vacuum bags, retail trays, cardboard boxes, plastic liners Restricted ingredients or allergens None Other None DATE: APPROVED BY: 5Listall meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, packaging material used in production of this product. This is important to help identify any special ingredientsor processes to address in the HACCPplan. 6FSIS and the Food and Drug Administration (FDA) have a memorandum of understanding (MOU) that establishes the working relationship followed when responding to notifications for the use of food additives intended for use in the production of FSISregulated products. FSISdetermines the suitability of theuseoffood ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDAon the requirements under the Food,Drug&CosmeticActand its implementing regulations. See FSISDirective 7120.1, Safe and Suitable Ingredients Used in MeatPoultry and Egg Productsfor the list of suitable ingredients. 7\u2013Organic acid\u201d is a placeholder for the product to beused by the establishment. Page 3of 23", "...".I ..... ..\_\_\_\_\_,--\_\_\_\_ J \|~ 1 1~1 1 1 \|\u2022 11111.1 i 11111111 1--1 EXAMBLE PROCESS FLOW CHART8 NPIS Poultry Slaughter \u2013 Whole Carcasses, Parts, Other Intact Poultry Products 2.Unloading, Stunning, Bleeding 1. Receive Live Birds 3.Scalding, Picking, Head, and FeetRemoval 1a. Receive Non-meat Items 4. Pre-evisceration antimicrobial application by Wash, Spray, or Dip (for example, Antimicrobials, Packaging 5.Evisceration, including neck removal, venting, Materials) opening, drawing viscera from carcass 7.Harvest of Giblets, Necks and Feet 12. Trimming 16.Chilling of all products CCP 4 20.Transfer carcasses to cut up or further processing 8.Giblets, Necks, and 17.Packaging and Labeling Feet Packaging

6. Establishment sorting of carcasses (and associated viscera) and disposal of carcasses exhibiting septicemic and toxemic conditions, routing of carcasses with digestive tract contaminants to reprocessing and routing carcasses with localized pathology (e.g., airsacculitis) to offline salvage 10. Crop, Lung, and Kidney Removal 9. Offline Reprocessing and Salvage CCP 2 11. Inside and Outside Carcass Wash 13. Online Reprocessing (optional) 14. Monitoring Carcasses for Fecal Contamination and septicemic and toxemic conditions CCP 1 15. Pre-chilling antimicrobial application CCP 3 19. Shipping 18. Cold Storage 8. This is an example flow diagram. Establishments \u2019 flow diagrams for the same product may be different. Establishments determine which steps are included in their process. The steps must represent all relevant hazards in the hazard analysis. Step 6, Establishment Sorting of Carcasses (and associated viscera), is represented in this model by a single box in the flow chart. Establishments use different approaches and a variety of processing techniques leading up to their sorting activity (9 CFR 381.76 (b)(6)(ii)(A)). Therefore, step 6 may represent a number of different carcass preparation practices.

Page 4 of 23, "EXAMPLE POULTRY SLAUGHTER HAZARD ANALYSIS"

Column 1 Column 2 Column 3 Column 4 Column 5 Column 6 Ingredient \ Process Step

Potential Hazards (introduced or controlled) at this step 10 Is the Potential Food Safety Hazard Reasonably Likely to Occur (RLTO)? (Yes or No) 11 Justification \ Basis for Decision 12 If yes in Column 3 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels 13 Is this Step a Critical Control Point (CCP)? 14 1. Receive Live Birds B: Pathogens Salmonella, Campylobacter Yes Live birds may have pathogens on feathers, skin, feet, and in the digestive tract. The hazard is controlled at later steps with visual examination for contaminants, antimicrobial application and chilling (CCPs 1 and 2, CCP 3, CCP 4). No 10 Refer to FSIS Meat and Poultry Hazards and Controls Guide and DRAFT FSIS Compliance Guideline For Controlling Salmonella and Campylobacter in Raw Poultry for suggested practices and controls. 10 Hazards are grouped into three categories: Biological (B), Chemical (C), and Physical (P). Biological hazards are living organisms. Chemical hazards maybe naturally occurring in foods, used, or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification. 12 Place the justification for your decision in column 4. Include control measures in column 4 for hazards not reasonably likely to occur and place them in column 5 for hazards reasonably likely to occur. If a hazard is reasonable likely to occur, then a CCP must be addressed at this step or a later step. See FSIS Meat and Poultry Hazards and Controls Guide for a list of frequently used controls. 13 Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced article must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from an FSIS program, then HACCP system design must be supported by documentary evidence \u2013 that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan. 14 Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to

maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation, page 5).

15 To develop an effective CCP, see the FSIS Guidebook for the Preparation of HACCP Plans for a CCP decision tree and guidance on how to control, reduce, or eliminate a hazard. Page 5 of 23", "Step Hazard RLTO Justification \ Basis Controls CCP Truck Sanitation SOP for cage cleaning between flocks. Pre-Harvest Controls. Feed Withdrawal Standard Operating Procedure (SOP). C: Drug residues No Low risk per FSIS Compliance Guide for Residue Prevention.15 Growers required to follow best preharvest practices, which include appropriate withdrawal requirements when antibiotics are prescribed. P: Foreign objects in the gizzards of live birds No Establishment historical data16 (that is, giblet quality monitoring) demonstrates low risk of foreign objects in gizzards after processing. Foreign Material SOP.17 Gizzard quality checks after chilling, which include monitoring for foreign objects, such as wire. 1a. Receive Non-meat Items (for example, B: None C: Inappropriate chemical or No Establishment historical data shows low risk of receipt of inappropriate 16 If the scientific justification is from FSIS, then list the document name. If justification is not from an FSIS program, then scientific or technical support is needed, and these non-FSIS supporting documents must be kept for the life of the HACCP plan. 17 Note: this historical data must be supported with evidence from the establishment through the establishment's history or validation data with reference to the actual SOP or prerequisite program. When historical data is not available (for example, a HACCP plan for a new process or product), then system design must be supported by other documentary evidence. Such as the FSIS Meat and Poultry Hazards and Controls Guide which states "monitor giblets for foreign materials" is a frequently used control for foreign material hazards in poultry slaughter.. 17 This Foreign Material SOP (prerequisite program) should have details on how this procedure is preventing the hazard from occurring (such as metal prevention controls) as well as the on-going verification procedures. These controls should be evident within the written document upon review. The Foreign Material SOP and plant data related to on-going verification activities then become part of recordkeeping and historic data.

Page 6 of 23", "Step Hazard RLTO Justification \ Basis Controls CCP Antimicrobials, Packaging Materials) concentration received chemicals and inappropriate chemical compounds Letters of Guarantee from suppliers. Identify and list all approved chemicals used in the operations. Check each chemical at receiving to assure that it is on the list at the correct concentration and is appropriately labeled. Safety Data Sheets (SDS) P: None 2. Unloading, Stunning, Bleeding B: Pathogens Salmonella, Campylobacter Yes Live birds may have pathogens on feathers, skin, feet, and in the digestive tract. The hazard is controlled at later steps with visual examination for contaminants, antimicrobial application and chilling (CCPs 1 and 2, CCP 3, CCP 4). Proper application of stunning methods and maintenance of stunning equipment to reduce involuntary

voiding of feces. Employee hygienic practices. Air flow directed away from further processes. No C: None P: None 3. Scalding, B: Pathogens Yes Scald water and picking machinery can The presence of pathogens is controlled No Picking, Head and Feet Removal Salmonella, Campylobacter increase pathogen cross-contamination. Pathogens can contaminate muscles of carcasses that are mutilated during picking. at later steps with antimicrobial application and chilling (CCP 3, CCP 4). Scalder operational procedures for freshwater intake and overflow, agitation of scald water. Page 7of 23","Step Hazard RLTO Justification \ Basis Controls CCP Multi-stage scald tanks with counter current water flow to result in lower bacterial levels where the birds exit the scalder compared to where the birds enter the scalder. Optional use of brushes to remove dirt and debris from birds prior to scalding. Water pH maintained either above or below optimum pH for Salmonella and Campylobacter growth. Antimicrobials, acidifiers and anti-foam chemicals applied in the scald water as part of a multi-hurdle approach to reduce enteric pathogens.<sup>18</sup> Prerequisite program to monitor antimicrobial and any other chemical concentrations. Trim mutilated portions from carcasses later in the process. Written Sanitation SOP for equipment cleaning and sanitation to prevent product contamination. C: Antimicrobial, No Establishment historical data shows defoamer, or pH low risk of chemical contamination by modifier not use of defoamers and pH boosters in appropriately scalders. mixed to meet 18 Provide reference for scientific support and validation for effective concentrations and support for critical operationalparameters that reduce biological hazards. FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat,Poultry and Egg Products contains the list of substances that maybe used in the production of meat and poultry products. The list contains the allowable amounts and the intended use of the approved antimicrobials. The list (Directive 7120.1) can be used as supporting documentation for chemical hazard controls(safety and suitability). Directive 7120.1 cannot be used as support for the control of biological hazards because the antimicrobial concentration needed to control bacteria is different fromthe concentrations required for safety and suitability. Page 8of 23","Step Hazard RLTO Justification \ Basis Controls CCP Generally Recognized as Safe (GRAS) parameters Written chemical mixing procedures and documented verification procedures to ensure that critical operating parameters are maintained. Chemicals are properly used to meet the chemical manufacturer\u2019s recommendations and GRAS parameters. P: None 4.

Preevisceration antimicrobial application by Wash, Spray, or Dip B: Pathogens Salmonella, Campylobacter Yes Pathogens introduced on live birds present on carcass skin and in the digestive tracts The hazard is controlled at later steps with visual examination, antimicrobial application and chilling (CCPs 1 and 2, CCP 3, CCP 4). Pre-evisceration wash, spray, or dip applies an approved antimicrobial solution as part of a multi-hurdle approach to reduce enteric pathogens. Prerequisite program to monitor antimicrobial concentration and method of application. No C: Antimicrobial No Establishment historical data shows low application not risk of inappropriate chemical within GRAS application. limits Written chemical mixing procedures and documented verification procedures to ensure that critical operating parameters are maintained. Chemicals are properly used to meet the chemical manufacturer\u2019s recommendations and GRAS parameters. P: None Page 9of 23","Step Hazard RLTO Justification \ Basis Controls CCP 5. Evisceration<sup>19</sup>, including neck removal, venting, opening, drawing viscera from carcass B: Pathogens Salmonella, Campylobacter Yes Pathogens introduced on live birds present on carcass skin and in the digestive tracts. The hazard is controlled at later steps

with visual examination, antimicrobial application and chilling (CCPs 1 and 2, CCP 3, CCP 4). Written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the slaughter and dressing operations incorporated as a prerequisite program to meet 9 CFR 381.65(g) requirements.<sup>20</sup> These requirements include sampling and analysis for microbial organisms to monitor and maintain process control. No C: None P: Foreign No Foreign materials could be introduced Material from broken machinery parts, broken shackles, and insanitary overhead structures. Foreign Material SOP. Preventive equipment and evisceration line maintenance to prevent metal or plastic contamination. Routine cleaning of shackle rails and overhead structures. 19 DRAFT FSIS Compliance Guideline for Controlling Salmonella and Campylobacter in Raw Poultry provides guidance on how to control pathogens throughout the slaughter operation. <sup>20</sup>The required written procedures to prevent contamination may also include:a preventive equipment maintenance program to ensure machinery functions as intended to prevent contamination with digestive tract contents throughout the evisceration process; programs to ensure the proper application of antimicrobials (for example, antimicrobial concentration and method of application); employee hygienic practicesand an operational sanitation SOP. Page 10 of 23", "Step Hazard RLTO Justification \ Basis Controls CCP 6. Establishment sorting and disposal of carcasses exhibiting septicemic and toxemic conditions, routing of carcasses with digestive tract contaminants to reprocessing, and routing carcasses with localized pathology (e.g., airsacculitis) to B: Pathogens Salmonella, Campylobacter, Septicemic or toxemic conditions Yes Carcasses affected with septicemic or toxemia conditions may harbor pathogens. Carcasses with digestive tract contaminants may harbor pathogens. The monitoring for and disposal of septicemic and toxemic conditions and the monitoring for digestive tract contents are verified at a later step CCP 1 Monitoring Carcasses for Fecal Contamination and septicemic and toxemic conditions. The presence of pathogens is address at a later step CCP 3 Pre-chilling antimicrobial application. Written sorting procedures to ensure that poultry carcasses affected with septicemic or toxemic conditions do not enter the chiller, and to dispose of carcasses and parts exhibiting condemnable conditions, and to route carcasses with digestive tract contamination to offline reprocessing (9 CFR 381.76(b)(6)(ii)). No offline salvage C: None P: None 7. Harvest Giblets, Necks and Feet B: Pathogens: Salmonella, Campylobacter Yes Delayed separation from inedible items may result in pathogen outgrowth. The presence of pathogens is addressed at a later step with CCP 3 Pre-chilling antimicrobial application. The outgrowth of pathogens is addressed at a later step with CCP 4 Chilling. Chilling time and temperature critical limits monitored through a CCP to ensure that giblets, necks, and feet temperatures No Page 11 of 23", "Step Hazard RLTO Justification \ Basis Controls CCP are promptly reduced to temperatures that 21 prevent pathogen outgrown. Antimicrobial added to immersion chiller media or applied through a spray or dip. Written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the slaughter and dressing operations incorporated as a prerequisite program to meet 9 CFR 381.65(g) requirements. C: Inappropriate No Establishment historical data shows low concentration of risk of inappropriate chemical antimicrobial application. Written chemical mixing procedures and documented verification procedures to ensure that critical operating parameters are maintained. Chemicals are properly used to meet the chemical manufacturer\u2019s recommendations and GRAS parameters. P: Foreign No Establishment historical data (giblet material (rocks, quality monitoring)

demonstrates low wires, other risk of foreign objects in gizzards after building processing materials etc.) from birds pecking at litter during live production Foreign Material SOP. Gilet quality checks after chilling, which include monitoring for foreign objects, such as wire, that may be lodged in gizzards. 22 The FSIS Compliance Guide: Modernization of Poultry Slaughter Inspection: Chilling Requirements describes how establishments can meet the poultry chilling regulatory requirements. Page 12 of 23", "Step Hazard RLTO Justification \ Basis Controls CCP 8. Gilet, Necks, and Feet Packaging B: Pathogen growth Salmonella, Campylobacter No Product is promptly packaged and placed in storage coolers or freezers to prevent product temperatures that promote pathogen outgrowth C: None P: None 9. Offline Reprocessing and Salvage B: Pathogens Salmonella, Campylobacter Yes Carcasses accidentally contaminated with digestive tract contents (feces and ingesta) at higher risk for pathogen contamination. Disease conditions may harbor pathogens. Digestive tract contaminants are addressed at this step with CCP 2: Poultry parts contaminated with visible fecal material do not enter the chilling system. The hazard is controlled through visual examination of parts and removal of contaminants. The presence of pathogens is addressed with CCP 3 Pre-chilling antimicrobial application. Offline reprocessing procedures incorporated into HACCP system as a prerequisite program to comply with 9 CFR 381.91(b)(2). Written procedures to remove localized disease conditions (for example, airsacculitis, inflammatory processes) and verify that establishment employees appropriately implement the procedures in a sanitary manner. Antimicrobial solution applied to salvaged carcasses and parts. Yes CCP 2 C: Inappropriate No Establishment historical data shows low concentration of risk of inappropriate chemical antimicrobial application. Written chemical mixing procedures and documented verification Page 13 of 23", "Step Hazard RLTO Justification \ Basis Controls CCP procedures to ensure that critical operating parameters are maintained. Chemicals are properly used to meet the chemical manufacturer\u2019s recommendations and GRAS parameters. P: None 10. Crop, Lung, and Kidney Removal B: Pathogens Salmonella, Campylobacter Yes Carcasses accidentally contaminated with digestive tract contents (feces and ingesta) at higher risk for pathogen contamination. Crop removal may cause ingesta contamination, which increases the risk for pathogens. Kidneys with disease conditions, including airsacculitis, are required to be removed from carcasses. The hazard is controlled at a later step with visual examination, antimicrobial application and chilling (CCP 1, CCP 3, CCP 4). Written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the slaughter and dressing operations incorporated as a prerequisite program to meet 9 CFR 381.65(g) requirements. No C: None No P: None No 11. Inside and Outside Carcass Wash B: Pathogens Salmonella, Campylobacter Yes Carcasses accidentally contaminated with digestive tract contents (feces and ingesta) at higher risk for pathogen contamination. The hazard is controlled at a later step with visual examination, antimicrobial application and chilling (CCP 1, CCP 3, CCP 4). Written program to monitor that the carcass wash functions as intended (for example, nozzles properly applying wash at appropriate pressures). No C: Inappropriate concentration of antimicrobial No Establishment historical data shows low risk of inappropriate chemical application. Page 14 of 23", "Step Hazard RLTO Justification \ Basis Controls CCP Written chemical mixing procedures and documented verification procedures to ensure that critical operating parameters are maintained. Chemicals are properly used to meet the chemical manufacturer\u2019s recommendations and GRAS parameters. P: None No 12. Trimming B: Pathogens Salmonella,

Campylobacter Yes Carcasses accidentally contaminated with digestive tract contents (feces and ingesta) at higher risk for pathogen contamination. The hazard is controlled at later steps through subsequent visual examination, antimicrobial application and chilling (CCP 1, CCP 3, CCP 4). Employee hygienic practices. Operational Sanitation SOPs. No C: None P: None 13.

Online Reprocessing (Optional) B: Pathogens Salmonella, Campylobacter Yes Carcasses accidentally contaminated with digestive tract contents (feces and ingesta) at higher risk for pathogen contamination. The hazard is controlled at later steps through subsequent visual examination, antimicrobial application and chilling (CCP 1, CCP 3, CCP 4). Online reprocessing procedures incorporated into HACCP system as a prerequisite program to meet 9 CFR 381.91(b)(1) requirements. No C: Inappropriate concentration of antimicrobial No

Establishment historical data shows low risk of inappropriate chemical application. Written chemical mixing procedures and documented verification procedures to ensure that critical operating parameters are maintained. Chemicals Page 15 of 23", "Step Hazard RLTO Justification \ Basis Controls CCP are properly used to meet the chemical manufacturer\u2019s recommendations and GRAS parameters. P: None 14. MonitoringB: Pathogens Yes Fecal material carries pathogens. Digestive tract contaminants and Yes Carcasses for Fecal Contamination and septicemic and toxemic conditions. Salmonella, Campylobacter Septicemic and toxemic conditions Septicemic and toxemic conditions may carry pathogens. septicemic and toxemic conditions are addressed with CCP 1 Monitoring Carcasses for Fecal Contamination and septicemic and toxemic conditions. No (zero) fecal contamination to enter chilling system. Monitoring for fecal CCP 1 contamination prior to the pre-chill antimicrobial application to ensure that poultry carcasses contaminated with visible fecal material do not enter the chiller (9 CFR 381.65(f)). Examine carcasses for evidence of septicemia or toxemia. Monitoring for and disposing of carcasses exhibiting septicemic or toxemic conditions (9 CFR 381.76(b)(6)(ii)(A)). Written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the slaughter and dressing operations incorporated as a prerequisite program to meet 9 CFR 381.65(g) requirements. The use of the approved on-line reprocessing system is optional. When the on-line reprocessing system is operating, the prerequisite program used to monitor reprocessing (Monitoring Page 16 of 23", "Step Hazard RLTO Justification \ Basis Controls CCP Online Reprocessing) is required. C: None P: None 15.

Pre-chilling Antimicrobial Application B: Pathogen Outgrowth Salmonella, Campylobacter Yes Carcasses accidentally contaminated with digestive tract contents (feces and ingesta) at higher risk for pathogen contamination. CCP 3 Pre-chilling antimicrobial application. Application of organic acid solution to carcasses, parts, giblets, necks and feet. Yes CCP 3 P: None C: Inappropriate No Establishment historical data shows low concentration of risk of inappropriate chemical antimicrobial application. applied Written chemical mixing procedures and documented verification procedures to ensure that critical operating parameters are maintained. Chemicals are properly used to meet the chemical manufacturer\u2019s recommendations and GRAS parameters. 16. Chilling B: Pathogen Outgrowth Salmonella, Campylobacter Yes Delayed chilling may result in pathogen outgrowth. Pathogen outgrowth is controlled with CCP 4 Chilling. Apply chilling procedures to lower internal temperatures of carcasses, parts, giblets, necks and feet. Written chilling procedures that address, at a minimum, the potential for pathogen outgrowth, the conditions affecting carcass chilling, and when the chilling process is complete (9 CFR 381.66(b)(ii)(3))22 Yes CCP 4 22 The FSIS

Compliance Guide: Modernization of Poultry Slaughter Inspection: Chilling Requirements describes how establishments can meet the poultry chilling regulatory requirements. Page 17 of 23", "Step Hazard RLTO Justification \ Basis Controls CCP C: Inappropriate concentration of antimicrobial No Establishment historical data shows low risk of inappropriate chemical application. Written chemical mixing procedures and documented verification procedures to ensure that critical operating parameters are maintained. Chemicals are properly used to meet the chemical manufacturer's recommendations and GRAS parameters. P: Foreign No Foreign material contamination from Material overhead structures and immersion chilling system moving parts. Foreign Material SOP. Carcasses monitored 2 times per shift for extraneous material contaminants after chilling. 17. Packaging and Labeling B: Pathogens Outgrowth: Salmonella, Campylobacter No Pathogen outgrowth may result if temperatures are not maintained at levels to prevent multiplication. Product is promptly packaged and placed in storage coolers or freezers to prevent product temperatures that promote pathogen outgrowth. C: None P: None 18. Cold B: Pathogen No Pathogen outgrowth may result if Storage Outgrowth Salmonella, Campylobacter temperatures are not maintained at levels to prevent multiplication. Written product storage procedures to maintain product at temperatures that Page 18 of 23", "Step Hazard RLTO Justification \ Basis Controls CCP will prevent pathogen outgrowth (9 CFR 381.66(b)(1)(ii)). C: None P: None 19. Shipping B: Pathogen Outgrowth Salmonella, Campylobacter No Pathogen outgrowth may result if temperatures are not maintained at levels to prevent multiplication during shipping. Products shipped on refrigerated transport vehicles. C: None P: None 20. Transfer Carcasses to Cut up or Further Processing B: Pathogen Outgrowth Salmonella, Campylobacter No Pathogen outgrowth may result if temperatures are not maintained at levels to prevent multiplication during transfer. Product is promptly transferred to prevent product temperatures that promote pathogen outgrowth. C: None P: None Page 19 of 23", "EXAMPLE NPIS Young Chicken Slaughter HACCP Plan23 Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action24 Verification Records What How Frequency Who CCP 1 Monitoring Carcasses for Fecal Contamination and septicemic and toxemic conditions. Pathogens: Salmonella, Campylobacter Carcasses affected with septicemic or toxemia conditions may harbor pathogens No (zero) fecal contamination to enter chilling system No (zero) carcasses with septicemic or toxemic conditions to enter chilling system. Visual examination for fecal material, and septicemic and toxemic conditions Examine the inside and outside surfaces of 10 carcasses for fecal contaminants, and septicemic and toxemic conditions. One 10-bird check for each production line per hour at random times selected during the production hour. Designated employees If a deviation from the critical limit occurs, the production supervisor will, per 9 CFR 417.3(a): 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Restore process control; 4. Take measures to prevent recurrence. Observe the person who monitors the CCP once each day of slaughter operations. Records reviewed once a week 9 CFR 417.4(a)(2)(i) Zero Fecal Check Form Corrective Action Log Sep\Tox Log ii). 24 This information is best suited for establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR)Part 417. The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. Establishments are required to

develop HACCP plans specific to their facilities, production practices, and products. 25 Each establishment must develop written corrective action procedures in response to a deviation from the critical limit to determine what to do with the affected product (from the last acceptable check), to eliminate the cause of the deviation, to bring the CCP back into control, and to prevent future deviations (CFR 417.3). Page 20 of 23", "Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 2 Pathogens: No (zero) Visual Examine parts One check for Designated If a deviation from Observe the Zero Poultry parts contaminated with visible fecal material do not enter the chilling system Salmonella, Campylobacter fecal contamination to enter chilling system. 9 CFR 381.65(f) examination for fecal material. for fecal contamination prior to when the parts enter the chilling system. Examine up to 10 parts for fecal contamination prior to chilling. If less than 10 parts are available examine all available parts. each production line per hour at random times selected during the production hour. employees the critical limit occurs, the production supervisor will, per 9 CFR 417.3(a): 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Restore process control; 4. Take measures to prevent person who monitors the CCP once each day of slaughter operations. Records reviewed once a week 9 CFR 417.4(a)(2)(ii) Fecal Check Form Corrective Action Log i). recurrence. Page 21 of 23", "Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 3 Prechilling antimicrobial applications 25 Pathogens: Salmonella, Campylobacter 600-700 ppm organic acid solution 26 Antimicrobial Solution concentration and method of application to carcasses, salvaged parts, reprocessed carcass parts, giblets, necks and feet. Measure the concentration of the antimicrobial solution at the point of application. (for example, 600-700 ppm organic acid solution) using titration kit supplied by chemical manufacturer. Twice per shift Designated employees If antimicrobial concentration wash exceeds critical limits, then all product from the last acceptable check will be retained and evaluated for further disposition. If a deviation from the critical limit occurs, the production supervisor will, per 9 CFR 417.3(a): 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence. Randomly, once per day, an employee observes the measurement of the concentration of the antimicrobial solution at the point of application. Records Reviewed once a week (9 CFR 417.4(a)(2)(iii)). Organic Acid Spray Concentration Form. Corrective Action Log 26 If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. However, if an establishment implements different critical operational parameters in the process from the scientific support, or the scientific support identified does not contain microbiological data, then the establishment should collect in-plant

data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological validation data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameter (FSIS Compliance Guideline HACCP Systems Validation, page 27). 27 Scientific or technical support is required to validate the critical limits and critical parameters (for example, time of exposure) of the organic acid spray. They are part of the hazard analysis and need to be maintained for the life of the HACCP plan (see FSIS Compliance Guideline HACCP Systems Validation); FSIS Directive 7120.1 Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products contains approved substances for use in poultry; however, each establishment must validate their own process. Page 22 of 23", "- Critical Critical Limits for Monitoring Procedures Corrective Action Verification Records Control Point (CCP) Significant Hazard(s) Each Control Measure What How Frequency Who CCP 4 Chilling of all Products Pathogen Outgrowth: *Salmonella*, *Campylobacter* Carcass temperature of 45 degrees or less within 6 hours. Parts, giblets, feet, and necks chilled to 44 degrees or less within 4 hours from the time they are removed from the inedible viscera. Carcass internal temperature. Parts, Giblets, Feet, and Necks internal temperature. Handheld properly calibrated thermometer inserted into the thickest portion of the breast muscle of the carcass, or thickest portion of the part, gullet, neck or foot. Check 10 carcasses for each production hour at random times selected during the production hour. Check up to 10 parts, giblets, necks or feet each production hour at random times selected during the production hour. If 10 units are not available at this time all units are checked. Designated employees If a deviation from the critical limit occurs, the production supervisor will, per 9 CFR 417.3(a): 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures Observe the person who monitors the CCP once each day the establishment slaughters. Once per week, supervisor will calibrate thermometer per manufacturer's procedures. Records reviewed once a week (9 CFR 417.4(a)(2)(iii)).

Carcass, Parts, Giblets, Necks and Feet Chilling Form Thermometer Calibration Form Corrective Action Log to prevent recurrence. Page 23 of 23"]}, {"file\_name": "FSIS\_GD\_2020\_0013", "title": "HACCP Model for Poultry Slaughter", "num": "FSIS-GD-2020-0013", "id": "0af929f11f36f78b569e2a4259cb79669aec2f0d983fd806604a8bc6176780d7", "corp\_us": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-03/HACCP-Model-for-Poultry-Slaughter.pdf", "type": "pdf", "n\_pages": 19, "word\_count": 5610, "text\_by\_page": ["Page 1 of 19 A Generic HACCP Model for Poultry Slaughter The United States Department of Agriculture (USDA) published the Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) Systems Final Rule in July 1996. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to address safety hazards reasonably likely to occur in their production process. Therefore, this HACCP model's focus, and the focus of the other HACCP models, is on product safety, not product quality characteristics. With the rule, FSIS made available a guidebook for the preparation of HACCP plans and a generic model for each food processing category defined in regulation 9 CFR 417.2(b)(1). The"]}

guidebook and the generic models have been updated since their initial publication to be consistent with current science and policy. FSIS recommends you use the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan. Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used as is. FSIS recommends that establishments tailor the model(s) to fit the establishment's operation. The model's critical control points (CCPs) do not necessarily apply to all operations or products in the product category. Products or operations may require fewer or more CCPs depending on the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. The food safety critical limits selected must come from scientific documents or other reliable sources to meet regulatory validation requirements. Each model includes references for guidance on the selection of critical limits. FSIS published two poultry slaughter HACCP models. This model can be used with the Streamlined Inspection System (SIS), New Evisceration Line Speed (NELS), New Turkey Inspection System (NTIS) and Traditional poultry slaughter inspection systems. The other published model can be used with the New Poultry Inspection System (NPIS). The defining difference between this model and the NPIS model is the additional NPIS responsibility of sorting and disposing of carcasses and viscera exhibiting septicemic and toxemic conditions. Many Small and Very Small poultry slaughter establishments operate under Traditional Inspection and this is the model best suited for those operations. The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis, are HACCP records ((CFR 417.5(a)). The selection of a poultry slaughter HACCP model is a preliminary step to completing a hazard analysis. The documents produced during the selection process are HACCP records. Ensure you maintain the documents produced while developing a HACCP plan. For further assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP webpage.", "Page 2 of 19 EXAMPLE PRODUCT DESCRIPTION1 Process \ Product Name: Poultry Slaughter2 Whole Carcasses, Parts, Other Intact Poultry Products Process \ product type name Young Ready-to-Cook chicken, other types of whole dressed poultry carcasses (turkeys, ducks, geese), single ingredient intact poultry products, such as parts, giblets, paws, and turkey fries Important product characteristics (Aw, pH, preservatives, etc.) Not Applicable How it is to be used For further processing at this facility or another establishment or Intended for cooking by end consumer Packaging (durability and storage conditions) Vacuum packaged, tray packs, giblets in plastic sealed containers, bulk pack boxes with liners. Shelf life and at what temperature3 Refrigerated - 10 Days at 40°F Frozen \u2013 180 Days at <10°F Where it will be sold (specify intended consumers, especially at-risk populations4) Sold direct to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI). Labeling instructions Product name, inspection legend and establishment number, handling statement, net weight statement, address line, nutrition facts, and safe handling instructions. What special distribution controls are required? Keep Refrigerated < 40°F Keep Frozen < 10°F DATE: APPROVED BY: 1 Prior to developing the HACCP plan please read the FSIS Guidebook for the Preparation of

HACCP Plans for detailed descriptions of the worksheets and hazard analysis. This information is best suited for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products. 2 This poultry slaughter model can be used with SIS, NELS, NTIS and Traditional poultry slaughter inspection systems. 3 Each establishment may have their own defined shelf life. 4 At-risk populations include young children, elderly, and immunocompromised persons.", "Page 3 of 19 EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIALS Process \ Product Name: Poultry Slaughter Whole Carcasses, Parts, Other Intact Poultry Products Poultry and poultry by-products Live birds Non-meat food ingredients None Antimicrobials<sup>6</sup> and processing aids Chlorine, Organic acid<sup>7</sup> Packaging material Plastic vacuum bags, retail trays, cardboard boxes, plastic liners Restricted ingredients or allergens None Other None DATE: APPROVED BY: 5 List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. See the FSIS Compliance Guideline Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling for detailed information on allergens. To review restrictions on the use of nitrite and sodium ascorbate or sodium erythorbate, see 9 CFR 424.22(b). 6 FSIS and the Food and Drug Administration (FDA) have a memorandum of understanding (MOU) that establishes the working relationship followed when responding to notifications for the use of food additives intended for use in the production of FSIS regulated products. FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDA on the requirements under the Food, Drug & Cosmetic Act and its implementing regulations. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat Poultry and Egg Products for the list of suitable ingredients. 7 \u201cOrganic acid\u201d is a placeholder for the product to be used by the establishment.", "Page 4 of 19 EXAMPLE PROCESS FLOW CHART<sup>8</sup> Poultry Slaughter \ Whole Carcasses, Parts, Other Intact Poultry Products 8 This is an example flow diagram. Establishments\ufe0f flow diagrams for the same product may be different. Establishments determine which steps are included in their process. The steps must represent all relevant hazards in the hazard analysis. 2. Unloading, Stunning, Bleeding 3. Scalding, Picking, Head, and Feet Removal 5. Harvest of Feet, Giblets and Necks 4. Evisceration, including neck removal, venting, opening, drawing viscera from carcass 6. Offline Reprocessing and Salvage 8. Carcass Wash 12. Chilling of all Products CCP 3 15. Cold Storage 1a. Receive and Store Non-meat Items (for example, Antimicrobials, Packaging Materials) 7. Crop, Lung, and Kidney Removal 9. Trimming 10. Monitoring Carcasses, Parts and Giblets for Fecal Contamination CCP 1 11. Pre-chilling antimicrobial application CCP 2 14. Packaging and Labeling 13. Transfer carcasses to cut up or further processing 16. Shipping 1. Receive Live Birds 17. Returned Product", "Page 5 of 19 EXAMPLE POULTRY SLAUGHTER HAZARD ANALYSIS<sup>9</sup> 9 Refer to FSIS Meat and Poultry Hazards and Controls Guide and DRAFT FSIS Compliance Guideline For Controlling Salmonella and Campylobacter in Raw Poultry for suggested practices and controls. 10 Hazards are grouped into three categories: Biological (B), Chemical (C), and Physical (P). Biological hazards are living

organisms. Chemical hazards may be naturally occurring in foods, used, or added during the processing of foods, or administered to live animals. Physical hazards are a component in a food product that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification.

11 Place the justification for your decision in column 4. Include control measures in column 4 for hazards not reasonably likely to occur and place them in column 5 for hazards reasonably likely to occur. If a hazard is reasonable likely to occur, then a CCP must be addressed at this step or a later step. See FSIS Meat and Poultry Hazards and Controls Guide for a list of frequently used controls.

12 Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced article must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from an FSIS program, then HACCP system design must be supported by documentary evidence \u2013 that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peerreviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan.

13 Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation, page 5).

14 To develop an effective CCP, see the FSIS Guidebook for the Development of HACCP Plans for a CCP decision tree and guidance on how to control, reduce, or eliminate a hazard.

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Ingredient	\ Process Step	Potential Hazards	(introduced or controlled)	at this step	10 Is the Potential Food Safety Hazard Reasonably Likely to Occur (RLTO)? (Yes or No)
Justification	\ Basis for Decision	11	If yes in Column 3 (hazard RLTO),	What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels	12
Justification	\ Basis	Controls CCP	Page 6 of 19	13 Is this Step a Critical Control Point (CCP)?	14 "Step Hazard RLTO
Justification	\ Basis	Controls CCP	Page 6 of 19	15 If the scientific justification is from FSIS, then list the document name.	

If justification is not from an FSIS program, then scientific or technical support is needed, and these nonFSIS supporting documents must be kept for the life of the HACCP plan

16 NOTE: This \u201chistoric data\u201d must be supported with evidence from the establishment through the establishment\u2019s history or validation data with reference to the SOP or prerequisite program. When historical data is not available (for example, a HACCP plan for a new process or product), then system design must be supported by other documentary evidence. Such as the FSIS Meat and Poultry Hazards and Controls Guide which

states \u201cMonitor giblets for foreign materials\u201d and \u201cMetal detection\u201d as frequently used controls for foreign material hazards in poultry slaughter.<sup>17</sup> This Foreign Material SOP (prerequisite program) should have details on how this procedure is preventing the hazard from occurring (such as metal prevention controls) as well as the on-going verification procedures. These controls should be evident within the written document upon review. The Foreign Material SOP and plant data related to on-going verification activities then become part of recordkeeping and historic data.

1. Receive Live Birds B: Pathogens Salmonella, Campylobacter Yes Live birds may have pathogens on feathers, skin, feet, and in the digestive tract. The hazard is controlled through subsequent visual examination, antimicrobial application and chilling (CCP 1, CCP 2, CCP 3). Truck Sanitation Standard Operating Procedure (SOP) for cage cleaning between flocks. Pre-Harvest Controls Feed Withdrawal SOP. No C: Drug residues No Low risk per USDA, Compliance Guide for Residue Prevention.<sup>15</sup> Growers required to follow best preharvest practices, which include appropriate withdrawal requirements when antibiotics are prescribed. P: Foreign objects in the gizzards of live birds No Establishment historical data<sup>16</sup> (that is, gilet quality monitoring) demonstrates low risk of foreign objects in gizzards after processing. Gizzard quality checks after chilling, which include monitoring for foreign objects, such as wire. Foreign Material SOP<sup>17</sup>, "Step Hazard RLTO Justification \ Basis Controls CCP Page 7 of 19<sup>18</sup> Provide reference for scientific support and validation for effective concentrations and support for critical operational parameters that reduce biological hazards.

FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products contains the list of substances that may be used in the production of meat and poultry products. The list contains the allowable amounts and the intended use of the approved antimicrobials. The list (Directive 7120.1) can be used as supporting documentation for chemical hazard controls (safety and suitability). Directive 7120.1 cannot be used as support for the control of biological hazards because the antimicrobial concentration needed to control bacteria is different from the concentrations required for safety and suitability.

1a. Receive and Store Non-meat Items (e.g., Antimicrobials, Packaging Materials) B: Contamination with Pathogens No Proper storage of non-meat ingredients under temperature control if needed. Procedure to protect non-meat ingredients from pests and environmental contamination. C: Inappropriate chemical or concentration received<sup>18</sup> No Establishment historical data shows low risk of receipt of inappropriate chemicals and inappropriate chemical compounds. Letters of Guarantee from suppliers. Identify and list all approved chemicals used in the operations. Check each chemical at receiving to assure that it is on the list at the correct concentration and is appropriately labeled. Safety Data Sheets (SDS) P: Foreign Materials No Visual inspection for foreign material. Protect packaging materials from environment.

2. Unloading, Stunning, Bleeding B: Pathogens Salmonella, Campylobacter Yes Live birds may have pathogens on feathers, skin, feet, and in the digestive tract. The hazard is controlled through subsequent visual examination, antimicrobial application and chilling (CCP 1, CCP 2, CCP 3). Proper application of stunning methods and maintenance of stunning No", "Step Hazard RLTO Justification \ Basis Controls CCP Page 8 of 19 equipment to reduce involuntary voiding of feces during stunning. Employee hygienic practices. C: None P: None

3. Scalding, Picking, Head and Feet Removal B: Pathogens Salmonella, Campylobacter Yes Scald water and picking machinery can increase pathogen cross-contamination. Pathogens can contaminate muscles of carcasses that are mutilated during picking. The hazard is controlled through subsequent visual

examination, antimicrobial application and chilling (CCP 1, CCP 2, CCP 3). Scald operational procedures for freshwater intake and overflow, agitation of scald water. Scald water is not reused as scalding water or wash water. Optional use of brushes to remove dirt and debris from birds prior to scalding. Water pH maintained either above or below optimum pH for *Salmonella* and *Campylobacter* growth. Antimicrobials, acidifiers and anti-foam chemicals applied in the scald water as part of a multi-hurdle approach to reduce pathogen levels. Prerequisite program to monitor antimicrobial and any other chemical concentrations Trim mutilated portions from carcasses later in the process. Written Sanitation SOP for equipment cleaning and sanitation to prevent product contamination. No", "Step Hazard RLTO Justification \ Basis Controls CCP Page 9 of 19 19 DRAFT FSIS Compliance Guideline for Controlling *Salmonella* and *Campylobacter* in Raw Poultry provides guidance on how to control pathogens throughout the slaughter operation. 20 The required written procedures to prevent contamination may also include: an equipment maintenance program to ensure machinery functions as intended to prevent contamination with digestive tract contents throughout the evisceration process; programs to ensure the proper application of antimicrobials (for example, antimicrobial concentration and method of application); employee hygienic practices and an operational sanitation SOP. C: Antimicrobial, defoamer, or pH modifier not appropriately mixed to meet Generally Recognized as Safe (GRAS) parameters No Establishment historical data shows low risk of chemical contamination by use of defoamers and pH boosters in scalders. Written chemical mixing procedures and documented verification procedures to ensure that critical operating parameters are maintained. Chemicals are properly used to meet the chemical manufacturer\u2019s recommendations and GRAS parameters. P: None 4. Evisceration19, including neck removal, venting, opening, drawing viscera from carcass B: Pathogens *Salmonella*, *Campylobacter* Yes Pathogens introduced on live birds present on carcass skin and in the digestive tracts. The hazard is controlled through subsequent visual examination, antimicrobial application and chilling (CCP 1, CCP 2, CCP 3). Written Sanitary Dressing Procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the slaughter and dressing operations incorporated as a prerequisite program to meet 9 CFR 381.65(g) requirements.20 These requirements include sampling and analysis for microbial organisms to monitor and maintain process control. No C: None", "Step Hazard RLTO Justification \ Basis Controls CCP Page 10 of 19 21 The FSIS Compliance Guide: Modernization of Poultry Slaughter Inspection: Chilling Requirements describes how establishments can meet the poultry chilling regulatory requirements. P: Foreign Material No Foreign materials could be introduced from broken machinery parts, broken shackles, and insanitary overhead structures. Equipment and evisceration line maintenance to prevent metal or plastic contamination. Routine cleaning of shackle rails and overhead structures. Foreign Material SOP. 5. Harvest of Giblets, Necks and Feet B: Pathogens: *Salmonella*, *Campylobacter* Yes Delayed separation from inedible items may result in pathogen outgrowth. The hazard is controlled through subsequent visual examination, antimicrobial application and chilling procedures (CCP 1, CCP 2, CCP 3). Chilling time and temperature critical limits monitored through CCP 3 to ensure that giblets, necks, and feet temperatures are promptly reduced to temperatures that prevent pathogen outgrowth.21 Antimicrobial added to immersion chiller media or applied through a spray or dip. Written Sanitary Dressing Procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout

the slaughter and dressing operations incorporated as a prerequisite program to meet 9 CFR 381.65(g) requirements. No", "Step Hazard RLTO Justification \ Basis Controls CCP Page 11 of 19 22 For an example hazard analysis for on-line reprocessing see step 13 of the HACCP Model for New Poultry Inspection System (NPIS) Poultry Slaughter. C: Inappropriate concentration of antimicrobial No Establishment historical data shows low risk of inappropriate chemical application. Written chemical mixing procedures and documented verification procedures to ensure that critical operating parameters are maintained. Chemicals are properly used to meet the chemical manufacturer\u2019s recommendations and GRAS parameters. P: Foreign material (rocks, wires, other building materials etc.) from birds pecking at litter during live production No Establishment historical data (giblet quality monitoring) demonstrates low risk of foreign objects in gizzards after processing. Foreign Material SOP. Giblet quality checks after chilling, which include monitoring for foreign objects, such as wire, that may be lodged in gizzards. 6. Offline Reprocessing and Salvage22 B: Pathogens Salmonella, Campylobacter Yes Carcasses accidentally contaminated with digestive tract contents (feces and ingesta) at higher risk for pathogen contamination. Disease conditions may contain pathogens. Digestive tract contaminants are addressed with CCP 1: Monitoring Carcasses, Parts and GIBLETS for Fecal Contamination. The presence of pathogens is addressed with CCP 2 Pre-chilling antimicrobial application and CCP 3 Chilling. Offline reprocessing procedures incorporated into HACCP system as a prerequisite program to comply with 9 CFR 381.91(b)(2). Written procedures to remove localized disease conditions (for example, airsacculitis, inflammatory processes) No", "Step Hazard RLTO Justification \ Basis Controls CCP Page 12 of 19 and verify that establishment employees appropriately implement the procedures in a sanitary manner. C: Inappropriate concentration of antimicrobial No Establishment historical data shows low risk of inappropriate chemical application. Written chemical mixing procedures and documented verification procedures to ensure that critical operating parameters are maintained. Chemicals are properly used to meet the chemical manufacturer\u2019s recommendations and GRAS parameters. P: None 7. Crop, Lung, and Kidney Removal B: Pathogens Salmonella, Campylobacter Yes Carcasses accidentally contaminated with digestive tract contents (feces and ingesta) at higher risk for pathogen contamination. Crop removal may cause ingesta contamination, which increases the risk for pathogens. Kidneys with disease conditions, including airsacculitis lesions are required to be removed from carcasses. The hazard is controlled at a later step with visual examination, antimicrobial application and chilling (CCP 1, CCP 2, CCP 3). Written Sanitary Dressing Procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the slaughter and dressing operations incorporated as a prerequisite program to meet 9 CFR 381.65(g) requirements. No C: None No P: None No 8. Carcass Wash B: Pathogens Salmonella, Campylobacter Yes Carcasses accidentally contaminated with digestive tract contents (feces and ingesta) at higher risk for pathogen contamination. The hazard is controlled at a later step with visual examination, antimicrobial application and chilling (CCP 1, CCP 2, CCP 3). Written program to monitor that the carcass wash functions as intended. No", "Step Hazard RLTO Justification \ Basis Controls CCP Page 13 of 19 C: Inappropriate concentration of antimicrobial No Establishment historical data shows low risk of inappropriate chemical application. Written chemical mixing procedures and documented verification procedures to ensure that critical operating parameters are maintained. Chemicals are properly used to meet the chemical manufacturer\u2019s

recommendations and GRAS parameters. P: None No 9. Trimming B: Pathogens Salmonella, Campylobacter No Employee hygienic practices. Operational Sanitation SOPs. C: None

10. Monitoring Carcasses, Parts and Giblets for Fecal Contamination B: Pathogens Salmonella, Campylobacter Yes Fecal material carries pathogens. Monitoring for fecal contamination prior to the pre-chill antimicrobial application to ensure that poultry carcasses contaminated with visible fecal material do not enter the chiller (9 CFR 381.65(f)). Written Sanitary Dressing Procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the slaughter and dressing operations incorporated as a prerequisite program to meet 9 CFR 381.65(g) requirements. No (zero) fecal contamination to enter chilling system. Examine the inside and outside surfaces of carcasses for fecal contamination at a Yes CCP 1","Step Hazard RLTO Justification \ Basis Controls CCP Page 14 of 19 23 If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. However, if an establishment implements different critical operational parameters in the process from the scientific support, or the scientific support identified does not contain microbiological data, then the establishment should collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological validation data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameter (FSIS Compliance Guideline HACCP Systems Validation, page 27). 24 If products are ice chilled in vats the hazard analysis should address any hazards associated with ice manufacture, storage and handling. point prior to the pre-chill antimicrobial application. Examine parts and giblets for fecal contamination prior to chilling. C: None P: None

11. Pre-chilling Antimicrobial Application B: Pathogen outgrowth Salmonella, Campylobacter Yes Carcasses accidentally contaminated with digestive tract contents (feces and ingesta) at higher risk for pathogen contamination. CCP 2 Pre-chilling antimicrobial application. Application of organic acid solution to carcasses, parts, giblets, necks and feet.23 Yes CCP 2 P: None C: Inappropriate concentration of antimicrobial applied No Establishment historical data shows low risk of inappropriate chemical application. Written chemical mixing procedures and documented verification procedures to ensure that critical operating parameters are maintained. Chemicals are properly used to meet the chemical manufacturer\u2019s recommendations and GRAS parameters.

12. Chilling of all Products24 B: Pathogen Outgrowth Salmonella, Campylobacter Yes Delayed chilling may result in pathogen outgrowth. Pathogen outgrowth is controlled with CCP 3 Chilling. Apply chilling procedures to lower internal temperatures of carcasses, giblets, necks, and feet. Written chilling procedures that address, Yes CCP 3","Step Hazard RLTO Justification \ Basis Controls CCP Page 15 of 19 25 The FSIS Compliance Guide: Modernization of Poultry Slaughter Inspection: Chilling Requirements describes alternative chilling procedures granted under the Salmonella Initiative Program (SIP)(page 5). The alternative procedures are validated to prevent the outgrowth of pathogens as product is being chilled. 26 Post-chill Poultry Finished Product Standards tests monitor for extraneous materials in the chill media. The tests are performed every 2 hours of

production time in Streamlined Inspection System, New Line Speed Inspection System, and New Turkey Inspection System establishments 27 The establishment must prevent the outgrowth of pathogens on chilled product as long as the product remains at the establishment (9 CFR 381.66(b)(2)). The FSIS Compliance Guide: Modernization of Poultry Slaughter Inspection: Chilling Requirements includes the former regulatory provisions (\u201csafe harbors\u201d) that an establishment can implement to prevent the outgrowth of pathogens in chilled product (page 4). at a minimum, the potential for pathogen outgrowth, the conditions affecting carcass chilling, and when the chilling process is complete (9 CFR 381.66(b)(3)).25 C: Inappropriate concentration of antimicrobial No Establishment historical data shows low risk of inappropriate chemical application. Written chemical mixing procedures and documented verification procedures to ensure that critical operating parameters are maintained. Chemicals are properly used to meet the chemical manufacturer\u2019s recommendations and GRAS parameters. P: Foreign Material No Foreign material contamination from overhead structures and immersion system moving parts. Foreign Material SOP. Carcasses monitored 2 times per shift for extraneous material contaminants after chilling.26 13. Transfer Carcasses to Cut up or Further Processing B: Pathogen Outgrowth Salmonella, Campylobacter No Pathogen outgrowth may result if temperatures are not maintained at levels to prevent multiplication during transfer. Product is transferred to cut up or further processing to prevent product temperatures that promote pathogen outgrowth (Tompkin, R.B. 1996).27", "Step Hazard RLTO Justification \ Basis Controls CCP Page 16 of 19 C: None P: None 14. Packaging and Labeling B: Pathogens: Salmonella, Campylobacter No Pathogen outgrowth may result if temperatures are not maintained at levels to prevent multiplication. Product is packaged and placed in storage coolers or freezers to prevent product temperatures that promote pathogen outgrowth (Tompkin, R.B. 1996). C: None P: None 15. Cold Storage B: Pathogen Outgrowth Salmonella, Campylobacter No Pathogen outgrowth may result if temperatures are not maintained at levels to prevent multiplication during shipping. Written product storage procedures to maintain product at temperatures that prevent pathogen outgrowth (9 CFR 381.66(b)(1)(ii)). C: None P: None 16. Shipping B: Pathogen Outgrowth Salmonella, Campylobacter No Pathogen outgrowth may result if temperatures are not maintained at levels to prevent multiplication during shipping. Products shipped on refrigerated transport vehicles. C: None P: None 17. Returned Product Reinspection SOP implemented before accepting returned product. Product enters the appropriate step of the production system based on findings of product evaluation. Opened packages are not accepted. Notify FSIS personnel when product has been returned.", "Page 17 of 19 28 This example HACCP plan is best suited for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products. 29 Each establishment must develop written corrective action procedures in response to a deviation from the critical limit to determine what to do with the affected product (from the last acceptable check), to eliminate the cause of the deviation, to bring the CCP back into control, and to prevent future deviations (CFR 417.3). EXAMPLE: Young Chicken Slaughter HACCP Plan28 Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action29 Verification Records What How Frequency Who CCP 1 Monitoring Carcasses, Parts and Giblets

for Fecal Contamination Pathogens: Salmonella, Campylobacter No fecal contaminants to enter chilling system. Visual examination for fecal material. Examine the inside and outside surfaces of 10 carcasses and all surfaces of 10 parts or giblets for fecal contaminants. Check 10 carcasses and 10 parts or giblets per production hour. Select random times to perform the checks. If less than 10 units are available examine all available units. Designated employee If a deviation from the critical limit occurs, a manager will, per 9 CFR 417.3(a): 1. Hold all product produced after last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Restore process control; 4. Take measures to prevent recurrence. A manager observes and then records the results of their verification of the CCP monitoring activity once each day of slaughter operations. A manager observes and then records the results of their observations of the corrective actions taken for each deviation from a critical limit. Records reviewed once a week 9 CFR 417.4(a)(2)(iii). Zero Fecal Check Form Corrective Action Log Preshipment Review Form", "Page 18 of 19 Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 2 Prechilling Antimicrobial Application 30 Pathogens: Salmonella, Campylobacter 600-700 ppm organic acid solution31 Monitor the preparation and mixing of the antimicrobial solution. Monitor the application of the solution. Measure and record the amount of antimicrobial and the amount of water used to make the solution. Monitor the employee's application of the solution to carcasses, parts and giblets. Check the amount of antimicrobial and water used to make up the solution once per shift. The application of the solution is monitored twice per shift. Designated employees If a deviation from the critical limit occurs, the production supervisor will, per 9 CFR 417.3(a): 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence. Randomly, once per shift, a manager observes the monitoring activity and records their findings. Records Reviewed once per week (9 CFR 417.4(a)(2)(iii) Organic Acid Spray Concentration Form. Corrective Action Log Pre-shipment Review Form 30 If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. However, if an establishment implements different critical operational parameters in the process from the scientific support, or the scientific support identified does not contain microbiological data, then the establishment should collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological validation data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameter (FSIS Compliance Guideline HACCP Systems Validation, page 27). 31 Scientific or technical support is required to validate the critical limits and critical parameters (for example, time of exposure) of the organic acid spray. They are part of the hazard analysis and need to be maintained for the life of the HACCP plan (see FSIS Compliance Guideline

HACCP Systems Validation); FSIS Directive 7120.1 Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products contains approved substances for use in poultry; however, each establishment must validate their own process.", "Page 19 of 19 Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective ActionError! Bookmark not defined. Verification Records What How Frequency Who CCP 3 Chilling of all Products Pathogen Outgrowth: Salmonella, Campylobacter Carcass temperatures of 45 degrees or less within 6 hours.32 Parts, giblets, feet, and necks chilled to 44 degrees or less within 4 hours from the time they are removed from the carcass. Carcass internal temperatures. Parts, giblets, feet, and necks internal temperatures. Handheld calibrated thermometer inserted into the thickest portion of the breast muscle of the carcass, or thickest portion of the part, giblet, neck or foot. Check 10 carcasses and 10 parts or giblets per hour. Select random times to perform the checks. If 10 units are not available check all available units. Designated employees If a deviation from the critical limit occurs, the production supervisor will, per 9 CFR 417.3(a): 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence A manager observes the monitoring of the CCP once each day of slaughter operations. Once per week, a manager will calibrate the thermometer per manufacturer\u2019s procedures. Records reviewed once a week 9 CFR 417.4(a)(2)(iii) Carcass, Parts, Giblets, and Feet Chilling Form Thermometer Calibration Form Corrective Action Log Pre-shipment Review Form 32 The critical limit\u201445 degrees or less within 6 hours\u2014is derived from an alternative procedure implemented by establishments that participated in SIP (Salmonella Initiative Program). See the FSIS Compliance Guide: Modernization of Poultry Slaughter Inspection: Chilling Requirements for additional guidance on implementing this \u2014safe harbor\u201d. For general guidance on establishing critical limits see the Guidebook for the Preparation of HACCP Plans (page 30)." ]}, {"file\_name": "FSIS\_GD\_2020\_0014", "title": "FSIS Guidance for a Suggested Reporting Table for the Certified Establishment List", "num": "FSIS-GD-2020-0014", "id": "c5e3d6d3b776af57b0a8746d563e634fec018224742a041aab20b04f715b6739", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-01/Suggested-Reporting-Table-Certified-Establishment-List.pdf", "type": "pdf", "n\_pages": 2, "word\_count": 1290, "text\_by\_page": ["1 FSIS Guidance for a Suggested Reporting Table for the Certified Establishment List By May 18th of each year, the Central Competent Authorities (CCAs) of countries wishing to maintain on-going equivalence and continue actively exporting meat, poultry, or egg products to the United States (U.S.) are required to provide the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) an up-to-date list of all certified establishments used in the production of products eligible for export to the U.S. Therefore, if the production chain involves more than one establishment (e.g., beef is slaughtered at one establishment, further processed at a different establishment, packaged and labeled at yet another establishment, and then exported to the U.S. from a different establishment), each establishment in the production chain, including the establishment providing the raw source material and the storage facility from where the product is exported, must be listed on the certified establishment list. Furthermore,"]}

countries that are not eligible to export raw product directly to the U.S. (e.g., due to USDA Animal and Plant Health Inspection Service (APHIS) animal disease requirements), but are eligible to use their own raw source materials to produce processed products are required to certify and list the establishments providing the raw source materials. Lastly, when listing an establishment that provides raw source material, please clearly identify the establishment as a source establishment on the certified establishment list. The reporting table below may be used to assist CCAs with providing the required information to FSIS by May 18th of each year. The format of the table is optional; however, the information noted with an asterisk (\*) is required to be sent to FSIS annually. For each certified establishment, CCAs should only include products that the country is currently eligible to export to the U.S., including raw source materials for further processing. In addition, if your country is prevented from exporting certain meat, poultry, or egg products to the U.S. due to an APHIS animal disease requirement, FSIS requests that the CCA clearly identify the product categories and product groups that each certified establishment intends to export to the U.S. To view which products your country is currently eligible to export to the U.S., refer to FSIS Import Library- Eligible Countries and Products. For a list of product categories and product groups, please refer to the FSIS Product Categorization Guide. Certified establishments that are no longer eligible to export products to the U.S. must be identified as delisted on the list provided to FSIS. Furthermore, FSIS requests that CCAs inform FSIS of any establishment delisting within 90 days. CCAs can submit the required information to FSIS by either uploading it into our Public Health Information System (PHIS) under question 4 of the 2019 self-reporting tool (SRT), or by submitting it to our International Coordination Executive at: US Department of Agriculture Food Safety and Inspection Service, Office of International Coordination, Room 3143 South Building, 1400 Independence Ave SW, Washington D.C. 20250-3700 E-mail: InternationalCoordination@usda.gov Date\u00b9\*

Eligibility Status \u00b2\* Establishment Number\* Establishment Name\* Establishment Address\* Type(s) of Operation\u00b3\* Process Category\u2074\* Species\u2075 \* Product Category Product Group MMI/DD/YYYY 1. Date \u2013 The date of an establishment\u2019s initial certification, delisting, or relisting. 2. Eligibility Status \u2013 If an establishment listed on the previous year\u2019s certified establishment list remains eligible to export products to the U.S., please leave this field blank. \u2022 New - Establishments that are newly certified as eligible to export products to the U.S. that were not previously certified as eligible to export products to the U.S. \u2022 Delisted \u2013 Establishments that were previously certified as eligible to export products to the U.S. and are no longer eligible to export products to the U.S. \u2022 Relisted \u2013 Establishments that were previously delisted and have been relisted as certified as eligible to export products to the U.S. 3. Type(s) of Operation \u2013 Slaughterhouse, Non-Slaughter Processing, Egg Processing, Cold Storage, Exporting Warehouse, or Source Establishment. \u2022 Slaughterhouse \u2013 Establishments where healthy, live animals are humanely slaughtered under sanitary conditions to produce meat or poultry products for human consumption. \u2022 In slaughter operations, FSIS requires continuous government inspection during slaughter activities to ensure that each and every livestock carcass, head, and viscera and each and every poultry carcass and viscera are inspected. \u2022 Non-Slaughter Processing - Operations include all non-slaughter activities, including but not limited to, boning, cutting, slicing, grinding, injecting, pumping, filleting, breading, adding ingredients through other mechanical means, formulating, cooking, smoking, cooling,

assembling, and packaging." "FSIS Guidance for a Suggested Reporting Table for the Certified Establishment List 2 \u2022 In processing operations (i.e., non-slaughter), FSIS requires that a government inspector be on the premises and performing inspection activities at least once per production shift during processing operations. The requirement for government inspection once per production shift during processing operations is not the same as inspection once daily; therefore, if an establishment has more than one production shift per day during which it produces product for export to the U.S., a government inspector must be present at least once during each production shift. \u2022 Egg Processing - Manufacturing of egg products, including breaking eggs, filtering, mixing, blending, pasteurizing, stabilizing, cooling, freezing, drying, or packaging egg products at certified establishments. \u2022 Cold Storage \u2013 Facility that receives and stores meat, poultry, or egg products from certified establishments and maintains products under refrigeration until export to the U.S. \u2022 Exporting Warehouse \u2013 Facility that receives and stores meat, poultry, or egg products from certified establishments until export to the U.S. Additionally, the facility where export verification and certification services for exports are provided. \u2022 Source Establishment - Slaughter establishment that provides raw source materials to certified establishments for the production of processed products intended for export to the U.S. Source establishments are not eligible to export product directly to the U.S. due to disease restrictions, regionalization, product ineligibility, or other reasons. However, source establishments must meet all U.S. requirements, be certified by the CCA, and be identified as a source establishment on the certified establishment list. 4. Process Category \u2013 1. Raw \u2013 Non Intact 4. Not Heat Treated - Shelf Stable 7. Heat Treated - Not Fully Cooked - Not Shelf Stable 2. Raw - Intact 5. Heat Treated - Shelf Stable 8. Product with Secondary Inhibitors - Not Shelf Stable 3. Thermally Processed - Commercially Sterile 6. Fully Cooked - Not Shelf Stable 9. Eggs\Egg Products For the purposes of this document the term \u201cprocessed\u201d refers to raw meat or poultry product that has been modified through an additional processing step. Methods of processing meat and poultry products include, but are not limited to, cooking, salting, curing, aging, fermentation, and smoking. Simple mechanical processes (sometimes referred to as further processing) such as cutting, grinding, or mixing of raw meat or poultry product are not included in this definition. \u2022 Raw meat and poultry products may be produced and certified under the following FSIS Process Categories: \u2022 Raw Product - Non-Intact and \u2022 Raw Product \u2013 Intact. \u2022 Processed meat and poultry products may be produced and certified under the following FSIS Process Categories: \u2022 Thermally Processed - Commercially Sterile, \u2022 Not Heat Treated - Shelf Stable, \u2022 Heat Treated - Shelf Stable, \u2022 Fully Cooked - Not Shelf Stable, \u2022 Heat Treated - Not Fully Cooked -Not Shelf Stable, and \u2022 Products with Secondary Inhibitors - Not Shelf Stable. The term \"egg products\" refers to eggs that are removed from their shells for processing. 5. Species \u2013 F: fish of the order Siluriformes O: lamb\mutton (ovine) SQ: squab B: beef (bovine) P: pork (porcine) EM: emu V: veal D: duck OS: ostrich CH: chicken GO: goose R: rhea C: goat (caprine) GU: guinea T: turkey

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Official Title Date"]},{"file\_name":"FSIS\_GD\_2020\_0015","title":"FSIS Guideline for Industry Response to Customer Complaints","num":"FSIS-GD-2020-0015","id":"9fa378dff4dfd6005b201e1f61b4c8d4fb53e027371a67c865c034d2354e7f6","corp

us":"fsis\_guidelines","source\_page\_url":"https:\/\/www.fsis.usda.gov\/policy\/fsis-guidelines","url":"https:\/\/www.fsis.usda.gov\/sites\/default\/files\/media\_file\/2021-01\/FSIS-Guideline-for-Industry-Response-to-Customer-Complaints.pdf","type":"pdf","n\_pages":26,"word\_count":8408,"text\_by\_page":["This guideline is designed to help meat and poultry establishments develop a written program to respond to customer complaints. This guidance covers: \u2022How to respond to customer complaints of adulterated or misbranded meat and poultry products \u2022The recall notification requirements in 9 CFR 418.2 FSIS Guideline for Industry Response to Customer Complaints 2020","2 Preface: FSIS developed this guideline to communicate what FSIS has identified as best practices for meat and poultry establishments to respond to customer complaints. The guideline was developed with appropriate review and public participation and has been revised in response to public comments. Some portions of the document have been rearranged to highlight FSIS recommendations for developing a customer complaint program and to further clarify existing FSIS regulatory requirements. This guideline follows the procedures in the Office of Management and Budget\u2019s (OMB) \u201cFinal Bulletin for Agency Good Guidance Practices\u201d (GGP). You can find more information on guidance documents on the Food Safety and Inspection Service (FSIS) Web page. The meat and poultry trade associations, along with their members, have developed a related document, Industry Best Practices for Customer Complaints of Foreign Material in Meat and Poultry Products. Establishment personnel may want to use guidance from both documents when developing a response to customer complaints. What is the purpose of this guideline? The purpose of this guideline is to inform industry of the procedures FSIS has identified as best practices for responding to customer complaints of adulterated and misbranded meat and poultry products. FSIS developed this document in response to an increase in the number of recalls of meat and poultry products adulterated with foreign materials. In many cases, the recalling establishment had received multiple customer complaints prior to these recalls. FSIS specifically developed this document to address foreign material customer complaints, but establishments can apply the information to other customer complaints of adulterated or misbranded products in commerce. This guideline represents FSIS\u2019s current thinking on this topic and should be considered usable as of the issuance date. Who is this guideline designed for? FSIS is issuing this document to assist all FSIS-regulated meat and poultry establishments in developing and implementing procedures for responding to customer complaints, and in preventing similar adulteration or misbranding occurrences. Does the guidance reflect requirements? This document is not regulatory. An establishment may choose to adopt different procedures than those outlined in this guideline. This guideline recommends each establishment develop a customer complaint program. However, an establishment can operate without a customer complaint program because there is no regulatory requirement to develop or implement a program to address customer complaints. If an establishment voluntarily decides to develop a customer complaint program, there is no requirement that a program be incorporated into its Hazard Analysis and Critical Control Point (HACCP) system. Customer complaints occur after the product has left the establishment, so a program to respond to complaints is not preventing hazards or adulteration. However, when a customer complaint results in findings of adulterated products, the establishment must meet applicable requirements as described below."],"3 What if I still have questions after I read this guideline? FSIS recommends that users search the

publicly posted Questions & Answers (Q&As) in the askFSIS database or submit questions through askFSIS. Documenting the questions helps FSIS improve and refine present and future versions of the guideline and associated issuances. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided: Subject Field: Enter FSIS Guideline for Industry Response to Customer Complaints. Question Field: Enter question with as much detail as possible. Product Field: Select General Inspection Policy from the drop-down menu. Category Field: Select Regulations\Agency Issuances from the drop-down menu. Policy Arena: Select Domestic (U.S.) Only from the drop-down menu. When all fields are complete, press Continue.","4 FSIS Guideline for Industry Response to Customer Complaints Table of Contents Preface:

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Background: FSIS is the public health regulatory agency responsible for ensuring that the nation\u2019s commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. In 2008, Congress amended the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) to require each establishment to promptly notify the Secretary if they believe, or have reason to believe, that adulterated or misbranded meat or poultry products have entered into commerce (21 U.S.C. 612 and 459(b)). The Secretary delegated this responsibility to FSIS. In 2012, FSIS issued final regulations reflecting these requirements (9 CFR part 418). Since the implementation of the regulation in May 2012, FSIS has observed an increase in the number of recalls associated with foreign materials and has developed this guideline to assist establishments in responding to complaints and meeting related regulatory requirements, when applicable. FSIS recommends, but does not require, that each establishment develop a program to receive and process customer complaints concerning possibly adulterated or misbranded products in commerce. When an establishment chooses to implement a customer complaint program, FSIS recommends it develop and maintain a program that addresses the receipt and investigation of complaints, the implementation of corrective actions, and the notification of FSIS that adulterated or misbranded products have entered commerce. A discussion of regulatory requirements is	

included later in the guideline; however, a customer complaint program is not a regulatory requirement. The regulatory requirements are included for informational purposes and may result in a more robust customer complaint program. KEY QUESTION Question: Is a meat or poultry establishment required to notify FSIS every time they have reason to believe that an adulterated or misbranded product has entered commerce? Answer: Yes, under 9 CFR 418.2, each establishment is required to notify the District Office within 24 hours of learning or determining that they have received or shipped into commerce adulterated or misbranded meat or poultry products. When a receiving establishment notifies FSIS inspection personnel, the establishment is in compliance with this regulation. The producing establishment is not expected to also notify FSIS if the receiving establishment has already notified the Agency of the issue.","6 Developing a Customer Complaint Program: \uf0d8 Overview of the Program A well-developed and implemented customer complaint program provides many benefits including assisting the establishment in complying with other regulatory requirements and reducing the long-term financial costs of recalls. A consumer complaint program should include the following components (discussed in more detail in this guideline): \uf0d8 Customer Complaint Reporting \uf0d8 Substantiation of a Customer Complaint \uf0d8 Response to a Customer Complaint o Establishment Response Plan and Investigation \uf0d8 Documentation of a Customer Complaint \uf0d8 Related Regulatory Requirements o FSIS Notification (when required by 9 CFR 418.2) o Corrective Actions (when required by 9 CFR 416.15 or 417.3) \uf0d8 Customer Complaint Reporting Customer complaints may originate from: another establishment, a household consumer, the USDA Consumer Complaint Monitoring System (CCMS), or another regulatory agency<sup>1</sup>. Regardless of the source, each customer complaint should be evaluated as a possible report of adulterated or misbranded products in commerce. Each establishment should develop appropriate mechanisms to receive and process customer complaints. The establishment should provide household consumers with a method for reporting a complaint, for example: \u2022 Postal address; \u2022 Toll-free number; \u2022 Website address; or \u2022 E-mail address. The establishment should provide non-household consumers (e.g., other establishments, hotels, restaurants, or institutions) with a method for reporting a complaint, for example: \u2022 Company representative contact information; or \u2022 Instructions within the contract or bill of lading. 1 Although other regulatory agencies are not \u201ccustomers\u201d they are included as possible sources of complaints and may be included in a robust program.","7 As technology and social networking change, other methods for reporting complaints may be developed and incorporated into the customer complaint program. The establishment may provide contact information and methods to report a complaint on product labels, shipping documents, or can post this information on the company\u2019s webpage. An establishment that re-labels or co-packs products should be aware that a customer might direct complaints to the company name on the label. As a result, FSIS recommends that co-packers work with the company named on the label to develop a method for reporting and tracking complaints. When the establishment uses a thirdparty contractor to collect and process customer complaints or when complaints are directed to a corporate address, the establishment should consider how these complaints will be relayed to the producing establishment. The establishment customer complaint process may also include quality complaints; however, a system should be in place to prioritize or triage those complaints that indicate adulterated or misbranded meat or poultry products have been produced at the

establishment. \uf0d8 Substantiation of the Customer Complaint An establishment should develop criteria and a mechanism for reviewing any customer complaint. The establishment should verify where the products were produced. Products are often similar and may be produced at multiple locations, so the establishment should verify that the products were produced at its location and, if not, notify the customer or other establishment when appropriate. The establishment should also develop criteria to determine whether tampering of the products occurred after shipment from the producing establishment. The establishment should determine what evidence, if any, the customer has of the adulteration and misbranding. Information that can be used to substantiate a claim includes: \u2022 Evidence of the physical contaminant, \u2022 Photographs, \u2022 Video, or \u2022 A sample of the product label, product, and any other applicable material. The product label provides information to verify the source of the product, including the lot number, establishment number, and product name. An image or a sample of the product provides information to verify that the product matches the label and can show the condition of the product. An image or a sample of any physical adulteration, such as foreign material, provides information that can be used to start the investigation into the cause of the adulteration. The purchase location may also be helpful to identify distribution channels that may have contributed to the adulteration or misbranding.

NOTE: If the product does not match the label, this could be the basis of a misbranding claim and should be evaluated as evidence of misbranding. Each establishment should begin to substantiate complaints as soon as possible when there is the possibility that adulterated products have been purchased by household consumers. Products available at the level of the household consumer add a degree of", "8 urgency to removing adulterated products before they are consumed, especially when the adulteration is a food safety hazard. At this point in the process, initial substantiation, it may not be possible to determine if the adulteration is a food safety hazard, so it is important to move quickly to gather information. When the establishment determines that hands-on examination of the products, labels, or any other material is important in determining whether adulterated products have been produced, it should not delay the shipment of the identified foreign objects, samples of the products, or labels for examination by the producing establishment. The FSIS recommended practice is to perform an initial substantiation and investigation using immediately available photographic or video evidence and take appropriate action based on that evidence and then follow up with additional actions, as warranted, if the physical material, products, or labels are made available for a hands-on examination. As soon as the establishment has reason to believe adulterated or misbranded products have entered commerce, then FSIS must be notified per 9 CFR 418.2. It may not be necessary to perform a physical examination of the products, material, or labels to have reason to believe adulterated products have entered commerce. For example, some customers may be able to provide a credible description of the product with adequate detail to have a reasonable belief that adulterated products entered commerce. Also, multiple reports of similar foreign materials, especially when the initial report has been validated, may be enough to take action without any physical evidence from the additional reports of adulteration. If there is epidemiological evidence that a specific product is implicated in a series of injuries or illness, that may be enough evidence to substantiate that adulterated products have entered commerce, without observing foreign material. Reports of adulterated or misbranded products from customers other than a household consumer are also critical and should be prioritized

over quality complaints. Quick action on these complaints can prevent distribution to households and consumer injury. The establishment should identify the specific establishment employee(s) (name or title) who will receive notification of complaints and will be responsible for their initial substantiation. Since complaints may occur on weekends, FSIS recommends that applicable contact information be included in the program. Early action is critical to identifying products in distribution channels, correcting the issue to prevent further adulteration or misbranding, and removing adulterated or misbranded products from households before they are consumed. When an establishment determines that a customer complaint claim is not valid or not applicable to FSIS-regulated products, FSIS recommends that the establishment maintain documentation to support how that decision was made. Such documentation Recommendation Each establishment should develop the criteria and mechanisms for determining if the products were produced at that establishment, if a customer complaint is genuine, authentic, and that no tampering of the products occurred after shipment from the producing establishment." "9 could be used to support why the establishment did not take any actions related to the products, especially if new evidence, which does support the initial claim, is identified in the future. The establishment must consider if any FSIS-regulated products are implicated by a complaint. The initial complaint may be related to a product under Food and Drug Administration (FDA) jurisdiction; however, when there are common ingredients or common production areas, the possible contamination of FSIS-regulated products must be considered. It is not an FSIS regulatory requirement to maintain documentation related to products that are not regulated by FSIS or whose production does not impact FSIS-inspected products. However, an establishment may want to maintain documentation regarding complaints about the FDA products that it produces and must comply with any FDA regulations regarding reporting and recalling adulterated products. NOTE: A valid complaint for products under FDA jurisdiction must be addressed as required by FDA regulations. Some examples of why a complaint may be found to be without merit related to FSIS principles include: \u2022 Implicated products not produced, distributed by, or owned at any point by an establishment or corporation. \u2022 A valid complaint determined not to involve an FSIS food safety hazard, adulterated products, or misbranding, e.g., a complaint about quality. \u2022 Products that are not under FSIS jurisdiction and there are no implications for FSIS-inspected products. When the establishment has identified a valid complaint and believes, or has reason to believe, that adulterated or misbranded products shipped or received by the establishment have entered commerce, the establishment must notify the FSIS District Office within 24 hours (9 CFR 418.2). Depending on the procedures used to validate the complaint, further investigation may or may not be required to make this determination. When an establishment receives a customer complaint and it is substantiated, the next two questions to ask are: 1) Is the product adulterated or misbranded? and 2) Has it entered commerce? What are adulterated or misbranded products? Adulterated: Meat or poultry products that are injurious to health or are for any other reason unsafe, unsound, unhealthful, unwholesome, or otherwise unfit for human food. Misbranded: Meat or poultry products that bear a false or misleading label or if any required feature is not prominent." "10 \uf0d8 What are adulterated or misbranded products? Meat or poultry products are adulterated, among other reasons, if they bear or contain any poisonous or deleterious substance that may render them injurious to health; are unhealthful, unwholesome, or otherwise unfit for human consumption; or were prepared, packaged, or held

under insanitary conditions whereby they may have been rendered injurious to health (see 21 U.S.C. 453(g) and 21 U.S.C. 601(m)). Meat or poultry products are misbranded if the label is false or misleading, or if it does not contain the required labeling features (see 21 U.S.C. 453(h) and 21 U.S.C. 601(n)). Meat and poultry products that are contaminated with foreign materials are adulterated under the FMIA and PPIA regardless of the physical characteristics of the foreign material (e.g., shape, size, hardness, etc.) because foreign materials are unfit for human consumption, may contain poisonous or deleterious substances, and may indicate conditions of filth. Material that is inherent to the species (e.g., bone, hide, feathers) can result in adulterated or misbranded products when the contamination\u2019s extent, size, or shape would render the products unwholesome or injurious to health. The establishment should evaluate each complaint and finding in the context of the specific product, intended use, HACCP system, and details of each incident to determine when meat or poultry products are adulterated. \uf0d8 When are products in commerce? An official establishment is required to report to FSIS when they believe, or have reason to believe, adulterated or misbranded products have entered commerce. In the context of this document and 9 CFR 418.2, FSIS considers products to have entered commerce when the products have left the direct control of the producing establishment and are in distribution. This includes products at retail and products moving between official establishments or other consignees and not yet available to institutional or household consumers at the retail level. FSIS considers the following to be indications What is \u201cin commerce\u201d? When products are not under the direct control of the producing establishment and are in distribution, they have entered commerce, this can include movement between FSISinspected establishments. \u2022 FSIS considers products to be in commerce when preshipment review is signed (unless there are other written methods to demonstrate direct control) and the products are in distribution. \u2022 Individual determinations are made on a case-by-case basis using information including the establishment procedures to demonstrate direct control and the physical location of the products.", "11 that the producing establishment maintains direct control of products, provided the controls are sufficiently documented and HACCP system decisions are consistent with the expressed controls: \u2022 Products are moved between two establishments owned by the same corporation, under a tamper-resistant seal applied by the producing establishment. \u2022 Products are at the establishment or located on premises owned or operated by the producing establishment. There may be other methods for an establishment to demonstrate it has maintained direct control of the products. New technologies and other innovation are continually implemented to improve product movement and this document is not intended to capture all possibilities. When considering new technologies, business models, and distribution, an establishment may want to consider these questions to determine if they are maintaining direct control: \u2022 Who owns the products now? \u2022 Can we prevent an employee (possibly of a different company) from physically moving\using the products? \u2022 What do we have in writing to demonstrate control? \u2022 If we needed to get the products back to our establishment, can we do so without involving other companies? \u2022 Do we have direct control of all comingled (possibly affected) products? \u2022 Has preshipment review been signed? This list is not all inclusive and the answers can vary, but these are the types of questions an establishment can ask when developing a distribution system or evaluating a current distribution system, to determine where \u201cdirect control\u201d stops and the

products have entered commerce. One method an establishment may use to demonstrate direct control and determine when products have entered commerce is by using preshipment review. As required in 9 CFR 417.5(c), prior to shipping products into commerce, the establishment must review the production records of the product, making sure that all processing requirements were met and, if necessary, all corrective actions were taken. The establishment should not sign preshipment review until it has reviewed all lot-specific documentation. Lot-specific documentation includes all records associated with that specific production including, but not limited to, critical control point (CCP) monitoring, HACCP verification, corrective actions, prerequisite programs, testing, and any other applicable programs associated with the production of that lot. Preshipment review indicates that the product has been determined to be free from food safety hazards as well as other causes of adulteration and is ready for commerce. The review of the appropriate documents and compliance with 9 CFR 417.5(c) occurs before the product leaves the control of the producing establishment and enters commerce. This review may occur when products are at a location other than the producing establishment, as long as the producing establishment maintains control of the products."

"12 \uf0d8 Establishment Response to a Customer Complaint When an establishment receives a customer complaint and determines that adulterated or misbranded products have entered commerce, the establishment should perform an investigation to determine the appropriate corrective actions. While a written plan for addressing customer complaints is not a regulatory requirement, it may be helpful to facilitate training and to document corrective actions. The establishment should quickly identify all affected products (e.g., lot, date, line) and identify where they were distributed. This is an important step in stopping further distribution and in implementing the establishment\u2019s recall plan. The FSIS recommended best practice is to draft and maintain a written response plan. The response plan should include:

- Investigation of the production that incorporates a review of relevant records generated during the production of the affected products;
- Performing a visual inspection of any questionable products or labels available at the establishment;
- Observing ongoing production of like products; and
- Talking to employees who may have information pertinent to the investigation.

Affected products that have not been shipped should be held and inspected prior to shipping so the establishment can determine if there are additional adulterated or misbranded products. The establishment should use additional information to evaluate the design and implementation of the HACCP system, including laboratory sampling results, intended use of the products, supporting documentation, and expert analyses. The establishment is required to maintain a written recall plan (9 CFR 418.3). Because some customer complaints may result in a recall, an establishment may choose to incorporate a customer complaint response into the recall plan. If the establishment determines that adulterated (and in some cases misbranded) products have been produced and shipped, the establishment must meet any applicable regulatory requirements, as discussed further below, under \u201cCorrective Action Requirements\u201d. \uf0d8 Documentation of the Customer Complaint The FSIS recommended best practice is for an establishment to document all customer complaints (whether substantiated or not), to 21 U.S.C. 610 and 458 Prohibited acts No person, firm, or corporation shall sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any such articles which are capable of use as human food and are adulterated or misbranded at the time of such sale,

transportation, offer for sale or transportation or receipt for transportation.", "13 include the investigative steps that were performed, and to describe how the claim was or was not substantiated. For substantiated claims of adulterated or misbranded products in commerce, the records should include how FSIS was notified, what corrective actions were performed, if a HACCP reassessment was performed, and the result of the reassessment. If the establishment did not reassess its HACCP plan, FSIS recommends that the establishment document how determinations were made and what evidence was used, even when a claim was not substantiated. If an FSIS investigation occurs at a future date and the establishment has documentation to support that past complaints were not substantiated, the documentation will help resolve the investigation and address questions about the complaint. The establishment should make records related to customer complaints available to FSIS for review upon request as required by 9 CFR part 320, 416.16, 417.5, and 418.4. Records of the investigations should include the following information (where applicable): \u2022 Dates of the complaint, any notification, corrective actions, recalls, etc.; \u2022 How the complaint was or was not substantiated; \u2022 Pictures; \u2022 Summary of the complaint including the complainant information; \u2022 Establishment number\ manufacturing location on the product label; \u2022 Injury or illness reported; \u2022 Product details and trace back information (product code, lot numbers, date codes); \u2022 Nature of foreign material (physical characteristics), as applicable; \u2022 Nature of misbranding, label information, label approval; \u2022 Notification of FSIS (who was notified, when, how); \u2022 Potential causes or contributing factors; \u2022 Other implicated products (same line, date, lot, ingredients, establishment); \u2022 Corrective actions, when applicable; \u2022 Preventive measures, when applicable; and \u2022 HACCP system reassessment, when applicable. The investigation documentation should also include how the establishment identified all implicated products and support for the determination. The establishment may wish to consider factors such as the physical layout of the establishment, Sanitation Standard Operating Procedures (SOPs), cleaning records, or testing results when developing the program to identify products that may be implicated by a complaint. The affected products will depend on the nature of the complaint. FSIS Regulatory Requirements Although the customer complaint program described in this guideline is not a regulatory requirement, the establishment may be required to perform certain actions in response to a finding of adulterated or misbranded products. Beyond the documentation and recordkeeping requirements already mentioned, several additional regulations outline the regulatory requirements an official establishment must meet to prevent direct", "14 contamination or adulteration of products or to respond to a finding of adulterated products. If a customer complaint credibly indicates that adulterated or misbranded products have entered commerce, the establishment must meet the reporting requirements of 9 CFR 418.2 as described in the \u201cFSIS Regulatory Requirements: Notification\u201d section below. If the outcome of a customer complaint investigation shows that the establishment produced adulterated products, the establishment must prevent affected products from entering commerce and, if necessary, remove products which may have already entered commerce. Depending on the nature and cause of the adulteration and how that type of adulteration is addressed in the HACCP system, the establishment must meet any applicable corrective action requirements. These requirements are described in the \u201cFSIS Regulatory Requirements: HACCP System\u201d section below. The establishment must also consider any relevant

customer complaint findings with respect to the design of the HACCP system in accordance with these general regulatory requirements: Notification 9 CFR 418.2 \u2013 \u201cEach official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded meat, meat food, poultry, or poultry product received by or originating from the official establishment has entered commerce, if the official establishment believes or has reason to believe that this has happened. The official establishment must inform the District Office of the type, amount, origin, and destination of the adulterated or misbranded product.\u201d Hazard Analysis 9 CFR 417.2(a)(1) \u2013 \u201cEvery official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment.\u201d Reassessment 9 CFR 417.4(a)(3)(i) \u2013 \u201cEvery establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The 24 hours starts when the establishment has reason to believe that adulterated or misbranded products may have entered commerce", "15 reassessment shall be performed by an individual trained in accordance with \u00a7417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of \u00a7417.2(c) of this part.\u201d Sanitation SOP 9 CFR 416.12(a) - \u201cThe Sanitation SOPs shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).\u201d Maintenance of Sanitation SOPs 9 CFR 416.14 \u2013 \u201cEach official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.\u201d Sanitation Performance Standards 9 CFR 416.4(d) - \u201cProduct must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.\u201d Recalls 9 CFR 418.3 - \u201cEach official establishment must prepare and maintain written procedures for the recall of any meat, meat food, poultry, or poultry product produced and shipped by the official establishment. These written procedures must specify how the official establishment will decide whether to conduct a product recall, and how the establishment will effect the recall, should it decide that one is necessary.\u201d FSIS Regulatory Requirements: Notification Once the establishment has reason to believe that adulterated or misbranded FSIS regulated products have entered commerce, they must notify FSIS as required by 9 CFR 418.2. The producing establishment must notify the FSIS District Office and the receiving establishment must notify either the FSIS District Office or FSIS inspection personnel. Contact information for notification is provided on the webpage [www.fsis.usda.gov](http://www.fsis.usda.gov) contact us. When FSIS personnel notify the official establishment that adulterated or misbranded products have entered commerce, it would be redundant for the

establishment to also notify the District Office of the same adulterated or misbranded products and this could result in duplicate cases. Thus, when an establishment is notified by FSIS personnel that adulterated or misbranded products have entered commerce, the establishment does not need to notify the FSIS District Office unless additional product or production dates are involved. Remember, \u201cin commerce\u201d includes movement between official establishments when the products are not under direct control of the producing establishment or have left the direct control of the producing establishment at any point. It is also a good practice to notify the District Office of the nature of the adulteration or misbranding (e.g., foreign material contamination, ingredient not present on the label, etc.). The specific nature of", "16 each incident will determine the actions taken by FSIS in response to an official establishment producing adulterated or misbranded products that entered commerce. FSIS recommends that the establishment include in the response plan how it will gather the information required in 9 CFR 418.2 for notification of the District Office when products have been shipped in commerce. The information required in 9 CFR 418.2 is: \u2022 Product type \u2022 Amount of implicated products \u2022 Origin \u2022 Destination When an establishment believes, or has reason to believe, that adulterated or misbranded products have entered commerce, the establishment must notify FSIS within 24 hours. The 24-hour period includes weekends or non-workdays. If an establishment believes, or has reason to believe, that adulterated or misbranded products have entered commerce on a Friday, they must still report it within 24 hours even if the establishment does not operate on Saturday. The regulation applies to both producing and receiving official establishments. If a producing establishment discovers that their products are adulterated or misbranded while the products are still under their direct control, they are not required by 9 CFR 418.2 to notify the District Office. When an establishment is unsure if a finding should be reported to FSIS, they should ask Inspection Program Personnel (IPP) or the District Office for clarification. 9 CFR 418.2 vs. FSIS Directive 8140-1 The regulatory requirement in 9 CFR 418.2 to notify the District Office when adulterated or misbranded products have entered commerce applies to official establishments. This regulatory requirement is separate from the instruction to FSIS inspection personnel found in FSIS Directive 8140.1, Notice of Receipt of Adulterated or Misbranded Product. FSIS Directive 8140.1 instructs FSIS personnel to use an internal notification tool when adulterated or misbranded products have moved between establishments, even if those products have not entered commerce. The instructions in FSIS Directive 8140.1 concern verification of existing recordkeeping regulations (9 CFR part 320, 416.16, 417.5, and 418.4) and do not create a new notification requirement for establishments. FSIS personnel are responsible for gathering information, completing FSIS Form 81401, and following the instructions in FSIS Directive 8140.1. The establishment is responsible for meeting the regulatory requirement as described in 9 CFR 418.2 and for providing information when requested by FSIS personnel to complete FSIS Form 81401. The notification requirements for the receiving and producing establishments are further discussed below. Responsibilities at the Receiving Establishment", "17 When an establishment receives adulterated or misbranded products and the products have entered commerce, the receiving establishment must notify FSIS in accordance with 9 CFR 418.2. The receiving establishment may notify the District Office directly using the contact information provided on the FSIS Contact Us page or notify IPP. If the receiving establishment elects to notify IPP instead of the District Office, then IPP will complete a paper or digital FSIS Form 8140-

1 to notify IPP at the shipping\producing establishment and the applicable District Offices. Notification should only be done using official FSIS email addresses, phone numbers for FSIS offices, FSIS programs such as PHIS, and FSIS issued electronic devices. NOTE: The receiving establishment is required per 9 CFR 418.2 to either notify the District Office directly or IPP, but not both. Even though FSIS will provide a copy of FSIS Form 8140-1 to the producing establishment, FSIS recommends that the receiving establishment notify the producing establishment to expedite the producing establishment\u2019s investigation. Responsibilities at the Producing Establishment The producing establishment must provide notification to the District Office consistent with 9 CFR 418.2 when they have reason to believe adulterated or misbranded product has entered commerce. The producing establishment may find out about the adulterated or misbranded products directly from the receiving establishment, from a customer, or from local IPP. The producing establishment must notify its District Office within 24 hours of learning or determining that adulterated or misbranded products have entered commerce. Learning of the event provides an establishment reason to believe that adulterated or misbranded products have entered commerce and a final investigation does not need to be completed before FSIS notification. When the producing establishment receives a customer complaint from a location other than an official establishment (e.g., state inspected establishment, retail store, restaurant, household consumer, foreign establishment, foreign consumer, etc.) that indicates adulterated or misbranded products have entered commerce, then the producing establishment is solely responsible for the notification of the District Office. NOTE: When FSIS personnel at the producing establishment receive e-mail notification from the District Office of products that have been shipped in commerce and discuss the report with the producing establishment, the producing establishment is not required to provide any additional notification to the District Office under 9 CFR 418.2, unless they identify additional implicated products. IPP will verify the producing establishment\u2019s corrective actions according to the instructions in FSIS Directive 5000.1, Verifying an Establishment\u2019s Food Safety System. When adulterated or misbranded products have entered commerce, the Agency may determine the need to convene the Health Hazard Evaluation Board (HHEB) as per FSIS Directive 8091.1, Procedures for the Food Safety and Inspection Service (FSIS) Health Hazard and Evaluation Board (HHEB). The HHEB may be convened if there are circumstances that require further evaluation. Additionally, factors that are considered by the FSIS recall committee in evaluation of the public health significance of an", "18 undeclared ingredient in meat or poultry products are described in Attachment 2 of FSIS Directive 8080.1, Recall of Meat and Poultry Products. An establishment may wish to use FSIS Directive 8080.1 as a reference when developing its customer complaint program and when determining when a food safety hazard exists. Attachment 2 is specific to ingredients, but a similar thought process could be used to assess foreign materials, other contamination, and misbranding. FSIS Regulatory Requirements: HACCP System Does a customer complaint impact the establishment\u2019s HACCP System? One part of responding to a customer complaint is determining what aspect of the establishment\u2019s programs failed to prevent the adulterated or misbranded products from entering commerce. The establishment\u2019s HACCP system consists of the plans, programs, measures, and procedures that are implemented to prevent, eliminate, or control identified food safety hazards and other adulteration in their products. The HACCP system includes the HACCP plan and Sanitation SOPs, prerequisite programs, and other plans in

operation at an establishment to prevent products from becoming adulterated. Each establishment should customize the program for their unique products, operations, and system. The establishment's HACCP system should function to prevent any adulterated products from entering commerce, even if the cause of the adulteration is not a food safety hazard (e.g., it does not result in a food to be unsafe for human consumption). For example, an establishment may determine that a specific foreign material does not pose a physical or chemical food safety hazard in the product; however, the presence of the foreign material in a food causes that food to be adulterated and unfit for human consumption. Each establishment must prevent human food containing foreign material from entering commerce through the proper design and implementation of its HACCP system. 9 CFR 417.6 indicates that an establishment's HACCP system may be inadequate if the establishment produced or shipped adulterated products. In addition, 9 CFR 500.3 authorizes FSIS to withhold the mark of inspection or suspend inspection when an establishment has produced and shipped adulterated or misbranded products. Corrective Action Requirements When adulterated products have been produced, the establishment must determine what part of the HACCP system failed to allow products to become adulterated. The incident may have occurred because of a deficiency in the Sanitation SOPs, HACCP plan, or a prerequisite program. The system must be evaluated to determine if safe and wholesome products can still be produced under the existing system or if modifications must be made. The specific requirements for corrective actions depend on which part of an establishment's HACCP system addresses foreign materials as described below. The HACCP regulations require corrective actions when a food safety hazard occurs (9 CFR 417.3). 9 CFR 417.3(a) describes the corrective actions that apply when the establishment determines that the adulterated products represent a deviation from a "19 critical limit and states, \u201cThe written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure: (1) The cause of the deviation is identified and eliminated; (2) The CCP will be under control after the corrective action is taken; (3) Measures to prevent recurrence are established; and (4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.\u201d The second part of the regulation, 9 CFR 417.3(b) describes the corrective actions that apply when the establishment determines that the adulterated products represent an unforeseen food safety hazard and states, \u201c(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall: (1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met; (2) Perform a review to determine the acceptability of the affected product for distribution; (3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce; (4) Perform or obtain reassessment by an individual trained in accordance with \u00a7417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.\u201d If the establishment determines that the adulteration does not represent a food safety hazard, the Sanitation SOP regulations describe the corrective actions that must be performed: \u201cEach official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's

Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s). Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein (9 CFR 416.15). It is important to consider each customer complaint on a case-by-case basis. When a complaint is reported, the establishment must determine if a food safety hazard exists. If a food safety hazard has occurred, the establishment must address the regulatory requirements for HACCP corrective actions in 9 CFR 417.3 and records as required in 9 CFR 417.5. If a food safety hazard does not exist, the products may still be adulterated, and the establishment must react accordingly. If no food safety hazard exists, the regulatory requirements for adulterated products in 9 CFR 416.15 and 9 CFR 416.16 Reassessment: A HACCP reassessment is required when an establishment is performing corrective actions for an unforeseen hazard or when a change occurs that impacts the Hazard Analysis or HACCP plan. A Sanitation SOP must be revised as necessary to keep them current and effective in preventing direct contamination or adulteration of the products." "20 apply. Either way, when adulterated products have been produced and shipped, the establishment must implement a corrective action. The specific corrective action requirements are determined by the applicable regulation. HACCP corrective actions If a food safety hazard posed by foreign material was previously identified as reasonably likely to occur (RLTO), a CCP was established to prevent the hazard from entering commerce, and the hazard then does occur in products in commerce, the establishment must implement corrective actions as described in 9 CFR 417.3(a). If the food safety hazard posed by the foreign material was identified through the hazard analysis as not reasonably likely to occur (NRLTO) due to a prerequisite program, but it does occur and foreign material entered commerce, then it would be an unforeseen hazard and the establishment must perform corrective actions as described in 9 CFR 417.3(b). This corrective action requirement includes a reassessment to determine if the decision in the hazard analysis is still supportable or if changes need to be made. HACCP corrective actions must be documented as described in 9 CFR 417.5. If products are adulterated and in commerce but the cause of the adulteration (e.g., foreign material) is determined not to be a food safety hazard, the establishment must still evaluate the efficacy of its HACCP system. Adulterated products that have been produced or shipped may indicate an inadequate HACCP system. Sanitation SOP corrective actions Sanitation SOPs must be designed to prevent the contamination or adulteration of products as outlined in 9 CFR 416.12(a). When adulterated food products are found in commerce, the Sanitation SOP may have failed to prevent adulteration of products and the establishment must perform corrective actions as described in 9 CFR 416.15 and document the corrective actions as described in 9 CFR 416.16. The 9 CFR 416.15 Sanitation SOP corrective action regulation applies when adulterated food products have been produced and shipped even when the program that failed is not specifically included in the Sanitation SOPs (e.g., equipment maintenance, employee tool sign-out). The establishment will have to determine if the programs need to be incorporated into the Sanitation SOPs in order to prevent future adulteration as part of the routine evaluation of Sanitation SOPs described in 9 CFR

416.14. Misbranding corrective actions The establishment must not discount misbranding as a labeling issue alone, since misbranding may result in a food safety hazard. One example of misbranding that is also a food safety hazard is when allergens are present but undeclared on the label. When an establishment determines that misbranded products have entered commerce, it is to notify the District Office, as required by 9 CFR 418.2. Misbranding events may require relabeling; the establishment should consult with the FSIS Office of Policy and Program Development (OPPD) Labeling and Program Delivery Staff (LPDS) to determine how to correct or replace the inaccurate labels. Certain misbranded products may be eligible for donation. Misbranded and economically adulterated meat and<sup>1</sup>,<sup>2</sup> poultry products can be donated provided the label does not contain any undeclared ingredients of public health concern as described in FSIS Directive 7020.1, Verifying Donation Of Misbranded And Economically Adulterated Meat And Poultry Products To Non-Profit Organizations. Other Actions Each establishment should be proactive in response to any adulteration or misbranding event, evaluate how the affected products were adulterated or misbranded, why they were shipped undetected, and assess the HACCP system for any other vulnerability. For example, if a piece of plastic in a food product is determined to be from a single conveyor belt, the establishment should consider whether it is an isolated incident. FSIS believes the best practice would be to re-inspect all belts and reevaluate the preventive maintenance program and controls that failed to detect the faulty belt resulting in adulterated products. The establishment should consider replacing gaskets, belts, screens, and other loose items with components that are detectable (e.g., bright color, radiolucent). Increased lighting, employee training, and enhanced screening of raw material are some additional corrective actions that may produce a meaningful result. Any corrective action should prevent additional adulterated or misbranded products from being produced at the establishment. Diversion to pet food as a corrective action If an establishment determines that adulterated products are not logistically or practically eligible for rework to be made unadulterated, then the products are inedible and must be handled as inedible materials in accordance with FSIS regulatory requirements (9 CFR 325.11, 381.193). In some cases, inedible materials can be sent to a pet food manufacturer. However, because pet food production is under the jurisdiction of the FDA, the establishment is cautioned to check with the manufacturer or the FDA prior to sending the adulterated products to the pet food facility. Some types of adulteration are not eligible for pet food and are not permitted by FDA to be sent for pet food. If the products are not eligible for pet food, the remaining options are rendering or a landfill. Please note that rendering companies may not be willing to accept products adulterated with foreign material if the materials will damage the equipment. The establishment is encouraged to verify that the products will be accepted by the renderer.<sup>1</sup>,<sup>2</sup> Suggested Tips: Follow these tips when writing a customer complaint program: \u2022 Provide customers with a method to notify you: \u2022 Consider the impact of co-packing or products produced in multiple establishments \u2022 Provide multiple modes of communication: email, telephone, mail, etc. \u2022 Facilitate the substantiation of any complaint: \u2022 Pay to have a label or foreign material mailed to you \u2022 Ask questions to gather as much information as possible \u2022 Develop investigation SOPs \u2022 Identify establishment and FSIS personnel who need to be notified and provide the contact information in the document, so you don\u2019t have to look for it later: \u2022 District Office contact information is available on the Contact Us page of www.fsis.usda.gov \u2022 Inspection personnel office phone

numbers are available to the individual establishment \u2022 Evaluate the HACCP system and relevant programs; \u2022 Document findings and make them available to FSIS upon request; \u2022 Consider that the complaint may indicate a larger issue; \u2022 Be proactive. \u2013 Put procedures in place now to prevent adulteration", "23 Example Flow Diagram of a Customer Complaint", "24 References: REGULATIONS United States Department of Agriculture, Food Safety and Inspection Service. 2012. Notification. 9 CFR Part 418.2. United States Department of Agriculture, Food Safety and Inspection Service. 2012. Preparation and maintenance of written recall procedures. 9 CFR Part 418.3. United States Department of Agriculture, Food Safety and Inspection Service. 1971. Reinspection, retention, and disposal of meat and poultry products at official establishments. 9 CFR Part 318.2. United States Department of Agriculture, Food Safety and Inspection Service. 1970. Handling and disposal of condemned or other inedible products at official establishments. 9 CFR Part 314. United States Department of Agriculture, Food Safety and Inspection Service. 1970. Transportation. 9 CFR Part 325. United States Department of Agriculture, Food Safety and Inspection Service. 1972. Disposal of condemned poultry products. 9 CFR Part 381.95. United States Department of Agriculture, Food Safety and Inspection Service. 1984. Poultry carcasses, etc., not intended for human food. 9 CFR Part 381.193. United States Department of Agriculture, Food Safety and Inspection Service. 1970. Definitions. 9 CFR Part 301.2. United States Department of Agriculture, Food Safety and Inspection Service. 2014. Definitions. 9 CFR Part 381.1. United States Department of Agriculture, Food Safety and Inspection Service. 2014. Sanitation. 9 CFR Part 416. United States Department of Agriculture, Food Safety and Inspection Service. 2014. Hazard Analysis and Critical Control Point (HACCP) Systems. 9 CFR Part 417. DIRECTIVES FSIS Directive 8080.1, RECALL OF MEAT AND POULTRY PRODUCTS FSIS Directive 8140.1, NOTIFICATION OF ADULTERATED OR MISBRANDED PRODUCT FSIS Directive 8091.1, PROCEDURES FOR THE FOOD SAFETY AND INSPECTION SERVICE (FSIS) HEALTH HAZARD AND EVALUATION BOARD (HHEB) FSIS Directive 7020.1, VERIFYING DONATION OF MISBRANDED AND ECONOMICALLY ADULTERATED MEAT AND POULTRY PRODUCTS TO NON-PROFIT ORGANIZATIONS", "25 Helpful Websites (Control + click to be directed to website) Food Safety and Inspection Service (FSIS)- FSIS homepage: <http://www.fsis.usda.gov/wps/portal/fsis/home> Contact Us Webpage: <https://www.fsis.usda.gov/wps/portal/informational/contactus> How to Develop a Meat and Poultry Product Recall Plan:

[https://www.fsis.usda.gov/shared/PDF/RecallPlanBooklet\\_0513.pdf](https://www.fsis.usda.gov/shared/PDF/RecallPlanBooklet_0513.pdf) The Physical Hazards of Foreign Materials, Presentation at Public Meeting on Foreign Material Contamination, September 24, 2002, David P. Goldman, MD, FSIS

[https://www.fsis.usda.gov/wps/portal/fsis/newsroom/speechespresentations/archive/presentations/ct\\_index999](https://www.fsis.usda.gov/wps/portal/fsis/newsroom/speechespresentations/archive/presentations/ct_index999) Food and Drug Administration (FDA)- FDA Compliance Policy Guide, CPG Sec 555.425 Foods, Adulteration Involving Hard Sharp Foreign Objects

<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074554.htm> Red Meat and Poultry Industry Guidance- Industry Best Practices for Customer Complaints of Foreign Material in Meat and Poultry Products, August 2018.

[https://www.nationalchickencouncil.org/wp-content/uploads/2018/08/Foreign-Material-BestPractices\\_Aug2018.pdf](https://www.nationalchickencouncil.org/wp-content/uploads/2018/08/Foreign-Material-BestPractices_Aug2018.pdf)", "26 <http://askfsis.custhelp.com/> FSIS/USDA [www.fsis.usda.gov 2020"\]](http://www.fsis.usda.gov/2020/), {"file\_name": "FSIS\_GD\_2020\_0016", "title": "FSIS Guideline to Assist with the Donation of Eligible Meat & Poultry Products to Non-Profit

Organizations","num":"FSIS-GD-2020-0016","id":"09380c39fe2adc8a76b147d26ed38858577415d0e6d2138d646fa0ac88b07e3c","corpus":"fsis_guidelines","source_page_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/media_file/2021-01/FSIS-Guideline-Food-Donation.pdf","type":"pdf","n_pages":14,"word_count":3461,"text_by_page":["1 This guideline provides information to meat and poultry establishments who are interested in donating products to non-profit organizations. FSIS Guideline to Assist with the Donation of Eligible Meat & Poultry Products to Non-Profit Organizations December 2020","2 Table of Contents Preface .....	4
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Products to Non-Profit Organizations. This guideline represents FSIS\u2019s current thinking on	

these topics and should be considered usable as of its issuance. This document is not regulatory. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. Purpose This guideline contains information to assist meat and poultry establishments and nonprofit organizations that donate and receive donated products comply with the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and FSIS regulations in 9 CFR Chapter III. This guideline includes information on: \u2022 Products eligible for donation; \u2022 Products ineligible for donation; \u2022 Shipping donated products; \u2022 Labeling donated products; \u2022 Donating products produced under inspection exemptions; \u2022 Donation recipient types; \u2022 Donating State-inspected products; \u2022 Donating \u201cexpired\u201d products; \u2022 Relabeling at non-profit organizations; and \u2022 Retail exemption at non-profit organizations. Reason for Issuing the Guideline FSIS developed this guideline to assist establishments and non-profit organizations that donate and receive donated meat and poultry products by addressing common food donation questions. FSIS has received several questions from meat and poultry establishments and non-profit organizations on this subject and has decided to address the major concerns associated with donation in this guideline. This guideline will be useful because it addresses issues that have been presented to FSIS related to food donation (e.g., products eligible for donation, labeling donated products, and donating products produced under exemption). This guideline will provide information that will help reduce food loss and waste and help battle food insecurity.", "5 How to Effectively Use the Guideline This guideline is organized to provide users with the current science and recommendations for topics related to the donation of meat and poultry products to nonprofit organizations. This guidance document includes recommendations for meat and poultry producers and non-profit organizations on how to donate and receive donated products in compliance with the FMIA, PPIA, and FSIS regulations in 9 CFR Chapter III. To use this guideline, FSIS recommends that readers use the navigation headings to move efficiently through the document sections of interest. Hyperlinks, where provided, will quickly take you to the correct place in the document electronically and are also provided to other complementary documents. How to Comment on the Guideline FSIS is seeking public comment on this guideline as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to content, readability, applicability, and accessibility. The comment period will be 60 days from publication of the Federal Register Notice and, as appropriate, the Agency may update this guideline in response to comments. Although FSIS may make changes to the guideline in response to comments, this document reflects current thinking, and FSIS encourages establishments producing products discussed in this document to review it and begin using it. Comments may be submitted by either of the following methods: \u2022 Federal eRulemaking Portal Online submission at regulations.gov. This website provides a way to type short comments directly into the comment field on the webpage or attach a file to submit lengthier comments. Follow the online instructions at that site to submit comments. \u2022 Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250-3700. All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title: FSIS Guideline to Assist with the Donation of Eligible Meat & Poultry Products to Non-Profit Organizations.

Comments received will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>. Questions Regarding Topics in this Guideline If after reading this guideline you still have questions, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the askFSIS database or submit questions through askFSIS. Documenting these questions helps FSIS improve and refine present and future versions of the guideline and associated issuances." "6 When submitting a question, use the Submit a Question tab, and enter the following information in the fields identified below as prescribed: Subject Field: FSIS Guideline to Assist with the Donation of Eligible Meat & Poultry Products to Non-Profit Organizations Question Field: Your question with as much detail as possible. Product Field: Select General Inspection Policy. Category Field: Select Donated Product from the drop-down menu. Policy Arena: Select Domestic (U.S.) Only from the drop-down menu. When all fields are complete, press Continue. FSIS Guideline to Assist with the Donation of Eligible Meat & Poultry Products to Non-Profit Organizations Background In the United States, food waste is estimated as constituting between 30-40 percent of the food supply. This figure, based on estimates from USDA\u2019s Economic Research Service of a 31 percent food loss at the retail and consumer levels, corresponds to approximately 133 billion pounds and \$161 billion worth of food in 2010. Wasted food is the single largest category of material placed in municipal landfills and represents nourishment that could have helped feed families in need. Additionally, water, energy, and labor used to produce wasted food could have been employed for other purposes. Effectively reducing food waste will require cooperation among federal, state, tribal and local governments, faith-based institutions, environmental organizations, communities, and the entire supply chain. In October 2018, the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA) launched the Winning on Reducing Food Waste Initiative in a formal agreement. As part of the initiative, the agencies affirmed their shared commitment to work towards the national goal of reducing food loss and waste by 50 percent by 2030. The agencies agreed to coordinate food loss and waste actions such as education and outreach, research, community investments, voluntary programs, public-private partnerships, tool development, technical assistance, event participation, and policy discussion on the impacts and importance of reducing food loss and waste. While there have been significant actions taken and commitments made through public-private partnerships to date, there is still much work to be done. See USDA\u2019s Winning on Reducing Food Waste page for more information on USDA\u2019s commitment to this cause. Meat and poultry businesses can be a critical component of reducing food loss and waste. FSIS encourages establishments to donate meat and poultry products to nonprofit organizations, when possible, to reduce food loss and waste." "7 Donation Flowchart This table represents the most common questions establishments face when deciding to donate meat or poultry products. More detailed information about each of these questions and answers is included in the following pages. Guidance for Donating Establishments \u2022 Products Eligible for Donation - Federally-Inspected and Passed Products Meat and poultry establishments may always donate federally-inspected meat and poultry products that are safe, wholesome, and not misbranded to non-profit organizations, such as charitable institutions, food banks, and government-supported facilities (e.g., correctional facilities, child welfare facilities, homes for senior populations, institutions for the physically or mentally ill, or similar qualifying institutions) (see 21 U.S.C.

673(a)(5)(A) and 21 U.S.C. 467b(a)(5)(A)). - Misbranded and Economically Adulterated Products Historically, safe and wholesome misbranded or economically adulterated meat and poultry products (further defined below) could be donated to non-profit organizations only after receiving temporary label approval from FSIS and marking each immediate container with a \u201cNot for Sale\u201d statement. However, in order to facilitate the donation of edible human food to non-profit organizations, FSIS has streamlined the donation procedures for certain misbranded and economically adulterated meat or poultry products. FSIS now allows official establishments to forego the temporary label", "8 approval and the marking of each immediate container with the \u201cNot for Sale\u201d statement for some products, if the FSIS inspection program personnel can verify that the Bill of Lading accompanying the products contains: 1. The quantity of the donated products; 2. A description of the donated products; 3. The reason products are diverted for donation (e.g., incorrect net weight); and 4. A statement that the products are \u201cNot for Sale.\u201d If the products are misbranded because they contain unlabeled ingredients of public health concern, the official establishment will have to take additional steps before donating. FSIS requires a temporary label approval from FSIS\u2019s Labeling and Program Delivery Staff (LPDS) (9 CFR 412.1(f)(1)), a \u201cNot For Sale\u201d statement on each immediate container of these products, along with identification of the ingredients. Ingredients of public health concern include the eight most common (\u201cThe Big 8\u201d) food allergens. \u201cThe Big 8\u201d allergens are: wheat, Crustacean shellfish (i.e., shrimp, crab, lobster), eggs, fish, peanuts, milk, tree nuts, and soybeans. Ingredients of public health concern also include ingredients that may cause food intolerance, such as sulfur-based preservatives (sulfites), lactose, Yellow 5 (tartrazine), gluten, and monosodium glutamate (MSG). The adverse reactions to these substances are caused by the ingredient itself or its chemical composition. Products are economically adulterated when any valuable constituent in whole or in part has been omitted or removed, when any less valuable substance has been substituted, when any substance is added or mixed, or when packaging misrepresents the weight or bulk making them appear to be of greater value (21 U.S.C. 601(m)(8) or 21 U.S.C. 453(g)(8)). In most cases of economic adulteration, a substance is added or intentionally substituted for the purpose of increasing the apparent value of the product. For example, a poultry carcass with added water that exceeds the maximum percentage of water that may be retained under 9 CFR part 441 would be economically adulterated, because the added water increases the product\u2019s net weight and makes it appear to be of greater value. FSIS personnel will follow the instructions found in FSIS Directive 7020.1 Verifying Donation of Misbranding and Economically Adulterated Meat and Poultry Products to Non-Profit Organizations or FSIS Directive 8410.1 Detention and Seizure when verifying donations of misbranded or economically-adulterated meat and poultry products to nonprofit organizations. - Products Intended for Export Meat and poultry producers may be permitted to donate certain products intended for export to domestic non-profit organizations if the products are safe and wholesome. FSIS requires a temporary label approval (9 CFR 412.1(f)(1)) for donated products originally intended for export unless the label bears no deviations from domestic requirements other than being labeled \u201cFor Export Only.\u201d If any language on the products\u2019 labeling is not translated into English, the translation will need to accompany", "9 the application for temporary approval in order to provide LPDS with adequate information. - Sample Products Meat and poultry producers may donate sample

products to non-profit organizations. Sample products are products that are made available for pre-market consumer testing, are available to the general public, and are not for sale. Because sample products are produced for general public consumption, they must be produced and labeled in accordance with the meat and poultry products inspection regulations. More information about sample products can be found in FSIS Directive 7000.2 Experimental and Sample Products Policy.

\u2022 Products Ineligible for Donation

Below are two ineligible product types that industry frequently requests information on donating. Additional products that are ineligible for donation are discussed in other sections of this guideline.

- Adulterated Products

An official establishment cannot dispose of adulterated products by donating them to a non-profit organization, except when products are found to only be economically adulterated (21 U.S.C. 601(m)(8) or 21 U.S.C. 453(g)(8)), as discussed above. Unwholesome, adulterated products may not be donated to non-profit organizations (21 U.S.C. 601(m)(3) or 21 U.S.C. 453(g)(3)).

- Experimental Products

Official establishments are not eligible to donate experimental products to non-profit organizations. Experimental products are new or existing products that introduce a new formulation or flavor. They are limited to research and development under the control of the producing official establishment. Because experimental products are not inspected, they may not enter commerce. More about experimental products can be found in FSIS Directive 7000.2 Experimental and Sample Products Policy.

\u2022 Shipping Donated Products

The donating establishment, the shipping firm, and the receiving non-profit organization all have a responsibility to maintain human food in an unadulterated state. More information on keeping products safe during transport can be found in the FSIS Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry, and Egg Products.

"10 \u2022 Labeling Donated Products - Incorrect Standards of Identity

An establishment can donate products that do not meet the standard of identity listed on the label (e.g., beef stew formulated with less than 25% beef) without having to contact LPDS, but the reason the product doesn't meet the standard of identity must be mentioned in the bill of lading.

- Statement of Limited Use/\u2022 Distribution

An official establishment can donate products bearing a statement of limited use (e.g., \u201cfor further processing,\u201d \u201cfor institutional use only\u201d) to a non-profit organization. A statement of limited distribution (i.e., \u201cNot for Sale\u201d or \u201cFor Charity Only\u201d) is not required on unadulterated, properly labeled meat or poultry products that are being donated to non-profit organizations. However, FSIS recommends adding a statement of limited distribution to the products\u2019 labeling to avoid further distribution of products by non-profit organizations. Such a statement may be generically-approved and added to the products per 9 CFR part 412. This statement can be applied to the immediate containers, shipping container, or the bill of lading accompanying the donated products to the non-profit organization. The statement \u201cNot for Sale\u201d is required on the labeling of economically-adulterated or misbranded products that have been detained by FSIS and disposed of by donation to non-profit organizations, per 21 U.S.C. 673 (a)(5)(A)(ii) and 21 U.S.C. 467(a)(5)(A)(iii).

\u2022 Donating Products Produced Under Inspection Exemptions - Can I Donate Meat Products Slaughtered and/\u2022 or Processed under an Exemption to Federal Inspection (see 9 CFR 303.1)?

Exemption Type Eligible to Donate? Personal Use No Custom Slaughter and Custom Processing No Retail Store Yes Restaurant Yes Caterer Yes Restaurant Central Kitchen Yes", "11 Further explanation of each meat inspection exemption type and its eligibility to be donated is found in

the FSIS Guideline for Determining Whether a Livestock Slaughter or Processing Firm is Exempt from the Inspection Requirements of the Federal Meat Inspection Act. - Can I Donate Poultry Products Slaughtered and\or Processed under an Exemption to Federal Inspection (See 9 CFR 381.10)? Exemption Type Eligible to Donate? Personal Use No Custom Slaughter\Processing No Producer\Grower 1,000 Bird Limit Yes, intrastate Producer\Grower 20,000 Bird Limit Yes, intrastate Producer\Grower or Other Person (PGOP) Yes, intrastate Small Enterprise Yes, intrastate Retail Dealer Yes Retail Store Yes Further explanation of each poultry inspection exemption type and its eligibility to be donated is found in the Guidance for Determining Whether a Poultry Slaughter or Processing Operation is Exempt from Inspection Requirements of the Poultry Products Inspection Act. The guideline does not address exemption requirements where state laws may be different from those in the Poultry Products Inspection Act (PPIA) and FSIS\USDA regulations. States may have additional requirements and regulations, beyond FSIS\u2019s requirements, for donating products produced under the Producer\Grower, PGOP, and Small Enterprise exemptions. \u2022 Donation Recipients - Donation to Schools for Human Consumption An establishment can donate meat and poultry products to a school if the final products are fully labeled and wholesome. - Non-Profit Fundraiser An establishment can donate products to a non-profit fundraiser to be sold if the products are inspected and passed by FSIS.", "12 \u2022 Donating State-Inspected Products Under the Cooperative Interstate Shipment (CIS) program, certain state-inspected establishments can operate the same as federally-inspected facilities. Under specific conditions, these establishments can ship their products in interstate and international commerce. Therefore, products produced under the CIS program are eligible for donation. If a state-inspected establishment has not produced the product under the CIS program, it is limited to donating product within its own state borders according to state laws. \u2022 Donating \u201cExpired\u201d Products Producers can donate products past the \u201cbest if used by\u201d or \u201ccell by\u201d date. Manufacturers provide dating to help consumers and retailers decide when food is of best quality. Except for infant formula, product dates are not an indicator of products\u2019 safety and are not required by Federal law. The quality of perishable products may deteriorate after the date passes, but the products should still be wholesome if not exhibiting signs of spoilage. Spoiled foods will develop an off odor, flavor or texture due to naturally occurring spoilage bacteria, making the food not wholesome. If a food has developed such spoilage characteristics, it should not be eaten. FSIS recommends that food banks, other charitable organizations, and consumers evaluate the quality of the products before their distribution and consumption to determine if there are noticeable changes in wholesomeness. More information on product dating can be found on FSIS\u2019s Food Product Dating page. Guidance for Organizations Receiving Donated Products \u2022 Relabeling (ID Services) Non-profit organizations that repackaging products need to ensure that the products they receive and distribute are properly labeled. This is especially important with raw products that may appear to be fully cooked (e.g., raw, breaded poultry products) because some consumers might not know how to properly handle and cook the product. Ensuring proper labeling can prevent inadequate cooking by consumers, reducing the risk of foodborne illness. A non-profit organization, such as a food bank, can receive federally inspected and passed products in bulk, break bulk, repackaging, label, and distribute them to customers in need under the retail exemption to federal inspection (see 9 CFR 303.1(d) and 381.10(d)). If the non-profit organization receives state-inspected products,

they may be distributed within the state only. The non-profit organization must ensure that the repackaged products meet all FSIS labeling requirements that apply at retail: the name of the product, the name and address of the manufacturer, packer or distributor of the product (which can be the food bank), a list of ingredients if the product is made from two or more ingredients, a special handling statements (like Keep Refrigerated) if", "13 product is perishable, nutrition information (unless an exemption applies, such as that the product will not be sold) and safe-handling instructions (if not ready-to-eat) (see 9 CFR 317.2 and 381 Subpart N). In accordance with 9 CFR 303.1(f) and 9 CFR 381.10(a)(1), the adulteration and misbranding provisions of the FMIA and PPIA apply to articles that are exempted from inspection. For a check list of required label features, please visit FSIS\u2019s \u201cLabel Submission Checklist\u201d page, and for more information on labeling requirements, please visit FSIS\u2019s Basics of Labeling page. Product exempt from FSIS inspection must not bear the FSIS inspection legend. \u2022 Retail Exemption- Preparation of Meat and Poultry Products at Non-Profit Organizations As mentioned above, non-profit organizations are eligible to prepare meat and poultry products under the retail exemption. Retail exempt products may be donated as retailers are required to use federally or state-inspected source materials when preparing any meat or poultry products under the retail exemption found in 9 CFR 303.1(d) and 9 CFR 381.10(d). Retailers are subject to the licensing requirements of state or local (county, city) authorities, while producing products under the retail exemption, without FSIS inspection. The adulteration and misbranding provisions of the FMIA and PPIA apply to products which are exempted from inspection.", "14 http://askfsis.custhelp.com/ USDA FSIS www.fsis.usda.gov 2020"]}, {"file\_name": "FSIS\_GD\_2020\_0017", "title": "Expansion of the Use of the Term \u201cHealthy\u201d", "num": "FSIS-GD-2020-0017", "id": "d419f7e2ab8524c4e23de4b8c19f4f411dd29423a2c9e7514652326a4d6f1fd9", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2020-07/2019-0008.pdf", "type": "pdf", "n\_pages": 3, "word\_count": 3078, "text\_by\_page": ["15759 Federal Register\\Vol. 85, No. 54\\Thursday, March 19, 2020\\Notices information is estimated to average 15 minutes per response. Respondents: Respondents are eligible certified organic handlers. Estimated Number of Respondents: 210. Estimated Number of Total Annual Responses: 210. Estimated Number of Responses per Respondent: 1. Estimated Total Annual Burden on Respondents: 52.5 hours. Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (2) the accuracy of the Agency\u2019s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) was to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Dated: March 12, 2020. Bruce Summers, Administrator, Agricultural Marketing Service. [FR Doc. 2020\u201305507 Filed 3\u201318\u201320; 8:45 am] BILLING CODE 3410\u201302\u2013P DEPARTMENT OF AGRICULTURE Submission for OMB Review; Comment Request March 16, 2020. The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork"], "text": "they may be distributed within the state only. The non-profit organization must ensure that the repackaged products meet all FSIS labeling requirements that apply at retail: the name of the product, the name and address of the manufacturer, packer or distributor of the product (which can be the food bank), a list of ingredients if the product is made from two or more ingredients, a special handling statements (like Keep Refrigerated) if", "13 product is perishable, nutrition information (unless an exemption applies, such as that the product will not be sold) and safe-handling instructions (if not ready-to-eat) (see 9 CFR 317.2 and 381 Subpart N). In accordance with 9 CFR 303.1(f) and 9 CFR 381.10(a)(1), the adulteration and misbranding provisions of the FMIA and PPIA apply to articles that are exempted from inspection. For a check list of required label features, please visit FSIS\u2019s \u201cLabel Submission Checklist\u201d page, and for more information on labeling requirements, please visit FSIS\u2019s Basics of Labeling page. Product exempt from FSIS inspection must not bear the FSIS inspection legend. \u2022 Retail Exemption- Preparation of Meat and Poultry Products at Non-Profit Organizations As mentioned above, non-profit organizations are eligible to prepare meat and poultry products under the retail exemption. Retail exempt products may be donated as retailers are required to use federally or state-inspected source materials when preparing any meat or poultry products under the retail exemption found in 9 CFR 303.1(d) and 9 CFR 381.10(d). Retailers are subject to the licensing requirements of state or local (county, city) authorities, while producing products under the retail exemption, without FSIS inspection. The adulteration and misbranding provisions of the FMIA and PPIA apply to products which are exempted from inspection.", "14 http://askfsis.custhelp.com/ USDA FSIS www.fsis.usda.gov 2020"]}, {"file\_name": "FSIS\_GD\_2020\_0017", "title": "Expansion of the Use of the Term \u201cHealthy\u201d", "num": "FSIS-GD-2020-0017", "id": "d419f7e2ab8524c4e23de4b8c19f4f411dd29423a2c9e7514652326a4d6f1fd9", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2020-07/2019-0008.pdf", "type": "pdf", "n\_pages": 3, "word\_count": 3078, "text\_by\_page": ["15759 Federal Register\\Vol. 85, No. 54\\Thursday, March 19, 2020\\Notices information is estimated to average 15 minutes per response. Respondents: Respondents are eligible certified organic handlers. Estimated Number of Respondents: 210. Estimated Number of Total Annual Responses: 210. Estimated Number of Responses per Respondent: 1. Estimated Total Annual Burden on Respondents: 52.5 hours. Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (2) the accuracy of the Agency\u2019s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) was to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Dated: March 12, 2020. Bruce Summers, Administrator, Agricultural Marketing Service. [FR Doc. 2020\u201305507 Filed 3\u201318\u201320; 8:45 am] BILLING CODE 3410\u201302\u2013P DEPARTMENT OF AGRICULTURE Submission for OMB Review; Comment Request March 16, 2020. The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork"}]

Reduction Act of 1995, Public Law 104\ufe0f. Comments are required regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency\u2019s estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments regarding this information collection received by April 20, 2020 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website [www.reginfo.gov\](http://www.reginfo.gov/) public\do\PRAMain. Find this particular information collection by selecting \u2018\ufe0fCurrently under 30-day Review\ufe0fOpen for Public Comments\u2019\ufe0f or by using the search function. An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number. Farm Service Agency Title: Wildfires and Hurricanes Indemnity Program Pluses (WHIP+). OMB Control Number: 0560\ufe0f0294. Summary of Collection: The Additional Supplemental Appropriations for Disaster Relief Act, 2019 (Disaster Relief Act; Pub. L. 116\ufe0f 20) authorized \$3 billion in assistance for losses to crops, trees, bushes, and vines due to 2018 and 2019 hurricanes, floods, tornadoes, typhoons, volcanic activity, snowstorms, and wildfires. The Disaster Relief Act requires all participants who receive WHIP+ payments to purchase crop insurance or NAP coverage for the applicable crop years for which they are requesting assistance. Need and Use of the Information: The information submitted by respondents on the various forms will be used by FSA to determine eligibility and distribute payments to eligible producers under WHIP+. Failure to solicit application will result in failure to provide payments to eligible producers as intended by the Disaster Relief Act.

Description of Respondents: Farms. Number of Respondents: 26,592. Frequency of Responses: Reporting; Other (one-time). Total Burden Hours: 18,405. Ruth Brown, Departmental Information Collection Clearance Officer. [FR Doc. 2020\ufe0f05736 Filed 3\ufe0f2018\ufe0f201320; 8:45 am] BILLING CODE 3410\ufe0f021305\ufe0f0213P DEPARTMENT OF AGRICULTURE Food Safety and Inspection Service [Docket No. FSIS\u2019\ufe0f02130008] Expansion of Use of the Term \u2018\ufe0f2018Healthy\u2019\ufe0f2019 AGENCY: Food Safety and Inspection Service, USDA. ACTION: Notice and request for comments. SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that it will allow establishments to use the implied nutrient content claim \u2018\ufe0f2018healthy\u2019\ufe0f2019 on their labels which: (1) Are not low in total fat, but have a fat profile makeup of predominantly mono and polyunsaturated fats; or (2) contain at least ten percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or vitamin D. FSIS is making this announcement to maintain consistent requirements for food labels by allowing the same uses of the claim \u2018\ufe0f2018healthy\u2019\ufe0f2019 for meat and poultry products as are currently allowed for food products under the Food and Drug Administration\u2019s (FDA\u2019s) jurisdiction. DATES: This notice is applicable March 19, 2020. Submit comments on or before

May 18, 2020. ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods: Federal eRulemaking Portal: This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments. Mail, including CD\u2013ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250\u2013700. Hand- or Courier-Delivered Items: Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250\u2013700. Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS\u20132019\u20130008. Written comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>. Docket: For access to background documents or comments received, call VerDate Sep<11>2014 17:05 Mar 18, 2020 Jkt 250001 PO 00000 Frm 00002 Fmt 4703 Sfmt 4703 E:\FR\FM\19MRN1.SGM 19MRN1 jbell on DSKJLSW7X2PROD with NOTICES", "15760 Federal Register\Vol. 85, No. 54\Thursday, March 19, 2020\Notices 1[https://health.gov/dietaryguidelines/2015/resources/2015-2020\\_Dietary\\_Guidelines.pdf](https://health.gov/dietaryguidelines/2015/resources/2015-2020_Dietary_Guidelines.pdf). (202) 720\u20135627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250\u2013700.

FOR FURTHER INFORMATION CONTACT: Jeff Canavan, Deputy Director, Labeling and Program Delivery Staff, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Stop Code 3784, Patriots Plaza 3, 9\u2013146, 1400 Independence Avenue SW, Washington, DC 20250\u20133700; Telephone (301) 504\u20130879; Fax (202) 245\u20134792.

SUPPLEMENTARY INFORMATION: Background FSIS is the public health regulatory agency in the USDA that is responsible for ensuring that the nation's commercial supply of meat and poultry products is safe, wholesome, and accurately labeled and packaged. Under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601\u2013695, at 607) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451\u2013470, at 457), the labels of meat and poultry products must be approved by the Secretary of Agriculture, who has delegated this authority to FSIS, before these products can enter commerce. The FMIA and PPIA also prohibit the sale or offer for sale by any person, firm, or corporation of any article in commerce under any name or other marking or labeling that is false or misleading (21 U.S.C. 601(n) and 607(d); 21 U.S.C. 453(h) and 457(c)). FSIS Regulations for \u2018\u2018Healthy\u2019\u2019\u2019 Claims FSIS regulations (9 CFR 317.363(b) and 381.463(b)) define the parameters for the use of the implied nutrient content claim \u2018\u2018healthy\u2019\u2019 or any other derivative of the term \u2018\u2018health\u2019\u2019 and similar terms on meat and poultry product labeling. The definitions establish specific criteria for nutrients to limit in the diet, such as total fat, saturated fat, cholesterol, and sodium; and requirements for nutrients to encourage in the diet, including vitamin A, vitamin C, calcium, iron, protein, and fiber. On May 10, 1994, FSIS published a final rule defining the term \u2018\u2018healthy\u2019\u2019\u2019 that included new standards for sodium (59 FR 24220). FSIS created initial \u2018\u2018first-tier\u2019\u2019\u2019 sodium standards, and \u2018\u2018second-tier\u2019\u2019\u2019 sodium standards that would become more rigorous after a 24-month time period. After extending the first-tier sodium

standards in the Federal Register (63 FR 7279, 64 FR 72490, and 68 FR 460), FSIS decided, in 2006, to indefinitely defer to the first- tier sodium standards (71 FR 1683). Consequently, FSIS continues to apply the original (first-tier) levels of sodium established in the 1994 regulation when approving labels for \u2018\u2018healthy.\u2019\u2019 Recent Changes to Regulations and Policy In December 2015, USDA and the U.S. Department of Health and Human Services (HHS) published the 2015\u2013 2020 Dietary Guidelines for Americans.<sup>1</sup> The Dietary Guidelines were designed for professionals to help all individuals consume a healthy and nutritionally- adequate diet. Specific recommendations in the Dietary Guidelines have evolved over time, as nutrition science has advanced. For example, scientific understanding and nutrition guidance has shifted from recommending diets low in total fat to recommending keeping overall fat intake within the age-appropriate acceptable macronutrient distribution ranges (AMDR), and instead prioritizing replacing saturated fats with polyunsaturated and monounsaturated fats and keeping trans fat intake as low as possible. On May 27, 2016, FDA issued two final rules updating the Nutrition Facts label and serving size information for packaged foods (81 FR 33742 and 81 FR 34000). The above-mentioned 2015\u2013 2020 Dietary Guidelines for Americans served as the scientific basis for these two FDA final rules that included changes in the individual nutrients that must be declared on the Nutrition Facts label and changes to the DV of other individual nutrients. The changes reflected the most recent nutrition and public health research and recent dietary recommendations from expert groups. These rules also improved the presentation of nutrition information on the Nutrition Facts label to help consumers make more informed choices and maintain healthy dietary practices.

Consistent with FDA\u2019s final rules, FSIS has proposed to change its nutrition labeling regulations (82 FR 6732). In November 2016, FSIS published a Federal Register notice allowing FSIS products to voluntarily adopt the FDA Nutrition Facts label format (81 FR 80631). The notice explained that at least one label sketch with the FDA nutrition format must be submitted to FSIS before that format could be generically approved for other products. On September 28, 2016, FDA announced in the Federal Register that it was requesting comments on the use of the term \u2018\u2018healthy.\u2019\u2019 in the labeling of human food products (81 FR 66562). According to this Federal Register notice, FDA published the notice in accordance with the FDA Foods and Veterinary Medicine Program\u2019s 2016\u2013 2025 Strategic Plan and in response to a citizen petition requesting that FDA update the nutrient content claim regulations to be consistent with current Federal dietary guidance. Specifically, FDA\u2019s notice stated that the petitioner requested that the Agency amend the regulation defining \u2018\u2018healthy.\u2019\u2019 as it relates to total fat intake and to emphasize whole food and dietary patterns rather than specific nutrients. Additionally, in the same Federal Register publication, FDA announced the availability of a guidance document for industry entitled \u2018\u2018Use of the Term \u2018Healthy\u2019 in the Labeling of Human Food Products: Guidance for Industry\u2019\u2019 (81 FR 66527). According to FDA, the science supporting public health recommendations for the intake of various nutrients had evolved, as evidenced in the 2015\u2013 2020 Dietary Guidelines. FDA also announced the Agency\u2019s intention to temporarily exercise enforcement discretion with respect to some of the criteria for bearing the implied nutrient content claim \u2018\u2018healthy.\u2019\u2019 until 21 CFR 101.65(d)(2) is amended through rulemaking. In the Federal Register notice, FDA explained that it intended to exercise enforcement discretion with respect to the current requirement that any

food bearing the nutrient content claim \u2018\u2018healthy\u2019\u2019 meet the low-fat requirement provided that: (1) The amounts of mono- and polyunsaturated fats are declared on the label; and (2) the amounts of mono- and polyunsaturated fats declared constitute most of the fat content. FDA also stated, in the notice, that it intends to exercise enforcement discretion with respect to the current requirement that any food bearing the nutrient content claim \u2018\u2018healthy\u2019\u2019 contain at least ten percent of the DV per RACC of vitamin A, vitamin C, calcium, iron, protein, or fiber, if the food instead contains at least ten percent of the DV per RACC of potassium or vitamin D. FDA\u2019s guidance document is available at <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM521692.pdf>. FSIS\u2019s Policy To maintain consistent requirements for food labels, FSIS has used its enforcement discretion to allow the same uses of the claim \u2018\u2018healthy\u2019\u2019 for meat and poultry products as are VerDate Sep<11>2014 17:05 Mar 18, 2020 Jkt 250001 PO 00000 Frm 00003 Fmt 4703 Sfmt 4703 E:\\FR\\FM\\19MRN1.SGM 19MRN1 jbell on DSKJLSW7X2PROD with NOTICES", "15761 Federal Register\\Vol. 85, No. 54\\Thursday, March 19, 2020\\Notices 2FSIS\u2019s Label Submission and Approval System (LSAS) is a web-based software application that integrates and implements an electronic label application process for establishments to submit label applications to FSIS. allowed for food products under FDA jurisdiction under FDA\u2019s 2016 guidance. There are few labels that qualify for the \u2018\u2018healthy\u2019\u2019 claim under the allowances in this notice that wouldn\u2019t qualify otherwise. According to FSIS\u2019s Label Submission and Approval System (LSAS)2data, the types of products utilizing FDA\u2019s guidance for the claim \u2018\u2018healthy\u2019\u2019 are mostly products that meet the definition of meal-type in 317.313(l)/381.413(l). Egg product labels are not affected by this policy because FSIS inspected egg products are required by regulation to use the FDA nutrition requirements in 21 CFR part 101 in compliance with 9 CFR 590.411(e)\u2014as such, egg product labeling follows the FDA nutrition panel and the FDA enforcement discretion even though FSIS\u2019s Labeling and Program Delivery Staff (LPDS) reviews and approves FSIS inspected egg product label applications. Because FSIS has received multiple questions from industry about our policy, FSIS is announcing in this Federal Register notice that it will continue to recognize FDA\u2019s 2016 guidance to alleviate consumer confusion and promote uniformity in the marketplace. Specifically, FSIS has allowed and will continue to allow the implied nutrient content claim \u2018\u2018healthy\u2019\u2019 on foods that have a fat profile of predominantly mono and polyunsaturated fats (i.e. sum of monounsaturated fats and polyunsaturated fats are greater than the total saturated fat content of food), but do not meet the regulatory definition of \u2018\u2018low fat,\u2019\u2019 as specified in 9 CFR 317.363(b)(1)/381.463(b)(1) or that contain at least ten percent of the DV per RACC of potassium or vitamin D as one of the options in 9 CFR 317.363(b)(4) and 381.463(b)(4), provided the remaining criteria for healthy in 9 CFR 317.363 and 381.463 have been met. FSIS\u2019s LPDS has reviewed many proposed labels referencing FDA\u2019s \u2018\u2018healthy\u2019\u2019 notice, and most have contained errors and needed correction. If a company wishes to use FDA\u2019s \u2018\u2018healthy\u2019\u2019 claim, they will first need to submit at least one label sketch to LPDS for approval. A corporation\u2019s parent-company only needs to submit one label application for a product produced in multiple establishments that are owned by the corporation. Subsequent similar

labels for other products that use FDA\u2019s \u2018\u2018healthy\u2019\u2019 claim can be generically approved. Submitting one label and receiving approval helps ensure that the rest of the labels are in compliance with FDA and FSIS regulations. Labels using the modified \u2018\u2018healthy\u2019\u2019 claim must be submitted to LPDS in the new FDA nutrition panel format. FSIS will continue to allow the use of implied nutrient content claim \u2018\u2018healthy\u2019\u2019 on foods that have a fat profile of predominantly mono and polyunsaturated fats (i.e., sum of monounsaturated fats and polyunsaturated fats are greater than the total saturated fat content of food), but do not meet the regulatory definition of \u2018\u2018low fat,\u2019\u2019 as specified in 9 CFR 317.363(b)(1) and 381.463(b)(1) or that contain at least ten percent of the DV per RACC of potassium or vitamin D as one of the options in 9 CFR 317.363(b)(4) and 381.463(b)(4), provided the remaining criteria for healthy in 9 CFR 317.363 and 381.463 have been met until FSIS\u2019s \u2018\u2018healthy\u2019\u2019 regulations (9 CFR 317.363(b) and 381.463(b)) are amended through rulemaking. FSIS will continue to coordinate with FDA on any changes to these regulations. Additional Public Notification Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this Federal Register publication on-line through the FSIS web page located at: <http://www.fsis.usda.gov/federal-register>. FSIS will also announce and provide a link to it through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Constituent Update is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

Congressional Review Act Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this notice is not a \u2018major rule,\u2019 as defined by 5 U.S.C. 804(2). USDA Nondiscrimination Statement No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/\u00b7 parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination, any person in the United States under any program or activity conducted by the USDA. How To File a Complaint of Discrimination To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at: [http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain\\_combined\\_6\\_8\\_12.pdf](http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf), or write a letter signed by you or your authorized representative. Send your completed complaint form or letter to USDA by mail, fax, or email: Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250\u20139410. Fax: (202) 690\u20137442. Email: [program.intake@usda.gov](mailto:program.intake@usda.gov). Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA\u2019s TARGET Center at (202) 720\u20132600 (voice and TDD). Done at

Washington, DC. Paul Kiecker, Administrator. [FR Doc. 2020\u201305738 Filed 3\u201318\u201320; 8:45 am] BILLING CODE 3410\u2013DM\u2013P DEPARTMENT OF AGRICULTURE Rural Business-Cooperative Service Rural Housing Service Rural Utilities Service Notice of Solicitation of Applications (NOSA) for the Strategic Economic and Community Development Program for Fiscal Year (FY) 2020; Amendment AGENCY: Rural Business-Cooperative Service, Rural Housing Service, and Rural Utilities Service, USDA (Rural Development). ACTION: Notice of Solicitation of Applications; Amendment. VerDate Sep<11>2014 17:05 Mar 18, 2020 Jkt 250001 PO 00000 Frm 00004 Fmt 4703 Sfmt 4703 E:\\\\FR\\\\FM\\\\19MRN1.SGM 19MRN1 jbell on DSKJLSW7X2PROD with NOTICES"]}, {"file\_name": "FSIS\_GD\_2021\_0001", "title": "HACCP Model for the New Swine Inspection System (pork slaughter)", "num": "FSIS-GD-2021-0001", "id": "1035b53f451d9bbf7c3b2b5f71740ad2a8a8741d4b894ae8d790325c3a174a3f", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-06/HACCP-Model-New-Swine-Inspection-System-2021-0001.pdf", "type": "pdf", "n\_pages": 20, "word\_count": 6182, "text\_by\_page": ["Page 1 of 20 A Generic HACCP Model for New Swine Inspection System (NSIS) The United States Department of Agriculture (USDA) published the Pathogen Reduction\\Hazard Analysis Critical Control Point (HACCP) Systems Final Rule in July 1996. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to address safety hazards reasonably likely to occur in their production process. Therefore, this HACCP model\\u2019s focus, and the focus of the other HACCP models, is on product safety, not product quality characteristics. With the rule, FSIS made available a guidebook for the preparation of HACCP plans and a generic model for each food processing category defined in the regulation (9 CFR 417.2(b)(1)). The guidebook and the generic models have been updated since their initial publication to be consistent with current science and policy. FSIS recommends you use the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan. Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used \\u201cas is\\u201d. FSIS recommends that establishments tailor the model(s) to fit the establishment\\u2019s operation. Establishments that slaughter market hogs may choose to operate under NSIS. Market hog slaughter establishments that do not choose to operate under the NSIS may operate under the traditional inspection system. FSIS has published a generic HACCP model for Traditional Swine Slaughter. The NSIS model\\u2019s critical control points (CCPs) do not necessarily apply to all NSIS operations. Products or operations may require fewer or more CCPs depending on the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. The food safety critical limits selected must come from scientific documents or other reliable sources to meet regulatory validation requirements. This model includes references for guidance on the selection of critical limits. The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis are HACCP records (CFR 417.5(a)). Ensure you maintain the

documents produced while developing a HACCP plan. For further assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP webpage.", "Page 2 of 20 EXAMPLE PRODUCT DESCRIPTION1 Process \ Product Name: New Swine Inspection System (NSIS) Market Hog Slaughter and Variety Meats Process \ Product name NSIS Market Hog Slaughter and Variety Meats (carcasses, variety meats (offal) and head meat) Important product characteristics (Aw, pH, Preservatives, etc.) Not Applicable Intended use2 For further processing at this facility or another establishment or Intended for cooking by end consumer Packaging (durability and storage conditions) Vacuum-packaged, bagged, boxed or in combos (catch weights) Shelf life and at what temperature Carcasses: 7 days when stored at less than 40\u2109 Variety Meats: 15 days at less than 40\u2109, Frozen \u2013 180 Days at less than 10\u2109 Where it will be sold (specify intended consumers, especially at-risk populations3) Carcasses and variety meats are either further processed inhouse or sold direct to another establishment or to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI). Labeling instructions Product name, inspection legend and establishment number, handling statement, net weight statement, address line, nutrition facts, and safe handling instructions. What special distribution controls are required? Keep refrigerated < 40\u2109 or frozen < 10\u2109 DATE: APPROVED BY: 1 Prior to developing the HACCP plan please read the FSIS Guidebook for the Preparation of HACCP Plans for detailed descriptions of the worksheets and hazard analysis. The FSIS Guidebook for the Preparation of HACCP Plans and the NSIS generic HACCP model are intended for establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products. 2 The intended use or consumer of the product must be identified in accordance with 9 CFR 417.2(a)(2). Identifying the product\u2019s intended use in the product description is one way to meet the regulatory requirements specific to 417.2(a)(2). 3 At-risk populations include young children, the elderly and immunocompromised persons.", "Page 3 of 20 EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL4 Process \ Product Name: NSIS Market Hog Slaughter and Variety Meats Meat and meat by-products Live hogs Non-meat food ingredients None Antimicrobials5 or processing aids6 Scald agents, organic acid Packaging material Foam bone protectors, cardboard boxes and combos, selfadhesive labels, plastic vacuum bags, plastic combo bin and box liners. Restricted ingredients or allergens None Other None DATE: APPROVED BY: 4 List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. 5 FSIS and the Food and Drug Administration (FDA) have a memorandum of understanding (MOU) that establishes the working relationship followed when responding to notifications for the use of food additives (including ingredients) intended for use in the production of FSIS regulated products. FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDA on the requirements under the Federal Food, Drug & Cosmetic Act and its implementing regulations. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat Poultry and Egg Products for the list of suitable ingredients. 6 There are many different

organic acids (for example, lactic acid, acetic acid). Establishments will need to research the various organic acids and select the antimicrobial intervention best suited for their unique circumstances and validate its effectiveness. Antimicrobial agents are listed in FSIS Directive 7120.1 Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products.", "Page 4 of 20 EXAMPLE PROCESS FLOW DIAGRAM7 Process \ Product Name: NSIS Market Hog Slaughter and Variety Meats 17. Returned Product8 12. Variety Meats (offal) Feces and Ingesta Verification CCP 3 and Organic Acid Spray CCP 4.9 DATE: APPROVED BY: 7 This is an example flow diagram. Establishments\u2019 flow diagrams for the same product may be different. Establishments determine which steps are included in their process. The steps must represent all relevant hazards in the hazard analysis. 8 The Returned Product step (16) is shown as not connected to another process step. Returned product may re-enter the production system at different process steps depending on condition or food safety concerns. Returned product may be relabeled, re-processed, discarded, etc. 9 This model demonstrates the use of a CCP to ensure carcasses, heads and variety meats (offal) intended for human consumption are free of visible feces and ingestra. 9 CFR 310.18(a) states: \u201cCarcasses, organs, and other parts shall be handled in a sanitary manner to prevent contamination with fecal material, urine, bile, hair, dirt, or foreign matter\u201d. 5. Pre-Evisceration Wash 6. Head Washing \ Head Dropping \ Bung Removal \ Carcass opening \ Evisceration 14. Variety Meats Chilling and Cold Storage 13. Variety Meats Packaging \ labeling 16. Shipping 1. Live Hog Receiving \ Live Hog Sorting CCP 1 1b. Non-Meat Receiving (Antimicrobials, Packaging Material, Processing Aids) 2. Stunning \ Sticking \ Bleeding 3. Scalding 4. Dehairing \ Gambrelling \ Singeing \ Polishing \ Shaving \ Knife Trimming 8. Carcass Splitting 11. Carcass Chilling 10. Final Wash and Organic Acid Spray on Carcasses CCP 4 1a. Live Wash for Heavy Contamination (Optional) 9. Trimming \ Final Rail \ Feces and Ingesta Verification CCP 3 7. Carcass, Head and Viscera sorting CCP 2 15. Cold storage \ transfer to Fabrication HACCP plan or Shipping", "Page 5 of 20 EXAMPLE NSIS MARKET HOG SLAUGHTER AND VARIETY MEATS HAZARD ANALYSIS10 10 See FSIS Compliance Guideline for Controlling Salmonella in Market Hogs, FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork and Products Containing Pork, and FSIS Compliance Guide: Modernization of Swine Inspection \u2013 Developing Microbiological Sampling programs in Swine Slaughter Establishments for suggested slaughter best practices and a list of scientific and technical references. 11 Hazards are grouped into three categories: Biological (B), Chemical (C), and Physical (P). Biological hazards are living organisms. Chemical hazards may be naturally occurring in foods, used, or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification. 12 Place the justification for your decision in column 4. Include control measures in column 4 for hazards not reasonably likely to occur and place them in column 5 for hazards reasonably likely to occur. If a hazard is reasonable likely to occur, then a CCP must be addressed at this step or a later step. See FSIS Meat and Poultry Hazards and Controls Guide for a list of frequently used controls. 13 Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced article must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from an FSIS

program, then HACCP system design must be supported by documentary evidence \u2013 that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan.<sup>14</sup> Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation, page 5).<sup>15</sup> To determine a CCP, see Guidebook for the Preparation of HACCP Plans for a CCP decision tree. Use the tool to evaluate the areas of control (column 5) to determine the best CCP to control, reduce, or eliminate a hazard. Column 1 Column 2 Column 3 Column 4 Column 5 Column 6 Ingredient \ Process Step Potential Hazards (Introduced or Controlled) at This Step<sup>11</sup> Is the Potential Food Safety Hazard Reasonably Likely to Occur<sup>12</sup> (RLTO) (Yes or No) Justification \ Basis for Decision<sup>13</sup> If yes in Column 3 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels?<sup>14</sup> Is this Step a Critical Control Point (CCP)?<sup>15</sup>,"Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 6 of 20<sup>16</sup> See FSIS Compliance Guideline for Controlling Salmonella in Market Hogs, FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork and Products Containing Pork for options used to prevent the control of Trichinella in pork and pork products. 1. Live Hog Receiving \ Live Hog Sorting B: Live animals showing physical signs of central nervous system (CNS) disease, pyrexia, or moribund conditions. Pathogens (Salmonella) Trichinella<sup>16</sup> Yes Yes No Market hogs may exhibit physical signs of CNS disease, pyrexia, or moribund conditions. Well documented that Salmonella are known to be present in digestive tracts swine. Acquire market hogs from herds with a Trichinæ Certification Program. Therefore, Trichinella is a hazard not reasonably likely to occur and treatment of such products for the destruction of Trichinæ is not necessary. CCP 1 Live Hog Sorting Sorters follow written Live Hog Sorting Standard Operating Procedure (SOP). Sorting procedures to remove hogs exhibiting conditions described in 9 CFR 309.19 prior to FSIS ante-mortem inspection Controlled at subsequent CCP 3 Feces and Ingesta Verification, and CCP 4 Organic Acid Spray Maintain adequate sanitation in holding pens, part of Good Manufacturing Practices (GMPs). CCP 1 No C: Drug residues No Low risk per FSIS Residue Monitoring Program, Compliance Guide for Residue Prevention. Residue certifications for live animals. Written Drug Residue Control SOP.", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 7 of 20<sup>17</sup> This Foreign Material SOP (prerequisite program) should have details on how this procedure is preventing the hazard from occurring (such as metal prevention controls) as well as the on-going verification

procedures. These controls should be evident within the written document upon review. The Foreign Material SOP and plant data related to ongoing verification activities then become part of recordkeeping and historic data. 18 Note: this \u201chistorical data\u201d must be supported with evidence from the establishment through the establishment\u2019s history or validation data with reference to the actual SOP or prerequisite program. When historical data is not available (for example, a HACCP plan for a new process or product), then system design must be supported by other documentary evidence, such as the FSIS Meat and Poultry Hazards and Controls Guide which states \u201cvisual examination of carcass for foreign material during slaughter\u201d is a frequently used control for foreign material hazards in swine slaughter. 19 The criteria used to determine when the live wash will be used should be clearly established in a prerequisite program. P: Foreign material \u2225 metal (needles, buckshot, bullets, hardware in intestinal tract) No Recorded historic data from written Foreign Material Standard Operating Procedure17 indicates low likelihood at this establishment and from suppliers.18 1a. Live Wash for Heavy Contamination19 (Optional) B: Pathogens (Salmonella) Yes Skin and hair from swine are a significant source of contaminants in slaughter operations. Controlled at subsequent CCP 3 Feces and Ingesta Verification, and CCP 4 Organic acid spray. Written Optional Wash SOP with conditions for use of optional wash (processing conditions, suppliers, customer specifications, etc.); wash parameters to decrease pathogens and prevent cross-contamination and ensure humane handling of swine. No C: None P: None 1b. Non-Meat Receiving (Antimicrobials, B: None C: Incorrect chemical \u2225 No Letters of Guarantee (LOG) from suppliers.,"Step Potential Hazard RLTO Justification \u2225 Basis Controls CCP Page 8 of 20 20 Provide reference for scientific support and validation for effective concentrations and support for critical operational parameters that reduce biological hazards. FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products contains the list of substances that may be used in the production of meat and poultry products. The list contains the allowable amounts and the intended use of the approved antimicrobials. The list (Directive 7120.1) can be used as supporting documentation for chemical hazard controls (safety and suitability). Directive 7120.1 cannot be used as support for the control of biological hazards because the antimicrobial concentration needed to control bacteria is different from the concentrations required for safety and suitability. Packaging Material, Processing Aids) concentration received.20 Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer\u2019s instructions and is within the allowable limits identified in Directive 7120.1 (FCN# [insert number]) Safety Data Sheets (SDS) sheets. P: None 2. Stunning \u2225 Sticking \u2225 Bleeding B: Pathogen (Salmonella) Yes It is well documented that Salmonella is known to be present in digestive tracts of warm-blooded animals including swine. Contaminants on swine hair or skin maybe transferred to product during dressing procedures. Controlled at subsequent CCP 3 Feces and Ingesta Verification, and CCP 4 Organic acid spray. Written Slaughter SOP describing removal (trimming) of visible contaminants from the stick wound and sanitation of the stick knife (heat or chemical) prior to each use. No C: None P: None 3. Scalding B: Pathogens (Salmonella) Yes Potential for cross-contamination through stick wound as well as scalding process. Controlled at subsequent CCP 3 Feces and Ingesta Verification, and CCP 4 Organic Acid Spray. Written Scalding SOP for procedures to minimize contamination during scalding and use of processing aids, scald agent, anti-foam, and time and No","Step Potential Hazard RLTO

Justification \ Basis Controls CCP Page 9 of 20 temperature parameters used in scalding process to decrease pathogen load. Written Sanitation SOP for maintaining sanitary conditions of scalding (carcass transit time, water temperature, easy to clean and in good repair, counter current application to increase heating efficiency and water cleanliness). Trimming of stick wound after scalding. C: Inappropriate chemical or concentration of scald agent used. No LOG from suppliers. SDS on file. Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer's instructions and is within the allowable limits identified in Directive 7120.1 (FCN# [insert number]) P: None 4. Dehairing, Gambrelling, Singeing \ Polishing \ Shaving \ Knife Trimming B: Pathogen (Salmonella) Yes Pathogens may be present on hog's skin. Potential for cross-contamination during dehairing operation. Singeing may reduce pathogens somewhat but is not a means to eliminate pathogens on skin. Controlled at subsequent CCP 3 Feces and Ingesta Verification, and CCP 4 Organic Acid Spray. Written Sanitation SOP to maintain equipment in sanitary conditions and to minimize cross-contamination. Written Sanitary Dressing SOP to minimize cross-contamination through adequate sanitary dressing procedures, remove visible hair to an acceptable level without breaking skin, describe procedures for steam or hot No", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 10 of 20 21 Pre-evisceration wash can be a control step where application parameters are monitored and documented in a prerequisite program. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products for the list of suitable compounds for pre-evisceration wash. Concentrations and control parameters in prerequisite programs should be evaluated (see FSIS Compliance Guide HACCP Systems Validation). water vacuuming de-hairing, trim fecal contaminants, and other dressing defects. Sanitary Dressing SOP includes preevisceration sampling at this step per 9 CFR 310.18(c). C: None P: None 5. PreEvisceration Wash21 B: Pathogen (Salmonella) Yes Pathogens may be present on hog's skin. Washing may reduce pathogens, but washing is not a means to eliminate pathogens from the skin. Controlled at subsequent CCP 3 Feces and Ingesta Verification, and CCP 4 Organic Acid Spray. Written Pre-evisceration Wash SOP to minimize overspray from cabinet. Written Pre-evisceration Carcass Wash SOP for control parameters (hot water, organic acid rinse, steam or other approved antimicrobial intervention, monitoring of chemical concentrations, water temperatures, nozzles, and solution application pressure regularly to verify effectiveness and to prevent driving contaminants into the tissues and overspray) at this step to prevent cross-contamination and reduce pathogen loads. Process Control SOP for sampling of microbial organisms to monitor the No", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 11 of 20 22 FSIS recommends that slaughter operations focus on their sanitary dressing procedures in order to prevent carcass contamination and the creation of insanitary conditions. Document the training of employees and training material used. Poor sanitary dressing procedures result in carcass contamination (visible or invisible, for example, microbial contaminants) and limit the effectiveness of antimicrobial interventions. establishment's ability to maintain process control (9 CFR 310.18). C: Inappropriate antimicrobial use or concentration No LOG from suppliers. SDS on file. Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer's instructions and is within the allowable limits identified in Directive 7120.1 (FCN# [insert number]) P: None 6.

Head Washing \ Head Dropping \ Bung Removal \ Carcass Opening \ Evisceration B: Pathogens (Salmonella) Yes Well documented that Salmonella are known to be present in digestive tracts of warm-blooded animals including swine. Contaminants may be transferred to product during dressing procedures. Cross-contamination from unsanitary dressing procedures and employee handling. Controlled at subsequent CCP 3 Feces and Ingesta Verification, and CCP 4 Organic Acid Spray. Documentation of properly trained employees.<sup>22</sup> Written Sanitation SOP for procedures and compliance of equipment sanitized between each carcass to minimize cross-contamination. Written SOP for tying the esophagus to prevent contamination with stomach contents. Written Head Wash SOP to minimize overspray from cabinet. No C: None P: None", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 12 of 20 23 Note: this \u201chistorical data\u201d must be supported with evidence from the establishment through the establishment\u2019s history or validation data with reference to the actual SOP or prerequisite program. When historical data is not available (for example, a HACCP plan for a new process or product), then system design must be supported by other documentary evidence, such as the FSIS Meat and Poultry Hazards and Controls Guide, which identifies \u201cminimize cross-contamination through sanitary dressing procedures; Sanitation SOPs\u201d as a frequently used control of biological hazards in swine slaughter.<sup>24</sup> Documentation to support this statement using in-plant data collected from prerequisite program (Sanitation SOP) validation and on-going verification check.

7. Carcass, Head and Viscera Sorting B: Septicemia, Toxemia, Pyemia, or cysticercosis Yes Carcasses, heads and viscera may exhibit signs of septicemia, toxemia, pyemia, and cysticercosis. CCP 2 Carcass, Head and Viscera Sorting. Sorters follow written Carcass, Head and Viscera Sorting SOP.

Establishment post-mortem sorting procedures to remove carcasses, heads and viscera with septicemia, toxemia, pyemia, or cysticercosis prior to FSIS inspection in accordance with 9 CFR 310.26. CCP 2 C: None P: None 8. Carcass Splitting B: Pathogen (Salmonella) Yes Meat may become contaminated with pathogens during dressing procedures and processing. The splitting saw may transfer contaminants from carcass to carcass. Recorded historic data from written Sanitation SOP Split Saw Check (sanitation of the saw between carcasses to prevent crosscontamination) indicates low likelihood of occurrence.<sup>23,24</sup> Controlled at subsequent CCP 3 Feces and Ingesta Verification, and CCP 4 Organic Acid Spray. Written Sanitary Dressing SOP for minimizing carcass transit time, and for monitoring time and temperature of product to move quickly through process to reduce pathogen growth. No C: None P: None", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 13 of 20 25 The CCP to reduce, control, or eliminate the previous hazards associated with fecal material and ingesta as designated by \u201cyes\u201d in column 6. 26 If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. However, if an establishment implements different critical operational parameters in the process from the scientific support, or the scientific support identified does not contain microbiological data, then the establishment should collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND

should collect in-plant microbiological validation data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameters (FSIS Compliance Guideline HACCP Systems Validation, page 27). 9. Trimming \ Final Rail \ Feces and Ingesta Verification B: Pathogen (Salmonella) Yes Well documented that carcasses, parts and organs are to be handled in a sanitary manner to prevent contamination with fecal material or ingesta. CCP 3 Feces and Ingesta Verification Yes CCP 325 C: None P: None 10. Final wash and Organic Acid Spray on Carcasses B: Pathogen (Salmonella) Yes Salmonella are known to be present on skin and in digestive tracts of warm-blooded animals including swine. Contaminants may be transferred to product during dressing procedures. CCP 4 Organic Acid Spray. Organic Acid sprays documented to reduce contaminants on carcasses, variety meats (offal), and meat.<sup>26</sup> Yes CCP 4 C: Inappropriate concentration of organic acid No Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer's instructions and is within the allowable limits identified in Directive 7120.1 (FCN# [insert number]). Written Final Wash and Acid Spray SOP to minimize overspray from cabinet and ensure complete coverage. P: None", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 14 of 20 27 Document training of personnel and training material used. 28 Reference can be used to justify temperature and time during processing (e.g., Tompkin, R.B. 1996. The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50°F. Presented during the Joint FSIS\FDA Conference on Time\Temperature, November 18-20, 1996 Washington, DC). 11. Carcass Chilling B: Pathogen outgrowth (Salmonella) No Written Chilling SOP to monitor carcass time and temperature chilling parameters. Sanitation procedures in coolers and sanitary handling while moving carcasses in the coolers. Process Control SOP for sampling of microbial organisms to monitor the establishment's ability to maintain process control (9 CFR 310.18). C: None P: None 12. Variety Meats (Offal) Feces and Ingesta Verification CCP 3 and Organic Acid Spray CCP 4 B: Pathogen outgrowth Yes It is well documented that Salmonella are known to be present in digestive tracts of warm-blooded animals including swine. Contaminates may be transferred to product during carcass dressing procedures. CCP 3 Feces and Ingesta Verification, and CCP 4 Organic Acid Spray. Organic acid sprays documented to reduce contaminants on carcasses, variety meats (offal), and meat. Properly trained<sup>27</sup> employees to examine variety meats (offal) for feces and ingesta. Written Sanitation SOPs to prevent cross-contamination and for time temperature conditions to minimize outgrowth of pathogens.<sup>28</sup> Yes CCP 3 CCP 4 C: Inappropriate concentration of organic acid Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer's instructions and is within the allowable limits identified in Directive 7120.1 (FCN# [insert number]).", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 15 of 20 Written Final Wash and Acid Spray SOP to minimize overspray from cabinet and ensure complete coverage. P: None 13. Variety Meats Packaging \ Labeling B: Pathogen outgrowth (Salmonella) No Written Fabrication SOP to address temperature control for the processing room to reduce pathogen outgrowth (Tompkin, R.B. 1996). Written Sanitation SOP includes procedures for sanitary handling of product. C: None P: None 14. Variety Meats Chilling and Cold Storage B: Pathogen outgrowth (Salmonella) No Chilling SOP to monitor variety meats time and temperature chilling parameters. Sanitation procedures in coolers and

sanitary handling while moving product. Written Cooler Storage SOP for proper cooler storage temperature when product is present in the coolers. (Tompkin, R.B. 1996) C: None P: None 15. Cold Storage \ Transfer to Fabrication B: Pathogen outgrowth (Salmonella) No Written Cooler Storage SOP for proper cooler storage temperature when carcasses are present. (Tompkin, R.B. 1996) Written Sanitation SOP to address cooler sanitation." , "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 16 of 20 DATE: APPROVED BY: 29 Official swine slaughter establishments, except for very low-volume establishments, must collect and analyze carcass samples for microbial organisms at the pre-evisceration and post-chill points in the process (9 CFR 310.18(c)(1)). HACCP plan or Shipping Sanitary Dressing SOP includes post-chill sampling at this step. 29 Sanitation procedures in coolers and sanitary handling while moving product. C: None P: None 16. Shipping B: None C: None P: None 17. Returned Product B: None Reinspection SOP implemented before accepting returned product. Entity returning the product must demonstrate the product was held in the appropriate temperature range and in a sanitary manner. When such assurance is not available, returned product is rejected or destroyed. Opened packages are not accepted. Accepted product enters the appropriate step of the production system based on findings of product evaluation. Notify FSIS personnel when returned product has been accepted. C: None P: None", "Page 17 of 20 Example NSIS Market Hog Slaughter HACCP Plan 30 Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 1 Live Hog Sorting Pyrexia, central nervous system (CNS) disorders, and moribundity. 9 CFR 309.19 All hogs exhibiting signs of pyrexia, central nervous system disorders, and moribundity are sorted before the point of FSIS ante-mortem inspection. Monitor for hogs exhibiting signs of pyrexia, central nervous system disorders, and moribundity. Observe 300 hogs in motion and 300 hogs at rest for animals exhibiting signs of pyrexia, central nervous system disorders, and moribundity. Twice per shift. Auditor or designee When the auditor observes a hog exhibiting signs of pyrexia, central nervous system disorders, or moribundity, which was not identified during the sorting activity, the auditor will observe the remaining hogs in the group. Additionally, the auditor will again monitor the group while it is held for slaughter and just prior to the group going to slaughter. Hogs observed exhibiting signs of pyrexia, central nervous system disorders, or moribundity are to be segregated and prevented from entering the slaughter department. A member of management will ensure that corrective actions are completed. The production supervisor will per 9 CFR 417.3(a): 1. Hold all product produced until appropriate disposition taken (no product injurious to health will be sold); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; and 4. Take measures to prevent recurrence. Supervisor will conduct daily direct observations of monitoring activities and corrective actions. Supervisor will review records daily. Daily- calibrate thermometer used to measure pyrexia. Antemortem audit log HACCP deviation log Preshipment Records review form 30 This information is best suited for establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP model is for demonstration purposes only. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products.", "Page 18 of 20 Example NSIS Market Hog Slaughter HACCP Plan Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 2

Carcass, Head and Viscera Sorting Carcasses, heads and viscera exhibiting septicemia, toxemia, pyemia, or cysticercosis (condemnable conditions listed in 9 CFR 310.26). All carcasses, heads and viscera exhibiting septicemia, toxemia, pyemia, or cysticercosis are sorted before the point of FSIS post-mortem inspection of carcasses. Monitor for carcasses, heads and viscera exhibiting septicemia, toxemia, pyemia, or cysticercosis. Observe 12 carcasses, 12 heads and 12 viscera sets for lesions consistent with septicemia, toxemia, pyemia, and cysticercosis. Once per three hours of production time. Auditor or designee. If one or more carcasses, heads or viscera sets are observed with septicemia, toxemia, pyemia, or cysticercosis, the auditor will document food safety disease or condition found and inform a supervisor so the supervisor can initiate the appropriate corrective action and preventive measures. All affected product will be disposed of. Conduct a recheck of an additional set of 12 carcasses, heads, or viscera within 1530 minutes. If recheck finds the condemnable conditions, reduce the line speed by 5% and increase the frequency of checks to once every \u00bd hour. Isolate the carcasses, heads, and viscera in the cooler produced after the last acceptable check for re-auditing. A member of management will ensure that corrective actions are completed. The supervisor will per 9 CFR 417.3(a): 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; and 4. Take measures to prevent recurrence. Supervisor will conduct daily direct observation verification. Supervisor will review records daily. Carcass, Head and Viscera Sorting Audit form HACCP deviation log Preshipment Records review form", "Page 19 of 20 Example NSIS Market Hog Slaughter HACCP Plan Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 3 Feces and Ingesta Verification (Carcass and Variety Meats) 9 CFR 310.18 B: Pathogens: Salmonella No visibly detected fecal material, milk, or ingestra contaminants on carcasses, head meat, cheek meat, weasand meat and offal. Select and examine 12 carcasses and 20 pounds of head meat, cheek meat, weasand meat and offal. Observe all surfaces of each split carcass before the FSIS inspection station. Observe all sides of each piece of head meat, cheek meat, weasand meat and offal at packaging. Once every three hours of production. QA Tech designee Contaminants are knife trimmed. Contaminated carcasses may be railed out for trimming.31 The production supervisor will per 9 CFR 417.3(a): 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; and 4. Take measures to prevent recurrence. A member of management will ensure that corrective actions are completed. Once per day a QA Manager will directly observe the monitoring of carcasses, head meat, cheek meat, weasand meat and offal. QA Manager will conduct a daily record review. Feces and Ingesta Verification Form32 HACCP Deviation Log Verification Records Pre-shipment Records review form 31 For example, an SOP describing the corrective actions might include this statement \u201ceach carcass with a deviation will be railed out by the employee and reported and shown to the supervisor. The supervisor will determine the cause of the deviation, take whatever measures are necessary to restore the CCP to control, and document the corrective actions in the Corrective Actions log. If more than one deviation is found in a shift, the line will be slowed x% until xx minutes\u2019 production successfully passes the CCP.\u201d 32 One form for all three CCP monitoring locations and

verification activities.", "Page 20 of 20 33 FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products identifies the ingredients that are safe to use; however, each establishment must validate their own process. See FSIS Compliance Guideline HACCP Systems Validation for validation guidance. 34 FSIS does not endorse any specific antimicrobial intervention. \u201cOrganic acid\u201d is used as an example. If an antimicrobial is used, each establishment will need to find an antimicrobial intervention that works with their unique situation and they will need to validate the product\u2019s use. The critical limits should closely match the specific parameters for use as found in the technical or scientific supporting documentation. 35 NOTE: Critical operating parameters need to be addressed in this section as they are related to the scientific justification for use. Critical parameters include but are not limited to the following: type of sprayer (hand, cabinet), volume, coverage, chemical contact time, solution temperature, etc. The defined operational parameters are specific to each establishment. Example NSIS Market Hog Slaughter HACCP Plan Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure33 Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 4 Organic Acid Spray (Carcass, head meat, cheek meat, weasand meat, and offal) B: Pathogens: Salmonella The application of an organic acid34 (for example, organic acid at 25%). Mix solution per manufacturer\u2019s instructions to achieve 2-5% solution of organic acid not to exceed 55oC (131oF) sprayed directly onto carcasses, head meat, cheek meat, weasand meat and offal at 20-30 psi35 until all surfaces are dripping wet and some of the solution drips off. Observe the preparation and mixing of the solution and its application to verify the operational parameters are achieved. Observe the mixing of the solution and test the concentration of the organic acid (test kit). Observe the pressure gauges to determine the pressure at which the solution is being applied. Check thermometer for the temperature of the solution at the point of application. Observe for complete coverage of the product at the point the solution is applied. Once during each hour of slaughter operations. QA Tech or designee If a deviation from the critical limit occurs, the QA manager or designee will take corrective actions per 9 CFR 417.3(a): 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; and 4. Take measures to prevent recurrence. Randomly, once per week, QA Manager observes QA Tech performing monitoring functions. Each week, a QA Tech calibrates the pressure of the sprayers per manufacturer\u2019s instructions. Weekly calibrate cabinet thermometers by checking temperature with a calibrated hand-held thermometer. Daily Records Review QA will review Organic Acid Wash CCP CCP 4 Organic Acid Spray Form. Corrective Action Log Preshipment Records review form Verification Records"]}, {"file\_name": "FSIS\_GD\_2021\_0002", "title": "HACCP Model for Bacon (Heat-Treated, Not Fully Cooked)", "num": "FSIS-GD-2021-0002", "id": "8a7f1094e1ede7c25a723374664b9ebefc45e89389591965b4c6d6308b2d011e", "cprus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-06/HACCP-Model-Bacon-Heat-Treated-Not-Fully-Cooked-Not-Shelf-Stable-2021-0002.pdf", "type": "pdf", "n\_pages": 14, "word\_count": 4066, "text\_by\_page": ["Page 1 of 14 A Generic HACCP Model for Heat-Treated, Not Fully Cooked (Bacon) The United States Department of Agriculture (USDA) published the Pathogen Reduction/Hazard Analysis Critical"]}

Control Point (HACCP) Systems Final Rule in July 1996. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to address safety hazards reasonably likely to occur in their production process. Therefore, this HACCP model's focus, and the focus of the other HACCP models, is on product safety, not product quality characteristics. With the rule, FSIS made available a Guidebook for the Preparation of HACCP Plans and a generic model for each food processing category defined in the regulation (9 CFR 417.2(b)(1)). The guidebook and the generic models have been updated since their initial publication to be consistent with current science and policy. FSIS recommends you use the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan. Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used as is. FSIS recommends that establishments tailor the model(s) to fit the establishment's operation. This generic model uses bacon to illustrate the Heat-Treated, Not Fully Cooked processing category. Bacon is a cured and smoked pork product. Bacon is made with salt as a curing agent. Nitrite is the other most frequently used additive. Bacon may also contain sugars, wood smoke, flavorings, and spices. Bacon receives a heat processing step but the application of heat is not adequate to achieve food safety. Therefore, bacon is not ready-to-eat, it must be kept refrigerated or frozen, and it is cooked before consumption. This model's critical control point (CCP) does not necessarily apply to all operations or bacon products. HACCP plans may require more CCPs depending on the product and the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. The food safety critical limits selected must come from scientific documents or other reliable sources to meet regulatory validation requirements. This model includes references for guidance on the selection of critical limits. The selection of this processing category and bacon HACCP model are preliminary steps to completing a hazard analysis. The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis are HACCP records ((CFR 417.5(a))). Ensure you maintain the documents produced while developing a HACCP plan. For further assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP plans and the guidance materials available on the FSIS HACCP webpage." "Page 2 of 14 EXAMPLE PRODUCT DESCRIPTION1 Product Name and Process Type: Bacon (Heat-Treated, Not Fully Cooked) Product Name and Process Type Bacon; Heat-Treated, Not Fully Cooked Important product characteristics (Aw, pH, Preservatives, etc.) Contains Sodium Nitrite (120 ppm)2 How it is to be used3 Intended for cooking Packaging (durability and storage conditions) Vacuum packaged Shelf life and at what temperature4 1 month at 40°F or less or 6 months frozen at 0°F Where it will be sold (specify intended consumers, especially at-risk populations)5 Sold to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI). Labeling instructions and requirements Product name, nutrition facts, ingredients statement, allergen statement, establishment number, keep refrigerated, keep frozen, cooking instructions, safe handling instructions Special distribution control Keep refrigerated or frozen DATE: APPROVED BY: 1 Prior to developing the HACCP plan please read the FSIS Guidebook for the Preparation of

HACCP Plans for detailed descriptions of the worksheets and hazard analysis. The FSIS Guidebook for the Preparation of HACCP Plans and the generic HACCP models are intended for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP models are for demonstration purposes only. The models do not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products. 2 Pumped bacon has a regulatory requirement for 120 ppm ingoing Sodium Nitrite or an equivalent amount of potassium nitrite (148 ppm ingoing) and 550 ppm Sodium Ascorbate or Sodium Erythorbate (9 CFR 424.22(b)). 3 The intended use or consumer of the product must be identified in accordance with 9 CFR 417.2(a)(2). Identifying the product\u2019s intended use in the product description is one way to meet the regulatory requirements specific to 417.2(a)(2). 4 Each establishment may have their own defined shelf life. 5 At-risk populations include young children, the elderly, and immunocompromised persons." , "Page 3 of 14

**EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL6** Product Name and Process Type: Bacon (Heat-Treated, Not Fully Cooked) Meat and Meat by-products Pork belly Non-Meat food ingredients Sugar, Salt, Flavor and Spice mixture Antimicrobial interventions<sup>7</sup> and processing aids Sodium Nitrite Packaging material Plastic vacuum bags Restricted ingredients and allergens Sodium Nitrite, Sodium Erythorbate Other None DATE: APPROVED BY: 6 List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. See the FSIS Compliance Guideline Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling for detailed information on allergens. To review restrictions on the use of nitrite and sodium ascorbate or sodium erythorbate, see 9 CFR 424.22(b). 7 FSIS and the Food and Drug Administration (FDA) have a memorandum of understanding (MOU) that establishes the working relationship followed when responding to notifications for the use of food additives (including ingredients) intended for use in the production of FSIS regulated products. FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDA on the requirements under the Federal Food, Drug & Cosmetic Act and its implementing regulations. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat Poultry and Egg Products for the list of suitable ingredients." , "Page 4 of 14 **EXAMPLE PROCESS FLOW DIAGRAM8** Product Name and Process Type: Bacon (Heat Treated, Not Fully Cooked) 12. Returned Product<sup>9</sup> DATE: APPROVED BY: 8 This is an example flow diagram. Establishments\u2019 flow diagrams for the same product may be different. Establishments determine which steps are included in their process. The steps must represent all relevant hazards in the hazard analysis. 9 The Returned Product step (12) is shown as not connected to another process step. Returned product may re-enter the production system at different process steps depending on condition or problem. Returned product may be relabeled, discarded, etc. 1. Pork Receiving (fresh) 1a. Non-Meat Ingredients Receiving and Storage 1b. Packaging Materials Receiving and Storage 2. Cold Storage 5. Hanging 6. Smoke (Low Temperature Heat-Treatment) 8. Slicing 9. Packaging and Labeling 11. Storage and Distribution 3. Weighing and Mixing Marinade Ingredients (including restricted ingredient) 4. Injecting Pork Belly 7. Cooling CCP 1 10. Rework and Work in Progress", "Page 5 of 14 **EXAMPLE HAZARD**

ANALYSIS10 Product Name and Process Type: Bacon (Heat Treated, Not Fully Cooked) 10 See FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products for suggested best practices and a list of scientific and technical references. 11 Hazards are grouped into three categories: Biological (B), Chemical (C), and Physical (P). Biological hazards are living organisms. Chemical hazards may be naturally occurring in foods, used, or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification. 12 Place the justification for your decision in column 4. Include control measures in column 4 for hazards not reasonably likely to occur and place them in column 5 for hazards reasonably likely to occur. If a hazard is reasonable likely to occur, then a CCP must be addressed at this step or a later step. See FSIS Meat and Poultry Hazards and Controls Guide for a list of frequently used controls. 13 Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced article must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from an FSIS program, then HACCP system design must be supported by documentary evidence \u2013 that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peerreviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan. 14 Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation, page 5). 15 To determine a CCP, see the Guidebook for the Preparation of HACCP Plans for a decision tree to evaluate the areas of control (column 5) to determine the best CCP to control, reduce, or eliminate a hazard. Column 1 Column 2 Column 3 Column 4 Column 5 Column 6 Ingredient \Process Step Potential Hazards (introduced or controlled) at this Step11 Is the Potential Food Safety Hazard Reasonably Likely to Occur? (Yes or No)12 Justification \ Basis for Decision in Column 313 If \u201cyes\u201d in Column 3 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels14 Is this Step a Critical Control Point (CCP)?15 1. Pork Receiving (fresh) B: Salmonella No It is well documented that raw pork may be contaminated with pathogens. Bacon (like other forms of not ready-to-eat pork products, including all forms of fresh pork) is customarily well-cooked in the home or elsewhere before being served to the consumer and

the product bears safe handling", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 6 of 14 16 See FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork and Products Containing Pork for more information regarding Trichinella spiralis. 17 Prerequisite programs (SOP, Sanitation SOP, GMP) used as controls must be written procedures or protocols. The name of the program (for example, Receiving Trim SOP) must be listed, and the program and plant data become part of recordkeeping. These programs must have a description of controls and on-going verification used to prevent hazards from occurring. 18 FSIS recognizes the author's work since it was presented at a public hearing on a proposed regulation. The full title of the document is: Tompkin, R.B. 1996. The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50°F. Presented during the Joint FSIS/FDA Conference on Time/Temperature.

November 18, Washington, DC. Trichinella spiralis16 No instructions. Written Pork Receiving Standard Operating Procedure (SOP) to establish controls to prevent hazards.17 Written Pork Receiving SOP followed to establish controls for purchase specifications, ensure only qualified pork products are received and that product has been prepared and handled by the supplier in a manner that minimizes or eliminates the possibility of pathogen contamination. Written Temperature Control SOP for maintaining product at temperatures that preclude bacterial growth (<45°F, (Tompkin, R.B. 1996).18 Letter of Guarantee (LOG) is on file for each supplier of incoming pork. Bacon (like other forms of not ready-to-eat pork products, including all forms of fresh pork) is customarily well-cooked in the home or elsewhere before being served to the consumer. The product bears safe handling instructions. C: None", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 7 of 14 19 This Foreign Material SOP (prerequisite program) should have details on how this procedure is preventing the hazard from occurring (such as metal prevention controls) as well as the on-going verification procedures. These controls should be evident within the written document upon review. The Foreign Material SOP and plant data related to on-going verification activities then become part of recordkeeping and historic data. P: Foreign Material No Written Foreign Material SOP19 for visual inspection of containers and product at receiving. 1a. NonMeat Ingredient Receiving and Storage B: Presence and growth of pathogens e.g., Salmonella, E. coli, Listeria monocytogenes No Spices and flavorings may introduce pathogens. LOGs from suppliers describing quality controls and prevention procedures. Written Incoming Ingredients SOP for procedures to examine incoming non-meat ingredients including temperature (<45°F, (Tompkin, R.B. 1996) and sanitary conditions. Written Sanitation SOP for procedures used to protect ingredients from environmental contamination. C: Allergens, Sodium Nitrite, Sodium Erythorbate No The product formulation does not include an allergenic compound (Big 8). Allergenic ingredients are in other product formulations. Written Sanitation SOP for procedures used to protect non-allergenic ingredients and products from crosscontamination with allergenic ingredients. LOG for all non-meat ingredients describing quality controls and prevention procedures. Written Incoming Ingredients SOP for procedures to examine incoming non-meat ingredients including sanitary conditions. Written Sanitation SOP for procedures used to protect non-meat ingredients from environmental contamination. P: None", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 8 of 14 1b. Packaging Materials Receiving and Storage B: Contamination with Pathogens No Procedures to protect packaging materials from pests and environmental contamination. C: Chemical hazards No Packaging materials may

introduce chemical hazards. Letter of Guarantee for all packaging materials describing quality controls and prevention procedures. Written Packaging Material SOP for procedures to examine incoming materials including sanitary conditions. Written Sanitation SOP for procedures used to protect packaging materials from environmental contamination. P: Physical contaminants No Written Sanitation SOP for procedures used to protect packaging materials from contamination with physical hazards. 2. Cold Storage B: Pathogen outgrowth No Written Sanitation SOP for condition of use in coolers to prevent outgrowth of microorganisms. Written Temperature Control SOP for maintaining product at temperatures that preclude bacterial growth (<45\u00b0F, (Tompkin, R.B. 1996). C: None P: Physical contaminants No Written Sanitation SOP for procedures used to protect packaged product from contamination with physical hazards. B: None", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 9 of 14 3. Weighing and Mixing Marinade Ingredients (including restricted ingredient) C: Sodium Nitrite, Sodium Erythorbate, Allergens No Inappropriate levels of Sodium Nitrite or Sodium Erythorbate added to marinade mix creating potential toxic or uncured condition. Written SOP for Weighing Marinade Spices and Restricted Ingredients. Brine (concentration) records maintained for lots and batching. Written Sanitation SOP for procedures used to protect non-allergenic ingredients and products from crosscontamination with allergenic ingredients. P: None 4. Injecting Pork Belly B: Pathogen outgrowth No Duration of this step (Injecting Pork Belly) is short enough that pathogen outgrowth is not reasonably likely to occur. According to Tompkin, R.B. 1996, Salmonella growth is limited to < 1-log if product temperatures are no more than 70\u00b0F for up to 9 hours. This would be longer than a shift, so outgrowth is not reasonably likely to occur. Bacon (like other forms of not ready-to-eat pork products, including all forms of fresh pork) is customarily well-cooked in the home or elsewhere before being served to the consumer and the product bears safe handling instructions. C: Sodium Nitrite, Sodium Erythorbate No Written SOP for injection process ensures restricted ingredient limits are not exceeded and minimum levels of Sodium Nitrite are achieved. P: Metal from injector needles No Written SOP for equipment inspection during operations. No history of findings from daily equipment preoperational inspections (covered in Sanitation", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 10 of 14 20 Note: this \u201chistorical data\u201d must be supported with evidence from the establishment through the establishment\u2019s history or validation data. When historical data is not available (for example, a HACCP plan for a new process or product), then system design must be supported by other documentary evidence, such as the FSIS Meat and Poultry Hazards and Controls Guide which states \u201capropriate screening procedure for monitoring equipment\u201d is a frequently used control for foreign material hazards in processing. 21 See FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A for information that small and very small establishments can use to produce safe products with respect to Salmonella and other pathogens. 22 If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and

concentration. (FSIS Compliance Guideline HACCP Systems Validation, page 27). SOPs).20 No history of consumer complaints. 5. Hanging B: Pathogen outgrowth Duration of this step (Hanging) is short enough that outgrowth is not reasonably likely to occur. According to Tompkin, R.B. 1996, Salmonella growth is limited to < 1-log if product temperatures are no more than 70°F for up to 9 hours. This would be longer than a shift, so outgrowth is not reasonably likely to occur. Bacon (like other forms of not ready-to-eat pork products, including all forms of fresh pork) is customarily well-cooked in the home or elsewhere before being served to the consumer and the product bears safe handling instructions. C: None P: None 6. Smoke (Low Temperature HeatTreatment)21 B: Clostridium perfringens, Clostridium botulinum, and No Pathogens present on raw meat. Pre-requisite formulation SOP to ensure sufficient ingredient levels (salt, brine, sodium nitrite, sodium erythorbate, sodium phosphate) for preventing outgrowth of Staphylococcus aureus, Clostridium perfringens and Clostridium botulinum during smoking.<sup>22</sup>, "Step Potential Hazard RLTO Justification √ Basis Controls CCP Page 11 of 14 23 See FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and the Appendix B for suggested best practices and a list of scientific and technical references. 24 Provide reference for scientific support and validation for effective concentrations and support for critical operational parameters that reduce biological hazards. FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products contains the list of substances that may be used in the production of meat and poultry products. The list contains the allowable amounts and the intended use of the approved antimicrobials that can be used as supporting documentation for chemical hazard controls (safety and suitability). Directive 7120.1 cannot be used as support for the control of biological hazards because the antimicrobial concentration needed to control bacteria is different from the concentrations required for safety and suitability. 25 Taormina, P.J. and Bartholomew, G.W. 2005 Validation of Bacon processing Conditions to Verify Control of Clostridium perfringens and Staphylococcus aureus. Journal of Food Protection. 68(9): 1831-1839 Staphylococcus aureus Pre-requisite smoking SOP to ensure heating come up-time is met (heat to 120°F within 6 hours) while natural smoke applied: for preventing outgrowth of Staphylococcus aureus, Clostridium perfringens and Clostridium botulinum during smoking. C: None P: None 7. Cooling23 B: Clostridium perfringens, Clostridium botulinum, Staphylococcus aureus Yes Bacteria can grow and spores can survive the smoke step (#6) and can germinate and grow if not cooled quickly. Bacterial outgrowth can occur if product temperature reduction times are not met. Rapid and controlled cooling ensures no multiplication of toxigenic microorganisms such as Clostridium botulinum and no more than 1-Log multiplication of Clostridium perfringens. CCP 1 Cooling. Pre-requisite formulation SOP to ensure sufficient ingredient levels (salt, brine, sodium nitrite, sodium erythorbate, sodium phosphate) for preventing outgrowth of Staphylococcus aureus, Clostridium perfringens and Clostridium botulinum during cooling.<sup>24,25</sup> Yes, CCP 1 C: None P: None 8. Slicing B: Growth and recontamination of pathogens. No Written Temperature Control SOP for monitoring product temperature to prevent outgrowth of microorganisms. Product is sliced at temperatures", "Step Potential Hazard RLTO Justification √ Basis Controls CCP Page 12 of 14 that preclude bacterial growth (<45°F, (Tompkin, R.B. 1996). Written Sanitation SOP controls potential crosscontamination of product from slicer. C: None P: Metal No Written SOP for equipment

inspection during operations. No history of findings from daily equipment preoperational inspections (covered in Sanitation SOPs). No history of consumer complaints. 9. Packaging and Labeling B: Growth of pathogens. No Written Temperature Control SOP for monitoring product temperature to prevent outgrowth of microorganisms. Product is packaged at temperatures that preclude bacterial growth (<45°F, (Tompkin, R.B. 1996). C: Allergens No Allergenic ingredients are present in this facility and used in other products. Written SOP for procedure used to ensure products are correctly labeled. P: None 10. Rework and Work in Progress B: Growth of pathogens. No Written Temperature Control SOP for monitoring product temperature to prevent outgrowth of microorganisms. Product is reworked at temperatures that preclude bacterial growth (<45°F, (Tompkin, R.B. 1996). C: None P: None", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 13 of 14 DATE: \_\_\_\_\_ APPROVED BY: 11. Storage, Distribution B:Growth of pathogens No Written Temperature Control SOP for monitoring product temperature to prevent outgrowth of microorganisms. Product is stored at temperatures that preclude bacterial growth (<45°F, (Tompkin, R.B. 1996). Written Final Product SOP for procedures to examine outgoing materials including sanitary conditions of truck, functioning refrigeration unit, and package integrity. C: None P: None 12. Returned Product B: None Reinspection SOP implemented before accepting returned product. Entity returning the product must demonstrate the product was held in the appropriate temperature range and in a sanitary manner. When such assurance is not available, returned product is rejected or destroyed. Opened packages are not accepted. Accepted product enters the appropriate step of the production system based on findings of product evaluation. Notify FSIS personnel when returned product has been accepted. C: None P: None", "Page 14 of 14 CCP 1 Cooling B: Clostridium perfringens, Clostridium botulinum, and Staphylococcus aureus Cooling: from 120°F to 80°F in 5 hours and 80°F to 45°F in 10 hours (15 hours total cooling time)26 Measure product temperature and the time taken to determine the number of hours product is held in the 120°F to 80°F and 80°F to 45°F temperature zones. Measure product temperature in center of largest piece in the batch and held in the cooler\u2019s warmest spot, and record times between critical temperatures at regular intervals. Each batch Designee If a deviation from the critical limit occurs, the supervisor will: 1. Hold all product produced from last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence 9 CFR 417.3. Once per week a supervisor observes designee perform chill temperature checks. Once per week, a supervisor calibrates thermometers to be used for product and coolers as per the manufacturer\u2019s instructions. A manager performs records review once per week. Temperature Smoke \ Cool Log. Thermometer Calibration Log. Direct Observation Log Records Review Log. Corrective Actions Logs. DATE:

\_\_\_\_\_ APPROVED: \_\_\_\_\_ 26

Taormina, P.J. and Bartholomew, G.W. 2005 Validation of Bacon processing Conditions to Verify Control of Clostridium perfringens and Staphylococcus aureus. Journal of Food Protection. 68(9): 1831-1839 EXAMPLE HACCP PLAN for Bacon (Heat-Treated, Not Fully Cooked) Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who"]},{"file\_name":"FSIS\_GD\_2021\_0003","title":"HACCP Model for Raw Ground Beef (Raw

Non-Intact)","num":"FSIS-GD-2021-0003","id":"53420c0c6d825340f611158271f2fb676d4635019e5f8a1b7e5daae76dd6d833","corpus":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/media\_file/2021-06/HACCP-Model-Beef-Raw-Non-Intact-2021-0003.pdf","type":"pdf","n\_pages":13,"word\_count":4171,"text\_by\_page":["Page 1 of 13 HACCP Model for Raw Non-Intact Beef The United States Department of Agriculture (USDA) published the Pathogen Reduction\Hazard Analysis Critical Control Point (HACCP) Systems Final Rule in July 1996 mandating all USDA inspected meat and poultry establishments implement a HACCP system. Hazard Analysis Critical Control Point (HACCP) is a systematic and scientific method of process control for the production of safe food products. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to improve the safety of their products. The HACCP models\u2019 focus is on product safety, not product quality characteristics. With the rule, FSIS made available a guidebook for the preparation of HACCP plans and a generic model for each food processing category defined in the regulation (9 CFR 417.2(b)(1)). The guidebook and the generic models have been revised since their initial publication to be consistent with current science and policy. FSIS recommends you use the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan. Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used \u201cas is\u201d. Establishments are to tailor the model(s) to fit the establishment\u2019s operation. The model\u2019s critical control points (CCPs) do not necessarily apply to all operations or products. Products or operations may require fewer or more CCPs depending on the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. The food safety critical limits selected must come from scientific documents or other reliable sources. Each model includes references for guidance on the selection of critical limits. This model illustrates how establishments might include, in the production of ground beef, products from beef intended for intact use and from beef intended for non-intact use. The \u201csources\u201d here include beef from: 1) in-house slaughter product that underwent antimicrobial interventions and verification testing for STEC (shiga toxin-producing E. coli strains O157, O26, O45, O103, O111, O121 and O145); 2) purchased product intended for non-intact use with a certificate of analysis (COA) for STEC testing; and 3) product purchased without a COA and intended for intact use. The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis, are HACCP records (CFR 417.5(a)). The selection of processing categories and HACCP models are preliminary steps to completing a hazard analysis. The documents produced during the selection process are HACCP records. Ensure you maintain the documents produced while developing a HACCP plan. For further assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP webpage."],"Page 2 of 13 EXAMPLE PRODUCT DESCRIPTION1 Process \ Product Name: Raw, Non-Intact Beef Process \ Product Name Raw Non-Intact Beef: Ground Beef, Beef Patties,

Jalapeno Cheddar Burgers, Tenderized Steaks, and Cubed (tenderized) Steaks. Important product characteristics (Aw, pH, preservatives, etc.) None How it is to be used2 Intended for cooking. Packaging (durability and storage conditions) Plastic chubs, tray packages, vacuum sealed packages or in butcher paper. Shelf Life and at what temperature Not shelf stable \u2013 Keep refrigerated (7 days at \u226440\u00b0F) or frozen (180 days at \u226410\u00b0F). Where it will be sold (specify intended consumers, especially at-risk populations3) Sold to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI). Labeling Instructions Product name, inspection legend and establishment number, handling statement, net weight statement, ingredients statement, address line, nutrition facts, and safe handling instructions. Validated cooking instructions for needle and blade tenderized products. What special distribution controls are required? None DATE: APPROVED BY: 1 Prior to developing the HACCP plan please read the FSIS Guidebook for the Preparation of HACCP Plans for detailed descriptions of the worksheets and hazard analysis. The FSIS Guidebook for the Preparation of HACCP Plans and the generic HACCP models are intended for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP models are for demonstration purposes only. The models do not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products. 2 The intended use or consumer of the product must be identified in accordance with 9 CFR 417.2(a)(2). Identifying the product's intended use in the product description is one way to meet the regulatory requirements specific to 417.2(a)(2). 3 At-risk populations include young children, the elderly and immunocompromised persons.", "Page 3 of 13 EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL4 Process \ Product Name: Raw, Non-Intact Beef Meat and Meat by-products 1. Beef and beef heart meat intended for non-intact use from In-house slaughter department. 2. Purchased beef intended for non-intact use and with a COA (certificate of analysis). 3. Purchased beef intended for intact use and without a COA. Non-meat food ingredients Wheat, Non-Fat Dry Milk, Soy, Cheese, Vegetables (Jalapenos), binders, spices, seasonings, and solutions for injection. Antimicrobial5 Interventions and processing aids Organic Acid6 Packaging Material Plastic, foam, or paper. Restricted Ingredients and Allergens Allergens - Wheat, Non-Fat Dry Milk, Cheese and Soy. Other None DATE: APPROVED BY: 4 List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. See the FSIS Compliance Guideline Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling for detailed information on allergens. To review restrictions on the use of nitrite and sodium ascorbate or sodium erythorbate, see 9 CFR 424.22(b). 5 FSIS and the Food and Drug Administration (FDA) have a memorandum of understanding (MOU) that establishes the working relationship followed when responding to notifications for the use of food additives (including ingredients) intended for use in the production of FSIS regulated products. FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDA on the requirements under the Federal Food, Drug & Cosmetic Act and its implementing regulations. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products for the list of suitable ingredients. 6There are many

different organic acids (for example, lactic acid, acetic acid). Establishments will need to research the various organic acids and select a product best suited for their unique circumstances and validate its effectiveness." "Page 4 of 13 EXAMPLE PROCESS FLOW

DIAGRAM7 Process \ Product Name: Raw, Non-Intact Beef 1a. Meat Receiving: Beef and beef heart meat from inhouse slaughter HACCP plan intended for non-intact use<sup>8</sup> 7 This is an example flow diagram. Establishments\u2019 flow diagrams for the same product may be different. Establishments determine which steps are included in their process. The steps must represent all relevant hazards in the hazard analysis.<sup>8</sup> The flow diagram and hazard analysis demonstrate the use of three differently sourced beef products. They are from in-house slaughter production (step 1a) that underwent interventions as part of the slaughter HACCP plan, purchased product intended for nonintact use (with COA) (step 1b) and purchased product intended for intact use (without a COA) (step 1c). Note that CCP 1 Organic Acid Application (step 4) is a control measure only for purchased beef intended for intact use and without a COA. Also note the organic acid application occurs before the beef (in step 1c) is ground or subject to other further processing (step 5). Three source types are used to illustrate how establishments might address STEC in incoming materials that have received different interventions and microbial analysis.

1e. Organic Acid Receiving and Storage 1d. Packaging Materials Receiving and Storage 1b. Meat Receiving: Purchased beef intended for non-intact use and with a COA 1c. Meat Receiving: Purchased beef intended for intact use and without a COA 3. Fabrication and Cutting 4. Organic Acid Application CCP 1 2. Cold Storage 6. Packaging and Labeling CCP 2 Product Temperature 7. Rework and Work in Progress 5. Processing (includes: pumping, tenderizing, blending, grinding, stuffing, forming, portioning) 9. Distribution 1f. Ingredient Receiving and Storage 8. Finished Product Cold Storage 10. Returned Product 2. Cold Storage 3. Fabrication and Cutting", "Page 5 of 13 EXAMPLE HAZARD ANALYSIS9 Process \ Product Name: Raw, Non-Intact Beef Column 1 Column 2 Column 3 Column 4 Column 5 Column 6 Ingredient \ Process Step Potential Hazards (introduced or controlled) at this Step<sup>10</sup> Is the Potential Food Safety Hazard Reasonably Likely to Occur (RLTO)? (Yes or No)<sup>11</sup> Justification \ Basis for Decision<sup>12</sup> If yes in Column 3 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels<sup>13</sup> Is this Step a Critical Control Point (CCP)? 9 See Meat and Poultry Hazards and Controls Guide for lists of potential biological, physical, and chemical hazards and frequently used controls and preventive measures.

10 Hazards are grouped into three categories: Biological (B), Chemical (C), and Physical (P). Biological hazards are living organisms. Chemical hazards may be naturally occurring in foods, used or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification.

11 Place the justification for your decision in column 4. Include control measures in column 4 for hazards not reasonably likely to occur and place them in column 5 for hazards reasonably likely to occur. If a hazard is reasonable likely to occur, then a CCP must be addressed at this step or a later step. See FSIS Meat and Poultry Hazards and Controls Guide for a list of frequently used controls.

12 Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced article must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from

an FSIS source, then HACCP system design must be supported by documentary evidence \u2013 that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan. 13 Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation, page 5).", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 6 of 13 1a. Meat Receiving: Beef and beef heart meat from in-house slaughter HACCP Plan intended for non-intact use B: Presence of pathogens: - Shiga-toxin producing Escherichia coli (STEC) (E. coli O157:H7, O26, O45, O103, O111, O121 and O145) - Salmonella B: Outgrowth of pathogens STEC and Salmonella. B: Bovine Spongiform Encephalopathy (BSE) Prions associated with Specified Risk Materials (SRM) (9 CFR 310.22). No No No No STEC known to be present and may cause illness if not controlled. In-house product from slaughter operations was subjected to slaughter sanitary dressing procedures, a Zero Tolerance CCP, and an Organic Acid CCP. In-house product from slaughter operations is subject to the Written Raw Beef Testing SOP for verification of STEC controls. Product that tests positive for STEC is removed from human food supply (inedible), or fully cooked under federal inspection. In-house product from slaughter operations was subjected to slaughter sanitary dressing procedures, a Zero Tolerance CCP, an Organic Acid CCP. Written Cold Storage Program to maintain product \u226445\u00b0F to prevent outgrowth (Tompkin, R.B. 1996).14 Written SRM Program to remove, segregate and dispose of SRMs (9 CFR 310.22). C: None P: None 1b. Meat Receiving: Purchased beef intended B: Presence of pathogens: STEC and Salmonella. No STEC and Salmonella are known to be present and may cause illness if not controlled. 14 The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50\u00b0F (Tompkin, R.B. 1996)", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 7 of 13 for non-intact use and with COA. B: Outgrowth of pathogens STEC and Salmonella. B: BSE \ SRMs No No An annual Letter of Guarantee15 (LOG) from each supplier indicating the STEC and Salmonella controls were applied, and the products are intended for non-intact use. A COA for each purchased lot supporting STEC are not present. Written Raw Beef Testing SOP for verification of STEC controls. Written Receiving Program to receive product \u226445\u00b0F to prevent outgrowth (Tompkin, R.B. 1996). SRMs are required to be removed by supplier prior to receipt. Only boneless beef received and supplier LOG on file. C: None P: None 1c. Meat Receiving: Purchased beef intended for intact use and without COA B: Presence of pathogens: STEC and Salmonella B: Outgrowth of pathogens STEC

and Salmonella B: BSE \ SRMs Yes No No STEC and Salmonella are known to be present and may cause illness if not controlled. Supplier intends for product to remain intact. The product was not subject to interventions and microbial analysis. Written Receiving Program to receive product \u226445\u00b0F to prevent outgrowth (Tompkin, R.B. 1996). Only boneless beef received. SRMs are required to be removed by supplier prior to release into commerce.

Controlled later at CCP 1. Written Raw Beef Testing SOP for verification of STEC and Salmonella controls. C: None P: None 14 An annual update for Letters of Guarantee (LOG) is not a regulatory requirement. Each establishment must determine the frequency at which the LOG are updated. The frequency should be sufficient to adequately describe the supplier\u2019s process to support the decision(s) made.,"Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 8 of 13 1d. Packaging Materials Receiving and Storage B: Contamination with Pathogens No Procedure to protect packaging materials from pests and environmental contamination. C: Non-food grade materials No LOG for packaging materials (9 CFR 317.24) and safely stored. P: Foreign materials No Visual inspection for foreign material. Protect packaging materials from environment. 1e. Organic Acid Receiving and Storage B: None C: Non-Food Grade Chemical No LOG maintained for organic acid. Low risk of receipt of inappropriate chemicals and inappropriate chemical compounds. Identify and list all approved chemicals used in the operations. Check each chemical at receiving to assure that it is on the list at the correct concentration and is appropriately labeled. Safety Data Sheets (SDS). P: None 1f. Ingredient Receiving and Storage B: Contamination with Pathogens No Procedure to protect ingredients from pests and environmental contamination. Spices and flavorings may introduce pathogens. Written Incoming Material SOP include procedures used to examine materials including temperature and sanitary conditions. LOG from suppliers describing quality controls and prevention procedures. C: Allergens No Written Allergen Program to monitor allergens, labels and prevent cross-contamination. P: None 2. Cold Storage B: Outgrowth of pathogens STEC and Salmonella No Written Cold Storage Program to maintain product \u226445\u00b0F to prevent outgrowth (Tompkin, R.B. 1996).,"Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 9 of 13 C: None P: None 3. Fabrication and Cutting B: Outgrowth of pathogens STEC and Salmonella. Yes Processing could result in product temperatures above 45\u00b0F, permitting pathogen growth. Controlled at CCP 2 Product Temperature. Temperature Control SOP for production room temperature. No C: None P: None 4. Organic Acid Application (including solution preparation) B. Presence of pathogens: STEC and Salmonella. B: Outgrowth of pathogens STEC and Salmonella. Yes Yes Eliminate or reduce pathogens. Organic acid applied to purchased product that was intended for intact use and without a COA. Processing could result in product temperatures above 45\u00b0F, permitting pathogen growth. CCP 1 Organic Acid Application. Organic Acid applied and effectiveness verified through inhouse STEC testing.16 Written Raw Beef Testing SOP. Product temperature controlled later at CCP 2. Temperature Control SOP for production room temperature. CCP 1 C: Incorrect acid concentration No Written Acid Preparation and Monitoring Program.17 Chemical used in accordance with supporting 16 If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable

characteristics of the critical operational parameters, such as pressure, temperature, and concentration. (FSIS Compliance Guideline HACCP Systems Validation, page 27). 17 Provide reference for scientific support and validation for effective concentrations and support for critical operational parameters that reduce biological hazards. FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products contains the list of substances that may be used in the production of meat and poultry products. The list contains the allowable amounts and the intended use of the approved antimicrobials. The list (Directive 7120.1) can be used as supporting documentation for chemical hazard controls (safety and suitability).

Directive 7120.1 cannot be used as support for the control of biological hazards because the antimicrobial concentration needed to control bacteria is different from the concentrations required for safety and suitability.", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 10 of 13 documentation and FSIS Directive 7120.1. P: None 5. Processing (includes tenderizing, cubing, blending, grinding, stuffing, forming) B: Presence of pathogens: STEC and Salmonella. B: Outgrowth of pathogens STEC and Salmonella. No Yes Previous controls applied to eliminate STEC (COA for outside sources, in-house slaughter interventions or CCP 1 for outside product without COA) regularly verified through inhouse STEC verification testing.

Processing could result in product temperatures above 45\u00b0F, permitting pathogen growth. Controlled later at CCP 2. Temperature Control SOP for production room temperature.

No C: Allergens No Written Allergen Program to monitor allergens, labels and prevent cross-contamination. P: Foreign Material, Metal. No No history of findings from daily equipment pre-operational inspections (covered in Sanitation SOPs).18 No history of consumer complaints. 6. Packaging and Labeling B: Outgrowth of pathogens STEC and Salmonella. Yes Processing could result in product temperatures above 45\u00b0F, permitting pathogen growth. Product temperature taken at packaging. CCP 2 Product Temperature Temperature Control SOP for production room temperature. CCP 2 C: Allergens No Written Allergen Program to monitor allergens, labels and prevent cross-contamination. P: None 7. Rework and Work in Progress B: Presence of pathogens, STEC and Salmonella. No Previous controls applied to eliminate STEC (COA for outside sources, in-house slaughter interventions or CCP 1 for outside product without COA) verified through in-house STEC verification testing. No 18 Note: this \u201chistorical data\u201d must be supported with evidence from the establishment through the establishment\u2019s history or validation data. When historical data is not available (for example, a HACCP plan for a new process or product), then system design must be supported by other documentary evidence, such as the FSIS Meat and Poultry Hazards and Controls Guide, which states \u201capropriate screening procedure for monitoring equipment\u201d is a frequently used control for foreign material hazards in processing.", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 11 of 13 B: Outgrowth of pathogens STEC and Salmonella. Yes Processing could result in product temperatures above 45\u00b0F, permitting pathogen growth. Controlled later at CCP 2. Temperature Control SOP for production room temperature. C: Allergens No Written Allergen Program to monitor allergens, labels and prevent cross-contamination. P: None 8. Finished Product Cold Storage B: Outgrowth of pathogens STEC and Salmonella. No Written Cold Storage Program to maintain product \u226445\u00b0F to prevent outgrowth (Tompkin, R.B. 1996). C: None P: None 9. Distribution B: None C: None P: None 10. Returned Product B: None Reinspection SOP implemented before accepting returned product. Entity returning the product must demonstrate the product was

held in the appropriate temperature range and in a sanitary manner. When such assurance is not available, returned product is rejected or destroyed. Opened packages are not accepted. Accepted product enters the appropriate step of the production system based on findings of product evaluation. Notify FSIS personnel when returned product has been accepted. C: None

P: None DATE: APPROVED BY: \_\_\_\_\_,"Page 12 of 13

EXAMPLE HACCP PLAN for Raw, Non-Intact Beef Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 1 Organic Acid Application Presence of pathogens: STEC (E. coli O157:H7, O26, O45, O103, O111, O121 and O145) Mix the solution using the volume of water and other components as indicated in the manufacturer\u2019s guidance to achieve 2-5% solution of organic acid.<sup>19</sup> The solution will be applied to each piece until all surfaces are dripping wet and some of the solution drips off. The components are correctly measured and mixed. The solution is correctly applied to beef pieces. Observations documented. Observe the employee measure the components and mix the solution. Observe the application of the solution to beef pieces. Document on the Organic Acid Application Form. Monitor the mixing once at the beginning of the slaughter day. Monitor the application of the solution twice per shift. Designee If a deviation from the critical limit occurs, the manager will:

1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence

9 CFR 417.3 Once per week, a manager will directly observe the designee performing monitoring functions and record their observations. Once per week, a manager will conduct the records review. Once before the shift begins and once during the remainder of the shift a manager verifies the concentration of the organic acid with a test kit recommended by the manufacturer. Organic Acid Application Form Verification Form Corrective Action Form Preshipment Review Form Organic Acid Spray SOP 19 These limits, procedures and frequencies are examples. Limits, procedures and frequencies can vary by establishment. Title 9 CFR 417.2(c) requires each CCP to include a critical limit, and 9 CFR 417.5(a)(2) requires support for the selection and development of the CCP and critical limits. Title 9 CFR 417.2(c) requires the HACCP plan to include monitoring and verification procedures and frequencies, and 9 CFR 417.5(a)(2) requires support for the select procedures and frequencies. Title 9 CFR 417.4 requires each HACCP plan to be validated. If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. (FSIS Compliance Guideline HACCP Systems Validation, page 27).","Page 13 of 13 EXAMPLE HACCP PLAN for Raw, Non-Intact Beef Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 2 Product Temperature Pathogen outgrowth: STEC (E. coli O157:H7, O26, O45, O103, O111, O121 and O145) Internal product temperature is \u226445\u00b0F at packaging. Product temperature is measured at packaging. Observations documented. Observe the employee measure product temperature with a

handheld digital thermometer. Record results on the Product Temperature Form. Twice each day Designee If a deviation from the critical limit occurs, the manager will: 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence 9 CFR 417.3 Once per week, a manager will directly observe the monitoring activity, conduct the records review and calibrate the thermometer (per manufacturer\u2019s instructions). Product Temperature Form Verification Form Corrective Action Form Pre-shipment Review Form Thermometer Calibration Form DATE: APPROVED BY:

\_\_\_\_\_, {"file\_name": "FSIS\_GD\_2021\_0004", "title": "HACCP Model for Ready-to-Eat, Heat-Treated, Shelf-Stable (Beef Jerky)", "num": "FSIS-GD-2021-0004", "id": "9f02130b8cef55235b0a90bf52d2b1d8676a9b290eea7e7bbf5dbab53254b48c", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-06/HACCP-Model-Ready-to-Eat-Heat-Treated-Shelf-Stable-Beef-Jerky-2021-0004.pdf", "type": "pdf", "n\_pages": 15, "word\_count": 4714, "text\_by\_page": ["Page 1 of 15 A Generic HACCP Model for Ready-to-Eat, Heat-Treated, Shelf-Stable (Beef Jerky) The United States Department of Agriculture (USDA) published the Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) Systems Final Rule in July 1996. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to address safety hazards reasonably likely to occur in their production process. Therefore, this HACCP model\u2019s focus, and the focus of the other HACCP models, is on product safety, not product quality characteristics. With the rule, FSIS made available a Guidebook for the Preparation of HACCP Plans and a generic model for each food processing category defined in the regulation (9 CFR 417.2(b)(1)). The guidebook and the generic models have been updated since their initial publication to be consistent with current science and policy. FSIS recommends you use of the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan. Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used \u201cas is\u201d. FSIS recommends that establishments tailor the model(s) to fit the establishment\u2019s operation. The model\u2019s critical control points (CCPs) do not necessarily apply to all operations or products in the product category. Products or operations may require fewer or more CCPs depending on the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. The food safety critical limits selected must come from scientific documents or other reliable sources to meet regulatory validation requirements. Each model includes references for guidance on the selection of critical limits. The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis, are HACCP records ((CFR 417.5(a)). The selection of processing categories and HACCP models are preliminary steps to completing a hazard analysis. The documents produced during the selection process are HACCP records. Ensure you maintain the documents produced while developing a HACCP plan. For further

assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP webpage.", "Page 2 of 15 EXAMPLE PRODUCT DESCRIPTION1 PROCESS \ PRODUCT NAME: Beef Jerky (Ready-to-Eat, Heat-Treated, Shelf-Stable) Process \ Product Name Beef Jerky (Ready-to-Eat, Heat-Treated, Shelf-Stable) Important Product Characteristics2 (water activity, pH, Preservatives, etc.) Contains Sodium Nitrite and Sodium Erythorbate Water activity < 0.85 Intended Use Ready-to-eat3 Packaging (Durability and storage conditions) Plastic vacuumed packed single-serve units and stored at ambient temperature Shelf Life and at what temperature 240 days unopened and not refrigerated Where it will be sold (specify intended consumers, especially at-risk populations4) Sold to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI). Labeling instruction Product name, inspection legend and establishment number, handling statement, net weight statement, ingredients statement, allergen statement, address line, and nutrition facts. What special distribution controls are required? None DATE:

\_\_\_\_\_ APPROVED BY: 1 Prior to developing the HACCP plan please read the FSIS Guidebook for the Preparation of HACCP Plans for detailed descriptions of the worksheets and hazard analysis. The FSIS Guidebook for the Preparation of HACCP Plans and the generic HACCP models are intended for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP models are for demonstration purposes only. The models do not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products. 2 This jerky example is a product cured with sodium nitrite. See the Food Standards and Labeling Policy Book for jerky standards. Examples of jerky standards are products that have a moisture to protein ratio of 0.75:1 or less, they may be cured or uncured, and sodium nitrite is not required. Establishments should gather documentation to support the moisture to protein ratio standard using inplant data collected during initial validation and on-going verification. 3 The intended use or consumer of the product must be identified in accordance with 9 CFR 417.2(a)(2). Identifying the product\u2019s intended use in the product description is one way to meet the regulatory requirements specific to 417.2(a)(2). 3 At-risk populations include young children, the elderly and immunocompromised persons.", "Page 3 of 15 EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL5 Process \ Product Name: Beef Jerky (Ready-to-Eat, Heat-Treated, Shelf-Stable) Meat and Meat by-products Boneless beef top rounds and top sirloins Non-Meat food ingredients Sugar, Salt, Soy Sauce (water, wheat, soybeans, salt, sodium benzoate, brewing starter (*Aspergillus Sojae*)), Flavor and Spice Mixture Antimicrobials6 and processing aids None Packaging material Plastic vacuum bags Restricted ingredients and allergens Sodium Nitrite, Sodium Erythorbate, Soy Sauce (soy and wheat) Other None DATE: \_\_\_\_\_ APPROVED BY: 4 List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. See the FSIS Compliance Guideline Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling for detailed information on allergens. To review restrictions on the use of nitrite and sodium ascorbate or sodium erythorbate, see 9 CFR 424.22(b). 6 FSIS and the Food and Drug Administration (FDA) have a memorandum of understanding (MOU) that establishes the working relationship

followed when responding to notifications for the use of food additives (including ingredients) intended for use in the production of FSIS regulated products. FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDA on the requirements under the Federal Food, Drug & Cosmetic Act and its implementing regulations. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat Poultry and Egg Products for the list of suitable ingredients.", "Page 4 of 15

EXAMPLE PROCESS FLOW DIAGRAM<sup>7</sup> Process \ Product Name: Beef Jerky (Ready-to-Eat, Heat-Treated, Shelf-Stable)<sup>8</sup> 11. Returned Product<sup>9</sup> 6 This is an example flow diagram.

Establishments\u2019 flow diagrams for the same product may be different. Establishments determine which steps are included in their process. The steps must represent all relevant hazards in the hazard analysis. 7 For more information on general processing steps used in jerky production see the FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments. As discussed on pages 6-7, antimicrobial interventions may also be added before, during, or after marinating the strips of raw beef to increase the level of pathogen reduction beyond that achieved by cooking alone. 9 The Returned Product step (12) is shown as not connected to another process step. Returned product may re-enter the production system at different process steps depending on condition or food safety concerns. Returned product may be relabeled, repackaged, or discarded. 8. Packaging and Labeling 9.

Metal Detection 10. Storage and Distribution 1. Beef Receiving 1a. Non-Meat Ingredients Receiving and storage 1b. Packaging Receiving and Storage 2. Cold Storage 3. Slicing 5. Marinate Beef and Place on Racks or Trays 6. Cooking CCP 1 (Lethality Step) 7. Drying CCP 2 4. Weighing and Mixing Marinade Ingredients", "Page 5 of 15 EXAMPLE HAZARD ANALYSIS<sup>10</sup> Beef Jerky: Ready-to-Eat, Heat-Treated, Shelf-Stable 9 See FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments for suggested best practices and a list of scientific and technical support documents. 11 Hazards are grouped into three categories:

Biological (B), Chemical (C), and Physical (P). Biological hazards are living organisms. Chemical hazards may be naturally occurring in foods, used, or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the

Preparation of HACCP Plans for more information about hazards identification. 12 Place the justification for your decision in column 4. Include control measures in column 4 for hazards not reasonably likely to occur and place them in column 5 for hazards reasonably likely to occur. If a hazard is reasonable likely to occur, then a CCP must be addressed at this step or a later step.

See FSIS Meat and Poultry Hazards and Controls Guide for a list of frequently used controls. 13

Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced article must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from an FSIS program, then HACCP system design must be supported by documentary evidence \u2013 that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peerreviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan. 14 Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an

establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation, page 5). 15 Shiga toxin-producing *Escherichia coli* (STEC) includes serogroups O157:H7, O26, O45, O103, O111, O121 and O145). Column 1 Column 2 Column 3 Column 4 Column 5 Column 6 Ingredient \ Process Step Potential Hazards (introduced or controlled) at this Step11 Is the Potential Food Safety Hazard Reasonably Likely to Occur (RLTO)? (Yes or No)12 Justification \ Basis for Decision in Column 313 If yes in Column 3 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels?14 Is this Step a Critical Control Point (CCP)? 1. Beef Receiving B: Pathogens, *Escherichia coli* O157:H7 (STEC)15, *Salmonella* Yes It is well documented that raw beef may be contaminated with pathogens. Controlled at the Cooking CCP 1 process step. Written Beef Receiving SOP (Standard Operating Procedure) with purchase specifications that prevent hazards including the temperature of the No", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 6 of 15 16 The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50\u00b0F (Tompkin, R.B. 1996). 17 An annual update is not a regulatory requirement. Each establishment must determine the frequency at which the Letters of Guarantee are updated. The frequency should be sufficient to adequately describe the supplier\u2019s process. B: Bovine Spongiform Encephalopathy (BSE) Prions No Specified Risk Materials (SRMs) SOP ensures SRMs are not associated with beef products. product at receiving. Product is received at temperatures that preclude bacterial growth (<45\u00b0F, (Tompkin, R.B. 1996).16 Annual Letter of Guarantee17 (LOG) is on file for each supplier of incoming beef. C: None P: Foreign Material No Written Foreign Material SOP for visual inspection of containers and product at receiving. 1a. Non-Meat Ingredients Receiving and Storage B: Pathogens, *Salmonella* Yes Spices and flavorings used in the marinade may introduce pathogens. Controlled at the Cooking CCP 1 process step. Letters of Guarantee from suppliers describing quality controls and prevention procedures. Written Incoming Material SOP for procedures to examine incoming materials including temperature and sanitary conditions. Non-meat ingredients that are not shelf-stable are received at temperatures that preclude bacterial growth (<45\u00b0F, (Tompkin, R.B. 1996). Written Sanitation SOP for procedures used to protect ingredients from environmental contamination. No", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 7 of 15 C: Allergens (soy and wheat) Restricted Ingredients (Sodium Nitrite and Sodium Erythorbate) No Soy and wheat are both big 8 allergens. Sodium Nitrite is a restricted ingredient. Letters of Guarantee from suppliers describing quality controls and prevention procedures. Written Incoming Material SOP for procedures to verify proper identification of allergenic and restricted ingredients for each lot of incoming materials. Approved supplier program and ongoing communication with suppliers to

verify Letters of Guarantee. Written Sanitation SOP for procedures to ensure allergen containing products are segregated to prevent contamination of allergen-free products. P: None 1b. Packaging Receiving and Storage B: Contamination with Pathogens No Procedure to protect packaging materials from environment. C: Non-food grade materials No Packaging materials may introduce chemical hazards. Letter of Guarantee for all packaging materials describing quality controls and prevention procedures. Written Incoming Material SOP for procedures to examine incoming materials including sanitary conditions. Written Sanitation SOP for procedures used to protect packaging materials from environmental contamination. P: None 2. Cold Storage B: Pathogen outgrowth, No Prerequisite Temperature Control SOP (<45\u00b0F, Tompkin, R.B. 1996).", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 8 of 15 18 Note: this \u201chistorical data\u201d must be supported with evidence from the establishment through the establishment\u2019s history or validation data with reference to the actual SOP or prerequisite program. When historical data is not available (for example, a HACCP plan for a new process or product), then system design must be supported by other documentary evidence. Such as the FSIS Meat and Poultry Hazards and Controls Guide which states \u201cAppropriate screening procedure for monitoring equipment or product such as metal detector, screens or X-ray detector\u201d are frequently used controls for foreign material hazards in processing. 19 This Foreign Material SOP (prerequisite program) should have details on how this procedure is preventing the hazard from occurring (such as metal prevention controls) as well as the on-going verification procedures. These controls should be evident within the written document upon review. The Foreign Material SOP and plant data related to on-going verification activities then become part of recordkeeping and historic data. STEC, Salmonella C: None P: None 3. Slicing B: Pathogen outgrowth, STEC, Salmonella No Written Good Manufacturing Practices to prevent or minimize cross-contamination. The presence and growth of pathogens is prevented or minimized so that the pathogen load is not higher than what the process is designed to reduce. Prerequisite Temperature Control SOP (<45\u00b0F, Tompkin, R.B. 1996) to prevent outgrowth of microorganisms. C: None P: Foreign material (metal) contamination No Written Equipment Examination and Preventive Maintenance on Slicer SOP to prevent metal contamination from equipment. Written Prerequisite Program for Metal detection for operating and monitoring metal detection equipment at end of packaging line prior to boxing; plant records<sup>18</sup> indicate very low incidence of metal contamination indicating that metal contamination is not a hazard reasonably likely to occur.<sup>19</sup> 4. Weighing and Mixing Marinade Ingredients B: None C: Restricted Ingredients (Sodium nitrite No Incorrect levels of Sodium Nitrite or Sodium Erythorbate added to marinade mix may result in toxic conditions, uncured product. Product", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 9 of 15 20 Provide reference for scientific support and validation for effective concentrations and support for critical operational parameters that reduce biological hazards. FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products contains the list of substances that may be used in the production of meat and poultry products. The list contains the allowable amounts and the intended use of the approved antimicrobials. The list (Directive 7120.1) can be used as supporting documentation for chemical hazard controls (safety and suitability). Directive 7120.1 cannot be used as support for the control of biological hazards because the antimicrobial concentration needed to control bacteria is different from the concentrations

required for safety and suitability. and sodium erythorbate) Soy Sauce (soy and wheat) containing allergens but not labeled accordingly. Written SOP for determining batches and for weighing marinade spices and restricted ingredients.<sup>20</sup> Written Sanitation SOP to prevent crosscontamination of allergenic ingredients. Written labeling SOP to ensure application of correct label to prevent inadvertent consumption of allergens by consumer. P: None 5.

Marinate Beef and Place on Racks or Trays B: Pathogen outgrowth STEC, Salmonella No Marination performed under refrigeration. Prerequisite Temperature control SOP (<45\u00b0F Tompkin, R.B. 1996) to prevent outgrowth of microorganisms. C: Soy Sauce (soy and wheat) No Sanitation SOP prevents cross-contamination between products with and without allergens. P: None 6. Cooking (CCP 1, Lethality B Pathogens, STEC, Salmonella Yes Raw beef may be contaminated with pathogens. Cook to appropriate time, temperature, and humidity option to achieve at least a 5.0 log<sub>10</sub> reduction of Salmonella Yes CCP 1", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 10 of 15 21 See FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments for information that is more detailed and for scientific support. 22 For time, temperature and humidity combinations, refer to FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Meat and Poultry Products and Revised Appendix A. If alternative methods are used, see the validation and scientific support for the alternative lethality step as described in the FSIS Compliance Guideline HACCP Systems Validation. 23 If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. However, if an establishment implements different critical operational parameters in the process from the scientific support, or the scientific support identified does not contain microbiological data, then the establishment should collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological validation data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameters (FSIS Compliance Guideline HACCP Systems Validation, page 27). 24 See FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments for more detailed information and for scientific support. If alternative methods are used, validation and scientific support for the alternative lethality step as described in the FSIS Compliance Guideline HACCP Systems Validation. step) 21,22 species and at least a 5.0 log<sub>10</sub> reduction for STEC.<sup>23</sup> Dampers are closed within 30 minutes of product being placed in the heated oven to prevent product drying and increased heat-tolerance of Salmonella. C: Soy Sauce (soy and wheat) No Sanitation SOP prevents cross-contamination between products with and without allergens. P: None 7. Drying<sup>24</sup> CCP 2 B: Clostridium perfringens and Clostridium botulinum outgrowth during drying. Staphylococcus aureus outgrowth and Yes Drying at low temperatures while the water activity is above the growth limit (<0.93) may allow outgrowth of Clostridium perfringens and Clostridium botulinum. Inadequate drying may allow Staphylococcus aureus outgrowth and enterotoxin formation, and Listeria monocytogenes

outgrowth in product during storage. Drying at oven temperatures \u2265 170\u00b0F until water activity decreases below the growth limit of Clostridium perfringens and Clostridium botulinum (<0.93) to prevent outgrowth. Dry to water activity of 0.85 or less to prevent the growth of toxin producing bacteria (*Staphylococcus aureus*) (\u22640.85) and *Listeria monocytogenes* during storage (<0.92). Yes CCP 2","Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 11 of 15 25 See FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B for more information on water activity levels that preclude the growth of Clostridium perfringens and Clostridium botulinum. 26 Establishments may choose to test indirect and non-food contact surface samples as part of their *Listeria* Control Program, although they are not required by the *Listeria* Rule. Sampling indirect and non-food contact surfaces can give the establishment more information about possible harborage and cross-contamination in the environment. For more information see the FSIS Compliance Guideline: Controlling *Listeria monocytogenes* in Post-lethality Exposed RTE Meat and Poultry Products. enterotoxin formation. *Listeria monocytogenes* outgrowth during storage. FSIS Compliance Guideline for Meat and Poultry Jerky Produced in Small and Very Small Establishments. FSIS Compliance Guideline: Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products. FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B.25 C: Soy Sauce (soy and wheat) No Sanitation SOP prevents cross-contamination between products with and without allergens. P: None 8. Packaging and Labeling B: *Listeria monocytogenes* and growth of toxin-producing molds No *Listeria monocytogenes* is addressed with a prerequisite program for employee hygiene and strict adherence to written Sanitation SOP. The SOP includes testing of food contact surfaces and non-food contact surfaces<sup>26</sup> in the ready-to-eat (RTE) packaging area. The growth of *Listeria monocytogenes* in the postlethality environment is not reasonably likely to occur due to CCP 2, as is required to qualify for Alternative 2b.,"Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 12 of 15 SOP for oxygen free packaging makes mold growth unlikely. C: Improperly labeled allergens: Soy Sauce (soy and wheat) No Written Labeling SOP makes hazard unlikely. P: None 9. Metal Detection B: None C: None P: Metal Fragment Contamination No Written Prerequisite Program for Metal detection for operating and monitoring metal detection equipment at end of packaging line prior to boxing. Plant records indicate very low incidence of metal contamination indicating that metal contamination is not a hazard reasonably likely to occur. 10. Storage and Distribution B: None C: None P: None 11. Returned Product B: None Reinspection SOP implemented before accepting returned product. Entity returning the product must demonstrate the product was held in the appropriate temperature range and in a sanitary manner. When such assurance is not available, returned product is rejected or destroyed. Opened packages are not accepted. Accepted product enters the appropriate step of the production system based on findings of product evaluation. Notify FSIS personnel when returned product has been accepted. C: None","Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 13 of 15 DATE: \_\_\_\_\_ APPROVED BY: P: None","Page 14 of 15 27 This information is best suited for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9

CFR) Part 417. The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products. 28 At a minimum, establishments should maintain documentation that supports that when the oven dampers are closed, humidity is maintained in the ovens in addition to documentation that supports the oven dampers are closed for at least one hour or 50% of the cooking time \u2013 whichever is longer. Establishments may also choose to target recommended wet-bulb and relative humidity levels as shown in this example. See page 21 of the FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments for specific guidance for using the sealed oven option to introduce relative humidity. 29 In this example the critical limit used is from FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Meat and Poultry Products and Revised Appendix A. If other references are used for the critical limit determination and justification, then the entire research article with accompanying critical parameters must be kept on file for HACCP validation records. 30 Probe placements determined during cold-spot determination conducted under in-plant validation. EXAMPLE BEEF JERKY HACCP Plan27 Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 1 Cooking (Lethality Step) B: Pathogens Escherichia coli O157:H7 (STEC)(E. coli O157:H7, O26, O45, O103, O111, O121 and O145), Salmonella, Listeria monocytogenes Appendix A Internal product temperature 145\u00b0F for \u2265 4 minutes \u2265125\u00b0F wetbulb temperature for \u2265 1 hour28 \u226527% relative humidity for \u2265 1 hour Oven is sealed for 50% of the cooking time or 1 hour (whichever is longer)29 within 30 minutes of product being placed in the heated oven. Internal product temperature 30 and dwell time, wetbulb temperature, relative humidity, length of time oven is sealed. An employee will review records from smokehouse computerized system with internal product temperature, wet-bulb temperature, relative humidity, and time for each lot at completion of cooking cycle. The employee will review records from smokehouse computerized system with times dampers were open and closed at completion of cooking cycle. Continuous for each oven batch (lot) Designee If a deviation from the critical limit occurs, the designee will immediately report to a manager. The manager will: 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence. 9 CFR 417.3 Once every two weeks, per smokehouse manual, a manager will calibrate the dry bulb and wet bulb thermometers and the thermometer used for internal product temperatures per manufacturer\u2019s procedures. Once per week, a manager will observe the designee reviewing smokehouse records. Once per shift, a manager will observe the designee performing the relative humidity check. Once per week, a manager will review all records maintained. Smokehouse Log from computerized system Corrective Actions Log Thermometer Calibration Log Direct Observation Log Records Review Log", "Page 15 of 15 EXAMPLE BEEF JERKY HACCP Plan Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 2 Drying31 Clostridium perfringens and Clostridium botulinum outgrowth. Staphylococcus aureus outgrowth and enterotoxin formation. Listeria monocytogenes (Lm) outgrowth during storage.

Oven temperature setting of  $\leq 170^{\circ}\text{F}$ . Dry to water activity (aw) of 0.85 or less. Measure the temperature in the smokehouse using a drybulb thermometer. Measure water activity of product with a water activity meter per manufacturer's instructions. An employee will review smokehouse temperature records at the end of drying cycle and before the product is removed from the smokehouse. At the end of the drying cycle, an employee will check the water activity of at least 6 pieces of jerky chosen randomly from throughout the lot. Each oven batch (lot) Designee If a deviation from the critical limit occurs, the designated employee will immediately report to the manager. The manager will: 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence. 9 CFR 417.3 Once every two weeks, a manager will calibrate the dry bulb and wet bulb thermometers per manufacturer's procedures. Once per week, a manager will observe the employee reviewing smokehouse records. Once per shift, a manager will observe the employee performing the water activity check. Once per shift, a manager will review all records maintained. Before each use, a manager will calibrate the water activity meter per manufacturer's instructions. Water activity / Drying Log Corrective Actions Log Water Activity Calibration Log Direct Observation Log Records Review Log Thermometer calibration log DATE:

\_\_\_\_\_ APPROVED BY: 31 Moisture to protein ratio should be checked during validation process to ensure the jerky produced meets the standard of identity. However, water activity is a more accurate measurement for food safety. See FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments for more information."]}, {"file\_name": "FSIS\_GD\_2021\_0005", "title": "FSIS Guideline for Controlling Salmonella in Raw Poultry", "num": "FSIS-GD-2021-0005", "id": "7bac42c8cd7b489a9963d474e95428439603deb5b8cefbd6020ed5cd0be4164c", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-07/FSIS-GD-2021-0005.pdf", "type": "pdf", "n\_pages": 91, "word\_count": 28621, "text\_by\_page": ["This guideline is designed to help poultry establishments, including those that are small and very small, to: Identify and implement pre- and post-harvest interventions to control Salmonella as part of their HACCP system Utilize microbial testing results to monitor the performance of the HACCP system and inform decision-making FSIS Guideline for Controlling Salmonella in Raw Poultry June 2021", "1 Table of Contents Preface"]}

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.....	89","4 Preface This is a revised version of the FSIS Guideline for Controlling Salmonella and Campylobacter in Raw Poultry. This 2021 revision of the guideline was split into two separate documents in response to comments received: one for Salmonella and one for Campylobacter. This guideline represents FSIS\u2019 current thinking on these topics and should be considered usable as of its issuance. The information in this guideline is provided to assist poultry slaughter and processing establishments in controlling hazards and meeting the FSIS pathogen performance standards. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the regulations. Under the regulations, establishments may choose to implement different procedures than those outlined in this guideline, but they would need to validate and support how those procedures are effective. This guideline is focused on small and very small establishments in support of the Small Business Administration\u2019s initiative to provide small businesses with compliance assistance under the Small Business Regulatory Enforcement Fairness Act (SBREFA). However, all poultry establishments may apply the recommendations in this guideline. It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective Hazard Analysis Critical Control Point (HACCP) systems. FSIS has other guidance documents available for establishments that slaughter and process raw poultry products, including: \u2022 Information about the chilling of poultry products can be found in the Modernization of Poultry Slaughter Inspection: Amendments to Chilling Requirements. \u2022 Information about designing and implementing a microbiological sampling plan can be found in the FSIS Compliance Guideline: Modernization of Poultry Slaughter Inspection - Microbiological Sampling of Raw Poultry. \u2022 Information about controlling Campylobacter and Salmonella in chicken liver can be found in the FSIS Guideline: Chicken Liver. \u2022 Information about controlling Campylobacter can be found in the FSIS Guideline for Controlling Campylobacter in Raw Poultry."5 Congressional Review Act

Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this guideline is not a \u201cmajor rule,\u201d as defined by 5 U.S.C. 804(2). Reason for Issuing the Guideline FSIS developed this guideline to assist establishments that slaughter or process raw poultry products to prevent and minimize the risk of Salmonella in their operations. FSIS is updating and reissuing this guideline as part of continuing efforts to assess the scientific support and new technologies available to improve the effectiveness of policy documents and recommendations to industry. Specifically, FSIS revised this guideline to respond to public comments on the 2015 guideline and provide updated information for establishments to use to control pathogens in raw poultry products with the goal of reducing human illnesses from consuming poultry contaminated with Salmonella. In addition, since the 2015 revision, FSIS has implemented pathogen performance standards for chicken parts and comminuted chicken and turkey products. This guideline can assist establishments in meeting the Salmonella performance standards and reducing illnesses associated with Salmonella. This guideline describes concerns and controls for each step in the poultry slaughter process. However, the interventions suggested in this guideline cannot overcome poor preharvest production practices, poor sanitary practices in slaughter and dressing, or poor slaughter and further processing facility sanitation. Establishments can use this guideline to improve management practices, make changes at the appropriate locations, and improve process control. As a result, establishments can produce raw poultry products that have less contamination with pathogens, including Salmonella. Again, the information in this guideline is provided as guidance to assist poultry slaughter and processing establishments in reducing Salmonella contamination and is not legally binding from a regulatory perspective.<sup>6</sup>

Changes from the Previous Version of the Guideline This guideline is final. FSIS will update this guideline as necessary when new information becomes available. FSIS made the following specific changes to the guideline to reflect the peer-reviewed literature and address public comments received on the previous version of the guideline:

- \u2022 Removed the word \u201ccompliance\u201d from the document title and throughout the document to clarify that this document does not constitute regulatory requirements;
- \u2022 Separated the 2015 Draft Compliance Guideline for Controlling Salmonella and Campylobacter in Raw Poultry (4th Edition) into two distinct guidelines, one addressing Salmonella control and one addressing Campylobacter control;
- \u2022 Removed redundant language related to other current FSIS guidelines, providing hyperlinks to those resources where appropriate;
- \u2022 Added relevant, current peer-reviewed science related to poultry slaughter and processing, including a complete revision of the bedding and litter section, and additional literature resources specific to Salmonella;
- \u2022 Added information about antimicrobial carryover and considerations to mitigate its effect on microbiological sampling;
- \u2022 Updated data tables outlining the relative risk of various source materials used in further processed poultry products based on recent FSIS data; and
- \u2022 Updated the sanitizer data table in response to a public comment that pointed to a more recent revision.

How to Effectively Use the Guideline This guideline is organized to provide users with the current science and recommendations. To use this guideline, FSIS recommends that readers use the navigation headings to move efficiently through the document sections of interest. Hyperlinks, where provided, will quickly take you to the correct place in the document electronically and are also provided to other complementary documents. The reference list at the end of the document provides resource material used in

the development of this guidance (References).", "7 Questions Regarding Topics in this Guideline If after reading this guideline you still have questions, FSIS recommends searching the publicly posted Knowledge Articles (\u201cPublic Q&As\u201d) in the askFSIS database. If after searching the database, you still have questions, refer them to the Office of Policy and Program Development through askFSIS and select \u201cSampling\u201d as the Inquiry Type or by telephone at 1-800-233-3935. Documenting these questions helps FSIS improve and refine present and future versions of the guideline and associated issuances. Background FSIS regulated poultry slaughter and processing establishments are required to determine the \u201cfood safety hazards that can occur before, during, and after entry into the establishment\u201d (9 CFR 417.2(a)) in their hazard analysis. Pre-harvest interventions, adequate sanitary dressing procedures at slaughter, and adequate sanitary conditions during further processing are a part of an integrated approach to reduce the public health impact of Salmonella. This pathogen is a hazard that establishments producing raw poultry products can control through a HACCP plan or prevent in the processing environment through a Sanitation Standard Operating Procedures (Sanitation SOPs) or other prerequisite programs. FSIS has determined that contamination of poultry carcasses and parts by fecal material and enteric pathogens (including Salmonella spp.) is a hazard reasonably likely to occur (RLTO) in poultry slaughter establishments unless addressed in a Sanitation SOP or other prerequisite program.<sup>1</sup> For this reason, if an establishment relies on its Sanitation SOP or other prerequisite program to address enteric pathogens, the establishment\u2019s HACCP system must identify why such Sanitation SOP or other prerequisite program results in the enteric pathogens being not reasonably likely to occur (NRLTO). The measures outlined in this document will be most effective at decreasing Salmonella in raw poultry products when considered together. Food Safety and the HACCP Framework Unlike the production of ready-to-eat (RTE) product in which a lethality treatment destroys pathogens of public health concern, slaughter and further processing 1 79 FR 49565 (p.49613) Key Point Federally inspected poultry establishments are required to conduct a hazard analysis as part of their Hazard Analysis and Critical Control Point (HACCP) system. The hazard analysis is required to include \u201cfood safety hazards that can occur before, during, and after entry into the establishment\u201d (9 CFR 417.2(a)).", "8 operations do not have as many available treatment options capable of destroying all pathogens in raw products. Under HACCP regulations, establishments are required to have a system designed to ensure that poultry is processed in a manner that prevents and controls potential contamination hazards that are RLTO during slaughter and processing. Slaughter establishments have controls and procedures in place to reduce the level of incoming contamination on the exterior of the birds and to reduce or mitigate any contamination that can occur throughout the slaughter process. Establishments must document the controls and procedures they use to prevent contamination in their HACCP plan, Sanitation SOP, or applicable prerequisite program in accordance with 9 CFR 417.5.

<https://www.govinfo.gov/content/pkg/CFR-2020-title9-vol2/pdf/CFR-2020-title9-vol2sec417-2.pdf> HACCP Plan to Control Hazards If the establishment decides through its hazard analysis that Salmonella is a food safety hazard RLTO, 9 CFR 417.2 requires that the establishment\u2019s HACCP plan address this food safety hazard. The HACCP plan must meet all parts of 9 CFR 417.2(c), including having a critical control point (CCP) to address the pathogen. A CCP is defined as a point, step, or procedure in a food process at which a control

can be applied, and, as a result, a food safety hazard can be prevented, eliminated, or reduced to an acceptable level. As an example, an establishment might have a CCP at a point during slaughter for applying a validated antimicrobial intervention to carcasses. FSIS requires the establishment to develop critical limits (CLs) for CCPs to control hazards that are RLTO (9 CFR 417.2(c)(3)). CLs are the parameters that indicate whether the control measure at the CCP is in or out of control. A critical limit is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard (9 CFR 417.1). An example of CLs are the critical operational parameters for an antimicrobial intervention applied to carcasses at a point during slaughter. For example, critical operational parameters of an antimicrobial applied with a spray bar may include concentration, pH, and spray pressure. To determine whether CLs are being met, establishments must monitor them (9 CFR 417.2(c)(4)). Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification. Monitoring procedures usually involve either a measurement or an observation. For the example of a CCP of applying an antimicrobial intervention during slaughter, monitoring activities might include measuring the concentration, pH, and other critical limits of the antimicrobial intervention, at a frequency sufficient to determine whether the CCP is under control. If a CL is not met, the establishment must meet the corrective action requirements in 9 CFR 417.3. To document whether the establishment meets its CCP, the establishment records its measurements and corrective actions as part of a recordkeeping system." Verification ensures that the HACCP plan is being implemented as written and confirms the accurate monitoring of the CCPs. Guidance on validation and ongoing verification is available in the FSIS HACCP Systems Validation guideline. GENERAL CONSIDERATIONS Sanitation Cleaners and Detergents Cleaning followed by sanitizing is essential to control pathogens (e.g., *Salmonella*) in an establishment. Pathogens can attach to processing equipment or grow on food materials left behind on product contact surfaces. Properly cleaning an area requires removing debris, including dry pickup and pre-rinsing of gross soils, before using a cleaning agent (detergent). Alkaline detergents are frequently used as cleaning agents and vary in strength; examples include sodium hydroxide, nitrous oxide, sodium silicate, and trisodium phosphate (TSP). Acid detergents are also used as cleaning agents and vary in strength; examples include hydrochloric, sulfuric, phosphoric, and acetic acids. Quaternary ammonia is a type of synthetic detergent. Regardless of type of detergent used, they will need to be in contact with surfaces for enough time to ensure effectiveness of the product. Establishments can follow the manufacturer's instructions regarding application and contact time for detergents. Once a surface has been properly cleaned, sanitizers can be applied. There are several types of chemical sanitizers commonly used: quaternary ammonia, industrial strength bleach, iodine compounds, peracetic acid, steam, and ozone. There are areas within an establishment where it may be better to use one type of sanitizer over another. For example, to sanitize aluminum equipment, rubber belts, and tile walls, iodophors (e.g., betadine, iodine) are recommended. Active chlorine is best for other types of walls, wooden crates, and concrete floors. A study of *Salmonella* on food contact surfaces demonstrated biofilm formation on plastic, steel, and concrete surfaces; while iodophors and chlorine sanitizers were still generally effective, a higher contact time or concentration may be necessary when biofilms are present (Joseph, et al.,

2000). A listing of various sanitizers and their associated properties is presented below in Table 1." , "10 Table 1: Factors to Consider in Sanitizer Selection (Ecolab, 2016, 2020) Table 1 provides a comparison of several classes of sanitizers (X-axis) by associated properties (Y-axis).

\*Corrosion properties will depend on grade of stainless steel; ratings were provided assuming 304 stainless steel. \*\*\u201cVariable\u201d indicates that the sanitizer can be a formulated to specific outcome. As outlined in 9 CFR 416, each establishment\u2019s Sanitation SOPs, other prerequisite programs, or HACCP plans should address procedures that ensure that all slaughter and further processing equipment, food contact surfaces, and employees\u2019 hands, tools, and clothing are maintained in a sanitary manner to minimize the potential for cross contamination within and among lots of production. Establishments must develop and effectively implement Sanitation SOPs that address, at a minimum, the handling and cleaning and sanitizing of food contact surfaces, equipment, utensils, implements, and processing areas. The Sanitation SOPs must indicate the frequency with which these items will be cleaned and sanitized and the frequency at which the establishment will verify their cleanliness and removal of product residues." , "11 In addition to achieving pre-operational sanitation, maintaining operational sanitation can minimize cross contamination during poultry slaughter and further processing. Establishments are required to clean and sanitize both food contact and non-foodcontact surfaces as frequently as necessary to prevent the creation of insanitary conditions (9 CFR 416.4). Operational sanitation extends to active practices as well as maintaining sanitary equipment. Sanitation procedures are required to prevent crosscontamination from equipment, personnel, traffic, air flow, tables, and floors to product. Sanitation SOPs are required to ensure establishment employees regularly clean and disinfect knives or other product contact surfaces during use. When employees use knives during carcass trimming or cut-up operations, 9 CFR 416.4(a) requires an establishment to ensure that sanitation is maintained between carcasses. This may be achieved, in part, by sanitizing knives in 180\u00b0F water or antimicrobial-containing water between every carcass and using air or water knives instead of physical knives. Figure 1 shows an establishment employee washing their hands and their knife in water treated with an antimicrobial after cutting wings on each carcass; this is identified as a best practice. Figure 1 Best Practice: Establishment employee washes hands and knife with water treated with an antimicrobial after cutting wings on each carcass. This set up and practice reduces cross-contamination. Figure 2 shows cut-up stations in which fat and other product build up accumulates on the knife sharpeners, which establishment employees use as needed. No water for cleaning is available at each station. These practices are not recommended." , "12 Figure 2 Not Recommended: Cut-up stations do not include a mechanism for cleaning knives. Knife sharpeners are available at each cut-up station and are used as needed. This set up and practice increases crosscontamination. Employees are in continuous contact with the product. The production of wholesome products is difficult when employees do not maintain clean hands and clothing. Therefore, sanitation training and education, as well as supervision, are crucial. Sanitizing stations must be available and maintained for washing hands. It is important that all employees follow standard hygienic practices in accordance with 9 CFR 416.5. Outer garments, head coverings, aprons, gloves, and protective shields are worn to prevent contamination, and cleaned or changed as necessary. Jewelry, cell phones, food (including candy and gum), and tobacco products should be restricted within the establishment. In addition, care taken by employees when performing

tasks, including sanitation procedures, prevents cross-contamination. For example, covering exposed product prior to hosing floors prevents splash-back from contacting product. Figure 3 shows an establishment employee performing manual evisceration. The employee's arm is uncovered and is not being washed sufficiently to prevent crosscontamination, as shown by the organic material present on the bare arm, which may then enter another carcass."<sup>13</sup>

**Figure 3 Not Recommended:** Organic material is present on an establishment employee's arm (yellow arrow). Water is available for washing, but the employee is not washing with sufficient frequency to prevent crosscontamination during manual evisceration. Plastic sleeves are more sanitary and easier to wash than bare arms Sanitation requirements regarding dressing rooms, lavatories, and toilets must be followed per 9 CFR 416.2 (h)(1) and 416.2 (h)(2). Ensuring employee health and hygiene protects employees, product, and consumers. Keeping the processing areas and employee areas clean and in good repair is central to maintaining sanitary conditions. The sections on Slaughter and Further Processing provide additional guidance regarding maintaining sanitation during those processes.

#### Intervention Use

Establishments may choose to implement the use of antimicrobial interventions to prevent or control *Salmonella* contamination. For interventions used that are part of an establishment's HACCP system (HACCP plan, Sanitation SOP, or other prerequisite<sup>14</sup> programs), establishments must maintain scientific support for their effectiveness and implement the interventions according to their support. Because interventions applied as part of an establishment's HACCP system affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these interventions as supporting documentation for its hazard analysis (9 CFR 417.5(a)). Guidance on identifying and selecting critical operational parameters for antimicrobial interventions and validation is available in the FSIS Compliance Guideline HACCP Systems Validation. The guidance document discusses how to apply those parameters within an establishment as part of a HACCP system. FSIS has found that some poultry establishments measure critical operational parameters, such as pH, temperature, and concentration, at the point where chemicals are mixed rather than at the point where they are applied. Values for these parameters can differ between these two locations. For this reason, values including pH, temperature, and concentration are best measured at the point they are applied to the product, rather than where they are mixed or prepared. When selecting an antimicrobial intervention, establishments must ensure that antimicrobial interventions and levels used are safe and suitable. FSIS Directive 7120.1, Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products, includes a web-based lookup table of antimicrobial agents that have been deemed safe and suitable when applied to certain products. This FSIS Directive is updated monthly. Together, 9 CFR 424.21 and FSIS Directive 7120.1 provide a complete list of substances that have been reviewed and can be used in the production of meat, poultry, and egg products. However, FSIS Directive 7120.1 by itself is not sufficient scientific support for establishments' use of interventions because it does not contain efficacy data or all of the critical operational parameters. FSIS does not endorse the use of any particular antimicrobial agent included in FSIS Directive 7120.1. If a company or establishment wishes to use a substance (e.g., an antimicrobial processing aid applied as a dip or spray) in the production of meat or poultry products that is not listed in FSIS Directive 7120.1, or desires to apply it to a different product or use it at a different level than that for which the substance has been listed, it would need to submit a protocol to FSIS for

review and determination. Additional information on New Technology Submissions and Protocols is available in the FSIS Guideline: Procedures for New Technology Notifications and Protocols. With any antimicrobial intervention, carcass\product coverage is important. Figure 4 below shows examples of incomplete coverage of poultry carcasses and parts. An establishment can use simple verification procedures to ensure an antimicrobial intervention achieves carcass\product coverage. When applying antimicrobial interventions to ground product or to parts that are macerated (or otherwise not Key Point FSIS Directive 7120.1 by itself is not sufficient scientific support for the efficacy of an establishment\u2019s interventions.", "15 smooth), establishments can consider how they will ensure that the intervention will be thoroughly mixed in and cover surfaces where bacteria may be present.

Figure 4 Not Recommended: Incomplete coverage is because of inadequate reach of antimicrobial spray in both images. On the left, only part of the carcass is receiving the spray. On the right, no spray is applied to the underside of products. In addition, not all pieces on the conveyor belt, nor all of the belt, are being treated because the arc of the spray (just inside the yellow lines) is too narrow to cover all product that could pass on the conveyor. Spray is also not being applied to all pieces due to product piling up and overlapping on the conveyor belt. Using Microbiological Sampling and Testing The FSIS Compliance Guideline: Modernization of Poultry Slaughter Inspection - Microbiological Sampling of Raw Poultry provides guidance to help small and very small poultry slaughter establishments meet the sampling and analysis requirements under the final rule to modernize poultry slaughter inspection. It is designed to assist establishments as they develop a microbiological sampling plan; utilize microbial testing results to monitor process control; and make decisions on process control throughout the poultry slaughter process (79 FR 49566) so that the establishment meets the minimum requirements set forth in the final rule. While the Modernization of Poultry Slaughter Inspection - Microbiological Sampling of Raw Poultry Guideline provides guidance on how to meet the minimum requirements under the final rule, establishments may want to consider developing an integrated sampling program that addresses multiple points throughout the poultry production process and includes sampling at points during further processing as well as during slaughter. Microbiological testing provides a measure of the extent of control at the step being evaluated and the steps preceding it. By performing microbiological analyses at several points within a process, it is relatively easy to identify the segment of the process where", "16 there has been a loss of control if that occurs. For example, testing before and after an intervention application can demonstrate whether the expected reduction in contamination is achieved (e.g., that part of the process is \u201cin control\u201d). FSIS regulated establishments may perform microbiological testing (or contract with an outside laboratory to perform such testing) for a variety of reasons, including, but not limited to: 1. Fulfill regulatory requirements; 2. Support on-going verification of the establishment\u2019s HACCP plan (9 CFR 417.4 (a)(2); 3. Support decisions made in the establishment\u2019s hazard analysis and HACCP plan (9 CFR 417.5(a)(1) and 417.5(a)(2); 4. Evaluate the effectiveness of the establishment\u2019s sanitation program (9 CFR 416.14); and 5. Comply with customer\u2019s purchase specifications or requirements. General Considerations for Establishment Ongoing Verification Testing Verification testing is utilized to \u201cverify\u201d (i.e., confirm) that a process is performing as anticipated. Verification differs from validation in that validation utilizes an initial predetermined number of repetitions and tests, while verification involves

ongoing, periodic testing. Process verification testing is intended to demonstrate that the validated process is functioning as designed, and that the results obtained during verification testing are not significantly different than those observed during validation. Verification testing works as one of the pieces of the HACCP system to help inform the establishment of any weak points that may exist in its process and that, consequently, may lead to a loss of process control. Official establishments are responsible for ongoing verification of their entire HACCP system. Therefore, establishments could choose to sample at multiple points in the process to verify that each component of the HACCP system is continuing to function as designed. Testing only finished product will not typically provide the establishment with sufficient information to detect and correct vulnerabilities at specific steps in their HACCP system. Similarly, FSIS verification testing may reveal trends that indicate a vulnerability but are not adequate alone to trace the root cause.

**Key Points** An establishment can sample at multiple points in its process to verify that each component of the HACCP system is continuing to function as designed. Simply testing finished product will not typically provide sufficient information to detect and correct vulnerabilities at specific steps in the HACCP system."

"**17 Process Mapping** One way an establishment could ensure that its HACCP system is effective is to use process mapping. Process mapping (also known as carcass mapping or bio-mapping) can be used as a baseline for assessing the effectiveness of certain interventions as well as the effectiveness of the overall HACCP system. Process mapping is defined as conducting microbial sampling at selected points in the process where contamination levels can be assessed. The assessment measures microbiological loads on carcasses against a specific target organism or class of organisms. Process mapping shows areas where immediate improvements can be made, or where there is a need for process adjustments. A process mapping (testing) protocol could contain procedures for obtaining multiple samples from a single flock after each processing step. Plotting these test results creates a map of the microbial reduction at each intervention step in the system. The plot shows where process control is most effective, least effective, or needs modification. FSIS strongly recommends that establishments use process mapping techniques to develop their own sampling programs for *Salmonella* or indicator organisms.

**Written Microbiological Sampling Program** The written microbiological sampling program at a slaughter establishment is designed in order to (at a minimum) meet the requirements of 9 CFR 381.65(g). Additionally, sampling at both slaughter and further processing may support the HACCP plan by demonstrating control of a hazard or effectiveness of an intervention. The written procedures for sampling and analysis of microbial organisms must be incorporated into the establishment's HACCP Plan, Sanitation SOPs, or other prerequisite program (9 CFR 381.65(g)). The following are the basic elements of a written sampling program:

1. A description of the sample collection procedures, including how sampling that is representative of all lines and production shifts is achieved, how samples are Recommended Best Practices, Statistical Process Control
1. When defining process control limits, verify that the establishment is maintaining process control, so that values within the control limits will be representative of performance when the system is functioning as designed.
2. Statistical control limits that are too tight may be more likely to indicate that process control issues are present when they are not, while limits that are too relaxed may be more likely to miss potential process vulnerabilities.
3. Consider using the *Salmonella* performance standards published by FSIS to establish internal pathogen controls."

"**18 handled to ensure sample integrity**, how the

establishment ensures that samples are collected per the written program, and the establishment employees designated to collect the samples for testing; 2. Information on the method used to analyze the samples and the identity of the laboratory performing the analysis. The method used must be fit-for-purpose, such as an Association of Analytical Chemists (AOAC) official method or one validated by another recognized independent testing body. FSIS provides an online lookup table of Validated Test Kits to assist establishments with identifying applicable options; 3. The microbiological organisms (i.e., *Salmonella* or indicator organisms) that the establishment will test for to monitor the effectiveness of its process control procedures; 4. The locations within the process where samples are collected; 5. The methods to ensure integrity of the samples throughout collection, storage, and analysis; 6. The frequency of sample collection; 7. Scientific and technical documentation to support the design of the sampling program. Further information on scientific and technical documentation can be found in the FSIS Compliance Guideline HACCP Systems Validation; 8. The method for evaluating test results; and 9. Actions to take in response to test results. Designing a Sampling and Testing Program When a microbiological sampling and testing program is properly designed and implemented, it can provide valuable information about an establishment's process control. When not properly designed and implemented, the test results can provide inaccurate and unreliable information that may not represent the establishment's actual process control. This use of inaccurate or unreliable test results could lead to inaction or an inappropriate course of action by establishments and can lead to false assurances of product safety. Effective testing depends on implementation within an establishment's food safety culture. Treating adverse test results as undesirable may introduce bias, as employees may be apprehensive in reporting these findings. A proactive approach to adverse sampling results can prevent a loss of process control at a greater level. Results from "19 laboratory or quality assurance staff may identify negative trends or vulnerabilities in the HACCP system before a hazard reaches the level of not meeting an FSIS pathogen performance standard. There are a number of factors that need to be considered when designing a sampling plan. Sample collection and analysis involves multiple steps, all of which must be successfully performed and documented to maintain the identity and integrity of the sample. Before starting sampling, an establishment needs to consider the design of the sampling program. Establishments can find information on criteria for selecting a commercial or private microbiological testing laboratory to analyze establishment samples in FSIS's Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory. Target Organisms Establishments can consider the advantages and disadvantages of testing for the presence of selected indicator bacteria and pathogens for ongoing HACCP verification. Sampling and testing costs for indicator species may be lower than costs for pathogens. However, while elevated levels of indicator bacteria are usually interpreted to mean pathogens are more likely, this relationship is not perfect. In other words, high levels of indicator organisms do not always mean that the pathogen is present, and low levels do not guarantee the pathogen is controlled. Only pathogen testing can effectively verify that pathogens are controlled to acceptable levels in finished product. There are no identified indicator organisms that directly reflect the presence or absence of pathogens (e.g., *Salmonella*) in poultry. Therefore, FSIS recommends that an establishment test for pathogens at least intermittently and compare its results against the presence or absence of other non-pathogenic organisms (i.e., the indicator organisms the

establishment is using) to assess whether it is maintaining process control. The indicator organisms can provide evidence of control, while periodic testing for pathogens may verify that the establishment is reducing pathogens to acceptable levels. Establishments conducting their own ongoing verification sampling and testing of finished product for Salmonella can use the FSIS performance standards as indicators of process control. For example, an establishment could consider the FSIS \u201cmminimum number to assess\u201d for each FSIS performance standard as a guide to ensure that they collect enough data points to have statistical confidence in their pathogen percent positive. For most products, that is roughly one Salmonella sample per month (11 samples/52 weeks for young chicken carcasses, 14 for turkey carcasses, and 10 for chicken parts and comminuted poultry). This approach is supportable if the analytical method has comparable sensitivity to the FSIS method; the less sensitive the method, the more samples are needed to increase confidence in the accuracy of the results.<sup>20</sup> Statistical Process Control Statistical process control is a scientific visual method used to monitor, control, and improve processes by reducing variation from the process. Statistical process control provides a powerful tool for establishments to use to monitor and interpret data collected for ongoing HACCP verification. Statistical process control can provide establishments with an early warning that their process may not be functioning as designed. This early warning can allow establishments to make modifications to bring their process back into control prior to not meeting an FSIS pathogen performance standard or an individual establishment-identified pre-determined performance criteria. Statistical process control can provide establishments with reasonable assurance that their HACCP system is functioning as designed, and that they are likely to meet applicable performance standards. The FSIS Compliance Guideline: Modernization of Poultry Slaughter Inspection - Microbiological Sampling of Raw Poultry provides additional information on sampling frequency and analysis, including the use of statistical process control. A number of methods and approaches for statistical process control are available for establishments to follow. Establishments can consider available guidance and develop a statistically valid approach for interpreting sample results (Saini et al., 2011; De Vries & Reneau 2010). Establishments can consider available information provided by FSIS, including the Salmonella performance standards for young chicken and turkey carcasses, chicken parts and comminuted poultry,<sup>2</sup> to develop their own internal controls for pathogens in these products. FSIS has found that its category approach (Category 1, 2, and 3) to assess process control has worked to identify whether individual establishments are maintaining consistent process control. Establishments developing their own internal pathogen controls can consider how they may apply this concept. Sample Collection Method Proper sample collection techniques and procedures are necessary to ensure the accuracy of test results. Sample handling and collection procedures are specific to the type of product to be sampled (e.g., parts or comminuted), the sample collection method (e.g., parts rinse, comminuted product sampling), and the type of sample collected (e.g., rinsate sample, finished product samples, excision sample of skin). Individuals who will collect samples need to receive training on proper sample collection procedures. 281 FR 7285<sup>21</sup> Antimicrobial Interventions and Drip Time An establishment can consider how sample results are affected by the antimicrobials used in the process and the timing of the sample collection. Antimicrobial interventions used during processing steps may make it more difficult to detect remaining bacteria, particularly when non-destructive or surface sampling is conducted. For destructive sampling, in which the tissue

itself is collected for analysis at the laboratory, remaining antimicrobials will continue to be inactivated by organic material in the sample during shipment of the sample to the laboratory. Conversely, with rinsate or through other surface sampling, capturing the antimicrobial in a buffer or other sampling solution may prolong the antimicrobial's effective time. For example, consider poultry carcasses exiting a chiller tank where antimicrobial interventions are used. Contaminated carcasses may have bacteria that survived the chiller tank. However, those bacteria may not be detected through sampling if the carcass is not allowed adequate drip time before the establishment collects a rinse sample. Adequate drip time will allow excess antimicrobials to drip off the carcass. Immediate sample collection will include a significant amount of residual antimicrobials, which suspended in rinsate will remain active and make it harder for the laboratory to detect live bacteria. If the carcass is allowed adequate drip time, the sample will contain less residual antimicrobials, and the laboratory will be more likely to detect live bacteria. At this time, FSIS generally recommends establishments wait at least 60 seconds after application of antimicrobial interventions before collecting a sample to reduce the amount of antimicrobial carryover. A longer drip time may be recommended by the antimicrobial manufacturer for particular solutions. Tipping over the carcass to allow drainage of chiller water that has accumulated in the body cavity can also result in greater accuracy of the test result. Establishments could consider whether a neutralizing agent is available which could stop the action of any residual antimicrobial intervention, making it possible to more accurately detect live bacteria remaining on the sample. Examples of a neutralizing agent suited for particular antimicrobials would include lecithin for Cetylpyridinium Chloride (CPC), sodium thiosulfate for Peroxyacetic Acid (PAA), or sodium thiosulfate plus bicarbonate for Acidified Sodium Chlorite (ASC) (Gamble et al., 2016). To effectively use quantitative data to evaluate process control, the collection, handling, storage, and transportation of samples are carefully controlled to prevent temperature abuse, sample leakage, and other events that could affect sample integrity and lead to unreliable test results. Procedures for maintaining sample integrity are particularly important when samples need to be transported from the establishment to an off-site laboratory (e.g., by a delivery service, such as FedEx or courier) where they may not be under the direct control of the establishment or the laboratory for a period of time.<sup>22</sup>

**Selection of Products for Sampling** The samples are selected and collected in a manner and at a frequency that will ensure that they are representative of the establishment's production. If more than one shift is operating at the establishment, a sample can be taken on any shift. All shifts are sampled with sufficient frequency in order to assess process control for each shift. The FSIS Compliance Guideline: Modernization of Poultry Slaughter Inspection - Microbiological Sampling of Raw Poultry provides information on methods for selection of carcasses for sampling during the slaughter process. In order to meet the requirements of 9 CFR 381.65(g), slaughter establishments must sample carcasses at the pre- and post-chill locations (very small establishments are only required to test at post-chill). The same selection techniques can also be applied to further processed products in support of a HACCP system. Different methods of selecting the specific products for sampling can be used, but all require the use of random numbers to reduce bias. Examples of methods for selecting products for sampling include random number tables, calculator- or computer-generated random numbers, or drawing cards. **Sample Analysis** To obtain the most accurate microbiological testing results, establishments ensure the following: Recommended Best Practices, Ongoing Verification

Testing 1. Establishments must maintain support for their verification procedures and frequencies. (9 CFR 417.2(c)(7)) 2. Both indicator bacteria and pathogens can provide useful information. 3. Allow at least 60 seconds before sampling after application of any antimicrobials, to prevent excessive antimicrobial carryover in the collected sample.", "23 \u2022 The collected sample is either analyzed in the establishment the same day as it is collected or by the following day. If shipping to an offsite laboratory, the sample can be held under refrigeration until overnight shipment to the laboratory the day of collection or the following day. \u2022 Samples can be held at refrigerated temperature, not frozen, and shipped cold to the laboratory in an insulated shipping container with frozen gel packs. Frozen samples are discarded since the sample results may not be accurate.

**Microbiological Testing Method**

An establishment needs to determine whether sample analysis will be performed by an outside (third party) laboratory or in its own onsite microbiological testing laboratory (if available). Because of the costs and the logistics involved with maintaining an onsite microbiological testing laboratory, establishments may choose to have samples analyzed by an outside laboratory. FSIS has available the resource titled Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory. This guideline is intended to be useful to very small establishments when they are selecting a commercial or private laboratory to analyze their microbiological samples.

**NOTE:** Establishments can (and often do) analyze samples for non-pathogenic organisms, such as generic E. coli and APC, on-site.

**Recordkeeping**

Upon implementation of its sampling program, an establishment must maintain daily records sufficient to document the samples collected and subsequent test results. For slaughter establishments, records must document the required sampling, as outlined by 9 CFR 381.65(h). Daily sampling records that best support analysis of the sample results include: \u2022 Time, date, and location of the sample collection; \u2022 Sample collector's name; \u2022 Name or description of the product or sample source; and \u2022 Lot information and producer.

**Key Points**

To obtain the most accurate results, samples are analyzed as soon after collection as possible. If samples must be transported to an off-site laboratory, they can be refrigerated and then shipped refrigerated, on the same day they were collected or the following day, via an overnight delivery service to the laboratory.", "24 A best practice is for all sample records to be dated and initialed by the sample collector immediately upon completion of the entry. If an outside laboratory is used for testing, then these sample records would also include information such as date the sample was shipped to the laboratory for analysis. The receiving laboratory will document the: \u2022 Date received; \u2022 Condition of the sample upon receipt, including sample temperature; \u2022 Date the analysis was started and completed; and the \u2022 Analytical result. Test results are best recorded and linked to the sample collection records by a sample number, form number or some other unique identifier.

Data integrity is a key consideration when determining how to maintain these records. These records can be maintained in an electronic format, provided there are measures in place to ensure the security of the information. These records must be available for FSIS inspection program personnel upon request.

**Actions in Response to Test Results**

As part of its process control procedures, an establishment defines the actions it will take if the test results obtained through its sampling are above the limits it has set. The establishment delineates what its actions will be, who will take each action, how the outcome of these actions will be documented, and how it will be verified. If the establishment determines that the trends in its

test results indicate a loss of process control, the establishment can first take action to investigate the cause. As discussed in the previous section on process control, an establishment can consider how the pieces of the HACCP system work together, and how they impact the entire system. To do this, the establishment can evaluate the process control procedures and sanitary dressing practices to identify the cause and to take steps to correct the problem. This determination can include a review of its process monitoring records as well as an evaluation of the process during normal operations. The establishment can consider any implementation problems or changes in its practices, including but not limited to the following:

1. Implementation problems or changes in procedures for routine cleaning and sanitizing of equipment, including hand tools that are used to remove contamination or to make cuts into the carcass; 2. Changes in the design, configuration, and calibration of equipment to ensure proper function within operational parameters to prevent the contact between carcasses and parts and prevent contamination of carcasses during operation;" "25 3. Implementation problems or changes in employee hygiene practices, to ensure that employees frequently wash hands and aprons that come in contact with carcasses; and 4. Implementation problems or changes in antimicrobial or mechanical intervention treatments, such as carcass washes, sprays, dips, drenches, or brushes, in accordance with the limits selected by the establishment.

Following its investigation, the establishment responds appropriately to its findings using decontamination procedures and antimicrobial intervention treatments as necessary to address any contamination that may have occurred on the carcasses and parts. The establishment can also take steps to initiate any necessary equipment repair or recalibration and employee training when identified during the investigation as potential root causes of the loss in process control. Depending on how the establishment has incorporated sampling and sanitary dressing into the written programs, the establishment may also need to perform and document corrective actions as required by Sanitation SOP (9 CFR 416.15) or HACCP (9 CFR 417.3(a)) PRE-HARVEST Pre-Harvest Interventions and Management Practices Pre-harvest interventions and practices can prevent or reduce *Salmonella* colonization of live birds, increasing the effectiveness of post-slaughter interventions and establishment controls. This section identifies available pre-harvest interventions\practices, and how slaughter and processing

establishments can encourage their use by poultry producers. This section covers poultry production from breeder stock through transport to the slaughter establishment. Live receiving and subsequent slaughter steps are covered in the following section. Food Safety Hazards Colonization of the poultry gastrointestinal tract with *Salmonella* is a food safety hazard that can occur at pre-harvest (i.e., at grow-out, the hatchery, or at the breeder farm). Colonization can then result in fecal shedding of bacteria, which can contaminate skin and feathers during many steps from breeder farm to arrival at the slaughter establishment. External contamination can also occur during slaughter from rupture of the gastrointestinal tract and transfer of pathogens on contaminated equipment. FSISregulated establishments can, as part of their overall HACCP system, address these hazards through purchase specifications or other agreements to require that their suppliers implement certain pre-harvest management controls." "26 Pre-Harvest Interventions & Management Practices FSIS recommends that establishments use two main practices for managing preharvest colonization of poultry with *Salmonella*. Together, these practices are expected to reduce the number of birds colonized with or shedding pathogens, reduce the number of these pathogens in colonized birds, and

reduce the likelihood that contamination will be transferred from colonized to uncolonized birds. First, FSIS recommends that slaughter establishments receive birds from grow-out farms, hatcheries, and breeder flocks that implement the recognized pre-harvest interventions described in this section. Implementing these interventions can decrease the Salmonella contamination on birds received by slaughter and processing establishments (Cox & Pavic 2010; Volkova et al. 2011). Establishments may include specifications in their grow-out contracts for growers to incorporate strategies that address the potential contamination of Salmonella during hatching and grow-out. Reducing or eliminating Salmonella on incoming birds at slaughter establishments can reduce contamination of finished products and increase the likelihood that the establishment will meet FSIS performance standards for Salmonella.

Alternately, if an establishment does not require that Salmonella is addressed at preharvest, FSIS recommends that slaughter and processing establishments test incoming birds and poultry products before entry into the establishment and make processing decisions based on those test results. Further information about using pre-harvest sampling data for decision-making can be found in the following section, Scheduled Slaughter and Processing. Using these test results, an establishment could decide to implement a scheduled slaughter and processing plan based on the presence or absence (\u201cstatus\u201d) of Salmonella. Other decisions could be to utilize additional chemical interventions or divert products from positive flocks to lethality treatment (such as cooking). Scheduled Slaughter & Processing Maximizing the amount of finished product that is negative for Salmonella can be achieved by implementing a scheduled slaughter and processing plan based on the status of incoming birds. Scheduled slaughter and processing depend on lotting definitions that ensure lots are microbiologically independent. To implement a scheduled slaughter and processing plan, establishments must determine the Salmonella status of poultry flocks before their entry into the establishment. Using this information, establishments can then schedule pathogen-negative flocks for slaughter and processing separately from pathogenpositive flocks. \u201cSeparately\u201d can be defined as different slaughter and processing establishments, different production lines in the same establishment, or at different times on the same production line (negative before positive and lines are cleaned and sanitized before negative flocks or products). Establishments can also choose to utilize", "27 additional interventions or lethality treatments, such as cooking, for product derived from pathogen-positive flocks. Step One: Determine Salmonella Flock Status The first step in scheduled slaughter and processing is to obtain accurate and reliable information about the Salmonella prevalence in the live birds at pre-harvest. Status can be determined as close to slaughter as possible in order to increase the likelihood that Salmonella will be detectable through drag swabs, boot samples, or litter samples. However, the results need to be available to the establishment early enough to take action. This typically means sampling between 2 and 5 days before transport to slaughter. Further information on sampling in the grow-out house can be found under the heading Determining Flock Pathogen Status Prior to Harvest, in the Pre-Harvest section of this guidance. Step Two: Separate Slaughter and Processing Positive or negative flock status can be maintained throughout slaughter and processing, including if carcasses or parts are moved to other establishments for further processing. For example, if a negative flock is slaughtered separately from a positive flock, but the carcasses and parts are commingled during storage or further processing, all product can be considered positive (microbiological independence is not in place). In cases where positive and

negative flocks are slaughtered and processed on the same line, establishments will need to evaluate their process to determine where to establish independence between lots. If there is no clear break, the establishment can consider carcasses or other raw poultry components to be positive until the next cleaning and sanitizing is performed. For example, all carcasses in the chiller tank at the time the first carcass from a positive flock enters the tank can be considered positive, even if some of the carcasses originated from negative flocks. Then, the establishment can consider all carcasses passing through the tank to be positive until the production line is cleaned and sanitized.

**Step Three: Further Processing or Cooking Establishments** can also choose to utilize additional interventions for poultry products derived from positive flocks. Use of interventions could be based on the establishment's knowledge of the log reduction achievable through the interventions and processes used. Alternatively, positive birds and products could be sent to cooking or another lethality treatment in order to achieve full lethality for any *Salmonella* present in the affected product. Key Point Status can be maintained throughout slaughter and processing, including if carcasses or parts are moved to other establishments for further processing.

"**28 Pre-harvest Recommendations to Control *Salmonella*** This section provides information on interventions intended to prevent the exposure of birds to pathogens and available products intended to reduce the incidence or level of *Salmonella*. Interventions to prevent exposure and colonization in live birds are typically more effective than products that treat birds exposed to *Salmonella* to reduce incidence or levels, as it is more difficult to eliminate *Salmonella* from infected flocks. There are numerous routes of exposure to *Salmonella* during pre-harvest including:

- \u2022 Transmission through the egg from the breeder flock to chicks (vertical transmission) and transmission between birds during hatch and grow-out;
- \u2022 Exposure to contaminated water, feed, and bedding in the grow-out house; and
- \u2022 Environmental exposures due to poor biosecurity practices and inadequate pest control.

FSIS is not aware of a single pre-harvest intervention that eliminates *Salmonella* as a pre-harvest hazard. Instead, FSIS recommends that a multi-hurdle approach be employed; this means that multiple sequential pathogen interventions are used that can have an additive effect to reduce pathogens. Implementing multiple interventions and controls beginning at preharvest extends the multi-hurdle approach to *Salmonella* prevention and control across each bird's life. Using interventions with differing modes of action can further improve the extent of pathogen reduction when using a multi-hurdle approach. In this Guideline, FSIS is providing available effectiveness data for pre-harvest interventions, as identified in scientific literature. However, because many factors during the pre-harvest period can contribute to pathogen colonization of individual birds, the spread of pathogens between birds in a flock, and the excretion of pathogens by birds, use of a particular Recommended Best Practices, Scheduled Slaughter & Processing

1. Use microbiologically independent lotting practices to minimize commingling or cross-contamination.
2. Determine the presence or absence of *Salmonella* before flocks are transferred to slaughter.
3. Slaughter and process negative flocks separately from positive flocks (different establishment, different line, or on sanitized equipment).
4. Consider the use of additional interventions or cooking for product derived from positive flocks and poultry products.

**Key Points** Interventions to prevent exposure and colonization in live birds are preferable as it is more difficult to eliminate *Salmonella* from flocks once infected. Preventive interventions in live birds lose effectiveness if the flock is already infected. Consider using

multiple interventions throughout preharvest.", "29 intervention may have different efficacy than specified. Thus, the concept of a multihurdle approach is important to keep in mind. Establishments can consider requiring suppliers to use the interventions listed here. Establishments can use these pre-harvest controls as part of their HACCP system (through purchase specifications or other agreements) and to support their decisionmaking. FSIS will work with other federal agencies, such as USDA-Animal and Plant Health Inspection Service (APHIS), Food and Drug Administration (FDA), and USDAAgricultural Research Service (ARS), to develop additional information on pre-harvest interventions. This Guideline breaks the pre-harvest interventions into six categories focused on physical, biological, and hygienic approaches to reduce pre-harvest exposure to *Salmonella*: Breeder Flock & Hatchery, Grow-out House, Bedding, Feed, Water, and Transportation. When considering the control of hazards on incoming birds, slaughter establishments can consider exposure-reducing interventions combined with one or more of the products available for pre-harvest control to reduce incidence or levels of *Salmonella* in poultry that may be exposed to these pathogens (Table 2). These products have different modes of action, but all produce the same result: reduced incidence of pathogen colonization and reduced pathogen levels in colonized birds. Efficacy depends on the specific product, and most can be used in consultation with a veterinarian. Using both types of pre-harvest approaches \u2014 those to reduce exposure and those that reduce incidence of colonization and levels of pathogens \u2014 will minimize pathogens on birds at harvest. Using the interventions and best practices recommended in this guideline can help to provide for animal welfare and bird health at pre-harvest, thereby reducing stress in poultry and reducing *Salmonella* in birds presented at slaughter. Evidence suggests that stress at pre-harvest can have adverse effects on food safety (Rostagno, 2009). Understanding the mechanism by which stress alters normal intestinal characteristics and induces susceptibility to enteric infections may help in developing additional preharvest strategies to reduce pathogen contamination in poultry. NOTE: In this section, the term '\u201cyoung chickens\u201d refers to all chickens raised for slaughter to distinguish it from chicken breeder stock. The term here is not limited to '\u201cbroilers\u201d as defined in 9 CFR 381.170(a)(1)(iii). In this section, '\u201cyoung turkeys\u201d refers to all turkeys raised for slaughter to distinguish it from turkey breeder stock." "30 Table 2. Pre-harvest products to reduce colonization and number (level) of *Salmonella* in poultry. Definition Notes on Use Vaccines: increase immunity to *Salmonella* by exposing the immune system to a controlled preparation. Vaccine types include live vaccines (an attenuated strain of *Salmonella*), subunit vaccines (a vaccine with minimal parts of the target for immune response), and autogenous vaccines (developed from bacteria isolated from the farm environment). Approved live-attenuated3 vaccines are available for use in breeder flocks and in young chickens and young turkeys and are administered orally or by injection. Other vaccine types, such as inactivated vaccines, may require multiple doses in order to produce the immune benefits. Special approvals from APHIS are required for long-term use of autogenous vaccines or for use of these vaccines with multiple flocks. Some vaccines were found to show a 9% reduction in *Salmonella* prevalence, a 1-2 log reduction, or a 2-3 log reduction of *Salmonella* recovered from poultry challenged after vaccination. Competitive Exclusion & Probiotics: preparations of beneficial bacteria that compete with *Salmonella* in the gut for space or nutrients. Also known as direct-fed microbials. Some products can be used on the day of hatch to establish healthy gut flora in chicks. Other products can be added to water

and feed for both breeders and young chickens and used to boost competition against pathogens throughout the bird's lifetime or when otherwise indicated (e.g., stress). One study on the effectiveness of a competitive exclusion culture in poultry found up to a 92% reduction of Salmonella following a Salmonella challenge. Prebiotics: specific nutrients that will allow beneficial bacterial species to more effectively compete against Salmonella. Can be added to the feed of both breeders and young chickens. The most common supplements include yeast extracts, such as beta-glucans and mannan oligosaccharides A study on the effectiveness of a prebiotic in poultry found a 34% reduction of Salmonella prevalence following Salmonella challenge. Organic Acids: increase the acidity of the gut, which can kill Salmonella. Because each bacterial species has a different susceptibility to organic acids, this can be added to both feed and water for breeders and young chickens. Adding to water during feed withdrawal is particularly important. After feed is withdrawn, birds may be more likely to peck at litter and may ingest pathogens. Additionally, during feed withdrawal, the gastrointestinal (GI) tract becomes 3 Live Salmonella vaccines administered to poultry presented for slaughter may have the potential to introduce a hazard into the establishment. Establishments should support how their use of such vaccines does not affect safety of poultry products derived from vaccinated poultry and does not interfere with FSIS inspection procedures.", "31 mechanism also increases the ability of beneficial bacteria to compete against pathogens. more susceptible to colonization by Salmonella because of the reduced organic acid concentration and higher pH. Organic acids added to the water will lower the pH in the crop and reduce pathogen colonization and growth. A review article found that use of most organic acid products resulted in up to a 1 log reduction of Salmonella. (References: Berge and Wierup 2012; Callaway et al. 2008; Desin, K\uf6ster, and Potter 2013; Feberwee et al. 2001; Hume et al. 1998; Khan et al. 2003; Penha et al 2009; Spring et al. 2000; Wales et al. 2013) Breeder Flock & Hatchery Breeder flocks and hatcheries can be the original source of Salmonella colonization for young chickens because infection can be transmitted through the egg (vertical transmission). Establishments can obtain broiler and turkey chicks from breeder flocks and hatcheries that follow National Poultry Improvement Plan (NPIP) procedures and recommendations. The NPIP was established in the early 1930's to provide a cooperative industry, state, and federal program through which new diagnostic technology can be effectively applied to the improvement of poultry and poultry products throughout the country. Because of the possibility of vertical transmission, establishment parent companies and independent growers can consider placing chicken and turkey chicks from breeder flocks free of Salmonella onto grow-out farms (Liljeblad et al. 2005; Crespo et al. 2004). (Note that pathogen-free breeder stock is not a requirement for participation in NPIP.) Chicken breeders also demonstrate variability in innate immunity to Salmonella; some chicken breeder stocks have been shown to be more resistant to colonization (Swaggerty et al. 2009). Utilization of these parental breeding stocks can produce broiler chicks that are more resistant to on-farm colonization. Consider the use of one or more of the products listed in Table 2 to prevent or reduce colonization with Salmonella in live birds that are destined for slaughter. Several of the probiotic, prebiotic, and organic acid products can be administered to both breeder flocks and young chickens, often through feed and water. Of special note for breeder flocks are vaccines for Salmonella, which can reduce the likelihood of vertical transmission to chicks (Desin, K\uf6ster, & Potter, 2013). Compared to the short grow-out period for young chickens, breeder flocks may remain productive for several months

or longer. As a result, a greater number of vaccine options are available in breeders compared to young chickens and turkeys. Competitive exclusion and probiotics can be administered to chicks on the day of hatch to inoculate the gastrointestinal tract with beneficial bacteria (Table 2). Inoculation with beneficial bacteria at the hatchery can be followed with use of appropriate prebiotics and organic acids at the grow-out house to maintain beneficial bacteria through growout. Chicks can be transported from the hatchery to the grow-out house in new or,"32 cleaned\sanitized, and ideally lined, containers (Cox & Pavic, 2010). Limit the number of individuals handling the chicks from the truck to the interior of the grow-out house to minimize chances for exposure. Although the following sections focus on young chickens and turkeys, the best practices identified also apply to chicken and turkey breeders and can serve to minimize pathogens in these flocks. Grow-out Houses Farms and houses can be designed to facilitate cleaning and disinfection between flocks (Cox & Pavic, 2010; Volkova et al., 2011). All poultry farms can develop and implement written biosecurity and hygiene plans. Poultry health is best monitored under the supervision of a veterinarian. Available research suggests that the following practices are correlated with a decreased likelihood of *Salmonella* in birds presented for slaughter (Cox & Pavic, 2010; Volkova et al., 2011; C. Wray et al., 1999): \u2022 Housing a single species (e.g., only chickens or only turkeys) on the farm; \u2022 Keeping birds of different ages in different houses; \u2022 Limiting the number of people with access to grow-out houses and using disinfecting boot dips or disposable foot coverings and disposable coveralls when entering the house (a study by Rabie et al. (2015) found that correct use of a boot dip effectively reduced *Salmonella*, although organic material can negatively impact effectiveness); \u2022 Removing vegetation around buildings, installing screens on windows and other openings, and increasing physical integrity of buildings to prevent access by rodents, birds, or insects; and \u2022 Using pest control measures including bait and traps.

Recommended Best Practices, Breeder Flock and Hatchery 1. Obtain chicks from pathogen-free breeder flocks and from breeders and hatcheries following NPIP procedures. 2. Use breeding stock with innate resistance to *Salmonella*. 3. Consider using one or more of the products listed in Table 4. 4. Transport chicks to grow-out in new or sanitized containers.", "33 In addition to reducing exposure to *Salmonella* with the measures described above, consider the use of one or more of the products in Table 2 to reduce colonization and the incidence or level of pathogens in exposed birds. Most probiotics, prebiotics, and organic acids can be used with both breeder and broiler flocks as feed or water additives. Vaccines remain an option for broiler flocks; however, manufacturer information can be used to determine whether immune protection can be achieved during the short grow-out period. Approved live-attenuated vaccines are available for use in young chickens and turkeys. Biologics, including vaccines and antibody products, are licensed for use by USDAAPHIS, which updates the complete listing on their webpage. Live vaccines may introduce *Salmonella* into flocks presented for slaughter; the establishment can consider this possibility when developing the HACCP plan and sampling programs accordingly. Bedding Litter or bedding can be considered a reservoir for *Salmonella* contamination (Bryan et al., 1979; Corrier et al., 1999). Downtime between flocks is recommended at around 10 -14 days, which allows moisture removal and desiccation of litter. Ensure that no new moisture is added and that wet caked areas are removed during the litter turn over (fluff). There are technologies that allow composting or windrowing of litter between flocks (Malone & Johnson, 2011; Wilkinson et al., 2011; Macklin et al., 2008). It is important to

note that litter is not uniform in moisture, organic carbon availability, pH, or microbial populations, which are all factors that can influence pathogen destruction or growth in litter during and following composting. Recommended Best Practices, Grow-out House 1. Implement on-farm biosecurity and hygiene plans, 2. Minimize the number of people with access to the grow-out house. 3. Require the use of disposable foot coverings or boot dips. 4. Consider the use of products in Table 4. Key Points Pre-harvest interventions must not: 1) Negatively impact product safety, 2) Jeopardize the safety of Federal inspection program personnel, 3) Interfere with inspection procedures, including FSIS sampling, or 4) Conflict with the Agency's regulations.", "34 Water activity ( $Aw$ ) and pH of the litter are positively correlated with pathogen growth (Opara, 1992; Terzich, 2000). Consider chemical treatment of the litter to reduce pH and  $Aw$  during production to reduce pathogen growth and contamination of the flock, which could reduce pathogen recovery at the processing establishment. Litter treatments to reduce pH are commonly added prior to flock placement because the early grow-out phase (~1st week for young chickens, ~ 3 weeks for turkeys) is when the birds are most susceptible to pathogen colonization (Santos et al., 2005; Payne et al., 2007). Several chemical additives have been used to decrease the pH of poultry litter, such as aluminum sulfate (Moore & Miller, 1994; Line, 2002), ferrous sulfate (Huff et al., 1984), phosphoric acid (Reece et al., 1979), sodium bisulfate (Moore et al., 1996) (Terzich, 1997), and acetic acid (Parkhurst et al., 1974). Experts recommend a pH of less than 4 to control *Salmonella* growth in litter and to prevent acid-tolerance in some strains of *Salmonella*. (Hardin & Roney, 1989; Payne et al., 2002; Payne et al., 2007). Reducing litter pH to less than 4 can reduce *Salmonella* to below detectable limits (Payne et al., 2007). Since litter pH increases to near neutral after the first week of production, reapplication of the litter treatment may be needed (Pope & Cherry, 2000). During grow-out, moisture in the house can be controlled with the use of tunnel ventilation systems. If the moisture in the litter is too high (as observed in the winter months due to decreased ventilation) *Salmonella* growth can increase. Wet litter can also be caused by environmental conditions (rain, poor drainage, leaky roofs), evaporative cooling systems, excess drinking, health problems, panting, excess bird density, and watering systems such as type of waterers (bell, trough, nipple), leaky valves, maladjusted waterers, too many birds per drinker, or broken water lines. *Salmonella*-positive birds can also spread the pathogen via aerosol when the environment is too dry (Gast et al., 2004). Feed Select growers that use feed that is free of *Salmonella*. Specifically, obtain feed from manufacturers that follow Good Manufacturing Practices to reduce or eliminate pathogens, such as those certified by the Safe Feed/Safe Food program administered by the American Feed Industry Association. Safe Feed/Safe Food producers may also conduct finished product testing to verify the product is negative of certain hazards. Clean and disinfect feeders between flocks and keep feeders in good repair. Consider adopting the use of feed additives that are effective in young chickens (Table 2). Recommended Best Practices, Bedding 1. Use a litter treatment to reduce litter pH  $< 4$  and  $Aw < 0.84$ . 2. Use a composting or windrow treatment during flock downtime. 3. Allow 10-14 days between flocks to desiccate litter and verify destruction of pathogens.", "35 Protect feed from contamination during transportation and storage. Transport the feed to the farm in accordance with the FDA's Sanitary Transportation of Human and Animal Food final rule (81 FR 20091), which includes provisions for cleaning transportation vehicles before transport of feed and measures to prevent contamination or tampering of feed during transportation. Store feed on-farm in a

manner that reduces the likelihood of contamination through contact with pests, fomites, or the environment (Berge & Wierup, 2012). If feed is stored on-farm in a manner that could result in contamination (such as open bins or bags), poultry producers can conduct periodic sampling of the feed to determine whether contamination has occurred during storage. Some research indicates that pelleted feed is more resistant to contamination during storage than mash, and that the addition of organic acids to the feed may also protect against contamination. The Association of American Feed Control Officials (AAFCO) provides additional recommendations on the production and distribution of animal feed in its document titled \u201cBest Management Practices for Manufacturing, Packaging & Distributing Animal Feeds and Feed Ingredients.\u201d Time feed withdrawal appropriately; withdrawal from feed can occur between 8 \u2013 12 hours before slaughter (Cox & Pavic, 2010). Withdrawing feed before slaughter can ensure that birds have an empty gastrointestinal tract during transport, slaughter, and evisceration, which can reduce external contamination with fecal material. However, some research indicates that early withdrawal may lead the birds to peck at the litter in the grow-out house and increase the likelihood that the bird will ingest pathogens and be contaminated at slaughter (Berge & Wierup, 2012). Also, the decrease in the acidity of the crop caused by the removal of feed that beneficial crop bacteria use to form organic acids allows *Salmonella* to grow in the crop (Hinton et al., 2000a, 2000b) because of a lower organic acid concentration and higher pH. Growers can consider providing water with organic acids (Table 2 and discussed below) during feed withdrawal to prevent colonization of the crop. Extended feed withdrawal may also make internal organs more fragile, increasing the likelihood that the crop or other organs will tear during processing and contaminate the carcass (Cox & Pavic, 2010). Most studies support a feed withdrawal period of 8-12 hours to prevent organ tearing (Rostagno et al., 2006; Cox & Pavic, 2010). Recommended Best Practices, Feed 1. Clean feeders between flocks. 2. Use feed that is pathogen free. 3. Consider use of appropriate feed additives (Table 4). 4. Protect feed from contamination during transport and storage 5. Pelleted and acidified feed may be more resistant to contamination during storage. 6. Time feed withdrawal appropriately (between 8 \u2013 12 hours) and supply water with organic acids during feed withdrawal.", "36 Water Provide abundant, potable water (Cox & Pavic 2010). If water is not from a chlorinated or municipal source, routine testing is recommended to ensure that the source is free of pathogens. Clean the water distribution system between flocks, ensuring that biofilms, which may be reservoirs for pathogens, are removed when possible. Ensure that the water system is free of cracks and leaks to minimize waste and to keep bedding dry. A number of the products listed in Table 2 are available as water additives for young chickens. Of note are organic acids added to water, particularly during feed withdrawal (Berge & Wierup 2012). Providing water during feed withdrawal distracts birds from pecking at the litter. Adding organic acids to this water source will increase the acidity of the crop, which can help protect the bird against any *Salmonella* they may ingest when pecking at the litter. Determining Flock Pathogen Status Prior to Harvest Understanding pathogen status on farm or at grow-out, prior to collecting birds for harvest, can provide valuable information to inform establishment decision-making for slaughter and further processing. Additional information and considerations to Recommended Best Practices, Water 1. Provide abundant, potable water. 2. Clean water distribution systems between flocks. 3. Consider feed and water additives listed in Table 4, particularly organic acids during feed withdrawal. Key Points Boot Swabs: single-use covers are placed over the

wearer's boots. After walking through the growout house, the covers are sent for lab analysis. Provides a measure of the entire house. Drag Swabs: collection swabs are dragged on strings throughout the grow-out house and sent for lab analysis. Provides a measure of the entire house. Litter Samples: a portion of the litter is collected and sent for lab analysis. Can only indicate contamination for the collected sample. Cloacal Swabs: a swab is used to collect material from the cloaca of a single bird. Multiple swabs can be collected but results will only represent the birds that are tested." "37 maximize use of on-farm sampling results can be found under the Scheduled Slaughter & Processing section. Pathogen status of the birds in each grow-out house can be determined. This may provide more accurate information than only sampling on farms, where only a portion of houses have colonized birds. In addition, this gives establishments the option to schedule negative houses separately from positive houses, provided the birds in negative versus positive houses can be transported separately. Several methods are available for collecting and analyzing samples from grow-out houses. Some studies suggest that boot swabs may be more sensitive than drag swabs, litter samples, or cloacal swabs; boot swabs provide establishments with a single sample site that represents conditions throughout the poultry house (MuellerDoblies et al., 2009). Samples can be analyzed for Salmonella. Recent research has shown that at least 30% of broiler flocks are Salmonella negative, based on testing fecal samples collected on the farm prior to slaughter or cecal samples collected at slaughter (Thakur et al., 2013). Flocks and houses that are negative for Salmonella can be considered negative for scheduled slaughter purposes. Flocks and houses that are positive for Salmonella can be considered positive for scheduled slaughter purposes.

Transportation The presence of Salmonella on birds at receiving at slaughter has been linked to dirty transport cages (Cory, et al., 2002; Slader, et al., 2002). Cross contamination of both birds and cages is frequently made worse when the birds are transported to the establishment. To prevent such contamination, transport birds in clean containers (Cox & Pavic 2010). Clean, single-use paper liners can be used when transporting chicks but are not recommended for transporting young chickens to slaughter. In all cases, clean and disinfect transportation cages between each load. Minimize the number of individuals involved in removing birds from the grow-out houses. Figure 5 shows a chicken transport crate that is not washed after every load." "38 Figure 5 Not Recommended: Transport crate that is not washed with sufficient frequency. There is a buildup of fecal material and feathers that can contaminate subsequent flocks during transport. Using cleaned and disinfected transport cages for each load of birds is especially important after flocks have been sampled prior to harvest. This is because contamination from dirty cages can change the pathogen status of a flock from negative to positive and reduce the effectiveness of scheduled slaughter and processing decisions.

Research suggests that a two-step process that first cleans and then disinfects the cages is effective at reducing Salmonella. Pre-cleaning the cages prior to immersing in hot water for 30 seconds at 60 °C (140 °F) or higher or immersing for 30 seconds in a solution of sodium hypochlorite at 750 ppm or higher reduces Salmonella on transport cages (Ramesh, et al., 2004).

Recommended Best Practices, Transportation

1. Use clean containers and sanitize containers between loads.
2. Use new disposable paper liners when transporting chicks to the farm.
3. Minimize number of individuals involved in transport.
4. Clean and disinfect transport crates between each load."

"39 SLAUGHTER AND PROCESSING Slaughter This section of the guideline provides information for establishments that slaughter poultry. The diagram below

presents the steps in poultry slaughter addressed in this section. How well an establishment conducts its slaughter dressing procedures has a direct bearing on whether the decontamination and antimicrobial intervention treatments in place in a poultry operation will have their intended effects. When contamination", "40 overwhelms the decontamination efforts and antimicrobial intervention treatments, the establishment may need to take additional steps to reduce pathogens. Live Receiving and Live Hanging This is the point in the slaughter process where poultry arrive at the establishment in transport crates or cages, are unloaded, and are hung on shackles. There is a potential for contamination with enteric pathogens including Salmonella. The feathers, skin, crop, colon, ceca, and cloaca of birds brought to slaughter are often highly contaminated with Salmonella (Kotula & Pandya, 1995). As described in the previous section, transport cages have been found to be sources of cross contamination of pathogens onto live birds transported to slaughter. Cleaning followed by sanitation of the unloading and holding area is important. High levels of Salmonella found on incoming birds can overwhelm establishment interventions. These levels are carried forward to the next steps of the slaughter process. Studies show links between Salmonella at live receiving and later in the process (Fluckey, et al., 2003). Employee traffic patterns and air flow can be controlled to prevent cross contamination and reduce levels of Salmonella. There can be positive airflow moving from inside to outside of the establishment. Standard operating procedures and training, including changing clothes and boots upon arrival, separate facilities for \u201cdirty\u201d versus \u201cclean\u201d employees, and restricting employee movement are measures that can be put in place. Most establishments keep detailed records of suppliers and slaughter schedules by lots to monitor output or yields of products. An establishment could use these records to correlate its own in-house testing programs to determine if there are suppliers that routinely deliver birds carrying a high microbial load. Addressing potential contamination sources with suppliers could lower the microbial level of incoming birds at receiving and thereby reduce microbial loads, particularly pathogens, in chilled carcasses. Recommended Best Practices - Live Receiving and Hanging 1. Control airflow and traffic patterns. 2. Provide SOP and employee training. 3. Schedule flocks for slaughter based on pathogen loads. Key Points The feathers, skin, crop, colon, ceca, and cloaca of birds brought to slaughter are often highly contaminated with Salmonella. Transport cages are an important source of cross contamination of birds with Salmonella.", "41 Stunning and Bleeding This is the point in the slaughter process where the bird is stunned, cut, and bled. Stunning methods render birds unconscious. The method of stunning may be electrical, mechanical, or chemical. Bleeding ensures death by slaughter and ensures that poultry have stopped breathing before going into the scalding tank (9 CFR 381.65(b)). Stunning reduces struggling and convulsions. However, wing flapping and quivering that may happen because of the electrical stunning can transfer bacterial pathogens from the inside to the outside of the bird and to nearby birds and equipment. Continuous Gas Stunning, or Controlled Atmospheric Stunning (CAS), is an additional available stunning method that uses a combination of gases to stun the birds before they are hung on the line. Any stunning method must be monitored and controlled to ensure effectiveness. By decreasing the amount of feces expressed, establishments can reduce fecal cross-contamination on the surface of the carcasses, in the scald tank, and on the feather removal equipment. This decreases the level of Salmonella carried forward into the next steps. Figure 6 shows young chickens entering the stunner with minimal external fecal contamination.

Figure 6 Best practice: These young chickens show minimal fecal contamination on their feathers as they enter the stunner. These birds are calmly entering the stunner.", "42 Scalding Scalding prepares carcasses for defeathering by breaking down the proteins that hold the feathers in place and opening up the feather follicles. It is the point in the slaughter process where the carcasses are placed in hot water in order to facilitate feather removal and is the first location during processing where carcasses are exposed to a common bath, which can allow Salmonella cells from positive carcasses to spread Salmonella to negative carcasses (Russell, 2012). However, scalding can reduce levels of Salmonella on the carcasses, since much of the dirt, litter, and feces on carcasses is removed at this step. Salmonella contamination consistently decreases when scalding is well controlled. Scalder water that contains high concentrations of fecal material is a problem. Birds may come into slaughter facilities with excessive fecal material on the feathers, which gets washed off in the scalder water. Figure 7 shows an immersion scald tank with excessive fecal material contamination. Salmonella has been recovered from 100% of the skin and feather samples entering the scald tank in some experiments (Geornaras, et al., 1997) and has been shown to survive in the scald tank. Bacteria present in the dirty water may be massaged into the skin and open feather follicles. Also, the organic material may be retained on the surface of the bird through evisceration and end up in the chiller, deactivating the chlorine and preventing disinfection. Scalding cannot overcome high numbers of pathogens carried forward from previous steps. To reduce this problem, a bird brush and washer used prior to the scalder can remove some of the incoming dirt and fecal material. There are two methods for scalding: \u2022 steam-spraying \u2022 immersion Steam spray systems work by applying a mixture of steam and air at a temperature and pressure designed to scald the surface of carcasses. Immersion scalding is carried out by placing the carcasses into a tank of hot water. Tanks are either single- or multistage. Immersion is more common than steam-spraying. However, under the right conditions, both methods can reduce Salmonella on carcasses (Dickens, 1989). Recommended Best Practices \u2013 Stunning and Bleeding 1. Electrical stunning and chemical (gas) stunning are very effective stunning methods when implemented correctly. 2. Use well-timed feed withdrawal practices to reduce feces release during stunning.", "43 Figure 7 Not recommended: Excessive fecal material is present in the scalder Several considerations can mitigate contamination at the scalding steps. Water flowing into the tank ideally moves through the system flowing against incoming carcasses. This flow creates a dirty-to-clean gradient. Carcasses moving through the tank are washed by ever-cleaner water. Multiple stages create more opportunities to clean the carcasses (Cason, et al., 2000). High flow rates of water and adequate agitation dilute the dry matter and bacterial load in the tank (Cason, et al., 2001). The water pH is a key operational parameter to monitor. A higher, more alkaline pH (9.0 \u00b1 .2) is best for reducing Salmonella in the water (Humphrey & Lanning, 1987). Making the pH more acidic (3-4) is also effective at decreasing levels of Salmonella (Okrend, et al., 1986)). Establishments can initially monitor the pH in scald tanks as frequently as necessary to determine the pH highs and lows occurring during operation. Once establishments can maintain a desirable pH, less monitoring is needed. Uric acid from poultry feces can reduce the pH from 8.4 to 6.0 in less than 2 hours (Humphrey, 1981). Organic matter in the tank acts as a buffer to maintain a more neutral pH (6-7). Salmonella is more heat resistant at a neutral pH (Okrend, et al., 1986). Understanding water characteristics is an important aspect in poultry slaughter operations. The source (well or treated surface water or

municipal water), hardness, mineral content, and pH influence the killing action of any antimicrobial chemicals that are added to the water, and water hardness may affect the ability of water to wash Key Points Scalding is an important step that can reduce levels of *Salmonella* on the carcasses. Water pH is a key parameter to monitor. Scalding can be used as an intervention if pH is properly maintained in the scald tank.","44 bacteria from the skin of carcasses during processing (Hinton & Holser, 2009). Poultry establishments using more than one water source might consider the potential effect of the water source on the chemicals used. FSIS Directive 7120.1 Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products and 9 CFR 424.21 provides a lookup table of approved chemicals that can be used in scalders. Most U.S. poultry processors prefer a hard scald to a soft scald. A hard scald is a shorter scald time at higher temperatures compared to a soft scald. This approach allows better removal of the outer layer of skin (epidermis). The correct water temperature for the appropriate amount of time is important to prepare the carcasses for feather removal. The correct water temperature also reduces dressing defects. When the water temperature is too high, the carcasses become oily. This oiliness makes it easier for *Salmonella* to stick to the surface of the skin. If the carcasses are overscalded, the meat may start to cook, and the carcasses may be marked unacceptable and rejected by inspectors for over-scald per 9 CFR 381.92. If the temperature is too low, the tank becomes a breeding ground for bacteria. *Salmonella* cannot grow at temperatures greater than 116.6 °F (47°C). Therefore, scalding temperatures higher than 116.6°F (47°C) can be sufficient to control *Salmonella* growth. Table 3 shows common scalding times and temperatures for various classes of poultry.

Temperature (°F)	Time (seconds)	Class
138.2	59-64	Broiler (hard scald)
123.8-129.2	51-54	Broiler (soft scald)
138.2-145.4	59-63	Turkey

Reduction of *Salmonella* during scalding generally increases with higher water temperatures (Yang et al., 2001). While scalding above 116.6 °F (47 °C) controls *Salmonella* growth and initiates inactivation, scalding at 140 °F (60 °C) reduced counts by an additional 0.3 log units more than scalding at 125.6 °F (52 °C) or 132 °F (56 °C) (Slavik et al., 1995). Yang et al. (2001) also found that scalding at 140 °F (60 °C) resulted in reductions similar to scalding at 131 °F (55 °C). Some religious traditions forbid scalding. Under Kosher slaughter, carcasses are soaked in cold water to make feather removal easier. This method, as well as the steam spray method, may produce carcasses with skin more susceptible to *Salmonella* (Clouser, et al., 1995). Establishments can consider this potential effect in deciding what sanitary practices they employ downstream because the high number of 45 pathogens not reduced during scalding can be transferred to future steps in the slaughter process.

**Picking** The feather removal process is designed to remove feathers and the uppermost layer of the skin before evisceration. Carcasses typically pass through rubber picking fingers that mechanically remove feathers from the carcass. Most establishments use a continuous process. However, batch (not continuous; done at specific, defined and limited times) and manual processes are sometimes used in low-volume establishments. Good process controls at picking are critical. Cross-contamination of the carcasses with *Salmonella* occurs during picking because of contact with contaminated rubber picking fingers and contaminated reuse water (Geornaras, et al., 1997). Fecal material is released when picking fingers agitate and rub the carcasses and can lead to crosscontamination

with fecal material between the carcasses (Allen, et al., 2003). Several researchers have determined that levels of *Salmonella* increase during this step (Berrang, et al., 2011). Regular equipment sanitation and maintenance are recommended to minimize crosscontamination when using either batch or continuous picking. Post-feather removal Recommended Best Practices \u2013 Scalding 1. Have water moving counter current to carcasses. 2. Have high flow rates of water with adequate agitation to dilute dry matter and bacteria. 3. Use multi-staged tanks. 4. Maintain water pH at either above or below the optimum pH for *Salmonella* growth (6.5-7.5). 5. Use pre-scald brush systems to clean birds prior to scald tank. 6. Maintain hard scald temperatures of 140 \u00baF and above.", "46 rinses for carcasses is ideally maintained at 160\u00b0 F. Chlorine, acetic acid, and hydrogen peroxide are types of chemical rinses used during defeathering. If birds are plucked manually, the establishment can prevent crosscontamination by keeping the picking area as clean as possible and preventing feather buildup. Establishments can apply washes or antimicrobial interventions post-picking. However, cut surfaces of hocks must not be washed until FSIS postmortem inspection is complete (9 CFR 381.76, Post-mortem inspection). Otherwise pathological exudate could be removed or obscured and prevent detection of synovitis by inspectors. Water reuse is addressed in 9 CFR 416.2(g)(3). This regulation states that water, ice, and solutions may be reused for the same purpose if measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. An establishment is required to have data to support all decisions regarding reuse, including a decision that reuse will or will not cause adulteration (9 CFR 416.2(g)(2)). Recommended Best Practices \u2013 Picking 1. Prevent feather buildup on equipment. 2. Regular cleaning and maintenance of rubber picking fingers. 3. Ensure coverage of sanitizer on picking rails and equipment. 4. Use a post picking antimicrobial intervention rinse. 5. Scientifically support any water reuse plan. Key Points Good process control procedures at picking are critical and can reduce *Salmonella*. Fecal material is released when picking fingers agitate and rub the carcasses and can lead to crosscontamination between the carcasses.", "47 Evisceration Evisceration is the point in the process where removal of the internal organs, and any processing defects, from the poultry carcasses occurs in preparation for chilling. Evisceration includes multiple processes. It begins at the transfer point (i.e., re-hang) and ends when the carcass enters the chiller. It is the point in the slaughter process where the removal of the viscera (including the gastrointestinal tract and edible offal such as heart, liver, and gizzard) occurs by automated or manual means, along with any trim of processing defects from the poultry carcasses in preparation for chilling. If viscera are not handled properly, or if employee hygiene practices are not followed, an increase in microbial contamination can occur. Feed withdrawal practices affect process control at this step. For the evisceration process to work well, carcasses need to be placed on the shackles correctly and monitored as they move through the system. Blades are ideally kept sharpened, and attention given to routine and thorough cleaning. Figure 8 shows an automated opener system that utilizes replaceable blades that are cleaned between each carcass. Figure 8 Best practice: Replaceable blades (middle of picture) are washed between each carcass (yellow arrows) to reduce cross contamination. Blades are replaced daily, which minimizes cross contamination as compared to blades that are replaced less often. Key Points Evisceration begins at rehang and ends when the carcass enters the chiller. Feed withdrawal practices affect process control throughout the evisceration step. For the evisceration processes to work efficiently, carcasses

need to be placed on the shackles correctly and machinery needs to be adjusted to accommodate bird size.", "48 Keeping the equipment in good sanitary condition, free from intestinal contents and segments, is important for maintaining good process control. Figure 9 shows viscera that was caught in the machine as well as fat and tissue build up on breast plates and other surfaces that is not being sufficiently rinsed and cleaned between carcasses. These practices can lead to cross contamination. Figure 9 Not recommended: Viscera are stuck in machine and there is product build up on breast plates and bars around wings and legs (yellow arrows). Automated transfer (re-hang), rather than manual transfer, of carcasses between the defeathering and evisceration lines can reduce external surface cross-contamination.

Equipment used throughout the evisceration process can be installed, adjustments made, and machine performance calibrated effectively to handle the size, shape, gender, feed digestion capability, and live average weights of the birds to be slaughtered. These considerations apply to manual evisceration processes as well. Figure 10 shows a manual venting gun that is rinsed with chlorinated water between each carcass. Processing flocks with varying weight ranges can result in evisceration machinery performing poorly. Inconsistent carcass sizes (for example, because of poor bird size uniformity within a grower house or processing male and female birds together) can result in mis-cuts and fecal contamination. If machines are set for the median weight of the flock, poultry carcasses that are heavier or lighter may not be properly eviscerated. If carcasses are lighter or heavier than the machines can accommodate, the carcasses are more likely to have their gastrointestinal (GI) tracts split open, resulting in contamination of both carcasses and equipment. The machines need to be maintained", "49 in optimum condition and be properly aligned. Failure to maintain eviscerators in optimum condition can result in damaged intestines leading to carcass contamination. Equipment such as crop removal devices can easily become contaminated with *Salmonella*, causing carcasses to later become cross contaminated (Mead et al., 1994). Retracting the viscera from the body cavity can transfer crop and upper GI contents to the interior body cavity (Byrd et al., 2002). In some operations, at least half of carcass surfaces are contaminated with crop and upper GI contents immediately before evisceration (Byrd et al., 2002). Poultry establishments can benefit from awareness of these factors that lead to contamination and can implement necessary machinery checks to ensure that evisceration equipment is indeed functioning effectively.

Figure 10 Best practice: This manual venting gun is rinsed with chlorinated water, supplied to the gun by the red hose, between each carcass. Carcass rinses or sprays can be effective interventions for removing incidental contamination from the carcass surface during evisceration. Studies have shown that *Salmonella* prevalence on carcasses can be reduced by 50-90% following rinses (Buncic & Sofos, 2012). These rinses complement consistent sanitary dressing procedures to control pathogens. A 20 ppm free available chlorine rinse postevisceration can decrease microbial contamination and improve food safety (Waldroup, et al., 1992). The incidence of *Salmonella*-positive carcasses can decrease by one third", "50 when carcass rinses are incorporated into the evisceration process (Notermans, et al., 1980). When applying water rinses and sprays, establishments can consider the water pressure applied. Some studies have found that elevated spray pressure may force bacteria into muscle or skin rather than washing it off (Buncic & Sofos, 2012). Note: This guideline uses the term \u201cfree available chlorine\u201d when referring to parts per million (ppm) chlorine. Free available chlorine is the concentration of hypochlorous acid (HOCl) and hypochlorite ions (OCL) existing

in chlorinated water. (Reference: Handbook of Chlorination and Alternative Disinfectants, Geo. Clifford White, Fourth Edition 1998. Wiley Interscience). Rinses or sprays can be designed, installed, and calibrated to remove incidental contamination. When not properly designed or implemented, rinses or sprays may not effectively remove contamination and may even spread contamination from one part of the carcasses to another part or even to adjacent carcasses. Figure 11 shows a rinse that is not calibrated to wash contamination. Figure 12 shows sprays that spread contamination onto other parts of the carcass. Figure 11 Not recommended: Rinses are not positioned to wash contamination off tail area. On the left, a contaminated carcass moves on the line toward two washes. On the right, the carcass has moved past the washes, and the contamination remains. In this situation, if the nozzles are moved up, it is likely that due to the high pressure and angle of the spray, contamination may not be washed off but instead may spread to surrounding areas of the carcass. Key Point Antimicrobial interventions are not a substitute for consistently implementing sanitary dressing practices", "51 Figure 12 Not recommended: Overspray spreads contamination to adjacent areas of the carcass. In the closeup on the right, the middle spray bar results in splashing of water from the thigh up over the back of the thigh and onto the abdomen area (under yellow arrow), where it will run down the breast area. The contaminated vent area visible on the left (inside the red box) will not be washed off when it goes through the middle spray bar. Instead it will spread contamination to adjacent areas. This is also true of the faint yellow contamination on the outside of the thigh and bird's side (black bar of the right image). Multiple Salmonella controls throughout the evisceration process are recommended. Pathogens are not effectively removed by using one carcass rinse, and a multiple hurdle approach works best against pathogens. Some poultry processors consistently produce Salmonella positive carcasses, while others produce carcasses that upon testing typically do not have detectable levels of Salmonella. These variable test results may be the result of differences in sanitary dressing practices. Sanitary dressing practices are implemented throughout the slaughter process, in a manner that produces a clean, safe, wholesome poultry product in a sanitary manner. For example, rates of visible contamination on the carcasses after crop removal vary greatly depending on crop removal practices. In some establishments, fewer crops rupture because the crops are extracted toward the head (and downward) rather than toward the thoracic inlet (and upward) (Buhr et al., 2000). This is an important consideration for Salmonella control because crop tissue often contains Salmonella (Hargis et al., 1995). Note that some carcasses may become incidentally contaminated with feces and ingesta even with strict sanitary dressing practices. However, fecal contamination can be minimized with strict sanitary dressing practices.", "52 Chilling This is the point where eviscerated carcasses are chilled in order to inhibit microbial growth and meet the regulatory requirements of 9 CFR 381.66(b)(3). Additional information on chilling requirements can be found in the FSIS compliance guide Modernization of Poultry Slaughter Inspection: Chilling Requirements. Antimicrobial Intervention Use for On-line and Offline Reprocessing and for Chilling Procedures Reprocessing systems are used to control Salmonella on visibly contaminated carcasses. Both on-line (OLR) and off-line (OFLR) reprocessing systems can be used to remove incidental contamination during evisceration. On-line reprocessing is not a remedy or a substitute for poor sanitary dressing practices during evisceration. The on-line reprocessing system may be able to remove visible contamination, but the invisible contamination can remain if the intervention is overwhelmed. NOTE: Carcasses must be free of

visible fecal contamination prior to entering the chilling system as required by 9 CFR 381.65(f). Recommended Best Practices \u2013 Evisceration 1. Adjust and maintain equipment regularly as needed to accommodate bird size. 2. Implement an antimicrobial rinse to reduce equipment contamination. 3. Implement multiple hurdles to reduce pathogens.", "53 FSIS has posted lists of the approved OLR and OFLR systems. The lists are regularly updated and attached to FSIS Directive 7120.1, Safe and Suitable Ingredients Used in The Production of Meat, Poultry, and Egg Products. If an establishment desires to use an OLR or OFLR system that has not been approved by FSIS\u2019s Risk Management and Innovations Staff (RMIS) or wishes to modify an approved OLR or OFLR system, the establishment is responsible for submitting a protocol requesting permission to conduct an in-plant trial. Per the Memorandum of Understanding (MOU) between FDA and FSIS, FSIS would consult with FDA regarding safety of the proposed chemical. FSIS would review the protocol for any prohibitions that can potentially affect product safety, safety of inspection personnel, interfere with inspection procedures, or require a change to the Agency\u2019s regulations. If the in-plant trial is granted, FSIS would issue a letter granting permission to conduct an in-plant trial. More information regarding in-plant trials can be found in the FSIS Compliance Guideline Procedures for New Technology Notifications and Protocols. An establishment that uses chlorine or other antimicrobials as a part of its sanitary dressing and process control procedures or employs a pre-chill carcass wash that may affect the pH of the chiller water should consider the effect of pH on the efficacy of any antimicrobials used in the chiller. On Line Reprocessing Addresses incidental fecal or ingesta contamination during evisceration Utilizes washing systems and antimicrobial systems to achieve desired results. Off line Reprocessing Addresses disease conditions and contamination that cannot be removed by other means Produces carcasses microbiologically equivalent to those routinely eviscerated on line", "54 Further Processing This section of the guideline provides information for establishments that further process raw poultry carcasses to produce products such as: \u2022 Poultry parts \u2022 Injected, mechanically tenderized, or vacuum tumbled poultry products \u2022 Commminuted (including ground) poultry products (includes products such as patties and sausages that are made using comminuted poultry) \u2022 Stuffed chicken products Raw Source Material Considerations and the HACCP System There are two different sources for raw materials used in further processing: 1) in-house source materials (e.g., source materials from an establishment\u2019s own slaughter operation) and 2) incoming source materials from one or more supplying establishments. An establishment\u2019s knowledge of the production of source materials from its own slaughter operation is different than the knowledge of the production of purchased or otherwise incoming product because it will have more information about product derived from its own slaughter operations. Whether the source of raw materials used in further processing is another establishment, an establishment\u2019s own slaughter operations, or both, an establishment can consider how the source materials it uses in its processes can affect food safety decisions. A prudent establishment would incorporate this knowledge into its hazard analysis decisions to inform development of its HACCP system, including developing Sanitation SOPs and other prerequisite programs, and CCPs in the HACCP plan. Along these lines, if an establishment produces a raw or otherwise Not-Ready-To-Eat (NRTE) chicken product from parts received from other establishments, it can consider using only parts that are at or below a specific Salmonella percent positive as the source material for making this product. The

receiving establishment may also specify maximum levels for contamination (enumeration). In this scenario, considering the carcass category of the supplying establishment (e.g., only accepting parts from FSIS Salmonella Performance Standards carcass category 1 establishments) would not be as useful because parts and not carcasses are the immediate source materials. FSIS sampling of the industry indicates that pathogen prevalence increases as products are further processed from carcasses, to parts, to comminuted product. It is unclear what benefit requirements for carcasses would provide when the incoming source materials used to produce the finished products are not carcasses. Category 1 carcasses may go on to further processing within an establishment and be cross-contaminated or Key Point Comminuted products are those that are ground, mechanically separated, or hand- or mechanically-deboned and further chopped, flaked, minced or otherwise processed to reduce particle size.", "55 otherwise processed to result in a higher level of pathogens on chicken parts (or comminuted) than the carcass results would suggest. In-House Source materials Slaughter establishments that further process carcasses they produce are self-suppliers (they produce in-house source materials). For in-house source materials, the establishment has direct knowledge regarding the source materials\u2019 production, including pre-harvest information, sanitary dressing procedures, zero tolerance findings, antimicrobial treatments and records of critical operating parameters, and any microbial testing data. The establishment also has direct control of its processes and can monitor, verify, and correct its own processes more quickly than for product received from outside suppliers. It can verify that sanitary dressing and any interventions are being applied consistently as designed; it can implement corrective actions when it identifies that sanitary dressing procedures and any interventions have not been applied as designed; and it can identify and correct underlying problems that result in any repeated sanitary dressing or intervention failures. Figure 13 below shows the direct knowledge the slaughter establishment has concerning the production of in-house source materials during the slaughter process. Figure 13 If an establishment identifies problems in its own slaughter operations, for example, that sanitary dressing was not consistently implemented, it can consider how this problem may impact food safety decision-making during further processing. Similarly, if an establishment identifies problems during further processing, for example, that ground", "56 poultry sampling identified that a lot exceeded acceptable pathogen levels, the establishment can identify whether factors at slaughter may have contributed to the problem. Incoming Source Materials from Supplying Establishments Establishments have less knowledge available about and control over source materials that are produced at other supplying establishments. However, there are a number of actions that establishments receiving raw poultry for further processing can take to limit Salmonella in their incoming source materials. All establishments receiving raw poultry from supplying slaughter establishments can require the supplier to follow good sanitary dressing procedures to prevent contamination of poultry during slaughter. In addition, establishments can consider requiring that incoming raw materials be treated with interventions shown to reduce Salmonella. Establishments could also require that suppliers test source materials for pathogens of concern and have a plan for how to use test results in their decision-making. Establishments receiving source materials from outside suppliers can consider implementing the above requirements as purchase specifications and incorporating such specifications in their HACCP plans, Sanitation SOPs, or other prerequisite programs. If establishments producing raw poultry products require their suppliers

(both within and outside their corporate structure) to meet purchase specifications, they can also ensure that their suppliers actually meet these purchase specifications. They may accomplish this in several ways, by requiring, for example: \u2022 a document (e.g., letter of guarantee (LOG)) from each supplier that provides assurance that the supplier employs CCPs or other control points that address Salmonella and that describes the CCP, the monitoring of the CCP, and the use of any interventions; and \u2022 certificates of analysis (COAs) (i.e., actual test results) and the sampling method used by the supplier of the source material. A further processing establishment receiving source materials can maintain records (e.g., its own testing results, ongoing communication with suppliers, or third-party audits) that verify on an on-going basis that the supplier is executing its program in a consistent and effective manner. Ongoing verification ensures that the receiving establishment consistently receives product in which Salmonella is prevented or controlled to acceptable levels. Establishments that receive source materials from outside suppliers can still consider applying validated interventions during further processing. Approved interventions are listed in the FSIS Directive 7120.1 lookup table along with any required parameters for each entry. Such establishments can also consider carrying out their own testing of Key Point As part of the entire HACCP system, food safety decisions made at slaughter impact further processing, regardless of where further processing occurs.", "57 incoming source materials. As described in the Sampling and Testing section, testing can measure the pathogen load of incoming source material so that establishments can ensure that their processes are not overwhelmed by the incoming pathogen load. In addition, they can consider testing finished products to verify their systems reduce pathogens to acceptable levels. An establishment may be able to obtain detailed information concerning the purchased\incoming source material on a lot-by-lot basis (preferably, lots are defined as being microbiologically independent) from its supplier. In this situation, the receiving establishment may be able to support that Salmonella is NRTL at receiving based on the implementation of a prerequisite program (e.g., purchase specifications) that prevents the potential hazard from becoming RLTO. Such establishments that address pathogens in this manner can do the following: \u2022 have a written program that describes the purchase specifications that it will implement to show that pathogens are NRTL at receiving; \u2022 require information (for example, through letters of guarantee) on the supplying establishment\u2019s interventions that provide assurance that the supplier uses interventions that address pathogens, such as Salmonella; \u2022 obtain certificates of analysis (COA) affirming that source materials have been tested (with results available at purchase). If a receiving establishment is unable to obtain COAs, the establishment can obtain other evidence that each shipment or lot of purchased\incoming source materials was tested. In these situations, establishments can: o be aware of the sampling and testing method the supplier uses, and o be aware of the supplying company\u2019s information concerning the specific product codes that were sampled and tested.", "58 Figure 14 below shows the knowledge of the source materials\u2019 production that the receiving establishment is able to obtain by having a relationship with its suppliers. Figure 14 It is possible that a receiving establishment is not able to obtain detailed information concerning the purchased product\u2019s production on a lot-by-lot basis from its supplier. When a receiving establishment is only able to obtain general information concerning the production of purchased\incoming source materials, the establishment must take other measures to support its hazard analysis decision-making (9 CFR 417.5(a)(1)) at receiving in

order to justify the conclusion that pathogens are NRLTO. These measures may include, but are not limited to, the following options: 1. The receiving establishment may determine that pathogens such as Salmonella are RLTO on incoming source materials and apply an antimicrobial treatment as a part of their HACCP system. 2. The receiving establishment may be able to support that Salmonella are NRLTO in incoming source materials at receiving based on the implementation of a prerequisite program (e.g., antimicrobial treatment preventive measures on incoming raw materials) that prevents the potential hazard from becoming RLTO during its process, including rigorous recordkeeping documentation. For this situation, establishments can do the following: o have a written program that describes the antimicrobial treatment preventive measures that it will implement to show that Salmonella are NRLTO at receiving; o maintain supporting documentation for the program;" "59 o maintain records that demonstrate that the program is being implemented as written (i.e., verification records of the critical operating parameters); o maintain records that provide on-going evidence that the program effectively reduces pathogens to acceptable levels (e.g., its own verification testing) to support its decision that pathogens such as Salmonella are NRLTO at receiving; and o describe actions that the establishment will take when it fails to implement the program, or when it otherwise finds that the program has failed to prevent the hazard. Note that for option 2, if establishments determine that Salmonella are hazards NRLTO because of prerequisite programs, they are required to have records associated with their Sanitation SOP or other prerequisite programs that show these programs are preventing a food safety hazard from being RLTO as part of their HACCP decision making documents. When prerequisite programs are not effectively designed or consistently implemented, the hazard analysis is not supported, and FSIS would consider the hazard to be reasonably likely to occur. In this case, establishments must then take corrective actions (including reassessment) as set forth in 9 CFR 417.3(b). 3. The receiving establishment may be able to support that pathogens including Salmonella are NRLTO in the purchased source materials at receiving based on the implementation of its own verification testing measures in conjunction with purchase specifications that require information on the supplying establishment\u2019s interventions that provide assurance that the supplier employs CCPs that address pathogens such as Salmonella. Sanitation and Reducing Cross-Contamination Poultry carcasses processed as parts or used to make ground products have a higher incidence of pathogens because of possible cross contamination between positive and negative parts and carcasses during further processing. The sanitation considerations discussed in the Sanitation section also apply to further processing operations. This section discusses factors that establishments producing parts or comminuted poultry can consider to maintain sanitation and minimize cross-contamination during further processing. Opportunities for cross-contamination during further processing exist in various situations. One situation is when products are commingled (for example, parts are collected in combo bins for further processing). Another situation when pathogen spread and cross-contamination may occur is during parts cut-up or during the grinding (or other comminuting) process, specifically when skin is cut, ground, or otherwise Key Point Salmonella can be found inside feather follicles in the skin. When skin is cut, these pathogens can be exposed and spread during processing to previously uncontaminated product." "60 broken. Salmonella can be found in feather follicles in the skin (Kim et al 1996; Wu et al., 2014). These areas may not be accessible until they are disturbed, for example during cut-up or grinding, when these processes can result in exposure

of and spread of pathogens. National prevalence data from FSIS\u2019s Chicken Parts Baseline sampling indicate that skin-on parts were more likely to be positive for Salmonella than parts without skin (FSIS, 2014). Opportunities for cross-contamination also occur following the heat treatment step during production of raw but heat-treated poultry (for example, NRTE breaded, stuffed poultry products). For these products, it is essential that the finished product be processed in a manner to reduce the frequency and level of contamination before packaging at the establishment (e.g., by controlling cross-contamination between the time when products emerge from the hot oil or other batter-setting process until they are in final packaging). Approaches may include aseptic handling (gloves, sterile implements), designated clean spaces or containment to prevent exposure to contamination after the heat treatment. Handling of these types of products by the consumer may contribute to cross contamination in the home. Cross contamination can also occur anytime that raw poultry products are produced in one part of an establishment and further processed in another part. How product containers are handled within an establishment can increase cross contamination. Figure 15 shows tub containers used to hold poultry parts for further processing. The tubs were stored on dirty pallets, and employees touched the bottoms of the tubs when they emptied their contents into a hopper before using their gloved hands to push the contents into the hopper. Not only does this practice result in cross contamination, it is also an example of an insanitary practice.",<sup>61</sup> Figure 15 Not recommended: Plastic tubs used to hold raw poultry parts are stacked on wooden pallets, which are moved to another area in the establishment for further processing. Establishment employees picked up the tubs and frequently touched the bottoms of the tubs when emptying them into the hopper. Then, without first sanitizing their gloves, employees pushed the parts into the hopper. This is an example of both cross contamination and not maintaining operational sanitation.",<sup>62</sup> Product contact surfaces such as belts, augers, paddles, knives, hooks, and other implements can be regularly cleaned and sanitized to reduce cross contamination during operations. Figures 16a and 16b show that sanitary conditions during further processing are not being maintained due to buildup of organic material. Figure 16a Not recommended: Sanitary operation is not being maintained. There is significant buildup of fat and other organic material on the belts. This presents an increased risk of cross contamination. Figure 16b Not recommended: Sanitary operation is not being maintained. There is a significant buildup of fat and other organic material on the conveyors, blades, and associated product contact surfaces. This presents an increased risk of cross contamination. Establishments can keep in mind that the finished poultry products they produce that go for further processing at other establishments may be used to produce non-intact products such as those that are injected, tenderized, or vacuum tumbled. Finished",<sup>63</sup> poultry products may also be used as source materials for comminuted products, such as ground, mechanically separated, or similarly processed products, including patties and sausages. Because processes used to manufacture such products may increase the risk of cross-contamination and pathogen spread, establishments producing poultry parts for further processing can minimize opportunities for cross-contamination and consider whether the use of additional interventions for such products may prevent or reduce pathogens to acceptable levels. Establishments can also consider how their lotting practices can be designed to minimize cross-contamination. Achieving microbiological independence between lots can also limit product that may be implicated in a recall associated with an outbreak. Additional considerations for Non-intact

parts and products (mechanically tenderized, injected, or vacuum tumbled) Mechanical tenderization, such as needle and blade tenderization, injection with solutions, and vacuum tumbling are methods that some establishments use to tenderize products, add flavor, or add ingredients to raw poultry parts and carcasses. However, these processes can contribute to cross-contamination with pathogens. Any contamination on the outside of carcasses or parts may be carried to the inside through penetration by needles and other devices. Reusing injection solutions, such as brines or marinades, also presents risk for contamination of the solution by pathogens. A prime example of this mechanism of internalizing pathogens is an outbreak of Escherichia coli O157:H7 in beef steaks that occurred in 2007 (FSIS, 2007).

Contamination can also occur through introduction of contaminated liquid that is injected or forced into the muscle by injecting or vacuum tumbling. Contamination may be increased the longer solutions are reused and the greater the volume of product treated. Establishments should consider the effects of injected solutions in its hazard analysis (9 CFR 417.2(a)) and Recommended Best Practices, Sanitation and Reducing Cross Contamination 1. Clean product contact surfaces, including knives, as often as required to maintain sanitation during operations. 2. Knives and other tools can be sanitized between each carcass. 3. Consider using an antimicrobial intervention on parts. Key Points Blades and needles can push outside contamination into the interior of muscle. Injection solution picks up bacteria from contaminated product. Reused injection solution can push high levels of bacteria into the interior of muscle. The longer injection solution is reused, the greater the contamination.", "64 support all decisions made in the hazard analysis, 9 CFR 417.5(a)(1). Establishments that choose to tenderize, inject, or vacuum tumble raw poultry should consider the following factors: Operational sanitation should be maintained during the process, including evaluating the frequency that needles need to be replaced to minimize product residue buildup on the inside of the needle, which can be very difficult to remove. Establishments should consider the microbiological impact of introducing pathogens mechanically (through needles and blades) and by reusing a solution. Any solution reuse should be addressed in the HACCP plan or in the Sanitation SOP or another prerequisite program. Risk from microbial pathogens introduced during non-intact processes may be reduced in several ways: \u2022 by limiting this process to products that will undergo a lethality treatment at another federally inspected establishment \u2022 applying antimicrobial interventions to product just prior to treatment with needles or blades \u2022 limiting the time that solution is reused and maintaining a solution temperature of less than or equal to 40 \u00b0F (4.4 \u00b0C) to prevent pathogen outgrowth \u2022 treating reused solution with interventions to minimize or eliminate pathogens. Ultraviolet (UV) light treatment (Beers et al., 2010) can reduce pathogens in recirculated brine. Establishments can also consider how any solution reuse affects the establishment's lot designation.

Recommended Best Practices, Sanitation During Production of Non-Intact Products 1. Consider applying antimicrobial interventions to products prior to tenderizing or injecting. 2. Do not reuse injection needles if product residue cannot be removed. 3. Limit reusing injection solution to poultry that will receive a lethality treatment. 4. Establishments that choose to reuse injection solution can consider adding antimicrobial processing aids to the solution and can limit the time it is reused prior to sanitizing the injection system.", "65 Additional considerations for comminuted products Producers of comminuted poultry products can also consider that because of the fine texture of these products, meat and protein residues of these products may

extend into very small or unexpected food contact surfaces in grinding and other equipment. In addition to the factors already discussed, establishments that make comminuted poultry products can consider the information in this section with regard to minimizing microbial pathogens and creating and maintaining sanitary conditions. Surfaces of processing equipment, including grinders, blenders, pipes, and other components and surfaces in contact with the product require focused attention to ensure adequacy of sanitation procedures. These surfaces may include hoppers, augers, blades, grates, product blenders, and patty makers.

Establishments can consider parts of equipment that can harbor bacteria, such as rubber gaskets and similar pieces that may be difficult to reach and sanitize and ensure that they are sanitized when other surfaces are. The fine texture of comminuted product and the processes used to make them create a situation where one contaminated component can spread contamination into multiple batches of product. Systematic sanitizing of belts and other implements can break the chain of any contamination that slips through. Rather than the contaminant being spread across lots, it will be stopped or at least diminished. Different source materials used to produce comminuted products can present different risks of pathogen contamination. Establishments can consider the information below when making processing decisions for comminuted products. Source Materials Can Affect Pathogen Status of Comminuted Product Certain poultry parts may be more likely to be contaminated with pathogens and are therefore riskier to use as source materials to produce comminuted poultry products. The FSIS Chicken Parts Baseline study (FSIS, 2013) found that chicken necks were significantly more likely to be contaminated with Salmonella (55%) than other parts, including breasts, legs, and wings (between 20-44%). Establishments can consider not using chicken necks in comminuted poultry products or only using them in comminuted products that are intended for a lethality treatment. Similarly, skin-on and bone-in source materials used in comminuted chicken products present increased risk of contamination with Salmonella. As previously discussed, skin can contain Salmonella in feather follicles that can be exposed during the grinding or other comminuting process and spread throughout a lot. Chicken neck skin has Key Point Contaminated source materials going into a grinder, mechanical separator, or other comminuted poultry equipment can result in contamination of all product until the next cleaning and sanitizing is performed.", "66 typically been found to be more contaminated than other parts of the carcass. Research by Wu et al. (2014) concluded that neck skin included in ground chicken presents a significant risk for the introduction of pathogens. Table 4 shows that ground and other raw comminuted chicken products (such as sausages and patties) sampled by FSIS that were produced using either bone-in or skin-on source materials were more likely to be contaminated with Salmonella4 than those fabricated from deboned, skinless source materials. Table 5 shows the risk for use of bone-in source materials for comminuted turkey products.

Table 4. FSIS exploratory sampling testing results, raw comminuted chicken by source material composition (6\1\13-6\30\15, 2,688 samples) The interior of poultry bones can contain pathogens as well. In a recent study, 0.8% of chicken bones sampled were positive for Salmonella (Wu et al., 2014). In a different study, 5.2% of turkey bones sampled were positive for Salmonella (Cui et al., 2014). Although these may appear to be low percentages, again because of the nature of comminuted processes, contamination can spread throughout an entire batch or lot from a few contaminated bones through cross contamination. FSIS sampling data indicate that both chicken and turkey raw comminuted products produced using bone-in

source materials are more likely to be contaminated with Salmonella than those 4 FSIS Not Ready-to-Eat Comminuted Poultry Exploratory Sampling Project results from samples collected June 1, 2013 through June 30, 2015. For bone-in and skin-on source materials, Salmonella prevalence in comminuted chicken was 56.0%. The lowest prevalence product, made from deboned and skinless source materials, was 34.8%. To calculate the relative risk, each source material type was divided by the lowest risk product:  $56.0 / 34.8 = 1.6$ . Comminuted Chicken Products Salmonella prevalence in this source material Salmonella presence risk relative to the lowest prevalence source material (Deboned & skinless)5 Mechanically separated 83.4% 2.4-fold increase Ground and Other Comminuted Chicken Products Salmonella prevalence in this source material Salmonella presence risk relative to the lowest prevalence source material (Deboned & skinless) Bone-in & Skin-on 56.0% 1.6 Bone-in & Skinless 58.4% 1.7 Deboned & Skin-on 54.8% 1.6 Deboned & Skinless 34.8% N/A", "67 produced using deboned source materials. Table 4 shows this for comminuted chicken products, and Table 5 shows this for comminuted turkey products. Tables 4 and 5 indicate pathogen prevalence for comminuted products based on whether source material contained bone (chicken and turkey) or skin (chicken only). Analysis of FSIS comminuted poultry sampling results shows that it is more likely that comminuted chicken will be positive for Salmonella when its source materials contain bone, skin, or both bone and skin (58.4, 54.8, and 56.0%, respectively). Comminuted chicken made from deboned and skinless source materials had the lowest prevalence for both pathogens (34.8%). The tables also indicate how much more likely products made from different source materials are to contain pathogens, as compared to the product with lowest prevalence (products made from deboned and skinless source materials). Raw comminuted chicken products made from bone-in and skin-on source materials were 1.6-1.7 times more likely to be positive for Salmonella compared to those made from deboned and skinless source materials.4 Mechanically separated poultry product nearly always contains skin and bones in their source materials, because of the nature of the processing of this product. FSIS sampling results indicate for comminuted chicken, Salmonella prevalence was highest for mechanically separated poultry. For this reason, establishments can consider not using mechanically separated poultry as a component in NRTE comminuted products, or only using it in comminuted products that are intended for a lethality treatment. Table 5. FSIS exploratory sampling testing results, raw comminuted turkey by source material composition (6/1/13-6/30/15, 934 samples) Comminuted Turkey Products Salmonella prevalence in this source material Salmonella presence risk relative to the lowest prevalence source material (Deboned) Mechanically separated 52.4% 1.4-fold increase Ground and Other Comminuted Turkey Products Salmonella prevalence in this source material Salmonella presence risk relative to the lowest prevalence source material (Deboned) Bone-in 56.8% 1.5 Deboned 37.7% N/A It is important to keep in mind that the data in Tables 4 and 5 represents FSIS data from all establishments sampled in the exploratory program, without consideration of the amount of skin or bone going into comminuted processes. Each individual", "68 establishment can determine the extent that skin-on and bone-in source materials may contribute to pathogens in finished product. This determination can be made by sampling and testing comminuted products made from different source materials. Establishments that do not test products by source material can consider the information provided in the tables during decision-making in their processes. Using the information in the prevalence column of the tables, establishments

can compare the relative risk of using different types of source materials. For example, in the absence of its own sampling results, an establishment can compare using bone-in and skin-on source materials (56.0% Salmonella prevalence) with using deboned and skinless source materials (34.8%) to determine that the relative risk is 1.61 (56/34.8). This means there is about a one and a half times greater chance that the bone-in, skin-on source material will result in Salmonella being present in the finished product. Therefore, there is likely a benefit to using the deboned skinless source materials instead of the bone-in, skin-on source materials.

**Interventions** Unless otherwise stated, interventions (antimicrobial processing aids) described in this section have been reviewed for safety and suitability and are listed in FSIS Directive 7120.1. Establishments, intervention manufacturers, and other users that would like to implement interventions not listed in FSIS Directive 7120.1 would need to submit for review a protocol to FSIS describing the proposed function of the substance in the specific poultry or meat product and conditions of use, as described in the Intervention Use section.

Establishments may consider using interventions during further processing to decrease pathogens. Antimicrobial interventions may be applied to source materials prior to further processing, to parts, during grinding or other comminuting process, and during blending of ground or comminuted products. Establishments should consider all applicable labeling requirements when choosing an antimicrobial, in particular when adding aqueous solutions to products with a standard of identity that does not allow added water (e.g., \u201cgroun chicken\u201d; 9 CFR 319.15(a)). High pressure pasteurization (HPP) is another intervention that may be applied to raw comminuted product. Although applying interventions to source materials used in comminuted products can reduce pathogens in finished product, contamination may still occur during the process itself when skin or bones are broken, releasing bacteria that were not exposed to the antimicrobial application. Establishments can consider these factors when evaluating their use of interventions. Establishments can evaluate the adequacy of any Salmonella interventions they apply to parts during further processing, including those source materials that are specifically intended for non-intact use (such as grinding or other comminuted processes). Part of the evaluation can include consideration of variability of Salmonella levels on source materials. The same considerations discussed in the general Interventions section apply to selecting and applying interventions during further processing. Those", "69 considerations also apply to parts that are sent to other establishments for any kind of further processing because they may be used as source materials in comminuted or otherwise non-intact raw product. Interventions to control Salmonella can be applied by spraying or dipping (immersion). Generally, immersion is more effective than spraying because it ensures better coverage and longer contact time (Buncic & Sofos, 2012; McKee, 2014). Loretz et al. (2010) reported that acetic acid (20 ppm at 4\u00b0C) resulted in a Salmonella log reduction (log CFU) of 1.4 when applied as a dip (immersion), compared to a log reduction of 0.8 when applied as a spray. A potential challenge with immersion is maintaining the proper level of active chemical as it becomes absorbed and neutralized by organic material such as fat and protein. Another challenge with immersion is maintaining the active concentration of the intervention despite the natural decomposition of the compound as a result of chemical reactions, heat, or light. It is important to verify with sufficient frequency that the critical operational parameters of an antimicrobial dip are maintained. It may be necessary to either add more chemical or even to completely change the solution to maintain effectiveness. Figure

17 shows an antimicrobial dip being applied to boneless, skinless poultry parts prior to grinding. Figure 17 Best practice: Boneless, skinless poultry parts receive an antimicrobial dip prior to being ground. The following pages present information on some antimicrobial interventions that may be used during further processing and which have been studied to control pathogens during further processing. This information is summarized in the attachment to this guideline. Establishments need to adhere to the limits in the conditions of use for chemicals as described in FSIS Directive 7120.1 and 9 CFR 424.21. In addition, the establishment", "70 needs to determine the optimum concentration for its process based on the critical operational parameters in its scientific support documentation. Any ranges for pH, concentration, or other parameters included in this section are provided to give a general indication of these values, but they do not represent critical operational parameters. Inorganic and Organic Chlorine-based Treatments Chlorine is relatively inexpensive, has a broad spectrum of activity, and is quick acting. Its drawbacks include corrosiveness to processing equipment at low pH, loss of effectiveness at higher pH values, loss of effectiveness with increasing organic matter load, and longer contact time required as compared to some other antimicrobial interventions.

Commonly used chlorine compounds include liquid chlorine, hypochlorites, inorganic chloramines, and organic chloramines. Chlorine is typically used at pH 6.0 \u2013 7.5. A number of chlorine entries for use with poultry are in the FSIS Directive 7120.1 lookup table along with their acceptable uses. Chlorine added to water produces free available chlorine in the forms of hypochlorous acid and hypochlorite ions. Hypochlorous acid is the form most lethal to microorganisms. Acidified sodium chlorite Acidified sodium chlorite (ASC) is a type of chlorine compound that is a strong oxidizer. It enters bacterial cells and weakens or kills them by lowering the pH inside. ASC is safe and suitable for use on poultry carcasses and parts at concentrations of 500-1200 ppm, as indicated in FSIS Directive 7120.1. It is used at pH 2.3-2.7 and acidified with an organic acid, such as lactic acid, citric acid, or acetic acid. A benefit of ASC is that it is not as highly affected by the presence of organic material as chlorine. Mehyar et al. (2005) reported a 1.1 log reduction in *Salmonella* on inoculated drumsticks when treated with ASC. Recommended Best Practices, Interventions during Further Processing 1. Applying antimicrobial interventions during further processing can be part of an effective multiple hurdle approach to reducing pathogens. 2. Dipping is generally a better application method than spraying as it ensures full coverage of an intervention for a longer period of time.", "71

Trisodium Phosphate Trisodium phosphate (TSP) is an inorganic, non-chlorine-containing compound with a high pH. Its pH is 11-13 and is used at concentrations of 8-12%. A benefit of high pH is that it gives TSP detergent-like activity, which can improve effectiveness against microorganisms. The main disadvantage of using TSP is disposal, as the high discharge of phosphate into the sewer may be a violation of local, state, or federal Environmental Protection Agency sewer discharge regulations. Quaternary Ammonium Compounds Quaternary ammonium compounds (QAC) are a group of positively charged organic compounds that may have detergent-like properties (Schmidt, 2012). Most have a high pH (pH 6-10), are used at concentrations \u22641%, and are effective in killing a wide variety of microbes.

Cetylpyridinium chloride (CPC) is an example of a QAC. CPC is an odorless, colorless, stable compound that does not self-decompose and is not affected by organic material. QACs persist in solution for a relatively long time. QACs are not compatible with soaps, anionic detergents, or low pH solutions. CPC must be rinsed off poultry after use with water containing no more

than 50 ppm chlorine. The major disadvantage of QAC is that some may be less effective in hard water that contains >500 mg/L hardness (Miller, 2012). Organic Acids and Organic Oxidizers  
Organic acids and organic oxidizers used at the proper pH are effective in being able to enter bacteria to inhibit or kill them from the inside. Peroxyacetic acid (PAA) is an organic oxidizer. It has been studied on poultry parts to control pathogens. PAA is a mixture of the peroxy compound, hydrogen peroxide, and acetic acid. It is a versatile compound, as different formulations are available that may be used over a wide temperature range (0 to 40°C) and wide pH range (3 to 7.5). PAA is affected by protein or other organic materials to a lesser degree than chlorine is (Bauermeister et al., 2008). Studies comparing chemical interventions In one study, Del Rio (2007) evaluated acidified sodium chlorite (ASC), trisodium phosphate (TSP), citric acid, and peroxyacids (PAA) against Salmonella on chicken legs. The concentrations used were: ASC 1200 ppm with citric acid added until pH 2.7 was reached (final pH 2.70); TSP 12% (final pH 13.03); and peroxyacids 200 ppm (Inspexx 100, Ecolab, St. Paul, MN; final pH 3.75). The temperature of the disinfection solution at use was 18°C. Chicken legs containing approximately 9 log CFU/ml Salmonella were dipped in the disinfection solutions for 15 minutes and drained at 20°C for 15 minutes. The number of bacteria killed was then measured. All treatments", "72 resulted in Salmonella reduction, with ASC and TSP having greater effectiveness than PAA (log reduction of 2.05, 1.86, and 0.93, respectively). In another study (Chen et al., 2014), researchers treated Salmonella inoculated chicken parts (bone-in and skin-on) with chlorine, PAA, and cetylpyridinium chloride (CPC) at various concentrations in a chilled immersion system for 25 sec. PAA and CPC significantly reduced Salmonella in a dose-dependent manner. Water and chlorine had little effect in reducing Salmonella. A study by McKee et al. (2013) compared the pathogen reduction of antimicrobial interventions applied to chicken parts, including those used to produce ground product. Chicken parts were treated with different concentrations (0.35% and 0.60%) of cetylpyridinium chloride (CPC), (0.07% and 0.10%) peracetic acid (PAA), and (0.003%) chlorine in a parts decontamination tank. Preliminary research shows that parts immersed/dipped into PAA had the greatest reductions of Salmonella followed by CPC. Chlorine was the least effective. However, this lack of effect may be related to short contact times (<20 sec) for chlorine. Findings from this study suggest that dips/immersions are more effective than single spray systems when treating parts because of their longer contact times and complete coverage. Bacteriophages Bacteriophages (also called phages) are naturally occurring organisms (viruses) that infect only a specific host bacterium (Hagens & Loessner, 2010). Phages cannot infect humans (Lu & Breidt, 2015). Phages are ubiquitous in the environment in the water, in soil, and on food consumed (Guenther, 2009). Once phages infect bacteria, they can multiply inside of the bacteria, destroy the cell wall of the bacteria, and then be released into the environment where they can infect other susceptible bacteria. Several phage applications demonstrated to infect Salmonella are listed in Directive 7120.1 for use with poultry. The phage application researched by Sukumaran, et al. (2015) was on chicken skin and skinless chicken breast filets. The study combined a 20 second dip at 4°C in organic antimicrobial compounds followed by a spray application of anti-Salmonella phage (108109 PFU/g). The organic antimicrobial compounds tested were: cetylpyridinium chloride (CPC) at 0.6%; lauric arginate (also known as lauramide arginine ethyl ester; LAE) at 200 ppm; and peroxyacetic acid (PAA) at 50 and 400 ppm. Chicken skin treated in this manner achieved the following Salmonella reductions: CPC, 2.1 log reduction; LAE, 2.4 log

reduction; PAA (50 ppm), 1.7 log reduction; and PAA (400 ppm), 0.9 log reduction. Skinless chicken breast treated in this manner achieved the following Salmonella reductions: CPC, 2.2 log reduction and LAE, 2.6 log reduction (the PAA dip was not studied on skinless chicken breast).", "73 Physical Interventions Electrolyzed Oxidizing Water Treatment Electrolyzed oxidizing (EO) water is inexpensive, must be generated on-site with specialized equipment, has strong bacterial killing effect, and has little residual (longlasting) effect. EO water is acidic and is an effective antimicrobial immersion\dip solution (Northcutt et al., 2007). However, it usually requires much longer contact time than other interventions, so spraying may not be an appropriate application method. EO water is produced by passing direct current voltage through a dilute sodium chloride (salt) solution. The result of the reaction is the production of two types of water (Hsu, 2005). It is the EO water that has low pH (2.3-2.7), high oxidation-reduction potential (>1000 mV), and high dissolved oxygen. A high oxidation-reduction potential means that more oxidation will occur. That translates to a greater capacity to form free radicals that kill bacteria (Venkitanarayanan, 1999). Huang (2008) and Hsu (2005) provide detailed descriptions on the concepts. The production of EO water containing sodium chloride (1-12% w\% v) results in the formation of sodium hypochlorite (NaOCl) and hypochlorous acid (HOCl). HOCl functions as if chlorine gas was added into the poultry parts disinfection solution without the need to store a dangerous gas. It is important to point out that although EO water is strongly acidic, it is different from strong acids, such as hydrochloric acid or sulfuric acid, in that it is not corrosive to skin, to mucous membranes in the nose and lungs, or to poultry carcasses or parts (Huang, 2008). However, the HOCl (sodium hypochlorite) generated by the EO process may cause breathing irritation that can be reduced with proper ventilation (Huang, 2008). High Pressure Inactivation A typical high pressure pasteurization (HPP) system consists of a pressure vessel, pressure transmission fluid (usually water), and pressure generating pumps. HPP is a technology by which a product is treated at a very high pressure. HPP requires specialized equipment and is usually applied off-site where that equipment is located. HPP treatment kills or inhibits microorganisms, and researchers have studied its effectiveness in reducing pathogens in comminuted chicken and chicken parts. An advantage of using HPP is that surviving microorganisms can be more sensitive to other types of antimicrobial interventions as compared to bacteria that have not been exposed to HPP (Alpas, 2000). Escriu (2009) treated finely minced chicken inoculated with 6 log CFU\g Salmonella with HPP at 400 MPa at 20\u00b0C for 2 min with a water-oil mixture used as the pressure transmission fluid. Salmonella was reduced 3.26 to 4.35 log CFU\g.", "74 Tananuwong (2012) applied HPP to chicken breast inoculated with Salmonella (7 log CFU\g) at 300 MPa at 35\u00b0C for 1 min and achieved approximately 2 log reduction. Irradiation using Ionizing Radiation Food irradiation is the process of exposing food to high levels of radiant energy and is applied by directing ionizing radiation to food products. Food can be irradiated commercially for several purposes: to extend shelf-life, eliminate insect pests, or reduce numbers of pathogenic microorganisms. Ionizing radiation can penetrate deeply into food, killing insect pests and microorganisms without raising the temperature of the food significantly (Jaczynski, 2003). Ionizing radiation kills bacterial cells and pests by damaging DNA (Tahergorabi, 2012; Verma, 2001). Ionizing radiation results from cobalt-60, cesium-137, x-rays, and electron beams. Cobalt-60 (60Co) is a common source of a form of ionizing radiation called gamma irradiation. It has high penetrating power (Ahn, 2013), which allows the treatment of poultry of variable sizes,

shapes, and densities (including frozen and unfrozen). X-rays are also used to produce ionizing radiation. X-rays have high penetrating power but are typically not used for treatment of food because it is not an efficient process (Tahergorabi, 2012). Another way of producing ionizing radiation is by applying an electron beam (e-beam). In this approach, a stream of high-energy electrons is applied to products. Because the radiation penetrates only a few centimeters, it is useful to treat thin layers of food (Jaczynski, 2003; Ahn, 2013). The electron beam may be applied over moving food on a conveyor, unlike some other sources of ionizing radiation. Electron beam systems require regular maintenance, high electric power, and cooling as the equipment produces high heat (Ahn, 2013). The maximum dosage of ionizing radiation is 3 kGy absorbed by raw poultry (fresh and frozen). The maximum dosage limit allowed for poultry is based on the safety determination that was made by FDA (21 CFR 179.26(b)(6)). A requirement that FDA placed on the use of irradiation is that the packaging of irradiated poultry must be air permeable and does exclude moisture and microorganisms from penetrating the package barrier. To promote processing flexibility and innovation that will lead to improvements in food safety, FSIS does not specify at which point irradiation may or may not be applied. Under HACCP, an establishment must control the conditions under which product is held from initial processing through irradiation and packaging to ensure and preserve the intended antimicrobial effects of irradiation (64 FR 72150)6. FSIS requires the labeling of irradiated meat and poultry products, including the radura symbol. These labeling requirements are outlined in the final rule, Irradiation of Meat Food Products, 64 FR 72150. 6 Irradiation of Meat Food Products; Final rule. Dec 21, 1999. Federal Register. 64: 72150-72166.","75 Thayer (1991) used gamma irradiation at 0 to 3.6 kGy on sterile, mechanically deboned chicken meat inoculated with approximately log 9.9 cfu/g Salmonella Typhimurium. In this study, the higher the dose of gamma radiation used, the higher the kill rates of Salmonella (log reductions). Gamma irradiation was also more lethal for S. Typhimurium at higher temperatures and in the presence of air (as opposed to in a vacuum). The researchers found that using gamma irradiation resulted in a log reduction between 5.5-7 log. More details of the conditions used to achieve these log reductions are available in the research article. In a different study, Thayer (1992) inoculated fresh, nonfrozen chicken wings with Salmonella Typhimurium and used five gamma irradiation doses: (0, 0.90, 1.80, 2.70, and 3.60 kGy) in air at 5\u00b0C. All Salmonella were killed on samples inoculated with 10 or 100 CFU/wing. Surviving Salmonella were detected on chicken wings inoculated with either 1,000 or 10,000 CFU/wing after irradiation with 1.8 kGy, but the numbers were very low (below enumeration limit). No Salmonella were detected following gamma radiation doses of 2.7 or 3.6 kGy. This study demonstrated that irradiating poultry could result in significant reductions in Salmonella on raw chicken wings. Another study found that applying electron beam irradiation to boneless, skinless chicken breasts containing naturally occurring bacteria resulted in an approximately 5log reduction in Salmonella and Campylobacter. The doses applied were 1.0 and 1.8 kGy at ambient temperature and both doses resulted in comparable reduction of Salmonella and Campylobacter (Lewis 2002).","76 References Ahn DU, Kim IS, and Lee EJ. 2013. Irradiation and additive combinations on the pathogen reduction and quality of poultry meat. Poult Sci. 92: 534-545. Allen VM, Hinton MH, Tinker DB, Gobson C, Mead GC, Wathes CM. 2003. Microbial cross-contamination by airborne dispersion and contagion during defeathering of poultry. Br Poult Sci 44:567-576. Allen VM, Tinker DB, Hinton MH, and Wathes CM. 2003. Dispersal of microorganisms in commercial

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alter appearance and texture of product Operates at pressures >100 MPa Application: N/A Liu, 2012 Simonin, 2012 Irradiation - No chemicals on food; no rinse required - Expensive to install - Typically done at a separate establishment - Labeling requirement \u22643.0 kGy packaging must be air permeable (21 CFR 179.26(b)(6)) Thayer 1991 and 1992"]}, {"file\_name": "FSIS\_GD\_2021\_0006", "title": "FSIS Guideline for Controlling Campylobacter in Raw Poultry", "num": "FSIS-GD-2021-0006", "id": "b0269584afc8f9b81214e066c0a35cc9697d2909d3dd308aa078d3e416ff2b9d", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-07/FSIS-GD-2021-0006.pdf", "type": "pdf", "n\_pages": 63, "word\_count": 19625, "text\_by\_page": ["This guideline is designed to help poultry establishments, including those that are small and very small, to: Identify and implement pre- and post-harvest interventions to control Campylobacter as part of their HACCP system Utilize microbial testing results to monitor the performance of the HACCP system and inform decision-making FSIS Guideline for Controlling Campylobacter in Raw Poultry June 2021"], "1 Table of Contents Preface .....

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Preface This is a revised version of the FSIS Guideline for Controlling Salmonella and Campylobacter in Raw Poultry. This is the 2021 edition of the FSIS Guideline for Controlling Campylobacter in Raw Poultry. This edition separates the guideline into two separate documents in response to comments received on the 2015 edition: one for Salmonella and one for Campylobacter. This guideline represents FSIS\u2019 current thinking on these topics and should be considered usable as of its issuance. The information in this guideline is provided to assist poultry slaughter and processing establishments in controlling hazards and meeting the FSIS pathogen performance standards. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the regulations. Under the regulations, establishments may choose to implement different procedures than those outlined in this guideline, but they would need to validate and support how those procedures are effective. This guideline is focused on small and very small establishments in support of the Small Business Administration\u2019s initiative to provide small businesses with compliance assistance under the Small Business Regulatory Enforcement Fairness Act (SBREFA). However, all poultry establishments may apply the recommendations in this guideline. It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective Hazard Analysis Critical Control Point (HACCP) systems. FSIS has other guidance documents availabe for establishments that slaughter and process raw poultry products, including: \u2022 Information about the chilling of poultry products can be found in the Modernization of Poultry Slaughter Inspection: Amendments to Chilling Requirements. \u2022 Information about designing and implementing a microbiological sampling plan can be found in the FSIS Compliance Guideline: Modernization	

of Poultry Slaughter Inspection - Microbiological Sampling of Raw Poultry. \u2022 Information about controlling Campylobacter and Salmonella in chicken liver can be found in the FSIS Guideline: Chicken Liver. \u2022 Information about controlling Salmonella can be found in the FSIS Guideline for Controlling Salmonella in Raw Poultry." , "4 Congressional Review Act Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this guideline is not a \u201cmajor rule,\u201d as defined by 5 U.S.C. 804(2). Reason for Issuing the Guideline FSIS revised this guideline to respond to public comments on the Draft Compliance Guideline For Controlling Salmonella and Campylobacter in Raw Poultry (4th Edition) and provide updated information for establishments to use to control pathogens in raw poultry products with the goal of reducing human illnesses from consuming poultry contaminated with Campylobacter. In addition, since the 2015 revision of this guideline, FSIS has implemented the more sensitive enrichment method for Campylobacter and is therefore revising Campylobacter pathogen performance standards for chicken parts, comminuted chicken and turkey products. This guideline can assist establishments in meeting Campylobacter performance standards and reducing illnesses associated with Campylobacter. CDC estimates Campylobacter is the #1 cause of bacterial diarrheal illness in the United States; most Campylobacter infections are associated with eating raw or undercooked poultry or from contamination of other foods by these items (CDC, 2017). This guideline describes concerns and controls for each step in the poultry slaughter process. The interventions suggested in this guideline cannot overcome poor preharvest production practices, poor sanitary practices in slaughter and dressing, or poor slaughter and further processing facility sanitation. Establishments can use this guideline to improve management practices, make changes at the appropriate locations, and improve process control. As a result, establishments can produce raw poultry products at a higher standard of pathogen control, including Campylobacter. Again, the information in this guideline is provided as guidance to assist poultry slaughter and processing establishments and is not legally binding from a regulatory perspective. Changes from the Previous Version of the Guideline This guideline is final. FSIS will update this guideline as necessary when new information becomes available." , "5 FSIS made the following specific changes to the guideline to reflect the peer-reviewed literature and address public comments received on the Draft Compliance Guideline For Controlling Salmonella and Campylobacter in Raw Poultry (4th Edition): \u2022 Removed the word \u201ccompliance\u201d from the document title and throughout the document to clarify that this document does not constitute regulatory requirements; \u2022 Separated information specific to controlling Campylobacter into a separate guideline; \u2022 Removed redundant language related to other current FSIS guidelines, providing hyperlinks to those resources where appropriate; \u2022 Added relevant, current peer-reviewed science related to poultry slaughter and processing, including a complete revision of the bedding and litter section, and additional literature resources specific to Campylobacter; \u2022 Added information about antimicrobial carryover and considerations to mitigate its effect on microbiological sampling; and \u2022 Updated data tables outlining the relative risk of various source materials used in further processed poultry products based on recent FSIS data. How to Effectively Use the Guideline This guideline is organized to provide users with the current science and recommendations. To use this guideline, FSIS recommends that readers use the navigation headings to move efficiently through the document sections of interest. Hyperlinks, where

provided, will quickly take you to the correct place in the document electronically and are also provided to other complementary documents. The reference list at the end of the document provides resource material used in the development of this guidance (References). Questions Regarding Topics in this Guideline If after reading this guideline you still have questions, FSIS recommends searching the publicly posted Knowledge Articles (\u201cPublic Q&As\u201d) in the askFSIS database. If after searching the database, you still have questions, refer them to the Office of Policy and Program Development through askFSIS and select \u201cSampling\u201d as the Inquiry Type or by telephone at 1-800-233-3935.","6 Documenting these questions helps FSIS improve and refine present and future versions of the guideline and associated issuances. Background FSIS regulated poultry slaughter and processing establishments are required to determine the \u201cfood safety hazards that can occur before, during, and after entry into the establishment\u201d (9 CFR 417.2(a)) in their hazard analysis. Pre-harvest interventions, adequate sanitary dressing procedures at slaughter, and adequate sanitary conditions during further processing are a part of an integrated approach to reduce the public health impact of *Campylobacter*. This pathogen is a hazard that establishments producing raw poultry products can control through a Hazard Analysis and Critical Control Point (HACCP) plan or prevent in the processing environment through Sanitation Standard Operating Procedures (Sanitation SOPs) or other prerequisite programs. FSIS has determined that contamination of poultry carcasses and parts by fecal material and enteric pathogens (including *Campylobacter*) is a hazard reasonably likely to occur (RLTO) in poultry slaughter establishments unless addressed in a Sanitation SOP or other prerequisite program.<sup>1</sup> For this reason, if an establishment relies on its Sanitation SOP or other prerequisite program to address enteric pathogens, the establishment\u2019s HACCP system must identify why such Sanitation SOP or other prerequisite program results in the enteric pathogens being not reasonably likely to occur (NRLTO). The measures outlined in this document will be most effective at decreasing *Campylobacter* in raw poultry products when considered together. Food Safety and the HACCP Framework Unlike the production of ready-to-eat (RTE) product in which a lethality treatment destroys pathogens of public health concern, slaughter and further processing operations do not have as many available treatment options capable of destroying all pathogens in raw products. Under HACCP regulations, establishments are required to have a system designed to ensure that poultry is processed in a manner that prevents and controls potential contamination hazards that are RLTO during slaughter and processing. Slaughter establishments can have controls and procedures in place to reduce the level of incoming contamination on the exterior of the birds and to reduce or mitigate any contamination that can occur throughout the slaughter process. 1 79 FR 49565 (p.49613) Key Point Federally inspected poultry establishments are required to conduct a hazard analysis as part of their Hazard Analysis and Critical Control Point (HACCP) system. The hazard analysis is required to include \u201cfood safety hazards that can occur before, during, and after entry into the establishment\u201d (9 CFR 417.2(a)).","7 Establishments must document the controls and procedures they use to reduce contamination in their HACCP plan, Sanitation SOP, or applicable prerequisite program in accordance with 9 CFR 417.5. HACCP Plan to Control Hazards If the establishment decides through its hazard analysis that *Campylobacter* is a food safety hazard that is RLTO, 9 CFR 417.2 requires that the establishment\u2019s HACCP plan address this food safety hazard. The HACCP plan must meet all parts of 9 CFR 417.2(c), including having a critical control point (CCP) to address the pathogen. A CCP is defined as a point, step, or

procedure in a food process at which control can be applied, and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. As an example, an establishment might have a CCP at a point during slaughter for applying a validated antimicrobial intervention to carcasses. FSIS requires the establishment to develop critical limits (CLs) for CCPs to control hazards that are RLTO (9 CFR 417.2(c)(3)). CLs are the parameters that indicate whether the control measure at the CCP is in or out of control. A critical limit is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard (9 CFR 417.1). An example of CLs are the critical operational parameters for an antimicrobial intervention applied to carcasses at a point during slaughter. For example, critical operational parameters of an antimicrobial applied with a spray bar may include concentration, pH, and spray pressure. To determine whether CLs are being met, establishments must monitor them (9 CFR 417.2(c)(4)). Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification. Monitoring procedures usually involve either a measurement or an observation. For the example of a CCP of applying an antimicrobial intervention during slaughter, monitoring activities might include measuring the concentration, pH, and other critical limits of the antimicrobial intervention, at a frequency sufficient to determine whether the CCP is under control. If a CL is not met, the establishment must meet the corrective action requirements in 9 CFR 417.3. To document whether the establishment meets its CCP, the establishment records its measurements and corrective actions as part of a recordkeeping system. Verification ensures that the HACCP plan is being implemented as written and confirms the accurate monitoring of the CCPs. Guidance on validation and ongoing verification is available in the FSIS HACCP Systems Validation guideline.", "8 GENERAL CONSIDERATIONS More general considerations, including information on sanitation, sampling, hazard analysis, scheduled slaughter, and HACCP, relative to controlling pathogens during poultry production are covered in the FSIS Guideline for Controlling Salmonella in Raw Poultry. These principles apply to both the control of Salmonella and Campylobacter. Additional sampling guidance is available in The FSIS Compliance Guideline: Modernization of Poultry Slaughter Inspection - Microbiological Sampling of Raw Poultry. Using Microbiological Sampling and Testing Use of Microbiological Sampling Data Following successful validation of its HACCP system, an establishment uses the validation data to implement its system. Establishments are required to support the monitoring and verification procedures selected and the frequency of those procedures (9 CFR 417.5(a)(2)). Microbiological verification data ideally includes samples collected at a number of points throughout the process (e.g., samples of starting materials, interim product, and finished product) for the same lot. Selecting samples in this way allows the establishment to determine whether the HACCP system is reducing contamination, and whether the HACCP system is working as designed, similar to process mapping. Samples at intermediate points provide additional information about intermediate process steps. Target Organisms Establishments can consider the advantages and disadvantages of testing for the presence of selected indicator bacteria and pathogens for ongoing HACCP verification. Sampling and testing costs for indicator species may be lower than costs for pathogens. However, while elevated levels of indicator bacteria are usually interpreted to mean pathogens are more likely, this relationship is not perfect. In other words, high levels of indicator organisms do not always

mean that the pathogen is present, and low levels do not guarantee the pathogen is controlled. Only pathogen testing can effectively verify that pathogens are controlled to acceptable levels in finished product. *Campylobacter* is not captured by commonly used indicator tests, including Aerobic Plate Count (APC) and Enterobacteriaceae (EB). There are no identified indicator organisms that directly reflect the presence or absence of pathogens in poultry (e.g., *Campylobacter*). Therefore, FSIS recommends that an establishment test for pathogens at least intermittently and compare its results against the presence or absence of other non-pathogenic organisms (i.e., the indicator organisms the establishment is using) to assess whether it is maintaining process control. For example, an establishment could consider the FSIS "minimum number to", "9 assess" for each FSIS performance standard as a guide to ensure that they collect enough data points to have statistical confidence in their pathogen percent positive. For most products, that is roughly one *Campylobacter* sample per month (for example, 11 samples/52 weeks for comminuted poultry). This approach is supportable if the analytical method has comparable sensitivity to the FSIS method; the less sensitive the method, the more samples are needed to increase confidence in the accuracy of the results. The indicator organisms can provide evidence of control, while periodic testing for pathogens may verify that the establishment is reducing pathogens to acceptable levels. Establishments conducting their own ongoing verification sampling and testing of finished product for *Campylobacter* can use the FSIS performance standards as indicators of process control. Sample Collection Method Proper sample collection techniques and procedures are necessary to ensure the accuracy of test results. Sample handling and collection procedures are specific to the type of product to be sampled (e.g., parts or comminuted), the sample collection method (e.g., parts rinse, comminuted product sampling), and the type of sample collected (e.g., rinsate sample, finished product samples, excision sample of skin). Individuals who will collect samples need to receive training on proper sample collection procedures. It is important for the establishment to be able to collect and ship samples properly. Onsite assistance or information on proper sample collection (aseptic techniques) and prompt shipment of samples to the laboratory from the establishment are also important. The final result of the analysis will be neither accurate nor meaningful if a laboratory has not implemented procedures to prevent mishandling of samples or alteration of records. In particular, *Campylobacter* is sensitive to light (Ultraviolet exposure) and freezing, so it is critical that samples are maintained in a refrigerated, but not frozen, place until shipped or transported to the laboratory. Maintaining temperature of the sample above 0 °C but below 15 °C before and during transport protects sample integrity. To effectively use data to evaluate process control, the collection, handling, storage, and transportation of samples must be carefully controlled to prevent temperature abuse, sample leakage, and other events that could affect sample integrity and lead to unreliable test results. Procedures for maintaining sample integrity are particularly important when samples need to be transported from the establishment to an off-site laboratory (e.g., by a delivery service such as FedEx or courier) where they may not be under the direct control of the establishment or the laboratory for a period of time. Examples of non-destructive sample collection techniques that an establishment may choose to use to collect poultry carcass samples are included as attachments to the FSIS Compliance Guideline: Modernization of Poultry Slaughter Inspection - Microbiological Sampling of Raw Poultry. Non-destructive techniques do not result in", "10 destruction of the product being sampled. A parts rinse sample

collection is an example of a non-destructive sampling technique. Antimicrobial Interventions and Drip Time Using antimicrobial interventions during processing steps may make it more difficult to detect remaining bacteria, particularly when non-destructive or surface sampling is conducted. For destructive sampling, in which the tissue itself is collected for analysis at the laboratory, remaining antimicrobials will continue to be inactivated by organic material in the sample during shipment of the sample to the laboratory. Conversely, with rinsate or through other surface sampling, capturing the antimicrobial in a buffer or other sampling solution may prolong the antimicrobial's effective time. For example, consider poultry carcasses exiting a chiller tank where antimicrobial interventions are used. Contaminated carcasses may have bacteria that survived the chiller tank. However, those bacteria may not be detected through sampling if the carcass is not allowed adequate drip time before the establishment collects a rinse sample. Adequate drip time will allow excess antimicrobials to drip off the carcass. Immediate sample collection will include a significant amount of residual antimicrobials, which suspended in rinsate will remain active and make it harder for the laboratory to detect live bacteria. If the carcass is allowed adequate drip time, the sample will contain less residual antimicrobials, and the laboratory will be more likely to detect live bacteria. At this time, FSIS generally recommends establishments wait at least 60 seconds after application of antimicrobial interventions before collecting a sample to reduce the amount of antimicrobial carryover. A longer drip time may be recommended by the antimicrobial manufacturer for particular solutions. Tipping over the carcass to allow drainage of chiller water that has accumulated in the body cavity can also result in greater accuracy of the test result. Establishments could consider whether a neutralizing agent is available which could stop the action of any residual antimicrobial intervention, making it possible to more accurately detect live bacteria remaining on the sample. Examples of a neutralizing agent suited for particular antimicrobials would include lecithin for Cetylpyridinium Chloride (CPC), sodium thiosulfate for Peroxyacetic Acid (PAA), or sodium thiosulfate plus bicarbonate for Acidified Sodium Chlorite (ASC) (Gamble et al., 2016). Recommended Best Practices, Ongoing Verification Testing 1. Prevent samples being analyzed for *Campylobacter* from exposure to freezing temperatures and Ultraviolet light exposure. 2. Both indicator bacteria and pathogens can provide useful information. 3. Allow at least 60 seconds before sampling after application of any antimicrobials, to prevent excessive antimicrobial carryover in the collected sample.", "11 PRE-HARVEST Pre-Harvest Interventions and Management Practices Pre-harvest interventions and practices can prevent or reduce *Campylobacter* contamination in live birds, increasing the effectiveness of post-slaughter interventions and establishment controls. This section identifies available pre-harvest interventions\practices, and how slaughter and processing establishments can encourage their use by poultry producers. This section covers poultry production from breeder stock through transport to the slaughter establishment. Live receiving and subsequent slaughter steps are covered in the following section. Food Safety Hazards Colonization of the poultry gastrointestinal tract with *Campylobacter* is a food safety hazard that can occur at pre-harvest (i.e., at grow-out, the hatchery, or at the breeder farm). Colonization can then result in fecal shedding of bacteria, which can contaminate skin and feathers during many steps from breeder farm to arrival at the slaughter establishment. External contamination can also occur during slaughter from rupture of the gastrointestinal tract and transfer of pathogens on contaminated equipment. FSISregulated establishments can,

as part of their overall HACCP system, address these hazards through purchase specifications or other agreements to require that their suppliers implement certain pre-harvest management controls. Pre-Harvest Interventions & Management Practices FSIS recommends that establishments use two main practices for managing preharvest colonization of poultry with *Campylobacter*. Together, these practices are expected to reduce the number of birds colonized with or shedding pathogens, reduce the number of these pathogens in colonized birds, and reduce the likelihood that contamination will be transferred from colonized to uncolonized birds. First, FSIS recommends that slaughter establishments receive birds from grow-out farms, hatcheries, and breeder flocks that implement the recognized pre-harvest interventions described in this section. Implementing these interventions can decrease *Campylobacter* contamination on birds received by slaughter and processing establishments (Cox & Pavic, 2010). Establishments may include specifications in their grow-out contracts for growers to incorporate strategies that address the potential contamination of *Campylobacter* during hatching and grow-out. Reducing or eliminating *Campylobacter* on incoming birds at slaughter establishments can reduce contamination of finished products and increase the likelihood that the establishment will meet FSIS performance standards for *Campylobacter*. Alternately, if an establishment does not require *Campylobacter* to be addressed at preharvest, FSIS recommends that slaughter and processing establishments test incoming", "12 birds and poultry products before entry into the establishment and make processing decisions based on those test results. By using these test results, an establishment could decide to implement a scheduled slaughter and processing plan based on the presence or absence (\u201cstatus\u201d) of *Campylobacter* (Katsma et al., 2007) as described in the FSIS Guideline for Controlling *Salmonella* in Raw Poultry. Other decisions could be to utilize additional chemical interventions or divert products from positive flocks to lethality treatment (such as cooking). Pre-harvest Recommendations to Control *Campylobacter* FSIS recommends that official establishments obtain birds produced from a system of breeder flocks, hatcheries, and grow-out houses that use the pre-harvest best practices and interventions described here. This section provides information on interventions intended to prevent the exposure of birds to pathogens and on available products intended to reduce the incidence or level of *Campylobacter* contamination in birds. Interventions to prevent exposure and colonization in live birds are typically more effective than products that treat birds exposed to *Campylobacter* to reduce incidence or levels, as it is more difficult to eliminate *Campylobacter* from colonized flocks. There are numerous routes of exposure to *Campylobacter* during pre-harvest including: \u2022 Exposure to contaminated water, feed, and bedding in the grow-out house; and \u2022 Environmental exposures due to poor biosecurity practices and inadequate pest control. Vertical transmission of *Campylobacter* (transmission via the egg from hen to chick) is not as well documented as that of *Salmonella*; however, contamination of the egg during laying by a colonized hen can lead to exposure during hatching, transferring the pathogen from parent to progeny (Cox et al., 2012). FSIS is not aware of a single pre-harvest intervention that eliminates *Campylobacter* as a pre-harvest hazard. Instead, FSIS recommends that a \u201cmulti-hurdle\u201d approach be employed; this means that multiple sequential pathogen interventions are used that can have an additive effect to reduce pathogens. Implementing multiple interventions and controls beginning at pre-harvest extends the multi-hurdle approach to *Campylobacter* prevention and control across each bird\u2019s life. Using interventions with

differing modes of action can further improve the extent of pathogen reduction when using a multi-hurdle approach. In this Guideline, FSIS is providing available effectiveness data for preharvest interventions, as identified in scientific literature. However, because many factors during the pre-harvest period can contribute to pathogen colonization of individual birds, the spread of pathogens between birds in a flock, and the excretion of Key Points Interventions to prevent exposure and colonization in live birds are preferable as it is more difficult to eliminate *Campylobacter* from flocks once infected. Preventive interventions in live birds lose effectiveness if the flock is already infected. Consider using multiple interventions throughout preharvest." "13 pathogens by birds, use of a particular intervention may have different efficacy than specified. Thus, the concept of a multi-hurdle approach is important to keep in mind.

Establishments can consider requiring suppliers to use the interventions listed here.

Establishments can use these pre-harvest controls as part of their HACCP system (through purchase specifications or other agreements) and to support their decisionmaking. FSIS will work with other federal agencies such as USDA-Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA), and USDA-Agricultural Research Service (ARS), to develop additional information on preharvest interventions. This Guideline breaks the pre-harvest interventions into six categories focused on physical, biological, and hygienic approaches to reduce pre-harvest exposure to *Campylobacter*: Breeder Flock & Hatchery, Grow-out House, Bedding, Feed, Water, and Transportation. Scheduled Slaughter is an additional approach, which is covered in the FSIS Guideline for Controlling *Salmonella* in Raw Poultry. When considering the control of hazards on incoming birds, slaughter establishments can consider exposurereducing interventions combined with one or more of the products available for preharvest control to reduce incidence or levels of *Campylobacter* in poultry that may be exposed to this pathogen (Table 1). These products have different modes of action, but all produce the same result: reduced incidence of pathogen colonization and reduced pathogen levels in colonized birds. Efficacy depends on the specific product, and most are used in consultation with a veterinarian. Using both types of pre-harvest approaches \u2014 those to reduce exposure and those that reduce incidence of colonization and levels of pathogens \u2014 will minimize pathogens on birds at harvest. Using the interventions and best practices recommended in this guideline can help to provide for animal welfare and bird health at pre-harvest, thereby reducing stress in live poultry and reducing *Campylobacter* in birds presented at slaughter. Evidence suggests that stress at pre-harvest can have adverse effects on food safety (Corry, 2001). Understanding the mechanism by which stress alters normal intestinal characteristics and induces susceptibility to enteric infections, may help in developing additional pre-harvest strategies to reduce pathogen contamination in poultry. NOTE: In this section, the term \u201cyoung chickens\u201d refers to all chickens raised for slaughter to distinguish it from chicken breeder stock. The term here is not limited to \u201cbroilers\u201d as defined in 9 CFR 381.170(a)(1)(iii). In this section, \u201cyoung turkeys\u201d refers to all turkeys raised for slaughter to distinguish it from turkey breeder stock. Table 1. Pre-harvest products to reduce colonization and number (level) of *Campylobacter* in poultry. Definition Notes on Use Vaccines: increase immunity to *Campylobacter* by exposing the immune Several vaccines are currently in development for the prevention of *Campylobacter* in live poultry. Proposed targets include the flagellar antigens as well as the", "14 system to a controlled preparation. Vaccine types include live vaccines (an attenuated strain of *Campylobacter*), sub-

unit vaccines (a vaccine with minimal parts of the target for immune response), and autogenous vaccines (developed from bacteria isolated from the farm environment). capsule of the bacteria (Poly et al., 2019). Special approvals from APHIS are required for long-term use of autogenous vaccines or for use of these vaccines with multiple flocks. Competitive Exclusion & Probiotics: preparations of beneficial bacteria that compete with *Campylobacter* in the gut for space or nutrients. Also known as direct-fed microbials. Some products can be used on the day of hatch to establish healthy gut flora in chicks. Other products can be added to water and feed for both breeders and young chickens and used to boost competition against pathogens throughout the bird's lifetime or when otherwise indicated (e.g., stress). One study on the effectiveness of a competitive exclusion culture in poultry found a statistically significant reduction in colonization and shedding of *Campylobacter* (Smialek et al, 2018). Prebiotics: specific nutrients that will allow beneficial bacterial species to more effectively compete against *Campylobacter*. Can be added to the feed of both breeders and young chickens. The most common supplements include yeast extracts, such as beta-glucans and mannan oligosaccharides. A study on the effectiveness of a prebiotic in poultry found that some available prebiotics reduced *Campylobacter* by more than 1 log, and when combined with probiotics, reduced *Campylobacter* by more than 3 logs (Kim et al, 2019). Organic Acids: increase the acidity of the gut, which can kill *Campylobacter*. Because each bacterial species has a different susceptibility to organic acids, this mechanism also increases the ability of beneficial bacteria to compete against pathogens. Can be added to both feed and water for breeders and young chickens. Adding to water during feed withdrawal is particularly important. After feed is withdrawn, birds may be more likely to peck at litter and may ingest pathogens. Organic acids in the water will lower the pH in the crop and reduce pathogen colonization and growth. One study found that use of lauric acid products resulted in up to a 1 log reduction of *Campylobacter* (Zieger, 2017).<sup>15</sup> Breeder Flock & Hatchery Breeder flocks and hatcheries can be the original source of *Campylobacter* colonization for young chickens because infection can be transmitted through the egg (vertical transmission). Establishments can obtain broiler and turkey chicks from breeder flocks and hatcheries that follow National Poultry Improvement Plan (NPIP) procedures and recommendations. The NPIP was established in the early 1930's to provide a cooperative industry, state, and federal program through which new diagnostic technology can be effectively applied to the improvement of poultry and poultry products throughout the country. Because of the possibility of vertical transmission, establishment parent companies and independent growers can consider placing broiler and turkey chicks from breeder flocks free of *Campylobacter* onto grow-out farms (Cox et al., 2012). (Note that pathogen-free breeder stock is not a requirement for participation in NPIP.) Broiler breeders also demonstrate variability in innate immunity to *Campylobacter*<sup>14</sup> some chicken breeder stocks have been shown to be more resistant to colonization (Han et al., 2016; Connell et al., 2012). Utilization of these parental breeding stocks can produce broiler chicks that are more resistant to on-farm colonization. Consider the use of one or more of the products listed in Table 1 to prevent or reduce colonization by *Campylobacter* in live birds that are destined for slaughter. Several of the probiotic, prebiotic, and organic acid products can be administered to both breeder flocks and young chickens, often through feed and water. Competitive exclusion and probiotics can be administered to chicks on the day of hatch to inoculate the gastrointestinal tract with beneficial bacteria (Table 1). Inoculation with beneficial bacteria at the hatchery can be followed with use

of appropriate prebiotics and organic acids at the grow-out house to maintain beneficial bacteria through growout. Chicks can be transported from the hatchery to the grow-out house in new or cleaned\sanitized, and ideally lined, containers (Cox & Pavic, 2010). Limit the number of individuals handling the chicks from the truck to the interior of the grow-out house to minimize chances for exposure. Recommended Best Practices, Breeder Flock and Hatchery 1. Obtain chicks from pathogen-free breeder flocks and from breeders and hatcheries following NPIP procedures. 2. Use breeding stock with innate resistance to Campylobacter. 3. Consider using one or more of the products listed in Table 1. 4. Transport chicks to grow-out in new or sanitized containers.", "16 Although the following sections focus on young chickens and turkeys, the best practices identified also apply to chicken and turkey breeders and can serve to minimize pathogens in these flocks. Grow-out Houses Farms and houses can be designed to facilitate cleaning and disinfection between flocks (Cox & Pavic, 2010). All poultry farms can develop and implement written biosecurity and hygiene plans. Poultry health is best monitored under the supervision of a veterinarian. Available research suggests that the following practices are correlated with a decreased likelihood of Campylobacter in birds presented for slaughter (Cox & Pavic 2010; Newell et al., 2011; Muenier et al., 2017): \u2022 Housing a single species (e.g., only chickens or only turkeys) on the farm; \u2022 Keeping birds of different ages in different houses; \u2022 Limiting the number of people with access to grow-out houses and using disinfecting boot dips or disposable foot coverings and disposable coveralls when entering the house (a study by Gibbens et al. (2001) found that correct use of a boot dip and house-specific boots and overalls reduced flock colonization of Campylobacter by 50%); \u2022 Removing vegetation around buildings, installing screens on windows and other openings, and increasing physical integrity of buildings to prevent access by rodents, birds, or insects; and \u2022 Using pest control measures including bait and traps.", "17 In addition to reducing exposure to Campylobacter with the measures described above, consider the use of one or more of the products in Table 1 to reduce colonization and the incidence or level of pathogens in exposed birds. Most probiotics, prebiotics, and organic acids can be used with both breeder and broiler flocks as feed or water additives. Biologics, including vaccines and antibody products, are licensed for use by USDA-APHIS, which updates the complete listing on their webpage. Live vaccines may introduce the target pathogen into flocks presented for slaughter; the establishment can consider this possibility and develop their HACCP plan and sampling programs accordingly. Bedding Litter or bedding can be considered a reservoir for Campylobacter contamination (Montrose et al., Shane, Harrington, 1985). Downtime between flocks is ideally around 10 -14 days which allows moisture removal and desiccation of litter. Ensure that no new moisture is added and that wet caked areas are removed during the litter turn over (fluff). There are technologies that allow composting or windrowing of litter between flocks (Malone & Johnson, 2011; Wilkinson et al., 2011; Macklin et al., 2008). It is important to note that litter is not uniform in moisture, organic carbon availability, pH, or microbial populations, which are all factors that can influence pathogen destruction or growth in litter during and following composting. Water activity (Aw) and pH of the litter are positively correlated with pathogen growth (Terzich, 2000). Consider chemical treatment of the litter to reduce pH and Aw during production to reduce pathogen growth and contamination of the flock, which could reduce pathogen recovery at the processing establishment. Recommended Best Practices, Grow-out House 1. Implement on-farm biosecurity and hygiene plans, 2.

Minimize the number of people with access to the grow-out house. 3. Require the use of disposable foot coverings or boot dips. 4. Consider the use of products in Table 1. Key Points Pre-harvest interventions must not: 1) Negatively impact product safety, 2) Jeopardize the safety of Federal inspection program personnel, 3) Interfere with inspection procedures, including FSIS sampling, or 4) Conflict with the Agency's regulations.","18 Litter treatments to reduce pH are commonly added prior to flock placement because the early grow-out phase (~1st week for young chickens, ~ 3 weeks for turkeys) is when the birds are most susceptible to pathogen colonization (Han, 2016). Several chemical additives have been used to decrease the pH of poultry litter, such as aluminum sulfate (Moore & Miller, 1994; Line, 2002;), ferrous sulfate (Huff et al., 1984), phosphoric acid (Reece et al., 1979), sodium bisulfate (Moore et al., 1996) (Terzich, 1997), and acetic acid (Parkhurst et al., 1974). Reducing litter pH to less than 4.5 can reduce *Campylobacter* to below detectable limits (Line, 2002). Since litter pH increases to near neutral after the first week of production, reapplication of the litter treatment may be needed (Pope & Cherry, 2000). During grow-out, moisture in the house can be controlled with the use of tunnel ventilation systems. If the moisture in the litter is too high (as observed in the winter months due to decreased ventilation), *Campylobacter* colonization of birds from contaminated litter can increase. Wet litter can also be caused by environmental conditions (rain, poor drainage, leaky roofs), evaporative cooling systems, excess drinking, health problems, panting, excess bird density, and watering systems such as type of waterers (bell, trough, nipple), leaky valves, maladjusted waterers, too many birds per drinker, or broken water lines. Feed Select growers that use feed that is free of *Campylobacter*. Specifically, obtain feed from manufacturers that follow Good Manufacturing Practices (GMPs) to reduce or eliminate pathogens, such as those certified by the Safe Feed/Safe Food program administered by the American Feed Industry Association. Safe Feed/Safe Food producers may also conduct finished product testing to verify the product is negative of certain hazards. Clean and disinfect feeders between flocks and keep feeders in good repair. Consider adopting the use of feed additives that are effective in young chickens (Table 1). Protect feed from contamination during transportation and storage. Transport the feed to the farm in accordance with the FDA's Sanitary Transportation of Human and Animal Food final rule (81 FR 20091), which includes provisions for cleaning transportation vehicles before transport of feed and measures to prevent contamination or tampering of feed during transportation. Store feed on-farm in a manner that reduces the Recommended Best Practices, Bedding 1. Use a litter treatment to reduce litter pH < 4 and Aw < 0.84. 2. Use a composting or windrow treatment during flock downtime. 3. Allow 10-14 days between flocks to desiccate litter and verify destruction of pathogens.","19 likelihood of contamination through contact with pests, fomites, or the environment (Hald et al., 2004). If feed is stored on-farm in a manner that could result in contamination (such as open bins or bags), poultry producers can conduct periodic sampling of the feed to determine whether contamination has occurred during storage. Some research indicates that pelleted feed is more resistant to contamination during storage than mash, and that the addition of organic acids to the feed may also protect against contamination. The Association of American Feed Control Officials (AAFCO) provides additional recommendations on the production and distribution of animal feed in its document titled '\u201cBest Management Practices for Manufacturing, Packaging & Distributing Animal Feeds and Feed Ingredients.\u201d Time feed withdrawal appropriately; withdrawal from feed can occur

between 8 \u2013 12 hours before slaughter (Cox & Pavic, 2010). Withdrawing feed before slaughter can ensure that birds have an empty gastrointestinal tract during transport, slaughter, and evisceration, which can reduce external contamination with fecal material. However, some research indicates that early withdrawal may lead the birds to peck at the litter in the grow-out house and decrease the acidity of the crop, increasing the likelihood that the bird will ingest pathogens and be contaminated at slaughter (Byrd et al., 1998). Consider providing water with organic acids (Table 1 and discussed below) during feed withdrawal to prevent colonization of the crop. Extended feed withdrawal may also make internal organs more fragile, increasing the likelihood that the crop or other organs will tear during processing and contaminate the carcass (Cox & Pavic, 2010). Most studies support a feed withdrawal period of 8-12 hours to prevent organ tearing (Cox & Pavic, 2010). Water Provide abundant, potable water (Cox & Pavic, 2010). If water is not from a chlorinated or municipal source, routine testing is recommended to ensure that the source is free of pathogens. Clean the water distribution system between flocks, ensuring that biofilms, which may be reservoirs for pathogens, are removed when possible. Ensure that the water system is free of cracks and leaks to minimize waste and to keep bedding dry. Recommended Best Practices, Feed 1. Clean feeders between flocks. 2. Use feed that is pathogen free. 3. Consider use of appropriate feed additives (Table 1). 4. Protect feed from contamination during transport and storage 5. Pelleted and acidified feed may be more resistant to contamination during storage. 6. Supply water with organic acids during feed withdrawal.", "20 A number of the products listed in Table 1 are available as water additives for young chickens. Of note are organic acids added to water, particularly during feed withdrawal (Byrd et al., 2001). Providing water during feed withdrawal distracts birds from pecking at the litter. Adding organic acids to this water source will increase the acidity of the crop, which can help protect the bird against any *Campylobacter* they may ingest when pecking at the litter.

Transportation The presence of *Campylobacter* on birds at receiving at slaughter has been linked to dirty transport cages (Slader, et al., 2002). Cross contamination of both birds and cages is frequently made worse when the birds are transported to the establishment. To prevent such contamination, transport birds in clean containers (Cox & Pavic 2010). Clean, single-use paper liners can be used when transporting chicks but are not recommended for transporting young chickens to slaughter. In all cases, clean and disinfect transportation cages between each load. Minimize the number of individuals involved in removing birds from the grow-out houses. Figure 1 shows a chicken transport crate that is not washed after every load.

Recommended Best Practices, Water 1. Provide abundant, potable water. 2. Clean water distribution systems between flocks. 3. Consider feed and water additives listed in Table 1, particularly organic acids during feed withdrawal.", "21 Recommended Best Practices, Transportation 1. Use clean containers and sanitize containers between loads. 2. Use new disposable paper liners when transporting chicks to the farm. 3. Minimize the number of individuals involved in transport. 4. Clean and disinfect transport crates between each load.

Figure 1 Not Recommended: Transport crate that is not washed with sufficient frequency. There is a buildup of fecal material and feathers that can contaminate subsequent flocks during transport. Using cleaned and disinfected transport cages for each load of birds is especially important after flocks have been sampled prior to harvest. This is because contamination from dirty cages can change the pathogen status of a flock from negative to positive and reduce the effectiveness of scheduled slaughter and processing decisions.", "22 SLAUGHTER AND

**PROCESSING Slaughter** This section of the guideline provides information for establishments that slaughter poultry. The diagram below presents the steps in poultry slaughter addressed in this section. How well an establishment conducts its slaughter dressing procedures has a direct bearing on whether the decontamination and antimicrobial intervention treatments in<sup>23</sup> place in a poultry operation will have their intended effects. When contamination overwhelms the decontamination efforts and antimicrobial intervention treatments, the establishment may need to take additional steps to reduce pathogens.

**Live Receiving and Live Hanging** Live receiving is the point in the slaughter process where poultry arrive at the establishment in transport crates or cages, are unloaded, and are hung on shackles. There is a potential for contamination with enteric pathogens, including *Campylobacter*. The feathers, skin, crop, colon, ceca, and cloaca of birds brought to slaughter are often highly contaminated with *Campylobacter* (Kotula and Pandya, 1995). As described in the previous section, transport cages have been found to be sources of cross contamination of pathogens onto live birds transported to slaughter. Cleaning followed by sanitation of the unloading and holding area is important. High levels of *Campylobacter* found on incoming birds can overwhelm establishment interventions. These levels are carried forward to the next steps of the slaughter process. Studies show links between *Campylobacter* at live receiving and later in the process (Fluckey, et al., 2003; Newell, et al., 2001). Establishments can consider how the frequency of cleaning transport cages might inform their lotting practices, since research has indicated *Campylobacter* positive birds were linked to dirty transport cages. If establishments lot product (to achieve microbiological independence) on a flock basis, they can clean and sanitize transport cages between each flock to maintain microbiological independence. Employee traffic patterns and air flow can be controlled to prevent cross contamination and reduce levels of *Campylobacter*. There can be positive airflow moving from inside to outside of the establishment. Standard operating procedures and training, including changing clothes and boots upon arrival, separate facilities for dirty versus clean employees, and restricting employee movement are measures that can be put in place. One study found employee clothing to be a source of contamination for birds relative to *Campylobacter* (Herman, et al., 2003). Most establishments keep detailed records of suppliers and slaughter schedules by lots to monitor output or yields of products. An establishment could use these records to correlate its own in-house testing programs to determine if there are suppliers that routinely deliver birds carrying a high microbial load. Addressing potential contamination sources with suppliers could lower the microbial level of incoming birds at receiving and thereby reduce microbial loads, particularly pathogens, in chilled carcasses.

**Key Points** The feathers, skin, crop, colon, ceca, and cloaca of birds brought to slaughter are often highly contaminated with *Campylobacter*. Transport cages are an important source of cross contamination of birds with *Campylobacter*.<sup>24</sup>

**Stunning and Bleeding** This is the point in the slaughter process where the bird is stunned, cut, and bled. Stunning methods render birds unconscious. The method of stunning may be electrical, mechanical, or chemical. Bleeding ensures death by slaughter and ensures that poultry have stopped breathing before going into the scalding bath (9 CFR 381.65(b)). Stunning reduces struggling and convulsions. However, wing flapping and quivering that may happen because of the electrical stunning can transfer bacterial pathogens from the inside to the outside of the bird and to nearby birds and equipment. Continuous Gas Stunning, or Controlled Atmospheric Stunning (CAS), is an additional available

stunning method that uses a combinations of gases (e.g., carbon dioxide, argon, and nitrogen) to stun the birds before they are hung on the line. Any stunning method must be monitored and controlled to ensure effectiveness. A study by Musgrove, et al., (1997) showed that *Campylobacter* increased in carcass rinses collected after stunning. Good feed withdrawal practices can greatly reduce this problem. By decreasing the amount of feces expressed, establishments can reduce fecal cross-contamination on the surface of the carcasses, in the scald tank, and on the feather removal equipment. This decreases the level of *Campylobacter* carried forward into the next steps. Figure 2 shows young chickens entering the stunner with minimal external fecal contamination. Recommended Best Practices - Live Receiving and Hanging 1. Control airflow and traffic patterns. 2. Provide SOP and employee training. 3. Schedule flocks for slaughter based on pathogen loads.", "25 Figure 2 Best practice: These young chickens show minimal fecal contamination on their feathers as they enter the stunner. These birds are calmly entering the stunner. Scalding Scalding prepares carcasses for defeathering by breaking down the proteins that hold the feathers in place and opening up the feather follicles. It is the point in the slaughter process where the carcasses are placed in hot water in order to facilitate feather removal and is the first location during processing where carcasses are exposed to a common bath, which can allow *Campylobacter* cells from positive carcasses to spread *Campylobacter* to negative carcasses. However, scalding can reduce levels of *Campylobacter* on the carcasses, since much of the dirt, litter, and feces on carcasses is removed at this step. *Campylobacter* contamination consistently decreases when scalding is well controlled (Slavik et al., 1994; Hinton et al, 2004). Scalder water that contains high concentrations of fecal material is a problem. Birds may come into slaughter facilities with excessive fecal material on the feathers, which gets washed off in the scalder water. Figure 3 shows an immersion scald tank with excessive fecal material contamination. Berrang and Dickens (2000) found  $3.80 \log_{10} \text{CFU/g}$  of *Campylobacter* in breast skin before entering the scald tank. *Campylobacter* may harbor in chicken skin, which may aid its survival through scalding (Lee et al., ", "26 1998). Bacteria present in the dirty water may be massaged into the skin and open feather follicles. Also, the organic material may be retained on the surface of the bird through evisceration and end up in the chiller, deactivating the chlorine and preventing disinfection. Scalding cannot overcome high numbers of pathogens carried forward from previous steps. To reduce this problem, a bird brush and washer used prior to the scalder can remove some of the incoming dirt and fecal material. There are two methods for scalding: \u2022 steam-spraying \u2022 immersion Steam spray systems work by applying a mixture of steam and air at a temperature and pressure designed to scald the surface of carcasses. Immersion scalding is carried out by placing the carcasses into a tank of hot water. Tanks are either single- or multistage. Immersion is more common than steam-spraying. However, under the right conditions, both methods can reduce *Campylobacter* on carcasses. Figure 3 Not recommended: Excessive fecal material is present in the scalder Several considerations can mitigate contamination at the scalding steps. Water flowing into the tank ideally moves through the system flowing against incoming carcasses. This flow creates a dirty-to-clean gradient. Carcasses moving through the tank are washed by ever-cleaner water. Multiple stage tanks create more opportunities to clean the carcasses (Cason, et al., 2000). High flow rates of water and adequate agitation dilute the dry matter and bacterial load in the tank (Cason, et al., 2001). The water pH is a key operational parameter to monitor. A higher, more alkaline pH (9.0 \u00b1

.2) is best for reducing Campylobacter in the water (Humphrey & Lanning, 1987).,""27 Making the pH more acidic (3-4) is also effective at decreasing levels of Campylobacter (Okrend, et al., 1986). Establishments can initially monitor the pH in scald tanks as frequently as necessary to determine the pH highs and lows occurring during operation. Once establishments are able to maintain a desirable pH, less monitoring is needed. Uric acid from poultry feces can reduce the pH from 8.4 to 6.0 in less than 2 hours (Humphrey, 1981). Organic matter in the tank acts as a buffer to maintain a more neutral pH (6-7). Campylobacter is most heat resistant at a pH of 7.0 (Humphrey & Lanning, 1987). Understanding water characteristics is an important aspect in poultry slaughter operations. The source (well or treated surface water or municipal water), hardness, mineral content, and pH influence the killing action of any antimicrobial chemicals that are added to the water, and water hardness may affect the ability of water to wash bacteria from the skin of carcasses during processing (Hinton & Holser, 2009). Poultry establishments using more than one water source might consider the potential effect of the water source on the chemicals used. FSIS Directive 7120.1 Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products and 9 CFR 424.21 provide a list of approved chemicals that can be used in scalders. Additives to raise the pH during scald have shown to be effective at reducing Campylobacter (Berrang et al., 2006). Most U.S. poultry processors prefer a hard scald to a soft scald. A hard scald is a shorter scald time at higher temperatures compared to a soft scald. This approach allows better removal of the outer layer of skin (epidermis). The correct water temperature for the appropriate amount of time is important to prepare the carcasses for feather removal. The correct water temperature also reduces dressing defects. When the water temperature is too high, the carcasses become oily. This oiliness makes it easier for Campylobacter to stick to the surface of the skin. If the carcasses are overscalded, the meat may start to cook, and the carcasses may be marked unacceptable and rejected by FSIS inspectors for overscald per 9 CFR 381.92. If the temperature is too low, the tank becomes a breeding ground for bacteria. Campylobacter cannot grow at temperatures greater than 116.6 °F (47°C). Therefore, scalding temperatures higher than 116.6°F (47°C) can be sufficient to control Campylobacter growth. Table 2 shows common scalding times and temperatures for various classes of poultry. Key Points Scalding is an important step that can reduce levels of Campylobacter on the carcasses. Water pH should be monitored carefully. Scalding can be used as an intervention if pH is properly maintained in the scald tank.,""28 Table 2. Common Scalding Times and Temperatures Class of Poultry Time /seconds Temperature °F Temperature °C Broiler (hard scald) 30-75 138.2-147.2 59-64 Broiler (soft scald) 90-120 123.8-129.2 51-54 Turkey 50-125 138.2-145.4 59-63 While scalding above 116.6 °F (47 °C) controls Campylobacter growth and initiates inactivation, scalding at 132 °F (56 °C) reduced Campylobacter counts most effectively (Slavik et al.,1995). Some religious traditions forbid scalding. Under Kosher slaughter, carcasses are soaked in cold water to make feather removal easier. Establishments can consider this potential effect in deciding what sanitary practices they employ downstream because the high number of pathogens not reduced during scalding can be transferred to future steps in the slaughter process. Picking The feather removal process is designed to remove feathers and the uppermost layer of the skin before evisceration. Carcasses typically pass through rubber picking fingers that mechanically remove feathers from the carcass. Most establishments use a continuous process. However, batch (not continuous; done at specific, defined and limited

times) and manual processes are sometimes used in low-volume establishments. Good process controls at picking are critical. Cross-contamination of the carcasses with *Campylobacter* occurs during picking because of contact with contaminated rubber Recommended Best Practices \u2013 Scalding 1. Have water moving counter current to carcasses. 2. Have high flow rates of water with adequate agitation to dilute dry matter and bacteria. 3. Use multi-staged tanks. 4. Maintain water pH at either above or below the optimum pH for *Campylobacter* growth (6.5-7.5). 5. Use pre-scald brush systems to clean birds prior to scald tank. 6. Maintain hard scald temperatures of 132 \u00baF and above.","29 picking fingers and contaminated reuse water (Geornaras, et al., 1997, Wempe, et al., 1983). Fecal material is released when picking fingers agitate and rub the carcasses and can lead to cross-contamination with fecal material between the carcasses (Allen, et al., 2003). Several researchers have determined that levels of *Campylobacter* increase during this step (Berrang & Dickens, 2001). Regular equipment sanitation and maintenance are recommended to minimize crosscontamination when using either batch or continuous picking. Post-feather removal rinses for carcasses is ideally maintained at 160\u00b0 F. Chlorine, acetic acid, and hydrogen peroxide are types of chemical rinses used during defeathering. If birds are plucked manually, the establishment can prevent cross-contamination by keeping the picking area as clean as possible and preventing feather buildup. Establishments can apply washes or antimicrobial interventions post-picking. However, cut surfaces of hocks must not be washed until FSIS postmortem inspection is complete (9 CFR 381.76, Post-mortem inspection). Otherwise, pathological exudate could be removed or obscured and prevent detection of synovitis by inspectors. Water reuse is addressed in 9 CFR 416.2(g)(3). This regulation states that water, ice, and solutions may be reused for the same purpose if measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. An establishment is required to have data to support all decisions regarding reuse, including a decision that reuse will or will not cause adulteration (9 CFR 416.2(g)(2)). Recommended Best Practices \u2013 Picking 1. Prevent feather buildup on equipment. 2. Regular cleaning and maintenance of rubber picking fingers. 3. Ensure coverage of sanitizer on picking rails and equipment. 4. Use a post picking antimicrobial intervention rinse. 5. Scientifically support any water reuse plan. Key Points Good process control procedures at picking are critical and can reduce *Campylobacter*. Fecal material is released when picking fingers agitate and rub the carcasses and can lead to crosscontamination between the carcasses.","30 Evisceration Evisceration is the point in the process where removal of the internal organs, and any processing defects, from the poultry carcasses occurs in preparation for chilling. Evisceration includes multiple processes. It begins at the transfer point (i.e., re-hang) and ends when the carcass enters the chiller. It is the point in the slaughter process where the removal of the viscera (including the gastrointestinal tract and edible offal such as heart, liver, and gizzard) occurs by automated or manual means, along with any trim of processing defects from the poultry carcasses in preparation for chilling. If viscera are not handled properly, or if employee hygiene practices are not followed, an increase in microbial contamination can occur. Feed withdrawal practices affect process control at this step. For the evisceration process to work well, carcasses need to be placed on the shackles correctly and monitored as they move through the system. Blades are ideally kept sharpened, and attention given to routine and thorough cleaning. Figure 4 shows an automated opener system that utilizes replaceable blades that are cleaned between each carcass. Figure 4 Best

practice: Replaceable blades (middle of picture) are washed between each carcass (yellow arrows) to reduce cross contamination. Blades are replaced daily, which minimizes cross contamination as compared to blades that are replaced less often. Key Points Evisceration begins at rehang and ends when the carcass enters the chiller. Feed withdrawal practices affect process control throughout the evisceration step. For the evisceration processes to work efficiently, carcasses need to be placed on the shackles correctly and machinery needs to be adjusted to accommodate bird size.", "31 Keeping the equipment in good sanitary condition, free from intestinal contents and segments, is important for maintaining good process control. Figure 5 shows viscera that was caught in the machine as well as fat and tissue build up on breast plates and other surfaces that is not being sufficiently rinsed and cleaned between carcasses. These practices can lead to cross contamination. Figure 5 Not recommended: Viscera are stuck in machine and there is product build up on breast plates and bars around wings and legs (yellow arrows). Automated transfer (re-hang), rather than manual transfer, of carcasses between the defeathering and evisceration lines can reduce external surface cross-contamination. Equipment used throughout the evisceration process can be installed, adjustments made, and machine performance calibrated effectively to handle the size, shape, gender, feed digestion capability, and live average weights of the birds to be slaughtered. These considerations apply to manual evisceration processes as well. Figure 6 shows a manual venting gun that is rinsed with chlorinated water between each carcass. Processing flocks with varying weight ranges can result in evisceration machinery performing poorly. Inconsistent carcass sizes (for example, because of poor bird size uniformity within a grower house or processing male and female birds together) can result in mis-cuts and fecal contamination. If machines are set for the median weight of the flock, poultry carcasses that are heavier or lighter may not be properly eviscerated. If carcasses are lighter or heavier than the machines can accommodate, the carcasses are more likely to have their gastrointestinal (GI) tracts split open, resulting in contamination of both carcasses and equipment. The machines need to be maintained in optimum condition and be properly aligned. Failure to maintain eviscerators in optimum condition can result in damaged intestines leading to carcass contamination.", "32 Equipment such as crop removal devices can easily become contaminated with *Campylobacter*, causing carcasses to later become cross contaminated. In some operations, at least half of carcass surfaces are contaminated with crop and upper GI contents immediately before evisceration (Byrd et al., 2002). Retracting the viscera from the body cavity can transfer crop and upper GI contents to the interior body cavity (Byrd et al., 2002). Poultry establishments can benefit from awareness of these factors that lead to contamination and can implement necessary machinery checks to ensure that evisceration equipment is indeed functioning effectively. Figure 6 Best practice: This manual venting gun is rinsed with chlorinated water, supplied to the gun by the red hose, between each carcass . Carcass rinses or sprays can be effective interventions for removing incidental contamination from the carcass surface during evisceration. However, establishments can aim to consistently implement sanitary dressing procedures to control pathogens. Rinses with an antimicrobial have been shown to reduce *Campylobacter* by 1.5 log", "33 (Bashor, et al., 2004). When applying water rinses and sprays, establishments can consider the water pressure applied. Some studies have found that elevated spray pressure may force bacteria into muscle or skin rather than washing it off (Buncic & Sofos, 2012). Note: This guideline uses the term \u201cfree available chlorine\u201d when referring to parts per

million (ppm) chlorine. Free available chlorine is the concentration of hypochlorous acid (HOCl) and hypochlorite ions (OCL) existing in chlorinated water. (Reference: Handbook of Chlorination and Alternative Disinfectants, Geo. Clifford White, Fourth Edition 1998. Wiley Interscience). Rinses or sprays can be designed, installed, and calibrated to remove incidental contamination. When not properly designed or implemented, rinses or sprays may not effectively remove contamination and may even spread contamination from one part of the carcasses to another part or even to adjacent carcasses. Figure 7 shows a rinse that is not calibrated to wash contamination. Figure 8 shows sprays that spread contamination onto other parts of the carcass. Figure 7 Not recommended: Rinses are not positioned to wash contamination off tail area. On the left, a contaminated carcass moves on the line toward two washes. On the right, the carcass has moved past the washes, and the contamination remains. In this situation, if the nozzles were moved up, it is likely that due to the high pressure and angle of the spray, contamination may not be washed off but instead may spread to surrounding areas of the carcass. Key Point Antimicrobial interventions are not a substitute for consistently implementing sanitary dressing practices.", "34 Figure 8 Not recommended: Overspray spreads contamination to adjacent areas of the carcass. In the closeup on the right, the middle spray bar results in splashing of water from the thigh up over the back of the thigh and onto the abdomen area (under yellow arrow), where it will run down the breast area. The contaminated vent area visible on the left (inside the red box) will not be washed off when it goes through the middle spray bar. Instead it will spread contamination to adjacent areas. This is also true of the faint yellow contamination on the outside of the thigh and bird's side (black bar of the right image). Multiple Campylobacter controls throughout the evisceration process are recommended. Pathogens are not effectively removed by using one carcass rinse, and a multiple hurdle approach works best against pathogens. Some poultry processors consistently produce Campylobacter positive carcasses, while others produce carcasses that upon testing typically do not have detectable levels of Campylobacter. These variable test results may be the result of differences in sanitary dressing practices. Sanitary dressing practices are implemented throughout the slaughter process, in a manner that produces a clean, safe, wholesome poultry product in a sanitary manner. For example, rates of visible contamination on the carcasses after crop removal vary greatly depending on crop removal practices. In some establishments, fewer crops rupture because the crops are extracted toward the head (and downward) rather than toward the thoracic inlet (and upward) (Buhr et al., 2000). This is an important consideration for Campylobacter control because crop tissue often contains Campylobacter (Byrd et al., 1998). Note that some carcasses may become incidentally contaminated with feces and ingesta even with strict sanitary dressing practices. However, fecal contamination can be minimized with strict sanitary dressing practices.", "35 Chilling This is the point where eviscerated carcasses are chilled in order to inhibit microbial growth and meet the regulatory requirements of 9 CFR 381.66(b)(3). Additional information on chilling requirements can be found in the FSIS Compliance Guide: Modernization of Poultry Slaughter Inspection: Chilling Requirements. Antimicrobial Intervention Use for On-line and Offline Reprocessing and for Chilling Procedures Reprocessing systems are used to control Campylobacter on visibly contaminated carcasses. Both on-line (OLR) and off-line (OFLR) reprocessing systems can be used to remove incidental contamination during the evisceration. On-line reprocessing is not a remedy or a substitute for poor sanitary dressing practices during evisceration. The on-line reprocessing

system may be able to remove visible contamination, but the invisible contamination can remain if the intervention is overwhelmed. NOTE: Carcasses must be free of visible fecal contamination prior to entering the chilling system as required by 9 CFR 381.65(f).

Recommended Best Practices \u2013 Evisceration 1. Adjust and maintain equipment regularly as needed to accommodate bird size. 2. Implement an antimicrobial rinse to reduce equipment contamination. 3. Implement multiple hurdles to reduce pathogens.", "36 FSIS has posted lists of the approved OLR and OFLR systems. The lists are regularly updated and attached to FSIS Directive 7120.1, Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products. If an establishment desires to use an OLR or OFLR system that has not been approved by FSIS\u2019s Risk Management and Innovations Staff (RMIS) or wishes to modify an approved OLR or OFLR system, the establishment is responsible for submitting a protocol to FSIS requesting permission to conduct an in-plant trial. Per the Memorandum of Understanding (MOU) between FDA and FSIS, FSIS would consult with FDA regarding safety of the proposed chemical. FSIS would review the protocol for any prohibitions that can potentially affect product safety, safety of inspection personnel, interfere with inspection procedures, or require a change to the Agency\u2019s regulations. If the in-plant trial is granted, FSIS would issue a letter granting permission to conduct an in-plant trial. More information regarding in-plant trials can be found in the FSIS Compliance Guideline Procedures for New Technology

Notifications and Protocols. An establishment that uses chlorine or other antimicrobials as a part of its sanitary dressing and process control procedures, or employs a pre-chill carcass wash that may affect the pH of the chiller water, can consider the effect of pH on the efficacy of any antimicrobials used in the chiller. On Line Reprocessing Addresses incidental fecal or ingesta contamination during evisceration Utilizes washing systems and antimicrobial systems to achieve desired results. Off line Reprocessing Addresses disease conditions and contamination that cannot be removed by other means Produces carcasses microbiologically equivalent to those routinely eviscerated on line", "37 Further Processing This section of the guideline provides information for establishments that further process raw poultry carcasses to produce products such as: \u2022 Poultry parts \u2022 Injected, mechanically tenderized, or vacuum tumbled poultry products \u2022 Commminuted (including ground) poultry products, includes products such as patties and sausages that are made using comminuted poultry \u2022 Stuffed chicken products Source Materials Can Affect Pathogen Status of Commminuted Product Certain poultry parts may be more likely to be contaminated with pathogens and therefore riskier to use as source materials to produce comminuted poultry products. The FSIS Chicken Parts Baseline study (FSIS, 2013) found that chicken necks were significantly more likely to be contaminated with Campylobacter (55%) than other parts, including breasts, legs, and wings (between 16-43% for Campylobacter). Establishments can consider not using chicken necks in comminuted poultry products or only using them in comminuted products that are intended for a lethality treatment. Similarly, skin-on and bone-in source materials used in comminuted chicken products present increased risk of contamination with Campylobacter. As previously discussed, skin can contain Campylobacter in feather follicles that can be exposed during the grinding or other comminuting process and spread throughout a lot. Chicken neck skin has typically been found to be more contaminated than other parts of the carcass. Table 3 shows that ground and other raw comminuted chicken products (such as sausages and patties) sampled by FSIS that were produced using skin-on source materials were more likely to be

contaminated with Campylobacter2. Table 4 shows the risk for use of bone-in source materials for comminuted turkey products. 2 FSIS Not Ready-to-Eat Comminuted Poultry Exploratory Sampling Project results from samples collected June 1, 2013 through June 30, 2015. Key Point Comminuted products are those that are ground, mechanically separated, or hand- or mechanically-deboned and further chopped, flaked, minced or otherwise processed to reduce particle size.", "38 Table 3. FSIS exploratory sampling testing results, raw comminuted chicken by source material composition (6\1\13-6\30\15, 2,688 samples) The interior of poultry bones can contain pathogens as well. Because of the nature of comminuted processes, contamination can spread throughout an entire batch or lot from a few contaminated bones through cross contamination. FSIS sampling data indicates that both chicken and turkey raw comminuted products produced using bonein source materials are more likely to be contaminated with Campylobacter than those produced using deboned source materials. Table 3 shows this for comminuted chicken products, and Table 4 shows this for comminuted turkey products. Tables 3 and 4 indicate pathogen prevalence for comminuted products based on whether source material contained bone (chicken and turkey) or skin (chicken only). Analysis of FSIS comminuted poultry sampling results shows that it is more likely that comminuted chicken will be positive for Campylobacter when its source materials contain both bone and skin (12.1%). Comminuted chicken made from deboned and skinless source materials had the lowest prevalence for Campylobacter (1.7% for Campylobacter). 3 For bone-in and skin-on source materials, Campylobacter prevalence in comminuted chicken was 12.1%. The lowest prevalence product, made from deboned and skinless source materials, was 1.7%. To calculate the relative risk, each source material type was divided by the lowest risk product: 12.1\1.7 = 7.1. Comminuted Chicken Products Campylobacter prevalence in this source material Campylobacter presence risk relative to the lowest prevalence source material (Deboned & skinless)3 Mechanically separated 20.2% 11.9-fold increase Ground and Other Comminuted Chicken Products Campylobacter prevalence in this source material Campylobacter presence risk relative to the lowest prevalence source material (Deboned & skinless)3 Bone-in & Skin-on 12.1% 7.1 Bone-in & Skinless 4.4% 2.6 Deboned & Skin-on 3.6% 2.1 Deboned & Skinless 1.7% N\A", "39 The tables also indicate how much more likely products made from different source materials are to contain Campylobacter, as compared to the product with lowest prevalence (products made from deboned and skinless source materials). Raw comminuted chicken products made from bone-in and skin-on source materials were more likely to be positive for Campylobacter compared to those made from deboned and skinless source materials.3 Mechanically separated poultry products nearly always contain skin and bones in their source materials, because of the nature of the processing of this product. FSIS sampling results indicate that Campylobacter prevalence was highest for mechanically separated chicken. For this reason, establishments can consider not using mechanically separated chicken as a component in not-ready-to-eat (NRTE) comminuted products, or only using it in comminuted products that are intended for a lethality treatment. Table 4. FSIS exploratory sampling testing results, raw comminuted turkey by source material composition (6\1\13-6\30\15, 934 samples) Comminuted Turkey Products Campylobacter prevalence in this source material Campylobacter presence risk relative to the lowest prevalence source material (Deboned) Mechanically separated 2.4% 1.2-fold increase Ground and Other Comminuted Products Campylobacter prevalence in this source material Campylobacter presence risk relative to the lowest

prevalence source material (Deboned) Bone-in 9.8% 4.9 Deboned 2.0% N/A It is important to keep in mind that the data in Tables 3 and 4 represents FSIS data from all establishments sampled in the exploratory program, without consideration of the amount of skin or bone going into comminuted processes. Each individual establishment can determine the extent that skin-on and bone-in source materials may contribute to pathogens in finished product. This determination can be made by sampling and testing comminuted products made from different source materials. Establishments that do not test products by source material can consider the information provided in the tables during decision-making in their processes. Using the information in the prevalence column of the tables, establishments can compare the relative risk of using different types of source materials. For example, in the absence of ", "40 its own sampling results, a chicken establishment can compare using bone-in and skinon source materials (12.1% Campylobacter prevalence) with using deboned and skinon source materials (3.6%) to determine that the relative risk is 3.36 (12.1\3.6). This means there is about a 3 times greater chance that the bone-in source material will result in Campylobacter being present in the finished product. Therefore, there is likely a benefit to using the deboned source materials instead of the bone-in source materials. Additional guidance regarding the use of in-house source materials and incoming source materials purchased from supplying establishments, including the use of Certificates of Analysis or Letters of Guarantee, is available in the FSIS Guideline for Controlling Salmonella in Raw Poultry. Interventions Unless otherwise stated, interventions (antimicrobial processing aids) described in this section have been reviewed for safety and suitability and are listed in FSIS Directive 7120.1. Establishments, intervention manufacturers, and other users that would like to implement interventions not listed in FSIS Directive 7120.1 would need to submit for review a protocol to FSIS describing the proposed function of the substance in the specific poultry or meat product and conditions of use, as described in the FSIS Compliance Guideline Procedures for New Technology Notifications and Protocols. Establishments may consider using interventions during further processing to decrease pathogens. Antimicrobial interventions may be applied to source materials prior to further processing, to parts, during grinding or other comminuting process, and during blending of ground or comminuted products. Establishments should consider all applicable labeling requirements when choosing an antimicrobial, in particular when adding aqueous solutions to products with a standard of identity that does not allow added water (e.g., \u201cground chicken\u201d; 9 CFR 319.15(a)). High pressure pasteurization (HPP) is another intervention that may be applied to raw comminuted product. Although applying interventions to source materials used in comminuted products can reduce pathogens in finished product, contamination may still occur during the process itself when skin or bones are broken, releasing bacteria that were not exposed to the antimicrobial application. Establishments can consider these factors when evaluating their use of interventions. Establishments can evaluate the adequacy of any Campylobacter interventions they apply to parts during further processing, including those source materials that are specifically intended for non-intact use (such as grinding or other comminuted processes). Part of the evaluation can include consideration of variability of Campylobacter levels on source materials. That consideration also applies to parts that are sent to other establishments for any kind of further processing because they may be used as source materials in comminuted or otherwise non-intact raw product. Interventions to control Campylobacter can be applied by spraying or dipping (immersion). Generally,

immersion is more effective than spraying because it ensures better coverage and longer contact time (Loretz, 2010). A potential challenge with<sup>41</sup> immersion is maintaining the proper level of active chemical as it becomes absorbed and neutralized by organic material, such as fat and protein. Another challenge with immersion is maintaining the active concentration of the intervention despite the natural decomposition of the compound as a result of chemical reactions, heat, or light. It is important to verify with sufficient frequency that the critical operational parameters of an antimicrobial dip are maintained. It may be necessary to either add more chemical or even to completely change the solution to maintain effectiveness. Figure 9 shows an antimicrobial dip being applied to boneless, skinless poultry parts prior to grinding. Figure 9 Best practice: Boneless, skinless poultry parts receive an antimicrobial dip prior to being ground. The following pages present information on some antimicrobial interventions that may be used during further processing and which have been studied to control pathogens during further processing. This information is summarized in the attachment to this guideline. Establishments need to adhere to the limits in the conditions of use for chemicals as described in FSIS Directive 7120.1 and 9 CFR 424.21. In addition, the establishment needs to determine the optimum concentration for its process based on the critical operational parameters in its scientific support documentation. Any ranges for pH, concentration, or other parameters included in this section are provided to give a general indication of these values, but they do not represent critical operational parameters.<sup>42</sup>

Inorganic and Organic Chlorine-based Treatments Chlorine is relatively inexpensive, has a broad spectrum of activity, and is quick acting. Its drawbacks include corrosiveness to processing equipment at low pH, loss of effectiveness at higher pH values, loss of effectiveness with increasing organic matter load, and longer contact time required as compared to some other antimicrobial interventions. Commonly used chlorine compounds include liquid chlorine, hypochlorites, inorganic chloramines, and organic chloramines. Chlorine is typically used at pH 6.0 – 7.5. A number of chlorine entries for use with poultry are in the FSIS Directive 7120.1 lookup table along with their acceptable uses. Chlorine added to water produces free available chlorine in the forms of hypochlorous acid and hypochlorite ions. Hypochlorous acid is the form most lethal to microorganisms. Acidified Sodium Chlorite Acidified sodium chlorite (ASC) is a type of chlorine compound that is a strong oxidizer. It enters bacterial cells and weakens or kills them by lowering the pH inside. ASC is safe and suitable for use on poultry carcasses and parts at concentrations of 500-1200 ppm, as indicated in FSIS Directive 7120.1. It is used at pH 2.3 - 2.7 and acidified with an organic acid, such as lactic acid, citric acid, or acetic acid. A benefit of ASC is that it is not as highly affected by the presence of organic material as chlorine. Oyarzabal et al. (2004) reported ~ 1 log reduction of *Campylobacter* and Mehyar et al. (2005) reported a 1.5 log reduction in *Campylobacter* on inoculated drumsticks. Trisodium Phosphate Trisodium phosphate (TSP) is an inorganic, non-chlorine-containing compound with a high pH. Its pH is between 11-13 and is used at concentrations of 8 – 12%. A benefit of high pH is that it gives TSP detergent-like activity, which can improve effectiveness against microorganisms. The main disadvantage of using TSP is disposal, as the high discharge of phosphate into the sewer may be a violation of local, state, or federal Environmental Protection Agency sewer discharge regulations. Recommended Best Practices, Interventions during Further Processing 1. Applying antimicrobial interventions during further processing can be part of an effective multiple hurdle approach to reducing pathogens. 2. Dipping is generally a better

application method than spraying as it ensures full coverage of an intervention for a longer period of time." "43 Quaternary Ammonium Compounds Quaternary ammonium compounds (QAC) are a group of positively charged organic compounds that may have detergent-like properties (Schmidt, 2012). Most have a high pH (pH 6-10), are used at concentrations  $\leq 1\%$ , and are effective in killing a wide variety of microbes. Cetylpyridinium chloride (CPC) is an example of a QAC. CPC is an odorless, colorless, stable compound that does not self-decompose and is not affected by organic material. QACs persist in solution for a relatively long time. QACs are not compatible with soaps, anionic detergents, or low pH solutions. CPC must be rinsed off poultry after use with water containing no more than 50 ppm chlorine. The major disadvantage of QAC is that some may be less effective in hard water that contains  $>500 \text{ mg/L}$  hardness (Miller, 2012). Organic Acids and Organic Oxidizers Organic acids and organic oxidizers used at the proper pH are effective in being able to enter bacteria to inhibit or kill them from the inside. Peroxyacetic acid (PAA) is an organic oxidizer. It has been studied on poultry parts to control pathogens. PAA is a mixture of the peroxy compound, hydrogen peroxide, and acetic acid. It is a versatile compound, as different formulations are available that may be used over a wide temperature range (0 to  $40^\circ\text{C}$ ) and a wide pH range (3 to 7.5). PAA is affected by protein or other organic materials to a lesser degree than chlorine is. When added to the chiller at a concentration of 200 ppm for one hour of contact time, PAA demonstrated a 1.5 log reduction of *Campylobacter* (Bauermeister et al., 2008). Applied as a dip with 1000 ppm PAA and a 20 second contact time demonstrated a 2.0 log reduction of *Campylobacter* (Nagel et al., 2013). In contrast, when applied as a spray, PAA requires increased contact time/increased concentrations to achieve similar reductions (Bertram et al., 2019). Studies Comparing Chemical Interventions In a study by Chen et al. (2014), researchers treated *Campylobacter* inoculated chicken parts (bone-in and skin-on) with chlorine, PAA, and CPC at various concentrations in a chilled immersion system for 25 sec. PAA and CPC significantly reduced *Campylobacter* in a dose-dependent manner. Water and chlorine had little effect in reducing *Campylobacter*. Another study by McKee et al. (2013) compared the pathogen reduction of antimicrobial interventions applied to chicken parts, including those used to produce ground product. Preliminary research shows that parts immersed/dipped into a tank containing antimicrobials had the greatest reductions. Findings from this study suggest that dips/immersions are more effective than single spray systems when treating parts because of their longer contact times and complete coverage." "44 Bacteriophages Bacteriophages (also called phages) are naturally occurring organisms (viruses) that infect only a specific host bacteria (Hagens & Loessner, 2010). Phages cannot infect humans (Lu & Breidt, 2015). Phages are ubiquitous in the environment in the water, in soil, and on food consumed (Guenther, 2009). Once phages infect bacteria, they can multiply inside of the bacteria, destroy the cell wall of the bacteria, and then be released into the environment where they can infect other susceptible bacteria. Phage preparations for *Campylobacter* have been developed, but have not yet been approved for use in FSIS-regulated products; inclusion in FSIS Directive 7120.1 for use in meat, poultry, egg, or fish products would require a New Technology submission for review of these phage applications. Physical Interventions Electrolyzed Oxidizing Water Treatment Electrolyzed oxidizing (EO) water is inexpensive, must be generated on-site with specialized equipment, has strong bacterial killing effect, and has little residual (longlasting) effect. EO water is acidic and is an effective antimicrobial immersion/dip solution. However, it usually requires much longer

contact time than other interventions, so spraying may not be an appropriate application method. EO water is produced by passing direct current voltage through a dilute sodium chloride (salt) solution. The result of the reaction is the production of two types of water (Hsu, 2005). It is the EO water that has low pH (2.3-2.7), high oxidation-reduction potential (>1000 mV), and high dissolved oxygen. A high oxidation-reduction potential means that more oxidation will occur. That translates to a greater capacity to form free radicals that kill bacteria (Venkitanarayanan, 1999). Huang (2008) and Hsu (2005) provide detailed descriptions on the concepts. The production of EO water containing sodium chloride (1-12% w/v) results in the formation of sodium hypochlorite (NaOCl) and hypochlorous acid (HOCl). HOCl functions as if chlorine gas was added into the poultry parts disinfection solution without the need to store a dangerous gas. It is important to point out that although EO water is strongly acidic, it is different from strong acids, such as hydrochloric acid or sulfuric acid, in that it is not corrosive to skin, to mucous membranes in the nose and lungs, or to poultry carcasses or parts (Huang, 2008). However, the HOCl (sodium hypochlorite) generated by the EO process may cause breathing irritation that can be reduced with proper ventilation (Huang, 2008). In a study by Park and others (2002), EO water treatment with a contact time of only 10 seconds demonstrated an equal reduction of *Campylobacter* as chlorinated water (50 ppm) at about 3 log<sub>10</sub> CFU/g.

"45 High Pressure Inactivation A typical high pressure pasteurization (HPP) system consists of a pressure vessel, pressure transmission fluid (usually water), and pressure generating pumps. HPP is a technology by which a product is treated at a very high pressure. HPP requires specialized equipment and is usually applied off-site where that equipment is located. HPP treatment kills or inhibits microorganisms, and researchers have studied its effectiveness in reducing pathogens in comminuted chicken and chicken parts. An advantage of using HPP is that surviving microorganisms can be more sensitive to other types of antimicrobial interventions as compared to bacteria that have not been exposed to HPP (Alpas, 2000). Liu (2012) investigated high pressure inactivation of *Campylobacter* in comminuted chicken breast meat (individual meat particle size of \u22641 mm<sup>3</sup>) inoculated with *Campylobacter jejuni* at 6 log CFU/g. Polyethylene glycol was used as the pressure transmission fluid. Compression and decompression rates were 300 MPa/min. The temperature of the system was maintained by a water-jacketed unit. The temperature during compression and decompression did not exceed 2\u00b0C. Pressure at 400 MPa for 30 min reduced *Campylobacter* counts from 6 log to below the detection limit of 1.48 log CFU/g (reduction of approximately 4.5 log). Cryogenic Freezing Cryogenic freezing is defined as freezing at -74.2\u00b0F (-59\u00b0C) or below (Balasubramanian, 2012) using liquefied gases called cryogens. Two popular cryogens used are liquid carbon dioxide (CO<sub>2</sub>) and liquid nitrogen (N<sub>2</sub>). Cryogens are completely inert (non-reactive or flammable), colorless, odorless, tasteless, and have minimal environmental effects. Tunnel and spiral belt are the two common commercial designs (Shaikh & Prabhu, 2007). Cryogenic freezers are insulated enclosures or chambers surrounding a product conveyor with a method to introduce and regulate the amount of cryogen into the chamber. It is important to note that during cryogenic freezing, meat is not immersed into the cryogen, e.g., liquid carbon dioxide or liquid nitrogen. The meat is sent on a conveyor a short distance above the cryogen. It is the vapor of the cryogen that causes the meat to freeze. Gunther (2015) studied the effect of cryogenic freezing (using liquid nitrogen vapor) on *Campylobacter*-inoculated ground turkey patties containing

polyphosphates. It is important to note that polyphosphates are not part of the cryogenic freezing process. Rather, some establishments add polyphosphates during routine poultry processing to enhance the moisture absorbance, color, and flavor and to reduce product shrinkage of poultry. Gunther analyzed the patties for surviving Campylobacter after the patties were cryogenically frozen at -80°F (-62.2°C) for 4 minutes (using liquid nitrogen vapor) and stored at -20°F for 7 and 33 days.<sup>46</sup> This treatment achieved log reductions of Campylobacter in the frozen patties after 7 and 33 days at -20°C of 2.5 logs and 3.2 logs, respectively. Cryogenic freezing is similar to individual quick freezing (IQF) in that the outcome results in poultry that is completely frozen solid. The way cryogenic freezing differs from IQF is the technology used to achieve the frozen state, including how it is applied to product and associated operational parameters. Establishments performing IQF typically use conventional compressor-type refrigeration units, e.g., blast freezing such as in spiral freezers. It would not be sufficient to indicate that IQF or other processing freezing procedures reduce pathogens without scientific support that such a procedure results in a pathogen reduction and identifies the associated critical operational parameters.

**Irradiation using Ionizing Radiation**

Food irradiation is the process of exposing food to high levels of radiant energy and is applied by directing ionizing radiation to food products. Food can be irradiated commercially for several purposes: to extend shelf-life, eliminate insect pests, or reduce numbers of pathogenic microorganisms. Ionizing radiation can penetrate deeply into food, killing insect pests and microorganisms without raising the temperature of the food significantly (Jaczynski, 2003). Ionizing radiation kills bacterial cells and pests by damaging DNA (Tahergorabi, 2012; Verma, 2001). Ionizing radiation results from cobalt-60, cesium-137, x-rays, and electron beams.

Cobalt-60 (<sup>60</sup>Co) is a common source of a form of ionizing radiation called gamma irradiation. It has high penetrating power (Ahn, 2013), which allows the treatment of poultry of variable sizes, shapes, and densities (including frozen and unfrozen). X-rays are also used to produce ionizing radiation. X-rays have high penetrating power but are typically not used for treatment of food because it is not an efficient process (Tahergorabi, 2012). Another way of producing ionizing radiation is by applying an electron beam (e-beam). In this approach, a stream of high-energy electrons is applied to products. Because the radiation penetrates only a few centimeters, it is useful to treat thin layers of food (Jaczynski, 2003; Ahn, 2013). The electron beam may be applied over moving food on a conveyor, unlike some other sources of ionizing radiation. Electron beam systems require regular maintenance, high electric power, and cooling as the equipment produces high heat (Ahn, 2013). The maximum dosage of ionizing radiation is 3 kGy absorbed by raw poultry (fresh and frozen). The maximum dosage limit allowed for poultry is based on the safety determination that was made by FDA (21 CFR 179.26(b)(6)). A requirement that FDA placed on the use of irradiation is that the packaging of irradiated poultry must be air permeable and does not exclude moisture and microorganisms from penetrating the package barrier. To promote processing flexibility and innovation that will lead to improvements in food safety, FSIS does not specify at which point irradiation may or may not be applied.<sup>47</sup> Under HACCP, an establishment must control the conditions under which product is held from initial processing through irradiation and packaging to ensure and preserve the intended antimicrobial effects of irradiation (64 FR 72150). FSIS requires the labeling of irradiated meat and poultry products, including the radura symbol. These labeling requirements are outlined in the final rule, Irradiation of Meat Food Products, 64 FR 72150. One study found that applying

electron beam irradiation to boneless, skinless chicken breasts containing naturally occurring bacteria resulted in an approximately 5-log reduction in *Salmonella* and *Campylobacter*. The doses applied were 1.0 and 1.8 kGy at ambient temperature and both doses resulted in comparable reduction of *Campylobacter* (Lewis, 2002). 4 Irradiation of Meat Food Products; Final rule. Dec 21, 1999. Federal Register. 64: 72150-72166. ", "48 References Acuff GR, Vanderzant C, Hanna MO, Ehlers JG, Golan FA, and Gardner FA. 1986. Prevalence of *Campylobacter jejuni* in turkey carcass processing and further processing of turkey products. *J Food Prot* 45:712-717. Ahn DU, Kim IS, and Lee EJ. 2013. Irradiation and additive combinations on the pathogen reduction and quality of poultry meat. *Poult Sci.* 92: 534-545. Allen VM, Hinton MH, Tinker DB, Gobson C, Mead GC, Wathes CM. 2003. Microbial cross-contamination by airborne dispersion and contagion during defeathering of poultry. *Br Poult Sci* 44:567-576. Allen VM, Tinker DB, Hinton MH, and Wathes CM. 2003. Dispersal of microorganisms in commercial defeathering systems. *Br Poult Sci* 44:53-59. Allen, V.M., Burton, C.H., Wilkinson, D.J., Whyte, R.T., Harris, J.A., Howell, M., Tinker, D.B. 2008. Evaluation of the performance of different cleaning treatments in reducing microbial contamination of poultry transport crates. *Br Poult Sci* 49:233-240. Alonso-Hernando A, Alonso-Calleja C, and Capita R. 2013. Growth kinetic parameters of Gram-positive and Gram-negative bacteria on poultry treated with various chemical decontaminants. *Food Control.* 33: 429-432. Alonso-Hernando A, Guevara-Franco JA, Alonso-Calleja C, and Capita R. 2013. Effect if the temperature of the dipping solution on the antimicrobial effectiveness of various chemical decontaminants against pathogenic and spoilage bacteria on poultry. *J. Food Prot.* 76: 833-842. Alpas H, Kalchayanand N, Bozoglu F, and Ray B. 2000. Interactions of high hydrostatic pressure, pressurization temperature and pH on death and injury of pressure-resistant and pressure-sensitive strains of foodborne pathogens. 60: 33-42. Balasubramanian S, Gupta MK, and Singh KK. 2012. Cryogenics and its application with reference to spice grinding: A review. *Crit. Rev. Food Sci. and Nut.* 52: 781-794. Bashor M, Curtis PA, Kenner KM, Sheldon BW, Kathariou S, and Osborne JA. 2004. Effects of carcass washers on *Campylobacter* contamination in large broiler processing plants. *Poult Sci* 83:1232-1239. Bauermeister, LJ, Bowers JWJ, Townsend JC, and McKee SR. 2008. The microbial and quality properties of poultry carcasses treated with peracetic acid as an antimicrobial treatment. *Poultry Sci.* 87:2390-2398. ", "49 Beers KL, Cook PE, Coleman CW, and Waldroup AL. 2010. Efficacy of ultraviolet light systems for control of microorganisms in poultry and beef brine and marinade solutions. *Poult Sci.* 89 (E-Supplement 1): 615. Beier RC, Byrd JA, Caldwell D, Andrews K, Crippen TL, Anderson RC, and Nisbet DJ. 2019. Inhibition and Interactions of *Campylobacter jejuni* from Broiler Chicken Houses with Organic Acids. *Microorganisms* 7,223: 1-18. Berrang ME, Buhr RJ, and Cason JA. 2000. *Campylobacter* Recovery from External and Internal Organs of Commercial Broiler Carcass Prior to Scalding. *Poult Sci* 79:286290. Berrang ME, Buhr RJ, and Cason JA. 2001. Broiler Carcass Contamination with *Campylobacter* from Feces during Defeathering. *J Food Pro* 64,12: 1063-2066. Berrang ME, Cox NA, Meinersmann RJ, Oakley BB, & Line JE. 2015. Detection of *Campylobacter* in 100 commercial flocks\u2013Evaluation of plating media and filtration method. *J Appl Poult Res*, 24:240-245. Berrang ME and Dickens JA. 2000. Presence and level of *Campylobacter* spp. on broiler carcasses throughout the processing plant. *J Appl Poult Res* 9:43-47. Berrang ME, Dickens JA, and Musgrove MT. 2000. Effects of Hot Water Application After Defeathering on the Levels of *Campylobacter*, Coliform Bacteria and *Escherichia coli* on Broiler Carcasses. *Poult Sci* 79:1689-

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Cryogenic Freezing - No chemicals on food; no rinse required - Odorless, colorless, tasteless - Expensive to install and operate - CO<sub>2</sub> or N<sub>2</sub> are dangerous to handle Operates at approximately -59°C Application: N/A Shaikh and Prabhu, 2007 High Pressure Processing (HPP) - No chemicals on food; no rinse required - Expensive to install - Typically done at a separate establishment - Can alter appearance and texture of product Operates at pressures >100 MPa Application: N/A Liu, 2012 Simonin, 2012 Irradiation - No chemicals on food; no rinse required - Expensive to install - Typically done at a separate establishment - labeling requirement 22643.0 kGy packaging must be air permeable (21 CFR 179.26(b)(6)) Thayer 1991 and 1992"]}, {"file\_name": "FSIS\_GD\_2021\_0008", "title": "FSIS Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Beef (including Veal) Slaughter Operations", "num": "FSIS-GD-2021-0008", "id": "cbb23be9a4566f230ef8a7d510294002e59546e8b18a89306b07b1949e8972d0", "co\_rpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-08/FSIS-GD-2021-0008.pdf", "type": "pdf", "n\_pages": 64, "word\_count": 17373, "text\_by\_page": ["This guideline is to assist establishments that slaughter beef (including veal) to: \u2022 Implement effective sanitary dressing procedures designed to prevent carcass contamination; \u2022 Implement effective decontamination and antimicrobial interventions; \u2022 Properly assess microbial testing results, including results for indicators of process control, at any point during slaughter; and \u2022 Use the results from the implementation of these components of the food safety system to assess the effectiveness of the overall HACCP system. Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Beef (including Veal) Slaughter Operations 2021 Guideline", "2 Preface What is the purpose of this Guideline? The purpose of this guideline is to provide beef (including veal) slaughter establishments information concerning best practices at slaughter that may be used to prevent, eliminate, or reduce levels of fecal and associated microbiological contamination in beef (including veal), specifically (1) Shiga toxin-producing Escherichia coli O157:H7 and non-O157(STEC), and (2) Salmonella. For the purpose of this guideline, wherever it references beef, it includes veal. This document is not meant to be a comprehensive Salmonella control guide, however many of the best practices included in this document may also reduce Salmonella contamination that occurs during the slaughter process. This guideline provides guidance to assist establishments in meeting FSIS regulations. The guidance represents best practice recommendations by FSIS based on the most current science available and practical considerations. It does not represent regulatory requirements that must be met. Establishments may choose to adopt different procedures from those outlined in this guideline to prevent contamination, but they would need to support why those procedures are effective. This guideline represents FSIS\u2019 current thinking on this topic and should be considered usable as of the issuance date. This guideline is focused on assisting small and very small establishments in support of the Small Business Administration\u2019s initiative to provide these establishments with assistance under the Small Business Regulatory Enforcement and Fairness Act (SBREFA). However, all FSIS regulated beef slaughter establishments may be able to apply the recommendations in this guideline. It is important that small and very small establishments have access to a full range of scientific and technical support and the assistance needed to establish safe and effective

Hazard Analysis and Critical Control Point (HACCP) systems. Although large establishments can benefit from the guidance that FSIS provides, focusing the guidance on the needs of small and very small establishments provides those establishments with information that may be otherwise unavailable to them. FSIS strives to provide small and very small establishments with as much technical knowledge as possible through, in part, publication of best practices in industry guidelines. Establishments can apply this knowledge and best practices to their operations as they see fit to establish a compliant HACCP system. Who is this guideline designed for? FSIS designed this guideline for beef (including veal) slaughter establishments. The best practices discussed in this guideline may also be useful to establishments that slaughter bison. Key Point This guideline provides information concerning best practices at slaughter that may be used to prevent, eliminate or reduce levels of STEC in beef (including veal). Salmonella is also covered where scientific information is available.", "3 Is this version of the guideline final? Yes. This version of the guideline is final. FSIS responded to public comments received on the previous version of this guideline. Comments were received from two industry groups and one individual. FSIS made the following changes in response to these comments. \u2022 FSIS clarified that the Agency\u2019s recommendations are not regulatory requirements; \u2022 FSIS removed information pertaining to lymph node harborage of Salmonella and will include it in Salmonella specific guidance materials; \u2022 FSIS removed best practice recommendations on the use of chlorophyll to detect contamination on carcasses and air inflation for bunging; \u2022 FSIS clarified the Agency\u2019s recommendations on cattle washing to reduce pathogen transfer and added more information on humane handling during cattle washing; \u2022 FSIS added more information on pre-harvest interventions; \u2022 FSIS clarified the Agency\u2019s recommendations about when feet, eardrums, and bruises should be removed; and \u2022 FSIS provided more information to support its recommendations on chilling and storage of carcasses and parts; \u2022 After additional internal review, FSIS emphasized that it considers the presence of certain STEC strains to be adulterants when they are present in raw non-intact beef products and raw intact beef source materials intended for use in such non-intact beef products or when the intended use is unclear. These adulterant STEC strains include E. coli O157:H7 as well as strains that have certain O groups (O26, O45, O103, O111, O121, and O145) and contain two specific virulence genes (stx and eae). This addition was created to clarify FSIS policy regarding STEC in relation to product recalls; and \u2022 After additional internal review, FSIS added a section on how \u201cdrying\u201d can be used as an intervention to reduce pathogens, including STEC. FSIS will update this guideline in response to changes in science and technology and based on public comments, as necessary. What if I still have questions after I read this guideline? FSIS recommends that users of this guideline search the publicly posted Questions & Answers (Q&As) in the askFSIS database or submit questions through askFSIS. Documenting these questions helps FSIS improve and refine present and future versions of this guideline and associated issuances. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided: Subject Field: Enter FSIS Industry Guideline for Minimizing the Risk of Shiga Toxin- Producing Escherichia coli (STEC) in Beef (including Veal) Slaughter Operations 2021; Question Field: Enter question with as much detail as possible; Product Field: Select General Inspection Policy from the drop-down menu; Category Field: Select Sampling from the drop-down menu; and Policy Arena: Select Domestic (U.S.) only from

the drop-down menu. When all fields are complete, press Continue.", "4 Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Beef (including Veal) Slaughter Operations Table of Contents Preface

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"Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Beef (including Veal) Slaughter Operations Why did FSIS develop this guideline? Since issuing the first version of this guideline in September 2002, FSIS has made significant changes to policies and testing procedures affecting beef slaughter establishments. This guideline has been updated to reflect policy and procedural changes. Some of the more significant changes include: In October 2002, FSIS issued a Federal Register notice (FRN) 67 FR 62325 that required all establishments producing raw beef products to reassess their HACCP plans in light of new FSIS testing methods and higher prevalence estimates for E.coli O157:H7. In the September 20, 2011 Federal Register (76 FR 58157), FSIS declared six non-O157 STECs (O26, O45, O103, O111, O121, and O145) adulterants in raw, non-intact beef products and product components. In November 2011, FSIS issued FSIS Directive 6410.1, Verifying Sanitary Dressing and Process Control Procedures by Off-line Inspection Personnel (IPP) in Slaughter Operations of Cattle of Any Age to IPP to verify that cattle slaughter operations are implementing sanitary dressing and process control procedures and that the procedures they are implementing prevent contamination of carcasses and ensure that insanitary conditions are not created. Those instructions are still in place. In June 2012, FSIS began testing for non-O157 STEC in addition to E. coli O157:H7 in beef manufacturing trimmings (BMT). In June 2014, FSIS began analyzing for Salmonella in all raw beef samples it collects for STEC analysis. FSIS announced its intention to develop a new ground beef performance standard for Salmonella based on these data. In August 2014, FSIS began a Beef-Veal carcass baseline study to test carcasses for the presence\absence and levels (enumeration) of STEC, Salmonella and certain indicator organisms during the beef slaughter process. FSIS intends to use the results from this study to develop guidance for establishments that slaughter beef-veal to use in assessing their process control of sanitary dressing and other slaughter controls. In August 2014, FSIS issued the revised FSIS Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers concerning the sampling of BMT for STEC. The guidance includes information on the development and implementation of statistical process control procedures that slaughter\fabrication establishments can use to assess (1) the effectiveness of their controls for preventing contamination to the carcass during the slaughter process and (2) to verify they

are reducing STEC to a non-detectable level. The guidance also recommends criteria for high event periods (HEPs). In January 2015, FSIS issued FSIS Directive 10,010.3 Traceback Methodology for Escherichia Coli (E.coli) O157:H7 in Raw Ground Beef Products and Bench Trim to IPP on how to conduct traceback activities from the grinder or bench trim establishment and to verify that an establishment's action in response to an HEP is appropriate. In September 2015, FSIS issued Sanitary Dressing and Antimicrobial Intervention",<sup>7</sup> Implementation at Veal Slaughter Establishments: Identified Issues and Best Practices. This document identifies best practices for sanitary dressing specific to Veal slaughter establishments. Cattle have been identified as an important reservoir for pathogens, including STEC and Salmonella, which are known causes of foodborne disease. The hides, hooves, and gastrointestinal (GI) tracts of cattle can contain these pathogens. Contamination can be transferred from the hide, hooves, and GI tracts of cattle through poor sanitary dressing procedures. Effective sanitary dressing procedures underpin the interventions that an establishment has in place to prevent, eliminate, or reduce to an acceptable level, the food safety hazards that are reasonably likely to occur in the slaughter process. FSIS recommends that slaughter operations focus on their sanitary dressing procedures to prevent carcass contamination and the creation of insanitary conditions. Poor sanitary dressing procedures result in carcass contamination (visible or invisible, e.g., fecal or nonvisible microbial contamination) and limit the effectiveness of antimicrobial interventions. FSIS developed this guideline to assist establishments that slaughter beef (including veal) to prevent and minimize the risk of STEC in their operations. This guidance will: Help establishments design comprehensive written sanitary dressing programs that focus on preventing contamination of the carcass throughout the slaughter process; Describe for establishments how to implement antimicrobial interventions effectively; and Assist establishments with developing verification activities to ensure sanitary dressing procedures are consistently performed and effective. As described in the FSIS Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers, establishment verification testing results for BMT are likely the best available objective information a slaughter establishment can use to determine the ongoing effectiveness of its slaughter/dressing operation. Establishments that incorporate statistical process control procedures into their testing programs, as described in the beef trimmings sampling guideline, and apply the information and best practices in this guideline should have an improvement to the design and implementation of their slaughter HACCP system. Further, in the beef trimmings sampling guideline above, FSIS recommends that Key Points Most food safety hazards inherent in raw processes originate with the live animals that enter the slaughter establishment. Salmonella and STEC are commonly found in the GI tract, and on the hides, and hooves of cattle. Effective sanitary dressing procedures during slaughter can reduce microbial contamination.",<sup>8</sup> slaughter establishments develop criteria for identifying HEPs or to follow FSIS criteria for identifying HEPs. HEPs are periods of time in which slaughter establishments experience a high rate of positive results for STEC (or virulence markers) in BMT samples from production lots containing the same source materials. That is, the BMT was produced from one or more carcasses slaughtered and dressed consecutively or intermittently within a defined period of time (e.g., shift). A HEP may mean that a systemic breakdown of the slaughter/dressing operation has occurred and has created an insanitary

condition applicable to all parts of the beef carcass (e.g., primal cuts in addition to the BMT and other raw ground beef and patty components). FSIS recommends that establishments identify HEP criteria so that they can determine whether they need to withhold product from commerce when a HEP has occurred. A HEP may indicate more widespread adulteration of product, beyond the specific product found positive. If establishments identify and respond to a HEP, they will minimize the chance that they release adulterated product into commerce. More information on the development and implementation of statistical process control procedures, recommended criteria for identifying a HEP, and guidance for responding to a HEP are included in the FSIS Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers. What regulatory requirements are addressed by this guideline? Regulation Description 9 CFR 310.18(a) Requires establishments to handle carcasses, organs, and other parts in a manner to prevent contamination. 9 CFR 416.1 through 416.5 Requires establishments to operate in a manner to prevent the creation of insanitary conditions and prevent product adulteration. 9 CFR 417.2(a)(1) Requires an establishment to conduct a hazard analysis to identify food safety hazards that might occur in the production process, assess which hazards are reasonably likely to occur, and develop measures to prevent, eliminate, or reduce the identified hazards to an acceptable level. 9 CFR 417.2(c)(3) Requires the establishment to develop critical limits for critical control points (CCPs) to control hazards that are reasonably likely to occur. 9 CFR 417.4(a)(2) Requires establishments to verify that the HACCP system is effectively implemented on an ongoing basis.", "9 How should establishments use this guideline document to incorporate these recommendations into a comprehensive, robust food safety system? This guideline provides an overview of the slaughter process and includes the best practices at each step in the slaughter process to minimize contamination. As discussed above, FSIS recommends that establishments develop written sanitary dressing procedures designed to prevent contamination from occurring throughout the slaughter process and to develop verification activities to ensure the sanitary dressing procedures are performed consistently and are effective. Establishments can use the information in Appendix 1, Establishment SelfAssessment Checklist, to develop written sanitary dressing procedures designed to prevent contamination throughout the slaughter process and design verification activities to ensure that their employees are performing the procedures on an on-going basis. Establishments can use Appendix 2, Carcass Sanitary Dressing Audit, to verify, in real-time using carcass audits, that their sanitary dressing procedures are effectively preventing contamination throughout the slaughter process. FSIS also recommends that establishments implement antimicrobial intervention treatments, as needed, to reduce contamination to acceptable levels. This guideline discusses antimicrobial intervention treatments, their role in a comprehensive food safety system, and how to design and implement their use effectively. FSIS recommends that establishments test BMT for STEC (or virulence markers) to assess the effectiveness of their controls for preventing contamination during the slaughter operation. As is discussed above, FSIS developed a guidance document, FSIS Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers, for beef slaughter\fabrication establishments to use to develop and implement statistical process control procedures for STEC (or virulence markers) BMT testing to assess the effectiveness of slaughter operations. The beef trimmings sampling guideline also includes

recommended HEP criteria for identifying situations that indicate when a 9 CFR 417.5(a)(1) Requires establishments to maintain supporting documentation associated with the hazard analysis. 9 CFR 417.5(a)(2) Requires establishments to maintain decision-making documents associated with the selection and development of CCPs and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures. Key Point \u2022 The goal of this guideline is to help establishments design and implement a robust food safety system to minimize product contamination, specifically with pathogens. \u2022 Establishments that use this guidance can reduce their likelihood of producing adulterated products." "10 systemic breakdown of the slaughter operation has occurred and created an insanitary condition applicable to all parts of the beef carcass (e.g., primal cuts in addition to the BMT and other raw ground beef and patty components). FSIS recommends that establishments use the beef trimmings sampling guideline with the information in this guideline to design and implement a robust food safety system to improve their process over time.

**Overview of the Beef Slaughter Process**

What are the food safety hazards of concern during beef slaughter and where do they originate? FSIS considers the presence of certain STEC strain adulterants when they are present in raw non-intact beef products and raw intact beef source materials intended for use in such non-intact beef products. These adulterant STEC strains include *E. coli* O157:H7 as well as strains that have certain O groups (O26, O45, O103, O111, O121, and O145) and contain two specific virulence genes (*stx* and *eae*). The best practices for effective sanitary dressing procedures, antimicrobial intervention strategies, and appropriate use of microbial data in decision-making as outlined in this guideline will assist establishments in reducing these pathogens. Most of the food safety hazards inherent in raw processes originate with the live animals that enter the slaughter establishment. Common hazards include the biological hazards of bacterial pathogens, the chemical hazards of residues and the physical hazards of foreign material. These hazards could be present in raw product in any step of food production. Enteric organisms, such as *E. coli* and *Salmonella* are commonly found as part of the normal bacteria of the intestinal tract of animals. Some strains, notably the STEC, including *E. coli* O157:H7, and certain *Salmonella* serotypes can cause serious foodborne illness in humans. Cattle may carry STEC and *Salmonella* in their GI tracts and these pathogens may also be present on the hides and hooves of animals presented for slaughter.

**KEY DEFINITIONS:**

- Sanitary Dressing:** The practice of handling carcasses by establishment employees and machinery in a sanitary environment and a manner that produces a safe and wholesome product.
- Process Control Procedure:** A defined procedure or set of procedures designed by an establishment to provide control of those operating conditions necessary for the production of safe, wholesome food. The procedures typically include some means of evaluating system performance by using process control criteria, actions to take to ensure the system remains under control, and planned measures to take in response to a loss of process control. The procedures can be used as support for decisions made in the hazard analysis."
- "11 What are the guiding principles for minimizing the risk of STEC at slaughter? The four main guiding principles for minimizing the risk of STEC contamination during the slaughter process are: 1) Effective sanitary dressing procedures; 2) Antimicrobial interventions; 3) Establishment validation and verification that the system is functioning as intended; and 4) Evaluation of slaughter procedures during all steps of the process. These principles are interrelated and are vital components of an effective slaughter food safety

system. A description of each principle follows.

**PREVENTION VALIDATED ANTIMICROBIAL INTERVENTIONS**

Slaughter operations should develop and validate sanitary dressing procedures that prevent carcass contamination and the creation of insanitary conditions throughout the slaughter process. Effective and consistently performed sanitary dressing procedures that focus on preventing contamination directly impact whether interventions used will effectively reduce pathogens. Establishments should implement decontamination and validated antimicrobial intervention treatments as needed to reduce STEC to a non-detectable level. Establishments are required to identify and maintain documentation that provides support for their interventions, and identify the critical operational parameters that are necessary for the interventions to be effective (element one of validation), and to", "12 As discussed in the FSIS Compliance Guideline HACCP Systems Validation best practice documents such as; this FSIS Guideline, the BIFSCO Best Practices for Beef Slaughter and FSIS Directive 6410.1, Verifying Sanitary Dressing and Process Control Procedures by Off-line Inspection Program Personnel (IPP) in Slaughter Operations of Cattle of Any Age, may be used as scientific support that an establishment\u2019s sanitary dressing program prevents contamination with microbiological hazards such as STEC. Best Practices for Sanitary Dressing and Process Control

**NOTE:** While the recommendations in this guide apply to both veal and cattle slaughtering establishments, specific recommendations for veal can be found in the September 2015 FSIS document Sanitary Dressing and Antimicrobial Intervention Implementation at Veal Slaughter Establishments: Identified Issues and Best Practices.

What is the importance of sanitary dressing and process control procedures? FSIS sampling has found enteric pathogens, including *Salmonella*, adulterant non-O157 STEC and *E. coli* O157:H7, in BMT. Additionally, FSIS has found these bacteria in other raw ground beef components (including head meat and cheek meat) and raw ground beef. The presence of these enteric pathogens in these beef products can be attributed, in part, to ineffective sanitary dressing and process control procedures that create insanitary conditions during slaughter.

**VERIFICATION EVALUATION** have in-plant observations, measurements, microbiological test results, or other information demonstrating the control measures in the HACCP system can perform as expected within a particular establishment to achieve the intended food safety objective (element two of validation). Establishments are required to develop and implement verification activities that demonstrate that their slaughter process is effectively reducing hazards. Verification activities should generate real-time data of employees performing procedures as written that verify the procedures were effectively implemented (e.g., carcass audits after points in the slaughter process where carcasses are vulnerable to contamination). Establishments should develop microbiological testing procedures designed to detect contamination in product lots and generate microbiological test results to demonstrate the lots are free of contamination. Establishments should be able to demonstrate process control of the slaughter process through review of data collected (i.e., the implementation of their sanitary dressing procedures, antimicrobial interventions, and verification testing results) to determine the overall effectiveness of their food safety system.", "13 Insanitary practices and conditions during slaughter can introduce microbial and visible contamination (e.g., fecal material, ingesta and milk) to carcasses and parts. Effective sanitary dressing and process control procedures, coupled with effective decontamination and antimicrobial intervention treatments, are necessary to prevent the creation of insanitary conditions. Establishments create the potential for the contamination of carcasses and parts

when they fail to control these procedures and treatments in their food safety systems. Effective sanitary dressing and process control procedures support the CCPs that an establishment has in place to prevent, eliminate or reduce to an acceptable level the food safety hazards identified in the slaughter process and support that the HACCP system is functioning as intended. If sanitary dressing and process control procedures are not properly implemented, the HACCP system may be inadequate. Insanitary practices can introduce a level of contamination that overwhelms the decontamination and antimicrobial intervention treatments used to reduce pathogens to acceptable levels. FSIS recommends that slaughter establishments should consistently focus on sanitary dressing and process control procedures to prevent carcass contamination and the creation of insanitary conditions in their operations. Fundamental sanitary dressing practices to prevent carcass contamination and the creation of insanitary conditions.

1. Maintain adequate separation of carcasses, parts and viscera during dressing to prevent cross contamination.

2. Routinely clean and sanitize or sterilize equipment and hand tools that are used to remove contamination or to make cuts into the carcass.

Cleaning and sanitizing equipment between each dirty cut and between each carcass are the most effective way to prevent insanitary conditions.

3. Design and arrange equipment to prevent the contact of successive carcasses and parts with contaminated equipment and do not allow the hide during its removal to flap or splatter which could cause contamination of the same or nearby carcasses.

4. Frequently wash hands, gloves, and aprons that come in contact with the carcass and parts.

Key Points

\u2022 Effective sanitary dressing measures address multiple points in the slaughter process where carcasses are vulnerable to contamination.

\u2022 All controls in slaughter and dressing procedures should be aimed at preventing contamination.

\u2022 If sanitary dressing and process control procedures are not properly implemented, the HACCP system may be inadequate."

"14 What verification activities related to sanitary dressing should establishments develop? Establishments should observe employees to verify that they are performing the sanitary dressing procedures as written. Establishments should verify that the procedures are effective by conducting carcass audits (periodic visual evaluation of the carcass throughout the dressing process, as shown in Appendix 2) and by sampling and testing BMT, other raw ground beef components (including head meat and cheek meat), and raw ground beef for microorganisms. Sampling for adulterant STEC (or virulence markers) in the products previously discussed is an important verification activity that demonstrates whether the establishment\u2019s HACCP system is effectively reducing STEC to below detectable levels and that hazard analysis decisions concerning STEC are supported on an ongoing basis. As explained in the FSIS Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-producing Escherichia coli (STEC) Organisms or Virulence Markers, establishment verification testing results for BMT are likely the best available objective information a slaughter establishment can use to determine the ongoing effectiveness of its slaughter\dressing operation. FSIS recommends that establishments incorporate their sampling and testing of beef products, in addition to their generic E.coli testing (9 CFR 310.25), into their process control procedures for sanitary dressing because the results from such testing are a direct reflection of the effectiveness of the slaughter operation. The establishment\u2019s process control criteria should define when its process is in control (such as an occasional, sporadic positive result) and when the establishment has lost process control as indicated by many positives over time. If past sample results lead establishment

management to believe the process is out of control, the establishment should carefully investigate to find all contributing causes. This type of investigation would be more involved than a follow-up investigation when an occasional positive result is found. Establishments should continually strive to eliminate STEC by tightening their process control criteria as they gain more control over their slaughter operations. FSIS has found that microbiological testing results can drive establishments to enhance their food safety systems when they use the test results to inform their processes and adjust their processes as needed in response to the test results. While performing the Beef Sanitary Dressing task, FSIS IPP verify whether cattle slaughter operations are implementing sanitary dressing and process control procedures and that the procedures they are implementing prevent contamination of carcasses and ensure that insanitary conditions are not created. (See FSIS Directive 6410.1, Verifying Sanitary Dressing and Process Control Procedures by Off-line Inspection Personnel (IPP) in Slaughter Operations of Cattle of Any Age). FSIS IPP also verify, through microbial sampling, HACCP verification tasks and Hazard Analysis 5. Implement decontamination and antimicrobial intervention treatments such as washes or sprays on carcasses and parts, in accordance with the limits selected by the establishment and documented to be adequate to address contamination.", "15 Verification (HAV) tasks for whether beef slaughter establishments adequately address STEC. (See FSIS Directive 10,010.1, Sampling Verification Activities for Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef products, and FSIS Directive 10,010.2, Verification Activities for Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef Products.) Enforcement, Investigations, and Analysis Officers (EIAOs) assess and analyze an establishment\u2019s food safety system to verify that the establishment is able to produce safe and wholesome meat products. (See FSIS Directive 5100.4 Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology and FSIS Directive 5100.1, Enforcement, Investigations and Analysis Officer (EIAO) Food Safety Assessment Methodology.)", "16 Best Practices for Each Beef Slaughter Processing Step Pre-harvest Control Sticking Cattle Receiving & Holding Head Removal Rodding the Weasand Brisket Opening Packaging\Finishing Product Storage & Transport Carcass Fabrication Carcass Splitting Head & Cheek Meat Processing Chilling Bunging Hide Removal (manual & mechanical) Evisceration \uf073 Processing steps in red are points in the slaughter process where FSIS has identified deficiencies that contributed to multiple STEC positive results. See section on FSA findings for additional information on commonly identified deficiencies and best practices section for ways to mitigate risk.", "17 What are pre-harvest considerations and best practices? FSIS encourages pre-harvest interventions as the first control steps in an integrated beef products food safety system, and the Agency has developed a guidance document, Pre -Harvest Management Controls and Intervention Options for Reducing Shiga Toxin-Producing Escherichia coli Shedding in Cattle: An Overview of Current Research, explaining pre-harvest management controls for reducing STEC shedding in cattle. Pre-harvest interventions, adequate sanitary dressing procedures at slaughter, and adequate sanitary conditions during further processing are all part of an integrated approach to reduce the public health impact of STEC. Below are additional recommendations not covered in this pre-harvest guidance document. What are mud scores and how can establishments use them to improve their food safety system? Mud scores are classifications concerning the overall cleanliness of cattle lots at receiving. For example, establishments can classify cattle into four groups: 1) Cattle that are less than 25% covered by dirt or mud; 2) Cattle that are greater than

25% and less than 50% covered by dirt or mud; 3) Cattle that are greater than 50% and less than 75% covered by dirt or mud; and 4) Cattle that are greater than 75% covered by mud. After classifying cattle at receiving into one of these four groups, establishments can develop specific measures they will take based on the classification of the cattle for the lot or lots. For example, if the cattle are in the third and fourth classification groups, the establishment may decide to slow the line speed to give its employees more time to effectively dress the cattle that have higher gross contamination. The establishment may also add more trimmers or interventions, such as a hide-on carcass wash. It is important for the establishment to use the information it gathers at cattle receiving and develop measures to react to the information that is collected. Other factors should be considered when using mud scores to modify production processes. For instance, during certain times of the year, cattle may have higher mud scores than at other times of the year (e.g., winter months versus summer months) when seasonal animal handling practices may influence the mud score. Therefore, different scoring criteria and trend analysis that varies by season may be needed to identify outliers. What are best practices during cattle transport, receiving, and holding? This is the point where cattle arrive at the slaughter establishment and are held before slaughter. There is an increased potential for contamination with enteric pathogens such as adulterant STEC and Salmonella during this time because of the presence of these microorganisms on the hide and hooves, and in the feces of cattle. Additionally, transportation to the slaughter facility, handling during transport and unloading, and interaction with other cattle may cause stress and increased shedding of pathogens." , "18 Best Practices during Cattle Transport, Receiving and Holding \u2022 Identify and obtain cattle from farms or feedlots that employ one or more production system or feedlot controls shown to reduce the carriage of STEC and Salmonella. Effective farm and feedlot management and control can reduce fecal shedding of the organism, as well as reduce the microbial load on the animals, and in the intestinal tract. More information can be found in PreHarvest Management Controls and Intervention Options for Reducing Shiga Toxin-Producing Escherichia coli Shedding in Cattle: An Overview of Current Research. \u2022 Clean the unloading areas and pens periodically to reduce the contamination of animals. \u2022 Washing cattle may be considered to reduce visible contamination which in turn may reduce pathogen transfer to the carcass. If an establishment decides to wash livestock pre-slaughter, they should ensure the washing is done in a humane manner. \u2022 Apply a water mist in the holding pens to reduce dust and dirt particles. \u2022 Use a mud scoring system (a system to quantify the amount of mud on live animals) to identify cattle that may present an increased likelihood of contamination during hide removal. \u2022 Apply an approved bacteriophage treatment to incoming cattle and allow the bacteriophage appropriate contact time (a list of approved bacteriophages can be found in FSIS Directive 7120.1). \u2022 Determine the incoming bacterial load on animals through microbiological sampling and testing of incoming cattle hides. \u2022 Determine whether the age, type of cattle received (e.g. veal calves), or season (i.e., high prevalence season) represent a concern relative to pathogen load and whether adjustments to the food safety system need to be made as a result." , "19 What are the best practices during sticking? This is the point in the process where the animal is bled. Regardless of the slaughter method, it is important for the establishment to minimize contamination of the carcass during any cut conducted at this step. What are best practices during hide removal? This is the point in the process where the hide is removed from the animal. Hides are a

significant source of contamination, and hide removal represents the greatest opportunity for carcass contamination. Contamination may be visible (e.g., dust, dirt, feces, mud) or invisible (i.e., microbiological). Establishments should take appropriate measures to prevent contamination during the de-hiding process. The fact that hides are a significant source of contamination, and that hide removal represents the greatest opportunity for carcass contamination, is clearly illustrated in the study described in Nou et. al. 2004. This study sampled two groups of cattle at lairage and after de-hiding. One group of cattle underwent a typical de-hiding procedure. Sampling of these carcasses immediately after de-hiding showed that 50% were positive for E. coli O157:H7. The other group of cattle was subjected to a chemical dehauling process prior to hide removal. Carcasses in this group showed only a 1% positive rate for E. coli O157:H7 and a significantly lower level of other indicator organisms as compared to the other group of cattle. This study demonstrates that transfer of contamination from the hide is a major contributor to the microbiological load onto carcasses. Best Practices during Sticking \u2022 Keep the \u201cdry landing\u201d area where the stunned animals exit from the knocking box clean and dry of all blood, feces, ingesta, and mud between each animal. \u2022 Use one knife to cut through the hide, and another knife (or the same knife sanitized) to cut the artery. \u2022 Use a dual knife system (i.e., one knife is being used while one knife is being sanitized) and clean the hand between sticking each carcass. \u2022 Use the smallest cut possible to accomplish bleeding. \u2022 Ensure blood collection devices and blood containers for edible blood are clean. Rinse and clean the collection funnel and knife after each carcass and sanitize after each identifiable lot of blood is drawn. Do not save blood from condemned animals." "20 Best Practices during Hide Removal \u2022 Apply a validated hide-on intervention prior to hide removal. If cattle hides are wet after the antimicrobial treatment, remove excess moisture because run-off can contaminate exposed tissue during hide opening. Sanitized squeegees can be used to remove excess moisture from the hides to reduce the chance of contamination. \u2022 Mud balls on hides can also be a source of contamination. Establishments can use whizzard knives with dull blades or curry combs to remove the mud balls and other dirt from the hide prior to hide opening. \u2022 When using a bed or cradle for hide removal, remove the front and hind feet before making any other incisions through the hide. Minimize the amount of foreshank tissue exposed. \u2022 Ensure the skinning bed (for bed operations) is clean before lowering the carcass. \u2022 Prevent the neck and shoulders from contacting the floor when lowering the carcass into the skinning bed. If this is not possible, install a surface on the floor that can be sanitized where the neck and shoulders contact. \u2022 Prevent fecal matter that is expressed as the carcass is laid on the bed from contacting the exposed carcass. \u2022 Direct the knife toward the hair side of the skin when opening the hide to prevent contaminating the carcass. \u2022 Remove visible contamination at the cut line. \u2022 Steam vacuum or apply another validated antimicrobial treatment to pattern lines (cut lines where the hide is opened) even if visible contamination is not present. \u2022 Remove visible fecal contamination as soon as possible after it occurs to prevent microbial attachment. \u2022 Use a dual knife system or, if not possible, dip the knife in the sterilizer after each incision through the hide. \u2022 Space carcasses a sufficient distance apart to prevent contamination of skinned parts with adjacent carcasses. \u2022 Design facilities to provide sufficient spacing between carcasses and walls, platforms and other fixed objects." "21 Best Practices during Hide Removal (Continued) \u2022 Remove lactating udders

in a manner to prevent carcass contamination with udder contact. \u2022 Trim any contamination from udder content immediately. \u2022 Reflect the hide away and preferably downward from the carcass as skinning proceeds. Skin each area back far enough to permit the hide to stay in a rolled-back position before the Skinner proceeds to another skinning location. \u2022 Prevent hides from flapping and contacting exposed carcass. Using hide clips is one way to prevent hide flaps from contact with the exposed carcass. Clean and sanitize hide clips as necessary to prevent the creation of insanitary conditions. \u2022 Prevent contamination to the tail or carcass while skinning the tail. Frequently clean hands and equipment at this step because the tail and switch are highly contaminated with urine and manure. This is particularly important when the same employee performs other tasks involving carcass contact. \u2022 Clean and sterilize the clamp used to suspend the tail from the overhead spreader between each use or remove and discard the tip of the tail ahead of the clamped portion. \u2022 Remove tail switches and bag the tails before using the tail puller. \u2022 Inject air under the skin of skulls to facilitate hide removal from the head while using the hide puller. \u2022 Ensure that mechanical hide pullers, side pullers, and tail pullers are properly adjusted. If they are not appropriately adjusted (e.g., pulling too fast, hard, or contacting exposed carcass), they can lead to carcass contamination and splatter. \u2022 Monitor pullers on an on-going basis for proper adjustment. \u2022 When using mechanical hide pullers, the tremendous energy exerted during the final removal of the hide can generate aerosols. During this process best practices in preventing cross contamination are to:

- o Establish a maintenance program for the mechanical pullers;
- o Monitor pullers on an on-going basis for proper adjustment;
- o Install shields or devote an employee to hold up a shield; and
- o Direct air flow away from the carcasses being skinned to prevent contamination of carcasses with the aerosols created at this step.

"22 What are best practices during bunging? This is the point in the slaughter process where a cut is made around the rectum (i.e., terminal portion of the large intestine) to free it from the carcass, and then it is tied off and bagged to prevent spillage of fecal material. If the bung is not tied and bagged properly, the bung can contaminate the carcass. When bunging is performed before the hide of the rump is removed, the outside of the bag can become contaminated from the hide. Then, when the GI is removed during evisceration and the bagged bung is pulled through the pelvic inlet, the contamination on the outside of the bag can cause carcass contamination and the creation of insanitary conditions.

**Best Practices during Hide Removal (Continued)**

\u2022 A simple way to evaluate if the hide, side or tail puller is causing contamination is for an establishment employee to hold up a white piece of cardboard between the hide puller and the carcass during de-hiding and adjacent carcasses (to the side of and behind, if the line wraps around). If the piece of cardboard becomes dirty, the unit is likely causing cross-contamination and needs to be adjusted (i.e., the wheel spin needs to be slowed down) or the establishment should use shields.

\u2022 Apply a physical barrier (e.g., paper towels or plastic) to the carcass tissue adjacent to the hide to protect exposed carcass surface in the event the hide turns over when using the hide puller. In this case, if the hide turns over, the hide will touch the barrier rather than the exposed carcass tissue.

\u2022 Maintain clean mechanical hide puller contact points with the hide, hands, and garments of the employees handling the hide and the carcass, and knives and other equipment contacting the de-hided carcass.

\u2022 Apply antimicrobial treatments (e.g., organic acids) immediately after using the mechanical pullers.

\u2022 Place a hide chute where hides are removed from carcasses. Do not

spread hides on the slaughter floor. \u2022 Ensure employees maintain proper hygiene practices to prevent carcass contamination and the creation of insanitary conditions. Do not touch the carcass with soiled hands, tools, or garments.", "23 What are best practices during weasand rodding? This is the point in the process where the establishment uses a metal rod to free the esophagus (weasand) from the trachea and surrounding tissues. Weasand meat may be salvaged from the remainder of the GI tract for use in raw ground beef production. Typically, the weasand is closed (i.e., tied) to prevent rumen spillage. If the weasand is not closed, ingesta and ruminal content can result in carcass contamination. It is important, at this point in the process, that contamination is not transferred from the exterior of the carcass to the interior or onto the weasand. Also, if during the rodding process the GI tract is punctured, ingesta content can contaminate the carcass interior and exterior. Alternatively, establishments could send weasand meat for cooking or other full-lethality treatment (e.g., high pressure processing or irradiation). Best Practices during Weasand Rodding \u2022 Close the esophagus to prevent leakage of rumen contents. \u2022 Change or sanitize the weasand rod between each carcass. \u2022 Ensure that employees maintain proper hygiene practices to prevent carcass contamination and the creation of insanitary conditions. Do not touch the carcass with soiled hands, tools, or garments. \u2022 Clean and chill the weasand quickly to limit contamination and pathogen multiplication. Best Practices during Bunging \u2022 Drop the bung during the final part of rumping or at a time that minimizes cross contamination to the carcass. \u2022 Bag and tie off bungs to prevent carcass contamination. \u2022 Maintain proper employee hygiene practices to prevent carcass contamination and the creation of insanitary conditions. Do not touch the carcass with soiled hands, tools, or garments. \u2022 Apply a validated decontamination process to the local area (e.g., steam vacuum) or antimicrobial treatment to the entire carcass at this point or a point later in the process, that is effective in reducing the presence or counts of microbial contaminants.", "24 What are best practices during head removal? This is the point in the slaughter process where the head is removed from the carcass. It is important to maintain sanitary conditions because cross contamination can occur if the head comes into contact with insanitary heads, equipment, or employee hands or garments. Best Practices during Head Removal \u2022 Maintain adequate separation between skinned heads, carcasses, the floor, and fixed objects. \u2022 While skinning the head, the head Skinner should sterilize the knife as frequently as necessary to prevent cuts from cross-contaminating the head. \u2022 Remove heads as soon as possible after skinning to further reduce contamination exposure. \u2022 Sanitize the neck breaker or knives as necessary. \u2022 Prevent contamination with rumen contents during head removal. This can usually be accomplished by tying the esophagus and then pulling the head sharply to the side as the gullet is cut. Removal of rumen content contamination is difficult because of its finely textured character, which makes prevention even more important. \u2022 Remove the horns, all pieces of hide and eardrums from each head in a manner to minimize contamination. \u2022 Clean the equipment used to hold heads for trimming and\or dehorning between each head. Disinfect the equipment after use on each suspect, retained or other obviously diseased head. \u2022 Prevent cross-contamination of other heads or adjacent carcasses and limit airborne contaminants. \u2022 Thoroughly flush the oral and both nasal cavities before washing the outer surfaces of each head. \u2022 Head hooks in washing cabinets should be removable to allow for cleaning and sterilizing or sanitizing. Clean hooks between each use and sterilize hooks

after handling suspect, retained, or obviously diseased heads. If the head hooks are not removable, the equipment should be designed for in-place sterilization and equipped with an integral thermometer or other temperature-measuring device. \u2022 Have procedures in place to make sure heavily contaminated heads do not cross contaminate other heads in head wash cabinets (e.g., shut off the cabinet before heavily contaminated heads enter the cabinet and recondition or discard affected product after inspection.) \u2022 Clean and sterilize head inspection racks after each use involving a retained head. Since this is impractical to accomplish with hooks installed on a continuous chain, provide all such installations with a suitable wash cabinet or other device that will clean and sterilize each hook prior to its subsequent use."<sup>25</sup> What are best practices during brisket opening? This is the point in the process where the brisket is split (i.e., cut along the centerline) to facilitate the easy removal of the thoracic viscera. The thoracic cavity is entered blindly and there is no way of knowing if abscesses or other pathological conditions are present. Therefore, the saw, or other instrument used to split the brisket, should be disinfected after each use, making sure to remove remnant tissue from the saw. Best Practices during Head Removal (Continued) \u2022 The minimum temperature for hot water sterilization is 180\u00b0F. Use an integral thermometer or other temperature-measuring device for continuous monitoring to ensure a minimum temperature of 180\u00b0F is met for hot water sterilization. Maintain proper employee hygiene practices to prevent carcass contamination and the creation of insanitary conditions. Do not touch the head with soiled hands, tools, or garments. \u2022 Address specified risk materials in accordance with 9 CFR 310.22. \u2022 At this point apply to the head a validated decontamination process (e.g., hot water wash) or antimicrobial treatment that is effective in reducing the presence or counts of microbial contaminants. Best Practices during Brisket Opening \u2022 Clean and sanitize the brisket saw and knife between each carcass and ensure the GI tract is not punctured. \u2022 Ensure that employees maintain proper employee hygiene practices to prevent carcass contamination and the creation of insanitary conditions. Do not touch the carcass with soiled hands, tools or garments. \u2022 Apply a validated decontamination process to the local area (e.g., steam vacuum) or antimicrobial treatment to the carcass at this point or a point later in the process that is effective in reducing the presence or counts of microbial contaminants."<sup>26</sup> What are best practices during evisceration? This is the point in the process where the removal of the viscera (e.g., the edible offal that includes the heart, intestines, paunch, liver, spleen and kidneys when presented with viscera) occurs. The actual removal of the viscera from the carcass is a critical phase of the dressing operation. Care should be taken to avoid cutting or breaking the paunch and intestines because the GI tract can contain pathogens. If the viscera are not handled properly, or if employee hygiene practices are not being followed, contamination of the carcass and edible offal can occur. What are the best practices during head and cheek processing? This is the point in the process where the meat is removed from the head and cheek. This meat can be used in the production of raw beef products, including ground beef. It is important for the establishment to maintain sanitary conditions when removing meat from the head and cheeks. Best Practices during Evisceration \u2022 The boot cleaning compartment should be conveniently located and constructed so as to prevent splash of contaminants onto carcasses or viscera. Thoroughly clean and disinfect contaminated footwear, apron, or knife. \u2022 Thoroughly clean and disinfect the viscera inspection truck, especially if it becomes soiled with visceral contents (e.g., feces, ingesta) or contaminated with

purulent material or viscera from a condemned carcass. To prevent fat buildup on the metal pluck pan or paunch and viscera portion of the inspection truck, periodically clean with hot water. Prevent cross contaminating product or equipment when rinsing a viscera inspection truck. \u2022 Ensure that employees maintain proper hygiene practices to prevent carcass contamination and the creation of insanitary conditions. Do not touch the carcass with soiled hands, tools, or garments. \u2022 Address specified risk materials in accordance with 9 CFR 310.22. \u2022 Apply a validated post-evisceration decontamination or antimicrobial treatment to the entire carcass and edible offal." , "27 What are best practices during carcass splitting? This is the point in the process where carcasses are split vertically into two halves. Prior to splitting, the establishment should remove all contamination, bruises, grubs, and tissue damaged by grubs from the midline area of the back. This is necessary to prevent spreading these contaminants to bone and other surfaces by the saw. Best Practices during Head and Cheek Processing \u2022 Properly maintain and clean knives. \u2022 Provide adequate separation or use compartments or shields to prevent cross contamination of heads. \u2022 Ensure that employees maintain proper hygiene practices to prevent head contamination and the creation of insanitary conditions. Do not touch heads with soiled hands, tools or garments. \u2022 Address specified risk materials in accordance with 9 CFR 310.22. \u2022 Quickly chill head and cheek meat to limit pathogen multiplication. \u2022 Apply any validated decontamination process or antimicrobial intervention treatments to the head and cheek meat that are effective in reducing the presence or counts of microbial contaminants after lymph node incision. Alternatively, send head and cheek meat for cooking or other full-lethality treatment (e.g., high pressure processing or irradiation). \u2022 Conduct microbiological testing (e.g., STEC) for process control to assess the effectiveness of the establishment's sanitary dressing procedures and any antimicrobial intervention treatments that are applied to the head and cheek meat as these products may undergo different interventions than the carcass." , "28 Best Practices during Carcass Splitting \u2022 Remove organic material, bruises, grubs, and tissue damaged by grubs from the midline area of the back prior to splitting to reduce potential contamination to the split saw, surrounding tissues, and other surfaces. \u2022 Sanitize saws and knives as necessary. Disinfect the splitting saw after each use on suspect, retained, or obviously diseased carcasses. \u2022 Allow adequate separation between carcasses to limit carcass-to-carcass contact. \u2022 Ensure that employees maintain proper hygiene practices to prevent carcass contamination and the creation of insanitary conditions. Do not touch the carcass with soiled hands, tools, or garments. \u2022 Address specified risk materials in accordance with 9 CFR 310.22. \u2022 When splitting is done at the half-hoist position, take measures to prevent the neck and foreshanks from contacting the floor. If necessary, install a surface that can be sanitized so the neck and foreshanks do not contact the floor. \u2022 Apply any validated decontamination or antimicrobial intervention treatments to the carcass at this point or a point later in the process that are effective in reducing the presence or counts of microbial contaminants. KEY QUESTION Carcass Wash Cabinets Question: How do establishments use carcass wash cabinets appropriately? Answer: Develop and implement measures, such as those listed directly below, to prevent spreading contamination to adjacent carcasses. \u2022 Remove all visible contamination before carcasses enter the cabinet. \u2022 Prevent overspray of water from the cabinet onto adjacent carcasses. \u2022 Prevent carcasses with conditions such as open abscesses, septic bruises, or the presence of parasites and

parasitic lesions from entering the cabinet. Wash from the top of the carcass in a downward direction so that contaminants gravitate away from the clean areas. Have procedures in place to make sure heavily contaminated carcasses do not cross contaminate other carcasses (e.g., shut off the cabinet before heavily contaminated carcasses enter the cabinet and recondition or discard affected product after inspection).", "29 What are the best practices during chilling? This is the point in the process where the temperature of the carcass and parts is reduced. Temperature control and sanitation measures ensure the microbial load reductions affected by the interventions are maintained. Temperature control limits pathogen multiplication and sanitary measures prevent re-contamination. Conduct on-going verification to ensure that any re-circulated hot water used in the cabinet meets 9 CFR 416.2 (g)(3). This regulation states that, Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination to prevent contamination or adulteration of product. Reuse that has come into contact with raw product may not be used on ready-to-eat product.\u201d \u2022 Have procedures in place to prevent carcasses identified with U.S. Suspect or Retained tags from entering the cabinets or have procedures in place to prevent cross-contamination of adjacent carcasses (e.g., shut off the cabinet before U.S. Suspect or Retained carcasses enter the cabinet and recondition or discard affected product). NOTE: Establishments can wash U.S. Suspects in these cabinets only with permission of the USDA Public Health Veterinarian (PHV) and in consideration of whether the design of the cabinet prevents cross-contamination of other carcasses. \u2022 Address potential hazards associated with water reuse in non-food processing areas to prevent the creation of insanitary conditions.", "30 Best Practices during Chilling Note: The times and temperatures listed on this page are based upon past industry practices and are not regulatory requirements. Establishments may select other times or temperatures if they maintain scientific support for the selection of those parameters. \u2022 Begin carcass chilling within approximately one hour after bleed-out to limit pathogen multiplication. \u2022 Begin chilling variety meats as quickly as possible after removal from the carcass to limit pathogen multiplication. \u2022 Implement temperature control and sanitation procedures to maintain the microbial reductions achieved by the antimicrobial intervention treatments. \u2022 Define and monitor refrigeration parameters so that carcasses reach a temperature of 40\u00b0F (4.4\u00b0C) or less within 24 hours and so that this temperature is maintained for all products. Take and record carcass temperature from 5 randomly selected carcasses in various cooler locations, usually 1 mm under fascia on the inside round (see Appendix 4, Chilling of Carcasses). \u2022 Maintain finished product storage areas at 40 \u00b0F or lower or have other supporting documentation for the temperature limit chosen. \u2022 Provide adequate distance between carcasses, walls and equipment to prevent cross contamination and allow for efficient air circulation to prevent or minimize condensation. \u2022 Ventilate coolers with negative-pressure systems to prevent cross contamination from airflow from slaughter operations. \u2022 If carcasses are held longer than 7 days in the cooler before fabrication, maintain scientific support for cooler parameters which may include temperature, humidity, and air flow. \u2022 Transport carcasses for hot boning (deboned before chilling) to the boning areas directly from the slaughter department. Do not delay boning. Maintain the boning room environmental temperature at 50 \u00b0F (10 \u00b0C) or lower. \u2022 At this point apply any validated decontamination or antimicrobial

intervention treatments to the carcasses and variety meats to reduce microbiological contamination. \u2022 Ensure that employees maintain proper hygiene practices to prevent the creation of insanitary conditions (e.g., touching the carcass with soiled hands, tools, or garments). \u2022 Prevent cross-contamination from airflow during slaughter operations. \u2022 Establish traffic patterns to eliminate movement of personnel, pallets, and refuse containers between slaughter and further processing. If employees must work in both areas, have procedures in place that require the employees to change outer and other soiled clothing, wash and sanitize hands, and clean and sanitize footwear before moving from slaughter to further processing areas.", "31 What are best practices during carcass fabrication? This is the point in the process where the carcass is broken down into primal and subprimal cuts and trimmings. Temperature control limits pathogen multiplication and sanitary measures prevent re-contamination. What are best practices during packaging, product storage, and product transport? These are the points in the process where products are packaged, stored, and transported for further distribution. Temperature control limits pathogen multiplication while sanitary measures prevent product re-contamination. Best Practices during Carcass Fabrication \u2022 Implement temperature control and sanitation procedures to maintain the microbial reductions achieved by the antimicrobial intervention treatments. \u2022 Maintain processing room temperature at 50\u00b0F (10\u00b0C) or lower. \u2022 Provide for efficient air circulation to prevent or minimize condensation. \u2022 Ventilate coolers with negative-pressure systems to prevent cross contamination from airflow from slaughter operations. \u2022 Ensure that employees maintain proper hygiene practices to prevent the creation of insanitary conditions. Do not touch the carcass with soiled hands, tools or garments. \u2022 Clean and sanitize knives, saws, slicers, and other food contact surfaces as frequently as necessary to prevent the creation of insanitary conditions. \u2022 Establish traffic patterns to eliminate movement of personnel, pallets, and refuse containers between slaughter and further processing. If they must work in both areas, have procedures in place so employees change outer and other soiled clothing, wash and sanitize hands, and clean and sanitize footwear before moving from slaughter to further processing areas. \u2022 At this point in the process, employ any validated decontamination or antimicrobial intervention treatments that are effective in reducing the presence or counts of microbial contaminants on the carcasses. \u2022 Conduct microbiological testing (e.g., STEC) of BMT as per the establishment's HACCP Plan, Sanitation SOPs, Good Manufacturing Practices (GMPs), or other prerequisite programs, to verify pathogens have been eliminated.", "32 Beef Slaughter Interventions How do antimicrobial intervention treatments fit into the HACCP regulatory framework? Establishments implement antimicrobial interventions as needed to reduce STEC and Salmonella. The HACCP regulations require establishments to provide scientific support for their interventions and to implement their interventions according to that support. 9 CFR 417.2(a) requires that an establishment identify any food safety hazards that might occur in the production process, assess which hazards are reasonably likely to occur, and develop measures to prevent, eliminate, or reduce to an acceptable level those hazards. The establishment must maintain documents to support the decisions it makes during its hazard analysis (9 CFR 417.5(a)(1)). Establishments may incorporate the use of interventions in their HACCP plan, sanitation SOPs, or other prerequisite program. Establishments may incorporate the use of interventions in their HACCP plan and apply the intervention as a CCP to control hazards that are reasonably likely to

occur (9 CFR 417.2(c)(3)). Alternatively, an establishment may determine that a hazard is not reasonably likely to occur because the establishment maintains preventive measures as part of a prerequisite program that prevents the hazard from occurring. In either case, the establishment should identify the critical operating parameters for any antimicrobial interventions used in its Best Practices during Packaging, Product Storage and Product Transport \u2022 Implement temperature control and sanitation procedures to maintain the microbiological reductions achieved by the antimicrobial intervention treatments applied during the slaughter process. \u2022 Maintain storage room and transportation vehicles at 40\u00b0F (4.4\u00b0C) or lower. \u2022 Maintain the average internal meat temperature during storage at 40\u00b0F (4.4\u00b0C) or lower. \u2022 Monitor and record environment and product temperature during product storage and product transport. \u2022 Provide for efficient air circulation to prevent or minimize condensation. \u2022 Prevent contamination from airflow, traffic, people, and other environmental sources. \u2022 Ensure employees maintain proper hygiene practices to prevent the creation of insanitary conditions. Do not touch the product with soiled hands, tools or garments.", "33 supporting documentation. HACCP plans control hazards; prerequisite programs (including sanitation SOPs) prevent hazards from entering the establishment\u2019s food safety system. What are critical operating parameters and how do they fit into the establishment\u2019s HACCP system? As described in the FSIS Compliance Guideline HACCP Systems Validation, critical operating parameters are the specific conditions (e.g., time, concentration, temperature, full product, or carcass coverage) that the intervention must operate under for it to be effective. The establishment should incorporate the critical operating parameters into its critical limits if the establishment applies the intervention as part of a CCP. Alternatively, the establishment should incorporate the critical operating parameters into appropriate procedures if it implements the intervention as part of a sanitation SOP or other prerequisite program. To be effective, the process procedures should be consistent with the critical operational parameters in the scientific support. If the establishment\u2019s specific parameters do not closely match the scientific documentation, the establishment should consider developing a decision-making document that explains the scientific rationale for why the different level would not affect the efficacy of the intervention or process. Why is it important for establishments to incorporate antimicrobial interventions into their HACCP systems? Despite good slaughter and dressing practices, contamination of carcasses can occur. Thus, the use of effective antimicrobial intervention strategies is an important component of an integrated food safety system. FSIS recommends that establishments implement antimicrobial interventions throughout the slaughter and fabrication processes, specifically just after points in the process where carcasses are most vulnerable to contamination (e.g., during hide removal and post-evisceration), as part of a multi-hurdle approach. Further, FSIS recommends that establishments identify the typical microbial loads introduced into their slaughter process and develop a multi-hurdle approach that is designed to reduce microbial hazards to acceptable levels. FSIS also recommends that establishments account for the higher prevalence season for STEC (April - October) and make necessary adjustments to their food safety system to address STEC. Can dry aging be used as an intervention to reduce STEC in a HACCP system? Yes. Dry aging can be used as an intervention to reduce pathogens, including STEC. It is the process of reducing the bacterial load on the carcass through surface desiccation. This process", "34 is not to be confused with the product

quality process of dry aging, which is used to improve tenderness and\or flavor. To desiccate the surface of the carcass to reduce pathogens, the carcasses are maintained in a cooler for a time, usually days or weeks, under specific environmental conditions that may vary, depending upon the support used by the establishment. Proper temperature, air flow, and relative humidity are needed to desiccate the surface of the carcass and minimize mold growth. Using the scientific support provided in Tittor et al., an establishment can develop an aging program as an intervention to reduce STEC to nondetectable levels. In this study, beef lean and beef fat were inoculated with multiple strains of E. coli O157:H7. The dry aged samples were suspended in a cooler that had the following parameters: 37.4\u2070F, 80% relative humidity and 0.0 to 0.25 m\s air velocity. A decrease in E. coli O157:H7 14 days to 28 days in lean tissue and from 7 days to 28 days in fat tissue was reported in the study. These specific parameters could be implemented, and an establishment could validate that they are able to consistently meet the critical operating parameters from the study. NOTE: FSIS does not object to establishments using the Tittor et al. final report as support until a peer reviewed journal article is published. Alternately, the establishment may implement other specific parameters for dry aging using other scientific supporting documentation or additional in-house validation data to support the alternative procedures, provided the same or better results as Tittor et al. are achieved. The FSIS Compliance Guideline HACCP Systems Validation describes how establishments can conduct in plant validation monitoring. In addition to the critical operating parameters, establishments using dry aging to address pathogens may need to monitor for mold growth and develop procedures to reduce the growth of mold and remove mold from the carcass when growth occurs. FSIS has reviewed the article by Algino, et al. (2007) and determined that this article does not provide sufficient scientific support alone for the use of dry aging beef carcasses as an effective intervention to reduce STEC to non-detectable levels. Algino R.J., Ingham S.C., and Zhu J. 2007. Survey of Antimicrobial Effects of Beef Carcass Intervention Treatments in Very Small State-Inspected Slaughter Plants. Journal of Food Science. Vol 72: 173-179 FSIS made this determination because the authors used indicator organisms, (e.g., generic E.coli) as a surrogate for E.coli O157:H7 or non-O157 STEC. FSIS is not aware of any supporting documentation that demonstrates a strong correlation to support the use of generic E. coli testing as a surrogate for E.coli O157:H7 or non-O157 STEC. If an establishment chooses to use this article as support for its dry aging intervention, additional data (e.g., microbiological data gathered in-plant) would be needed to support the dry aging intervention to reduce STEC to a non-detectable level.,"35 How do establishments identify critical operating parameters? As explained in the FSIS Compliance Guideline HACCP Systems Validation, establishments are required to identify and maintain supporting documentation that closely matches their interventions and should identify, implement and monitor the critical operating parameters from the scientific supporting documentation relevant to their interventions. Critical operating parameters are the specific conditions under which an intervention must be used for it to be effective. These critical operating parameters should be incorporated into the establishment\u2019s HACCP system (including prerequisite programs). As part of validation, establishments must also maintain documentation showing that they have effectively implemented these parameters in their operations. The critical operating parameter may or may not be incorporated into the establishment\u2019s HACCP plan as a critical limit for a CCP. If an establishment uses a scientific study as its supporting documentation, the critical

operating parameters from the scientific study should match the intervention implemented by the establishment as closely as possible. In some circumstances, establishments may be able to support using critical operating parameters that are different from those in its supporting documentation (e.g., different concentrations of antimicrobial agents or temperature of the antimicrobial). In cases where critical operating parameters are different from the supporting documentation, establishments should provide justification to support that the critical operating parameters chosen are at least as effective as those in the supporting documentation. This justification is needed because deviating from the critical operating parameters in supporting documentation may not always provide an equally effective result. For example, antimicrobial agents may only be effective within a certain concentration range; above or below that the efficacy may decrease. In addition to ensuring that the concentration range of interventions chosen are at least equally effective, establishments should ensure the concentrations are also safe and suitable. FSIS Directive 7120.1, Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products is updated monthly and includes a list of antimicrobial agents that are safe and suitable for certain products under certain conditions of use. Establishments have flexibility in how they verify that they are implementing the critical operating parameters for applying antimicrobial interventions.

**Key Points**  
Establishments are required to maintain supporting documentation that closely matches their interventions, identify the critical operating parameters that are necessary for the interventions to be effective, and maintain documentation showing that they have effectively implemented their interventions so that they meet these critical operating parameters.<sup>36</sup> What are examples of critical operating parameters for applying antimicrobial or hot water interventions on carcasses and fabricated raw beef products? Examples of critical operating parameters for applying antimicrobial or hot water interventions to carcasses and fabricated raw beef products include the following: Product coverage pH Contact time Dwell time Temperature Pressure Equipment settings or calibration Concentration There are simple verification procedures an establishment can use to ensure its antimicrobial intervention achieves carcass/product coverage. For example, the establishment could apply the intervention using fluorescein dye instead of the antimicrobial to evaluate carcass/product coverage. Alternatively, the establishment could apply paper towels or an edible spray cream before the intervention and evaluate the carcass/product for full coverage after the intervention. FSIS developed the FSIS Compliance Guideline HACCP Systems Validation to assist establishments in complying with initial validation requirements that address validation of critical operating parameters for antimicrobial or hot water interventions. What are examples of antimicrobial interventions? Antimicrobial intervention strategies are designed to reduce microbial contamination on carcasses and parts and usually involve the application of organic acids, hot water, steam, removal by physical means, such as knife trimming, or a combination of these, in a sequence, referred to as a multi-hurdle approach. The integration of established intervention methods, such as knife trimming, in combination with other antimicrobial decontamination methods, such as steam vacuuming, steam pasteurization cabinets, acid or hot water spray washing systems, can help to improve the microbial safety of beef carcasses immediately post-slaughter. Dry aging can be used as an intervention as part of a multi-hurdle approach or as a stand-alone intervention. Establishments should apply these interventions according to their scientific support. The table below shows the antimicrobial

interventions that can be used during the beef slaughter process. Intervention Type

**Intervention Description**

Hide-on carcass washes Hide-on carcass washes are an effective means to significantly reduce bacterial populations on the hide, a significant source of contamination in slaughter operations. Hide-on carcass washes commonly used include<sup>37</sup>, hypobromous acid; sodium hydroxide and a proprietary surfactant with a sodium hypochlorite rinse; and water washes with chlorine. Steam vacuum systems The hot water sprayed onto a carcass kills bacteria and detaches contamination, such as ingesta or feces, which is then vacuumed off. Many establishments utilize the steam vacuum system at multiple points in the slaughter process. For example, there may be a steam vacuum location after each part of the carcass de-hiding process. Pre-evisceration wash and final carcass organic acid wash The pre-evisceration wash consists of using a carcass spray immediately after hide removal and serves to remove bacteria before they have the opportunity to attach themselves to the carcass surface and begin growing. The final carcass organic acid rinse provides a significant kill step for any bacteria that remain on the carcass surface at the end of the slaughter process. This intervention is commonly applied after the slaughter process is complete and before the carcasses enter the cooler. The organic acids commonly used are acetic and lactic, although citric acid is also approved for this purpose. The concentration of the organic acid is normally between 1.5% and 2.5% and can be as high as 5% in the case of lactic acid. Hypobromous acid is another effective acid that is commonly used in the industry. Organic acids may be applied as a mist, fog, or a small droplet rinse. Studies have shown that washing followed by an organic acid rinse is significantly more effective in reducing bacterial numbers than washing alone.

Pre-evisceration and final carcass hot water washes High temperature water sprayed on the carcass (hot water rinse) as a preevisceration wash and a post-evisceration wash prior to chilling have been shown to be effective in substantially reducing STEC and Salmonella.

**Steam pasteurization**

Steam pasteurization is a process in which the carcasses are placed in a slightly pressurized, closed chamber at room temperature and sprayed with steam that blankets and condenses over the entire carcass, raising the surface temperature (generally to 185°F) and killing up to 95-99% of all bacteria. Carcasses are then sprayed with cold water.

**Dry aging**

Dry adding intervention reduces pathogens on the surface of the carcass through desiccation under specific environmental conditions. Why is it important for establishments to conduct verification testing? FSIS requires that establishments perform ongoing verification activities to ensure that their food safety systems are functioning as intended (9 CFR 417.4(a)(2)) and to support decisions made in their hazard analyses, including their sampling locations (9 CFR 417.2 and 417.5(a)(1)). FSIS recommends that establishments incorporate statistical process control procedures into their testing programs to assess the effectiveness of their controls for preventing contamination during slaughter and dressing operations and to verify that they are reducing pathogen levels, including STEC to below detectable levels. Establishments are required to support the frequency of their verification activities (9 CFR 417.5(a)(2)).

Establishments can use microbial test results to support decisions made in their HACCP systems and to verify that their food safety system is functioning as intended. Establishment sampling and testing programs can be supplemented with other types of verification activities associated with the production of other raw ground beef and patty components.<sup>38</sup>

**Beef Slaughter Processing Deficiencies**

What are common deficiencies that FSIS identified in beef slaughter establishments? FSIS conducted a review of food safety assessments (FSAs) and onsite visits to

beef slaughter establishments with a history of multiple positive STEC results from FSIS testing. During the review, FSIS identified the following common deficiencies: \u2022 Inadequate sanitary dressing; \u2022 Ineffective implementation of antimicrobial intervention; and \u2022 Failure to use microbial data appropriately in decision making. What are examples of sanitary dressing deficiencies FSIS observed repeatedly at beef slaughter establishments? FSIS identified that some beef slaughter establishments repeatedly failed to do the following relative to sanitary dressing: \u2022 Implement a comprehensive sanitary dressing program that includes: written procedures designed to prevent contamination from occurring throughout the process, adequate employee training concerning these written procedures, and a management commitment to the program. \u2022 Verify that the sanitary dressing procedures are performed as written, effective, and consistently performed. \u2022 Properly design facilities and equipment to: prevent carcasses from contacting each other NOTE: Generic E. coli data required under 9 CFR 310.25 should not be used to verify whether the establishment\u2019s HACCP system is addressing STEC. Differences in laboratory method sensitivity demonstrate that STEC can still be recovered from a sample when below the limit of detection of direct plate generic E. coli methods. Further, detectable levels of generic E. coli do not mean STEC specifically is present. Therefore, testing for generic E. coli is not an effective verification procedure for assessing STEC controls. Key Point With any antimicrobial intervention, carcass\product coverage is important.", "39 or non-food contact surfaces, prevent overspray of antimicrobial treatments or aerosolization of particulate matter, and allow adequate visualization of dressing procedures (e.g., through proper lighting or access). \u2022 Perform robust sampling and testing, according to their supporting documentation, to obtain reliable results to verify their slaughter operation is addressing hazards. \u2022 Adequately respond to FSIS or establishment positive test results with effective and sustainable corrective actions that identify the cause, eliminate it and prevent recurrence. \u2022 Apply antimicrobial interventions according to supporting documentation. Examples of Sanitary Dressing Deficiencies Cutting through the hide and into the carcass without sanitizing knives, gloves, and equipment, resulting in carcass contamination. Note how grossly contaminated the hide is, further increasing the risk of contamination. Proper hide removal is a critical step in preventing carcass contamination and the creation of insanitary conditions.", "40 Inadequately sanitizing knives, gloves, and equipment resulting in carcass contamination along pattern lines during hide removal (part 1 of 2).", "41 Inadequately sanitizing knives, gloves, and equipment resulting in carcass contamination along pattern lines during hide removal (part 2 of 2).", "42 Contaminated carcass as a result of contact with non-food contact surfaces. (circled in yellow). Carcass contamination from the hide flaps during hide removal. This photo shows hide flaps that have curled under after hide removal and are contaminating the carcass.", "43 Splatter contamination resulting from improperly adjusted hide pullers. Improperly adjusted hide pullers can cause carcass contamination.", "44 Bagged bung contacting hide resulting in carcass contamination. This photo shows the bagged bung contacting the hide (yellow arrow) while the employee is tying the bagged bung. Bunging performed before the hide of the rump is removed results in contamination of the carcass. This occurs because the bagged bung will likely contact the hide and later contaminate the carcass as the gastrointestinal tract is removed during evisceration and the bagged bung is pulled through the pelvic inlet. Failing to bag and tie the bung. The contaminated bung is contacting the exposed carcass (yellow arrows). When

establishments apply hot water or antimicrobial interventions to an exposed bung, they may further spread contamination.", "45 Contamination during evisceration. Punctured paunch and intestines during evisceration causing carcass contamination with ingesta (second photo).", "46 What are examples of antimicrobial intervention deficiencies FSIS has observed repeatedly at beef slaughter establishments? FSIS identified that some beef slaughter establishments repeatedly failed to do the following: \u2022 Apply antimicrobial interventions according to their supporting documentation; \u2022 Identify critical operational parameters in their supporting documentation; \u2022 Incorporate the critical operational parameters into their HACCP system; and \u2022 Implement the antimicrobial treatments so that critical operational parameters are met. Examples of Antimicrobial Intervention Implementation Deficiencies Cross-contamination during antimicrobial intervention treatment. \u2022 Cross contamination of heads from carcass intervention overspray. (Water sprayed onto the carcass in the direction of the arrows, water spray seen within the yellow oval.) \u2022 Cross contamination (not shown in image) when employees spray equipment, the floor, and other surfaces, establishments do not take appropriate precautions to prevent overspray from contacting carcasses. \u2022 Carcasses with visible contamination entering a wash cabinet or when manual application of water or antimicrobial sprays occurs on visibly contaminated carcasses, this can result in cross contamination. .", "47 Failing to achieve full carcass coverage with intervention, thus reducing the intervention's effectiveness. This photo shows the practice of suspending a carcass from a single hook, which prevents antimicrobial and hot water interventions from achieving full carcass\product coverage. Ensuring that the entire carcass surface is treated, is necessary for the intervention to operate effectively and as intended. Failing to achieve full product coverage with intervention, thus reducing the intervention's effectiveness. Product coverage is essential for the intervention to be effective. The top photo shows that the arc of the spray nozzles (inside each yellow line) is not sufficient to reach product on the sides of the conveyor belt (yellow arrows). Both pictures show that the spray intervention is being applied only to one side of the trim. These pictures also show product that is folded on top of itself so that the intervention is not applied to all product surfaces (the top photo shows the trim is piled up and the bottom photo shows that each piece has a single fold).", "48 What are examples of FSIS observations regarding establishments that fail to properly use microbial data in decision-making? Some establishments that had multiple STEC positive samples from FSIS testing failed to properly assess the impact the test results had on their slaughter operations. Test results reflect the effectiveness of the establishment\u2019s slaughter operation, including the effectiveness of its sanitary dressing procedures and antimicrobial treatments. In response to the test results, establishments failed to take meaningful corrective actions designed to identify and eliminate the cause of the positive test results and prevent recurrence. The scope of the corrective actions was limited to ensuring that lots contaminated with STEC received appropriate disposition. Corrective actions were not aimed to improve the design and implementation of slaughter operations. Additionally, some establishments did not conduct robust sampling, which could have provided them meaningful information concerning the effectiveness of their slaughter operations. In some situations, establishments had designed rigorous sampling programs but were not implementing them effectively. Specifically, establishments were not properly collecting N60 samples. Sample slices were smaller in size than the N60 method requires. Additionally, external surfaces were not

targeted for N60 sampling and, in some cases, the tissues were thicker, which reduces the sensitivity of the method. Establishments that conduct proper robust sampling have ongoing information concerning the effectiveness of their slaughter operations and can respond to the microbial data to improve their operations. FSIS recognizes some establishments may utilize other sample collection methods (e.g. surface sampling or core shaving methods) that have received a No Objection from FSIS as being at least equal to the N60 sample collection method for the detection of low levels of STEC.", "49 APPENDICES", "50 Appendix 1. Establishment Self-Assessment Checklist for Sanitary Dressing Procedures Live Receiving\Holding Questions Yes No Comment Do we take measures, such as periodic cleaning of the unloading areas and pens, to reduce the contamination of animals during unloading and holding? Do we apply a bacteriophage to cattle? Do we conduct cattle washing? Do we have data showing that washing decreases incoming bacterial loads? Do we monitor the cattle washing process to ensure that contamination is minimized? Do we use water mist as a means to reduce airborne dust and dirt particles in the holding area? Do we use a \u201cmud-scoring\u201d system to identify cattle that may present an increased likelihood of contamination during hide removal? Do we react to cattle showing increased loads of contamination on their hides? Do we determine the incoming bacterial load on animals? Do we consider differences in the age or type of cattle we receive (e.g. veal calves, sale barn cattle, feedlot cattle, hide condition) and does that indicate a concern related to pathogen load that we address?", "51 Sticking Questions Yes No Comment Do we use the smallest cut possible to accomplish the bleeding? Do we use a two-knife system for sticking and clean the hand between sticking each carcass? Do we sanitize knives between animals? Do we employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?", "52 Hide Removal Questions Yes No Comment Do we use a validated hide-on carcass wash? Do we use a two-knife system for the entire de-hiding process? Do we remove the udder in a manner to prevent contamination of the carcass with milk, and to prevent contamination of the exposed carcass by the hide, or by a soiled knife or employee hand? Do we remove visible contamination from the pattern (cut line)? Do we trim or steam vacuum pattern lines? Do we prevent wicking of moisture into hide openings? Are carcasses or parts of carcasses touching or banging into each other? Are there excessive turns or switchbacks in the de-hiding line such that hide-on cattle are passing by carcasses with the hide partially removed? Do we have shields between the carcasses and hide puller to minimize potential contamination? Do we remove the tail switch when using the hide puller to minimize the possibility that contaminants can become airborne from splattering or flapping the hide? Is the hide puller causing carcass contamination or cross contamination of adjacent carcasses? If we use a cradle, are live animals in such close proximity to the partially dressed animal on the cradle that airborne contamination is a concern? If we use mechanical hide pullers, do they pull away from the carcass (e.g., downward or backward and not upward), thereby reducing the potential for contamination from drip splatter? When the hide is pulled from the carcass, does it splatter the dressed carcass or adjacent carcasses? If employees are handling carcasses during hide pulling, does the hide cross-contaminate the carcass or employees\u2019 equipment and clothing? If so, is the contamination removed from employee\u2019s equipment and clothing before continuing dressing procedures? Does the exterior side of the hide touch or slap the carcass as the hide is removed?", "53 Do we maintain clean mechanical

hide puller contact points with the hide, hands, and garments of the employees handling the hide and carcass, and knives and other equipment contacting the de-hided carcass? Do our employees maintain proper employee hygiene practices to prevent the creation of insanitary conditions (e.g., touching the carcass with soiled hands, tools, or garments)? In the process of reflecting the hide from the carcass, do our employees intentionally or accidentally cut through the hide? Do we clean and sanitize knives, air knives, or other equipment and clothing before proceeding to reflect the hide away from the carcass any further? Do we allow for adequate distance between carcasses throughout the slaughter dress process to minimize carcass-to-carcass contact and cross contamination? Do we allow adequate separation of carcasses, parts, and viscera during dressing? This would include at switchbacks (sharp turns) and areas where carcasses in the hide-on area pass by in close proximity to carcasses in the hide-off area. Are the hides (especially of feet, legs, tails) of carcasses in the hide-on area cross contaminating equipment and clothing of the employees (aprons, scabbards, steels, gloves)? If so, do we clean and sanitize contaminated equipment or clothing? Do we apply a carcass wash cabinet at this point or any other point in the slaughter process? If so, do we ensure that cabinets do not spread contamination to adjacent carcasses? Do we control overspray from the carcass wash cabinet? Do we address conditions such as open abscesses, septic bruises, or the presence of parasites and parasitic lesions before carcasses enter the carcass wash cabinet? Do we address pooling of water around the anus of the carcass prior to dropping the bung? Do we ensure that carcasses with excessive contamination do not cross contaminate other carcasses (i.e., create an insanitary condition)? Do we ensure that carcasses identified with U.S. Suspect or Retained tags, that should be removed from the slaughter line at a further point in the process, do not enter the carcass wash cabinets unless measures are in place to prevent cross contamination of equipment or other carcasses? \*U.S. Suspects are to be washed in these cabinets only with permission of the PHV, and in consideration of whether the design of the cabinet prevents cross contamination of other carcasses. Do we employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?", "54 Bunging Questions Yes No Comment Do we put plastic bags and ties on the bung in a sanitary manner? Do we maintain proper employee hygiene practices to prevent the creation of insanitary conditions (e.g., touching the carcass with soiled hands, tools, or garments)? Do we employ any validated decontamination or antimicrobial intervention treatment that is effective in reducing the presence or counts of microbial contaminants at this point in the process? Brisket Opening Questions Yes No Comment Do we clean and sanitize the brisket saw and knife between each carcass, and ensure that we do not puncture the gastrointestinal tract? Do employees maintain proper hygiene practices to prevent the creation of insanitary conditions (e.g., touching the carcass with soiled hands, tools, or garments)? Do we employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?", "55 Rodding the Weasand (Esophagus) Questions Yes No Comment Do we close the esophagus to prevent leakage of rumen contents? Do we maintain proper employee hygiene practices (e.g., wash hands and arms often enough to prevent contamination of the carcass)? Do we change or sanitize the weasand rod between each carcass? Do we properly maintain and clean knives? Do we clean and chill the weasand quickly to limit contamination and pathogen multiplication? Do we employ any validated

decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants? Evisceration Questions Yes No Comment Do we remove visible contamination from the area to be cut (e.g., by trimming, by using air knives, or by steam vacuuming) before the cut is made? Do we remove the uterus in a manner that prevents contamination of the carcass and viscera? Do we properly use knives to prevent damage (i.e., puncturing) to the paunch and intestines? Do we remove contamination in a timely manner and in accordance with accepted reconditioning procedures? Do our employees on moving evisceration lines use footbaths and separate footwear to prevent the footwear from contaminating other parts of the slaughter and dressing operation? Do we employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?", "56 Carcass Splitting Questions Yes No Comment Do we clean and sanitize the saws and knives between each carcass? Do we allow for adequate distance between carcasses (i.e., limit carcass-to-carcass contact)? Do we employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants? Do we address the removal of spinal cords in accordance with 9 CFR 310.22? Head and Cheek Meat Processing Questions Yes No Comment Do we properly maintain and clean knives? Do we prevent cross contamination of heads? Do we maintain proper employee hygiene practices to prevent the creation of insanitary conditions (e.g. touching the head with soiled hands, tools, or garments)? Do we quickly chill head and cheek meat to limit pathogen multiplication? Do we employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?", "57 Appendix 2.

Carcass Sanitary Dressing Audit COMMENTS: CORRECTIVE ACTIONS TAKEN: FURTHER ACTION(S) RECOMMENDED: DATE: CARCASS MONITORING (THREE TIMES PER PRODUCTION PERIOD) Effective Prevention of Contamination at Slaughter Steps TIME: AUDIT LOCATION: \uf071 AFTER LEGGING \uf071 AFTER HIDE PULLER \uf071 PRIOR TO PRE-EVIS \uf071 POST EVIS \uf071 PRIOR TO OTHER WASHES \uf071 ZERO TOLERANCE \uf071 COOLER CARCASS # CONTAMINATION OBSERVED CONTAMINATION TYPE F fecal I ingesta H hair O other (e.g. milk, abscess) GHM grease\hook marks RF rail fallout CONTAMINATION LOCATION H hock RD round RP rump SR sirloin SL short loin R rib C chuck FS foreshank B brisket SP short plate F flank N neck DEGREE OF CONTAMINATION MILD MOD moderate SEV severe 1. \uf071 YES \uf071 NO \uf071 F \uf071 I \uf071 H \uf071 O \uf071 GHM \uf071 RF \uf071 H \uf071 RD \uf071 RP \uf071 SR \uf071 R \uf071 C \uf071 FS \uf071 B \uf071 SP \uf071 F \uf071 N \uf071 MILD \uf071 MOD \uf071 SEV 2. \uf071 YES \uf071 NO \uf071 F \uf071 I \uf071 H \uf071 O \uf071 GHM \uf071 RF \uf071 H \uf071 RD \uf071 RP \uf071 SR \uf071 R \uf071 C \uf071 FS \uf071 B \uf071 SP \uf071 F \uf071 N \uf071 MILD \uf071 MOD \uf071 SEV 3. \uf071 YES \uf071 NO \uf071 F \uf071 I \uf071 H \uf071 O \uf071 GHM \uf071 RF \uf071 H \uf071 RD \uf071 RP \uf071 SR \uf071 R \uf071 C \uf071 FS \uf071 B \uf071 SP \uf071 F \uf071 N \uf071 MILD \uf071 MOD \uf071 SEV 4. \uf071 YES \uf071 NO \uf071 F \uf071 I \uf071 H \uf071 O \uf071 GHM \uf071 RF \uf071 H \uf071 RD \uf071 RP \uf071 SR \uf071 R \uf071 C \uf071 FS \uf071 B \uf071 SP \uf071 F \uf071 N \uf071 MILD \uf071 MOD \uf071 SEV 5. \uf071 YES \uf071 NO \uf071 F \uf071 I \uf071 H \uf071 O \uf071 GHM \uf071 RF \uf071 H \uf071 RD \uf071 RP \uf071 SR \uf071 R \uf071 C \uf071 FS \uf071 B \uf071 SP \uf071 F \uf071 N \uf071 MILD

\uf071 MOD \uf071 SEV 6. \uf071 YES \uf071 NO \uf071 F \uf071 I \uf071 H \uf071 O \uf071  
GHM \uf071 RF \uf071 H \uf071 RD \uf071 RP \uf071 SR \uf071 R \uf071 C \uf071 FS \uf071 B  
\uf071 SP \uf071 F \uf071 N \uf071 MILD \uf071 MOD \uf071 SEV 7. \uf071 YES \uf071 NO  
\uf071 F \uf071 I \uf071 H \uf071 O \uf071 GHM \uf071 RF \uf071 H \uf071 RD \uf071 RP  
\uf071 SR \uf071 R \uf071 C \uf071 FS \uf071 B \uf071 SP \uf071 F \uf071 N \uf071 MILD  
\uf071 MOD \uf071 SEV 8. \uf071 YES \uf071 NO \uf071 F \uf071 I \uf071 H \uf071 O \uf071  
GHM \uf071 RF \uf071 H \uf071 RD \uf071 RP \uf071 SR \uf071 R \uf071 C \uf071 FS \uf071 B  
\uf071 SP \uf071 F \uf071 N \uf071 MILD \uf071 MOD \uf071 SEV 9. \uf071 YES \uf071 NO  
\uf071 F \uf071 I \uf071 H \uf071 O \uf071 GHM \uf071 RF \uf071 H \uf071 RD \uf071 RP  
\uf071 SR \uf071 R \uf071 C \uf071 FS \uf071 B \uf071 SP \uf071 F \uf071 N \uf071 MILD  
\uf071 MOD \uf071 SEV 10. \uf071 YES \uf071 NO \uf071 F \uf071 I \uf071 H \uf071 O \uf071  
GHM \uf071 RF \uf071 H \uf071 RD \uf071 RP \uf071 SR \uf071 R \uf071 C \uf071 FS \uf071 B  
\uf071 SP \uf071 F \uf071 N \uf071 MILD \uf071 MOD \uf071 SEV CARCASS # CORRECTIVE  
ACTION? CORRECTIVE ACTION \u00aa7417.4 (A)(2)(II) MONITORING DIRECT OBSERVATION 1.  
\uf071 YES \uf071 NO \uf071 TRIMMED \uf071RAILED REWORK VERIFICATION ARE THE  
PROCEDURES FOR THIS SLAUGHTER STEP EFFECTIVELY PREVENTING CONTAMINATION? IF NOT,  
STATE WHY IN THE COMMENTS SECTION BELOW. \uf071 YES \uf071 NO VER. INIT.

2. \uf071 YES \uf071 NO \uf071 TRIMMED \uf071RAILED REWORK 3.

\uf071 YES \uf071 NO \uf071 TRIMMED \uf071RAILED REWORK 4. \uf071 YES \uf071 NO \uf071  
TRIMMED \uf071RAILED REWORK 5. \uf071 YES \uf071 NO \uf071 TRIMMED \uf071RAILED  
REWORK 6. \uf071 YES \uf071 NO \uf071 TRIMMED \uf071RAILED REWORK 7. \uf071 YES  
\uf071 NO \uf071 TRIMMED \uf071RAILED REWORK 8. \uf071 YES \uf071 NO \uf071 TRIMMED  
\uf071RAILED REWORK 9. \uf071 YES \uf071 NO \uf071 TRIMMED \uf071RAILED REWORK 10.  
\uf071 YES \uf071 NO \uf071 TRIMMED \uf071RAILED REWORK", "58 How to Use Appendix 2.  
Carcass Sanitary Dressing Audit AUDIT LOCATION: Indicate at what point in the slaughter  
process this audit is being performed (check one box). CARCASS #: Indicate the identifying  
number of each carcass included in the audit. CONTAMINATION OBSERVED: Indicate  
\u2018yes\u2019 or \u2018no\u2019 by checking the correct box. CONTAMINATION TYPE:  
Indicate the type of contamination by checking the box by the correct letter. F = Fecal  
contamination I = Ingesta H = Hair GHM = Grease\hook marks, also oil RF = Rail fallout or rail  
dust O = other (such as milk, abscess or any other form of contamination) CONTAMINATION  
LOCATION: Indicate the location of contamination on the carcass by checking the box by the  
correct letter (see diagram below for reference) H = Hock RD = Round RP = Rump SR = Sirloin SL  
= Short Loin R = Rib C = Chuck FS = Foreshank B = Brisket SP = Short Plate F = Flank N = Neck  
DEGREE OF CONTAMINATION: Indicate how much contamination is found on the carcass by  
checking the correct box. Multiple mild or moderate contaminations or one or two severe  
contaminations indicate a significant loss of process control. All slaughter establishments  
should develop process control criteria for each slaughter step and identify criteria for when  
the process is out of control. Establishments should use those criteria to determine the  
effectiveness of their slaughter dressing procedures. The following are examples only.  
Establishments will want to develop their own criteria for each slaughter step to define when  
their process is out of control. - MILD = mild. Contamination is limited to a small area in one  
location on the carcass. For example, a cluster of 3-4 hairs, a speck of fecal contamination, or a  
few small pieces of rail fallout in a small area. - MOD = moderate. Contamination is over one

medium sized area, or is small, but in 3-4 locations on the carcass. For example, multiple clusters of 3-4 hairs over the carcass or one larger cluster of hair. - SEV = severe. Contamination is spread over multiple locations on the carcass, or in one large location. For example, a large streak of fecal contamination, such as may occur from a hide slap. CORRECTIVE ACTION: Indicate \u2018yes\u2019 or \u2018no\u2019 by checking the correct box. CORRECTIVE ACTION TAKEN: Indicate whether the carcass was trimmed or railed out and reworked.

VERIFICATION: Indicate whether the procedures in the slaughter process selected as the audit location effectively prevent contamination by checking \u2018yes\u2019 or \u2018no\u2019 and initial. Establishments should use their process control criteria for determining whether the sanitary dressing procedures at the process step\audit location effectively prevented contamination. COMMENTS: Record further comments, corrective actions (including preventive measures) and recommended actions in the space available.", "59 DIAGRAM TO ASSIST WITH IDENTIFICATION OF CONTAMINATION LOCATION", "60 Appendix 3. Guidance Documents Developed by Industry that include Beef Slaughter and Microbiological Sampling Best Practices Best Practices for Beef Harvest

([https://www.bifsc.org/Media/BIFSCO/Docs/harvest\\_best\\_practice\\_final.pdf](https://www.bifsc.org/Media/BIFSCO/Docs/harvest_best_practice_final.pdf)) This document provides best practices to control microbial contamination throughout the slaughter operation. The implementation of these best practices, with current science and technology, would allow slaughter operators to produce visibly clean carcasses and reduce the incidence level of pathogenic contamination. Best Practices for Spinal Cord Removal

([https://www.bifsc.org/Media/BIFSCO/Docs/spinal\\_cord\\_removal2002.pdf](https://www.bifsc.org/Media/BIFSCO/Docs/spinal_cord_removal2002.pdf)) This document provides Good Manufacturing Practices (GMPs) to improve process control for assuring the removal of spinal cord from vertebral bone. Industry Best Practices for Holding Tested Products

([https://www.bifsc.org/Media/BIFSCO/Docs/holding\\_tested\\_products\\_sept2005.pdf](https://www.bifsc.org/Media/BIFSCO/Docs/holding_tested_products_sept2005.pdf)) This document describes effective best practices to help establishments develop and implement an optimal system for sampling and testing their own products and for holding products when government agencies take a sample. Best Practices for Using Microbiological Sampling

([https://www.bifsc.org/Media/BIFSCO/Docs/microbiological\\_sampling\\_bp\\_march2008.pdf](https://www.bifsc.org/Media/BIFSCO/Docs/microbiological_sampling_bp_march2008.pdf)) This document provides best practices for developing procedures to use microbiological testing to verify process control. Antimicrobial Interventions Reference Document

(<https://www.bifsc.org/Media/BIFSCO/Docs/antimicrobial-interventions-for-beef.pdf>) This document, funded by the beef checkoff, describes the actions that can be taken by industry to reduce the potential for carcass contamination including scientifically proven antimicrobial interventions that can be applied individually or in combination with other treatments to reduce pathogens on carcass surfaces. Sampling, Lotting and Sample Analysis Guidance

([https://www.bifsc.org/Media/BIFSCO/Docs/lotting\\_and\\_sampling\\_of\\_beef\\_products\\_for\\_pathogens\\_analysis\\_update\\_april\\_-2019.pdf](https://www.bifsc.org/Media/BIFSCO/Docs/lotting_and_sampling_of_beef_products_for_pathogens_analysis_update_april_-2019.pdf)) This document provides industry best practices for developing and implementing components (lotting, sampling and laboratory analysis) of a pathogen-testing program as a part of an overall food safety system.", "61

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Combbase Growth Model (<https://www.combase.cc/index.php/en/>) \u2022 BARANYI, J., & TAMPLIN, M. L. (2004). ComBase: A Common Database on Microbial Responses to Food Environments. *Journal of Food Protection*, 67(9), 1967-1971. <https://doi.org/10.4315/0362-028x-67.9.1967> For E.coli was used to predict the growth of E. coli. if the bacterium was deposited onto the sterile carcass surface during the hide removal\ dressing steps. The Growth Predictor Model predicts the response of a range of pathogens and spoilage microorganisms characterizing the food environment. \uf0a7 The parameters selected were left at the ComBase default values of initial level = 3 log10, pH 7, physiological state as recommended by ComBase, and either water activity at 0.997, or 0.6% NaCl. Dry Aging o Tittor, A.W., Tittor, M.G., Brashears, M.B., Brooks, J.C., Miller, M.F. Reduction of Escherichia coli O157:H7 and Salmonella spp. using Dry Chilling in small processing plant environments.  
<https://www.fsis.usda.gov/news-events/publications/reduction-e.coli-and-salmonellausing-dry-chilling-small-processing-plants.>,"64  
<https://www.fsis.usda.gov/contact-us/askfsis> www.fsis.usda.gov  
2021"]},{"file\_name":"FSIS\_GD\_2021\_0009","title":"HACCP Model for Beef Slaughter","num":"FSIS-GD-2021-0009","id":"287b9b738166de9b0575319d7c60330a58773b21053bf41beac23e80d5520452","corpus":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/media\_file/2021-07/FSIS-GD-2021-0009.pdf","type":"pdf","n\_pages":16,"word\_count":4374,"text\_by\_page":["HACCP Model for Beef Slaughter The United States Department of Agriculture (USDA) published the Pathogen Reduction\Hazard Analysis Critical Control Point (HACCP) Systems Final Rule in July 1996 mandating all USDA inspected meat and poultry establishments implement a HACCP system. Hazard Analysis Critical Control Point (HACCP) is a systematic and scientific method of process control for the production of safe food products. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to improve the safety of their products. The HACCP models\u2019 focus is on product safety, not product quality characteristics. With the rule, FSIS made available a guidebook for the preparation of HACCP plans and a generic model for each food processing category defined in the regulation (9 CFR 417.2(b)(1)). The guidebook and the generic models have been revised since their initial publication to be consistent with current science and policy. FSIS recommends you use the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan. Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used \u201cas is\u201d. Establishments are to tailor the model(s) to fit the establishment\u2019s operation. This generic HACCP model illustrates the slaughter processing category. Although this is a beef slaughter model, the model may be used as a starting point for developing a slaughter HACCP plan for other classes of livestock. The slaughter process has inherent food safety hazards that originate with the live animal.

Therefore, the slaughter process has heightened food safety significance. Slaughter establishments typically produce carcasses which are raw intact finished products. The food safety hazards identified for the slaughter process are also common to the Raw Intact and Raw Non-Intact processing categories. The model's critical control points (CCPs) do not necessarily apply to all slaughter operations or products. Products or operations may require fewer or more CCPs depending on the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. The food safety critical limits selected must come from scientific documents or other reliable sources. This model includes references for guidance on the selection of critical limits. The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis are HACCP records (CFR 417.5(a)). Ensure you maintain the documents produced while developing a HACCP plan. For further assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP webpage.", "Page 2 of 16 EXAMPLE PRODUCT DESCRIPTION1

Process \ Product Name: Beef Slaughter Process \ Product Name Carcass and carcass parts, tongue, heart, liver, kidney and intestine. Important product characteristics (Aw, pH, Preservatives, etc.) None How it is to be used2 For further processing at this facility or intended for cooking for or by the end consumer Packaging (durability and storage conditions) Product bags and cardboard boxes Shelf Life and at what temperature Not shelf stable \u2013 Keep refrigerated (7 days at \u226440\u00b0F) or frozen (180 days at \u226410\u00b0F) Where it will be sold (specify intended consumers, especially atrisk populations3) Sold direct to household consumers, through retail outlets or distributed to hotels, restaurants, and institutions. Labeling instructions and requirements Product name, inspection legend and establishment number, handling statement, net weight statement, address line, nutritional labeling (when needed) and safe handling instructions. What special distribution controls are required? None DATE: APPROVED BY: 1 Prior to developing the HACCP plan, please read the FSIS Guidebook for the Preparation of HACCP Plans for detailed descriptions of the worksheets and hazard analysis. The FSIS Guidebook for the Preparation of HACCP Plans and the generic HACCP models are intended for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP models are for demonstration purposes only. The models do not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products. 2 The intended use or consumer of the product must be identified in accordance with 9 CFR 417.2(a)(2). Identifying the product's intended use in the product description is one way to meet the regulatory requirements specific to 417.2(a)(2). 3 At-risk populations include young children, the elderly and immunocompromised persons.", "Page 3 of 16 EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIALS Process \ Product Name: Beef Slaughter Meat and meat by-products4 Beef Non-Meat food ingredients None Antimicrobials5 or processing aids Organic Acid6 Packaging material Product bags and cardboard boxes Restricted ingredients or allergens None Other None DATE: APPROVED BY: 4 List all meat (beef), processing aids, and packaging material used in production of these products. This is important to help identify any special ingredients or processes to address in the HACCP plan. 5 FSIS and the Food and Drug Administration (FDA) have a memorandum of understanding (MOU) that establishes the

working relationship followed when responding to notifications for the use of food additives (including ingredients) intended for use in the production of FSIS regulated products. FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDA on the requirements under the Federal Food, Drug & Cosmetic Act and its implementing regulations. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products for the list of suitable ingredients. 6 There are many different organic acids (for example, lactic acid, acetic acid). If used, establishments will need to select a product best suited for their unique circumstances.", "Page 4 of 16 7 This is an example flow diagram. Establishments\u2019 flow diagrams for the same product may be different. Establishments determine which steps are included in their process. The steps must represent all relevant hazards in the hazard analysis. The Meat and Poultry Hazards and Controls Guide (starting on page 5) describes the usual process steps, potential hazards and frequently used controls for beef slaughter. 8 The Returned Product step (16) is shown as not connected to another process step. Returned product may re-enter the production system at different process steps depending on condition or problem. Returned product may be relabeled, re-processed, discarded, etc. 9 In this model, beef heart undergoes the same CCPs as carcasses because the heart meat may be a component of ground beef. EXAMPLE PROCESS FLOW CHART7 Process \u201c Product Name: Beef Slaughter 16. Returned Product8 9a. Harvest Hearts9 2. Stunning 3. Sticking \u201c Bleeding 1a. Cattle Receiving and Holding 7. Zero Tolerance Examination (carcass and hearts) CCP 1 12. Chilling CCP 3 13. Cold Storage 8. Carcass & Hearts Rinse 11. Organic Acid Application CCP 2 9. Harvest Tongue, Liver, Kidneys and Intestine 14. Hanging carcasses and parts transferred to InHouse HACCP Process. 10. Package Tongue, Liver, Kidney, and Intestine 1b. Receive and Store Organic Acid Heads Not Saved. 4. Hide Removal 5. Evisceration 6. Carcass Splitting 15. Product Shipping 1c. Receive and Store Packaging Materials DATE: \_\_\_\_\_ APPROVED BY:

","EXAMPLE BEEF SLAUGHTER HAZARD ANALYSIS10 Column 1  
Column 2 Column 3 Column 4 Column 5 Column 6 Ingredient\u201c/ Process Step Potential Hazards (introduced or controlled) at this step11 Is the Potential Food Safety Hazard Reasonably Likely to Occur (RLTO)? (Yes or No)12 Justification \u201c Basis for Decision13 If yes in Column 3, (RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels14 Is this step a Critical Control Point (CCP)? 1a. Cattle Receiving and Holding C: Drug Residues No No cattle purchased from suppliers with history of violative residues (Residue Repeat Violators List). Supplier provides an affirmation. P: Foreign Material No Lack of historical findings from visual inspection during livestock handling and slaughter.15 10 This is an example hazard analysis. Each establishment\u2019s flow chart, hazards analysis, hazards, decision-making, and support may be different. An establishment can determine what \u201csteps\u201d are included in the overall process if all of the hazards are considered in the hazard analysis. The FSIS Meat and Poultry Hazards and Controls Guide (starting on page 5) describes the usual process steps for beef slaughter. 11 Hazards are grouped into three categories: Biological (B), Chemical (C), and Physical (P). Biological hazards are living organisms. Chemical hazards may be naturally occurring in foods, used or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification. 12 Place the

justification for your decision in column 4. Control measures either go in column 4 for hazards not reasonably likely to occur or go in column 5 for hazards reasonably likely to occur. If a hazard is reasonably likely to occur, then a CCP must be addressed at the step where the hazard is recognized or a later step. See FSIS Meat and Poultry Hazards and Controls Guide for a list of frequently used controls. 13 Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced article must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from an FSIS document, then HACCP system design must be supported by documentary evidence \u2013 that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan. 14 Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur (NRLTO) because the implementation of a prerequisite program (e.g., Sanitation Standard Operating Procedure (Sanitation SOP), written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation). 15 Note: this \u201chistorical data\u201d must be supported with evidence from the establishment through the establishment\u2019s history or validation data with reference to the actual SOP or prerequisite program. When historical data is not available (for example, a HACCP plan for a new process or product), then system design must be supported by other documentary evidence, such as the FSIS Meat and Poultry Hazards and Controls Guide which states \u201cvisual examination of carcass, parts and viscera\u201d is a frequently used control for foreign material hazards in beef slaughter.", "Step Potential Hazard RLTO Justification \u2014 Basis Controls CCP Page 6 of 16 (needles, wire, buckshot, bullets). B: Presence of pathogens, Shiga-toxin producing Escherichia coli (STEC) (E. coli O157:H7, O26, O45, O103, O111, O121 and O145) and Salmonella. B: Bovine Spongiform Encephalopathy (BSE) Prions associated with Specified Risk Materials (SRMs). Yes No The intestinal tract, mouth, hide, and hooves of cattle may harbor these pathogens. Non-ambulatory cattle are not slaughtered (9 CFR 309.3(e)). Written SRM Program to remove, segregate and dispose of SRMs (9 CFR 310.22). Controlled later at CCP 1 Zero Tolerance Examination, CCP 2 Organic Acid Application and CCP 3 Chilling. No 1b. Receive and Store Organic Acid B: None C: Non-Food Grade Chemical. No Letter of Guarantee (LOG) maintained for organic acid. Written Incoming Materials Receiving and Storage Standard Operating Procedure (SOP). P: None", "Step Potential Hazard RLTO Justification \u2014 Basis Controls CCP Page 7 of 16 1c. Receive and Store Packaging Materials B: Contamination with Pathogens No Packaging materials are protected from pests and

environmental contaminates. C: Non-food grade materials No Letter of guarantee (LOG) for all packaging materials. Written Incoming Materials Receiving and Storage SOP with procedures to examine packaging materials and to protect packaging materials from environmental contaminates. P: None 2. Stunning B: Presence of pathogens, STEC and Salmonella. B: BSE √ SRMs Yes No The intestinal tract, mouth, hide, and hooves of cattle may harbor these pathogens. Written SRM Program to remove, segregate and dispose of SRMs (9 CFR 310.22). Heads are not saved Controlled later at CCP 1 Zero Tolerance Examination, CCP 2 Organic Acid Application and CCP 3 Chilling. No C: None P: Foreign Material No Firearms are used for stunning. Heads are not saved. (9 CFR 310.18(b)). 3. Sticking √ Bleeding B: Presence of pathogens, STEC and Salmonella Yes The intestinal tract, mouth, hide, and hooves of cattle may harbor these pathogens. Controlled later at CCP 1 Zero Tolerance Examination, CCP 2 Organic Acid Application and CCP 3 Chilling. Written Sanitary Dressing Procedures<sup>16</sup> to reduce likelihood No 16 The FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-producing Escherichia Coli (STEC) and Salmonella in Beef (including Veal) Slaughter Operations helps establishments design comprehensive written sanitary dressing programs; shows establishments how to implement antimicrobial interventions effectively, and helps establishments develop verification activities.", "Step Potential Hazard RLTO Justification √ Basis Controls CCP Page 8 of 16 of cross-contamination. C: None No P: None No 4. Hide Removal B: Presence of pathogens, STEC and Salmonella. Yes The intestinal tract, mouth, hide, and hooves of cattle may harbor these pathogens. Controlled later at CCP 1 Zero Tolerance Examination, CCP 2 Organic Acid Application and CCP 3 Chilling. Written Sanitary Dressing Procedures to reduce likelihood of cross-contamination. No C: None P: None 5. Evisceration B: Presence of pathogens, STEC and Salmonella. B: BSE √ SRMs Yes No The intestinal tract, mouth, hide, and hooves of cattle may harbor these pathogens. Written SRM Program to remove, segregate and dispose of SRMs (9 CFR 310.22). Controlled later at CCP 1 Zero Tolerance Examination, CCP 2 Organic Acid Application and CCP 3 Chilling. Written Sanitary Dressing Procedures to reduce likelihood of cross-contamination. No C: None P: None 6. Carcass Splitting B: Presence of pathogens, STEC and Salmonella. Yes Carcass splitting equipment may transfer contaminants from carcass to carcass. Controlled later at CCP 1 Zero Tolerance Examination, CCP 2 Organic Acid Application and CCP 3 Chilling. Written Sanitary Dressing Procedures to reduce likelihood No", "Step Potential Hazard RLTO Justification √ Basis Controls CCP Page 9 of 16 B: BSE √ SRMs No Written SRM Program to remove, segregate, and dispose of SRMs (9 CFR 310.22) of cross-contamination. Records indicate low likelihood of occurrence. 17 C: None P: None 7. Zero Tolerance Examination (carcass and hearts) CCP 1 B: Presence of pathogens, STEC and Salmonella. Yes FSIS enforces a zero-tolerance standard for visible fecal material, ingesta, or milk on carcasses (Livestock Carcasses and Poultry Carcasses Contaminated With Visible Fecal Material). Hearts are not subject to the FSIS zero-tolerance standard. Hearts are included in this step because they can become a component of raw ground beef products. Therefore, hearts undergo the same CCPs as the carcass. 18 CCP 1 Zero Tolerance Examination for carcasses and hearts. If contamination occurs, it is removed by trimming (9 CFR 310.18(a)). CCP 1 C: None P: None 8. Carcass and Hearts Rinse B: Presence of pathogens, STEC and Salmonella. Yes Rinse with potable water to remove blood, bone dust, and debris. Controlled later at CCP 2 Organic Acid Application and CCP 3 Chilling. No C: None P: None 17 When historical data is not available (for example, a HACCP plan for a new process or product), then system design must

be supported by other documentary evidence, such as the FSIS Meat and Poultry Hazards and Controls Guide which states \u201cmimimize cross-contamination through sanitary dressing procedures; Sanitation SOPs\u201d is a frequently used control for biological hazards in beef slaughter.<sup>18</sup> This generic beef slaughter HACCP model demonstrates how beef heart meat\u2014which is to be incorporated into ground beef\u2014can be addressed in the hazard analysis. In this model, hearts are subject to the CCP 1 Zero Tolerance Examination, although beef hearts are not subject to FSIS\u2019 zero tolerance policy. Beef hearts are subject to the requirements of 9 CFR 310.18(a).", "Step Potential Hazard RLTO Justification \u2225 Basis Controls CCP Page 10 of 16 9. Harvest Tongue, Liver, Kidney and Intestine B: Presence of pathogens, STEC and Salmonella. B: Outgrowth of pathogens, STEC and Salmonella. B: BSE \u2225 SRMs No Yes No The intestinal tract, mouth, hide, and hooves of cattle may harbor these pathogens. The STEC and Salmonella biological hazards for tongue, liver, kidney and intestine are recognized as not reasonably likely to occur because these products are not to be incorporated into raw ground beef products. Chilling inhibits growth of pathogens. (Tompkin, R.B. 1996). Outgrowth of STEC and Salmonella is reasonably likely to occur, and outgrowth is controlled with product chilling (CCP 3) and cold storage. Written SRM Program to remove, segregate and dispose of SRMs (9 CFR 310.22). Written Sanitary Dressing Procedures designed to reduce the likelihood of crosscontamination. Controlled later at CCP 3 Chilling. No C: None P: None 9a. Harvest Hearts B: Presence of pathogens, STEC and Salmonella. Yes Hearts may become contaminated during evisceration. The STEC and Salmonella biological hazards for beef hearts are recognized as reasonably likely to occur because heart meat is to be incorporated into raw ground beef product. Controlled later at CCP 1 Zero Tolerance Examination, CCP 2 Organic Acid Application and CCP 3 Chilling. Written Sanitary Dressing Procedures designed to prevent the likelihood of crosscontamination. No C: None P: None 10. Package Tongue, Liver, B: Outgrowth of pathogens, Yes Low product temperatures inhibit growth of pathogens. (Tompkin, R.B. 1996) Controlled with CCP 3 Chilling. No", "Step Potential Hazard RLTO Justification \u2225 Basis Controls CCP Page 11 of 16 Kidney, and Intestine STEC and Salmonella. C: None P: None 11. Organic Acid Application B. Presence of pathogens, STEC and Salmonella. Yes Eliminate or reduce STEC to non-detectable levels. Eliminate or reduce Salmonella. CCP 2 Organic Acid Application.<sup>19, 20</sup> CCP 2 C: Incorrect acid concentration. No We adhere to the manufacturer\u2019s guidance on storing, mixing, verifying concentrations, and applying the organic acid. The acid is used in accordance with FSIS Directive 7120.1.21 P: None 12. Chilling B: Outgrowth of pathogens, STEC and Salmonella. Yes Chilling inhibits growth of pathogens. FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia Coli (STEC) and Salmonella in Beef (including Veal) Slaughter Operations CCP 3 Chilling Process Control SOP (prerequisite program) for sampling of microbial organisms to monitor the establishment\u2019s ability to maintain process control (9 CFR 310.18). CCP 3 19 If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration (FSIS Compliance Guideline HACCP Systems Validation, page 27).<sup>20</sup> The Pennsylvania State University worked with Texas Tech University and Washington

State University to generate new data that very small establishments can use to effectively remove pathogens from carcass surfaces. See the Antimicrobial Spray Treatments for Red Meat Carcasses Processed in Very Small Meat Establishments for additional information. 21 FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products contains the list of substances that may be used in the production of meat and poultry products. The list contains the allowable amounts and the intended use of the approved antimicrobials. The list (Directive 7120.1) can be used as supporting documentation for chemical hazard controls (safety and suitability). Directive 7120.1 cannot be used as support for the control of biological hazards because the antimicrobial concentration needed to control bacteria is different from the concentrations required for safety and suitability. ", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 12 of 16 C: None P: None 13. Cold Storage B: Outgrowth of pathogens, STEC and Salmonella. No Written Cold Storage Program to maintain product \u226440\u00b0F to prevent outgrowth (Tompkin, R.B. 1996) C: None P: None 14. Hanging carcasses and parts transferred to In-House HACCP Process. B: None C: None P: None 15. Product Shipping B: Outgrowth of pathogens, STEC and Salmonella. No Written Final Product SOP for procedures to examine outgoing products including sanitary condition of trucks, functioning transport refrigeration unit, and package integrity. C: None P: None 16. Returned Product B: None Returned Product Evaluation SOP implemented before accepting returned product. Entity returning the product must demonstrate the product was held in the appropriate temperature range and in a sanitary manner. When such assurance is not available, returned product is rejected or destroyed. Opened packages are not accepted. Accepted product enters the appropriate step of the production system based on findings of product", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 13 of 16 evaluation. Notify FSIS personnel when returned product has been accepted. C: None P: None DATE: APPROVED BY:", "Page 14 of 16 EXAMPLE HACCP PLAN Beef Slaughter HACCP Plan Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 1 Zero Tolerance Examination Presence of pathogens: STEC (E. coli O157:H7, O26, O45, O103, O111, O121 and O145) and Salmonella in fecal material, ingesta and milk. Zero visible fecal material, milk, or ingesta on carcasses at the final rail inspection station and hearts after processing is completed in the slaughter department. Examine carcasses and hearts for contaminants. Document observations. Observe all surfaces of 2 randomly selected carcasses at the USDA final rail inspection station. Examine 2 randomly selected hearts after processing is complete in the slaughter department. Document observations on the Zero Tolerance Monitoring Form. Once per shift Designee If a deviation from the critical limit occurs, the supervisor will: 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence 9 CFR 417.3 Once per week, a supervisor observes the designee perform the monitoring activity. Once per week, a supervisor will conduct the records review. Zero Tolerance Monitoring Form Verification Form Corrective Action Form Preshipment Review Form", "Page 15 of 16 Example Beef Slaughter HACCP Plan Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 2 Organic Acid Application Presence of pathogens: STEC (E. coli O157:H7,

O26, O45, O103, O111, O121 and O145) and Salmonella Solution at appropriate concentration (e.g., 2-5%), per supporting documentation. Solution applied to each carcass and heart until all surfaces are visibly wet with solution. Solution concentration. Carcasses and hearts visibly wet. Monitor the measuring and combining of the solution components. Monitor application of the solution to carcasses and hearts. Document on the Organic Acid Application Form. Monitor the measuring and combining of the solution components once at the beginning of the slaughter day. Monitor the application of the solution once per slaughter day. Designee If a deviation from the critical limit occurs, the supervisor will: 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence 9 CFR 417.3 Once per week, a supervisor observes the designee perform the monitoring activity. Once per week, a supervisor will conduct the records review. Organic Acid Application Form Verification Form Corrective Action Form Pre-shipment Review Form", "Page 16 of 16 Example Beef Slaughter HACCP Plan Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 3 Chilling 22 Pathogen outgrowth: STEC (E. coli O157:H7, O26, O45, O103, O111, O121 and O145) and Salmonella Carcass, tongue, hearts, liver, kidney and intestine surface temperature will be \u226440\u00b0F within 24 hours of slaughter. The surface temperature. Insert a handheld digital thermometer 1 mm under the fascia on the inside round of carcasses and just under the surface of the hearts, liver, kidney and intestine. Document on the Chilling Monitoring Form. Within 24 hours of slaughter, for 2 randomly selected carcasses and 2 randomly selected hearts, livers, kidneys or intestines. Designee If a deviation from the critical limit occurs, the supervisor will: 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence 9 CFR 417.3 Once per week, a supervisor observes the designee perform the monitoring activity. Once per week, a supervisor will conduct the records review. Once per week, the supervisor or designee will calibrate the thermometer (per supporting documentation). Chilling Monitoring Form Corrective Action Form Preshipment Review Form Calibration Log DATE: APPROVED BY: 22 These limits, procedures and frequencies are all examples, and can vary by establishment. 9 CFR 417.2(c) requires each CCP to include a critical limit, and 9 CFR 417.5(a)(2) requires support for the selection and development of the CCP and critical limits. 9 CFR 417.2(c) requires the HACCP plan to include monitoring and verification procedures and frequencies, and 9 CFR 417.5(a)(2) requires support for the select procedures and frequencies. 9 CFR 417.4 requires each HACCP plan be validated."], {"file\_name": "FSIS\_GD\_2021\_0010", "title": "HACCP Model for Thermally Processed, Commercially Sterile product", "num": "FSIS-GD-2021-0010", "id": "e41235fd0c7b5ef05db9c9b8ae061dd84e275e6dadce93a44d27f16b80192714", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-08/FSIS-GD-2021-0010\_0.pdf", "type": "pdf", "n\_pages": 15, "word\_count": 3794, "text\_by\_page": ["Page 1 of 15 A Generic HACCP Model for a Thermally Processed, Commercially Sterile Product The United"]}

States Department of Agriculture (USDA) published the Pathogen Reduction\Hazard Analysis Critical Control Point (HACCP) Systems Final Rule in July 1996. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to address safety hazards reasonably likely to occur in their production process. Therefore, this HACCP model\u2019s focus, and the focus of the other HACCP models, is on product safety, not product quality characteristics. With the rule, FSIS made available a guidebook for the preparation of HACCP plans and a generic model for each food processing category defined in regulation 9 CFR 417.2(b)(1). The guidebook and the generic models have been updated since their initial publication to be consistent with current science and policy. FSIS recommends you use the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan. Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used \u201cas is.\u201d FSIS recommends that establishments tailor the model(s) to fit the establishment\u2019s operations. Thermally processed, commercially sterile (TPCS) products are commonly referred to as canned products although the containers can be metal cans, glass jars, flexible pouches, paperboard, and other types of hermetically sealed containers. Processors of TPCS products must identify their biological, physical, and chemical food safety hazards when performing their hazard analysis. Under 9 CFR 417.2(b)(3) of the HACCP regulations, establishments do not have to address the microbiological food safety hazards identified in its hazard analysis if the product is produced in accordance with the requirements of 9 CFR Part 431. However, canning establishments that identify chemical or physical food safety hazards as reasonably likely to occur (RLTO) are to address those hazards in their HACCP plan. The regulations provide that canning establishments do not have to address microbiological hazards in their HACCP plan because FSIS recognized that the canning regulations were based on HACCP concepts and provide for the analysis of thermal processing systems and controls to exclude biological food safety hazards. However, a canning establishment may choose to address the microbiological food safety hazards in its HACCP plan. In either case, the requirements in 9 CFR parts 431 and 417 must be met through the establishment\u2019s HACCP system. This HACCP model illustrates the scenario when the establishment does not address microbiological hazards in a HACCP plan and does not identify chemical or physical food safety hazards as reasonably likely to occur. Thus, this model does not include any critical control points (CCP). This model does contain the required product description, list of product ingredients and materials, flowchart, and hazard analysis. The model may not necessarily apply to all operations or products.

Products or operations may require CCPs depending on the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis, are HACCP records (9 CFR 417.5(a)). Ensure you maintain the documents produced while developing a HACCP plan. For further assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP webpage.", "Page 2 of 15 EXAMPLE PRODUCT DESCRIPTION1 Thermally Processed, Commercially Sterile: Beef Stew Process or

Product name Beef Stew Important product characteristics (Aw, pH, Preservatives, etc.) None Intended use<sup>2</sup> Ready-to-eat; typically heated before consumption. Packaging (durability and storage conditions) 3-piece metal, double seamed (\u201cSanitary\u201d) can. Shelf life and at what temperature<sup>3</sup> 3 years under cool (e.g., 75 \u00b0F or lower) and dry conditions; Protected from freezing. Where it will be sold (specify intended consumers, especially atrisk populations)<sup>4</sup> Sold to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI). Labeling instructions and requirements Product name, inspection legend and establishment number, heating instructions, net weight statement, address line, nutrition facts, and ingredients list. Special distribution control None DATE: APPROVED BY: 1 Prior to developing the HACCP plan please read the Guidebook for the Preparation of HACCP Plans for detailed descriptions of the worksheets and hazard analysis. The FSIS Guidebook for the Preparation of HACCP Plans and the generic HACCP models are intended for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products. 2 The intended use or consumer of the product must be identified in accordance with 9 CFR 417.2(a)(2). Identifying the product\u2019s intended use in the product description is one way to meet the regulatory requirements specific to 417.2(a)(2). 3 Each establishment\u2019s products may have their own defined shelf life. Thermally Processed, Commercially Sterile products must be shelf stable per 9 CFR 431.1. 4 At-risk populations include young children, the elderly, and immunocompromised persons." , "Page 3 of 15 EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIALS<sup>5</sup> Thermally Processed, Commercially Sterile: Beef Stew Meat and meat by-products Frozen beef Non-meat food ingredients Water, Frozen diced celery, Frozen sliced carrots, Frozen tomato puree, Modified food starch, Textured soy protein, Spice mix, Salt, Sugar. Antimicrobial interventions<sup>6</sup> and processing aids None Packaging material<sup>7</sup> 3-piece double seamed (\u201cSanitary\u201d) cans with capacities of 7 oz, 11.5 oz, 12 oz and 20 oz. Restricted ingredients or Allergens Texturized soy protein Other None DATE: APPROVED BY: 5 List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, and packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. See the FSIS Compliance Guideline Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling for detailed information on allergens. 6 FSIS and the Food and Drug Administration (FDA) have a memorandum of understanding (MOU) that establishes the working relationship followed when responding to notifications for the use of food additives (including ingredients) intended for use in the production of FSIS regulated products. FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDA on the requirements under the Federal Food, Drug & Cosmetic Act and its implementing regulations. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat Poultry and Egg Products for the list of suitable ingredients. 7 Establishments will follow different process schedules developed by a processing authority for the product packaged in different container sizes." , "Page 4 of 15 EXAMPLE PROCESS FLOW DIAGRAM<sup>8</sup> Thermally Processed, Commercially Sterile: Beef Stew 18. Returned Product<sup>9</sup> DATE: APPROVED BY: 8 This

is an example flow diagram. Establishments\u2019 flow diagrams for the same product may be different. Establishments determine which steps are included in their process. The steps must represent all relevant hazards in the hazard analysis. 9 The Returned Product step (18) is shown as not connected to another process step. Returned product may re-enter the production system at different process steps depending on condition or food safety concerns. Returned product may be relabeled, repackaged, or discarded.

1. Receiving and Storage of Frozen Beef  
3. Receiving and Storage of Cans and Packaging Materials  
9. Filling  
5. Pre-cooking Beef  
10. Sealing  
6. Pre-Weigh, Pre-mix and Prepare NonMeat Food Ingredients  
7. Mixing  
11. Thermal Processing  
8. Cleaning Cans  
16. Labeling and Packaging  
14. Storage  
17. Storage and Shipping  
13. Sample Incubation  
4. Cutting or Dicing Beef  
12. Cooling  
15. Defect Detection  
2. Non-Meat Ingredients Receiving and Storage", "EXAMPLE HAZARD ANALYSIS Thermally Processed, Commercially Sterile: Beef Stew Potential Hazards

10 Is the Hazard Reasonably Likely to occur (RLTO)?  
11 Justification or Basis for Decision  
i If yes in Column 2 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels  
ii Is this Step a Critical Control Point (CCP)?  
10 Hazards are grouped into three categories: Biological (B), Chemical (C), and Physical (P). Biological hazards are living organisms. Chemical hazards may be naturally occurring in foods, used or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification.  
11 Place the justification for your decision in column 3. Control measures for hazards not reasonably likely to occur are entered in column 3. Control measures for hazards reasonably likely to occur are entered in column 4. If a hazard is reasonable likely to occur, then a CCP must be addressed at this step or a later step. See FSIS Meat and Poultry Hazards and Controls Guide for a list of frequently used controls.

1. Receiving and Storage of Frozen Beef  
B: Presence and outgrowth of pathogens, Shiga-toxin producing Escherichia coli (STEC) (E. coli O157:H7, O26, O45, O103, O111, O121 and O145), Salmonella and Clostridium botulinum  
No Beef may be contaminated with Shiga-toxin producing Escherichia coli (STEC) (E. coli O157:H7, O26, O45, O103, O111, O121 and O145), Salmonella and Clostridium botulinum.  
9 CFR 417.2(b)(3) exempts establishment from having to address microbiological food safety hazards in the HACCP plan if the product is produced in accordance with the requirements in 9 CFR Part 431. Written receiving program to ensure product specifications, temperature, and package integrity. Written Sanitation Standard Operating Procedure (SOP), including temperature control and maintenance of sanitary conditions. The product is thermally processed during the thermal process step in accordance with 9 CFR Part 431.", "Potential Hazard RLTO Justification or Basis Controls CCP Page 6 of 15  
12 This Foreign Material SOP (prerequisite program) should have details on how this procedure (such as metal prevention controls) is preventing the hazard from occurring as well as the on-going verification procedures. These controls should be evident within the written document upon review. The Foreign Material SOP and plant data related to on-going verification activities then become part of recordkeeping and historical data.  
BSE (Prions)  
No Bovine Spongiform Encephalopathy (BSE)  
Prions associated with specified risk materials (SRM) is a potential hazard in beef products. Only boneless beef received from approved suppliers according to company purchasing program. SRMs are required to be removed by supplier prior to release into commerce. Letters of Guarantee (LOGs) from suppliers describing SRM controls.

C: Antibiotic

and pesticide residues No Letters of Guarantee (LOG) from suppliers describing quality controls and prevention procedures. The blanket LOG is updated annually. Approved supplier program and ongoing communication with suppliers to verify LOGs. P: Foreign materials, i.e., metal, rubber, plastic, and wood. No Visual examination procedures in the Foreign Material SOP.12 Establishment Foreign Material SOP records demonstrate no incidents of foreign materials detected in products received. 2. Non-meat Ingredients Receiving and Storage B: Presence and outgrowth of pathogens, e.g., STEC, Salmonella and Clostridium botulinum No 9 CFR 417.2(b)(3) exempts establishment from having to address microbiological food safety hazards in the HACCP plan if the product is produced in accordance with the requirements in 9 CFR 431. Written receiving program to ensure product specifications, temperatures, and package integrity. Purchasing program to ensure microbiological specifications for non-meat ingredients are met. Written Sanitation SOP including storage temperature control and", "Potential Hazard RLTO Justification or Basis Controls CCP Page 7 of 15 13 Note: this \u201chistorical data\u201d must be supported with evidence from the establishment through the establishment\u2019s history or validation data with reference to the actual SOP or prerequisite program. When historical data is not available (for example, a HACCP plan for a new process or product), then system design must be supported by other documentary evidence, such as the FSIS Meat and Poultry Hazards and Controls Guide which states \u201cletters of guarantee, certificate of analysis, approved supplier program and proper storage to prevent contamination of allergen-free products\u201d as frequently used controls for the receiving and storage of pesticides and allergens. maintenance of sanitary conditions. C: Pesticide residues and undeclared allergens No Written receiving program to ensure product specifications. Allergen Control SOP to verify proper identification of allergenic containing ingredients for each lot. Approved supplier program and ongoing communication with suppliers to verify LOGs. Establishment records demonstrate no incidents of chemical hazards detected in products received.13 Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer\u2019s instructions and is within the allowable limits identified in Directive 7120.1. P: Foreign materials, i.e., metal, rubber, plastic, and wood. No Visual examination procedures in the Foreign Material SOP. Approved supplier program and ongoing communication with suppliers to verify LOGs. Establishment Foreign Material SOP records demonstrate no incidents of foreign materials detected in products received.", "Potential Hazard RLTO Justification or Basis Controls CCP Page 8 of 15 3. Receiving and Storage of Cans & Packaging Materials B: Postprocess contamination due to container defects No Packaging materials are stored, handled, and conveyed according to SOP to prevent damage that could affect the hermetic condition of the sealed container (9 CFR 431.2). C: Chemicals No LOGs for all packaging materials describing the material\u2019s intended use complies with the Federal Food, Drug, and Cosmetic Act (FFDCA) and all applicable food additive regulations. Incoming packaging material examination procedures per 9 CFR 431.2. Approved supplier program. P: Foreign material No Cans are inverted and washed with hot water at step 8 in accordance with 9 CFR 431.2 4. Cutting or Dicing Beef B: Pathogen outgrowth No Written Sanitation SOP to prevent or minimize cross-contamination. Temperature control SOP in the processing area to prevent the outgrowth of pathogens. Beef is cut into sizes in accordance with the process schedule developed by a processing authority (9 CFR 431.3(a) &(b)). The product is thermally processed during the thermal process step in

accordance with 9 CFR Part 431. C: None P: Foreign materials, i.e., metal from No Metal fragments could come from processing equipment. Daily equipment examination and preventive maintenance SOP on equipment and conveyor to prevent foreign materials, i.e., metal, rubber.", "Potential Hazard RLTO Justification or Basis Controls CCP Page 9 of 15 processing equipment plastic from contaminating the product. 5. Pre-cooking Beef B: Presence and outgrowth of pathogens: e.g., STEC, Salmonella and Clostridium botulinum No Written Sanitation SOP to prevent or minimize cross-contamination. Beef is pre-cooked according to the procedures defined by a processing authority (9 CFR 431.3). The product is thermally processed during the thermal process step in accordance with 9 CFR Part 431. C: None P: None 6. Pre-Weigh, Pre-mix and Prepare Non-Meat Food Ingredients B: Presence and outgrowth of pathogens No Written Sanitation SOP to prevent or minimize cross-contamination. Non-meat ingredients are pre-mixed according to the written formulation SOP. Temperature control SOP to prevent the outgrowth of pathogens. C: Undeclared allergen No Formulation is conducted in accordance with established process schedules. Allergen Control SOP ensures ingredient statements on finished product labels match ingredient formulation. Written Good Manufacturing Practices (GMPs) prevent and minimize the likelihood of cross-contamination with allergens and chemicals.", "Potential Hazard RLTO Justification or Basis Controls CCP Page 10 of 15 P: Foreign materials No Daily equipment examination and preventive maintenance SOP on equipment and conveyor to prevent foreign materials, i.e., metal, rubber, plastic from contaminating the product. 7. Mixing B: Clostridium botulinum No 9 CFR 417.2(b)(3) exempts establishment from having to address microbiological food safety hazards in the HACCP plan if the product is produced in accordance with the requirements in 9 CFR Part 431. Improper formulation may cause process deviation and survival of Clostridium botulinum spores. Written formulation SOP defined by a processing authority. 14 C: Undeclared allergens No Formulation is conducted in accordance with established process schedules. Allergen Control SOP ensures ingredient statements on finished product labels match ingredient formulation. Written Good Manufacturing Practices (GMPs) to prevent and minimize the likelihood of cross-contamination with allergens and chemicals. P: Metal fragments No Metal fragments could come from processing equipment. Daily equipment examination and preventive maintenance SOP on equipment and conveyor to prevent foreign materials, i.e., metal, rubber, 14 If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. However, if an establishment implements different critical operational parameters in the process from the scientific support, or the scientific support identified does not contain microbiological data, then the establishment should collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological validation data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameter (FSIS Compliance Guideline HACCP Systems Validation, page 27).", "Potential Hazard RLTO Justification or Basis Controls CCP Page 11 of 15 plastic from contaminating the product. 8. Cleaning Cans B: None C: None P: Foreign materials

No Cans are inverted and cleaned per 9 CFR 431.2 9. Filling B: Clostridium botulinum No Improper fill may cause process deviation and survival of Clostridium botulinum spores. Fill-in weight15 checked by inline scale monitoring SOP. Written formulation and filling procedure defined by a processing authority (9 CFR 431.3). C: None P: None 10. Sealing B: Container defects causing spoilage of product due to defective No Routine visual and teardown examinations during the operation and seamer per 9 CFR 431.2. Reject non-conforming products in accordance with closure and teardown examinations SOP. 15 The process schedule developed by a processing authority determines whether the fill-in weight is a critical factor. Establishment is required to measure, control, and record the critical factors specified in the process schedule per 9 CFR 431.4." "Potential Hazard RLTO Justification or Basis Controls CCP Page 12 of 15 seaming Formation of Staphylococcal enterotoxins No Daily equipment examination and preventive maintenance SOP. The maximum time lapse between closure of containers and initiation of thermal processing is controlled to be less than 2 hours per 9 CFR 431.2(f)(2). C: None P: None 11. Thermal Processing B: Clostridium botulinum No Proper application of process schedule developed for the product by a processing authority (9 CFR 431.3). Operation procedures in accordance with requirements in 9 CFR part 431. C: None P: None 12. Cooling B: Post-process contamination No Containers are cooled using potable water per 9 CFR 431.6(h) and cooling water is not reused in the retort system. C: None P: None", "Potential Hazard RLTO Justification or Basis Controls CCP Page 13 of 15 13. Sample Incubation B: Spoilage of product due to process deviation or post-process deviation No At least one container per load16 of product will be selected for 10 days incubation per 9 CFR 431.10(b). C: None P: None 14. Storage B: Spoilage of product due to process deviation or post-process contamination No The lot will be on hold during the 10 days incubation period. Written SOP for the handling of abnormal containers to ensure only normal appearing safe and stable product are released per 9 CFR 431.10(a). Written GMPs to prevent and minimize container defects due to rough handling (9 CFR 431.2(f)(1)). C: None P: None 15. Defect Detection B: Spoilage of product due to container No Visual examination of containers to ensure only normal appearing containers are labelled and released (9 CFR 431.10(c)). Written Container Examination SOP including procedures for, and records 16 In this HACCP model, the establishment is using a steam-still, batch-type retort. If the establishment is using a continuous-type retort system, such as continuous rotary retorts or hydrostatic retorts, it will select at least one container per 1000 for incubation per 9 CFR 431.10(b)." "Potential Hazard RLTO Justification or Basis Controls CCP Page 14 of 15 defects or process deviation of, container examinations and handling of abnormal containers. C: None P: None 16. Labeling and Packaging B: None C: Undeclared Allergens No Formulation is conducted in accordance with established process schedules (9 CFR 431.3(a)). Allergen Control SOP ensures ingredient statements on finished product labels match ingredient formulation. P: None 17. Storage and Shipping B: None C: None P: None 18. Returned Product B: None Reinspection SOP implemented before accepting returned product. Person(s) or business returning the product must demonstrate the product was held in the appropriate temperature range and in a sanitary manner. When such assurance is not available, returned product is rejected or destroyed. Opened packages are not accepted. Accepted product enters", "Potential Hazard RLTO Justification or Basis Controls CCP Page 15 of 15 the appropriate step of the production system based on findings of product evaluation. Notify FSIS personnel when returned product has been accepted. C: None P: None

DATE: APPROVED BY: i Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced articles must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from an FSIS program, then HACCP system design must be supported by documentary evidence \u2013 that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan. ii Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, or antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation, page

5."}],{"file\_name":"FSIS\_GD\_2021\_0011","title":"FSIS Guideline on Kit Product Labeling","num":"FSIS-GD-2021-0011","id":"a68e06de73090989d349bc3e798cc4986580c2f81d3f9d1fc02792a9d4183da8","corpus":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/media\_file/2021-09/FSIS-GD-2021-0011.pdf","type":"pdf","n\_pages":8,"word\_count":1856,"text\_by\_page":[{"1": "This guideline is designed to help establishments and other food handling facilities producing a nonretail-exempt, multicomponent food kit (kit product) determine: \u2022Whether the kit product needs to be prepared under FSIS inspection; and \u2022How to label a kit product that contains inspected and fully labeled meat or poultry components. FSIS Guideline on Kit Product Labeling September 2021"}, {"2": "Table of Contents"}]

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7", "3 Preface This is a revised version of the FSIS Guideline on Kit Product Labeling. FSIS updated it in response to comments received on the previous version posted on June 9, 2019. The Agency revised the guideline to announce that FSIS no longer will provide mandatory inspection services for the assembly of kits as described in this guideline, and that such kits are eligible for FSIS voluntary inspection; clarify that it does not apply to products produced under the retail exemption; clarify that kits labeled as a standardized product must meet the regulatory standard; and clarify that uninspected kits placed into shipping containers must not bear the USDA legend on the shipping container. The guideline also includes changes to improve its readability. \u2022 This guideline represents FSIS\u2019 current thinking on these topics and should be considered usable as of its issuance. Establishments that used previous versions of the FSIS Guideline on Kit Product Labeling as food safety system support (9 CFR 417.5(a)(1) and 9 CFR 417.4(a)(1)) should update their procedures based on this guideline as necessary. The information in this guideline is provided to assist meat and poultry establishments in meeting the regulatory requirements. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to industry regarding existing requirements under the regulations. This guideline is focused on small and very small establishments in support of the Small Business Administration\u2019s initiative to provide small businesses with assistance under the Small Business Regulatory Enforcement Fairness Act (SBREFA). However, all meat and poultry establishments may apply the recommendations in this guideline. Although large plants can benefit from the information, focusing the guideline on the needs of small and very small establishments provides them with assistance that may be otherwise unavailable to them.

Congressional Review Act Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this guideline is not a \u201cmajor rule,\u201d as defined by 5 U.S.C. 804(2).

Purpose This guideline contains information to assist meat and poultry establishments comply with the inspection and labeling requirements of the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and the labeling requirements in 9 CFR part 317 and 9 CFR 381 subpart N for wholesale multi-component food kits (henceforth, kit products) that contain an inspected and labeled meat or poultry component. This guideline includes information on:

"4 \u2022 The definition of \u201ckits\u201d in the context of this guideline;

\u2022 Types of kits that may be assembled without inspection; and

\u2022 Labeling requirements for kits assembled without FSIS inspection.

Reason for Issuing the Guideline FSIS has received numerous inquiries on how kit products should be labeled to ensure compliance with FSIS regulations and policies, and whether certain kit products may be assembled without FSIS inspection. In the past, FSIS has not considered kit products that did not reference meat or poultry in the product name, such as \u201cStir Fry\u201d or \u201cSkillet Meal,\u201d as products of the meat or poultry industry because the product name often makes no reference to meat or poultry. However, manufacturers have increasingly wanted to highlight the meat or poultry component in the coined name, e.g., \u201cChicken Skillet Meal\u201d or \u201cGourmet Beef Dinner.\u201d Historically, the Agency has required kit products purporting to be meat or poultry products to be assembled under FSIS inspection. After further evaluation, the Agency has determined that the act of assembling a kit product whose label makes reference to meat or poultry in its name does not need to be done under FSIS inspection, as long as certain conditions are met. Changes

from the Previous Version of the Guideline This guideline is final. FSIS will update this guideline, as necessary, should new information become available. FSIS made the following changes to this guideline to address the comments received on the previous version during the comment period and to include additional scientific information. This version incorporates the following changes: \u2022 Announce that FSIS no longer will provide mandatory inspection services for the assembly of kits as described in this guideline, and that such kits are eligible for FSIS voluntary inspection under 9 CFR 350.3(c); \u2022 Clarify that the guideline does not apply to products produced under the retail exemption; \u2022 Clarify that a kit named as an FSIS standardized product must meet the standard when prepared; and \u2022 Clarify that when an official establishment places a kit assembled without FSIS inspection into a container for shipping, the establishment may not apply the USDA inspection legend to the outer container.

How to Effectively Use the Guideline", "5 This guideline is organized to provide users with current recommendations. To use this guideline, FSIS recommends that readers use the navigation headings to move efficiently through the document sections of interest. Hyperlinks, where provided, will quickly take you to the correct place in the document electronically and are also provided to other complementary documents.

Questions Regarding Topics in this Guideline If after reading this guideline you still have questions, FSIS recommends searching the publicly posted Knowledge Articles (\u201cPublic Q&As\u201d) in the askFSIS database. If after searching the database, you still have questions, refer them to the Office of Policy and Program Development through askFSIS and select Labeling as the Inquiry Type or by telephone at 1-800-233-3935. Documenting these questions helps FSIS improve and refine present and future versions of the guideline and associated issuances.", "6 FSIS Guideline on Kit Product Labeling

Background This guideline is for official establishments under FSIS inspection and establishments under the Food and Drug Administration\u2019s jurisdiction that plan to assemble kit products that contain an already inspected and labeled meat or poultry component in a common container or packaging marketed as a single unit. This guidance does not apply to instances in which the meat or poultry component is processed (e.g., sliced), or portioned and packaged by the facility assembling the kit, if the kit will be sold for resale, because such activities require FSIS inspection.

Kit Products In the context of this guideline, a kit product consists of individually-packaged meat or poultry products and other food components sold together as a single unit. Examples of kit products include: \u2022 A \u201cSpaghetti Dinner Kit\u201d which includes a bag of fully-cooked meatballs, a jar of marinara sauce, and uncooked spaghetti; \u2022 A \u201cChicken Fiesta Kit\u201d which includes a packet of raw, marinated chicken breast strips, flour tortillas, a can of refried beans, and a package of rice; and \u2022 A \u201cNugget Lunch Kit\u201d which includes a bag of fully-cooked nugget-shaped chicken patties, a container of cole slaw, a slice of corn bread, and a juice box. There are many varieties of kit products, including but not limited to: wraps, pizza, stew, salads, fajitas, stroganoff, or stir fry skillet meals, that include meat or poultry components. Kit products may be marketed to provide one meal to multiple consumers, such as a \u201cBeef Stew Kit\u201d with multiple servings, or a kit product could be a single serving meal for one, such as an \u201cIndividual Pizza Lunch Kit\u201d with pizza components, a brownie, and a soda. The meat or poultry items are commonly sold as fully-cooked; however, some of these items may require cooking.

Assembly Without Inspection The Agency has determined that the act of assembling a kit product whose label makes reference to meat or poultry in its name does not

need to be done under FSIS inspection, as long as the following conditions are met: 1. The meat\poultry component is prepared and separately packaged under FSIS inspection and labeled with all required features, including: \u2022 Product name, \u2022 Handling statement (e.g., Keep Refrigerated), if product is perishable, \u2022 USDA legend and establishment number of the official establishment that packaged and labeled the meat\poultry component,"7 \u2022 Name and address of the manufacturer, packer, or distributor, \u2022 Ingredients statement (if composed of more than one ingredient), and \u2022 Safe handling instructions if the meat or poultry component is not ready-to-eat; 2. The outer label for the kit product identifies all the individual components in the kit; and 3. The outer kit label clearly identifies the product as a single unit or \u201ckit,\u201d such as \u201cChicken Barbecue Dinner Kit\u201d or \u201cBeef Lasagna Meal.\u201d Although the word \u201ckit\u201d is not required on the label, all labeling must clearly indicate that the product consists of individual components. If assembly of kit products occurs at an official establishment, the assembly would be performed without FSIS inspection and may be done outside the official hours of inspection. Thus, official establishments would not incur any charges for FSIS inspection or for overtime. The assembly of kit products meeting the above conditions remains eligible for FSIS voluntary inspection as a food inspection service under 9 CFR 350.3(c). Going forward, FSIS will no longer provide mandatory inspection services for the assembly of such kits. FSIS has determined that providing inspection for these products as a voluntary food inspection service is the best use of Agency resources. Note: The guideline does not apply to boxes of ingredients (including FSIS-inspected, fully labeled meat and poultry products) that are shipped directly to consumers to help them prepare home-cooked meals. These boxes\kits are typically prepared and packed without FSIS inspection under the retail exemption (see 9 CFR 303.1(d) and 381.10(d)). The retail exemption from FSIS inspection is unchanged by this document.

**Labeling** Although FSIS will no longer conduct mandatory inspection of the assembly of the kit product, the meat or poultry component of the kit remains under FSIS\u2019 jurisdiction and, as such, is required to meet all applicable FSIS labeling requirements, including product standards described in 9 CFR 319 and 381 Subpart P. Labels for such kit products assembled without FSIS inspection are not required to be submitted to FSIS for approval. Kit products assembled without FSIS inspection will not bear the USDA mark of inspection on the label of the common packaging containing the components of the kit. The mark of inspection, instead, would be on the label and packaging of the meat or poultry component included in the kit. When kits that were not assembled under FSIS inspection and therefore, do not bear the USDA legend, are placed into a larger container for shipping, the outer shipping container may not bear the USDA legend."8 https://www.fsis.usda.gov/contact-us/askfsis USDA FSIS www.fsis.usda.gov 2021"]},{"file\_name":"FSIS\_GD\_2021\_0012","title":"HACCP Model for Raw, Non-Intact Turkey","num":"FSIS-GD-2021-0012","id":"96ac125f13b39909548bc44b905c9990c09f8a2ac6c75fe35dbc8b7cc73f1ce4","corp\_us":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/media\_file/2021-10/FSIS-GD-2021-0012.pdf","type":"pdf","n\_pages":12,"word\_count":3768,"text\_by\_page":["HACCP Model for Raw, Non-Intact Turkey The United States Department of Agriculture (USDA) published the Pathogen Reduction\Hazard Analysis Critical Control Point (HACCP) Systems Final Rule in July

1996 mandating all USDA inspected meat and poultry establishments implement a HACCP system. Hazard Analysis Critical Control Point (HACCP) is a systematic and scientific method of process control for the production of safe food products. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to improve the safety of their products. The HACCP models\u2019 focus is on product safety, not product quality characteristics. With the rule, FSIS made available a guidebook for the preparation of HACCP plans and a generic model for each food processing category defined in regulation (9 CFR 417.2(b)(1)). The guidebook and the generic models have been revised since their initial publication to be consistent with current science and policy. FSIS recommends you use the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan. Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used \u201cas is\u201d. Establishments are to tailor the model(s) to fit the establishment\u2019s operation. This Raw, Non-Intact model uses a ground turkey product to demonstrate hazard analysis and HACCP plan principles. The model may serve as a starting point for any ground poultry product. The model\u2019s critical control points (CCPs) do not necessarily apply to all operations or products. Products or operations may require fewer or more CCPs depending on the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. The food safety critical limits selected must come from scientific documents or other reliable sources. This model includes references for guidance on the selection of critical limits. The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis are HACCP records (CFR 417.5(a)). The selection of processing categories and HACCP models are preliminary steps to completing a hazard analysis. The documents produced during the selection process are HACCP records. Ensure you maintain the documents produced while developing a HACCP plan. For further assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP webpage.<sup>1</sup> This information is best suited for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products.","Page 2 of 12 EXAMPLE PRODUCT DESCRIPTION2 Process Type and Product Name: Raw, Non-Intact Turkey Product Name Fresh or Frozen Ground Turkey (Raw, Non-Intact) Important product characteristics (Aw, pH, Preservatives, etc.) None How it is to be used For further processing at this facility or another establishment or intended for cooking for or by end consumer3 Packaging (durability and storage conditions) Tray packs (Case ready) Shelf life and at what temperature<sup>4</sup> 7 Days at <40\u00baF; 180 days at < 0\u00baF Where it will be sold (Specify intended consumers, especially at-risk populations)<sup>5</sup> Sold direct to another establishment or to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI). Labeling instructions Product name, keep refrigerated or frozen, safe handling instructions, nutrition facts, establishment number, and cooking

instructions Special distribution control Keep refrigerated or frozen DATE: APPROVED BY: 2 Prior to developing the HACCP plan please read the FSIS Guidebook for the Preparation of HACCP Plans for detailed descriptions of the worksheets and hazard analysis. The FSIS Guidebook for the Preparation of HACCP Plans and the generic HACCP models are intended for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP models are for demonstration purposes only. The models do not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products. 3 The intended use or consumer of the product must be identified in accordance with 9 CFR 417.2(a)(2). Identifying the product's intended use in the product description is one way to meet the regulatory requirements specific to 417.2(a)(2). 4 Each establishment's products may have their own defined product shelf life. 5 At-risk populations include young children, the elderly, and immunocompromised persons.", "Page 3 of 12 EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL6 Process Type and Product Name: Raw, Non-Intact Turkey Meat and Meat by-products Turkey trim (dark and light meat, skin on and skin off) from outside source purchase and in-house slaughter operations Non-meat food ingredients None Antimicrobial interventions and processing aids7 Antimicrobial Acid8 Packaging materials Tray packaging, retail plastic packaging and rollstock plastic, self-adhesive labels Restricted ingredients and allergens None Other None DATE: APPROVED BY: 6 List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, and packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. See the FSIS Compliance Guideline Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling for detailed information on allergens. To review restrictions on the use of nitrite and sodium ascorbate or sodium erythorbate, see 9 CFR 424.22(b). 7 FSIS and the Food and Drug Administration (FDA) have a memorandum of understanding (MOU) that establishes the working relationship followed when responding to notifications for the use of food additives (including ingredients) intended for use in the production of FSIS regulated products. FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDA on the requirements under the Federal Food, Drug & Cosmetic Act and its implementing regulations. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products for the list of suitable ingredients. 8 Antimicrobial interventions even if considered processing aids must be addressed in the HACCP system. See the FSIS Compliance Guideline HACCP Systems Validation April 2015 (page 5).", "Page 4 of 12 EXAMPLE PROCESS FLOW DIAGRAM9 Process Type and Product Name: Raw, Non-Intact Turkey10 9. Returned Product11 DATE: APPROVED BY: 9 This is an example flow diagram. Establishments' flow diagrams for the same product may be different. Establishments determine which steps are included in their process. The steps must represent all relevant hazards in the hazard analysis. 10 If receiving both in-house and outside (purchased) trim, product flow and lots should be separated for traceability reasons. When inhouse and purchased trim is combined, maintain a record of the finished product source material(s). 11 The Returned Product step (9) is shown connected to step 8 Storage and Distribution. Returned product may re-enter the production system at different process steps depending on condition

or problem. Returned product may be relabeled, re-ground, discarded, tempered, etc. 1a. Receiving of Turkey Components from Outside Source and In-house Slaughter 2. Cooler Storage 7. Packaging and Labeling CCP 2 8. Storage and Distribution 4. Grinding (trim) 5. Metal Detection 3. Antimicrobial Application for Turkey Components CCP 1 1b. Receiving and Storage of Packaging Material and Antimicrobial Products 6. Rework", "EXAMPLE HAZARD ANALYSIS 12 Raw, Non-Intact Turkey 12 See the FSIS Guideline for Controlling Campylobacter in Raw Poultry, and the FSIS Guideline For Controlling Salmonella in Raw Poultry for best practices and a list of scientific and technical references. 13 Hazards are grouped into three categories: Biological (B), Chemical (C), and Physical (P). Biological hazards are living organisms. Chemical hazards may be naturally occurring in foods, used or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification. 14 Place the justification for your decision in column 4. Control measures for hazards not reasonably likely to occur are entered in column 4. Control measures for hazards reasonably likely to occur are entered in column 5. If a hazard is reasonably likely to occur, then a CCP must be addressed at this step or a later step. See FSIS Meat and Poultry Hazards and Controls Guide for a list of frequently used controls. 15 Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced article must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from FSIS, then HACCP system design must be supported by documentary evidence \u2013 that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan. 16 Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation standard operating procedures (Sanitation SOP), written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, or antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation, page 5). 17 To determine a CCP, see FSIS Guidebook for the Development of HACCP Plans for decision tree to evaluate the areas of control (column 5) to determine the best CCP to control, reduce, or eliminate a hazard. Column 1 Column 2 Column 3 Column 4 Column 5 Column 6 Ingredient \ Process Step Potential Hazards (introduced or controlled) at this Step 13 Is the Potential Food Safety Hazard Reasonably Likely to Occur (RLTO)? (Yes or No) 14 Justification \ Basis for Decision in Column 3 15 If yes in Column 3 (hazard RLTO), What Control Measures Can Be Applied to Prevent,

Eliminate, or Reduce the Hazard to Acceptable Levels<sup>16</sup> Is this Step a Critical Control Point (CCP)?<sup>17</sup> 1a. Receiving of Turkey Components from Outside Source and In-house Slaughter B: Outgrowth of Pathogens: Salmonella, Campylobacter No Turkey components received from establishments with validated HACCP systems or from the establishment's slaughter process include antimicrobial applications and other measures to reduce biological hazards to acceptable levels. Written Turkey Receiving Standard Operating Procedure (SOP) to establish product specifications at receiving to prevent the introduction of hazards at the receiving step. Letter of Guarantee (LOG) is on file for each supplier of turkey", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 6 of 12 18 This Foreign Material SOP (prerequisite program) should have details on how this procedure is preventing the hazard from occurring (metal prevention controls) as well as the ongoing verification procedures. These controls should be evident within the written document upon review. The Foreign Material SOP and plant data related to on-going verification activities then become part of recordkeeping and historical data. product. Prerequisite program at product receiving to monitor incoming product temperatures and packaging or container conditions to prevent pathogen outgrowth and product contamination. C: None P: Foreign Material No Written Foreign Material SOP<sup>18</sup> for visual inspection of product containers at receiving. 1b. Receiving and Storage of Packaging Material and Antimicrobial Products B: None C: Non-food grade packaging material and Antimicrobials No Letter of Guarantee (LOG) for packaging materials and antimicrobials. Written Chemical Receiving, Storage, and Use SOP for management of antimicrobials. P: Foreign material No Receiving Letters of Guarantee (LOG) from suppliers for foreign material specifications. Written Foreign Material SOP for visual inspection of product containers at receiving. Written Storage SOP for packaging materials and antimicrobials.", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 7 of 12 2. Cooler Storage B: Pathogen outgrowth (Salmonella, Campylobacter) No Pathogen outgrowth may result if temperatures are not maintained at levels to prevent bacterial multiplication. Product is placed in storage coolers or freezers to prevent product temperatures that promote pathogen outgrowth (Tompkin, R.B. 1996).<sup>19</sup> Written Sanitation and Temperature Control SOP for condition of use and maintaining cooler temperatures to prevent outgrowth of microorganisms. C: None P: None 3. Antimicrobial Application for Turkey Components B: Outgrowth of Pathogens (Salmonella, Campylobacter) Yes Well documented that raw poultry may carry pathogens. Antimicrobial dips are documented to reduce pathogenic contamination to acceptable levels on meat. Antimicrobial dips and their scientifically validated critical operational parameters are used to reduce pathogens.<sup>20</sup> Yes CCP 1 C: Inappropriate concentration of antimicrobial dips No Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer's instructions and is within the allowable limits identified in Directive 7120.1 (Food Contact Notification (FCN) number).<sup>21</sup> 19 The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50°F (Tompkin, R.B. 1996) 20 If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure,

temperature, and concentration. However, if an establishment implements different critical operational parameters in the process from the scientific support, or the scientific support identified does not contain microbiological data, then the establishment should collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological validation data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameters (FSIS Compliance Guideline HACCP Systems Validation, page 27). 21 Provide reference for scientific support and validation for effective concentrations and support for critical operational parameters that reduce biological hazards. FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products contains the list of substances that may be used in the production of meat and poultry products. The list contains the allowable amounts and the intended use of the approved antimicrobials. The list (Directive 7120.1) can be used as supporting documentation for chemical hazard controls (safety and suitability). Directive 7120.1 cannot be used as support for the control of biological hazards because the antimicrobial concentration needed to control bacteria is different from the concentrations required for safety and suitability.", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 8 of 12 P: None 4. Grinding (trim) B: Pathogen outgrowth (Salmonella, Campylobacter) Yes Pathogen outgrowth may occur during processing procedures due to processing room temperatures, product handling and grinding equipment. The hazard is controlled later at CCP 2 Packaging and Labeling. Written Sanitation program for grinding operation. Temperature Control During Grinding SOP to prevent pathogen outgrowth during production. No C: None P: Metal contamination and Bone fragments No Written Equipment Examination and Preventive Maintenance on Grinder SOP22 to prevent metal contamination from equipment. Written Preventive Maintenance of Bone Separator on Grinder SOP to establish controls for bone contamination prevention. 5. Metal Detection B: None C: None P: Metal contamination No Written Metal Detection SOP for products. Metal Detection SOP records supporting historical data for low likelihood of occurrence due to routine maintenance of grinding equipment.23 22 This Written Equipment Examination and Preventive Maintenance on Grinder SOP (prerequisite program) should have details on how this procedure is preventing the hazard from occurring (such as metal prevention controls) as well as the on-going verification procedures. These controls should be evident within the written document upon review. The Grinder SOP and plant data related to on-going verification activities then become part of recordkeeping and historical data. 23 Note: this \u201chistorical data\u201d must be supported with evidence from the establishment through the establishment\u2019s history or validation data with reference to the actual SOP (which is a prerequisite program). When historical data is not available (for example, a HACCP plan for a new process or product), then system design must be supported by other documentary evidence. Documentary evidence such as the FSIS Meat and Poultry Hazards and Controls Guide, which states \u201cappropriate screening procedure for monitoring equipment\u201d is a frequently used control for foreign material hazards when grinding products.", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 9 of 12 6. Rework B: Pathogen outgrowth (Salmonella, Campylobacter) No Written Rework Procedures SOP for establishing rework procedures, lot, and temperature control. C: None P: None 7. Packaging and Labeling B: Pathogen outgrowth (Salmonella, Campylobacter) Yes Processing could result in product temperatures above 45\u00b0F. CCP 2

includes a measure of the product temperature as the ground turkey is packaged. Written Sanitation program for packaging operation. Yes CCP 2 C: None P: None 8. Storage and Distribution B: Pathogen Outgrowth (Salmonella, Campylobacter) No Pathogen outgrowth may result if temperatures are not maintained at levels to prevent bacterial multiplication. Product is packaged and placed in storage coolers or freezers to prevent product temperatures that promote pathogen outgrowth (Tompkin, R.B. 1996). Written Refrigerated Storage Conditions and Temperatures SOP including controls and verification. Written Cooler Sanitation SOP for cleaning of storage coolers\freezers. Written Product Loading SOP for monitoring truck holding temperature at loading. C: None P: None Written Product Loading SOP for monitoring the cleanliness of the product holding compartment at the time of loading." "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 10 of 12 9. Returned Product B: Pathogen Outgrowth (Salmonella, Campylobacter) No Reinspection SOP implemented before accepting returned product. Person(s) or business returning the product must demonstrate the product was held in the appropriate temperature range and in a sanitary manner. When such assurance is not available, returned product is rejected or destroyed. Opened packages are not accepted. Accepted product enters the appropriate step of the production system based on findings of product evaluation. Notify FSIS personnel when returned product has been accepted. Pathogen outgrowth may result if product temperature was not maintained at levels to prevent multiplication. (Tompkin, R.B. 1996). C: None P: Foreign material No Reinspection SOP implemented before accepting returned product. DATE: APPROVED BY:,"Page 11 of 12 EXAMPLE HACCP PLAN Raw, Non-Intact Turkey Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 1 Antimicrobial Application for Turkey Components24 Pathogens: Salmonella, Campylobacter25 The antimicrobial solution is mixed to an effective concentration of 650-750 ppm (FCN #).26 Solution is applied to all surfaces. Monitor the preparation and mixing of the antimicrobial solution. Assess the solution concentration at the point of application. Observe product during application of the solution. Record observations. Mix solution per manufacturer\u2019s instructions. Use titration kit to check the solution\u2019s antimicrobial concentration. Record observations on the Antimicrobial Check Form The preparation and mixing of the solution is observed once per shift. The concentration is checked once during each two-hour period of production. The application of the antimicrobial dip is observed once per shift. Designee If a deviation from the critical limit occurs, a supervisor will: 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence (9 CFR 417.3) Randomly, once per week, a supervisor observes each monitoring function. Once per week, a supervisor verifies the implementation of corrective actions for each critical limit deviation. Once per shift a supervisor reviews records per (9 CFR 417.4(a)(2)(iii)) Antimicrobial Check form Pre-shipment Records Records Review Form Verification Records Corrective Action Log DATE:

APPROVED: \_\_\_\_\_ 24 FSIS

Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products contains approved substances for use; however, each establishment must validate their own process for efficacy and control of biological hazards. See FSIS Compliance Guideline HACCP Systems

Validation. 25 See the FSIS Guideline for Controlling Campylobacter in Raw Poultry, and the FSIS Guideline For Controlling Salmonella in Raw Poultry for best practices and Campylobacter and Salmonella controls. 26 Scientific or technical support is required to validate the critical limits (parameters) for antimicrobial use, are part of the hazard analysis, and need to be maintained for the life of the HACCP plan (see FSIS Compliance Guideline HACCP Systems Validation).

NOTE: Critical operating parameters need to be addressed in this section as they are related to the scientific justification for use. Critical parameters include but are not limited to the following: type of sprayer, dip, volume, coverage, chemical contact time, solution temperature, etc. Define operational parameters which are specific to each establishment.", "Page 12 of 12 EXAMPLE HACCP PLAN Raw, Non-Intact Turkey Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 2 Packaging and Labeling Pathogen: Salmonella, Campylobacter Temperature of product as it is packaged will be at 40\u00b0F or less. Measure ground product temperature Use a calibrated handheld infrared thermometer to assess product temperature. Two case ready packages each hour during grinding operations. Designee If a deviation from the critical limit occurs, a supervisor will: 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence (9 CFR 417.3) Once per shift, a supervisor will observe the designee measure product temperature. Once per shift, a supervisor will review records. Once per week, a supervisor will calibrate thermometer per manufacturer\u2019s procedures. Pre-shipment Records Review Form Product Temperature Form Thermometer Calibration Form"]}, {"file\_name": "FSIS\_GD\_2021\_0013", "title": "FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B)", "num": "FSIS-GD-2021-

0013", "id": "d4a8b4a9872f02715f696c85b6732058d79a9856aad977b88801ed1aba75a3de", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-12/Appendix-B.pdf", "type": "pdf", "n\_pages": 95, "word\_count": 30300, "text\_by\_page": ["1 This guideline provides information on the Agency regulatory requirements associated with safe production of heat-treated ready-to-eat (RTE) and not-ready-to-eat (NRTE) meat and poultry products with respect to preventing or limiting the growth of spore-forming bacteria and other pathogens. It applies to small and very small meat and poultry official establishments although all meat and poultry establishments may apply the recommendations in this guideline. It relates to 9 CFR 318.17(a)(2), 9 CFR 318.23(c)(1), 9 CFR 381.150(a)(2), 9 CFR 381.150(b), and 9 CFR 417. FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B) December, 2021 Document ID: FSIS-GD-2021-13", "2 FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B) Table of Contents

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Procedures .....78 Attachment B8. Using Journal Articles to Support Alternative Stabilization or Cooling Procedures .....80 Table 15. Time and Temperature Parameters Reported in the Literature for Stabilization Processes..82 Journal Articles not Acceptable without Further Support.....92", "4 Preface This is a revised version of the FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B). It has been updated in response to comments received on the previous version and renamed. In addition, the guideline has been revised to include recommendations from previous versions and new updates based on up-to-date science. The guideline also includes changes to improve its readability. This guideline represents FSIS\u2019s current thinking on these topics and should be considered usable as of its issuance. Establishments that used previous versions of Appendix B as support should either: \u2022 Update to this 2021 FSIS Stabilization Guideline (Revised Appendix B); or \u2022 Identify alternative support by December 14, 2022. The information in this guideline is provided to assist meat and poultry establishments in meeting the regulatory requirements. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to industry regarding existing requirements under the regulations. Under the regulations, meat and poultry establishments may choose to implement different procedures than those outlined in this guideline, but they would need to validate and support how those procedures are effective. This guideline is focused on small and very small plants in support of the Small Business Administration\u2019s initiative to provide small businesses with compliance assistance under the Small Business Regulatory Enforcement Fairness Act (SBREFA). However, all meat and poultry establishments may apply the recommendations in this guideline. It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective Hazards Analysis and Critical Control Point (HACCP) systems. Although large plants can benefit from the information, focusing the guideline on the needs of small and very small establishments provides them with assistance that may be otherwise unavailable to them. Purpose of this Guideline This guideline contains information to assist meat and poultry establishments producing products that undergo cooking in complying with the HACCP regulatory requirements in 9 CFR 417. This guideline includes information on: \u2022 Biological hazards during stabilization. \u2022 Regulatory requirements associated with the safe production of stabilized heat-treated and partially heat-treated products. \u2022 Options establishments can use to prevent the growth of *C. perfringens* and other pathogens." "5 \u2022 Processes that do not have validated research available (Scientific Gaps), and options establishments can use until research is available. \u2022 Recommendations for evaluating cooling deviations. \u2022 Resources for alternative support. Establishments can always seek guidance from State university extension service specialists and HACCP Coordinators on developing programs and plans not provided in this guideline to comply with HACCP regulatory requirements. History of this Guideline and Reason for Reissuance In the 1980s, FSIS included prescriptive time and temperature cooling parameters in the regulations for cooked beef, roast beef, and cooked corned beef in response to several outbreaks associated with these products and research performed to determine how to prepare them safely (47 FR 31854; 48 FR 24314). When the Pathogen Reduction/\ Hazard Analysis and Critical Control Points (PR\HACCP) final rule published in 1996 and included performance standards for the production of certain meat and

poultry products, FSIS eliminated the prescriptive cooling regulations (to allow no growth of *C. botulinum* and no more than 1 log multiplication of *C. perfringens*; 9 CFR 318.17(a)(2), 9 CFR 318.23(c)(1), and 9 CFR 381.150(a)(2)). FSIS converted these former regulations to optional \u201cSafe Harbors\u201d in an appendix to the final rule called \u201cAppendix B\u201d (64 FR 732). Establishments have been using FSIS\u2019s Appendix B, as published in 1999, as support for cooling processes for many years. The original requirements and subsequent guidance have been important to prevent human illness outbreaks and ensure the production of safe food. Over time, FSIS determined that some of its recommendations in the 1999 version of Appendix B were vague, putting establishments at risk of producing unsafe products.

Additionally, some elements of the 1999 version of Appendix B guidance were misunderstood or overlooked, resulting in FSIS guidance being applied in ways that increased food safety risks to consumers and potential risks to industry, including the risk of recalls. FSIS also determined establishments were broadly applying the recommendations for operating parameters in Appendix B beyond those meat and poultry products it was originally designed to support. To provide the needed updates and clarifications, FSIS issued revisions of both its Cooking (revised Appendix A) and Stabilization (revised Appendix B) guidelines in 2017. The 2017 versions of the guidelines took into account new and emerging technologies, processes, and science. FSIS also expanded the information included in Appendix B beyond cooling to include other methods of stabilization. FSIS has updated this guideline in response to comments received on the 2017 version and has included additional options for cooling and hot-holding stabilization support based on updated science and technology. The Agency is releasing this current 2021 version of the Stabilization Guideline for Meat and Poultry Products (Revised Appendix B) to replace all previous versions."

"6 Changes from the Previous Versions This guideline dated December 14, 2021 is final. FSIS will update this guideline as necessary should new information become available. FSIS made the following changes to this guideline to reflect the comments received on the previous version during the comment period for the previous version and to include additional scientific information. For Appendix B, FSIS made changes to specify:

\u2022 Cooling options for both RTE and NRTE products that are cooked to lethality are included in Table 1 and incorporate the previous options, 1, 2, 3 and 4 as options 1.1, 1.2, 1.3 and 1.4.

\u2022 Cooling options for partially cooked products are included in a separate table (Table 2) and include former Option 1 as Option 2.1.

\u2022 Tables 1 and 2 list the critical operating parameters for each option.

\u2022 One additional option for partially cooked products, Option 2.2.

\u2022 That cooling in stage 1 of option 1.2 from 120 to 80 \u00b0F should occur in 1 hour.

\u2022 That the heating come-up-time (CUT) in Option 2.1 for partially cooked products should be limited to 1 hour between 50 and 130\u00b0F. FSIS extended the CUT up to 3 hours in Option 2.2 for partially cooked products, if the product meets the critical operating parameters for concentrations of salt, nitrite, and a cure accelerator sufficient for purpose.

\u2022 New options 1.5 \u2013 1.8 that provide additional cooling time during the first stage of cooling.

\u2022 That to use Option 1.3, establishments should incorporate at least 250 ppm sodium erythorbate or ascorbate, along with at least 100 ppm ingoing sodium nitrite (either from a purified or natural source such as celery powder).

\u2022 That natural sources of nitrite and ascorbate should not be mixed with purified or synthetic sources.

\u2022 FSIS removed the recommendation to cool from 120 to 80 \u00b0F in 2 hours in Option 1.4 and replaced it with the critical operating parameter that the process cause a continuous drop in product

temperature. To support all the cooling options, additional research and modeling results using up-to-date validated cooling models are included in Attachment B3. FSIS' Predictive Microbial Modeling Support for 1-Log Cooling Options (page 50).<sup>7</sup> To support common bacon and scrapple processes, FSIS updated references to research in Attachment B8. Using Journal Articles to Support Alternative Stabilization or Cooling Procedures (page 80) to address comments requesting support for these processes. Practical recommendations for improving product cooling in Attachment B4. Steps an Establishment Can Take to Cool Products More Rapidly. Where gaps exist (See Scientific Gaps as indicated in Table 3 (page 29)), recommendations from its older cooling guidance can be used until research is completed for: 1. Large mass non-intact products that cannot cool quickly enough to follow the new options in Table 1. 2. Partially heat-treated, smoked products that contain nitrite and erythorbate or ascorbate and have long heating come-up and cooling times and cannot follow the options in Table 2. 3. Smoked bacon that contains nitrite and erythorbate/ascorbate that cannot use Option 1.3 because lethal time and temperature combination is achieved but relative humidity is not addressed. 4. Immersion or dry-cured products that contain nitrite and use equilibration time instead of erythorbate or ascorbate but cannot meet cooling options without nitrite in Table 1 (for products cooked to full lethality) or Table 2 (for products not cooked to full lethality). 5. Products that contain nitrite and use equilibration time instead of erythorbate or ascorbate, but do not have a brine concentration of 6% to meet Option 1.4. 6. Scalded offal that cannot cool quickly enough to follow the new options in Table 2. For Appendix B, FSIS removed: Specific recommendations for obtaining a waiver to permit 2-Log growth of *C. perfringens* during cooling. This information was removed since it was interpreted to apply to all establishments when it was only intended for establishments that wanted to support a lower level of spores in their source product. In addition, FSIS has not received any waiver requests, but establishments may request a waiver in the future (9 CFR 303.1(h) and 9 CFR 381.3(b)). In addition to these changes, the guidelines format was restructured to make it easier to use as described in the next section.<sup>8</sup> How to Effectively Use this Guideline As explained above in the Changes from the Previous Versions, the guidelines format was restructured to make it easier to use. Specifically, the guideline is organized to include the following topics in the body of the guideline: Biological hazards during stabilization. Regulatory requirements associated with the safe production of stabilized heat treated and partially heat-treated products. Options establishments can use to prevent the growth of *C. perfringens* and other pathogens. Processes that do not have validated research available (Scientific Gaps), and options establishments can use until research is available. Recommendations for evaluating cooling deviations. Resources for alternative support. Information included in the body of the guideline is intended as scientific support that can be used alone by establishments to meet Element 1 of validation (9 CFR 417.4(a)(1)) and to support decisions in the hazard analysis (9 CFR 417.5(a)(1)). The following topics are included in Attachments to the guideline: Resources for alternative support. Recommendations for evaluating cooking deviations. Information provided in the attachments is not sufficient to use as sole support and additional documentation is needed. For example, this guideline contains attachments with summaries of scientific articles. However, the summaries are not considered adequate support on their own because they do not contain the details of each study. For this reason, establishments must have the full copy of

the article on-file as scientific support for their HACCP System. The summaries are provided to help establishments identify journal articles related to their process. Each establishment needs to determine if the operating parameters of a particular study match the establishment's process. Establishments are not limited to using the scientific articles listed and summarized as support. In addition, the guideline contains recommendations for evaluating product safety in the event of a deviation. This information is not considered adequate support on its own because establishments should perform predictive microbial modeling and may conduct sampling and testing to support product disposition. Other information included in attachments is intended to be supplementary.", "9 Questions Regarding Topics in this Guideline If after reading this guideline you still have questions, FSIS recommends searching the publicly posted Knowledge Articles (\u201cPublic Q&As\u201d) in the askFSIS database. If after searching the database, you still have questions, refer them to the Office of Policy and Program Development through askFSIS and select HACCP Deviation & HACCP Validation as the Inquiry Type or by telephone at 1-800-233-3935. Documenting these questions helps FSIS improve and refine present and future versions of the guideline and associated issuances.", "10 FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B) Background What is Stabilization? Stabilization is the process of preventing or limiting the growth of spore-forming bacteria capable of producing toxins either in the product or in the human intestine after consumption (See Attachment B1. Characteristics of Clostridial pathogens page 41 for more information about spore-forming bacteria). Establishments may use a variety of different stabilization processes, such as: \u2022 Cooling. \u2022 Hot-holding (e.g., hot-holding of soups prior to hot-fill packaging). \u2022 Meeting and maintaining certain pH, % brine (salt) concentration in the product, or water activity levels. Stabilization is an important food safety control of the growth of pathogens in food products. Products and Processes Covered by this Guideline This guideline addresses stabilization of meat and poultry products after a full or partial heat treatment is applied. Establishments may use FSIS Cooling Options in Table 1 for products that do not contain nitrite and erythorbate or ascorbate (i.e., Options 1.1., 1.2. 1.5-1.8), including for cooling of rice, pasta and bean products (see FSIS Support for Application of Options 1.1, 1.2, 1.5-1.8 to Rice, Pasta, and Beans page 61). Products Not Covered by this Guideline Fish of the order Siluriformes (e.g., catfish) are considered meat under the FMIA. However, fish of the order Siluriformes and fish products are not covered by this Stabilization Guideline because the options in the KEY DEFINITIONS Stabilization is the process of preventing or limiting the growth of spore-forming bacteria capable of producing toxins either in the product before consumption or in the human intestine after consumption. Establishments may use a variety of different stabilization processes, such as cooling, hot-holding, and meeting and maintaining certain pH or water activity levels. Bacterial spores are dormant cells that can survive environmental conditions that would normally kill bacteria. These conditions include high temperature, high UV irradiation, desiccation, chemical damage, and enzymatic destruction. The extraordinary resistance to such stresses makes spores of particular importance because they are not readily killed by many antimicrobial treatments, including traditional cooking.", "11 guideline have only been validated for livestock products. Establishments may use FDA's Fish and Fishery Products Hazards and Controls Guidance or Section 3-501.14 Cooling of the 2017 FDA Food Code as support for cooling of fish of the order Siluriformes. Cooling guidance found in the FDA Food Code is discussed further in

Attachment B6. Other Published Processing Guidelines for Cooling page 77. For more information on FSIS\2019 regulatory requirements related to fish of the order Siluriformes see FSIS Compliance Guideline for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products. Biological Hazards of Concern During Stabilization The following section is designed to complement FSIS\2019 Meat and Poultry Hazards and Control Guide and to further assist establishments in conducting a hazard analysis for heat-treated meat and poultry products as required by 9 CFR 417.2(a)(1) and for supporting decisions in the hazard analysis as required by 9 CFR 417.5(a)(1). The primary hazards of concern during cooling and hot holding are: \u2022 C. perfringens and \u2022 C. botulinum. Clostridia are Gram-positive, rod-shaped, spore-forming bacteria that can occur as either vegetative cells (active cells that can grow, multiply and produce toxin) or spores (dormant cells that are resistant to heat and other extreme conditions). Vegetative cells can produce spores and spores can germinate back into vegetative cells. Clostridia (both vegetative cells and spores) are usually found in soil and water. These are anaerobic organisms; in other words, they can grow without oxygen. Clostridia do not grow well in the presence of normal amounts of oxygen; however, they do not need a complete lack of oxygen to grow well. This is an important consideration for establishments as they assess hazards, design processes, and assess supporting documentation to prevent Clostridia growth and spore formation because it would not be appropriate to assume that Clostridia are not a hazard of concern just because oxygen is present. Even products that are exposed to oxygen may support Clostridia growth. Meat and poultry products may become contaminated with Clostridia during the slaughter and dressing process and by cross-contamination in the processing environment when insanitary conditions are present. Added ingredients, such as spices and herbs can contribute to the amount of Clostridia spores in raw formulated cooked\heat-treated meat and poultry products. For example, in one survey, C. perfringens spores were isolated from 80% of 54 different spices and herbs (Juneja and Sofos, 2010).", "12 Why Clostridia Spores Survive Cooking As explained above, raw meat and poultry products may become contaminated with Clostridia spores and vegetative cells. Heating meat and poultry products to full lethality (cooking) is generally sufficient to destroy vegetative cells; however, under these same conditions, spores may survive cooking and multiply during cooling when the conditions favor their growth (Figure 1). The destruction of vegetative cells (from Clostridia as well as bacteria such as Salmonella, Shiga toxin-producing Escherichia coli (STEC), and indigenous microflora) during heat treatment leaves little competition for the sporeforming pathogens to grow during cooling. Anaerobic, non-refrigerated conditions facilitate multiplication and growth of spore-forming pathogens. If cooling is rapid, growth can be limited to safe levels. However, if cooling is slow, excessive growth may occur. Similarly, situations where meat and poultry products cooked without reaching full lethality and then cooled could create an ideal environment for growth of C. perfringens and C. botulinum. This is because cumulative growth can occur over the course of the partial heating and cooling steps. Cooking by the consumer, retailer, or other end user may not eliminate these bacteria or the toxins that form in meat and poultry products especially if they grow to high levels. Therefore, it is important that an establishment producing meat and poultry products control bacterial growth in the products, to the extent possible, before they reach the end user or consumer. Figure 1. Schematic depicting how spores can form, germinate, and grow in meat and poultry products after heat is applied. C. perfringens and C. botulinum form spores that can survive cooking.

Spores can germinate and grow during cooling. Cooling products quickly, will limit pathogen growth and keep food safe.", "13 General Considerations for Designing HACCP Systems to Control the Growth of Clostridia Stabilization in the HACCP System FSIS has established performance standards in the regulations for the stabilization of specific heat-treated products as listed in Attachment B2. FSIS Stabilization Performance Standards or Targets for Clostridia Growth (page 47). These performance standards establish permissible levels of growth of spore-forming bacteria allowed during stabilization. \u2022 RTE cooked beef, RTE roast beef, RTE cooked corned beef must be stabilized to allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens* to comply with 9 CFR 318.17(a)(2). \u2022 RTE uncured beef patties must be stabilized to allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens* to comply with 9 CFR 318.23(c)(1). \u2022 RTE cooked poultry must be stabilized to allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens* to comply with 9 CFR 381.150(a)(2). \u2022 NRTE partially cooked and char-marked meat patties and partially cooked poultry breakfast strips must be stabilized to allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens* to comply with 9 CFR 318.23(c)(1) and 9 CFR 381.150(b). For products that are not subject to a performance standard, FSIS recommends the following pathogen Log reductions (i.e., targets) be achieved in order to support decisions in the hazard analysis (9 CFR 417.5(a)(1)): \u2022 For other NRTE, heat-treated meat and poultry products, FSIS recommends establishments allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens*. KEY DEFINITIONS Performance standards described in this guideline are quantifiable pathogen growth limit requirements set by FSIS for the stabilization of certain meat and poultry products. Targets described in this guideline are quantifiable pathogen growth limits set by the establishment to produce safe products in the absence of regulatory performance standards. Critical operating parameters are those parameters of an intervention that must be met for the intervention to operate effectively and as intended. Such parameters may include but are not limited to time, temperature, water activity, concentration, relative humidity, and type of equipment (to the extent that the use of different equipment would result in an inability to achieve the critical operating parameters of the study).", "14 An establishment should identify the performance standard (for products subject to the standard) or specific Log growth target (for other heat-treated products) its process is designed to achieve as part of its HACCP plan or supporting documentation to meet record-keeping requirements (9 CFR 417.5(a)(1)). In addition, according to 9 CFR 417.2(c)(3), establishments must design their critical limits for the critical control points (CCPs) to meet all applicable performance standards or targets. NOTE: If an establishment uses the stabilization options from this guideline, it does not need to indicate the specific Log growth that its process achieves in its HACCP plan or supporting documentation. It would be sufficient for the establishment to indicate that it uses the critical operating parameters from this guidance document. CCPs versus Prerequisite Programs Establishments have flexibility regarding how they address critical operating parameters in their HACCP systems. \u2022 If a critical operating parameter is addressed as part of a CCP, the establishment is required to list the critical limits (9 CFR 417.2(c)(3)), and support the monitoring procedures, and frequencies chosen for monitoring each CCP to ensure

compliance with the critical limits (9 CFR 417.2(c)(4) and 9 CFR 417.5(a)(2)). Establishments are required to calibrate process-monitoring instruments as part of ongoing verification activities (9 CFR 417.4(a)(2)). Furthermore, establishments are required to support their verification procedures and frequencies of those procedures per (9 CFR 417.5(a)(2)). \u2022 If a critical operating parameter is addressed in a prerequisite program, and the establishment determines that the implementation of that program results in potential hazards being not reasonably likely to occur, then it must have supporting documentation for the decisions made in the hazard analysis (9 CFR 417.5(a)(1)). If the establishment does not include the critical operating parameters in its HACCP plan or one or more prerequisite programs and has no documentation to show why they are not needed in its processes, FSIS will likely find that the establishment is not meeting the recordkeeping requirements of (9 CFR 417.5(a)(1)). Validation, Monitoring, Calibration, and Recordkeeping It is important the establishment\u2019s cooling procedures are designed to ensure all products limit the growth of spore forming pathogens and for the monitoring procedures to be designed to detect a deviation when it occurs. To achieve this, establishments should carefully consider the selection of the critical limit as well as the design of their monitoring procedures. Establishments are required to validate that their HACCP system works as intended to address these hazards (9 CFR 417.4(a)). For more information on validation see the, FSIS Compliance Guideline HACCP Systems Validation. To understand the situations", "15 when both RTE and NRTE products would be considered adulterated due to Clostridia outgrowth under the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA), refer to Attachment B2., subsections: What is the public health concern of *C. perfringens* and *C. botulinum* in RTE Products? (page 48) and What is the public health concern of *C. perfringens* and *C. botulinum* in NRTE Products (page 49). Below are specific considerations for monitoring the critical operational parameters of product temperature. \u2022 While cooling is a continuous process, FSIS recommends that establishments monitor temperature in two distinct temperature intervals, called stages, to better document pathogen control. This does not mean that cooling starts and stops at each of these stages. However, monitoring is performed at two different points. The first stage of cooling corresponds to the optimal growth temperatures for pathogens of concern (see Appendix B1. Subsection: Product Characteristics that Affect Clostridia Growth, page 42). Reducing time that the product spends in the first stage of cooling provides greater pathogen control. The second stage of cooling takes the product temperature down to the point where pathogens cannot grow, so it needs to be monitored as well. \u2022 FSIS recommends establishments measure the temperature of the product throughout cooling. If the scientific support in their validated system identifies multiple stages of cooling, establishments must ensure product is chilled to meet the time limit for each stage. During initial validation, establishments should initially gather sufficient time-temperature data to understand the rate of temperature change in each stage of cooling. For example, the establishment should determine whether the product cools down quickly at first and then takes longer as the process continues, or if it cools at the same rate throughout the entire process. The rate of temperature change throughout cooling can have a significant impact on the amount of growth of *C. perfringens* and *C. botulinum*. Even if two processes take the same total amount of time to chill product when the product starts at the same temperature, if the cooling rate is different, then KEY QUESTION Question: Are establishments required to use this Stabilization Guideline as support for cooling meat and poultry products?

Answer: No. Establishments are NOT required to use this guideline as scientific support for cooling and stabilization processes. Establishments may choose to adopt different procedures than those provided in the guideline; however, they would need to support that those procedures are effective to meet validation requirements and support decisions in their hazard analysis (9 CFR 417.4(a)(1) and 9 CFR 417.5(a)(1)). A few resources that may be used as alternative support for cooling processes have been included in this guideline, see Customized Processes and Alternative Support (page 26). (pag26)." "16 the amount of pathogen growth can vary significantly. FSIS recommends establishments gather time-temperature data in 15- to 30-minute increments when the product temperature is between 130\u00b0F and 80\u00b0F. The time-temperature data should be in 30- to 60-minute increments when the product temperature is between 80\u00b0F and final temperature (40\u00b0F or 45\u00b0F depending upon the option used). o This is particularly important for FSIS Option 1.2, since *C. perfringens* grows fastest at temperatures between 120 and 80\u00b0F. However, establishments are not required to demonstrate that every lot of the product is chilled from 120 to 80\u00b0F in one hour or less, if data is gathered during initial validation and as part of ongoing verification to support a reduced monitoring frequency (see FSIS HACCP Systems Validation Guideline). o If establishments choose not to measure each stage of cooling, they should recognize that a deviation may affect additional product and pathogen modeling may not be an available option to determine product disposition. \u2022 In addition, as part of the initial validation, FSIS recommends that the establishment use worst-case scenarios to ensure that the product will meet the critical operating parameters on an ongoing basis. Conditions affecting consistent cooling include: o Size, shape, and weight of product; o Stacking\storage in the cooler and the amount of product in the cooler; \u2022 For example, a relatively empty cooler might not cool at the same rate as an overfilled cooler. o Air velocity and initial temperature of the cooler\freezer; and o Product composition (e.g., fat level and moisture content). Worst-case scenarios should take into account all of these factors (i.e., largest size or weight product, fullest cooler, highest initial cooler temperature, etc.). For more information on factors that affect product cooling rate, see Attachment B4. Steps an Establishment Can Take to Cool Products More Rapidly (page 63). Establishments producing stabilized meat and poultry products are required to have sufficient monitoring equipment, including recording devices, to assure that the critical operating parameters of the stabilization processes\u2014including time, temperature, and pre-cooling conditions\u2014are being met (9 CFR 417.5(a)(2)). The establishment should take the normal variation of the monitoring equipment into account when designing the critical limits. For example, if a minimum internal temperature of 140\u00b0F is necessary to control pathogen growth while hot-holding a product and the thermometer has an accuracy of \u00b1 2\u00b0F, the critical limit should be set no lower than 142\u00b0F. The written reasoning and equipment specification materials are required to be kept as part of the establishment\u2019s supporting documentation (9 CFR 417.5(a)(2)). In addition, establishments are required to maintain documents supporting the selection of monitoring procedures and associated frequencies (9 CFR 417.5(a)(2)). It is important that establishments take into account variation within the cooling process", "17 when developing monitoring procedures to ensure they are sufficient to identify any deviations. Ultimately, the establishment should ensure that the whole HACCP system is operating as intended to produce a safe and wholesome product. Product Characteristics and Processes to Control Clostridia

**Growth** Several factors affect the growth of *C. perfringens* and *C. botulinum* during stabilization. These include the: \u2022 Product time-temperature profile. \u2022 pH. \u2022 % brine concentration in product. \u2022 Type and concentration of phosphates (wt\wt basis). \u2022 Water activity (aw). \u2022 Type and concentration of organic acid salts (e.g., lactate\diacetates and others). \u2022 Ingoing sodium nitrite and erythorbate or ascorbate concentrations. For more information on these factors\u2014including the use of natural sources of nitrite and ascorbate\u2014which effect Clostridia species growth see Attachment B1. Characteristics of Clostridial Pathogens (page 41). Much of the scientific support establishments can use to validate their process will include one or more of these factors. For more information on scientific support see FSIS Options for Stabilization (page 21) or Customized Processes and Alternative Support (page 27) of this guideline.", "18 FSIS Critical Operating Parameters for Stabilization (Revised Appendix B) Establishments have many options for the types of scientific support documentation that can be used to demonstrate that their stabilization process results in acceptable levels of Clostridia growth. Product characteristics (e.g. pH) and specific cooling schedules (e.g. Appendix B cooling options) are commonly used as critical limits. Product sampling results may not be used as scientific support for a stabilization process, because these results do not provide information regarding the level of growth allowed by the process. NOTE: FSIS is aware that several common processes cannot achieve the critical operating parameters in this guideline and scientific research is not readily available to support several common processes. For information on these processes\resultant products see Scientific Gaps Identified by FSIS (page 27) of this guideline. **Product Characteristics as Critical Limits** If heat-treated meat and poultry products are produced in a manner such that the final product has a certain specific characteristic or characteristics, then the growth of Clostridia is inherently inhibited; see Attachment B1. Characteristics of Clostridial Pathogens page 41 of this guideline. Establishments may use any one of the specific characteristics listed below as a sole critical limit to demonstrate Clostridia outgrowth is controlled provided, the characteristic is achieved before cooling: \u2022 pH: pH of 4.6 or less; or \u2022 Brine Concentration in Product:10% or more; or \u2022 Water activity (aw): A water activity of 0.92 or less. **KEY DEFINITIONS** Brine Concentration is a measure of the amount of salt in the water phase of the product. Brine concentration can\u2019t be determined by the formulation; it is a value calculated from the total salt content and total water content values obtained by a lab analysis. %

Processing Inspectors\u2019 Calculations Handbook Chapter 14 for more information.";"19 To use any of the above characteristics as a critical limit, it is very important that the product achieves the target value quickly, throughout the entire product, and before cooling.

Establishments that use a marinade or other solution to lower the pH of their product should be aware that it can take time for the product to equilibrate (balance) to the pH of the solution. If a product takes too long to equilibrate, significant growth of *C. perfringens* and *C. botulinum* can occur (see Chitterlings Example below). Establishments that use pH or aw as critical operating parameters for stabilization, may still need to cool their product in a timely manner (i.e., continuously) depending on the final pH or aw. Products that use low pH for stabilization should ensure the product has equilibrated prior to cooling. If the product cannot be equilibrated prior to cooling, then the product should be cooled using different scientific support such as one of the cooling options in this guideline. Establishments that choose to stabilize through reduced water activity after a cooking lethality treatment should ensure that product temperature remains at 140°F or higher until water activity decreases below the growth limit of *Clostridium perfringens* and *Clostridium botulinum* (< 0.93) to prevent outgrowth as discussed. Establishment may be able to monitor oven temperatures in lieu of product temperature as discussed in the 2020 Cooking Guideline. Product stabilized by one of these characteristics should be cooled continuously because the products could become contaminated with *Listeria monocytogenes* (Lm) or *Staphylococcus (S. aureus)* during cooling, and these pathogens may be able to grow in the product depending on the final pH or aw. For example, while *C. perfringens* and *C. botulinum* cannot grow in products with an aw < 0.93, *S. aureus* can grow in products stored aerobically with an aw as low as 0.86 (ICMSF, 1996). If FSIS collects a RTE sample that is positive for Lm during cooling, FSIS will verify whether the establishment has identified and eliminated the root cause of the incident as part of corrective actions (9 CFR 417.3(b)) and that the establishment can still support its cooling procedure.

Importance of Achieving target pH or water activity before cooling: Chitterlings Example FSIS verification activities have identified a trend in establishment sampling results that show high levels of *C. perfringens* (2 to 4-Log CFU/g) in chitterlings that establishments try to stabilize using low pH brine. FSIS analyses uncovered a recurring incorrect assumption by establishments that the pH of the chitterlings is reduced to 4.6 as soon as the brine is added to the hot

chitterlings, when it actually may take several hours for the pH to be reduced, during which time the product is cooling and outgrowth of *C. perfringens* is occurring. As stated above, products should achieve a pH  $\geq 4.6$  before cooling to achieve food safety control. These findings are important because the levels of *C. perfringens* found through testing indicate growth may occur at a level of public health concern when FSIS's critical operating parameters are not followed." "20 FSIS Hot-Holding Options Hot-holding is the process of holding meat and poultry products that have been cooked to full lethality at hot temperatures (typically above  $130^{\circ}\text{F}$ ) prior to distribution. Often, products such as meals or meat pies are held at hot temperatures and then shipped hot to customers (either consumers or to retailers, such as convenience stores) for immediate consumption. Soups may also be hot-held prior to hot-filling into the final packaging. FSIS is including in this guideline recommendations for hot-holding that were previously found in FSIS Directive 7110.3 Time\Temperature Guidelines for Cooling Heated Products, which has been cancelled. Hot-holding Temperatures Uncured cooked products should be held for: Up to 4 hours if kept above  $130^{\circ}\text{F}$ , or An extended period if kept above  $140^{\circ}\text{F}$ . If product drops below  $130^{\circ}\text{F}$  for over 30 minutes, the processor should: Continuously cool it to meet the critical operating parameters of the chosen support document, immediately reheat it to  $160^{\circ}\text{F}$ , or Discard it. NOTE: Establishments should choose a hot holding critical operating temperature above  $140^{\circ}\text{F}$  unless they have established consistent temperature control over every portion of the product. Thus, establishments should maintain product above  $140^{\circ}\text{F}$  when in transit, in the absence of container temperature monitoring, and in similar cases where control procedures are not established and monitored. Establishments should also have ongoing communication with the retailer to support that the product is being hot-held appropriately. Intermediate Holding Temperatures Occasionally, some establishments will need to hold product at an intermediate temperature ( $< 60^{\circ}\text{F}$ ) prior to completion of cooling. When this occurs, FSIS recommends: Products are heated above  $155^{\circ}\text{F}$ , then promptly cooled from  $130^{\circ}\text{F}$  to  $60^{\circ}\text{F}$  within 2 hours. These products may be held for up to 4 hours, if they are: Kept below  $60^{\circ}\text{F}$  during the 4 hours, Protected from post-cooking contamination, and At the end of the 4-hour holding period, are cooled to  $40^{\circ}\text{F}$  within 2 hours." "21 FSIS Cooling Options Tables 1 and 2 summarize all of the FSIS cooling options that limit the growth of *C. perfringens* to  $\leq 1.0\text{-Log}_{10}$  colony forming units per gram<sup>1</sup> (CFU/g) and allow for no multiplication of *C. botulinum*. These options are intended for products that are cooled in a continuous manner and do not apply to processes where cooling starts and stops multiple times or processes where the product is cooked to a full lethality, cooled, and then partially heat-treated and cooled again. For processes with multiple heating steps, FSIS recommends establishments use microbial modeling to design custom cooling schedules as described in Attachment B5. Predictive Microbial Modeling (page 64). Gray boxes in Tables 1 and 2 are parameters that changed from the 1999 version of Appendix B or are new. The food safety significance of these changes is explained on page 28 of this guideline. FSIS considers the cooling options in Tables 1 and 2 to be validated process schedules.2 Establishments that struggle to meet any of the cooling options in Tables 1 and 2 may find Attachment B2. Stabilization Requirements for Specific Meat and Poultry Products (page 47) useful. Other establishments may use processes that FSIS has identified as a Scientific Gap (page 27). Further information about using FSIS's Cooling Tables is included below. 1 In

the rest of this document, Log<sub>10</sub> colony forming units per gram (Log<sub>10</sub> CFU/g) will be annotated simply as \u201cLog.\u201d All notations of \u201cLog\u201d should be read as in the unit Log<sub>10</sub> CFU/g unless other information is provided.

2 The scientific research and data used to develop each option is included in Attachment B3. FSIS\u2019 Predictive Microbial Modeling Support for 1-Log Cooling Options, page 68. Importance of Pathogen Modeling for Multiple Cooling Steps: Tamales Example Many establishments produce a meat or poultry product that involves multiple heating and cooling steps. One example is an establishment that will cook meat to lethality and then cool the meat product. During that first cooling, *C. perfringens* may grow up to 1-Log. The establishment will then reheat the meat product, such as a tamale filling. The tamale with the filling will be heated and then cooled. Spore-forming pathogens, already at 1-Log of growth from the first cooling will then have the opportunity to grow during non-lethal reheating and the 2nd cooling. This could result in sufficient growth to create a public health concern. Establishments that choose to reheat a meat or poultry product may be able to design the process so that the cumulative growth from all of the heating and cooling steps is less than 1-Log. In order to design a process with multiple heating and cooling steps, FSIS recommends the establishment use predictive microbial models. For more information on how to perform predictive microbial modeling for multiple cooling steps see the Section titled Using Predictive Microbial Models to Assess Growth of Clostridia when a Process Incorporates Multiple Heat Treatments page 69 of this guideline.", "2 To Use FSIS Cooling Tables 1 and 2: First, choose the applicable table. Table 1 should be used if the product is cooked to full lethality (RTE or NRTE). \u2022 Cooked to full lethality refers to achieving lethality following validated critical operating parameters such as those in the FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A). FSIS recognizes that products may continue to be cooked for longer dwell times or to higher temperatures for quality reasons. To apply Table 1, the establishment must support that its products meet all critical operating parameters from their chosen scientific support for cooking to lethality. For example, if the supporting document is the FSIS Cooking Guideline, the cooking process must address relative humidity and come-up-time (CUT), in addition to internal endpoint time-temperature. \u2022 Products that receive a lethality treatment that achieves sufficient Log reduction of *Salmonella* may be classified as RTE or NRTE as long as they are not defined by a standard of identity as a RTE product. For more information on product reclassification see Attachment 1.2 on pages 22-23 and Appendix 1.2 on pages 28-29 of the 2014 FSIS Compliance Guideline: Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products. Table 2 should be used if the product does not receive a full lethality treatment (NRTE). \u2022 Many products may be heated during processing to temperatures that do not achieve full lethality. These products are also referred to as partially heat-treated. Examples include smoked breakfast sausages, smoked pork bellies, and par-fried breaded patties or nuggets (cooked enough to set the breading). \u2022 Table 2 includes heating CUT as a critical operating parameter to control the cumulative outgrowth of *C. perfringens* and *C. botulinum* during the entire process, since any pathogen growth during heating will not be eliminated due to the lack of a full lethality time-temperature (See Why Clostridia Spores Survive Cooking page 12). Second, choose the option that matches the process, and follow all critical operating parameters. \u2022 To use the FSIS Cooling Options as support for decisions in the hazard analysis, establishments must follow all critical operating parameters in the chosen option. If an

establishment does not follow all critical operating parameters of an option, it should provide support for why that option should still limit growth of *C. perfringens* to 1.0-log and allow for no multiplication of *C. botulinum*.<sup>1,2</sup> Temperatures referred to in Tables 1 and 2 are internal product temperatures. However, establishments may provide support for monitoring surface temperatures of intact products (such as beef brisket or a picnic shoulder that is not injected or vacuum tumbled). The internal temperature of product that is deboned and rolled or non-intact should be taken at the coldest point of the product interior (See Key Definitions to the right for an explanation of intact vs. non-intact). Monitoring for cooling is performed at two different points. The first stage of cooling is the most important for stabilizing the product, as it is the optimal growth temperature for pathogens of concern. If an establishment can shorten the time it takes to complete the first stage of cooling, the establishment may add the remaining time to the second stage of cooling. However, the total cooling time would remain the same as the original option. For helpful tips on how to cool products faster, refer to Attachment B4. Steps an Establishment Can Take to Cool Products More Rapidly (page 63). In the event that a process deviates from FSIS's Cooling Options, the establishment may use its monitoring records to perform predictive microbial modeling to develop support for product disposition. For more information see Attachment B5. Predictive Modeling, subsection Corrective Actions to Perform When a Cooling Deviation Occurs, page 71.

**KEY DEFINITIONS** Intact refers to products where the interior remains protected from pathogens migrating below the exterior\outside. Non-Intact refers to products where pathogens may have been introduced below the surface. Examples include products that have been mechanically tenderized or vacuum tumbled. Come-up-time (CUT) refers to the amount of time product temperature is between 50 to 130°F while heating.<sup>3,4,5</sup> Table 1. FSIS Cooling Options for Products Cooked to Full Lethality

Option	1.1	1.2	1.3	1.4	1.5	1.6	1.7
1st stage of cooling (temperature reduction\time)	130 to 80°F / 1.5 hours	80 to 40°F / 5 hours	130 to 80°F / 6.5 hours	130 to 80°F / 15 hours	130 to 80°F / 10 hours	126 to 80°F / 7 hours	126 to 80°F / 6.5 hours
2nd stage part of cooling (temperature reduction\time)	80 to 40°F / 1 hour	80 to 40°F / 5 hours	80 to 40°F / 6 hours	80 to 40°F / 20 hours	80 to 40°F / 5 hours	80 to 40°F / 3.25 hours	80 to 55°F / 3.75 hours
Total cooling time	130 to 80°F / 1.5 hours	80 to 40°F / 5 hours	130 to 80°F / 6.5 hours	130 to 80°F / 20 hours	130 to 80°F / 5 hours	126 to 80°F / 3.25 hours	126 to 80°F / 3.75 hours
Chilling must begin within	90 minutes after the cooking cycle is complete	90 minutes after the cooking cycle is complete	90 minutes after the cooking cycle is complete	90 minutes after the cooking cycle is complete	90 minutes after the cooking cycle is complete	90 minutes after the cooking cycle is complete	90 minutes after the cooking cycle is complete
pH	6.0	6.0	6.0	6.0	6.0	6.0	6.0
aw	0.92	0.92	0.92	0.92	0.92	0.92	0.92
Na	120 to 40°F / 20 hours	120 to 40°F / 5 hours	120 to 40°F / 6 hours	120 to 40°F / 20 hours	120 to 40°F / 5 hours	120 to 40°F / 3.25 hours	120 to 55°F / 3.75 hours
Options	1.1	1.2	1.3	1.4	1.5	1.6	1.7

5 FSIS's Scientific Support and references used to develop these options can be found in (Attachment B3. FSIS's Predictive Microbial Modeling Support for 1-Log Cooling Options,

page 68). 6 Nitrite and erythorbate\ascorbate may be added using natural or synthetic sources (page 45). 7 This option does not require a cure accelerator due to the high brine concentration inhibiting spore outgrowth. Nitrite is optional if the product has a aw \u2264 0.92.","25 Table 2. FSIS Cooling Options for Products that Do NOT Receive a Full Lethality8,9 Option Critical Operating Parameters Pre-Cooling Conditions 1st stage of cooling 2nd stage of cooling Total cooling time Option 2.1 CUT between 50- 130\u00b0F \u2264 1 hour 130 to 80\u00b0F \u2264 1.5 hours 80 to 40\u00b0F \u2264 5 hours \u2264 6.5 hours Option 2.2 CUT between 50- 130\u00b0F \u2264 3 hours; and \u2265 2% salt; and \u2265 150 ppm sodium nitrite10 and cure accelerator or natural source of ascorbate (sufficient for purpose) 130 to 80\u00b0F \u2264 1.5 hours 80 to 40\u00b0F \u2264 5 hours \u2264 6.5 hours 8 Options and operating parameters that changed since 1999 Appendix B are bolded and shaded grey. 9 FSIS\u2019 Scientific Support and references used to develop these options can be found in (Attachment B3. FSIS\u2019 Predictive Microbial Modeling Support for 1-Log Cooling Options, page 68). 10 Nitrite and erythorbate\ascorbate may be added using natural or synthetic sources (page 45).","26 Food Safety Significance of Changes Why do partially cooked products have fewer options for cooling (only those in Table 2)? In general, for partially cooked meat and poultry products, the cooling options are more limited because without a validated lethality step, cumulative growth of *C. perfringens* and *C. botulinum* can occur over the course of the partial cooking or heating and cooling steps. Cumulative growth allows for more vegetative cells in the finished product and having a vegetative high cell count increases illness risk. To limit cumulative growth, FSIS recommends a heating CUT for partially cooked products. CUT as used in this guideline refers to the time the product temperature is between 50 and 130\u00b0F during heating, because this is the primary range of concern for pathogen growth. While CUT is important for fully cooked products, the CUT is not addressed in stabilization options for fully cooked products cooked to full lethality, because all vegetative cells of *C. perfringens* and *C. botulinum* are destroyed by the cooking process. Note that on page 24 of the FSIS Cooking Guideline, FSIS has recommended CUTs for fully cooked products cooked to full lethality to ensure *S. aureus* growth is controlled. Why did FSIS change Option 1.2 to include a first-stage of cooling (120 to 80 \u00b0F in \u2264 1 hour)? When Appendix B was developed as a safe harbor to the stabilization performance standards, FSIS added the note that \u201cif product remains between 120 to 80\u00b0F more than one hour, compliance with the performance standard is less certain.\u201d However, validated pathogen modeling and research from 2018 supports that cooling between 120 to 80\u00b0F for 3-4 hours can result in 2 to 3-Log growth of *C. perfringens* (Smith, et al., 2018), which would definitely exceed the performance standard or target. One outbreak occurred from a RTE large diameter turkey loaf product that can take several hours to cool between 120 to 80\u00b0F. FSIS has included options in Table 1 that extend the time during 120 to 80\u00b0F as much as possible when considering other intrinsic product characteristics, such as pH. Why does Option 1.3 include the recommendation to add at least 250 ppm erythorbate or ascorbate, in addition to the original recommendation to add at least 100 ppm nitrite? Research from 2015 found that erythorbate or ascorbate is needed in addition to sodium nitrite to control the growth of *C. perfringens* to safe levels. Why does Option 1.4 no longer apply to products formulated with \u2265 120 ppm of sodium nitrite or its equivalent and a brine concentration of 3.5% or more? Currently available validated pathogen modeling programs have indicated these parameters may result in > 2.0-log *C. perfringens*

growth. Why does Option 1.4 no longer have an option for the first stage of cooling to cool from 120 to 80°F in 2 hours or less? FSIS determined that these parameters were based on *S. aureus* growth on the surface of the product which is not the hazard this Option is designed to address. Instead, establishments should demonstrate a continuous drop in temperature without the need to demonstrate any particular timeframe is met between 120 to 80°F.<sup>27</sup> Customized Processes and Alternative Support FSIS recognizes that not all products can be stabilized using the FSIS critical operating parameters included in this guideline. To assist establishments in stabilizing their products, FSIS has identified resources that could be used as scientific support. Resources in the attachments include information on the following:

\u2022 Customized Cooling Schedule: Establishments may design a customized cooling plan with multiple cooling and heating steps using validated pathogen models. See Attachment B5.

Predictive Microbial Modeling page 64.

\u2022 Processing Guidelines: Other government agencies have published validated cooling guidelines that establishments could use as scientific support. See Attachment B6. Other Published Processing Guidelines for Cooling page 77.

\u2022 Challenge Studies: Establishments could conduct challenge studies to determine if their proposed process would meet the performance standard. See Attachment B7. Using Challenge Studies to Support Alternative Stabilization\Cooling Procedures page 78.

\u2022 Journal Articles: Establishments could identify a published journal article that shows a specific process meets the performance standard and use this as scientific support. See Attachment B8. Using Journal Articles to Support Alternative Stabilization\Cooling Procedures page 80.

Scientific Gaps Identified by FSIS FSIS has identified several common stabilization processes that can\u2019t achieve the critical operating parameters included in this guideline. FSIS encourages establishments to conduct challenge studies when other support is not available (page 78). However, the Agency realizes it may not be cost effective for establishments to conduct individual challenge studies for commonly produced meat and poultry products. To address these common processes that lack readily available scientific support, FSIS has identified and communicated scientific gaps and is working to facilitate filling these gaps. FSIS posted research priorities on its website to communicate clear research needs with USDA Agricultural Research Service (ARS) and academic researchers. As additional data becomes available, FSIS will update the recommendations for these scientific gaps with the latest available scientific support. An establishment producing products using processes that fall under an identified scientific gap may continue to use the critical operating parameters in this guideline as scientific support (see Table 3). Table 3 also describes specific vulnerabilities with using the gaps as scientific support and recommends steps to reduce the vulnerabilities. In addition to those specific vulnerabilities, FSIS has the following concerns with establishments continuing to process products using the critical operating parameters in Table 3:

\u2022 Use of these critical operating parameters represents a vulnerability because these processes have not been validated to address all hazards of concern.<sup>28</sup>

If a process deviation occurs for a process that is listed as a scientific gap, it is unlikely an establishment would be able to identify adequate support for product safety without performing product testing.

\u2022 If FSIS or the establishment collects a RTE product sample that is positive for a pathogen or the product is implicated in a food safety investigation (i.e., is associated with reports of illness or outbreak), FSIS would verify, as part of the corrective actions (9 CFR 417.3(b)), that the establishment can demonstrate that inadequate lethality or stabilization was not the root cause of the positive

sample or the confirmed illness or outbreak, which it would need to do if it wants to continue to use the older recommendation. As additional data becomes available, FSIS will change the recommendations for processes that fall under one of these scientific gaps. NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Additionally, Products Not Covered by this Guideline would NOT be adequately supported by the critical operating parameters listed in Table 3. FSIS will update this guideline as more research becomes available and new options can be developed. Scientific gaps are processes which have not been validated to achieve stabilization and address all potential hazards during cooling, but establishments may continue to use this guidance as support for those processes to allow additional time for research to be conducted.", "NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 3). 29 Table 3: Scientific Gaps where Critical Operating Parameters from Older Guidance May be Used Scientific Gaps Example Products Critical Operating Parameters from Older Guidance Vulnerability with Continuing to Follow Parameters from Older Guidance

1. Large mass non-intact products that cannot cool quickly enough to follow the new options in Table 1. Processes that meet this gap include all of the following: Cooked to full lethality. Non-intact. Large product size or weight >4.5 inches or >8 pounds. Non-intact turkey breast > 8 pounds or roast beef that is > 4.5 inches thick. Chilling begins within 90 minutes after the cooking cycle is complete. Cooling occurs from 120 to 55°F in 6 hours. Continuous chilling until 40°F. These parameters do not take into account the amount of time product remains between 120 to 80°F. If products take more than 1 hour to cool between 120 to 80°F, excessive growth of *C. perfringens* and *C. botulinum* may occur, particularly if products are non-intact. In the event of a deviation, if product takes more than 1 hour to cool between 120 to 80°F, it is unlikely that pathogen modeling will support product safety, and sampling may be needed. To minimize this vulnerability, establishments may choose to validate any of the following: If possible, limit the time between 120°F to 80°F to no more than 2.5 hours or between 80°F and 55°F for more than 3.5 hours (6 hours total cooling time) to limit *C. perfringens* growth to 2-log or less. If that is not possible, identify the shortest amount of time it is thermodynamically possible to go from 120 to 80°F, and monitor this point on a routine basis. Conduct finished product testing for *C. perfringens* (see page 74). Add antimicrobials. Reduce product diameter or thickness. Perform a challenge study or pathogen modeling for particular product.", "NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 3). 30 Scientific Gaps Example Products Critical Operating Parameters from Older Guidance Vulnerability with Continuing to Follow Parameters from Older Guidance

2. Partially heat-treated, smoked products, that contain nitrite and erythorbate/ascorbate and have long come-up and cooling times in Table 2. Processes that meet this gap include all of the following: Partial heat treatment, Smoked. Slower CUT (greater than 3 hours in Option 2.2). Formulated with at least 100 ppm nitrite or nitrate (synthetic or natural). Formulated

with at least 250 ppm 250ppm erythorbate or ascorbate (synthetic or natural). Hams containing nitrite and erythorbate or ascorbate. Apply Option 1.3 to this partially heat-treated product\* specifically: 130 to 80°F in 5 hours and 80 to 40°F in 10 hours, with 15 hours total cooling time. \*NOTE: No CUT parameter. These parameters may allow excessive cumulative growth of *C. perfringens* during heating and cooling if CUT is not addressed, although smoke, nitrite, and erythorbate/ascorbate may help limit growth. To minimize this vulnerability, establishments may choose to validate any of the following: \u2022 Cook the product to lethality, which would allow a CUT of up to 6 hours between 50-130°F per FSIS Cooking Guideline. This product may then apply Option 1.3 without being in a Scientific Gap for Stabilization. \u2022 Perform a challenge study or pathogen modeling for a particular product.

\*NOTE: Products cooked to full lethality which exceed a CUT of 6 hours between 50-130°F may meet the conditions for a Cooking Guideline Scientific Gap. Note: While this gap may be applied to bacon there is research that supports some common partially heat-treated bacon processes.", "NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 3). 31 Scientific Gaps Example Products Critical Operating Parameters from Older Guidance Vulnerability with Continuing to Follow Parameters from Older Guidance 3. Smoked bacon, that contains nitrite and erythorbate/ascorbate that cannot use Option 1.3 because lethal time and temperature combination is achieved but relative humidity is not addressed. Processes that meet this gap include all of the following: \u2022 Lethal time and temperature combination but relative humidity has not been addressed (therefore, product is not considered to achieve \u201cfull lethality\u201d)\*. \u2022 Formulated with at least 100 ppm nitrite or nitrate (synthetic or natural). \u2022 Formulated with at least 250 ppm erythorbate or ascorbate (synthetic or natural). \*Note: relative humidity does not need to be monitored when cooking meat or poultry products that are 10 pounds or more in an oven maintained at or above 250 °F (121 °C). Bacon containing nitrite and erythorbate or ascorbate. Apply Option 1.3 to this partially heat-treated product\* specifically: 130 to 80°F in 5 hours and 80 to 40°F in 10 hours, with 15 hours total cooling time. \*NOTE: No CUT parameter These parameters may allow insufficient surface lethality of pathogens such as *Salmonella*. To minimize this vulnerability, establishments may choose to validate any of the following: \u2022 Cook the product to lethality, which would include using a humidity option. Apply Option 1.3 without being in a Scientific Gap for Stabilization. \u2022 Perform a challenge study or pathogen modeling for a particular product.

\*NOTE: Products cooked to full lethality which exceed a CUT of 6 hours between 50-130°F may meet the conditions for a Cooking Guideline Scientific Gap. Note: While this gap may be applied to bacon there is research that supports some common partially heat-treated bacon processes.", "NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 3). 32 4. Immersion or dry-cured products that contain nitrate and/or nitrite and use of equilibration time instead of erythorbate or ascorbate but cannot meet cooling options without nitrite in Table 1 or Table 2. Processes that meet this gap include all of the following: \u2022 A heat treatment (full or partial). \u2022 Immersion or

dry-cured. \u2022 Slower CUT (greater than 3 hours in Option 2.2). \u2022 Formulated with at least 100 ppm nitrite or nitrate (synthetic or natural). \u2022 Formulated without erythorbate or ascorbate (synthetic or natural). \u2022 Allow equilibration time for the cure reaction to occur (e.g., at least 2 to 3 days). Immersion or dry-cured bacon and ham containing nitrite without erythorbate or ascorbate. Apply Option 1.3 to product without erythorbate or ascorbate\* specifically: 130 to 80\u00b0F in \u2264 5 hours and 80 to 40\u00b0F in \u2264 10 hours, with 15 hours total cooling time \*NOTE: No CUT parameter for partially heat-treated products. One vulnerability is the potential for excessive cumulative growth of *C. perfringens* during heating and cooling if CUT is not addressed. To minimize this vulnerability, establishments may choose to: \u2022 Cook the product to lethality, which would allow a CUT of up to 6 hours between 50-130\u00b0F per FSIS Cooking Guideline. NOTE: Ensuring adequate equilibration time is still critical (see second vulnerability). A second vulnerability is the minimum equilibration time needed to ensure nitrite conversion to produce antimicrobial activity without a cure accelerator is unknown. To minimize this vulnerability, establishments may choose to validate any of the following: \u2022 Equilibration time for salt and nitrite to penetrate throughout product and time to allow nitrite to convert to active form and limit growth or. \u2022 Perform a challenge study or pathogen modeling for a particular product. NOTE: Products cooked to full lethality which meet this Stabilization Guideline Scientific Gap may also meet the conditions for a Cooking Guideline Scientific Gap if CUT exceeds 6 hours.", "NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 3). 33 Scientific Gaps Example Products Critical Operating Parameters from Older Guidance Vulnerability with Continuing to Follow Parameters from Older Guidance 5. Products that contain nitrite and use equilibration time instead of erythorbate or ascorbate, but do not have a brine concentration \u2265 6% to meet Option 1.4. Processes that meet this gap include all of the following: \u2022 Any heat treatment, \u2022 Pumped with nitrite, \u2022 Formulated with at least 120 ppm nitrite or nitrate (synthetic or natural), \u2022 Formulated without erythorbate or ascorbate (synthetic or natural), \u2022 Brine concentration of 3.5% or more and \u2022 Allows equilibration time for the cure reaction to occur (e.g., at least 2 to 3 days). Pumped ham containing nitrite without erythorbate or ascorbate. Apply Option 1.4 to product\* with \u2265 120 ppm nitrite and \u2265 3.5% brine concentration 120 to 40\u00b0F \u2264 20 hours; Continuous temperature drop \*NOTE: No CUT parameter for partially heat-treated products There is a vulnerability that there may be excessive cumulative growth of *C. perfringens* during heating and cooling if CUT is not addressed, although smoke and nitrite may help limit growth. To minimize this vulnerability, establishments may choose to validate any of the following: \u2022 Equilibration time for salt and nitrite to penetrate throughout product and time to allow nitrite to convert to active form; \u2022 Cook the product to lethality, which would allow a CUT of up to 6 hours between 50 to 130\u00b0F per FSIS Cooking Guideline; or. \u2022 Perform a challenge study or pathogen modeling for a particular product. NOTE: Products cooked to full lethality which meet this Stabilization Guideline Scientific Gap may also meet the conditions for a Cooking Guideline Scientific Gap.", "NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not

Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 3). 34 Scientific Gaps Example Products Critical Operating Parameters from Older Guidance Vulnerability with Continuing to Follow Parameters from Older Guidance

6. Scalded offal that cannot cool quickly enough to follow the new options in Table 2. Processes that meet this gap include all of the following: \u2022 Edible offal which is partially heat-treated or scalded. Scalded beef tripe or pork stomachs. Product chilled to 45\u00b0F in \u2264 24 hours. These parameters do not take into account the amount of time product remains between 120 to 80\u00b0F. If products take more than 1 hour to cool between 120 to 80\u00b0F, excessive growth of *C. perfringens* and *C. botulinum* may occur. In the event of a deviation, if product takes more than 1 hour to cool between 120 to 80\u00b0F, it is unlikely that pathogen modeling will support product safety, and sampling may be needed. To minimize this vulnerability, establishments may choose to validate any of the following:

\u2022 If possible, limit the time between 120\u00b0F to 80\u00b0F to no more than 2.5 hours nor between 80\u00b0F and 55\u00b0F for more than 3.5 hours (6 hours total cooling time) to limit *C. perfringens* growth to 2-log or less. If that is not possible, identify the shortest amount of time it is thermodynamically possible to go from 120 to 80\u00b0F, and monitor this point on a routine basis.

\u2022 Conduct finished product testing for *C. perfringens* (see page 74).

\u2022 Add antimicrobials.

\u2022 Perform a challenge study or pathogen modeling for a particular product.

NOTE: Establishments may limit the time between 120\u00b0F to 80\u00b0F by increasing the amount of dry ice when packing the product, packing offal in smaller boxes, or not stacking as many boxes on a pallet which can impede airflow.

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Public Health Risk in Meat and Poultry Clostridia can be a problem in foods other than heat-treated meat and poultry products, such as improperly canned low acid foods ( $\text{pH} > 4.6$ ), raw honey, and fermented, smoked, and salted seafood. Most illness outbreaks associated with *C. perfringens* are traced to food served in restaurants, homes for the elderly, or at buffet-style gatherings. In fact, *C. perfringens* is often referred to as the “food service germ,” because outbreaks may occur if the products are held at room temperature for too long or they are cooled in large batches, allowing pathogens to grow. A limited number of *C. perfringens* illnesses are attributed to products produced under FSIS inspection. A 2005 FSIS risk assessment found that stabilization at processing plants accounted for 0.05% and 0.4% of predicted *C. perfringens* illnesses at 1-Log and 2-Log allowable growth, respectively. There have been a limited number of *C. perfringens* outbreaks associated with commercially produced meat and poultry products in the U.S. Specifically, one outbreak was associated with *C. perfringens* from a commercially produced RTE turkey loaf product (CDC, 2000; personal communication, R.F. Woron, N.Y. State Department of Health, August 2002). *C. perfringens* and *C. botulinum* cause human illness in different ways. *C. perfringens* causes illness when people ingest a large infectious dose of 6-Log/g or higher ( $10^6 \text{ CFU/g}$ ). These high levels of cells occur when the product remains at growth temperatures for too long, allowing the vegetative cells to grow. If a large enough dose of *C. perfringens* is ingested, vegetative cells may survive the environment in the stomach and briefly persist in the gut. These conditions cause this pathogen to form spores and produce a toxin in the gut. *C. perfringens* is estimated to cause 965,958 illnesses, including 438 hospitalizations and 26 deaths in the U.S. each year (Scallan et al., 2011). *C. botulinum* causes human illness when people ingest a potentially deadly neurotoxin (botulin) that is produced in affected food. After 12 to 36 hours following ingestion, botulin can cause muscle paralysis and suffocation with as little as 1 nanogram (ng) of toxin per kilogram (kg) of body weight. Botulin is considered one of the most toxic naturally occurring toxins. While human botulism cases are rare in the U.S., it is estimated that *C. botulinum* causes approximately 55 illnesses, including 42 *C. perfringens* grows the fastest of the spore-forming pathogens. It is a good indicator of food safety during stabilization.", "42 hospitalizations and 9 deaths each year (Scallan et al., 2011). There are six distinct Clostridia that produce botulinum toxin; two of which are associated with food: *C. botulinum* Group I (proteolytic) and *C. botulinum* Group II (non-proteolytic). Proteolytic *C. botulinum* is the most common group associated with illness from meat and poultry products in the United States. Although non-proteolytic *C. botulinum* is typically associated with fish and marine products, there have been several recent outbreaks in Europe associated with non-proteolytic *C. botulinum* and home-prepared (salted) ham (Peck et al., 2015). Because of the potency of the neurotoxin that this pathogen produces, it is critically important to control *C. botulinum* in food products. NOTE: *B. cereus* is a spore-forming bacterium that may also be a hazard of concern during severe deviations of cooling and hot-holding (e.g., where pathogen modeling shows the potential for  $10^3$  3-Log *C. perfringens* growth). *B. cereus*, if allowed to grow to high levels (typically 5-Log CFU/g) can produce emetic and diarrheal toxins in the food. However, *B. cereus* is not discussed in further detail in this guideline because if *C. perfringens* and *C. botulinum* growth are adequately controlled or prevented using options discussed in this guideline, then *B. cereus* growth will be adequately addressed as well. For this reason, FSIS did not identify outgrowth of *B. cereus* as a hazard of concern at the cooling/stabilization step in

the FSIS Meat and Poultry Hazards and Control Guide. Product Characteristics that Affect Clostridia Growth Below is a review of the critical operating parameters that are important for cooling heat-treated RTE and NRTE meat and poultry products. Product time-temperature profile An establishment's cooling schedule should take into account the amount of time a product takes to cool in certain temperature ranges associated with growth as follows:

The optimum growth temperature for *C. perfringens* is 109.4 °F (43 - 47°C), and the lower and upper growth limits are 50°F and 126°F (6°C and 54°C), respectively (Solberg and Elkind, 1970). The optimum temperature for growth for *C. botulinum* (proteolytic, which is the kind found in meat) is 95 °F (35 - 40°C), and the lower and upper growth limits are between 50°F and 122°F (10.0°C and 50.0°C), respectively (ICMSF, 1996). In addition, establishments should also design their cooling process to match the timetemperature profile in their scientific support. General Considerations for Designing HACCP Systems to Control the Growth of Clostridia contains additional recommendations for initial validation of cooling processes (page 13).<sup>1</sup>

The lower and upper pH growth limits for *C. perfringens* are 5.0 and 8.3, respectively. For *C. botulinum* (proteolytic, which is the kind found in meat), the lower and upper pH growth limits are 4.7 and 9, respectively (Hauschild, 1989; Labbe, 1989). As the pH decreases, the growth of *C. perfringens* and *C. botulinum* becomes slower. Brine concentration in product As the brine concentration increases (defined on page 18), the growth of *C. perfringens* and *C. botulinum* becomes slower. The minimum inhibitory brine concentration is 8% for *C. perfringens* (ICMSF, 1996) and 10% for *C. botulinum* (proteolytic) (Lund and Peck, 2000). The type and concentration of phosphate (wt/wt basis) A high phosphate concentration, 0.4-0.5 %, can have a limited effect on inhibiting the growth of *C. perfringens* in the product (Akhtar et al., 2008; Singh et al., 2010). Water activity (aw) As the water activity decreases, growth of *C. perfringens* and *C. botulinum* slows. The water activity limit for growth and germination of both *C. perfringens* and *C. botulinum* is 0.93. (ICMSF, 1996). Therefore, a water activity less than 0.93 is required to control the growth and toxin formation of Clostridia. The type and concentration of sodium lactate/diacetates Many establishments are now adding sodium lactate/diacetate or other organic salts as an antimicrobial agent to RTE meat or poultry products to meet the requirements of Alternative 1 or Alternative 2, Choice 2 of the Lm regulations (9 CFR 430.1 and 9 CFR 430.4). Establishments should ensure that the sodium lactate/diacetate or organic acid salt used in their process matches the antimicrobial used in their scientific support and should also ensure or consider the following:

That the scientific support is based on the specific trade name for the sodium lactate/diacetate or organic acid salt product used during product formulation;

That the active component concentrations (%) of sodium lactate/diacetate or organic acid salt in the commercially formulated product used during product formulation is the same as that in the scientific support; and

The concentration (wt/wt basis) of the sodium lactate/diacetate or organic acid salt in the product after formulation. Several published research articles have shown lactate/diacetate products and other organic salts can significantly inhibit the growth of *C. perfringens* during cooling, and even extend the chilling times from 15 to 21 hours for cooked, uncured meat or poultry products. (See the research articles summarized in Attachment B8. Using Journal Articles to Support Alternative Stabilization or Cooling Procedures, Table 15. that include lactate/diacetate products; page

82).","44 Ingoing sodium nitrite\ nitrate concentration and erythorbate or ascorbate Sodium nitrite slows the growth of *C. perfringens* and inhibits the growth and toxin formation of *C. botulinum*, if it is used in combination with a cure accelerator, such as sodium erythorbate or ascorbate or a high salt concentration (King et al., 2015). The amount of sodium nitrite and erythorbate or ascorbate needed will depend on the establishment\u2019s scientific support. Establishments should be aware that a minimum of 120 ppm ingoing nitrite should be added in all cured \u201cKeep Refrigerated\u201d products, unless the establishment can demonstrate that safety is assured by some other preservation process, such as thermal processing, pH, or moisture control. This 120 ppm recommendation is based on safety data reviewed when the bacon standard was developed (FSQS, 1978). Natural Sources of Nitrite and Ascorbate Research supports that naturally occurring sources of nitrite (e.g., from celery powder) are functionally equivalent to pure sodium nitrite for inhibiting the growth of *C. perfringens* if a sufficient quantity of a natural source of ascorbate (e.g., from cherry powder) is also used (King et al., 2015). Similar research has not been performed on the growth of *C. botulinum*. However, FSIS has determined from expert opinion that nitrite from natural sources will likely also control the growth of *C. botulinum*, if sufficient quantities of nitrite and ascorbate are used (J. Sindelar, personal communication, 2015). When using natural sources of nitrite, establishments must provide support that the level of nitrite and ascorbate used are effective to control the growth of *C. perfringens* and *C. botulinum*. Natural sources of nitrite are generally available in two forms: \u2022 Vegetable juices and powders that contain sodium nitrate. The establishment should use these products in combination with a bacterial culture that reduces the nitrate to nitrite in the product. When using natural sources of sodium nitrate, the quantity of sodium nitrite present is not known because the conversion of nitrate to nitrite that occurs in the product as a result of the presence of a bacterial culture can occur at varying rates. Because the nitrate to nitrite conversion rate may vary from batch to batch, there is concern about obtaining a consistent conversion and thus the sodium nitrite level in the product (Jackson et al., 2011b). \u2022 Vegetable juices and powders in which the sodium nitrate has been preconverted to sodium nitrite by the supplier so there is no need to add a bacterial Synthetic versions of cure accelerators may not be used with natural sources of nitrate or nitrite.", "45 culture. Because the sodium nitrate has been pre-converted, the concentration of sodium nitrite in the natural source is known. However, the amount may still vary between lots of the natural source due to differences in the conversion rate. Establishments should ensure the levels of sodium nitrite are safe and suitable according to FSIS Directive 7120.1, \"Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products\" and 9 CFR 424.21(c)). If establishments are using natural sources of sodium nitrite, FSIS recommends that, when possible, establishments use natural sources of sodium nitrite with known concentrations of nitrite. By knowing the concentration of nitrite, establishments can ensure they neither use too little nor too much in their formulation. In order to use one of the cooling Options for products formulated with sufficient nitrite, establishments must support that they have added sufficient quantities of nitrite (e.g., for Option 1.3 at least 100 ppm nitrite). (Note that mixing natural sources of nitrate\ nitrite with synthetic versions of a cure accelerator would not be eligible for using option 1.3.) Establishments using nitrite may need to request this information from the supplier. Suppliers of sodium nitrite with known concentrations may supply this information as either: \u2022 Certificate of Analysis (COA) for each lot that states the sodium

nitrite in parts per million. An establishment would then need to calculate the quantity of nitrite to add to a given formulation in order to obtain the final ingoing concentration. See the Processing Inspectors\2019 Calculations Handbook for example calculations on page 11; or \2022 Standardized formulation directions for the natural source of nitrite (e.g. in a Letter of Guarantee or LOG). Some suppliers standardize the concentration of nitrite from lot to lot. These suppliers may provide formulation directions to achieve a specific concentration of nitrite, e.g., "Add 1 pound of [the blend] to 100 pounds of meat block." The establishment should maintain documentation of this final concentration achieved in the formulation.", "46 Natural Sources of Nitrite and Ascorbate \2013 Approvals and Labeling Celery powder and other natural sources of nitrite are approved by FSIS and FDA for use as antimicrobials and flavorings but are not approved as curing agents. Cherry powder and other natural sources of ascorbate are also approved for use as antimicrobials and flavorings but are not approved as cure accelerators. Ingredients approved for use as curing agents and cure accelerators are listed in 9 CFR 424.21(c) and the FSIS Directive 7120.1, Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products. According to 9 CFR 424.21(c) cure accelerators may only be used if the product contains an approved curing agent. Therefore, synthetic versions of cure accelerators may not be used with natural sources of nitrate or nitrite as these are not approved as curing agents. Celery powder and other natural sources of nitrite are considered safe and suitable as antimicrobials, if used in combination with a natural source of ascorbate, such as cherry powder (See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products). Celery powder may be added to meat and poultry products as a flavoring in accordance with 9 CFR 317.2(f)(1)(i)(B) and 9 CFR 381.118(c)(2) along with other natural sources of nitrite, such as beet juice and sea salt. Because celery powder and other natural sources of nitrite are not currently approved for use in 9 CFR 424.21(c) as curing agents, products that are required to contain curing agents and cure accelerators as part of a standard of identity in 9 CFR 319 or 9 CFR 317.17(b), but instead are formulated with natural sources of nitrite and ascorbate, must be labeled as "\201cuncured\201d under 9 CFR 319.2. Also, the label must contain the statement "\201cno nitrates or nitrites added\201d (9 CFR 317.17) that is qualified by the statement "\201cexcept for those naturally occurring in [name of natural source of nitrite such as celery powder]\201d as to not be considered misbranded due to false and misleading labeling under 9 CFR 317.8. For example, hot dogs and corned beef that contain celery powder instead of sodium or potassium nitrite, and cherry powder instead of ascorbate, must be labeled as "\201cuncured\201d" and contain the qualifying statement "\201cexcept for those naturally occurring in celery powder.\201d It would not be appropriate to label products with natural sources of nitrite with other terms such as "\201cnaturally cured\201d or "\201calternatively cured.\201d

NOTE: Products formulated with natural sources of nitrate and ascorbate that contain an amount of salt sufficient to achieve a brine concentration of 10% or more are exempted from the "\201cUncured\201d and accompanying "\201cno nitrates or nitrites added\201d statement and the qualifier labeling requirement per 9 CFR 317.17(c)(3).", "47 Attachment B2. Stabilization Requirements for Specific Meat and Poultry Products To ensure safety of heat-treated RTE meat and poultry products, FSIS has developed performance standards and recommended targets, for *C. perfringens* and *C. botulinum* growth in RTE and NRTE products. By designing their HACCP systems to meet these standards, establishments should be able to

avoid producing adulterated product (See: What is the public health concern of *C. perfringens* and *C. botulinum* in RTE Products? (page 48). As described under the section titled Stabilization in the HACCP System (page 13) of this guideline, for each biological hazard identified, establishments must design their HACCP systems to meet applicable performance standards or targets for reduction or prevention. For stabilization, targets are used by the establishment to demonstrate that its processes prevent the outgrowth of Clostridia to acceptable levels and prevent any outgrowth of botulinum. Whether an establishment must meet a required performance standard or identify a target, depends on whether the meat or poultry products are RTE or NRTE, and whether the products are subject to a regulatory stabilization performance standard. Table 4 lists the regulatory performance standards for specific meat and poultry products and describes the recommended targets for other RTE meat and poultry products and other NRTE, heat-treated meat and poultry products. Table 4. Stabilization performance standards and recommended targets for Clostridia growth If an establishment produces: Then its stabilization treatment must: RTE cooked beef RTE roast beef RTE cooked corned beef Allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens* to comply with 9 CFR 318.17(a)(2). RTE uncured beef patties Allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens* to comply with 9 CFR 318.23(c)(1). RTE cooked poultry Allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens* to comply with 9 CFR 381.150(a)(2). Other RTE meat products Consider the food safety hazards that are reasonably likely to occur in stabilization processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level (9 CFR 417.2). FSIS recommends that establishments set a target to allow no more than a 1-Log multiplication of *C. perfringens* within the product and no multiplication of *C. botulinum*.," "48 If an establishment produces: Then its stabilization treatment must: NRTE partially cooked and char-marked meat patties, and partially cooked poultry breakfast strips Allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens* to comply with 9 CFR 318.23(c)(1) and 9 CFR 381.150(b). Other NRTE, heat-treated meat and poultry products Consider the food safety hazards that are reasonably likely to occur in stabilization processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level (9 CFR 417.2). FSIS recommends that establishments set a target to allow no more than a 1-Log multiplication of *C. perfringens* within the product and no multiplication of *C. botulinum*. NOTE: The recommendation that the stabilization of NRTE meat and poultry products should limit the growth of *C. perfringens* and *C. botulinum* to the same levels in RTE meat and poultry products is consistent with guidance for controls in any raw meat or poultry process. In both cases, the establishment needs to document in its hazard analysis the necessary controls that must be maintained to minimize microbial growth to a level such that customary cooking practices would be sufficient to make the product safe. As described in 9 CFR 303.1(h), the Administrator may in specific classes of cases waive for limited periods any provisions of the regulations to permit experimentation so that new procedures, equipment, and/or processing techniques may be tested to facilitate definite improvements. What is the public health concern of *C. perfringens* and *C. botulinum* in RTE Products? Certain pathogens, including *Salmonella* and Lm, when present in a RTE meat or poultry product at any level, cause the product to be adulterated since consumption of the

product would be \u201cinjurious to health\u201d as per 21 U.S.C. 601(m)(1) and 453(g)(1)). Other pathogens, such as *C. perfringens*, are only a public health concern when growth occurs at levels that could lead to toxin formation; this indicates the products were prepared, packed, or held under insanitary conditions as per 21 U.S.C. 601(m)(4) and 453(g)(4). \u2022 For *C. perfringens*, spore levels found in raw meat and poultry are usually 2-3Log. These spores can survive cooking and germinate into vegetative cells during cooling (see page 12). If conditions during cooling allow for 3-Log growth or higher of these vegetative cells, then there is a public health concern because this would result in total levels of > 5-Log. At 5-Log, a toxin could be produced in the gut and cause illness. \u2022 For *C. botulinum*, conditions permitting spore germination and any growth of vegetative cells in the product are a public health concern because the toxin is "the most toxic natural substance known to humankind (Montville and Matthews, 2008). FSIS considers predictive modeling results with mean growth > 0.30-Log to be evidence of *C. botulinum* growth. What is the public health concern of *C. perfringens* and *C. botulinum* in NRTE Products? NRTE products that are contaminated with toxins such as the *botulinum* toxin are adulterated because cooking by consumers may not destroy the toxins, rendering the products injurious to health (21 U.S.C. 601(m)(1) and 453(g)(1)). In addition, if levels of growth occur that would be considered a public health concern (i.e., \u2265 3-Log of *C. perfringens*; or > 0.30-Log of *C. botulinum*), the product would be adulterated. In this situation, products would also be adulterated because they were prepared, packed, or held under insanitary conditions (21 U.S.C. 601(m)(4) and 453(g)(4)). NOTE: Examples of NRTE meat and poultry products include char-marked patties, partially cooked poultry breakfast strips, or products like hams or sausage that are cooked to a lethal time-temperature, but the establishment chooses to reclassify as NRTE.

*C. perfringens*: Some growth is acceptable before the product is considered adulterated. *C. botulinum*: Any level of growth is a concern and makes the product adulterated.", "50 Attachment B3. FSIS\u2019 Predictive Microbial Modeling Support for 1-Log Cooling Options This section contains the supporting documentation FSIS used to develop its 1-Log cooling options. A summary of each option is provided with the original journal articles used to develop the option. Also included is the most current research and pathogen modeling to support each option. All pathogen modeling FSIS performed was based on linear cooling in each stage. Also, the modeling was based on the use of a worst-case scenario pH of 6.2 and a salt concentration of 1% (Mohr et al., 2015). In addition to the modeling results, a figure showing the modeling output was also included for each option. This Appendix also includes FSIS Support for Application of Options 1.1, 1.2, 1.5-1.8 to Rice, Pasta, and Beans page 61. FSIS\u2019 Support for Option 1.1. Table 5. Summary of Option 1.1 (for products cooked to full lethality). Option Pre-Cooling Conditions 1st Stage of Cooling 2nd Stage of Cooling Total Cooling Time Option 1.1 130 to 80\u00b0F \u2264 1.5 hours 80 to 40\u00b0F \u2264 5 hours \u2264 6.5 hours The original option was developed using research found in: \u2022 Blankenship, L.C., Craven, S.E., Leffler, R.G., Custer, C. 1988. Growth of *Clostridium perfringens* in cooked chili during cooling. *Applied Environmental Microbiology*. 54(5):1104-1108. \u2022 Thompson, D.R., Willardsen, R.R., Busta, F.F., Allen, C.E. 1979. *Clostridium perfringens* population dynamics during constant and rising temperatures in beef. *Journal of Food Science*. 44(3):646-651. Up-to-date validated modeling provided the following results for products cooked to full lethality: \u2022 ComBase Perfringens Predictor Results = 0.52-Log growth (see Figure 2 for modeling output.)", "51 Figure 2. ComBase Perfringens Predictor

Modeling Output for Option 1.1. FSIS\u2019 Support for Option 1.2 Table 6. Summary of Option 1.2 (for products cooked to full lethality). Option Pre-Cooling Conditions 1st Stage of Cooling 2nd Stage of Cooling Total Cooling Time Option 1.2 Chilling will begin within 90 minutes after the cooking cycle is complete 120 to 80\u00b0F \u2264 1 hour 80 to 55\u00b0F \u2264 5 hours; Continuous chilling until 40\u00b0F \u2264 6 hours The original option was developed using research found in: \u2022 Ohye, D.F., Scott, W.J. 1957. Studies in the physiology of Clostridium botulinum type E. Australian Journal of Biological Sciences. 10(1):85-94. Up-to-date validated modeling provided the following results for products cooked to full lethality: \u2022 ComBase Perfringens Predictor Results = 0.38-Log growth (see Figure 3 for modeling output.)", "52 Figure 3. ComBase Perfringens Predictor Modeling Output for Option 1.2.

FSIS\u2019 Support for Option 1.3 Table 7. Summary of Option 1.3 (for products cooked to full lethality). Option Pre-Cooling Conditions 1st Stage of Cooling 2nd Stage of Cooling Total Cooling Time Option 1.3 \u2265 100 ppm sodium nitrite and \u2265 250 ppm sodium ascorbate or erythorbate 130 to 80\u00b0F \u2264 5 hours 80 to 45\u00b0F \u2264 10 hours \u2264 15 hours The original option was developed using research found in: \u2022 Roberts, T.A., Gibson, A.M., Robinson, A. 1981. Factors controlling the growth of Clostridium botulinum types A and B in pasteurized, cured meats: Part I. Growth in pork slurries prepared from \u2018low\u2019 pH meat (pH range 5.5\u20136.3). International Journal of Food Science & Technology. 16(3):239-266. \u2022 Roberts, T.A., Gibson, A.M., Robinson, A. 1981. Factors controlling the growth of Clostridium botulinum types A and B in pasteurized, cured meats: Part II. Growth in pork slurries prepared from \u2018high\u2019 pH meat (pH range 6.3\u20136.8) International Journal of Food Science & Technology, 16: 267-281.", "53 Up-to-date validated modeling provides the following results for products cooked to full lethality: \u2022 Results of modeling using the ComBase Perfringens Predictor ranged from 3.92Log C. perfringens growth for a product with 1% salt to 2.8-Log C. perfringens growth for a product with 2% salt concentration. Due to the high levels of predicted growth for C. perfringens, a figure of the modeling output has not been included in the guideline. FSIS decided, however, to still include the option itself in the guideline because the modeling is likely overestimating growth as follows: 1. The modeling was based on a worst-case salt scenario and cured products have higher salt concentrations. The modeling was based on the use of a worst-case scenario pH of 6.2 and a salt concentration of 1%. However, many cured products have higher salt concentrations inherent to their formulation or as a result of processing (Desmond, 2006); and. 2. The modeling does not take into account the role of cure accelerators that have been found to increase the effectiveness of nitrite. Research by King et al., 2015 supports that products formulated with at least 100 ppm sodium nitrite and at least 250 ppm erythorbate or ascorbate that are cooled following FSIS Option 1.3 allow \u2264 1-Log C. perfringens growth. The research supports that other combinations of nitrite and erythorbate or ascorbate are effective at limiting the growth of C. perfringens. Although the research was performed with a poultry product, the authors indicated this was chosen as a worst-case scenario itself and that the results also apply to meat products (Personal Communication, 2017). FSIS\u2019 Support for Option 1.4 Table 8. Summary of Option 1.4 (for products cooked to full lethality) Option Pre-Cooling Conditions 1st Stage of Cooling 2nd Stage of Cooling Total Cooling Time Option 1.4 \u2265 40 ppm sodium nitrite and \u2265 6% brine concentration OR aw \u2264 0.92 120 to 40\u00b0F \u2264 20 hours; Continuous temperature drop Not Applicable \u2264 20 hours The original option was

developed using research found in: \u2022 Roberts, T.A., Gibson, A.M., Robinson, A. 1981. Factors controlling the growth of Clostridium botulinum types A and B in pasteurized, cured meats: Part I. Growth", "54 in pork slurries prepared from \u2018low\u2019 pH meat (pH range 5.5\u20136.3). International Journal of Food Science & Technology. 16(3):239-266. \u2022 Roberts, T.A., Gibson, A.M., Robinson, A. 1981. Factors controlling the growth of Clostridium botulinum types A and B in pasteurized, cured meats: Part II. Growth in pork slurries prepared from \u2018high\u2019 pH meat (pH range 6.3\u20136.8) International Journal of Food Science & Technology, 16: 267-281. Up-to-date validated modeling shows the following results for products cooked to full lethality, formulated with \u2265 40 ppm of sodium nitrite or its equivalent, and a brine concentration of 6% or more: \u2022 ComBase Perfringens Predictor Results = 0.19-Log growth (see Figure 4 for modeling output.) Figure 4. ComBase Perfringens Predictor Modeling Output for Option 1.4 (products formulated with \u2265 40 ppm of sodium nitrite or its equivalent and a brine concentration of 6% or more). Up-to-date validated modeling provides the following results for products cooked to full lethality formulated with or without nitrite (such as salt cured product), and with a maximum water activity of 0.92: \u2022 ComBase Perfringens Predictor Results = 0.16-Log growth (see Figure 5 for modeling output)."55 Figure 5. ComBase Perfringens Predictor Modeling Output for Option 1.4 (products with a maximum water activity of 0.92). FSIS\u2019 Support for Option 1.5 Table 9. Summary of Option 1.5 (for products cooked to full lethality). Option Pre-Cooling Conditions 1st Stage of Cooling 2nd Stage of Cooling Total Cooling Time Option 1.5 130 to 80\u00b0F \u2264 2 hours 80 to 40\u00b0F \u2264 5 hours \u2264 7 hours Option 1.5 is a modification of Option 1.1 that FSIS developed using validated modeling. Up-to-date validated modeling provides the following results for products cooked to full lethality: \u2022 ComBase Perfringens Predictor Results = 1.02-Log growth (see Figure 6 for modeling output)"56 Figure 6. ComBase Perfringens Predictor Modeling Output for Option 1.5. FSIS\u2019 Support for the Development of Option 1.6 Table 10. Summary of Option 1.6 (for products cooked to a fully lethality). Option Pre-Cooling Conditions 1st Stage of Cooling 2nd Stage of Cooling Total Cooling Time Option 1.6 126 to 80\u00b0F \u2264 1.75 hours 80 to 55\u00b0F \u2264 4.75 hours; Continuous chilling until 40\u00b0F \u2264 6.5 hours Options 1.6 is a modification of Option 1.2 that was designed to extend the time during the 1st stage of cooling as long as possible using validated modeling. Up-to-date validated modeling provides the following results for products cooked to full lethality: \u2022 ComBase Perfringens Predictor Results = 1.02-Log growth (see Figure 7 for modeling output)."57 Figure 7. ComBase Perfringens Predictor Modeling Output for Option 1.6. FSIS\u2019 Support for Option 1.7 Table 11. Summary of Option 1.7 (for products cooked to full lethality). Option Pre-Cooling Conditions 1st Stage of Cooling 2nd Stage of Cooling Total Cooling Time Option 1.7 pH\u2264 6.0 126 to 80\u00b0F \u2264 2.25 hours 80 to 55\u00b0F \u2264 3.75 hours; Continuous chilling until 40\u00b0F \u2264 6 hours Option 1.7 is a modification of Option 1.2 developed using validated modeling. Up-to-date validated modeling provides the following results for products cooked to full lethality: \u2022 ComBase Perfringens Predictor Results = 1.06-Log growth (see Figure 8 for modeling output)."58 Figure 8. ComBase Perfringens Predictor Modeling Output for Option 1.7. FSIS\u2019 Support for Option 1.8 Table 12. Summary of Option 1.8 (for products cooked to full lethality). Option Pre-Cooling Conditions 1st Stage of Cooling 2nd Stage of Cooling Total Cooling Time Option 1.8 pH\u2264 5.8 126 to 80\u00b0F \u2264 2.75 hours 80 to 55\u00b0F

\u2264 3.25 hours; Continuous chilling until 40\u00b0F \u2264 6 hours Option 1.8 is a modification of Option 1.2 developed using validated modeling. Up-to-date validated modeling provides the following results for products cooked to full lethality: \u2022 ComBase Perfringens Predictor Results = 0.97-Log growth (see Figure 9 for modeling output).", "59 Figure 9. ComBase Perfringens Predictor Modeling Output for Option 1.8. FSIS\u2019 Support for Option 2.1 Table 13. Summary of Option 2.1 (for products not cooked to full lethality). Option Pre-Cooling Conditions 1st Stage of Cooling 2nd Stage of Cooling Total Cooling Time Option 2.1 CUT between 50 - 130\u00b0F \u2264 1 hour 130 to 80\u00b0F \u2264 1.5 hours 80 to 40\u00b0F \u2264 5 hours \u2264 6.5 hours Option 2.1 is a modification of Option 1.1 for products not cooked to full lethality. The original option (Option 1.1) was developed using research found in: \u2022 Blankenship, L.C., Craven, S.C., Leffler, R.G., and Custer, C. 1988. Growth of Clostridium perfringens in Cooked Chili during Cooling. Appl. Environ. Microbiol. 54:1104-1108; and \u2022 Thompson, D.R., Willardsen, R.R., Busta, F.F., Allen, C.E. 1979. Clostridium perfringens population dynamics during constant and rising temperatures in beef. Journal of Food Science. 44(3):646-651. Option 2.1 was developed using validated modeling. To develop the critical operating parameter to limit the CUT between 50 to 130\u00b0F to one hour, FSIS used the SmithSchaffer Model because this model allows input of data as the product temperature increases (during the heating CUT) and input of data as the product temperature decreases (during cooling). The application of the Smith-Schaffner Model with a one- hour CUT followed by the cooling process in Option 1.1 resulted in a 1.13-Log", "60 cumulative increase in C. perfringens. This is slightly above the regulatory requirement of no more than a 1-Log multiplication of C. perfringens for partially heat-treated products (9 CFR 318.23(c)(1) and 9 CFR 381.150(a)(2)). However, the modeling was performed based on a worst-case time-temperature profile assuming linear heating and cooling. Normally, meat and poultry products heat up and cool down exponentially. Linear modeling of the heating come up and cool down result in underestimating pathogen growth during the short heating come up period but overestimating pathogen growth during the longer cool down period, resulting in an overall overestimation of pathogen growth. Therefore, FSIS considers this modeling result fail-safe (that is a result that is not accurate in modeling terms but that errs on the side of the product being safe). FSIS\u2019 Support for Option 2.2 Table 14. Summary of Option 2.2(for products not cooked to full lethality). Option Pre-Cooling Conditions 1st Stage of Cooling 2nd Stage of Cooling Total Cooling Time Option 2.2 CUT between 50 - 130\u00b0F \u2264 3 hours and \u2265 2% salt and \u2265 150 ppm sodium nitrite and cure accelerator or natural source of ascorbate (sufficient for purpose) 130 to 80\u00b0F \u2264 1.5 hours 80 to 40\u00b0F \u2264 5 hours \u2264 6.5 hours Option 2.2 is also a modification of Option 1.1 for products not cooked to full lethality. Option 2.2 was also developed using validated modeling. This option was developed based on the use of the ARS PMP Online Cooling Model for Growth of C. perfringens in Cooked Beef supplemented with NaCl, Sodium nitrite, and Sodium pyrophosphate, which allows for input of the heating CUT, the cooling time, and NaCl (salt) and nitrite concentrations. The ARS cooling model estimates the growth of C. perfringens to be 1.03-Log based on modeling in a conservative manner. The ARS cooling model is more conservative when compared against predictions from the validated ComBase Perfringens Predictor (see Figure 10 for modeling output).", "61 Figure 10. ARS PMP Online Cooling Model for Growth of C. perfringens in Cooked Beef Supplemented with NaCl, Sodium nitrite, and

Sodium pyrophosphate Modeling Output for Option 2.2. FSIS Support for Application of Options 1.1, 1.2, 1.5-1.8 to Rice, Pasta, and Beans As stated in the section titled Products and Processes Covered by this Guideline, page 10, establishments may use FSIS Cooling Options in Table 1 for products that do not contain nitrite and erythorbate or ascorbate (i.e., Options 1.1, 1.2, 1.5-1.8) or for the cooling of rice, pasta and bean products. This recommendation is based on the scientific rationale that the time and temperature conditions that would generally limit the growth of *C. perfringens* to 1-Log or less would also effectively limit the growth of *Bacillus cereus* (*B. cereus* is a spore-former that is a greater hazard of concern than *C. perfringens* in rice, pasta, and bean products) and prevent multiplication of *C. botulinum*, since these pathogens generally grow more slowly than *C. perfringens*. For example, the shortest generation time (the time it takes to double in population) for *C. perfringens* under optimum growth temperatures (i.e., 43°C to 47°C) is approximately seven (7) minutes in ground beef (Willardson, et al., 1978), whereas the shortest generation time for *B. cereus* ranged from 18 to 27 minutes in tryptic soy broth (TSB)<sup>62</sup> and rice under optimum growth temperatures (i.e., 35°C to 45°C) (Johnson, et al., 1983). In addition, the cooling options in Table 1 for products that do not contain nitrite and erythorbate or ascorbate are similar to the FDA Food Code cooling recommendations which are designed to control the growth of all spore-forming bacterial pathogens including *B. cereus* in all cooked products (see Attachment B6. Other Published Processing Guidelines for Cooling, page 77).<sup>63</sup>

Attachment B4. Steps an Establishment Can Take to Cool Products More Rapidly Some establishments may have challenges meeting the cooling recommendations in this guideline, particularly for large mass products. For products that are close to meeting the time-temperature parameters for the cooling options in this guideline, establishments may benefit from critically examining their cooling process and system and making minor improvements such as:

- Making sure the cooling system is operating properly.
- Ensuring cooler door seals and gaskets are in good repair and properly seal when each door is closed.
- Pre-chilling the cooler before loading the product.
- Using a lower temperature setting in the cooler.
- Increasing airflow (e.g., adding a fan) to speed cooling.
- Leaving more space between products to allow increased air circulation between products.
- Allowing space between product and the walls, floors, and ceiling to improve air circulation.
- Agitating or stirring liquid products while cooling.
- Cooling product before packaging, stacking, or palletizing because stacks of product can insulate those products in the middle and inhibit cooling. May also make smaller stacks of product because smaller pieces or smaller groups of products cool faster.
- Reducing the amount of product in each batch or lot placed in the cooler at one time to reduce the total heat load to be removed.
- Taking steps that would decrease the temperature of the product prior to placing it in the cooler to reduce the heat load on the cooling system. For example, apply a liquid cooling procedure (e.g., cold brine shower, ice bath) or dry ice to rapidly cool the product prior to placing it in the cooler.
- Making minor production changes to reduce product size or diameter (e.g., by cutting large roasts into smaller portions or using a smaller size casing for sausages), provided these changes do not impact product quality.<sup>64</sup>

Attachment B5. Predictive Microbial Modeling and Corrective Actions Following a Deviation This appendix on predictive modeling includes the following several sections:

- Recommendations when Conducting Predictive Microbial Modeling
- Validated Pathogen Models
- Assessing Growth of Clostridia when a Process Incorporates Multiple Heat

Treatments \u2022 Corrective Actions to Perform When a Cooling Deviation Occurs Predictive food microbiology uses models (i.e., mathematical equations) to describe the growth, survival, or inactivation of microbes in food systems based on knowledge of the intrinsic and extrinsic factors of the food over time. Establishments can use predictive microbial models to help guide the design of a customized cooling process for processes that can\u2019t meet the critical operating parameters recommended in this guideline. Predictive microbial models can also be used to support product safety in the event of a cooling deviation, potentially preventing the need to perform sampling. There are many free predictive microbial models available to establishments either online or through a download. Establishments should not rely on the results of a predictive model alone unless the model has been validated for the particular food of interest. Note that there are several validated predictive models available for assessing *C. perfringens* growth. Recommendations when Conducting Predictive Microbial Modeling FSIS recommends that the establishments abide by the following principles when choosing and using a predictive microbial model to assure they model useful scientific support. 1. Use a model that has been validated for the product of interest. 2. Conduct modeling using at least five time-temperature data points. 3. Conduct modeling based on the worst-case cooling time-temperature profile for the product of interest. 4. Input accurate pH and salt concentrations, if included in the model; and 5. Maintain the results of the modeling electronically or via a hardcopy file. More detail on each of these principles is below: 1. Use a model that has been validated for the product of interest. Do not rely solely on a model unless the model has been validated for the particular food of KEY DEFINITIONS Intrinsic factors are those parameters inherent to a food that affect the growth of microorganisms. Examples of intrinsic factors include pH, moisture content, salt concentration, water activity, and nutrient content. Extrinsic factors are those parameters that are external to the food that affect the growth of microorganisms. Examples of extrinsic factors include, temperature of storage, time of storage, and relative humidity. KEY DEFINITIONS Intrinsic factors are those parameters inherent to a food that affect the growth of microorganisms. Examples of intrinsic factors include pH, moisture content, salt concentration, water activity, and nutrient content. Extrinsic factors are those parameters that are external to the food that affect the growth of microorganisms. Examples of extrinsic factors include temperature of storage unit, time of storage, and relative humidity.","65 interest. A validated cooling model is a model in which predictions have been found to agree with or are more conservative than the actual observed results. If a model has not been validated for a particular food of interest, establishments need to provide additional documentation to support the results from the model (e.g., sampling data or comparison with other model results). \u2022 These four cooling models have been validated for assessing the growth of *C. perfringens* in cooked\heat-treated meat and poultry products: 1. ComBase Perfringens Predictor Model a. uncured and cured meat, and b. poultry 2. USDA ARS Predictive Microbiology Information Portal (PMP Online) models for: a. cooked, uncured beef, pork, and chicken; b. cured pork and beef; and c. cooked beef supplemented with NaCl, sodium nitrite, and sodium pyrophosphate; 3. USDA ARS Pathogen Modeling Program (download version 7.0\8.0) models for: a. cooked, cured beef and chicken; and 4. Smith-Schaffner Model\u2014Version 3 a. uncured meat and poultry products \u2022 This cooling model failed validation testing and is not recommended: ARS *C. perfringens* in beef broth model. This model has been found to typically under-predict the growth of *C. perfringens* (Mohr et al., 2015).

Because the model failed to be validated, it has been removed from the ARS website although some establishments may have it downloaded on their computers. \u2022 This cooling model has not been validated, but may be used: ARS C. botulinum in beef broth cooling model (Available through PMP Online or the downloaded version of the ARS Pathogen Modeling Program). Although this model has not been validated, it is the best tool available at this time. Therefore, FSIS does not object to the use of this model without additional support.

2. Conduct modeling using at least five time-temperature data points. At least five data points are needed to run certain cooling models and to get an accurate estimate. If less than five data points are available, establishments may be able to develop a cooling curve by interpolating additional points, assuming a linear decrease between known values. One common error is incorrectly inputting time points using the wrong units; hours instead of minutes or minutes instead of hours.

3. Conduct modeling based on the worst-case cooling time-temperature profile for the product of interest. To assess what the worst-case cooling scenario might be, the establishment should account for its actual cooling CCP or prerequisite program critical limits. For example, if the establishment\u2019s,"66 customized cooling process schedule critical limits are to cool from 130\u00b0F to 80\u00b0F in 2 hours and between 80\u00b0F and 40\u00b0F in 5.5 hours, it should assume the worstcase (that is, a linear decrease) between these values in order to determine the growth of C. perfringens.

4. Input accurate pH and salt concentrations, if included in the model. Knowledge of intrinsic and extrinsic factors (e.g., pH, aw, temperature, salt concentration) used as inputs for the model is essential to have confidence in the results. Establishments should determine and use values for these parameters that represent the worst-case of possible processing conditions and have documentation to support the values used. If the establishment does not know the pH and salt concentrations, it should assume a worst-case pH of 6.2 and salt concentration of 1% unless no salt is added and then 0% should be used.

5. Maintain modeling results on file. Both the input and the output of the modeling results should be maintained as part of the supporting documentation for the life of the plan (9 CFR 417.5(a)(1)), along with support that the model has been validated (which could include this guideline).

**Validated Pathogen Models**

As described above, establishments should not rely on the results of a model alone unless the model has been validated for the particular food of interest. This section describes, in more detail, the sources for validated cooling models currently available for assessing the growth of C. perfringens in cooked\heat-treated meat and poultry products, with information on their availability. Not all models cover a full range of growth parameters. Therefore, knowledge of the basis for the model and its limitations in different food systems is key to making supportable determinations and using a model properly.", "67 ComBase Perfringens Predictor Model: The ComBase website contains a number of predictive microbial models. One in particular, The ComBase Perfringens Predictor model (see Figure 11) available at [https://browser.combase.cc/Perfringens\\_Predictor.aspx](https://browser.combase.cc/Perfringens_Predictor.aspx) has been validated<sup>11</sup> for cooked, cured, and uncured meat and poultry products. Therefore, establishments may rely on the results from this model alone. Establishments should be aware that this model provides an accurate estimation of the growth of C. perfringens in cooked, cured, and uncured meat and poultry products. Furthermore, in addition to taking into account whether the products are cured or uncured, the ComBase Perfringens Predictor model takes into account the pH and salt concentration of the meat or poultry product, which the other cooling models do not. Establishments may select the \u201ccured\u201d option for products

that contain at least 100 ppm of ingoing nitrite from a synthetic or natural source. USDA ARS Predictive Microbiology Information Portal (PMIP or PMP Online): The USDA ARS PMP Online, available at <https://pmp.errc.ars.usda.gov/PMPOnline.aspx>, contains a number of predictive microbial models (See Figure 12 for an example.).<sup>68</sup> A copy of the validation report is available from the Food Standard Agency, United Kingdom. The cooling model research has been published in the International Journal of Food Microbiology (Yvan Le Marc et al., 2008). Figure 11. Screenshot of ComBase Perfringens Predictor.<sup>69</sup> The following three cooling models for uncured meat and poultry products on PMP Online have been validated (Mohr et al., 2015): C. perfringens in cooked, uncured beef. C. perfringens in cooked, uncured pork. C. perfringens in cooked, uncured chicken. Establishments may, therefore, rely on the results from these cooling models alone, without any additional supporting documentation. In addition, the following models for cured meat and poultry products have been validated (Mohr, 2018): C. perfringens in cooked, cured beef. C. perfringens in cooked, cured pork. C. perfringens in cooked beef supplemented with NaCl, sodium nitrite, and sodium pyrophosphate. Establishments may, therefore, also rely on the results from these cooling models alone. Establishments should be aware that, in most cases, these cooling models will overestimate the amount of growth of C. perfringens in a meat or poultry product involved in a cooling deviation or for a customized cooling schedule. In addition, establishments should not rely solely on the results of other models within the PMP Online because most of them have not been validated. USDA ARS Pathogen Modeling Program (download version 7.0/8.0) The USDA's ARS has a number of predictive microbial models that are available in its downloadable Pathogen Modeling Program. The downloadable version of the Pathogen Modeling Program can be found at: <https://portal.errc.ars.usda.gov/PMP.aspx>. The following cooling models are available within the downloadable Pathogen Modeling Program (both version 7.0 and 8.0): C. perfringens in cooked, cured beef. C. perfringens in cooked, cured chicken. These cooling models have been validated (Mohr, 2018). Therefore, establishments may rely on the results from these cooling models alone. Figure 12. Screenshot of ARS PMP Online.<sup>70</sup> Establishments should be aware that in most cases these cooling models will overestimate the amount of growth of C. perfringens in a meat or poultry product involved in a cooling deviation or for a customized cooling schedule. In addition, establishments should not rely solely on the results of other models within the PMP Online since most of them have not been validated. Smith-Schaffner Model<sup>71</sup>: The Smith-Schaffner Model, Version 3, a Microsoft Excel-based model, is another cooling model that can be used for assessing the growth of C. perfringens. The Smith-Schaffner Model, Version 3, also meets the FSIS criteria for acceptable performance and validation for food safety<sup>72</sup> (Mohr et al., 2015). Therefore, establishments may rely on the results of this model alone. This model has been validated for cooked, uncured meat and poultry products. It is a reliable model for assessing the severity of cooling deviations for cooked, uncured meat and poultry products with typical pH values and typical levels of salt and phosphate. It is also a useful model for evaluating deviations because it allows for input of data where the temperature decreases and then increases and decreases a second time. The Smith-Schaffner Model is no longer available online but establishments may request a copy through askFSIS. Using Predictive Microbial Models to Assess Growth of Clostridia when a Process Incorporates Multiple Heat Treatments As previously explained, FSIS guidance is designed for cooling processes where the product is

cooked or heated once and then cooled. A full lethality treatment will destroy all vegetative cells of Clostridia, leaving only the spores to survive. It is the outgrowth of spores and the production of toxins or high levels of vegetative cells that are the concerns during stabilization. However, for some processes where the products are cooked, cooled, and then undergo a partial heat treatment followed by cooling, establishments should assess the cumulative growth of Clostridia. Establishments should take the following into account when determining whether they need to assess the growth of Clostridia over multiple heating and cooling steps:

- \u2022 If the process incorporates multiple full lethality treatments (i.e., by achieving FSIS Cooking Guideline conditions), the establishment needs to assess the growth of Clostridia during the cooling step following each individual lethality treatment and does not need to assess the cumulative growth over the multiple steps; and
- \u2022 If the process incorporates a full lethality treatment, and then is followed by a post-lethality heat treatment that does not achieve a full lethality and then restabilizes (cools) the product, the establishment should assess the cumulative growth of *C. perfringens* that occurs during the first cooling process, the growth,"70 that occurs during the heating come-up, and the growth that occurs during the cooling come-down time of the subsequent post-lethality treatment or warming step. Common examples of processes that use post lethality heat treatments include double smoking, applying heat to the surface of a cooled RTE product after slicing, reheating a filling, or frying a tamale that contains cooked meat. To assess the cumulative growth of *C. perfringens* in the process, as described in the second bullet above, establishments should perform predictive microbial modeling of certain heating and cooling steps in the process. More specifically, this modeling should include the first cooling step and the heating come-up and cooling come-down time of the subsequent post-lethality treatment or warming step using the same model. FSIS recommends that to perform the modeling, establishments collect time-temperature profiles for each of the aforementioned heating and cooling steps. Establishments that receive previously cooked product from a supplier and then apply a heat treatment should communicate with their supplier to obtain its worst-case cooling profile or its cooling critical limits\prerequisite program limits to determine the worst-case cooling profile (e.g., by interpolating additional points for modeling by assuming a linear decrease between time-temperature limits). Based on the worst-case time-temperature profiles, establishments can use one of the options below for modeling cooked meat and poultry products:

1. Use the ComBase Perfringens Predictor cooling model (found under Food Models on the ComBase website) and the ComBase *C. perfringens* Growth Model (found under Growth Models on the ComBase website) to assess the cumulative growth of *C. perfringens* during the entire time-temperature profile based upon a worst-case scenario approach. For this option, FSIS recommends that establishments:
  - \u2022 Use the ComBase Perfringens Predictor to estimate the *C. perfringens* growth during the first cooling step and then add those results to the results obtained by performing the next step below.
  - \u2022 Use the ComBase *C. perfringens* Growth Model to estimate the *C. perfringens* growth during the heating come-up and cooling come-down time of the subsequent post-lethality treatment or warming step.
  - o Use a physiological state of 1 (no lag phase) to model in a conservative manner, given that many of these predictive microbial growth models are not fail-safe for predicting the lag phase (Tamplin, 2002; Vold, et al., 2000; Walls and Scott, 1996).
  - o Use a temperature of 59\u00b0F (15\u00b0C) for the product\u2019s time-temperature data points that are below 59\u00b0F (15\u00b0C) to

overcome one of the shortcomings of using the ComBase C. perfringens growth model. NOTE: It is only appropriate to conduct separate models for each of the steps in the process (e.g., modeling the first cooling step and then the second heating CUT and cooling step separately) if a physiological state of 1 is used to indicate no lag phase, when using the ComBase C. perfringens Growth Model. Otherwise, the modeling would assume C. perfringens undergoes a lag phase,"71 each time the model is run, which would not be representative of the actual process. 2. Use the ComBase C. perfringens Growth Model to assess the cumulative growth of C. perfringens during the entire time-temperature profile based upon a worst-case scenario approach. For this option, FSIS recommends that establishments: \u2022 Use a physiological state of 1 to model, in a conservative manner, especially given that many of these predictive microbial growth models are not fail-safe for predicting the lag phase (Tamplin, 2002; Vold, et al., 2000; Walls and Scott, 1996); and \u2022 Use a temperature of 59\u00b0F (15\u00b0C) for product\u2019s time-temperature data points that are below 59\u00b0F (15\u00b0C) to overcome one of the shortcomings of using the ComBase C. perfringens growth model. 3. Use the Smith-Schaffner Model to assess the cumulative growth of C. perfringens during the entire time-temperature profile based upon a worst-case scenario approach. The modeling results should demonstrate that the entire process allows no more than the performance standard or the target the establishment identifies (i.e., 1.0-Log total growth of C. perfringens and no multiplication of C. botulinum) in the finished product before shipment. When employing a post-lethality heat treatment, establishments should remember that C. perfringens will not grow at temperatures of 130\u00b0F or greater. Establishments may also choose to conduct a challenge study to demonstrate that the entire process allows no more than the performance standard or the target the establishment identifies (i.e., 1.0-Log total growth of C. perfringens and no multiplication of C. botulinum) in the finished product before shipment.

**Corrective Actions to Perform When a Cooling Deviation Occurs**

Cooling deviations occur when an establishment fails to meet its cooling CCP critical limit or cooling process schedule. Common causes for cooling deviations are exceeding the chilling capacity of the coolers, power failures, or breakdowns of refrigeration equipment. Establishments are required to take corrective actions, as per the HACCP regulations, regardless of whether the cooling process is addressed through a CCP or prerequisite program. In such situations, establishments must be able to ensure that no product that is injurious to health or otherwise adulterated because of the deviation enters commerce, and to support its product disposition decisions (9 CFR 417.3(a) and (b)). NOTE: FSIS included the Corrective Actions to Perform When a Cooling Deviation Occurs within the Pathogen Modeling section because FSIS recommends pathogen modeling as the first step to evaluate product safety. FSIS does not recommend testing without modeling first."72 When cooling is addressed through a CCP, establishments are required to determine the cause of all cooling deviations, no matter how small (9 CFR 417.3(a)(1)), and ensure measures are established to prevent recurrence (9 CFR 417.3(a)(3)). Ultimately, if the cause of each small cooling deviation is not traced and corrected when first noticed, the problem will likely recur and become more frequent and more severe. The establishment should consider an occasional small deviation to be an opportunity to find and correct a problem. Large deviations or continual small ones always constitute unacceptable risk. Also, continual or repetitive deviations from the critical limit demonstrate that the establishment is unable to control its process and that corrective actions are not preventing problems as intended (9 CFR 417.4(b)).

When cooling is addressed through a prerequisite program and a deviation occurs, establishments are required to reassess their food safety system to determine whether the newly identified deviation or unforeseen hazard should be addressed and incorporated into the HACCP plan (9 CFR 417.3(b)(4)). Also, an establishment may not be able to continue to support the decision in its hazard analysis that spore-formers are not reasonably likely to occur, if it has continual or repetitive deviations from its cooling prerequisite program (9 CFR 417.5(a)(1)). To determine the safety of the product affected by a cooling deviation, FSIS recommends that establishments first conduct modeling using validated cooling models. Depending on the results of the modeling, sampling may be recommended. As part of the support for product safety, FSIS recommends establishments write up an assessment of the deviation that addresses the specific hazards and includes: \u2022 The predictive microbial model selected (including supporting documentation that the model has been validated). \u2022 The data inputs to the model (and in the case of missing data, a rationale or support for data used). \u2022 An assessment of the results generated by the model. \u2022 A product disposition determination." "73 Using Pathogen Modeling to Assess a Cooling Deviation FSIS recommends establishments use validated predictive microbial models to assess cooling deviations, such as the ComBase Perfringens Predictor model. General recommendations regarding cooling models can be found on page 64 of this guideline. Predictive microbial models (i.e., cooling models) are an excellent tool to use in assessing the severity of a cooling deviation, provided the model has been validated for the specific product. In the case of a cooling deviation, establishments should input the time-temperature profile as documented through monitoring. If an establishment does not know the pH or salt concentration of the product that experienced the cooling deviation, it should assume a worst-case pH of 6.2 and a salt concentration of 1% (Mohr et al., 2015). Once establishments obtain modeling results, they should evaluate them to determine product disposition. The disposition of RTE and NRTE product resulting from cooling deviations and based on modeling and\or sampling should follow the criteria below: \u2022 Result 1. There is no more than 1-Log growth of *C. perfringens* and no *C. botulinum* growth (mean net growth \u2264 0.30-Log)<sup>12</sup> then the process meets the stabilization performance standard or policy and the product may be: o Released into commerce. \u2022 Result 2. There is more than a 1-Log growth of *C. perfringens*, no *C. botulinum* growth<sup>13</sup> (mean net growth \u2264 0.30-Log), less than 3.0-Log growth of *B. cereus*<sup>14</sup>, and the establishment does not have support that spore levels in the product are low, then product may be: o Recooked, o Sampled and Tested (N \u2265 10), or 12If there is no more than 1-Log growth of *C. perfringens*, then multiplication of *C. botulinum* is unlikely based on FSIS\u2019s review of modeling that establishments conducted in response to deviations and FSIS\u2019 modeling performed to support its cooling recommendations. Therefore, establishments can support the products\u2019 safety using *C. perfringens* alone without conducting modeling for *C. botulinum*. <sup>13</sup>In the event of a cooling deviation for cured meat and poultry products, establishments can support the safety of affected product using modeling for *C. perfringens* alone without conducting modeling for *C. botulinum* because the presence of nitrite, salt, and a cure accelerator such as sodium erythorbate, should ensure that no multiplication of *C. botulinum* occurred during the deviation <sup>14</sup>In general, establishments only need to assess *B. cereus* growth when modeling estimates *C. perfringens* growth is \u02c3 3.0-Log\u2014because *C. perfringens* grows faster than *B. cereus*. Establishments can assess *B.*

cereus growth using the ComBase Growth Model for *B. cereus* (found under ComBase Predictor Growth Models). Although this model has not been validated, it is the best tool available, so establishments may use it. Establishments should use a physiological state of 1 to model in a conservative manner, especially given that many of these predictive microbial growth models are not failsafe for predicting the lag phase.","74 o Destroy the product (rendered or denatured per 9 CFR 314.3(a), 9 CFR 325.11(a), 9 CFR 325.13(a)(1) through 325.13(a)(7), or 9 CFR 381.95 and sent to a landfill). \u2022 Result 3. There is greater than a 1.0-Log growth of *C. perfringens* and greater than a 0.30-Log increase of *C. botulinum*, then product must be: o Destroy the product (rendered or denatured per 9 CFR 314.3(a), 9 CFR 325.11(a), 9 CFR 325.13(a)(1) through 325.13(a)(7), or 9 CFR 381.95 and sent to a landfill). Sampling after Pathogen Modeling If an establishment has conducted modeling that showed Result 2 above, then the establishment may conduct sampling to assess the safety of the product involved in a deviation. FSIS recommends that establishments conduct modeling prior to any sampling, because it provides greater confidence for estimating levels of *C. perfringens* growth. Sampling is more limited because *C. perfringens* is generally not evenly distributed throughout the product. Therefore, depending on the results of the modeling, sampling may be an appropriate tool to provide information to the establishment to help support product disposition. Specifically, if modeling indicates there is more than a 1-Log growth of *C. perfringens* and no *C. botulinum* growth (mean net growth \u2264 0.3-Log), less than 3-Log growth of *B. cereus*, and the establishment does not have support that spore levels in the product are low, then product may be sampled to further support product safety. The following are FSIS recommendations for conducting this sampling and testing: \u2022 At least 10 samples per affected lot should be taken at random. Samples should NOT be composited because the analysis is quantitative for each sample to determine product disposition. \u2022 Samples should be refrigerated at 2-10\u00b0C (35-50\u00b0F) immediately after collection. Samples should be shipped to the laboratory under refrigerated (2-10\u00b0C) conditions overnight or for receipt within 24 hours at the laboratory. Upon laboratory receipt, samples should be inspected for condition and temperature and immediately refrigerated (2-10\u00b0C). The laboratory should promptly analyze samples to avoid loss of cell viability. The laboratory should not analyze samples more than 24 hours after receipt or that have been compromised during shipping. \u2022 Testing should be performed to specifically assess for *C. perfringens* or gas forming anaerobes (GFAs). FSIS considers modeling results that demonstrate > 0.30-Log increase of *C. botulinum* to indicate multiplication. In general, predictive models FSIS recommends, such as the ARS *C. botulinum* in beef broth model, do not predict zero growth. As a practical way to evaluate cooling deviations, the Agency has regarded a predicted growth of no more than 0.3-Log (an approximate doubling, or one generation) as an indication that there has been no growth.","75 \u2022 If no sample exceeds 100 CFU/gram and no more than two samples equal 100 CFU/gram, then the lot can be released into commerce and sold as is. If no more than two samples exceed 100 CFU/gram and none exceeds 500 CFU/gram, then establishments should recook the lot of product. If more than two samples equal or exceed 100 CFU/gram or any exceed 500 CFU/gram, then the product should be destroyed. Recooking after Pathogen Modeling If an establishment has conducted modeling that showed Result 2 above, then the establishment also has the option to recook the product (without sampling and testing). FSIS recommends establishments conduct predictive microbial modeling for *C. botulinum* before

recooking, because in the event the modeling shows greater than a 0.3-Log increase of C. botulinum, then recooking is not an appropriate method of product disposition. A minimum recock temperature of 149°F with a holding time of at least two minutes, or a minimum instantaneous temperature of 169°F, is recommended when recocking product. This will address the hazard of C. perfringens vegetative cells because it will result in at least a 5.0-Log reduction. FSIS recommends establishments recock only when: (1) All product was either immediately refrigerated after the deviation or can be immediately recooked after the deviation. (2) The recocking procedure can achieve a final internal product temperature of at least 149°F (65°C) for two (2) minutes or an instantaneous internal product temperature of 169°F. Subsequent to recocking, the product must again be cooled according to the establishment's support. (3) When the product is to be reworked with another raw product, the recocking procedure for the combined product must achieve a minimum internal product temperature of 149°F (2 minutes holding time) to address the cooling deviation. The time-temperature for the combined product should be increased further, if necessary, to be in accord with any other requirement relative to microbiological safety for the intended final product. The reworked product must again be cooled to meet these same stabilization performance standards or targets. FSIS recommends establishments recock product to a final internal product temperature of at least 149°F (65°C) for two (2) minutes or an instantaneous internal product temperature of 169°F, because C. perfringens is more heat tolerant once a product has been cooked. The time-temperature options in the FSIS Cooking Guideline meat table are based on thermal death time studies for Salmonella in raw ground beef. Therefore, the recommendations may not be sufficient to address C. perfringens in a cooked product. For example, Vijay et al., 1998 showed that contaminated cooked beef should be re-heated to an internal temperature of 62.5°C (144.5°F) for at least 9.6 minutes and cooked turkey for at least 7.8 minutes to achieve at least a 6-Log, 76 reduction of C. perfringens. However, the FSIS Cooking Guideline time-temperature table for meat products only has a dwell time of 5 minutes at 62.2°C (144°F). FSIS's recocking recommendations are based on D- and z-values reported in the published research (Vijay et al., 1998). FSIS defined instantaneous temperature based on a dwell time of 10 seconds. Establishments may recock to other temperatures, provided they can support that the procedure would result in at least a 5.0-Log reduction of C. perfringens in a product that has been cooked. These values may not be suitable if the product to be recocked underwent a drying process after the original cooking step. (77 Attachment B6. Other Published Processing Guidelines for Cooling FDA Time-Temperature Recommendations for Cooling The Food and Drug Administration (FDA) Food Code is another type of support that establishments may use for cooling. Section 3-501.14 Cooling of the 2017 FDA Food Code recommends the following parameters for cooling products cooked to full lethality: (A) Cooked TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cooled: (1) Within 2 hours from 57°C (135°F) to 21°C (70°F); and (2) Within a total of 6 hours from 57°C (135°F) to 5°C (41°F) or less. This option applies to: 1. Products cooked to full lethality (including intact or non-intact meat or poultry). Establishments must keep the most up-to-date copy of the FDA Food Code on file as supporting documentation to use this cooling procedure. CFIA Time-Temperature Recommendations for Cooling An establishment may follow the cooling parameters from the Canadian Food Inspection Agency

(CFIA) cooling procedure found in the CFIA\u2019s Cooling of Heat Processed Meat Products, because FSIS has verified this option results in \u2264 1 log growth of *C. perfringens* and no multiplication of *C. botulinum*. During continuous cooling immediately after the heating cycle is completed: (A) The product's maximum internal temperature must not remain between 54\u00b0C (129.2\u00b0F) and 27\u00b0C (80.6\u00b0F) for more than two (2) hours, and (B) Not remain between 54\u00b0C (129.2\u00b0F) and 4\u00b0C (39.2\u00b0F) for more than 7 hours." , "78 Attachment B7. Using Challenge Studies to Support Alternative

Stabilization\Cooling Procedures In cases where an establishment\u2019s process does not match available scientific support documents, such as this guideline or a published journal article, establishments may decide to conduct an inoculation challenge study to support that their process achieves adequate cooling and controls the growth of Clostridia. In a challenge study, the number of organisms before and after the application of the control measure are counted to determine the effect of the control measure. Challenge studies should be conducted by a microbiologist trained in performing challenge studies in a laboratory to avoid the possible spread of contamination in an establishment. The challenge study should be designed to match the establishment\u2019s time-temperature cooling profiles and intrinsic factors in the establishment\u2019s actual process in order to establish these as critical operating parameters. It is also important for the challenge study to be conducted using the pathogen of interest and that the appropriate inoculation level be 1 to 3-Log CFU\g to show limited Log growth of the target pathogens. *C. perfringens* can be used alone in an inoculated pack study to demonstrate that the cooling performance standard or target is met for both *C. perfringens* and *C. botulinum*. This is because conditions of time-temperature that would limit the growth of *C. perfringens* to 1-Log or less would also prevent multiplication of *C. botulinum*, which is much slower. A cocktail of various strains of *C. perfringens* spores is often used for this purpose.

Relatively \"fast\" growing toxigenic strains of *C. perfringens* should be used to develop a worst-case scenario. However, the spore strains selected should also be heat-tolerant and among those that have been historically implicated in an appreciable number of outbreaks, especially in products similar to those being prepared by the establishment. In consultation with ARS, FSIS recommends establishments use a cocktail of the following three strains of *C. perfringens*: NCTC 8238 (Hobbs serotype 2), NCTC 8239 (Hobbs serotype 3) and NCTC 10240 (Hobbs serotype 13). The final measure of bacterial load in the product after cooling should include a measure of both spore levels and vegetative cells. Challenge studies should contain an equivalent level of detail as peer-reviewed scientific literature and should use methodology equivalent to that used in peerreviewed research. As stated in the FSIS Validation Guideline, page 8, challenge studies should be based on a sound statistical design (i.e., a statistical design that ensures confidence in the data) and should employ positive and negative controls. The statistical design should include the number of samples collected at each time interval and the number of study replicates needed to ensure the validity of the study. There are quantitative methods for assessing the statistical quality of a study (e.g., power analysis). As recommended by the National Advisory Committee on Microbiological Criteria of Foods (NACMCF), the minimum number of samples to be analyzed initially and at each time interval during processing or storage should be at least two; however, NACMCF recommends analysis of three or more samples. According to NACMCF, replicates should also be conducted. Replicates should be independent trials using different lots of product and inoculum to account for variations in

product, process, inoculum, and other factors. When the number of samples analyzed at each time interval is only two, it is better for the study to be repeated (replicated) more than two","79 times. In studies with three or more samples tested at each time interval, two replicates are usually adequate. All the critical elements of the study discussed above need to be included to permit evaluation or confirmation of the results. For more information on conducting challenge studies please review the article, \u201cParameters for Determining Inoculated Pack\Challenge Study Protocols\u201d published by the NACMCF in the Journal of Food Protection in 2010.", "80 Attachment B8. Using Journal Articles to Support Alternative Stabilization or Cooling Procedures Establishments may use published journal articles as scientific support for their process as they are a type of peer-reviewed scientific data discussed in the FSIS Validation Guideline. If an establishment chooses to use a journal article as scientific support, it should ensure that all critical operating parameters used in the study match those used in the actual process. Examples of critical operational parameters that should be compared include cooling time-temperature profile, amenable species of meat or poultry used in the product, pH, water activity, salt concentration, sodium nitrite concentration, and any added antimicrobial ingredients. Some of these critical operational parameters may become part of the critical limits of a CCP, may be incorporated into a prerequisite program or may be monitored at the set-up of the food safety system as part of initial validation. If one or more of the critical operating parameters are not addressed in the establishment\u2019s process or do not match the parameters used in the support, then the establishment should document a science-based justification for why the parameter does not need to be met or measured, or why it differs from the support. Additionally, an establishment should have knowledge of the products it produces, including knowledge of the pH, salt concentration, etc. even if these are not critical operating parameters in its scientific support because this information can be helpful in the event of a cooling deviation. FSIS has compiled a summary table of journal articles that establishments may use as scientific support for their process in Table 15 (page 82). In response to common questions, FSIS has included in this table articles for the stabilization of partially heat-treated bacon and fully cooked scrapple (Table 15). FSIS has also provided recommendations for using published research on bacon heating CUT along with predictive microbial modeling to support stabilization of bacon processes (page 81). Table 15 is only to be used as a quick reference guide so an establishment can identify a similar product and process. This table is not valid support for a HACCP system. Rather, establishments should maintain a copy of any articles it uses for scientific support of their systems.", "81 Alternative support for partially heat-treated bacon FSIS is also aware of a study by Sindelar et al. (2019) evaluating C. perfringens growth during slow partial heat treatment of pork instead of smoked pork bellies. This article was not included in the summary table (Table 15) since it does not address C. perfringens growth during stabilization (cooling). However, establishments may consider using this article and predictive microbial modeling to support a custom cooling schedule for partially heat-treated bacon products with long CUT. To do this, the establishment would: 1. Follow the heating process schedule from the article (Sindelar et al., 2019), address all critical operating parameters, and maintain a copy of the article on file. 2. Use predictive microbial modeling to develop a custom cooling schedule that limits the growth of C. perfringens during cooling to 0.3-Log or less. To model the cooling, FSIS recommends using the ComBase C. perfringens Growth Model based upon a worst-case scenario approach. When performing modeling, FSIS

recommends that establishments:

- o Use a physiological state of 1 (no lag phase) to model in a conservative manner, since Sindelar et al. (2019) showed the bacteria will be out of the lag phase as the product starts to cool;
- o Use a temperature of 59\u00b0F (15\u00b0C) for product\u2019s time-temperature data points that are below 59\u00b0F (15\u00b0C) to overcome one of the shortcomings of using the ComBase C. perfringens Growth Model.

3. Maintain a copy of the custom modeling support on file (see Attachment B5. Predictive Microbial Modeling, page 64).

4. Maintain a decision-making document or a copy of this guidance to explain how the two scientific documents may be combined to address cumulative C. perfringens growth

- o Specifically, the Sindelar et al. (2019) estimated that 0.7-Log C. perfringens growth during the heating CUT, plus \u22640.3-Log growth during the custom cooling schedule, will ensure that total C. perfringens growth during heating and cooling of the bacon is limited to 1.0-Log or less.", "This Appendix is not considered adequate support on its own because it does not provide the details of each study (such as the concentration of salt and other ingredients) that an establishment needs to determine if the study is representative of the actual process. Establishments need to have the complete copy of the article on file as part of its supporting documentation to determine the levels of the critical operating parameters used.

82 Table 15. Time and Temperature Parameters Reported in the Literature for Stabilization Processes Key:  $\u22641 = \u22641.0 \log \text{CFU/g}$  C. perfringens growth  $\u22642 = > 1.0 \log \text{CFU/g}$  but  $\u22642.0 \log \text{CFU/g}$  C. perfringens growth  $>2 = > 2.0 \log \text{CFU/g}$  C. perfringens growth Product Critical Operational Parameters Provided Experimental Conditions for Chilling\|C. perfringens Growth Reference Roast Beef \|f0d8 pH range 5.51-5.77 \|f0d8 Salt (NaCl)16 \|f0d8 Potassium tetra pyrophosphate \|f0d8 Ional=buffered sodium citrate \|f0d8 Ional Plus=buffered sodium citrate supplemented with sodium diacetate \|f0d8 Purasal=sodium lactate \|f0d8 Optiform= sodium lactate supplemented with sodium diacetate \|f0d8 Single rate exponential cooling 54.4\u00b0C(130\u00b0F) to 7.2\u00b0C (45\u00b0F) 18 h 21 h Ional 0.75% \|2264 1 \|2264 1 Ional 1% \|2264 1 \|2264 1 Ional 1.3% \|2264 1 \|2264 1 Ional Plus 0.75% > 2 > 2 Ional Plus 1% \|2264 1 \|2264 1 Ional Plus 1.3% \|2264 1 \|2264 1 Purasal 1.5% \|2264 1 \|2264 2 Purasal 3% \|2264 1 \|2264 1 Purasal 4.8% \|2264 1 \|2264 1 Optiform 1.5% \|2264 1 \|2264 1 Optiform 3% \|2264 1 \|2264 1 Optiform 4.8% \|2264 1 \|2264 1 Juneja, V.K. and Thippareddi, H. 2004b. Roast Beef \|f0d8 pH 5.79 \|f0d8 aw 0.98 \|f0d8 Salt \|f0d8 Sodium pyro-and polyphosphate blend \|f0d8 MoStatin LV1 (buffered lemon juice and vinegar) \|f0d8 Single rate exponential cool 54.4\u00b0C (130\u00b0F) to 7.2\u00b0C (45\u00b0F) 6.5 h 9 h Beef (2.0% Salt) \|2264 1 \|2264 1 Beef (1.5% Salt) \|2264 2 \|2264 2 Beef (1.5%Salt + MoStatin) \|2264 1 \|2264 1 Lin, L. 2012. 16 The concentration of salt and other ingredients is not included in this attachment. For this reason, if an establishment chooses to use one of the articles provided in the attachment for scientific support, the establishment will need to have the complete copy of the article on file as part of its supporting documentation to determine the levels of the critical operational parameters used in the study.", "This Appendix is not considered adequate support on its own because it does not provide the details of each study (such as the concentration of salt and other ingredients) that an establishment needs to determine if the study is representative of the actual process. Establishments need to have the complete copy of the article on file as part of its supporting documentation to determine the levels of the critical operating parameters used.

83 Product Critical Operational Parameters Provided Experimental Conditions for

Chilling\|C. perfringens Growth Reference Roast Beef \uf0d8 Salt \uf0d8 Sodium citrate \uf0d8 Sodium lactate \uf0d8 Trisodium phosphate \uf0d8 Exponential cooling \uf0d8 Salt \uf0d8 Sodium acetate \uf0d8 Trisodium phosphate \uf0d8 Exponential cooling 54.4\u00b0C (130\u00b0F) to 4\u00b0C (39.2\u00b0F) 18 h Sodium citrate (pH 5.6) at 2.0% (wt\wt) \u2264 1 Sodium citrate (pH 5.6) at 4.8% (wt\wt) \u2264 1 Sodium citrate (pH 5.0) at 2.0% (wt\wt) \u2264 1 Sodium citrate (pH 5.0) at 4.8% (wt\wt) \u2264 1 Sodium citrate (pH 4.4) at 2.0% (wt\wt) \u2264 1 Sodium citrate (pH 4.4) at 4.8% (wt\wt) \u2264 1 Sodium lactate (pH 7.3) at 2.0% (wt\wt) \u2264 1 Sodium lactate (pH 7.3) at 4.8% (wt\wt) \u2264 1 54.4\u00b0C (130\u00b0F) to 4\u00b0C (39.2\u00b0F) 18 h Control \u2264 2 Sodium acetate (pH 9.0) at 0.25% (wt\wt) \u2264 2 Sodium diacetate (pH 4.5) at 0.25% (wt\wt) \u2264 1 Sabah, J.R. et al., 2003. Roast Beef \uf0d8 Salt \uf0d8 Potassium tetraphyrophosphate \uf0d8 Vacuum packaged 54.44\u00b0C (130\u00b0F) to 7.2\u00b0C (45\u00b0F) 9 h 12 h 15 h 18 h 21 h Control \u2264 2 > 2 > 2 > 2 > 2 S\u00e1nchez-Plata, M. et al., 2005. Cooked Ground Beef \uf0d8 Salt (NaCl) \uf0d8 Sodium nitrite \uf0d8 Sodium erythorbate \uf0d8 Sodium phosphates \uf0d8 54.4\u00b0C (130\u00b0F) to 8.5\u00b0C (47.3\u00b0F) 15 h 18 h 21 h NaCl 0.0% > 2 > 2 > 2 NaCl 1% > 2 > 2 > 2 NaCl 2% \u2264 1 \u2264 1 NaCl 3% \u2264 1 \u2264 1 \u2264 1 NaCl 4% \u2264 1 \u2264 1 Zaika, L. 2003.", "This Appendix is not considered adequate support on its own because it does not provide the details of each study (such as the concentration of salt and other ingredients) that an establishment needs to determine if the study is representative of the actual process. Establishments need to have the complete copy of the article on file as part of its supporting documentation to determine the levels of the critical operating parameters used.

84 Product Critical Operational Parameters Provided Experimental Conditions for Chilling\|C. perfringens Growth Reference Cooked Ground Beef \uf0d8 Salt \uf0d8 Chili \uf0d8 Sodium lactate \uf0d8 Sodium citrate \uf0d8 Garlic \uf0d8 Herbs \uf0d8 Curry \uf0d8 Oregano \uf0d8 Clove \uf0d8 Sodium triphosphate \uf0d8 Exponential cooling 54.4\u00b0C (130\u00b0F) to 7.2\u00b0C (45\u00b0F) 15 h 18 h 21 h Control > 2 > 2 > 2 Chili \u2264 2 > 2 > 2 Chili+Sodium Lactate \u2264 1 \u2264 1 \u2264 1 Chili+Sodium Citrate \u2264 1 \u2264 217 \u2264 1 Garlic and Herbs > 2 > 2 > 2 Garlic and Herbs+Sodium Lactate \u2264 1 \u2264 2 \u2264 2 Garlic and Herbs+Sodium Citrate \u2264 1 \u2264 25 \u2264 1 Curry > 2 > 2 > 2 Curry+Sodium Lactate \u2264 2 \u2264 2 \u2264 2 Curry+Sodium Citrate \u2264 1 \u2264 1 \u2264 1 Oregano \u2264 1 > 2 > 2 Oregano+Sodium Lactate \u2264 1 \u2264 1 \u2264 1 Oregano+Sodium Citrate \u2264 1 \u2264 1 \u2264 2 Clove \u2264 2 \u2264 2 > 2 Clove+Sodium Lactate \u2264 1 \u2264 25 \u2264 1 Clove+Sodium Citrate \u2264 1 \u2264 1 \u2264 2 Sodium Lactate \u2264 1 \u2264 1 \u2264 2 Sodium Citrate \u2264 1 \u2264 1 \u2264 25 \u2264 1 Sabah, J.R., Juneja, V.K., and Fung, D.Y.C. 2004. 17 Establishments should be aware that the 21-hour treatment time had less growth than the 18-hour treatment time. FSIS recommends establishments assume the longer cooling time would result in the same amount of growth if not higher than the shorter time.", "This Appendix is not considered adequate support on its own because it does not provide the details of each study (such as the concentration of salt and other ingredients) that an establishment needs to determine if the study is representative of the actual process. Establishments need to have the complete copy of the article on file as part of its supporting documentation to determine the levels of the critical operating parameters used.

85 Product Critical Operational Parameters Provided Experimental Conditions for Chilling\|C. perfringens Growth Reference Cooked Ground Beef (70% Lean)

\uf0d8 Thymol \uf0d8 Cinnamaldehyde \uf0d8 Oregano Oil \uf0d8 Carvacrol \uf0d8 Single rate exponential cooling 54.4\u00b0C (130\u00b0F) to 7.2\u00b0C (45\u00b0F) 12 h 15 h 18 h 21 h 0.10% Thymol \u2264 1 \u2264 2 > 2 > 2 0.50% Thymol \u2264 1 \u2264 2 > 2 > 2 1.00% Thymol \u2264 1 \u2264 2 > 2 > 2 2.00% Thymol \u2264 1 \u2264 1 \u2264 1 \u2264 1 0.10% Cinnamaldehyde \u2264 1 > 2 > 2 > 2 0.50% Cinnamaldehyde \u2264 1 \u2264 2 \u2264 118 \u2264 1 1.00% Cinnamaldehyde \u2264 1 \u2264 1 \u2264 1 \u2264 1 2.00% Cinnamaldehyde \u2264 1 \u2264 1 \u2264 1 \u2264 1 0.10% Oregano oil \u2264 1 > 2 > 2 > 2 0.50% Oregano oil \u2264 1 > 2 > 2 > 2 1.00% Oregano oil \u2264 1 \u2264 2 > 2 > 2 2.00% Oregano oil \u2264 1 \u2264 1 \u2264 1 0.10% Carvacrol \u2264 1 > 2 > 2 > 2 0.50% Carvacrol \u2264 1 > 2 > 2 > 2 1.00% Carvacrol \u2264 1 \u2264 1 > 2 > 2 2.00% Carvacrol \u2264 1 \u2264 1 \u2264 1 \u2264 1 \u2264 1 Juneja, V.K., Thippareddi, H., and Friedman, M. 2006. Cooked Ground Beef (93% Lean) \uf0d8 GTE=Green tea polyphenols \uf0d8 GTL=powdered tea sample with 20% of green tea polyphenols \uf0d8 Single rate exponential cooling 54.4\u00b0C (130\u00b0F) to 7.2\u00b0C (45\u00b0F) 12 h 15 h 18 h 21 h 0.5% GTE > 2 > 2 > 2 1% GTE \u2264 1 > 2 > 2 2% GTE \u2264 1 \u2264 1 0.5% GTL > 2 > 2 1% GTL > 2 > 2 > 2 > 2 2% GTL > 2 > 2 Juneja, V.K. et al., 2007. While the 18-hour and 21-hour times have less growth than the 15-hour treatment, FSIS recommends that establishments assume the longer cooling time would result in the same amount if not more growth than the 15-hour results.", "This Appendix is not considered adequate support on its own because it does not provide the details of each study (such as the concentration of salt and other ingredients) that an establishment needs to determine if the study is representative of the actual process. Establishments need to have the complete copy of the article on file as part of its supporting documentation to determine the levels of the critical operating parameters used.

86 Product Critical Operational Parameters Provided Experimental Conditions for Chilling\|C. perfringens Growth Reference Cooked Ground Pork \uf0d8 GTE=Green tea polyphenols \uf0d8 GTL=powdered tea sample with 20% of green tea polyphenols \uf0d8 Single rate exponential cooling 54.4\u00b0C (130\u00b0F) to 7.2\u00b0C (45\u00b0F) 12 h 15 h 18 h 21 h 0.5% GTE \u2264 2 > 2 > 2 1% GTE \u2264 1 \u2264 2 > 2 2% GTE \u2264 1 \u2264 1 0.5% GTL > 2 > 2 1% GTL > 2 > 2 > 2 > 2 2% GTL \u2264 2 > 2 Juneja, V.K. et al., 2007. Pork Scrapple \uf0d8 Salt \u2264 11(g\100g) \uf0d8 Moisture \u2264 70.28(g\100g) \uf0d8 aw \u2264 0.97 after cooking, before cooling \uf0d8 pH \u2264 6.40 \uf0d8 Cook to \u2265 200\u00b0F for at least 20 minutes 54.4\u00b0C (130\u00b0F) to 27.8\u00b0C (82\u00b0F) \u2264 4 h 27.8\u00b0C (82\u00b0F) to 7.2\u00b0C (45\u00b0F) \u2264 8 h 12 h \u2264 1 54.4\u00b0C (130\u00b0F) to 26.5\u00b0C (80\u00b0F) \u2264 5 h 26.5\u00b0C (80\u00b0F) to 7.2\u00b0C (45\u00b0F) \u2264 8 h 14 h \u2264 1 Juneja, V.K. et al. 2010. Bacon \uf0d8 Liquid smoke (or natural smoke) \uf0d8 \u2264 1.6% salt \uf0d8 \u2264 5.2% brine that contained: 120 ppm sodium nitrite 547 ppm sodium erythorbate 0.5% sodium phosphate 54.5\u00b0C (120\u00b0F) to 26.7\u00b0C (80\u00b0F) in 5 hours 26.7\u00b0C (80\u00b0F) to 7.2\u00b0C (45\u00b0F) in 10 hours 15 h 19 \u2264 1 Taormina, P.J. and Bartholomew, G.W 2005. Ham A (Commercially Obtained) \uf0d8 Salt (NaCl) \uf0d8 Sodium nitrite \uf0d8 Sodium erythorbate \uf0d8 Sodium phosphates \uf0d8 54.4\u00b0C (130\u00b0F) to 8.5\u00b0C (47.3\u00b0F) 15 h 18 h 21 h NaCl 2.4% \u2264 2 \u2264 2 > 2 NaCl 3.1% \u2264 1 \u2264 1 \u2264 1 NaCl 3.6% \u2264 1 \u2264 1 \u2264 1 NaCl 4.1% \u2264 1 \u2264 1 \u2264 1 Zaika, L. 2003. 19 Bacon was heated to 120\u00b0F (48.9\u00b0C) with a 6-hour heating CUT", "This Appendix is not considered adequate support on its own because it

does not provide the details of each study (such as the concentration of salt and other ingredients) that an establishment needs to determine if the study is representative of the actual process. Establishments need to have the complete copy of the article on file as part of its supporting documentation to determine the levels of the critical operating parameters used.

87 Product Critical Operational Parameters Provided Experimental Conditions for Chilling\|C. perfringens Growth Reference Ham B (Commercial ly Obtained) \uf0d8 Salt (NaCl) \uf0d8 Sodium nitrite \uf0d8 Sodium erythorbate \uf0d8 Sodium phosphates \uf0d8 54.4\u00b0C (130\u00b0F) to 8.5\u00b0C (47.3\u00b0F) 15 h 18 h 21 h NaCl 2.8% \u2264 2 > 2 \u2264 220 NaCl 3.3% \u2264 1 \u2264 1 NaCl 3.8% \u2264 1 \u2264 1 \u2264 1 NaCl 4.3% \u2264 1 \u2264 1 Zaika, L. 2003. Ham C (Commercial ly Obtained) \uf0d8 Salt (NaCl) \uf0d8 Sodium nitrite \uf0d8 Sodium erythorbate \uf0d8 Sodium phosphates \uf0d8 54.4\u00b0C (130\u00b0F) to 8.5\u00b0C (47.3\u00b0F) 15 h 18 h 21 h NaCl 2.0% > 2 \u2264 27 > 2 NaCl 2.5% \u2264 1 \u2264 1 NaCl 3.0% \u2264 1 \u2264 1 \u2264 1 NaCl 3.5% \u2264 1 \u2264 1 Zaika, L. 2003. Ham \uf0d8 pH 6.22 \uf0d8 aw 0.987 \uf0d8 Nitrite \uf0d8 Sodium erythorbate 54.4\u00b0C (130\u00b0F) to 7.2\u00b0C (45\u00b0F) 15 h Stored 3 h 15 h Stored 24 h Control \u2264 2 > 2 Nitrite 50 ppm \u2264 1 > 2 Nitrite 100 ppm \u2264 1 > 2 Nitrite 150 ppm \u2264 1 > 2 Nitrite 200 ppm \u2264 2 \u2264 1 Nitrite 50 ppm erythorbate 557 ppm > 2 > 2 Nitrite 100 ppm erythorbate 557 ppm \u2264 2 > 2 Nitrite 150 ppm erythorbate 557 ppm \u2264 2 \u2264 1 Nitrite 200 ppm erythorbate 557 ppm \u2264 2 \u2264 1 Redondo-Solano, M. et al., 2013. 20 Establishments should be aware that the 21-hour treatment time had less growth than the 18-hour treatment time and the 18-hour treatment had less growth than the 15hour treatment time. FSIS recommends establishments assume the longer cooling time would result in the same amount of growth if not higher than the shorter time.", "This Appendix is not considered adequate support on its own because it does not provide the details of each study (such as the concentration of salt and other ingredients) that an establishment needs to determine if the study is representative of the actual process.

Establishments need to have the complete copy of the article on file as part of its supporting documentation to determine the levels of the critical operating parameters used. 88 Product Critical Operational Parameters Provided Experimental Conditions for Chilling\|C. perfringens Growth Reference WholeMuscle Ham \uf0d8 aw (Raw batter) = 0.98 \uf0d8 aw (Peak cook temp) = 0.97 \uf0d8 Sodium nitrite (103 \u2013 140 ppm ingoing) \uf0d8 Sodium phosphate \uf0d8 Sodium erythorbate \uf0d8 4% brine concentration 54.4\u00b0C (130\u00b0F) to 7.2\u00b0C (45\u00b0F) 4.5 h \u2264 1 Taormina, P.J. and Bartholomew, G.W 2005. Chunked Ham (Pork) \uf0d8 aw (Raw batter) = 0.97 \uf0d8 aw (Peak cook temp) = 0.96 \uf0d8 Sodium nitrite (103 \u2013 140 ppm ingoing) \uf0d8 Sodium phosphate \uf0d8 Sodium erythorbate 3% brine concentration 54.44\u00b0C (130\u00b0F) to 7.2\u00b0C (45\u00b0F) 4.5 h \u2264 1 Taormina, P.J. and Bartholomew, G.W 2005. Pork \uf0d8 pH 5.8 \uf0d8 aw=0.992 \uf0d8 Salt \uf0d8 Phosphate \uf0d8 SAPP=sodium acid pyrophosphate (Source 1=Sigma-Aldrich, Source 2=BK Giulini) \uf0d8 TSPP=tetrasodium pyrophosphate 54.4\u00b0C (130\u00b0F) to 7.2\u00b0C (45\u00b0F) 6.5 h 9 h 12 h 15 h 18 h 21 h Control \u2264 1 > 2 > 2 > 2 > 2 > 2 SAPP1+SAPP2 \u2264 1 \u2264 1 \u2264 2 > 2 > 2 SAPP1+TSPP \u2264 1 \u2264 2 > 2 > 2 > 2 > 2 > 2 > 2 Singh, AA. et al., 2010. Pork (Pale, Soft, and Exudative, PSE) \uf0d8 pH=5.31 \uf0d8 aw=0.993 \uf0d8 Salt \uf0d8 Phosphate \uf0d8 SAPP Source 1 and 2 \uf0d8 TSPP 54.4\u00b0C (130\u00b0F) to 7.2\u00b0C

(45\00b0F) 6.5 h 9 h 12 h 15 h 18 h 21 h Control \u2264 1 \u2264 2 \u2264 2 > 2 > 2 > 2 SAPP1+SAPP2 \u2264 1 \u2264 1 \u2264 1 \u2264 1 \u2264 1 SAPP1+TSPP \u2264 1 \u2264 1 \u2264 1 \u2264 1 \u2264 2 > 2 SAPP2+TSPP \u2264 1 \u2264 1 \u2264 1 \u2264 1 > 2 > 2 Singh, AA. et al., 2010." , "This Appendix is not considered adequate support on its own because it does not provide the details of each study (such as the concentration of salt and other ingredients) that an establishment needs to determine if the study is representative of the actual process. Establishments need to have the complete copy of the article on file as part of its supporting documentation to determine the levels of the critical operating parameters used. 89 Product Critical Operational Parameters Provided Experimental Conditions for Chilling\<i>C. perfringens</i> Growth Reference Pork (Dark, Firm, and Dry, DFP) \u0d8 pH=5.92 \u0d8 aw=0.992 \u0d8 Salt \u0d8 Phosphate \u0d8 SAPP Source 1 and 2 \u0d8 TSPP 54.4\00b0C (130\00b0F) to 7.2\00b0C (45\00b0F) 6.5 h 9 h 12 h 15 h 18 h 21 h Control \u2264 1 > 2 > 2 > 2 > 2 SAPP1+SAPP2 \u2264 1 \u2264 2 \u2264 2 > 2 > 2 > 2 SAPP1+TSPP \u2264 1 \u2264 1 > 2 > 2 > 2 > 2 SAPP2+TSPP \u2264 1 \u2264 1 > 2 > 2 > 2 > 2 Singh, AA. et al., 2010. Acidified Ground Beef, Beef, Pork and Poultry \u0d8 pH 4.74 \u2013 6.35 \u0d8 Single rate exponential cooling 54.4\00b0C (130\00b0F) to 7.2\00b0C (45\00b0F)\*21 6 h 9 h 12 h 15 h 18 h 21 h Rotisserie-cooked pork shoulder (pH 6.35) \u2264 2 > 2 > 2 > 2 Boiled beef (pH 5.63) \u2264 1 \u2264 2 Acidified ground beef (pH 5.0) \u2264 1 > 2 Acidified poultry (pH 4.77) \u2264 1 Juneja, V.K. et al., 2013. Bologna (Beef, Pork, Chicken) \u0d8 aw (Raw batter) = 0.97 \u0d8 aw (Peak cook temp) = 0.96 \u0d8 Sodium nitrite (103 \u2013 140 ppm ingoing) \u0d8 Sodium and potassium phosphates \u0d8 Sodium erythorbate \u0d8 4% brine concentration 54.44\00b0C (130\00b0F) to 7.2\00b0C (45\00b0F) 4.5 h \u2264 1 Taormina, P.J., Bartholomew, G.W., and Dorsa, W.J. 2003. 21 \*Only results for low inoculum level are reported." , "This Appendix is not considered adequate support on its own because it does not provide the details of each study (such as the concentration of salt and other ingredients) that an establishment needs to determine if the study is representative of the actual process. Establishments need to have the complete copy of the article on file as part of its supporting documentation to determine the levels of the critical operating parameters used. 90 Product Critical Operational Parameters Provided Experimental Conditions for Chilling\<i>C. perfringens</i> Growth Reference Turkey (Injected Turkey Breast) \u0d8 pH=5.26 to 6.11 \u0d8 aw=0.987 \u0d8 Salt \u0d8 Calcium lactate \u0d8 Potassium lactate \u0d8 Sodium lactate \u0d8 Potassium tetraphosphate 54.4\00b0C (130\00b0F) to 7.2\00b0C (45\00b0F) 6.5 h 9 h 12 h 15 h 18 h 21 h Control \u2264 1 > 2 > 2 > 2 > 2 Calcium lactate 1% \u2264 1 \u2264 2 \u2264 2 > 2 > 2 Calcium lactate 2% \u2264 1 \u2264 1 \u2264 1 \u2264 1 Calcium lactate 3% \u2264 1 \u2264 1 \u2264 1 \u2264 1 Calcium lactate 4.8% \u2264 1 \u2264 1 \u2264 1 \u2264 1 Postassium lactate 1% \u2264 1 \u2264 2 > 2 > 2 > 2 Postassium lactate 2% \u2264 1 \u2264 1 \u2264 1 \u2264 2 \u2264 2 > 2 Postassium lactate 3% \u2264 1 \u2264 1 \u2264 1 \u2264 1 Postassium lactate 4.8% \u2264 1 \u2264 1 \u2264 1 \u2264 1 Sodium lactate 1% \u2264 1 \u2264 1 \u2264 1 \u2264 1 > 2 > 2 > 2 Sodium lactate 2% \u2264 1 \u2264 1 \u2264 1 \u2264 1 \u2264 1 \u2264 2 > 2 > 2 Sodium lactate 3% \u2264 1 \u2264 1 \u2264 1 \u2264 1 Sodium lactate 4% \u2264 1 \u2264 1 \u2264 1 \u2264 1 Velugoti, P.R., Bohra, L.K., Juneja, V.J., and Thippareddi, H. 2007. Deli-Style Turkey Breast \u0d8 At least 75 ppm nitrite from a natural source and at least 500 ppm ascorbate from a natural source OR \u0d8 At least 100 ppm nitrite from a natural source and at least 250 ppm ascorbate from a natural source 54.4\00b0C

(130\u00b0F) to 26.5\u00b0C (80\u00b0F) \u2264 5 h 26.5\u00b0C (80\u00b0F) to 7.2\u00b0C (45\u00b0F) \u2264 10 h 15 h \u2264 1 King, A.M., et al., 2015", "This Appendix is not considered adequate support on its own because it does not provide the details of each study (such as the concentration of salt and other ingredients) that an establishment needs to determine if the study is representative of the actual process. Establishments need to have the complete copy of the article on file as part of its supporting documentation to determine the levels of the critical operating parameters used. 91 Product Critical Operational Parameters Provided Experimental Conditions for Chilling\|C. perfringens Growth Reference Cooked Ground Chicken \uf0d8 GTE=Green tea polyphenols \uf0d8 GTL=powdered tea sample with 20% of green tea polyphenols. Single rate exponential cooling 54.4\u00b0C (130\u00b0F) to 7.2\u00b0C (45\u00b0F) 12 h 15 h 18 h 21 h 0.5% GTE > 2 > 2 > 2 1% GTE \u2264 1 \u2264 1 \u2264 2 2% GTE \u2264 1 \u2264 2 \u2264 122 0.5% GTL > 2 > 2 1% GTL > 2 > 2 \u2264 223 > 2 2% GTL > 2 > 2 Juneja, V.K. et al., 2007. 22 Establishments should be aware that the 21-hour treatment time had less growth than the 18-hour treatment time. FSIS recommends establishments assume the longer cooling time would result in the same amount of growth if not higher than the shorter time. 23 Establishments should be aware that the 18-hour treatment time had less growth than the 15-hour treatment time. FSIS recommends establishments assume the longer cooling time would result in the same amount of growth if not higher than the shorter time.", "92 Journal Articles not Acceptable without Further Support The table above summarizes journal articles that may be used as support. The following three articles are not acceptable as support because FSIS has identified methodological errors or flaws in the research or reporting: \u2022 Haneklaus A.N., Harris K.B., Cuervo M.P., Ilhak O.I., Lucia L.M., Castillo A., Hardin M.D., Osburn W.N., and Savell, J.W. 2011. Alternative Cooling Procedures for Large, Intact Meat Products to Achieve Stabilization Microbiological Performance Standards. Journal of Food Protection. Vol. 74: 101105. \u2022 Juneja, V.K., Snyder, O.P., and Cygnarowicz-Provost, M. 1994. Influence of Cooling Rate on Outgrowth of Clostridium perfringens Spores in Cooked Ground Beef. Journal of Food Protection. 57: 1063-1067. \u2022 Steele, F.M. and Wright K.H. 2001. Cooling Rate Effect on Outgrowth of Clostridium perfringens in Cooked, Ready-to-Eat Turkey Breast Roasts. Poultry Science. 80: 813-816. FSIS does not recommend establishments use these three articles alone because of the methodological errors identified, without additional support. If an establishment chooses to use one of these articles as support for its stabilization process, FSIS recommends the establishment gather additional data (e.g., microbiological data gathered in-plant or an inoculation challenge study) to address the concerns outlined below. The following information explains the methodology errors or flaws that FSIS has identified in each of the three articles of concern. Alternative Cooling Procedures for Large, Intact Meat Products to Achieve Stabilization Microbiological Performance Standards (Haneklaus et al., 2011) FSIS does not recommend establishments use this article alone based on the method the authors used to measure bacterial load in the final product. In this article, C. perfringens spore counts were used to measure bacterial load in the final product and to determine product safety. Although measuring C. perfringens spore counts is considered an appropriate method to quantify the initial levels of the C. perfringens inoculum, the final measure of bacterial load should include a measure of both spore levels and vegetative cells. FSIS recommends establishments measure the vegetative cells in addition to the spore levels, because during stabilization, C. perfringens

spores can germinate and grow into vegetative cells. Once vegetative cells reach a critical level, and the contaminated food is consumed, some of the cells will survive passage in the stomach and produce toxin during sporulation in the intestines to cause illness. Several published studies (Juneja, Thippareddi, and Friedman, 2006; Juneja, Bari, Inatsu, Kawamoto, and Friedman, 2007; Sabah, Juneja, and Fung, 2004; Sanchez-Plata, Amador-Quita, Blankenship, Burson, Juneja, and Thippareddi, 2005; Velugoti, "93 Rajagopal, Juneja, and Thippareddi, 2007) have used similar stabilization parameters to that used in the Haneklaus et al. (2011) article [i.e., cooled from 129.9°F (54.4°C) to 45°F (7.2°C) in 9, 12, or 15 hours] to measure total *C. perfringens* growth in cooked, uncured pork and beef products that are exponentially cooled. These studies have shown that, when these processes are used, significant growth (>1 Log increase) of *C. perfringens* will occur. The amount of total *C. perfringens* growth ranged from 1.72 to 5.37-Log depending on the experiment and the product's intrinsic factors (e.g., pH, percent salt, and percent phosphate) (Juneja et al., 2006; Juneja et al., 2007; Sabah et al., 2004; Sanchez-Plata et al., 2005; Velugoti et al., 2007). FSIS believes these studies accurately represent the combined vegetative and spore load of *C. perfringens* present in products that are exposed to stabilization parameters that are similar to those used in the Haneklaus, et al. (2011) study. When the published studies use shorter stabilization parameters [i.e., cooled from 129.9°F (54.4°C) to 45°F (7.3°C) in 6.5 hours], lower levels of growth of *C. perfringens* (1 Log increase) are observed, which is consistent with FSIS guidance in Option 1.1 of this guideline.

Influence of Cooling Rate on Outgrowth of *C. perfringens* Spores in Cooked Ground Beef (Juneja et al., 1994)

FSIS does not recommend establishments use this article alone based on the methods the authors used in which ground beef was packaged in Whirlpak bags as opposed to Spiral Biotech pouches, which are more commonly used in these types of studies. Juneja et al. (1994) study used the Whirlpak bags and demonstrated minimal growth of *C. perfringens* in cooked ground beef for cooling periods up to 15 hours that were supposed to represent anaerobic conditions. Subsequent research conducted by Smith et al. (2004) demonstrated that ground beef packaged in Whirlpak bags shows significantly less growth of *C. perfringens* than ground beef packaged in Spiral Biotech bags (Smith et al., 2004). This is probably due to the Whirlpak bag's greater oxygen permeability. For example, more than a 5-Log increase in *C. perfringens* was seen in ground beef contained within Spiral Biotech pouches compared with only a 0.81 to 2.05 Log increase in samples within WhirlPak bags during a 21-hour cooling cycle. Smith et al. (2004) concluded that the study demonstrates that the use of Whirlpak bags is unsuitable for use in challenge studies, because of the bags apparent high oxygen permeability, which probably suppresses or slows the growth of the anaerobe *C. perfringens*. Several published studies support that similar cooling profiles result in significant growth (> 1 Log increase) of *C. perfringens* in cooked beef products that are non-linearly cooled from 130°F (54.4°C) to 45°F (7.2°C) in 15 hours. The amount of *C. perfringens* growth ranged from 1.72 to 5.37-Log depending on the experiment and the product's intrinsic factors (e.g., pH, percent salt, and percent phosphate) (Juneja et al., 2006; Sabah et al., 2004; Smith et al., 2004; Zaika, 2003). Furthermore, the same studies showed that non-linear chilling from 54.4 to 7.2°C in 12 or 9 hours also resulted in more than 1 Log increase in *C. perfringens* (Juneja et al., 2006; Sabah et al., 2004; Zaika, 2003). Consequently, these more recently published studies contradict the 1994 Juneja study that

showed no growth of *C. perfringens* in cooked ground beef cooled from 54.4°C to 7.2°C during a 15-hour cooling period." "94 Cooling Rate Effect on Outgrowth of *C. perfringens* in Cooked, Ready-to-Eat Turkey Breast Roasts (Steele and Wright, 2001) FSIS does not recommend establishments use this article alone because the paper included inadequate information to allow comparison to an establishment's actual process. Published research and predictive microbial models have shown that the product's intrinsic factors (e.g., pH, sodium nitrite, salt, and phosphate concentration) can have a profound impact on the growth of *C. perfringens* during cooling, or temperature abuse of cooked/heated, not shelf-stable meat and poultry products. For example, research has shown that a high salt concentration can have a significant inhibitory effect on the growth of *C. perfringens* during cooling (Zaika, 2003). However, information on the product's intrinsic factors was not included in the article. Therefore, it would not be possible for establishments to assess how their products compare to the product(s) studied." "95 <https://www.fsis.usda.gov/contact-us/askfsis> FSIS USDA www.fsis.usda.gov

2021"]}, {"file\_name": "FSIS\_GD\_2021\_0014", "title": "FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A)", "num": "FSIS-GD-2021-0014", "id": "fd73f07b6f61a35fd97089125e3f3fb7d87ec275fae25dbb9792d9b2424abb34", "corp\_us": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-12/Appendix-A.pdf", "type": "pdf", "n\_pages": 92, "word\_count": 31284, "text\_by\_page": ["1 This guideline provides information on the Agency regulatory requirements associated with safe production of ready-to-eat (RTE) products with respect to the destruction of *Salmonella* and other pathogens. It applies to small and very small meat and poultry official establishments although all meat and poultry establishments may apply the recommendations in this guideline. It relates to 9 CFR 318.17(a)(1), 9 CFR 318.23, 381.150(a)(1), and 9 CFR 417. FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) December, 2021 Document ID: FSIS-GD-2021-14", "2 Table of Contents Preface

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Country-Cured Hams ..... 90", "4 Preface This is a revised version of the FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A). It has been updated in response to comments received on the previous version and renamed. In addition, the guideline has been revised to include recommendations from previous versions and new updates based on up-to-date science. The guideline also includes changes to improve its readability. This guideline represents FSIS\u2019s current thinking on these topics.

Establishments that utilized previous versions of Appendix A as support should either: \u2022 Update to this 2021 FSIS Cooking Guideline (Revised Appendix A) or \u2022 Identify alternative support by December 14, 2022. The information in this guideline is provided to assist meat and poultry establishments in meeting the regulatory requirements. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to industry regarding existing requirements under the regulations. Under the regulations, meat and poultry establishments may choose to implement different procedures than those outlined in this guideline, but they would need to validate and support how those procedures are effective. This guideline is focused on small and very small plants in support of the Small Business Administration\u2019s initiative to provide small businesses with compliance assistance under the Small Business Regulatory Enforcement Fairness Act (SBREFA). However, all meat and poultry establishments may apply the recommendations in this guideline. It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective Hazards Analysis and Critical Control Point (HACCP) systems.

Although large plants can benefit from the information, focusing the guideline on the needs of small and very small establishments provides them with assistance that may be otherwise unavailable to them. Purpose of this Guideline This guideline contains information to assist meat and poultry establishments producing products that undergo cooking in complying with the HACCP regulatory requirements in 9 CFR 417. This guideline includes information on:

\u2022 Biological hazards during cooking. \u2022 Regulatory requirements associated with the safe production of cooked ready-to-eat (RTE) products. \u2022 Options establishments can use to achieve lethality of Salmonella and other pathogens.", "5 \u2022 Processes that do not have validated research available (referred to as \u201ccientific gaps\u201d) and options establishments can use until research is available. \u2022 Resources for alternative support.

\u2022 Recommendations for evaluating cooking deviations. Establishments can always seek guidance from State university extension service specialists and HACCP Coordinators on developing programs and plans not provided in this guideline to comply with HACCP regulatory requirements. History of this Guideline and Reason for Reissuance In the 1970s and 1980s, FSIS included prescriptive time, temperature, and humidity operating parameters in the regulations for cooked beef, roast beef, and cooked corned beef (42 FR 44217; 47 FR 31854; 48 FR 24314) in response to several outbreaks associated with these products and research performed to determine how to prepare them safely. When the Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) final rule published in 1996, FSIS eliminated the prescriptive cooking regulations and replaced them with performance standards requiring a 6.5-Log reduction in Salmonella or alternative lethality for roast beef, cooked beef, and corned beef, minimum internal temperature and holding times for fully cooked patties that achieve a 5-Log reduction in Salmonella, and a 7-Log reduction in Salmonella or alternative lethality for poultry

products (9 CFR 318.17(a)(1), 9 CFR 318.23, 9 CFR 381.150(a)(1); see General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking, page 18. FSIS converted these former regulations to \u201cSafe Harbors\u201d in an appendix to the final rule called Appendix A (64 FR 732). Establishments have been using FSIS\u2019s Appendix A, as published in 1999, as support for cooking processes for many years. The original requirements and subsequent guidance have been important to prevent human illness outbreaks and ensure the production of safe food. See General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking, page 18 for more information on the current regulatory requirements. Over time, FSIS determined that some of its recommendations in the 1999 version of Appendix A were vague, putting establishments at risk of producing unsafe products. Additionally, some elements of the 1999 version of Appendix A were misunderstood or overlooked, resulting in FSIS guidance being applied in ways that increased food safety risks to consumers and potential risks to industry, including the risk of foodborne illness outbreaks. FSIS also determined establishments were broadly applying the recommendations for operating parameters in Appendix A beyond those meat and poultry products it was originally designed to support. To provide the needed updates and clarifications, FSIS issued revisions of both its Cooking (Appendix A) and Stabilization (Appendix B) guidelines in 2017. The 2017 version of the guidelines took into account new and emerging technologies, processes, and science. FSIS has updated this guideline in response to comments received on the 2017 version and has included additional options for cooking support based on updated", "6 science and technology. The Agency is releasing this current 2021 version of the FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) to replace all previous versions. Changes from the Previous Versions This guideline dated December 14, 2021 is final. FSIS will update this guideline, as necessary, should new information become available. FSIS made the following changes to this guideline to reflect the comments received on the previous version during the comment period and to include additional scientific information. For Appendix A, FSIS made changes to specify: \u2022 The following products are not covered by the guideline (page 11): Fish of the Order Siluriformes, pork rind pellets, rendered lard and tallow, dried products processed under dry conditions, partially heat-treated NRTE products, and RTE multi-hurdle products. \u2022 The food safety significance of FSIS\u2019s recommendations for relative humidity (page 17). \u2022 That relative humidity should be addressed for all cooked products (including poultry) unless the establishment can support that humidity does not need to be addressed. FSIS has not changed the relative humidity options (page 26) other than re-emphasizing that they apply to all products. \u2022 Additional resources for selecting a relative humidity option when following FSIS\u2019s cooking guidance (page 28). \u2022 The situations when relative humidity does not need to be addressed including by providing more information about situations considered to be direct heating (page 31) (e.g., by clarifying that relative humidity does not need to be addressed for meat patties cooked using FSIS\u2019s time-temperature table for meat, if the patties are cooked using direct heat (on page 31)). Previous guidance indicated it did not need to be addressed for meat patties with the assumption all meat patties are cooked using direct heat which is no longer the case. \u2022 That natural casings become semipermeable during cooking, maintaining moisture in the product, so that additional documentation to address relative humidity is not needed (page 33). \u2022 More detailed information for evaluating product safety following a heating deviation (page 66). The revision

also removes the recommendation for using the ComBase model for *Staphylococcus aureus* growth (which was not validated)", "7 because of the development and validation of the Danish Meat Research Institute (DMRI) Staphtox model in 2018. \u2022 Where gaps exist, recommendations from its older cooking guidance can be used until research is completed (see, Table 5. Scientific Gaps where Critical Operating Parameters From Older Guidance May be Used, page 43) for: 1. Products cooked for short times at high temperatures. 2. Products cooked using microwave cooking methods that are not designed to control relative humidity. 3. Products cooked using cooking methods that are not designed to control relative humidity. 4. Other processes that may inherently maintain relative humidity around the meat and poultry filling but cannot follow one of the relative humidity options. 5. Processes where the drying step comes before cooking under moist conditions. 6. Products with long heating come-up-times (CUTs). \u2022 That information is included about a listeriosis outbreak associated with a cooked country-cured ham product and recommendations for establishments that cook a similar product once (page 90). For Appendix A, FSIS removed: \u2022 Information about how establishments could remove poultry rolls from the cooking medium before product has achieved the target endpoint temperature and immediately apply another heating or processing method (64 FR 732). Since FSIS has clarified that limiting heating CUT is a critical operating parameter for applying any of FSIS cooking guidance (including these older options), the parameter to \u201cimmediately fully cook\u201d poultry rolls subject to multiple heating mediums and processes has been removed. \u2022 Specific recommendations for conducting a *Salmonella* baseline study on raw source materials as support for using cooking critical operating parameters that achieve a 5-Log reduction in *Salmonella* for meat products instead of a 6.5 or 7Log reduction. This information was removed since it was interpreted to apply to all establishments when it was only intended for establishments that wanted to support a lower level of pathogen reduction from cooking. In addition, FSIS is not aware of any establishments that have pursued such baseline sampling. In addition to these changes, the guidelines format was restructured to make it easier to use as described in the next section. This list of changes is not comprehensive, so", "8 establishments should read the section titled FSIS Critical Operating Parameters for Cooking and other relevant sections as needed. How to Effectively Use this Guideline As explained above in the Changes from the Previous Versions, the guidelines format was restructured to make it easier to use. Specifically, the guideline is organized to include the following topics in the body of the guideline: \u2022 Biological hazards during cooking. \u2022 Regulatory requirements associated with the safe production of cooked ready-toeat (RTE) products. \u2022 Options establishments can use to achieve lethality of *Salmonella* and other pathogens. \u2022 Processes that do not have validated research available (referred to as \u201cscientific gaps\u201d) and options establishments can use until research is available. Information included in the body of the guideline is intended as scientific support that can be used alone by establishments to meet Element 1 of validation (9 CFR 417.4(a)(1)) and to support decisions in the hazard analysis (9 CFR 417.5(a)(1)). The following topics are included in attachments to the guideline: \u2022 Resources for alternative support and \u2022 Recommendations for evaluating cooking deviations. Information provided in the attachments is not sufficient to use as sole support and additional documentation is needed. For example, Attachment A1. Customized Processes and Alternative Lethality Support (page 55), contains descriptions or brief summaries of available scientific articles. However, the summaries are not

considered adequate support on their own because they do not contain the details of each study. For this reason, establishments must have the full copy of the article on-file as scientific support for their HACCP System. The summaries are provided to help establishments identify journal articles related to their process. Each establishment needs to determine if the operating parameters of a particular study match the establishment's process. Establishments are not limited to using the scientific articles listed and summarized as support. In addition, Attachment A2. Cooking Deviations (page 66), contains recommendations for evaluating product safety in the event of a deviation but this information is not considered adequate support on its own because establishments should perform predictive microbial modeling and may conduct sampling and testing in order to support product disposition. Other information included in attachments is intended to be supplementary.", "9 Questions Regarding Topics in this Guideline If after reading this guideline you still have questions, FSIS recommends searching the publicly posted Knowledge Articles (\u201cPublic Q&As\u201d) in the askFSIS database. If after searching the database, you still have questions, refer them to the Office of Policy and Program Development through askFSIS and select HACCP Deviation & HACCP Validation as the Inquiry Type or by telephone at 1-800-233-3935. Documenting these questions helps FSIS improve and refine present and future versions of the guideline and associated issuances.", "10 FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) Background What is Lethality? Lethality treatments are processes used by establishments to eliminate Salmonella and other pathogens in RTE products. Lethality treatments achieve a specific reduction in the number of Salmonella and other pathogens in the product (i.e., an \u201cX-Log<sub>10</sub> colony forming units per gram1 (CFU/g)\u201d reduction). The combination of one or more lethality treatments must be sufficient to eliminate or adequately reduce Salmonella and other pathogens to undetectable levels and prevent the production of toxins or toxic metabolites in the RTE product (e.g., from *Staphylococcus aureus*). Establishments may use a variety of different lethality processes, such as: \u2022 Cooking the product (covered in this guideline). \u2022 Fermentation. \u2022 Drying. \u2022 Salt-curing. \u2022 Other processes that make the product safe for consumption. Products and Processes Covered by this Guideline This guideline addresses lethality of pathogens (e.g., Salmonella) in meat and poultry products<sup>2</sup> by heat treatment (cooking) including for products that are cooked to lethality but classified under a not-ready-to-eat HACCP plan. NOTE: FSIS has provided additional information about the safe production of meat and poultry jerky products in 1 In the rest of this document, Log<sub>10</sub> colony forming units per gram (Log<sub>10</sub> CFU/g) will be annotated simply as \u201cLog.\u201d All notations of \u201cLog\u201d should be read as in the unit Log<sub>10</sub> CFU/g unless other information is provided. 2 Throughout this document references to \u201cmeat and poultry products\u201d may be considered inclusive of meat by-products, meat food products, and poultry food products as defined in 9 CFR 301.2 and 9 CFR 381.1, unless otherwise stated (e.g., Products and Processes Not Covered by This Guidance). KEY DEFINITIONS A ready-to-eat (RTE) product is defined as a meat or poultry product that is in a form that is edible by the end consumer without additional preparation to achieve food safety and that may receive additional preparation for palatability, aesthetic, or culinary purposes (9 CFR 430.1). Lethality is the process (or combination of processes) that ensure a specific, reduction in the number of Salmonella and other pathogens in the product (i.e., an \u201cx-Log\u201d reduction). Lethality processes eliminate or adequately reduce Salmonella and other

pathogens and prevent the formation of their toxins or toxic metabolites, facilitating the production of a safe RTE food product.", "11 the FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments. The information for jerky production remains in a separate guideline because of the complexities of the process, including drying procedures, and to help address questions from small and very small processing establishments. Products and Processes Not Covered by this Guideline The recommendations in this guideline do not apply to the following specific products: Fish of the Order Siluriformes (e.g., catfish) FSIS cooking guidance was not validated for fish of the order Siluriformes. Therefore, this guidance should not be used for fish. Fish establishments may use the cooking guidance in Table A-3 of The Food and Drug Administration\u2019s (FDA\u2019s) Fish and Fishery Products Hazards and Control Guidance as support for the cooking step of fish products. The time-temperature recommendations are designed to achieve a 6-Log reduction in Listeria monocytogenes (Lm). Pork Rind Pellets Establishments may cook pork skins in pork fat or oil for several hours rendering the fat and reducing the skin into pellets. This intermediate product is then further processed by frying to produce a finished product such as pork rinds, cracklins (cracklings), or chicharrones. FSIS cooking guidance does not apply to the cooking or rendering of pork skins into a pellet. Establishments may use the cooking requirements in 9 CFR 94.8(b)(4) as support for cooking pork skins into a pellet. Although these are Animal Plant and Health Inspection Service (APHIS) requirements for imported pork skins from countries where foot-and-mouth disease, African swine fever, classical swine fever, or swine vesicular disease exist, these cooking requirements ensure at least a 6.5-Log reduction of Salmonella (Juneja, et al., 2001a; Murphy et al., 2003; Murphy et al., 2004). NOTE: FSIS cooking guidance may be used for cooking of pork skins for products other than pork rind pellets (e.g., for use in pickled products) and for frying of pork rind pellets into popped pork skins. Guidance for monitoring the cooking critical limit for these products can be found in the Key Question on page 21. Rendered Lard and Tallow FSIS cooking guidance does not apply to the rendering of animal fats, such as lard and tallow, which, due to the high fat content, generally need to reach higher temperatures and longer dwell times to achieve the same reductions in Salmonella (RamirezHernandez et al., 2018). However, based on the D values (time at a constant temperature necessary to destroy 90% or 1-Log of the target organism) reported by Ramirez-Hernandez et al. (2018), the cooking requirements for rendering in 9 CFR 315.1(a) are adequate to ensure an animal fat rendering process achieves at least 6.5- 3 \u201cdwell time\u201d refers to the time a product is held at a specific temperature. Other commonly used terms such as \u201chold time\u201d or \u201crest time\u201d may be considered synonymous for the purpose of this guideline.", "12 Log reductions of Salmonella. Therefore establishments may use 9 CFR 315.1 as support for a lard or rendering process, provided the critical operational parameters (\u2265 170\u00b0F for \u2265 30 minutes) are met throughout the product. Dried Products Processed Under Dry Conditions FSIS cooking guidance does not support lethality for a process that relies on drying alone (e.g., biltong), nor does this guidance support a process where the drying step comes before a cooking step that does not apply humidity or does not apply humidity during cooking at sufficient levels to rehydrate the product surface (e.g., biltong or country-cured ham that is cooked in an unsealed oven after drying). This guidance also does not support lethality for a dried product cooked under moist conditions several times after drying (e.g., country-cured ham that is cooked in a sealed oven several times after the hams

have been salt-cured and dried). Such dried products are typically considered intermediate moisture foods (i.e., those foods that do not require refrigeration to control pathogens). The water activity range of foods considered intermediate moisture varies in the literature. For example, FDA classifies intermediate moisture foods as those with a water activity between 0.60 and 0.85 (FDA, 2018). However, some meat and poultry products may have a water activity > 0.85 and still be considered intermediate moisture because of other factors such as pH and salt concentration (Leistner, 1987). For example, country-cured ham has an average water activity of 0.88 but is considered shelf-stable due to the combination of water activity, high salt, and nitrite (Mikel and Newman, 2003; Reynolds et al., 2001). Establishments that apply these types of processes must identify other support for their HACCP System (9 CFR 417.5(a)(1) and 9 CFR 417.4(a)(1)). NOTE: This guidance includes critical operating parameters for cooking products which are dried, then cooked under moist conditions. Scientific Gaps Identified by FSIS describes critical operating parameters (page 47) and Attachment A6. Cooking Country-Cured Hams includes additional tips, specific to country-cured hams (page 90).

**Partially Heat-Treated NRTE Products** This guideline does not cover partially heat-treated products that are not ready-to-eat (NRTE) and did not reach a validated lethality time-temperature combination (for example: partially heat-treated bacon and hams). These products are addressed in the FSIS Stabilization Guideline for Meat and Poultry Products because cumulative growth of Clostridium perfringens and Clostridium botulinum are hazards of concern over the course of partial cooking and cooling processes.

**KEY DEFINITIONS** Stabilization is the process of preventing or limiting the growth of spore-forming bacteria capable of producing toxins either in the product or in the human intestine after consumption. Stabilization processes may include cooling, hotholding, or meeting and maintaining a certain pH or water activity level and other processes, such as drying and fermentation/ acidification that render the product shelf-stable or safe at room temperatures."

"<sup>13</sup> NOTE: As noted under the Products and Processes Covered by this Guideline, this guideline may be used for products that are cooked to lethality but classified under a Not RTE (NRTE) HACCP plan. For such products, please refer to the product reclassification guidance in the Listeria Guideline, Attachment 1.2 on pages 22-23 and Appendix 1.2 on pages 28-29 for guidance related to labeling, HACCP categorization, and intended use.

**RTE Multi-hurdle Products** This guidance does not address the safe production of products that rely on multiple hurdles to achieve lethality and shelf-stability (e.g., fermented and dried sausage). However, some regulatory information associated with such products is included in General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking, page 18.

NOTE: Stabilization requirements and recommendations for cooling meat and poultry products after heat treatment are described in the FSIS Stabilization Guideline for Meat and Poultry Products.

**Biological Hazards of Concern During Cooking** The following section is designed to complement FSIS' Meat and Poultry Hazards and Control Guide and to further assist establishments in conducting a hazard analysis for cooked meat and poultry products as required by 9 CFR 417.2(a)(1) and for supporting decisions in their hazard analysis as required by 9 CFR 417.5(a)(1). The following hazard is present in raw products whose outgrowth during the heating come-up time should be controlled:

\u2022 *Staphylococcus aureus* (*S. aureus*)

The following are hazards present in raw products that the lethality treatment should be designed to destroy:

\u2022 *Salmonella*

\u2022 Shiga toxin-producing *Escherichia coli* (STEC) (in beef)

\u2022 *Campylobacter* (in poultry)

\u2022 *Lm*

\u2022 *Trichinae spiralis* and *Toxoplasma gondii*

(in pork, especially feral or nonconfinement raised swine) NOTE: Although all of these hazards are a concern, *Salmonella* is considered an indicator of lethality because the thermal destruction of *Salmonella* in cooked products would indicate the destruction of most other pathogens (64 FR 732). More details about *S. aureus* and *Salmonella* (an indicator of lethality) can be found on the following page.","14 *S. aureus* *S. aureus* is a bacterial pathogen that causes nausea, vomiting, and abdominal cramping with or without diarrhea. The Centers for Disease Control and Prevention (CDC) estimates over 240,000 illnesses annually in the U.S. are attributed to *S. aureus* (Scallan et al., 2011). *S. aureus* causes illness when the bacteria grows to high levels in food and one or more heat-stable enterotoxins are produced (Kadariya et al., 2014). Various types of foods serve as the optimum vehicle for *S. aureus*. The pathogen has been identified in meat products, such as fermented salami and brine-injected hams. In the 1980s, *S. aureus* enterotoxin outbreaks were frequently attributed to hams. Continued outbreaks at hotels, restaurants and institutions as documented in the National Outbreak Reporting System (NORS)<sup>4</sup> highlight that *S. aureus* is still a concern in hams particularly when prepared in these settings. For example, between 2013 to 2018, at least six *S. aureus* enterotoxin outbreaks at hotels, restaurants and institutions were reported in NORS in which ham was the suspected food vehicle. *S. aureus* can contaminate raw meat and poultry from the animal hide, skin, or tissue during slaughter. After slaughter and cooking, RTE meat or poultry products can be contaminated with *S. aureus* from handling by individuals carrying the organism. This pathogen is the main food safety concern during long heating come-up-times (CUT) (that is the amount of time product temperature is between 50 to 130°F while heating). *S. aureus* can be present on the raw meat or poultry and grow to high enough levels to produce a toxin in the food. Growth occurs from 45 to 118°F, but effectively begins at 60°F, especially in raw meats where the growth of other bacteria is inhibited by nitrite or salt. The critical level for human illness is 5-Log or higher which allows enterotoxin production (Kadariya et al., 2014). The toxin is not destroyed by the critical operating parameters described in this cooking guideline. FSIS recommends limiting the growth of *S. aureus* during processing to 2-Log or less. Normal levels of *S. aureus* in raw meat are usually 2-Log (Doyle and Buchanan, 2013; IFT, 2003; Waldroup, 1996). Limiting growth to 2-Log or less allows for a margin of safety before *S. aureus* would produce toxins. Conditions that allow 3-Log growth are considered a public health concern because they would result in a total of 5-Log *S. aureus* in the product which is considered the minimum critical level for human illness (Kadariya et al., 2014). To limit *S. aureus* growth, some establishments formulate products with antimicrobials such as phosphate or lactate. But the most common practice is to limit the amount of time products spend in the temperature range where *S. aureus* grows the fastest (i.e., 50 to 130°F). This guideline identifies CUT as a critical operating parameter to ensure lethality by cooking when applying the time-temperature tables (see FSIS Critical Operating Parameters for Cooking on page 23). FSIS is aware that establishments preparing some products (e.g., ham or beef brisket) may not be able to follow FSIS's Come-Up-Time Option because of the thermodynamics of the heating process. Therefore, FSIS identified long CUT as a Scientific Gap since support does not exist for many common processes (page 48). This gap supports the use of any of FSIS's applicable time-temperature combinations (pages 35, 37, 38) and relative humidity, 4 <https://www.cdc.gov/nors/index.html>,""15 without considering CUT as a critical operating parameter until research can be complete. *Salmonella* *Salmonella* is a bacterial

pathogen that causes diarrhea and fever. Infection with Salmonella may result in arthritis (Ajene et al., 2013). The CDC reports that nontyphoidal Salmonella species (spp.) is one of the leading causes of foodborne illness, with an estimated 1 million cases of foodborne Salmonella infection annually in the U.S (Scallan et al., 2011). Salmonella spp. infections are the second leading cause of foodborne illness in the United States. Meat and poultry outbreaks are frequently associated with Salmonella spp. Salmonella occurs naturally in raw animal products; however, Salmonella should not be found in RTE meat and poultry products because these products have undergone a lethality treatment. Also, RTE products are intended to be consumed without further preparation for safety (i.e., cooking), and if pathogens are present, their consumption may cause illness. FSIS considers all RTE meat and poultry products that are contaminated with Salmonella, as well as Listeria monocytogenes and STEC, to be adulterated under the Federal Meat Inspection Act and Poultry Products Inspection Act (21 U.S.C. 601(m)(1) and 453(g)(1)). Any detectable Salmonella or other pathogens of concern adulterates RTE products (64 FR 732). Salmonella as an Indicator of Lethality Meat and poultry products may be contaminated with Salmonella during the slaughter and dressing process and by crosscontamination in the processing environment when insanitary conditions are present. For cooked products, FSIS recommends that establishments use Salmonella as an indicator of lethality because the thermal destruction of Salmonella in cooked products would indicate the destruction of most other pathogens (64 FR 732). If the establishment's scientific support demonstrates that the lethality treatment achieves sufficient reduction in Salmonella, it does not need to provide additional support that adequate reduction of other pathogens such as STEC, Campylobacter, Lm, Trichinae spiralis or Toxoplasma gondii is achieved. As stated in the FSIS Compliance Guideline HACCP Systems Validation, establishments should not use pathogens other than Salmonella as indicators of lethality for cooked products unless the alternate pathogen displays similar or higher resistance to the lethality processes. NOTE: While Salmonella is considered an indicator of lethality for validation purposes, in the event of a deviation where the establishment missed its time-temperature parameters or applied insufficient relative humidity, FSIS recommends testing for other pathogens of concern (e.g., E. coli O157:H7 and Lm) because the absence of Salmonella does not KEY DEFINITIONS Critical operating parameters are those parameters of an intervention that must be met for the intervention to operate effectively and as intended. Such parameters include but are not limited to time, temperature, water activity, concentration, relative humidity, and type of equipment (to the extent that the use of different equipment would result in an inability to achieve the critical parameters of the study).", "16 assure the absence of other pathogens since the establishment was unable to follow the critical operational parameters in its scientific support. In addition, depending on the type of deviation, other pathogens may also be of concern (e.g., C. perfringens and C. botulinum). For more information see Attachment A2. Cooking Deviations, page 66. How to Control Salmonella Establishments must ensure the target Log reduction of Salmonella and other vegetative pathogens is achieved throughout the product. To ensure vegetative pathogens, including Salmonella, are killed on the interior of the product, the endpoint time-temperature combination the product achieves is a critical operating parameter. Most often, the target temperatures used during cooking reported in scientific support documents and this guideline are the internal temperatures that the product should reach. FSIS has found that some establishments use the recommendations established

for internal product temperature to set critical limits for the oven temperature. However, setting the oven temperature to the temperature identified in the FSIS time-temperature tables is not appropriate because doing so does not ensure that the product will reach the same target internal temperature. In addition to the product temperature, the amount of time the product is held at this temperature (also known as the dwell time) is also critical to ensuring that adequate lethality is achieved. If the product is held at the target temperature for less time than specified in the time-temperature tables in this guideline, then adequate lethality may not be achieved. To ensure a process achieves the target Log reductions of Salmonella on the surface of the product, moisture during cooking is a critical factor. Moisture (e.g., relative humidity) around a product during cooking promotes lethality on the product surface in two ways: \u2022 Moist cooking reduces surface evaporation from the product during heating (evaporative cooling). Producing products under conditions of high moisture early in the cooking process reduces evaporative cooling allowing product surfaces to reach higher temperatures resulting in a greater reduction in microorganisms; and \u2022 Moist cooking keeps the product surface (and any pathogens) wet which prevents product drying. Product drying reduces the water activity and concentrates solutes (e.g., sugar and salt). Research has demonstrated that bacteria can become more heat tolerant as their moisture levels decrease, and increased concentrations of solutes, especially salt, increase the heat resistance of bacteria (Buege et al., (2006), Boles et al., (2004), and Sindelar et al., (2016)). Therefore, drying of the product surface before pathogens are destroyed will increase pathogen heat resistance and allow the pathogens to survive the heating process. By incorporating moisture (e.g., relative humidity) to minimize evaporation and the loss of surface moisture from the product, the D values (time at a constant temperature necessary to destroy 90% or 1-Log of the target organism) that are the basis for the "17 time-temperature combinations, will remain valid (Goepfert, 1970; Goodfellow and Brown, 1978). If evaporation, drying, or an increase in solute concentration is likely to occur, the times and temperatures in scientific studies and supporting documentation are not likely to be sufficient to provide the required lethality. How does Moisture Ensure Bacteria on the Surface are Killed During Cooking? During cooking, achieving a high oven temperature and internal product temperature alone are not enough to ensure the final product is free of harmful bacteria. Establishments need to make sure that cooking is done in a moist environment to ensure lethality. When relative humidity is low, oven air is dry, and a process called evaporative cooling increases, which is something we do not want. Evaporative cooling is the same thing that allows humans to keep cool by sweating. When you get too hot, you produce sweat, and when that sweat evaporates, it cools you down. Evaporation equals cooling. Just like on a person's skin, evaporative cooling cools down the surface of meat and poultry during cooking. Although the oven is hot, because the surface of the product is cooling down, that moisture evaporation can actually prevent the surface of the product from becoming hot enough to kill off harmful bacteria. We can reduce evaporative cooling by keeping the humidity in the oven high. That way the moisture in the product does not evaporate as quickly, keeping the meat's surface moist and hot and resulting in an adequate bacterial kill. Why does this work? Imagine that you are in New Mexico or Nevada where it is really hot, but dry. If you're outside, you're more likely to sweat and that sweat will cool you down, so you don't feel as hot. Now imagine you're in Florida where it is not only really hot, but also humid. If you're outside where it is humid,

your skin\u2019s surface will stay sweaty and hot, your sweat will not evaporate, and you will not cool down. Since the air is already saturated, or full of moisture (humid), there is less evaporation from your body and, therefore, less cooling. The way humidity keeps you hot in Florida is the same way moisture keeps meat and poultry products hot, too. When you get too hot\u2026 \u2026you produce sweat. When that sweat evaporates\u2026 \u2026it cools you down. Evaporation = Cooling VS. Desert Dry Heat = Cooling Down Tropical More Humidity = Less Cooling", "18 General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking Addressing Lethality in the HACCP System FSIS has established performance standards in the regulations for specific ready-to-eat (RTE) products. The performance standards for specific products set required levels of Salmonella lethality during cooking as follows: \u2022 Cooked poultry products must be processed to achieve at least a 7-Log reduction of Salmonella or an alternative lethality per 381.150(a)(1). \u2022 Roast, cooked, and corned beef must be processed to achieve at least a 6.5-Log reduction of Salmonella or an alternative lethality (e.g., at least a 5-Log reduction) per 9 CFR 318.17. \u2022 Cooked uncured meat patties must be processed to meet or exceed the time-temperature combinations listed in 9 CFR 318.23, which will achieve a 5-Log reduction of Salmonella (and other pathogens including STEC). For products that are not subject to a performance standard, FSIS recommends the following pathogen Log reductions (i.e., targets) be achieved in order to support decisions in the hazard analysis (9 CFR 417.5(a)(1)): \u2022 For cooked meat products, FSIS recommends that establishments achieve a target 6.5-Log or 5-Log reduction of Salmonella in their process. To use a target 5-Log reduction, establishments should provide additional support for the safety of their process (see Supporting an Alternative Lethality Target (e.g., 5-Log) page 57). \u2022 For shelf-stable meat products, FSIS recommends that establishments achieve a target 5-Log reduction of Salmonella (see How is Alternative 5-Log Lethality Related to Risk of Foodborne Illness? page 57). KEY DEFINITIONS Performance standards described in this guideline are quantifiable pathogen reduction levels or growth limit requirements set by FSIS for lethality and stabilization of certain meat and poultry products. A Log reduction is a 90% reduction of a pathogen. For example, a 2-log reduction is a 99% reduction of a pathogen and a 3-log reduction is a 99.9% reduction of a pathogen in a product. Targets are quantifiable pathogen reduction levels or growth limits set by the establishment to produce safe products in the absence of regulatory performance standards. An alternative lethality is a treatment that achieves a different (often lower) Log reduction than what is prescribed in the regulations for certain products, but still achieves an equivalent probability that no viable Salmonella cells remain in the finished product, nor other pathogens and their toxins or toxic metabolites. An alternative lethality prevents adulteration and must be demonstrated to be achieved throughout the product (9 CFR 318.17(a)(1)).", "19 An establishment should identify the performance standard or specific Log reduction target its process is designed to achieve in its HACCP plan or supporting documentation. If it does not, and FSIS cannot determine the pathogen reduction level the process achieves, FSIS may determine the establishment lacks support for its decisions related to Salmonella control (9 CFR 417.5(a)(1)). In addition, according to 9 CFR 417.2(c)(3), establishments must design their critical limits for Critical Control Points (CCPs) to meet all applicable performance standards and targets. NOTE: If an establishment uses the time-temperature tables provided in this guideline or cooks beef patties according to 9 CFR 318.23, it does not need to indicate the specific Log reduction that its process achieves. It would be sufficient for the establishment to indicate that

it uses time-temperature combinations from one of these documents as these regulations were designed to achieve a 5-log reduction in Salmonella and other pathogens including STEC. Establishments are also required to validate that their HACCP system works as intended to address these hazards (9 CFR 417.4(a)). For more information on validation see the HACCP Systems Validation Guideline. Key Question Question: When a RTE meat food product is a mixture of meat and poultry such that the product has a meat legend, and the establishment is following this cooking guideline, does the RTE meat food product need to comply with the regulatory requirement found in 9 CFR 381.150(a)(1)? Question: If a RTE meat food product has any amount of poultry in it, does it automatically have to meet the poultry Log reduction in the FSIS Time-Temperature Tables? Answer: Yes to both questions. RTE meat or poultry food products consisting of any combination of meat and poultry must meet the poultry lethality performance standard in 9 CFR 381.150(a)(1). Under the published final rule \"Performance Standards for the Production of Certain Meat and Poultry Products,\" cooked product with any amount of poultry needs to meet the lethality requirements for the production of fully cooked poultry products (9 CFR 381.150(a)(1)) which stipulate a 7-Log Salmonella reduction or an alternative lethality that achieves an equivalent probability that no viable Salmonella organisms remain in the finished product. This provision is based on the FSIS national microbiological \"baseline\" survey of raw whole and ground meat and poultry products, which found higher levels of Salmonella in poultry than in meat (USDA 1994, 1996a-f). Consequently, FSIS established a higher lethality performance standard for RTE poultry products than for meat (based on highest \"worst case\" levels).\" 20 Alternative Lethality An alternative lethality is a treatment that achieves a different (often lower) Log reduction than what is prescribed in the regulations but still achieves an equivalent probability that no viable Salmonella cells remain in the finished product, as well as ensures the reduction of other pathogens and their toxins or toxic metabolites (e.g., from *S. aureus*) necessary to prevent adulteration. Establishments may use alternative lethality treatments to meet the performance standards (9 CFR 318.17(a)(1) and 9 CFR 381.150(a)(1)). When using an alternative lethality treatment (e.g., at least a 5-Log reduction of Salmonella), the establishment must validate its HACCP system to ensure that no viable Salmonella organisms (that is no organisms capable of causing human illness) remain in the finished product. Risk assessments have demonstrated that achieving a 5-Log reduction of Salmonella (instead of a 6.5-Log reduction) in cooked meat and poultry products that are not shelf stable is less protective of public health (Refer to text box: How is Alternative 5-Log Lethality Related to Risk of Foodborne Illness? page 57). Therefore, to use these lower targets, the establishment must provide additional support for its process as described in Attachment A1. Customized Processes and Alternative Lethality Support: Supporting an Alternative Lethality Target (e.g., 5-Log) on page 55. In contrast, risk assessments have shown that for shelf-stable meat and poultry products, a 5-Log reduction of Salmonella (instead of a 6.5-Log or 7Log reduction) is sufficient. Therefore, no additional support is needed to use a 5-Log reduction process in these shelf-stable products (9 CFR 417.5(a)(1) and 9 CFR 417.4(a)(1)). Monitoring, Calibration, and Recordkeeping The establishment\u2019s cooking procedures should be designed to ensure all products in a batch or lot achieve lethality, and the monitoring procedures should be designed to detect a deviation when it occurs. To achieve these goals, establishments should carefully consider the selection of the critical limit, as well as the design of their monitoring procedures. Lessons learned from several recalls attributed, in part, to

insufficient monitoring procedures are shared on page 22. Selection of the critical limit Establishments producing cooked meat and poultry products should have sufficient monitoring equipment, including recording devices, to assure that the time, temperature, and relative humidity operating parameters of their processes are being met. With any monitoring equipment, the establishment should take the normal variation of the monitoring equipment into account when designing the critical limits. For example, if a minimum internal temperature of 165°F is necessary to destroy pathogens in a product and the thermometer has an accuracy of ±1°F (plus or minus one degree), then the critical limit should be set no lower than 166°F. The written reasoning and equipment specification materials should be kept as part of the establishment's supporting documentation for its HACCP plan and the selection of its critical limit (9 CFR 417.5(a)(2)). All supporting documents and data from the recording devices must be made available to FSIS employees upon request (9 CFR 417.5).<sup>21</sup> Selection of the monitoring procedures Establishments are required to maintain documents supporting the selection of monitoring procedures and associated monitoring frequencies (9 CFR 417.5(a)(2)). It is important that establishments take into account variation within the cooking process when developing monitoring procedures to ensure the procedures they develop can identify any deviations. In addition, to accurately measure the internal temperature of the meat or poultry product, an establishment should understand the factors that can affect this temperature. These factors include cold spots in the oven, as well as variations in oven temperature during different seasons. Establishments should be aware that updated smokehouses that contain alternating or rotating dampers that result in varying breakpoints throughout the oven do reduce the temperature difference throughout the oven, but they do not eliminate it. Although monitoring the internal product temperature is strongly encouraged, an establishment can use the oven or smokehouse temperature in place of the product temperature, provided that the establishment has a consistent product and process and has sufficient data on file correlating the oven temperature selected with the internal product temperature in the scientific support. A disadvantage with monitoring oven temperature alone is that it may make supporting product disposition after a cooking deviation more difficult. In many cases, FSIS recommends using predictive microbial modeling programs to evaluate potential hazards (see Attachment A2. Cooking Deviations on page 66). Microbial modeling programs use product temperature to predict pathogen growth and potential Log outgrowth or reductions achieved. Without product temperature records, the establishment would need other support (e.g., product testing) to determine product disposition.

Key Question: How does an establishment develop a monitoring procedure for measuring endpoint temperature in meat or poultry products that are fried crispy such that a probe cannot be inserted into the product to measure internal temperature (e.g., popped pork skins, and bacon slices, pieces, or bits) because the product is too thin or hard or because the thin product cools as soon as the product exits the cooking medium? Answer: Depending on the product type, there are different recommendations. For example, for a product such as bacon slices, it may be possible to cut a slice twice as thick as normal so that the probe can be inserted. If this thicker piece reaches the lethality temperature, the thinner pieces should as well. This procedure is also recommended for jerky. It is not recommended to fold a piece of product over the thermometer, as this has been found to result in inaccurate temperatures (Buege et al., 2006). For small products, such as bacon pieces or bits, it may be possible to pile

the pieces or bits around the thermometer for measurement. If none of these procedures can be used, establishments may use other quantifiable measures such as a color scale value that is correlated to crispiness or the number of pieces that pass as \"fried until crispy in all parts\" based on a visual assessment as the critical limit for lethality for these products due to the physical challenges in monitoring the internal temperature, and the lack of outbreaks associated with them." "22 Lessons Learned from Undercooked Product Recalls In 2016 and 2017, there were five recalls associated with under-cooked RTE poultry products (RC-106-2016, RC-110-2016, RC-115-2016, RC-017-2017, and RC-0372017). For each of these recalls, FSIS determined that even though the establishments had documentation showing the critical limit (either 160\u00b0F or 165\u00b0F) was met, there were still pieces that may have entered commerce undercooked, indicating a loss of process control and insufficient monitoring procedures to identify a process deviation. Investigations revealed a variety of concerns related to monitoring procedures, including taking temperatures from products not in the coldest spot, taking multiple product temperatures, and averaging the results of multiple temperature measurements as opposed to recording the lowest temperature. Investigations also revealed a variety of contributing factors for inadequate cooking including: \u2022 Raw product was partially frozen. \u2022 Belt speed was increased. \u2022 Shorter dwell time and lower oven temperature than normal were used. \u2022 Product was stacked during sous vide cooking, preventing full immersion of the bags into the liquid cooking medium. \u2022 Higher than normal product load overwhelmed the oven. Each of these practices may have led to uneven or inadequate cooking. These findings also highlight the importance of maintaining process control of critical operating factors, such as oven temperature, product load, and belt-speed that affect the final product temperature, dwell time, and relative humidity. The establishment is required to validate that the entire HACCP system is operating as intended and to verify that it is producing a safe and wholesome product on an ongoing basis. Complete failure to document critical limit monitoring has also contributed to the recall of cooked poultry products in the past due to a processing defect (RC-009-2017). Such a failure highlights the importance of accurate records documenting the implementation of the critical operating parameters to support the production of safe products. Corrective Actions under HACCP Cooking Deviations Cooking deviations occur when an establishment fails to meet its cooking CCP critical limit or cooking humidity option. Common causes for cooking deviations include product overlap, power failures, or breakdown of cooking equipment. The HACCP regulations require establishments to take corrective actions in response to these deviations, regardless of whether the cooking process is addressed through a CCP or prerequisite program. Corrective actions include ensuring no product that is injurious to health or otherwise adulterated because of the deviation enters commerce and supporting product disposition decisions (9 CFR 417.3(a) and (b))." "23 When cooking is addressed through a CCP, establishments are required to determine the cause of all cooking deviations, no matter how small (9 CFR 417.3(a)(1)), and ensure measures are established to prevent recurrence (9 CFR 417.3(a)(3)). Continual or repetitive process deviations from the critical limit demonstrate that the establishment is unable to control its process. When cooking is addressed through a prerequisite program, establishments are required to reassess their HACCP system to determine whether the newly identified deviation or unforeseen hazard should be addressed and incorporated into the HACCP plan (9 CFR 417.3(b)(4)). Also, an establishment may not be able to continue to support the decision in

its hazard analysis that pathogens are not reasonably likely to occur, if it has continual or repetitive deviations from its cooking prerequisite program (9 CFR 417.5(a)(1)). For more information on evaluating product disposition after a cooking deviation see Corrective Actions to Perform When a Cooking Deviation Occurs (page 66). FSIS Critical Operating Parameters for Cooking (Time-Temperature Tables) Establishments that cook products to achieve lethality by applying the time-temperature combinations from this guideline need to consider the critical operating parameters that may affect pathogen Log reductions, specifically: \u2022 Come-up-time (CUT), \u2022 Relative Humidity, and \u2022 Endpoint Time-Temperature. Additionally, establishments cooking poultry products need to consider product species composition and fat content if applying FSIS cooking lethality guidance in the tables on pages 37 and 38. The FSIS Cooked Poultry Rolls Options (page 39) apply to all poultry products regardless of poultry species or fat content. For information about why product species should be considered when applying cooking lethality guidance on pages 37 and 38 and not when applying the FSIS Cooked Poultry Rolls Options see page 36. Come-Up-Time (CUT) When applying one of the time-temperature tables from this guideline, an establishment must also consider the heating CUT to be a critical operating parameter unless the establishment can provide a science-based rationale why heating CUT does not need to be addressed. For example, products that are fermented and then cooked to lethality may control *S. aureus* outgrowth by lowering the pH following the degree-hour concept as recommended in the American Meat Institute\u2019s Good Manufacturing Practices for Fermented Dry & Semi-Dry Fermented Sausage Products and therefore would not address CUT." "24 FSIS has developed a CUT Option that establishments may use to support its process control of *S. aureus* growth, specifically \u2264 2-Log that also prevents enterotoxin formation: Come-Up-Time Option: Total time product temperature is between 50 and 130\u00b0F is 6 hours or less. NOTE: This CUT Option is only for products that were cooked to lethality (including those cooked to lethality but classified as NRTE under a heat treated, not fully cooked, not shelf-stable HACCP plan). Please refer to the FSIS Stabilization Guideline for Meat and Poultry Products for the Agency\u2019s recommendations regarding CUT in partially cooked products that do not receive a full lethality. Please also refer to the product reclassification guidance in the Listeria Guideline, Attachment 1.2 on pages 2223 and Appendix 1.2 on pages 28-29. FSIS is aware that establishments preparing some products (e.g., ham or beef brisket) may not be able to follow FSIS\u2019s Come-UpTime Option above because of the thermodynamics of the heating process. Therefore, FSIS identified long CUT as a Scientific Gap since support does not exist for many common processes (page 48). Additionally, alternative support for certain long CUT processes have been included in Attachment A1. Customized Processes and Alternative Lethality Support (page 55). Temperatures referred to in FSIS\u2019s Come-Up-Time Option above, are internal temperatures. However, establishments may monitor surface temperatures during CUT, if the establishment provides support the product is intact and processed so pathogens have not been introduced below the product surface. Non-intact product temperatures should be taken internally at the center of the product (see Key Definitions panel to the right for an explanation of intact and nonintact products). Establishments should also take temperatures at the center of the product for products such as deboned and rolled hams where a portion of the product is rolled or folded over and pathogens may be internalized. NOTE: FSIS time-temp tables list internal endpoint temperatures during cooking. It is not supportable to use surface temperature to address

endpoint temperature. FSIS is only making this recommendation for its CUT option. KEY DEFINITIONS Come-up-time refers to the amount of time product temperature is between 50130\u00b0F while heating. Intact refers to products where the interior remains protected from pathogens migrating below the exterior\outside (such as beef brisket or a picnic shoulder that is not injected or vacuum tumbled). Non-Intact refers to products where pathogens may have been introduced below the surface. Examples include products that have been mechanically tenderized (including those that have been injected with marinade or solution) or vacuum tumbled.","25 Relative Humidity FSIS time-temperature tables use relative humidity as a critical operating parameter to ensure moist cooking and adequate surface lethality. An establishment that uses the FSIS time-temperature tables to support its cooking process must address humidity, unless it meets one of the criteria listed in Situations when Humidity is Not Needed (page 31) or provides additional support for why humidity would not be needed in its process to ensure lethality on the product surface. FSIS has included specific relative humidity options for use with the timetemperature tables (page 26). Additional resources for determining which relative humidity option to adopt are included in Relative Humidity Resources (page 28). NOTE: FSIS is aware that some establishments may not be able to use FSIS\u2019s humidity options because of the nature of the cooking process. Examples include products cooked for short times at high temperatures (e.g., for meat balls or chicken tenders) or other processes that do not allow the use of humidity (e.g., barbecue products cooked under dry heat including those cooked in smokehouses or open pits). Please refer to Scientific Gaps Identified by FSIS (page 41). Selection of the proper relative humidity option depends on the endpoint time-temperature. Products cooked to endpoint time-temperatures of at least 145\u00b0F plus the dwell time, may apply any of the relative humidity options in Table 1.

**Critical Operating Parameters for FSIS Humidity Options.** Key Question Question: An establishment cooks a brisket to full lethality but realizes the smoke coloring is too light and wants to recook it to deepen the color. Can the establishment apply a new 6 hour CUT for the second cook? Answer: Yes. Once a product achieves a lethal time-temperature combination, the allowed CUT is reset for the next cook. If the establishment chooses to recook the product, it may apply a new 6 hour CUT limit (page 23). However, if the product did not achieve a lethal time-temperature combination during the first cooking process, the CUT does not start over. The establishment should support the total time product temperature is between 50 and 130\u00b0F is 6 hours or less. Please review Attachment A2. Cooking Deviations subsection Missed Time-Temperature Parameter (page 67) for additional information. KEY DEFINITIONS Maintaining humidity means keeping the humidity at the same level throughout the cooking process. If the humidity drops during the cooking process, the establishment will need to provide additional support for the safety of the product A sealed oven is generally defined as one in which the smokehouse doors and oven dampers are closed to prevent moisture loss. The cooking time includes the time the product is placed in the heated oven (including surface preparation and color setting) until the product reaches the desired lethality timetemperature combination (also referred to as the \u201clethality treatment\u201d).","26 However, products cooked to an endpoint less than 145\u00b0F, should select Option 3 or 4 in Table 1. Critical Operating Parameters for FSIS Humidity Options depending on total cooking time. NOTE: To be most effective, humidity needs to be applied during the lethality treatment, before drying. Using this guideline to support lethality processes in which the drying step comes before the

moist cooking step (e.g., country-cured ham) creates a vulnerability in the establishment's HACCP system. Establishments using this guideline for these processes should read Attachment A6. Cooking CountryCured Hams (page 90) for recommendations to reduce this vulnerability, such as measuring water activity after cooking to verify it increases and the product surface was rehydrated during cooking. To ensure that adequate humidity is attained, the establishment should monitor the humidity throughout the lethality treatment. The process should be monitored using wet and dry bulb thermometers (used to determine relative humidity) or a humidity sensor. FSIS recommends that establishments monitor relative humidity for every lot or batch of product produced. Table 1. Critical Operating Parameters for FSIS Humidity Options CRITICAL OPERATING PARAMETERS Relative Humidity Endpoint

Temperature Cooking Time OPTION 1: The relative humidity of the oven is maintained by continuously introducing steam for 50 percent of the cooking time, or 1 hour, whichever is longer. \u2265145\u00b0F + dwell time \u22651 hour OPTION 2: The relative humidity of the oven is maintained by a sealed oven for at least 50 percent of the total cooking time, or 1 hour, whichever is longer. \u2265145\u00b0F + dwell time \u22651 hour OPTION 3: The relative

humidity of the oven is maintained at 90 percent or above for at least 25 percent of the total cooking time, or 1 hour, whichever is longer. Any \u22651 hour OPTION 4: The relative humidity of the oven is maintained at 90 percent for the entire cooking time. Any Any",<sup>27</sup>

Current Support for FSIS Relative Humidity Options Although the research cited as the basis of FSIS guidance dates as far back as 1978, newer research by McMinn et al., (2018) supports that the time-temperature parameters in FSIS's cooking guidance achieves sufficient reductions of Salmonella. This research by McMinn et al. (2018) was conducted with product cooked in vacuum-sealed bags supporting the importance of cooking in a high moisture environment. While newer research has not been conducted to validate the sealed oven and steam injection relative humidity options, research does continue to support the importance of moisture during cooking. For example, Mann and Brashears (2007), support the need for at least 30% relative humidity during cooking of roast beef. Based on FSIS knowledge of establishments' processes through its verification activities, the Agency believes when the oven is sealed, or steam is introduced, at least 30% relative humidity is maintained, suggesting that these practical recommendations result in adequate relative humidity. The Agency is also not aware of any establishments that have had Salmonella positives or been associated with a salmonellosis outbreak when following FSIS temperature, time, and relative humidity guidance while using effective monitoring procedures.

Key Question Question: To follow the sealed oven or steam injection options, must establishments achieve a specific relative humidity? Answer: No. Establishments do not need to achieve a specific relative humidity level in the oven if they are following the steam injection or sealed oven options in this guideline as their scientific support. Based on expert opinion, the 2014 FSIS Jerky Guideline recommended that establishments producing jerky that monitor relative humidity try to achieve a wet bulb temperature of at least 125-130\u00b0F for 1 hour or more along with a corresponding dry bulb temperature needed to achieve at least 27-32% relative humidity or more. However, the Jerky Guideline also noted, achieving a wet bulb temperature of at least 125-130\u00b0F and at least 27-32% relative humidity for 1 hour or more is not adequate on its own to support that the process is being implemented consistently with FSIS Humidity Options. Rather, establishments should ensure that all critical operating parameters described in this

guidance are met. Relative Humidity Resources (page 28 contains specific guidance for how to implement Option 1 steam injection and Option 2 sealed oven in a validated HACCP system. In addition, establishments should not apply the wet-bulb and relative humidity recommendations in the Jerky Guideline to other products without additional support.)

Relative Humidity Resources The following flow chart contains specific guidance for how to choose a humidity option and the resources on the next two pages are designed to help establishments implement Option 1 steam injection and Option 2 sealed oven in a validated HACCP system.

Flow Chart to Choose a Humidity Option

- \*Relative humidity (RH) is 90% or higher for at least 25% of the total cooking time, or 1 hour, whichever is longest.
- \*\*RH is maintained for 50% of the cooking time, or 1 hour, whichever is longest

For more information, refer to FSIS Relative Humidity Options on page 25.

\u2014 wouldn\u2019t it be good to put the information together? Additionally, the following information in the FSIS Jerky Guideline can be useful when deciding which humidity option to adopt:

- \u2022 Instructions for making your own wet bulb (reprinted with permission from the University of Wisconsin, page 49); and
- \u2022 An example of a time-temperature recorder chart to support the option of continuously injecting steam (page 53).

\*Relative humidity (RH) is 90% or higher for at least 25% of the total cooking time, or 1 hour, whichever is longest.

\*\*RH is maintained for 50% of the cooking time, or 1 hour, whichever is longest

For more information, refer to FSIS Relative Humidity Options on page 26.

Additionally, the following information in the FSIS Jerky Guideline can be useful when deciding which humidity option to adopt:

- \u2022 Instructions for making your own wet bulb (reprinted with permission from the University of Wisconsin, page 49); and
- \u2022 An example of a time-temperature recorder chart to support the option of continuously injecting steam (page 53).

Specific Guidance for Using the Sealed Oven Option To support the use of the sealed oven option for addressing relative humidity, FSIS recommends establishments follow all 4 steps below:

- 1) Maintain documentation that supports that the product achieves an internal product temperature equal to or greater than 145\u00b0F (plus the required dwell time) from the FSIS time-temperature tables. Such documentation could include:
  - a. Records of internal product temperature and time held at that temperature, (if applicable); or
  - b. Records of the oven or smokehouse temperature in place of internal product temperature provided that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the internal product temperature in the scientific support;
- 2) Maintain documentation that supports that the oven dampers are closed for at least one hour or 50% of the cooking time, whichever is longer. Such documentation could include:
  - a. Records from a computerized system that document the time at which the oven dampers were open and were closed; or
  - b. Records, made manually, of the times at which the oven dampers were open and closed;
  - c. Records demonstrating that the relative humidity level in the oven is maintained for at least one hour or 50% of the cooking time, whichever is longer (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement) with correlation data supporting a relationship between the relative humidity level in the oven and the time at which the oven dampers were open and closed;
- 3) Maintain documentation that supports that when the oven dampers are closed, humidity is maintained in the ovens. Such documentation could include:
  - a. Records demonstrating the relative humidity level in the ovens is maintained (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity

or use of a humidity sensor that provides a direct measurement), or b. Data gathered during the initial validation period along with ongoing verification that demonstrate that the relative humidity in the oven is maintained while the dampers are closed; and 4) Perform routine checks to ensure the oven dampers are properly working along with a maintenance program that includes periodic monitoring to ensure oven seals are intact and functional, and that when the oven dampers are closed, a tight seal is obtained. A tight seal is one that prevents a significant loss of humidity. FSIS acknowledges that a small amount of smoke or vapors might be seen escaping the smokehouse even when a tight seal is obtained. FSIS also recommends establishments consider whether there are other openings, particularly in older smokehouses, such as drain valves or air intake valves that need to be closed to ensure that a seal is obtained. Finally, some older ovens may have a stack or other opening that cannot be closed. For those establishments with older ovens that cannot be completely closed, the sealed oven method should not be used. However, the establishment may choose to close the parts of the oven it can, then add moisture in the system either by continuously introducing steam, or by using another validated method." "30 Specific Guidance for Using the \u201cContinuously Introducing Steam\u201d Option To support the use of the continuously introducing steam option for addressing relative humidity, FSIS recommends establishments follow all 3 steps below: 1) Maintain documentation that supports that the product achieves an internal product temperature equal to or greater than 145\u00b0F (plus the required dwell time) from the FSIS time-temperature tables. Such documentation could include: a. Records of internal product temperature and time held at that temperature, (if applicable); or b. Records of the oven or smokehouse temperature in place of internal product temperature provided that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the internal product temperature in the scientific support; 2) Maintain documentation that supports that steam is continuously introduced for at least one hour or 50% of the cooking time, whichever is longer. Such documentation could include: a. Records from a computerized system that contains the time at which the steam is turned on and off; or b. Records, made manually, of the times at which the steam is turned on and off; or c. Records demonstrating the relative humidity level in the oven is maintained for at least one hour or 50% of the cooking time, whichever is longer (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement), along with correlation data supporting a relationship between the relative humidity level in the oven and the time steam is turned on or a letter from the manufacturer stating that when the relative humidity is rising, it is because of live steam injection; and 3) Maintain documentation that supports that when steam is injected, humidity is maintained in the ovens. Such documentation could include: a. Records demonstrating the relative humidity level in the ovens is maintained (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement), or b. Data gathered during the initial validation period along with ongoing verification which demonstrates that the relative humidity in the oven is maintained while steam is being injected. NOTE: The \u201ccontinuously introducing steam\u201d option refers to the use of live steam. This option may also apply to establishments that spray water onto hot heating elements, which creates steam that in turn produces humidity in the smokehouse. \u201cContinuous\u201d does not mean that the steam is injected for at least

one hour during one stage. Rather, steam could be injected during specific stages or time intervals during the lethality (cooking) treatment as long as the total amount of time the steam is introduced adds up to at least one hour or 50% of the cooking time, whichever is longer. Furthermore, the establishment may turn the steam on and off throughout the cooking time when the target humidity is reached.","31 Situations when Humidity is Not Needed FSIS recognizes two situations when humidity does not need to be addressed to ensure adequate lethality: 1. When moisture is inherently maintained; or 2. When product is cooked using direct heat. Relative humidity does not need to be addressed when moisture is inherently maintained around the product. Examples of these types of processes include, but are not limited to:

- \u2022 Completely immersing the meat or poultry product in a liquid cooking medium throughout the entire cooking process;
- o E.g., unbagged, in water
- \u2022 Cooking the product in a sealed, moisture impermeable bag (e.g., cook-in-bag meat or poultry);
- o Cook-in-bag products may be eligible to be labeled as \u201cpasteurized\u201d (see Attachment A3. When can Products be Labeled as Pasteurized? page 81).
- \u2022 Cooking product in a casing that holds moisture (e.g., natural casings, cellulose casings, collagen casings, fibrous casings and plastic casings (sometimes called \u201csynthetic\u201d casings)).
- o See the question box on page 33 for information on cooking using natural casings.
- \u2022 Heating meat or poultry products that weigh 10 pounds or more in an oven maintained at 250\u00b0F (121\u00b0C) or higher throughout a process achieving one of the timetemperature combinations in this guideline.

NOTE: Humidity is not needed for products that weigh 10 pounds or more in an oven maintained at 250\u00b0F (121\u00b0C) or higher because they have a low surface to mass ratio (Goodfellow and Brown, 1978). Therefore, the surface dries out slower than smaller products and *Salmonella* is less likely to become heat tolerant. Establishments that use processes that match one of these situations do not need to monitor relative humidity as a critical operating parameter in their cooking procedure.

**Key definitions**

**Convective heating**: Heat is transferred directly into the food product by physical contact with the heating medium (e.g. heating product on a skillet).

**Radiant heating**: Heat is transferred directly into the food product by radiant energy without the movement of air or physical contact between the source and the food. Two common examples: Radiant energy from the sun warms Earth across the vacuum of space, or a flame emits radiant energy to heat food product in certain rotisserie ovens. Various forms of radiant energy also include gamma rays, electron beams, x-rays, and microwaves.

**KEY DEFINITIONS**

During convective heating the food product is indirectly heated by the movement of hot air. This type of heating is typical for solid foods cooked in a smoke house oven.

**Conductive Heating**: Heat is transferred directly into the food product by physical contact with the heating medium (e.g., heating product in a skillet).

**Radiant Heating**: Heat is transferred directly into the food product by radiant energy without the movement of air or physical contact between the source and the food. Two common examples: are (1) broiling where food is exposed to direct, intense radiant heat or (2) certain types of rotisserie ovens where a flame emits radiant energy to heat food.

Forms of radiant energy also include gamma rays, electron beams, and x-rays.","32 Relative humidity also does not need to be addressed for processes that apply direct heat via conduction or radiant heating. Unlike convective heating, which uses moving hot air or steam to heat the product (e.g., smoke house ovens, spiral ovens, impingement ovens), direct heating (e.g., conductive heating, radiant heating) puts the product in direct contact with the heating

medium. Direct heat ensures the product surface quickly reaches lethality temperatures before bacteria can develop heat tolerance due to the product's surface quickly drying out. Examples of direct heat include: Grill. Broil (exposure to direct, intense radiant heat). Heating coil, Flame. Certain rotisserie ovens that cook the meat or poultry over the heat source resulting in a product with a grilled quality. NOTE: Direct heat cooking is rarely used in conjunction with rotisserie cooking. Indirect heat cooking is most often used because it allows the meat or poultry to cook slowly and evenly, which is the primary purpose for using a rotisserie for cooking. For indirect heat cooking, the rotisserie is positioned in front of or next to the heat source and it is the heated air that cooks the product (convection cooking). Cooking meat patties per 9 CFR 318.23 does not include humidity considerations because these products were assumed to be cooked with direct heat such as a grill, heating coil, or flame. Meat patties cooked per 9 CFR 318.23 do not need to address relative humidity. For the definition of a patty see 9 CFR 318.23. NOTE: Products cooked using microwave cooking methods that are not designed to control relative humidity is considered a Scientific Gap because these common cooking processes can't achieve the relative humidity options included in this guideline; however, there is a lack of research to support alternative parameters. For the critical operating parameters in this guideline that can be used for these processes, if using FSIS guidance as scientific support, see Table 5. Scientific Gaps where Critical Operating Parameters From Older Guidance May be Used page 44. How is indirect heating identified? Moving air or steam is a sign of convective (indirect) heating. Ovens that use moving air to heat the product need to address relative humidity to ensure sufficient Log reductions for pathogens are achieved." "Do Products Cooked in Natural Casings Made from Animal Gastrointestinal Tracts Need to Address Relative Humidity? No, establishments using FSIS cooking guidance as support do not need to address relative humidity for products that are cooked in a natural casing, including products that are cooked and then dried.<sup>1</sup> Natural casings made from animal gastrointestinal tracts are typically considered permeable and many establishments take advantage of their permeability to produce dried products or smoked products. However, depending on how they are used, the permeability of natural casings may be reduced. Most cooking processes likely reduce the permeability of natural casings early in the process so that humidity around the product is inherently maintained throughout the remainder of cooking and does not have to be added or monitored. According to Sebranek, (2010), establishments will apply smoke early in the process while the casing is still moist and permeable to the smoke. Prior to smoke application, the casing surface should be \"tacky\" or \"sticky.\" After smoke deposition and color development, further cooking denatures the proteins in the casing reducing permeability to the point that later cooking can be applied without great moisture loss from the product. Proteins in natural casings begin denaturing at 126°F (Tornberg, 2005). However, most drying processes use lower temperatures and address relative humidity to maintain casing permeability so that moisture can evaporate from the product during drying. Although most cooking processes likely result in reduced permeability of natural casings early in the cooking process, little research has been performed to study the critical operating parameters that impact the reduction of permeability such as the length of the initial smoke application step, cooking temperature, total cooking time, use of steam, size of casings, composition of sausage batter, etc. For this reason, FSIS has posted a research study on its website to determine if natural casings maintain sufficient

moisture to ensure product lethality using Appendix A time and temperature tables.\u201d Without this additional research, the Log reduction of Salmonella is less certain if meat products in natural casings are cooked using one of the timetemperature parameters in this FSIS cooking guidance without following one of the humidity options. So, while FSIS has indicated establishments using FSIS cooking guidance as support do not need to address relative humidity for products that are cooked in a natural casing, if an establishment uses one of the time-temperature parameters in FSIS cooking guidance without addressing relative humidity has a positive Salmonella test result through FSIS or its own testing, it should, as part of corrective actions, provide evidence that lack of relative humidity was not the cause. In addition, if research is completed and data becomes available that indicates relative humidity needs to be addressed when products are cooked in a natural casing, FSIS may change its recommendation. 1NOTE: As described in the Products and Processes Not Covered by This Guidance, this guideline is not appropriate support for lethality of a process that relies on drying alone or to support a process where the drying step comes before a cooking step that does not apply humidity or does not apply humidity during cooking at sufficient levels to rehydrate the product surface during the cooking step under dry conditions.", "34 Endpoint Time-Temperature FSIS time-temperature tables in this guideline (Meat Table, the 5-Log Table, and the Poultry Time-Temperature Tables) list internal product temperatures and the corresponding dwell times needed to achieve specific Log reductions of Salmonella. These tables may be used as scientific support to ensure that the process meets regulatory requirements (see General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking, page 18). NOTE: To apply an alternative lethality and use Table 6. Time-Temperature Combinations for Meat Products to Achieve a 5-Log Reduction (page 59), an establishment must provide additional documentation showing that the product meets the performance standard (if applicable) and that potentially hazardous pathogens have been controlled (see Attachment A1. Customized Processes and Alternative Lethality Support subsection: Supporting an Alternative Lethality Target (e.g., 5-Log) on page 57). The support should demonstrate the incoming load of Salmonella is lower than FSIS estimated based on its baseline studies, and therefore, a lower reduction from cooking would result in no viable Salmonella in the finished product. Key Question Question: When an establishment decides to use a FSIS time-temperature table (i.e., the 5-Log Meat Table, 6.5-Log Meat Table, or the 7.0-Log Poultry Time-Temperature Tables) from this guideline as its scientific support for its cooking\lethality step, can the establishment use the entire table as its critical limit in its HACCP plan? Answer: Yes, the establishment can use the entire table to comply with 9 CFR 417.2(c)(3). The establishment needs to make a sound determination and support its decision in selecting and monitoring the time-temperature parameter(s) it uses for its production (9 CFR 417.5(a)(2)). In addition, establishments must collect in-plant data for at least one product from each HACCP category demonstrating the implementation of the critical operational parameters of the scientific support (9 CFR 417.4(a)(1)). At a minimum, the establishment will need to demonstrate that it is able to consistently meet a specific time-temperature from the table identified during the initial validation period to support the cooking\lethality process is validated (9 CFR 417.4(a)(1)).", "35 Table 2. Time-Temperature Combinations for Meat Products to Achieve Lethality Temperatures stated are the minimum internal temperatures that must be met in all parts of the meat product for the total dwell time listed.5 An establishment must ensure both

time and temperature parameters are met to use this table to support its process achieves the Log reduction target. Relative humidity<sup>6</sup> and heating come-up-time (CUT)<sup>7</sup> are also critical operating parameters when using this table. (See pages 37 and 38 for poultry endpoint timetemperature tables). 5 The required Log reductions are achieved instantly (0 seconds) when the internal temperature of a cooked meat product reaches 158°F or above.<sup>6</sup> Time-Temperatures  $\geq 145^{\circ}\text{F}$  (in blue square) are eligible for FSIS Relative Humidity Options 1 and 2. All time-temperatures may apply FSIS Relative Humidity Options 3 and 4 (page 26). 7 FSIS recommends limiting the total time product temperature is between 50 and 130°F to 6 hours or less (see page 23).", "36 Additional Critical Operating Parameters for Poultry Products The following are additional critical operational parameters that should be considered when cooking poultry products using FSIS newer guidance in the poultry timetemperature tables. Note: The older poultry recommendations for Cooked Poultry Rolls on page 39 apply regardless of species or fat because these were not considered critical operating parameters at the time the recommendation was developed. FSIS is not aware of any outbreaks or food safety incidents as a result of applying these recommendations to products of varying species or fat level. Product Species Generally, FSIS accepts that research for an intervention's effectiveness on one species of poultry (i.e., chickens, turkeys, ducks, geese, ratites, and squabs) can be applied to another species of poultry without additional support (FSIS Directive 5000.6, Performance of the Hazard Analysis Verification Task). However, research by Juneja et al. (2001a) demonstrated that in cooking processes, *Salmonella* heat tolerance depends on the poultry species. Therefore, when FSIS developed its time-temperature tables for poultry it developed two unique poultry time-temperature tables: one for chicken (page 37), another for turkey (page 38). When making poultry products containing poultry species other than chicken or turkey, or products made with a mixture of poultry species, FSIS recommends selecting an endpoint temperature, then using the longest dwell time recommended for the product fat content and endpoint temperature in either the chicken or turkey table. Comparing the tables and using the longest recommended dwell time ensures the HACCP system is designed to address the worst-case scenario for *Salmonella* survival in the product. Products that are a mixture of poultry and meat must achieve a 7-Log reduction of *Salmonella* (see Key Question on page 19). Fat Content In the presence of fats, the heat tolerance of some microorganisms generally increases (Jay et al., 2000). This is sometimes referred to as fat protection and is presumed to increase heat tolerance by affecting cell moisture. Juneja et al., (2001b) showed that higher fat levels in beef result in increased heat resistance of *Salmonella*, which is in agreement with publications regarding other food borne pathogens (Line et al., 1991; Ahmed et al., 1995). The Poultry Time-Temperature Tables (pages 37 and 38) provide establishments with time-temperature combinations that can be used to cook chicken and turkey products with different fat levels.", "37 Table 3. Time-Temperature Combinations for Chicken Products to Achieve Lethality Times for given temperatures and fat levels that are needed to obtain a 7-Log reduction of *Salmonella* in chicken products.<sup>8</sup> As described on page 23, relative humidity<sup>9</sup> and heating come-up-time (CUT)<sup>10</sup> are critical operating parameters when using this table. 8 A 7-Log reduction of *Salmonella* is achieved instantly at internal temperatures in which the holding time is 0 seconds (0 sec.). 9 Time-Temperatures  $\geq 145^{\circ}\text{F}$  (in blue square) are eligible for FSIS Relative Humidity Options 1 and 2. All time-temperatures may apply FSIS Relative Humidity Options 3 and 4 (page

26). 10 FSIS recommends limiting the total time product temperature is between 50 and 130°F to 6 hours or less (see page 23).,"38 Table 4. Time-Temperature Combinations for Turkey Products to Achieve Lethality Times for given temperatures and fat levels that are needed to obtain a 7-Log reduction of Salmonella in turkey products.11 As described on page 23, relative humidity<sup>12</sup> and heating come-up-time (CUT)<sup>13</sup> are critical operating parameters when using this table. 11 A 7-Log reduction of Salmonella is achieved instantly at internal temperatures in which the holding time is 0 seconds (0 sec.). 12 Time-Temperatures <sup>14</sup> 145°F (in blue square) are eligible for FSIS Relative Humidity Options 1 and 2. All time-temperatures may apply FSIS Relative Humidity Options 3 and 4 (page 26). 13 FSIS recommends limiting the total time product temperature is between 50 and 130°F to 6 hours or less (see page 23).,"39 Cooked Poultry Rolls Options FSIS recommends establishments use the options in the Poultry Time-Temperature Tables (page 37 and 38) (which include dwell times at 160°F that vary based on fat content and species) because they have been validated with updated research to address species and fat content as critical operating parameters to ensure adequate Log reductions of Salmonella. However, FSIS is including the two older options below for cooking poultry rolls and other poultry products because they still may be used by some establishments. Applying the cooked poultry rolls options below may achieve the same Log reductions as the time-temperature combinations in the Poultry TimeTemperature Tables, particularly when applied to a lean product, because the product may be maintained at 160°F for the recommended dwell times (between 13.7 to 26.9 seconds depending on species and fat) during the time it takes to complete temperature monitoring. Regardless, FSIS recommends establishments monitor the dwell time in the Poultry Time-Temperature Tables as opposed to relying on the older guidance for cooked poultry rolls below to better assure safety. The options below can be applied to any poultry product (not just cooked poultry rolls) regardless of fat content or poultry species. However, if FSIS collects a RTE sample that is positive for Salmonella or if the establishment is implicated in a food safety investigation related to Salmonella (i.e., is associated with reports of illness or outbreak), FSIS will review and determine the adequacy of the establishment's required corrective actions (taken under 9 CFR 417.3), to address process deviations. The establishment will need to show FSIS that inadequate lethality was not the root cause of the process deviation if it wants to continue to follow the cooked poultry rolls options. To use a cooked poultry rolls option, the establishment must address all critical operating parameters for cooking identified in this guideline (other than species or fat), including relative humidity (page 26) and CUT (page 23). 1. Cooked poultry rolls and other cooked poultry products must reach an internal temperature of at least 160°F (instantaneous) during the cooking process. 2. Cured and smoked poultry rolls and other cured and smoked poultry must reach an internal temperature of at least 155°F (instantaneous) during the cooking process. Key Question Question: Can establishments that produce poultry products with higher than 12% fat use values for 12% fat in the Poultry Time-Temperature Tables? Answer: Yes. The time-temperature combinations listed in the tables for poultry products with 12% fat can be used for products with higher percentages of fat and for products with unknown fat content. These time-temperature combinations will achieve sufficient lethality as long as adequate humidity (FSIS Relative Humidity Options page 26) is applied during the process.","40 Resources for Customized and Alternative Support FSIS recognizes that not all meat and poultry products can be cooked using

the FSIS critical operating parameters (humidity, CUT and endpoint time-temperature) included in this guideline. To assist establishments in cooking their products, FSIS has identified additional resources which may provide scientific support for a specific process or part of a process. Attachment A1. Customized Processes and Alternative Lethality Support includes information on the following:

- \u2022 Alternative Lethality Target: Under certain circumstances and with additional support, establishments may be able to use an alternative lethality target (e.g. 5Log). See Attachment A1. Supporting an Alternative Lethality Target, page 57 of this guideline.
- \u2022 Journal Articles: Establishments could identify a published journal article which shows a specific process meets the performance standard and use this as scientific support. See Attachment A1. Common Topics and Journal Articles Used for Alternative Support page 60 of this guideline.
- \u2022 Customized Cooking Schedule: Establishments may design a customized cooking plan using validated microbial models. See Attachment A1. Predictive Microbial Modeling for Critical Operating Parameters, page 62 of this guideline.
- \u2022 Challenge Studies: Establishments could conduct challenge studies to determine if their proposed process would meet the performance standard. See Attachment A1. Designing Challenge Studies for Cooking, page 63 of this guideline.

In addition to information for developing customized critical operating parameters, this guideline contains additional resources, listed below, to address common questions and issues establishments may have regarding cooking of meat and poultry products.

- \u2022 Pasteurized Label: Establishments may be able to label their cooked meat or poultry product as \u201cPasteurized.\u201d See Attachment A3. When can Products be Labeled as Pasteurized?, page 81 of this guideline.
- \u2022 Common Sources of Salmonella: Salmonella contamination may occur on cooked products for a variety of reasons. For information on sources of Salmonella contamination and Best Practices to implement to address it, see Attachment A4. Sources of Salmonella Contamination in RTE Products and Best Practices to Address It page 82 of this guideline.
- \u2022 Ready-to-eat (RTE) Self-Assessment Tool: FSIS has included a self-assessment tool that establishments can use to identify areas in their process where they could improve Salmonella control. See Attachment A5. RTE Salmonella Self-Assessment Tool page 87 of this guideline.

"41 Scientific Gaps Identified by FSIS FSIS has identified several common cooking processes that can\u2019t achieve the critical operating parameters included in this guideline. FSIS encourages establishments to conduct challenge studies when other support is not available (page 63). However, the Agency realizes it may not be cost effective for establishments to conduct individual challenge studies for commonly produced meat and poultry products. To address these common processes, which lack readily available scientific support, FSIS has identified and communicated scientific gaps and is working to facilitate filling these gaps. FSIS posted research priorities on its website to communicate clear research needs with USDA Agricultural Research Service (ARS) and academic researchers. As additional data becomes available, FSIS will update the recommendations for these scientific gaps with the latest available scientific support. An establishment producing products using processes that fall under an identified scientific gap may use the critical operating parameters in this guideline as scientific support (see Table 5. Scientific Gaps where Critical Operating Parameters From Older Guidance May be Used page 43). Table 5 also describes specific vulnerabilities with using the gaps as scientific support and recommends steps to reduce the vulnerabilities. In addition to those specific vulnerabilities, FSIS has the following concerns with establishments continuing to

process products using the critical operating parameters in Table 5: \u2022 Use of these critical operating parameters represents a vulnerability because these processes have not been validated to address all hazards of concern. The original research used to develop these critical operating parameters was performed on only the few products covered by the performance standard to be included in the 1999 version of Appendix A [64 FR 732]. \u2022 If a process deviation occurs for a process that is included as a scientific gap, it is unlikely an establishment would be able to identify adequate support for product safety without performing product testing. \u2022 If FSIS or the establishment collects a ready-to-eat (RTE) sample that is positive for Salmonella, or the establishment is implicated in a food safety investigation related to Salmonella (i.e., is associated with reports of illness or outbreak), FSIS would verify, as part of the corrective actions (9 CFR 417.3), that the establishment can support inadequate lethality was not the root cause, if it wants to continue to use the older recommendation. \u2022 As additional data becomes available, FSIS will change the recommendations for processes that fall under one of these scientific gaps.","42 NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps.

Additionally, Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical operating parameters listed in Table 5. FSIS will update this guideline as more research becomes available and new options can be developed. Scientific gaps are processes which have not been validated to achieve sufficient lethality and to address all potential hazards during cooking, but establishments may continue to use this guidance as support to allow additional time for research to be conducted and gaps filled.","NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5).

43 Table 5. Scientific Gaps where Critical Operating Parameters From Older Guidance May be Used Gap Examples of Products 1999 Critical Operating Parameters Vulnerability with Continuing to Follow 1999 Parameters 1. Products cooked for short times at high temperatures that cannot maintain 90% humidity per Option 4 and do not meet the Situations when Humidity is Not Needed (page 31). Processes that meet this gap include those in which product is: \u2022 Cooked for less than 1 hour, at dry bulb oven temperatures above 212\u00b0F. NOTE: Above 212\u00b0F the maximum relative humidity decreases as the temperature increases making it impossible to achieve 90% relative humidity in the oven regardless of the amount of moisture present. Cooking meatballs or poultry tenders using impingement, spiral, and steam-injected inline ovens. NOTE: Jerky products are not included under this gap. There are many validated lethality processes available for jerky products. Apply FSIS timetemperature tables (pages 35, 37, 38), addressing all critical operating parameters (page 23) except relative humidity. NOTE: Relative humidity does not need to be addressed for products cooked in completely immersed in water (page 31). These parameters may allow the surface of the product to dry out during cooking. Lack of humidity can cause pathogens to develop heat tolerance and allow them to survive the heating process. In addition, shorter cooking processes allow for limited additional lethality during the heating comeup time (sometimes called cumulative or integrated lethality) which reduces the safety margin the process provides. To minimize these vulnerabilities, an establishment may choose to implement, validate, and monitor as part of the HACCP system, any of the following to ensure moist cooking and demonstrate surface lethality:

- o Wet-bulb

temperature. o Dew point temperature. o Percent moisture by volume. o Increase dwell time or endpoint temperature. o Increase total cooking time to increase integrated lethality. Or perform a challenge study (page 63). Or conduct finished product testing for Salmonella as part of on-going verification.", "NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5). 44 Gap Examples of Products 1999 Critical Operating Parameters Vulnerability with Continuing to Follow 1999 Parameters 2. Products cooked using microwave cooking methods that are not designed to control relative humidity. Processes that meet this gap include those in which a meat or poultry product is cooked using a continuous or non-continuous microwave oven. Sliced bacon or bacon chips cooked using continuous microwave ovens. Apply FSIS timetemperature tables (pages 35, 37, 38), addressing all critical operating parameters (page 23) except relative humidity. These parameters may not ensure surface lethality. In addition, shorter cooking processes allow for limited additional lethality during the heating come-up time (sometimes called cumulative or integrated lethality) which reduces the safety margin the process provides. To minimize these vulnerabilities, an establishment may choose to implement, validate, and monitor, any of the following to ensure moist cooking and demonstrate surface lethality: o Increase dwell time or endpoint temperature. o Increase total cooking time to increase integrated lethality. Or perform a challenge study (page 63). Or conduct finished product testing for Salmonella as part of on-going verification. NOTE: There is an additional vulnerability with microwave cooking that the microwave energy may not result in lethality of pathogens on continuous belt surfaces (Taormina et al., 2011).", "NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5). 45 Gap Examples of Products 1999 Critical Operating Parameters Vulnerability with Continuing to Follow 1999 Parameters 3. Products cooked using cooking methods that are not designed to control relative humidity other than microwave ovens. Processes that meet this gap include those where product is either: \u2022 Cooked in ovens that are not designed to be sealed (e.g., no dampers) and designed without a mechanism to introduce steam. Or \u2022 Barbecue products cooked under dry heat to meet labeling requirements (e.g., 9 CFR 319.80; and 9 CFR 381.164). NOTE: This does not include smokehouses where the gaskets or dampers are broken or have been removed. Rotisserie chicken Products such as pork butt or beef brisket cooked using restaurant or foodservice type convection ovens. Barbecue products cooked under dry heat including those cooked in smokehouses or open pits. NOTE: Jerky products are not included in this gap. There are many validated lethality processes available for jerky products. Apply FSIS timetemperature tables (pages 35, 37, 38), addressing all critical operating parameters (page 23) except relative humidity. NOTE: Relative humidity does not need to be addressed for products 10 pounds or more cooked in an oven at 250\u00b0F or higher (page 31). These parameters may allow the surface of the product to dry out during cooking. Lack of humidity can cause pathogens to develop heat tolerance and allow them to survive the heating process. To minimize this vulnerability, an establishment may choose to implement, validate, and monitor, any of the following to ensure moist cooking and demonstrate surface lethality: o Wet-bulb temperature.

o Dew point temperature. o Percent moisture by volume. Depending on the process, pans of water may be added to increase moisture in the cooking chamber. Or perform a challenge study (page 63). Or conduct finished product testing for Salmonella as part of on-going verification." , "NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5). 46 Gap Examples of Products 1999 Critical Operating Parameters Vulnerability with Continuing to Follow 1999 Parameters 4. Other processes that may inherently maintain relative humidity around the meat and poultry filling but cannot follow one of the relative humidity options. Processes that meet this gap include those that involve: \u2022 Use of an edible wrapping that fully encloses a raw meat or poultry filling before cooking. Example wrappings include: o dough, o leaves, and o edible rice paper. NOTE: Products cooked in a natural casing are not included in this gap, since FSIS includes natural casing in Situations when Humidity is Not Needed (page 31). Baked pasties, empanadas, pot-stickers, and dumplings. Apply FSIS timetemperature tables (pages 35, 37, 38), addressing all critical operating parameters (page 23) except relative humidity. These parameters may allow the surface of the filling or wrapping to dry during cooking. Lack of humidity can cause pathogens to develop heat tolerance and allow them to survive cooking. To minimize this vulnerability, an establishment may choose to implement, validate, and monitor as part of the HACCP system, any of the following to ensure sufficient lethality on the outside and inside of the wrapped products: o Cook filling first. o Measure water activity of filling before and after cooking to support moisture is inherently maintained (water activity stays the same or increases after cooking). FSIS recommends establishments achieve the highest water activity possible during cooking. Values \u2265 0.96 have been shown to prevent pathogen heat tolerance, but this water activity may not be possible to achieve for all processes (Kieboom, et al. 2006). o Cook to a higher endpoint temperature than the FSIS time-temperature tables, to compensate for the low humidity conditions. Or perform a challenge study (page 63). Or conduct finished product testing for Salmonella as part of on-going verification." , "NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5). 47 Gap Examples of Products 1999 Critical Operating Parameters Vulnerability with Continuing to Follow 1999 Parameters 5. Processes where the drying step comes before cooking under moist conditions. Processes that meet this gap include those in which products are: \u2022 Dried to reduce the water activity and then cooked using one of the following options that ensures high relative humidity o Option 1, or o Option 3, or o Option 4, or o Cook-in-bag, or o Immersion cooking. NOTE: This gap does NOT apply products cooked after drying without applying relative humidity (e.g., cooking under dry conditions or direct heat), or to dried products cooked multiple times. It is not supportable for dried products to apply direct heat instead of addressing relative humidity, without additional support for surface lethality (page 31). Country-cured hams that are cooked-in-bag one time. Soups that have a reduced water activity due to a high salt concentration but are a liquid medium. NOTE: Jerky products are not included in this gap. There are many validated lethality processes available for jerky products. Apply: FSIS timetemperature tables (pages 35, 37, 38), addressing all critical operating parameters (page

23) and use relative humidity: o Option 1, or o Option 3, or o Option 4, or o Cook-in-bag, or o Immersion cooking. NOTE: FSIS does not consider a sealed oven (Option 2) to be adequate support that the surface of the product is rehydrated during cooking of reduced water activity products. There is a vulnerability if pathogens develop heat tolerance during drying which could allow them to survive the cooking process. To minimize this vulnerability, an establishment may choose to implement, validate, and monitor as part of the HACCP system, any of the following to ensure sufficient moisture during cooking: o Take water activity measurements of the surface of the product before and after cooking to support the surface is rehydrated (water activity increases after cooking). o Achieve the highest water activity possible during cooking. Values  $\leq 0.96$  have been shown to prevent pathogen heat tolerance, but this water activity may not be possible to achieve for all processes (Kieboom, et al. 2006). Or perform a challenge study (page 63). Or conduct finished product testing for Salmonella and Lm as part of on-going verification. Additional recommendations are included in Attachment A6. Cooking Country-Cured Hams on page 90." , "NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5). 48 Gap Examples of Products 1999 Critical Operating Parameters Vulnerability with Continuing to Follow 1999 Parameters 6. Products with long heating come-up-times (CUTs). This gap applies to processes that require a: \u2022 Heating come-up-time longer than 6 hours (page 23). NOTE: See page 62 for references supporting longer CUTs for fully cooked products formulated with antimicrobials to inhibit S. aureus that are cooked to lethality. Ham and beef brisket. NOTE: Drycured or immersion cured products produced under this Cooking Guideline Scientific Gap may also be produced under a Stabilization Guideline Scientific Gap if formulated without erythorbate or ascorbate. Apply any of FSIS\u2019s applicable timetemperature combinations (pages 35, 37, 38) and relative humidity, without considering CUT as a critical operating parameter. NOTE: For intact products, establishment may be able to monitor the surface temperature to allow for longer CUTs, instead of addressing this gap (page 24). A vulnerability exists in that S. aureus may grow to levels that result in the production of a heatstable enterotoxin if CUTs are longer than 6 hours without the use of antimicrobials. To minimize this vulnerability, an establishment may choose to implement, validate, and monitor as part of the HACCP system, any of the following to ensure S. aureus outgrowth is limited: o Critical parameters from a published journal article that supports extending the come-up-time in products and processes. (page 62). o Reduce product diameter to reduce CUT. o Conduct predictive pathogen modeling for a particular product and process (page 55). o Limit CUT between 50  $\leq 130\text{ }\mu\text{F}$  and set a defined limit based on the shortest CUT possible for the establishment\u2019s specific process. o Apply smoke, which may inhibit S. aureus and C. perfringens growth. Or perform a challenge study (page 63). Or conduct finished product verification testing for S. aureus enterotoxins (page 77); or", "49 References Ahmed, M.N., Conner, D.E. and Huffman, D.L. 1995. Heat resistance of Escherichia coli O157:H7 in meat and poultry as affected by product composition. Journal of Food Science 60:606-610. Ajene, A.N., Walker, C.L.F., Black, R.E. 2013. Enteric pathogens and reactive arthritis: a systematic review of Campylobacter, Salmonella and Shigella-associated reactive arthritis. Journal of Health, Population, and Nutrition. 31(3):299-307. AMIF (American Meat Institute Foundation). 1997. Good Manufacturing Processes for Fermented Dry &

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"55 Attachment A1. Customized Processes and Alternative Lethality Support Following FSIS Critical Operating Parameters for Cooking (Time-Temperature Tables) (page 23) will yield product that meets the lethality performance standards and targets. However, some establishments may want to develop customized processing procedures to achieve lethality. Establishments or their process authorities may develop customized processes or an alternative lethality that meets the performance standards or targets by using information obtained from the literature or by comparing their processes with established processes. However, all processes must achieve a supported Log reduction of pathogens and prevent the production of toxins or toxic metabolites (e.g., *Staphylococcus aureus*) to meet HACCP requirements and produce safe food (General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking, page 18). Regardless of the scientific support used, the establishment's actual process must match the critical operating parameters in the scientific support in order to achieve adequate lethality and meet validation requirements. In addition to the recommendations provided in the HACCP Systems Validation Guideline, FSIS recommends that establishments and processing authorities address the following questions when evaluating how journal articles and other sources of alternative support may apply to a cooking process:

1. Does the scientific support (e.g., book chapters,

journal articles) demonstrate that sufficient lethality of Salmonella (or a supported surrogate) is achieved in the product? o Negative results obtained from finished product sampling alone (without inoculation) are not sufficient to demonstrate that the product meets the performance standards or targets because they do not support any particular reduction in pathogens is achieved by the process. o Studies should evaluate the survival of a mixture (cocktail) of Salmonella, including strains associated with human illness and strains isolated from meat and poultry products. Ideally, some of the strains selected should be those with known heat-tolerance properties.

2. Does the scientific support identify all critical operating parameters used to achieve lethality (e.g., relative humidity)? o Many research studies designed to determine D-values of pathogens in different food matrices use enclosed systems that maintain moisture, such as sealed glass tubes, or impermeable bags immersed in hot water. These studies, as published in journal articles, may not specifically list controlling moisture during cooking as a critical operating parameter, but the methods used inherently maintain moisture in the system. To achieve", "56 the same result as the study, an establishment would need to consider how its process will apply moisture to ensure lethality on the product surface during cooking (see page 16).

Acceptability of Challenge Study Results

There are different ways to evaluate the results of challenge studies and scientific literature, such as journal articles. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), in its 2010 article \u201cParameters for Determining Inoculated Pack\u201d\Challenge Study Protocols\u201d recommends a statistical analysis be performed on results or, if not, a clear justification be provided. Below are three acceptable ways to determine if the results of the research are sufficient to support an establishment\u2019s lethality process:

1. The mean (average) is \u2265 performance standard or target log reduction.
2. Results for all replicates are \u2265 performance standard or target.
3. The lower 95% confidence limit for the results from the study is \u2265 performance standard or target.

o What this means is the reduction is calculated based on the mean log reduction minus 1.94 times the standard deviation. The recommendation to subtract 1.94 times the standard deviation from the mean log reduction is based on a study with an n of 6 (i.e., three replicates and two samples per replicate or two replicates and three samples per replicate). The approaches are listed in order of increasing confidence the results support an acceptable lethality process. The first approach (using the mean or average result) provides the least confidence the lethality process will consistently achieve the performance standard or target because it does not take into account variation found in the results. The third approach (using the lower 95% confidence limit) provides the greatest confidence but is also the most conservative because it takes into account a confidence interval based on variation found during the study.", "57 Supporting an Alternative Lethality Target (e.g., 5-Log) Establishments that use an alternative lethality (e.g., FSIS 5-Log Table) need to consider a number of factors that were identified in the Salmonella risk assessment, specifically: \u2022 Product categorization (shelf-stable or not shelf-stable). \u2022 Pathogen load in raw materials. \u2022 Storage and growth. \u2022 Consumer reheating. How is Alternative 5-Log Lethality Related to Risk of Foodborne Illness? Historically, FSIS has recommended that establishments achieve at least a 6.5-Log reduction of Salmonella in cooked meat products (other than beef patties which require a 5-Log reduction). The previous recommendations were due to the Risk Assessment of the Impact of Lethality Standards on Salmonellosis from RTE Meat and Poultry Products, 2005 (Salmonella Risk

Assessment), which showed that a 5Log reduction of Salmonella (instead of a 6.5-Log reduction) would result in a greater risk of illness in cooked meat products. The regulations for cooked beef, corned beef, and roast beef in 9 CFR 318.17(a)(1) allow for the use of alternative lethality, provided it provides equivalent probability that no viable Salmonella cells remain in the finished product, as well as ensures the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration. FSIS is providing guidance to establishments regarding how to validate the alternative lethality option of achieving at least a 5-Log reduction of Salmonella in cooked meat products other than beef patties to ensure the lower reduction does not result in a greater risk of illness. For shelf-stable products, that primarily rely on means other than cooking to achieve lethality, the Salmonella Risk Assessment did not show a substantially higher risk of illness for product with a 5Log reduction compared to a 6.5-Log reduction, so FSIS continues to recommend a 5-Log reduction of Salmonella for shelf-stable products. Therefore, establishments do not need to provide additional support for decisions in the hazard analysis (9 CFR 417.5(a)(1)) if they identify a 5-Log reduction of Salmonella as the lethality target for shelf-stable.", "58 An establishment can use the following bulleted options to support an alternative lethality target. The alternative lethality target may be from alternative supporting documentation (Attachment A1. Customized Processes and Alternative Lethality Support page 55) or with the time-temperature combinations in Table 6. TimeTemperature Combinations for Meat Products to Achieve a 5-Log Reduction (page 59). \u2022 Use source materials that have been tested or treated to reduce pathogens. The establishment can use a cooking process that achieves a 5-Log lethality of Salmonella if it uses source materials that have been tested or treated to reduce pathogens. The establishment should maintain support (e.g., Letters of Guarantee (LOG), Certificates of Analysis (COA), or sampling information) for each lot demonstrating that the levels of Salmonella are low enough to be controlled by a process achieving 5-Log reduction with an appropriate safety margin (e.g., 2-Log). For example, an establishment may provide a LOG indicating that a certain Log reduction (e.g., 1.5-Log or 2-Log) is achieved in the source materials using a validated antimicrobial intervention. \u2022 Conduct a Salmonella baseline study on the raw source material. The baseline study should be designed such that the establishment can demonstrate, with reasonable confidence, that less than 0.01% of the raw, formulated product contains concentrations > 10 CFU\gram of Salmonella before cooking. This is based on the premise that a 5-Log lethality step would reduce a Salmonella level of < 10 CFU\gram to < 1 CFU\ 100 grams and provide a 2-Log margin of safety (NACMCF, 2010). Challenges Supporting a 5-Log Alternative Lethality for Cooked Beef Products FSIS recognizes that extensive baseline sampling and testing needed to apply a 5-Log lethality may be cost prohibitive for small and very small establishments. However, this document provides multiple options for meeting the performance standards for certain RTE products. As noted in the question box above, establishments do not need additional testing or support to apply the 6.5-Log Meat Table, or the 7.0-Log Poultry Time-Temperature Tables in their process. Key Question Question: Do establishments that want to use the 6.5-Log Time-Temperature Tables need to perform raw product testing or provide other support? Answer: No. The times and temperatures listed in the tables for 6.5-Log or 7.0-Log reductions can be used without any additional support or testing. These time-temperature combinations will achieve sufficient lethality as long as adequate humidity (page 26) is applied during the process.", "59 Table 6. Time-Temperature

Combinations for Meat Products to Achieve a 5-Log Reduction Temperatures stated are the minimum internal temperatures that must be met in all parts of the product for the total dwell time listed<sup>14,15</sup>. An establishment must ensure both time and temperature parameters are met to use this table to support that its process achieves a 5-Log reduction of Salmonella. As described on page 23, relative humidity<sup>16</sup> and heating comeup-time (CUT)<sup>17</sup> are critical operating parameters when using this table. 14 A 5-Log reduction of Salmonella is achieved instantly (0 seconds) when the internal temperature of a cooked meat product reaches 158°F or above. 15 When using this table for not shelf-stable products other than meat patties, establishments must provide additional support to show why a 5-Log reduction is sufficient to ensure pathogens are eliminated (Supporting an Alternative Lethality Target (e.g., 5-Log) page 50). 16 Time-Temperatures 122-145°F (in blue square) are eligible for FSIS Relative Humidity Options 1 and 2. All time-temperatures may apply to FSIS Relative Humidity Options 3 and 4 (page 26). 17 FSIS recommends limiting the total time product temperature is between 50 and 130°F to 6 hours or less (see page 23).<sup>18</sup>

**60 Common Topics and Journal Articles Used for Alternative Support**

Many journal articles have been published that have increased scientific understanding of the critical role of certain operating parameters during cooking including relative humidity. FSIS recognizes that many of these journal articles, including that by Buege et al., (2006), support the use of less than 90% relative humidity (FSIS Relative Humidity Option 4; page 26). Establishments may use these journal articles as scientific support as long as establishments ensure the published critical operating parameters match the critical operating parameters being used in the establishment's process. FSIS agrees that wet-bulb temperature is a good indicator of surface lethality during cooking but does not believe there is enough information at this time to make a general recommendation that a single wet-bulb temperature can be used in place of the FSIS relative humidity options for all products. For more information see FSIS' wet-bulb video available at: <https://youtu.be/as-c2bCsoHQ>. Other commonly used alternatives to relative humidity include dew point temperature and percent moisture by volume. Alternative measures are particularly valuable in products cooked at high dry bulb temperatures. However, at this time, there is no consensus or scientifically supported recommendation for how to use those parameters or a targeted value to reach for each parameter. Consequently, FSIS has posted an FSIS research priority on its website and is aware that researchers are actively investigating this issue (Scientific Gaps Identified by FSIS page 41). Journal articles or reports establishments may consider using as scientific support, grouped by topic area, include:

- o 2022 Validated cook schedules for making beef jerky by controlling dry bulb and wet bulb temperatures.
- o Buege, D.R., Searls, G., Ingham, S.C. 2006. Lethality of commercial whole-muscle beef jerky manufacturing processes against *Salmonella* serovars and *Escherichia coli* O157: H7. *Journal of Food Protection*. 69(9):2091-2099.
- o Porto-Fett, A.C., Call, J.E., Luchansky, J.B. 2008. Validation of a commercial process for inactivation of *Escherichia coli* O157: H7, *Salmonella* Typhimurium, and *Listeria monocytogenes* on the surface of whole muscle beef jerky. *Journal of Food Protection*. 71(5):918-926.
- o Borowski, A. G., Ingham, S. C., Ingham, B. H. 2009. Lethality of home- style dehydrator processes against *Escherichia coli* O157: H7 and *Salmonella* serovars in the manufacture of ground-and-formed beef jerky and the potential for using a pathogen surrogate in process validation. *Journal of Food Protection*. 72(10): 2056-2064.
- o Dierschke, S., Ingham, S.C., Ingham, B.H. 2010. Destruction of *Escherichia coli* O157: H7,

Salmonella, Listeria monocytogenes, and Staphylococcus aureus achieved during manufacture of whole-muscle beef jerky in home-style dehydrators. *Journal of Food Protection*. 73(11):2034-2042." , "61 \u2022 Validated cook schedules for making turkey jerky by controlling dry bulb and wet bulb temperatures. o Porto-Fett, A.C.S., Call, J.E., Hwang, C.A., Juneja, V., Ingham, S., Ingham, B., Luchansky, J.B. 2009. Validation of commercial processes for inactivation of *Escherichia coli* O157: H7, *Salmonella Typhimurium*, and *Listeria monocytogenes* on the surface of whole-muscle turkey jerky. *Poultry Science*, 88(6):1275-1281. \u2022 Use of high temperature, short time cooking procedures and monitoring a wet bulb temperature target. The research provides scientific support for alternative processes including use of a wet-bulb temperature target. o Sindelar, J.J., Glass, K., Hanson, R. 2016. Investigating the development of thermal processing tools to improve the safety of Ready-To-Eat meat and poultry products. Foundation for Meat and Poultry Research and Education Final Report. <https://meatpoultryfoundation.org/research/investigating-developmentthermal-processing-tools-improve-safety-ready-eat-meat-and-poultry> Accessed 19 December 2018.

NOTE: Establishments may use this final report as scientific support until a peer-reviewed journal article is published. CUT Option FSIS\u2019s CUT option (page 23) was developed to support a wide variety of products. It is designed to use product characteristics that would allow the most *S. aureus* growth (worst-case scenario). Using worst-case conditions ensures that the option prevents *S. aureus* from being a hazard in all products. Establishments may be able to identify Why do some journal articles support using different critical operating parameters for cooking than those recommended by FSIS? FSIS guidance is designed to ensure lethality for a large number of meat and poultry products across broad product categories. Research on specific processes and product types may support adequate lethality can be achieved using different critical operating parameters for certain products (e.g., shorter dwell time or lower endpoint temperature), but research is not always available to support using those parameters across the many product categories and product types that this guidance covers. Establishments may choose to follow journal articles or other peer-reviewed scientific data instead of FSIS guidance, provided the same critical operating parameters are met (e.g., product type, dry-bulb temperature, wet-bulb temperature, internal product temperature, and intrinsic factors) and the process achieves sufficient reductions for *Salmonella* based on the establishment\u2019s desired target." , "62 journal articles with longer CUT for products with specific characteristics that inhibit pathogen growth (e.g., formulated with antimicrobials like sodium lactate). Example: \u2022 This following journal article provides critical limits for the brine injection and the thermal process that control *S. aureus* growth and enterotoxin production during a 14-hour CUT. o Ingham, S.C., Losinski, J.A., Dropp, B.K., Vivio, L.L., Buege, D.R. 2004. Evaluation of *Staphylococcus aureus* growth potential in ham during a slow-cooking process: use of predictions derived from the US Department of Agriculture Pathogen Modeling Program 6.1 predictive model and an inoculation study. *Journal of food protection*, 67(7):1512-1516. [https://meathaccp.wisc.edu/validation/heat\\_treatment.html](https://meathaccp.wisc.edu/validation/heat_treatment.html). \u2022 This following journal article provides critical operating parameters for hams formulated with phosphate and cooked to lethality while applying a long CUT. o Sindelar, J., Glass, K., Hanson, R., Sebranek, J.G., Cordray, J., Dickson, J.S. 2019. Validation for lethality processes for products with slow CUT: Bacon and bone-in-ham. *Food Control*. 104:147-151. NOTE: Although Sindelar et al. (2019) contains information on the growth of pathogens during the heating CUT for partially

heat-treated bacon, the article is not adequate sole support for controlling the growth of *C. perfringens* and *C. botulinum*. Please review the FSIS Stabilization Guideline for Meat and Poultry Products for additional details. Predictive Microbial Modeling to Support CUT Alternatively, establishments may use predictive microbiology modeling to develop custom critical operating parameters. Predictive food microbiology uses models (i.e., mathematical equations) to describe the growth, survival, or inactivation of microbes in food systems from knowledge of the intrinsic and extrinsic factors of the food over time. There are many free predictive microbial models available to establishments either online or through a download. Please refer to Predictive Microbial Modeling (page 72) for FSIS recommendations on using predictive microbial models to evaluate *S. aureus* growth during heating CUT deviations. These same recommendations can be applied when validating a custom CUT for a HACCP system.<sup>63</sup> Designing Challenge Studies for Cooking One of the most definitive tools at the disposal of an establishment or processing authority for validating a process is the challenge study. As stated in the HACCP Systems Validation Guideline, establishments may perform challenge (or inoculated pack) studies to provide scientific support for their processes. These studies are performed in a laboratory or pilot plant by a processing authority or expert. The documentation on file should specify the level of pathogen reduction, elimination, or growth control; describe the process, including all critical operating parameters affecting the reduction or elimination of the pathogen of concern; and give the source of the documentation. Such studies are often not published in peer-reviewed journal articles but should contain the same level of detail as is provided for peer-reviewed studies. Challenge studies should be designed and conducted to accurately simulate the commercial process. Challenge studies should be undertaken by individuals who have a thorough knowledge of laboratory methods used in *Salmonella* research. Challenge studies should be based on a sound statistical design (i.e., a statistical design that ensures confidence in the data) and should also employ positive and negative controls. The statistical design should include the number of samples collected at each time interval and the number of study replicates needed to ensure the validity of the study. There are quantitative methods for assessing the statistical quality of a study (e.g., power analysis). As per the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), the minimum number of samples to be analyzed initially and at each time interval during processing or storage should be at least two. However, NACMCF highly recommends analysis of three or more samples at each time interval. According to NACMCF, challenge studies should include replicates. Replicates should be independent trials using different lots of product and inoculum to account for variations in product, process, inoculum, and other factors. When the number of samples analyzed at each time interval is only two, NACMCF suggests it is better for the study to be repeated (replicated) more than two times. In studies with three or more samples tested at each time interval, two replicates are usually adequate. A cocktail of various serotypes of *Salmonella* should be used in an inoculated pack study to demonstrate that the lethality performance standard or target is met. At least five strains of the pathogen should be used in the inoculum. Relatively heat tolerant pathogenic strains should be included in the cocktail to develop a worst case. The serotypes\strains selected should be among those that have been historically implicated in an appreciable number of outbreaks. FSIS does not require establishments to validate that their process achieves a specific reduction of STEC or Lm in cooked product if they achieve sufficient reductions of *Salmonella* because FSIS considers

Salmonella an indicator of lethality for cooked products. Without further scientific support, establishments should not use pathogens other than Salmonella as indicators of lethality. For example, establishments should not", "64 use reductions in L<sub>m</sub> to support similar reductions in Salmonella without support that L<sub>m</sub> is at least equally as heat tolerant as Salmonella under the conditions being studied. If an establishment chooses to conduct a challenge study in a testing laboratory, the study should use at least five strains of Salmonella, including strains associated with human illness and strains isolated from meat and poultry products. Ideally, some of the Salmonella strains selected should be those with known heat-tolerance properties. FSIS recommends that establishments and their laboratories include a justification for the strains chosen (e.g., associated with human illness or isolated from meat or poultry products) in the challenge study report. In addition, the inoculum level should be at least 2-Log greater than the Log reduction to be demonstrated. FSIS recommends that establishments use Salmonella as an indicator of lethality (Goodfellow and Brown, 1978; Line et al., 1991) or an appropriate surrogate of Salmonella that has similar heat and drying-tolerance properties. For example, Enterococcus faecium has been validated as a suitable surrogate for Salmonella during cooking of ground beef (Ma et al., 2007). FSIS considers all Salmonella serotypes to be pathogens of public health concern. At a minimum, a study for a microbiological food safety hazard should identify: \u2022 The hazard (including the specific strains studied). \u2022 The expected level of hazard reduction or prevention to be achieved. \u2022 The processing steps that will achieve the specified reduction. \u2022 All critical operating parameters or conditions (e.g., time, temperature, and humidity) necessary to achieve the reduction. \u2022 Procedures to monitor the critical operating parameters or conditions. \u2022 The critical ingredients (e.g., concentration of salt, sugar, and cure). \u2022 The critical product characteristics (e.g., pH, water activity, moisture level, and fat content). NOTE: For more information on conducting challenge studies, please review the article, \u201cParameters for Determining Inoculated Pack\u201d/Challenge Study Protocols,\u201d Key Question Question: Should a Challenge Study use S. Senftenberg 775W? Answer: Not necessarily. FSIS would not require that. The FSIS Jerky Guideline states, \u201cOne good [strain] choice, for example, might be Salmonella enterica serovar Senftenberg strain 775W, which displays heat resistance properties (Ng et al., 1969). Salmonella enterica serovar Senftenberg occurs in the top 10 serotypes seen in FSIS testing for both cow\u201d/bull carcass testing and ground beef, as well as in turkeys (carcass and ground) (FSIS testing data, 2012), so it would also be an appropriate choice for what might be seen in these products being tested.\u201d However, additional studies have determined that Salmonella Senftenberg has much higher heat tolerance than other pathogens (McMinn, et al., 2018; Veeramuthu, et al., 1998). In addition, more recent data does not continue to identify it in the top 10 serotypes seen in FSIS testing." "65 published by the NACMCF in the Journal of Food Protection in 2010. For more information on the use of positive and negative controls in challenge studies as well as general guidance on how to select a microbiological testing laboratory please review FSIS\u201dEstablishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory.", "66 Attachment A2. Cooking Deviations Corrective Actions to Perform When a Cooking Deviation Occurs Cooking deviations occur when an establishment fails to meet its cooking CCP critical limit for endpoint time-temperature, cooking humidity option, or heating come-up time option. Common causes for cooking deviations include product overlap, power failures, or breakdown of cooking equipment.

Establishments are required to take corrective actions, as required by the HACCP regulations, regardless of whether the cooking process is addressed through a CCP or prerequisite program. This includes ensuring no product that is injurious to health or otherwise adulterated because of the deviation enters commerce (9 CFR 417.3(a) or (b)). When cooking is addressed through a CCP, establishments are required to determine the cause of all cooking deviations, no matter how small (9 CFR 417.3(a)(1)), and ensure measures are established to prevent recurrence (9 CFR 417.3(a)(3)). If the cause of each small cooking deviation is not traced and corrected when first noticed, the problem will likely recur and become more frequent and more severe. The establishment should consider an occasional small process deviation to be an opportunity to find and correct a process control problem. Large process deviations or continual small ones always constitute unacceptable risk. Also, continual or repetitive process deviations from the critical limit demonstrate that the establishment is unable to control its process and that its corrective actions are not preventing recurrence as intended. When cooking is addressed through a prerequisite program and a deviation occurs, establishments are required to reassess their HACCP system to determine whether the newly identified deviation or unforeseen hazard should be addressed and incorporated into the HACCP plan (9 CFR 417.3(b)(4)). Also, an establishment may not be able to continue to support the decision in its hazard analysis that pathogens are not reasonably likely to occur, if it has continual or repetitive deviations from its cooking prerequisite program (9 CFR 417.5(a)(1)). To assist establishments in determining and supporting product disposition as required 9 CFR 417.3(a) or (b), FSIS is including information regarding potential pathogens of concern during different types of cooking deviations and recommendations for using pathogen modeling and sampling. Establishments should carefully evaluate each deviation as each situation is unique and needs to be evaluated individually. Ultimately, the establishment should rely on the expertise of a processing authority to determine the severity of cooking deviations and subsequent appropriate disposition of the product in question. Knowledge of the specific product and factors that would favor or inhibit the growth of various bacterial pathogens is essential to determine product safety. As stated in the HACCP Systems Validation Guideline, the advice of processing authorities should include reference to established scientific principles as well as reference to peerreviewed scientific data.", "67 Pathogens of Concern During Cooking Deviations Cooking deviations can allow pathogens that are controlled under normal cooking procedures to become a hazard, depending on the type of cooking deviation (described below) that occurs. Specific pathogens of concern may include: *Salmonella*, *STEC* (in beef products), and *Lm*, which could grow as vegetative cells to levels that overwhelm the Log reductions achieved by cooking. *S. aureus*, if allowed to grow to high levels, may produce heat-stable enterotoxins in the food. *Bacillus cereus* (*B. cereus*) (in rare cases), if allowed to grow to high levels in the food, may produce a heat-stable emetic toxin in the food or enterotoxins in the small intestine. *Clostridium perfringens* (*C. perfringens*) and *Clostridium botulinum* (*C. botulinum*) spore-forming pathogens that can germinate and grow in product held at higher temperatures (e.g., > 80°F). Again, it is important someone knowledgeable such as a processing authority evaluates each deviation to determine the pathogens of concern. Three Common Types of Cooking Deviations When cooking products to lethality, deviations may occur due to three main reasons: 1. The establishment fails to meet a time-temperature parameter in its lethality CCP for meat or poultry products. 2. The

establishment fails to maintain sufficient humidity during the cooking step. 3. Slow heating CUT allows product to remain at temperatures that allow pathogen growth (e.g., product remains at temperatures 50°F to 130°F for more than 6 hours; see FSIS Critical Operating Parameters for Cooking Come-Up-Time (CUT), page 23). Specific recommendations for evaluating each type of cooking deviation, including the pathogens of concern, are provided below. Alternatively, the establishment can provide additional support for the safety of the product (e.g., a journal article, or support from a processing authority). These are general recommendations; the specific responses will vary based on the unique factors of each deviation.

Type 1. Missed Endpoint Time-Temperature When evaluating product disposition after the process fails to meet an endpoint time or temperature parameter, the first step is to assess whether the process met a different time-temperature combination in the reference table. In some cases, the process may not have achieved an instantaneous lethality temperature (e.g., 158°F for meat) identified in the CCP but may have achieved the dwell time needed for a lower", "68 temperature in the same table (e.g., 154°F for 27 seconds) when considering the total time product temperature was at or above the lower temperature. Did the process meet a different validated time-temperature combination? \u2022 If yes, then product is safe to release. \u2022 If no, then FSIS recommends contacting a processing authority who may help you identify proper D and z values to calculate integrated process lethality considering the product come-up -time and come-down-time. One common tool for calculating integrated lethality is the AMI Process Lethality Determination Spreadsheet. If properly conducted, the AMI lethality spreadsheet is a sound scientific approach for determining the overall lethality of a cooking process (Scott and Wedding, 1998). The D-values at the reference temperature for the three main pathogens of concern (*Salmonella* spp. *E. coli* O157:H7, and *Lm*) are generally conservative values and should be valid for most cooked meat ready-to-eat (RTE) processes provided that the product is moist when cooked (high relative humidity). However, if the product is not moist when cooked and the product surface is allowed to dry out during the lethality step, the D-values referenced in the AMI lethality spreadsheet are not valid. NOTE: There are many complexities involved in identifying appropriate D and z values needed as inputs for calculating integrated pathogen lethality. FSIS advises establishments to work with a processing authority or someone knowledgeable in thermal death-time values, to ensure they select appropriate values and are properly using the lethality calculator. \u2022 Establishments may consider re-cooking the product, but only if all critical operating parameters (including relative humidity and CUT time) were met during the initial heating and during re-cook. o If the relative humidity option in the scientific support was not applied, the establishment should also follow recommendations for evaluating a Type 2 Deviation: Insufficient Humidity During Cooking described on page 69, or o If the CUT parameter was not met, the establishment should also follow recommendations for evaluating a Type 3 Deviation: Long Heating CUT described on page 70, and contact a processing authority for assistance. NOTE: Cooking deviations that combine a missed time-temperature parameter with a long CUT are complex situations which may require considering *C. perfringens* and *C. botulinum* as described in the Stabilization Guideline, in addition to the other pathogens of concern.", "69 \u2022 If establishments cannot re-cook the product, they should consider the following alternative actions: o Provide alternative support (page 55) (e.g., information from a processing authority that includes scientific citations that product is safe to release); o Sample

and test the product (see Product Testing recommendations for Type 1 deviations, page 77); or

- o Destroy the product (renderer or landfill).

Type 2. Insufficient Humidity During Cooking As described on page 16, some bacteria can become more heat tolerant when they are exposed to moderate levels of heat, drying, and other factors. Bacteria can then survive at higher temperatures than they normally would. Below are general recommendations for an establishment to consider when evaluating products after a Type 2 cooking deviation resulting from insufficient humidity (i.e., the relative humidity option in the scientific support was not followed) during cooking.

- \u2022 Consider sampling and testing product for *Salmonella*, Lm, and *E. coli* O157:H7 (if a beef product), using a statistically based sampling program as described in Product Testing on page 77.
- \u2022 If recocking, apply a higher time-temperature combination validated to achieve lethality in a product with similar intrinsic factors (e.g., water activity).
- o It would not be appropriate to recock the product following FSIS Relative Humidity Options (page 26) without additional support that recocking conditions adequately rehydrate the product surface (see Attachment A6. Cooking Country-Cured Hams, page 90).
- o Under these circumstances, FSIS would need to verify that such scientific support is adequate in the context of the specific product, process, and situation. Examples of acceptable support may include support that:

- \u2022 Demonstrates that a validated wet bulb temperature target has been met to ensure lethality. To show that the surface has been rehydrated, the wet bulb target should be higher than the product surface temperature.
- \u2022 Includes water activity testing: A water activity increase after recocking (compared to water activity before recocking), may indicate that the surface has been rehydrated.

"70 NOTE: FSIS is not aware of any research validating recocking procedures for products that may have heat tolerant *Salmonella* because of a lack of relative humidity during the initial cook. However, FSIS plans to update these recommendations as more research becomes available.

Type 3. Long Heating CUT If the total time between 50 and 130\u00b0F is longer than hours 6, recocking alone may not be sufficient to ensure the safety of the product. That is because during the extended CUT toxigenic pathogens could grow rapidly (e.g., *S. aureus*), allowing enterotoxins to form. Some enterotoxins are extremely heat-stable and are not inactivated by normal cooking temperatures. Therefore, it is not always possible to recock the product alone to ensure its safety. The establishment should continue to recock the product to address vegetative pathogens (e.g., STEC, Lm, and *Salmonella*). It should also provide additional support that heat-stable enterotoxins do not present a hazard in the product after the recocking step. As noted in Type 1. Missed Endpoint Time-Temperature, cooking deviations that combine a missed time-temperature parameter with a long CUT are complex situations that may require considering *C. perfringens* and *C. botulinum* as described in the Stabilization Guideline, in addition to the other pathogens of concern. The establishment may want to contact a processing authority for assistance. To determine product disposition after a long heating CUT deviation, the establishment should:

1. Address growth of vegetative pathogens that do not produce toxins, AND
2. Address the potential enterotoxin formation as described below. If either hazard is not controlled to safe levels, then product should be destroyed. Further guidance on these two recommendations is provided below:

- 1. Address growth of vegetative pathogens: (e.g., STEC, Lm, and *Salmonella*).
- o FSIS recommends that establishments use microbial modeling (page 72) and other information (e.g., scientific journal articles, book chapters, and processing authorities) to estimate growth of *E. coli*, Lm, and *Salmonella*.

\u2022 If modeling estimates the growth of vegetative pathogens to be 1Log or less,

provided the predictive microbial modeling program is validated, modeling is adequate to show that the process prevented vegetative pathogen outgrowth and the establishment can address the potential for enterotoxin formation (see 2 on the next page). \uf0a7 If modeling estimates more than 1-Log growth of any vegetative pathogen, establishments should recook product OR sample and","71 test for vegetative pathogens to determine the safety of the product (see Type 3 deviation recommendations in Product Testing, page 77). \u2022 Many establishments avoid the cost of sampling and testing by recooking the product or consulting a processing authority to identify alternative support that vegetative pathogens are addressed. \u2022 If product is recooked, it should be done to a higher time and temperature that has been shown to achieve enough additional Log reductions to address the amount of vegetative cell growth the model predicted. Using a recock procedure that achieves the correct additional Log reduction is important to ensure increased pathogen load will not overwhelm the Log reductions achieved during the recock procedure (see page 72). For example, if predictive microbial modeling showed a 2.5-Log and 3.0-Log increase for Salmonella and E. coli O157:H7, respectively, in a roast beef product, the recock step should be adjusted so that the cooking time-temperature combination can achieve at least a 9.5-Log reduction of Salmonella instead of a 6.5-Log reduction. The AMI Process Lethality Determination Spreadsheet discussed on page 68 may be used to support the cooking time-temperature combination can achieve sufficient Log reductions.

2. Address potential enterotoxin formation: (e.g., S. aureus) by demonstrating that toxicogenic pathogens did not grow to levels of public health concern or produce enterotoxin. o FSIS recommends that establishments use microbial modeling (page 72) and other information (e.g., scientific journal articles, book chapters, and processing authorities) to provide additional information to determine product safety. \uf0a7 If predictive microbial modeling estimates a < 3-Log growth of S. aureus, modeling is adequate to show that the process prevented enterotoxin formation provided the predictive microbial modeling program is validated. If growth of vegetative pathogens is also addressed the product can be released. NOTE: Due to the rapid growth of S. aureus in meat and poultry products, modeling for B. cereus (which grows slower) is not needed when S. aureus growth is controlled (< 3-Log). \uf0a7 If microbial modeling estimates a \u2265 3-Log growth of S. aureus, then product should be tested for S. aureus enterotoxins A, B, C,","72 D, and E using a statistically representative sampling procedure. If the product contains non-meat ingredients previously associated with B. cereus associated illnesses (e.g., rice, or pasta) and microbial modeling estimates > 3-Log growth of S. aureus, then establishments may also want to consider testing for B. cereus emetic toxin (Product Testing page 77). NOTE: As stated previously, conditions that allow for 3-Log or higher growth of S. aureus are a public health concern (ICMSF, 1996). Furthermore, this level of growth (i.e., 3-Log) for S. aureus is consistent with the pass\fail criteria developed by the Institute of Food Technologists (IFT) for the FDA to control for this food safety hazard (IFT, 2003). Predictive Microbial Modeling Establishments may use predictive microbial modeling to estimate the relative growth of bacteria during a long heating CUT deviation (Type 3). As explained above for Type 3 heating deviations, modeling results can be used to support various product disposition options including release, recocking, sampling and testing, or destruction provided the model used has been validated. Predictive microbial modeling tools may be used to evaluate product disposition in the event of other types of deviations (e.g., for Type 1 deviations establishments may use the AMI Process Lethality Determination Spreadsheet).

However, this section is focused on evaluating product disposition during Type 3 heating deviations due to their complexity. When performing predictive microbial modeling, it is important that establishments:

1. Use validated models (see examples below):
  - o It is not appropriate to rely solely on one model unless the model has been validated for the particular food of interest. A validated cooking model is a model whose predictions have been found to agree with or are more conservative than actual observed results. If a model has not been validated for a particular food of interest, the establishment should provide additional supporting documentation to support the results from the model (e.g., sampling data or comparison with other model results).
  2. Enter accurate product formulation information: To support safe release of the product, both the vegetative pathogens and enterotoxin formation must be addressed with supporting documentation. If either hazard is not controlled to safe levels, then product should be destroyed."
  3. Enter accurate time and temperature information in the model:
    - o When entering time and temperatures into the model, the establishment should include all parts of the process, including cooking and recooking CUTs after a Type 1 or 3 cooking deviation. If the establishment does not include all parts of the process, it may underestimate pathogen growth.
    - o When determining the temperature, the establishment should take into account both the temperature at the coldest internal area (center) of the product and at the surface of the product.
    - o It is important to obtain an internal time and temperature profile of the product, and a wet bulb time and temperature profile of product since wet bulb can be used to describe the product\u2019s surface temperature. If an establishment does not have wet bulb temperature data, it can conduct predictive microbial modeling using the internal time-temperature profile of the product, provided that sufficient humidity was used during cooking. However, the establishment should take into account that the product surface temperature will be higher than the center of the product under high relative humidity conditions.
    - o For cases with large time gaps between known temperature observations, establishments may consider interpolating to estimate additional timetemperature data points between known observations assuming linear heating. However, if the product temperature dwells or holds between 90 and 120\u00b0F (the optimal growth range of *S. aureus*) for an extended period of time, excess *S. aureus* growth could result in a potential hazard in the product being uncontrolled. The establishment should consider the likely accuracy of the predicted growth when making a product disposition determination using linear interpolation.
    - o Assume no *S. aureus* growth above 120\u00b0F. NOTE: FSIS has included the time that product remains from 120 to 130\u00b0F in the heating CUT option (page 23) to reduce the risk *B. cereus* (a spore-former) could germinate and then grow at these higher temperatures, potentially producing a heat-stable emetic toxin."
4. Address model limitations in a conservative manner:
  - o If product characteristics or other conditions are outside the range of the model, accuracy is not guaranteed. Establishments should support how the model results represent the product or the worst-case scenario for the hazard in the product or should compare the results to several other pathogen models and should make decisions based off the model that shows the worst-case scenario (i.e., for *S. aureus* that is the model that

estimates the most outgrowth). NOTE: This guidance contains recommendations for addressing certain limitations in two recommended models at the time the guidance was written. Neither modeling program is controlled by USDA-FSIS and may change. FSIS will update its modeling recommendations in future revisions to be consistent with any changes made to the modeling programs. Recommended Models \u2022 Therm 2.0 model (*S. aureus*, *Salmonella*, and *E. coli* O157:H7). The University of Wisconsin Therm 2.0 model is designed to allow processors to input the product\u2019s time-temperature profile and it has been validated for estimating the growth of *S. aureus*, *Salmonella*, and *E. coli* O157:H7. The three input variables and their ranges for entering into the growth model are provided below (Ingham et al., 2009): o Input variables and ranges: \uf0a7 Temperature profile: 50\u00b0F to 110\u00b0F (10\u00baC to 43.33\u00baC) \uf0a7 Date\time: the model allows for entry of calendar date and time \uf0a7 Meats: \u2022 In meat and poultry products containing salt (\u2264 2.5%), establishments should use the Therm 2.0 model for Bratwurst for predicting pathogen growth. This model should be used because it was designed to take into account the bacterial pathogen\u2019s behavior in pork sausage and related products that contain higher fat levels, sodium chloride, and spices. For example, adding salt to product will inhibit the competing microorganisms, but allow for greater growth of salt tolerant *S. aureus*; the Therm 2.0 model will predict this. Because the Therm 2.0 model for Bratwurst was developed with data from a pork product, establishments should compare the results with another model, such as the DMRI Staphox Predictor when evaluating deviations involving poultry products.", "75 \u2022 In meat and poultry products without any added salt, establishments should use the Therm 2.0 model for Beef, Pork, or Poultry based on the product type (Ingham et al., 2009). o Overcoming model temperature limitations: (maximum 110\u00b0F) \uf0a7 The Therm 2.0 model does not automatically interpolate (estimate a linear change) between time-temperature data points entered by the user. Therefore, FSIS recommends establishments enter temperature observations for at least every 30 minutes, or at the lowest time interval available. \uf0a7 For temperatures >110\u00b0F, substitute 110\u00b0F for any temperature above 110\u00b0F up to 120\u00b0F. *S. aureus* grows fastest at 110\u00b0F. The growth rate slows as temperatures increase from 110 to 120\u00b0F. Modeling using 110\u00b0F for temperatures observed from 110 to 120\u00b0F will slightly overestimate the growth of *S. aureus*. \uf0a7 For temperatures between 120 and 130\u00b0F assume no growth of *S. aureus* (leave this out of the model). \u2022 DMRI Staphox Predictor (Version 1.0) (*S. aureus*) The Danish Meat Research Institute\u2019s (DMRI) Staphox predictor (Version 1.0) may also be used to predict the growth of *S. aureus* in meat and poultry products, with added salt (i.e., 1.8% to 4.2%). This model has been validated and was specifically designed to predict the growth of *S. aureus* in different meat product processes based on product composition and changes in temperature. The six input variables and their ranges for entering product composition information into the growth model are provided below (Gunvig et al., 2018): o Input variables and ranges: \uf0a7 Temperature profile: 32\u00b0F to 105.6\u00b0F (0\u00baC to 40.9\u00baC) \uf0a7 pH: 4.4 \u2013 6.1 \uf0a7 % sodium chloride (NaCl) in product (based on the total weight of the product formulation): 1.8 \u2013 4.2%. NOTE: The model converts % sodium chloride (NaCl) into the % water-phase salt. \uf0a7 % potassium chloride (KCl) in product (based on the total weight of the product formulation): 0.0 \u2013 4.2% \uf0a7 Sodium nitrite added to product: 0 \u2013 150 ppm \uf0a7 % water in final product (as determined through laboratory analysis):

62 \u2013 78%","76 o Worst Case Scenario: FSIS recommends using the values listed below as model inputs for any products where the values are unknown. These values represent a worst-case scenario for the growth of *S. aureus* based on product composition: \uf0a7 pH: 6.1 \uf0a7 % NaCl in product: 1.8% \uf0a7 % KCl in product: 0.0 \uf0a7 Sodium nitrite added to product: 0 ppm \uf0a7 % water in final product: 78% (highest allowed in model) \uf0a7 Initial level S. *aureus*: 100 CFU/g o Overcoming model temperature limitations: (maximum 105.6\00b0F) \uf0a7 For temperatures > 105.6\00b0F (40.9\00b0C), substitute 105.6\00b0F for any temperature above 105.6\00b0F (40.9\00b0C), up to 120\00b0F (48.9\00b0C). The fastest growth in this model is at 105.6\00b0F. As described above, *S. aureus* continues growing at higher temperatures, but the growth rate slows as temperature increases up to 120\00b0F (48.9\00b0C). For modeling, use 105.6\00b0F for temperatures observed from 105.8\00b0F (41\00b0C) up to 120\00b0F (48.9\00b0C), which will slightly overestimate the growth of *S. aureus* (fail-safe). \uf0a7 For temperatures between 120\00b0F (48.9\00b0C) and 130\00b0F (54.4\00b0C) assume no growth of *S. aureus* (leave out of the model). NOTE: Establishments may use the ComBase *S. aureus* model as support. However, this model has not been validated and establishments should follow the recommendation for using models that are not validated (i.e., compare the results of several models and make decisions using the worst-case results) as described above.","77 Product Testing As described in the cooking deviation and the microbial modeling recommendations (pages 67-72), if the establishment is unable to support the product disposition through predictive microbial modeling or some other means, the establishment can test a statistically-based number of samples of the product to support its safety. Table 7 identifies the hazards to be tested for according to the type of cooking deviation that took place. These are general recommendations; it is important that someone knowledgeable such as a processing authority evaluate each deviation to determine the appropriate sampling and testing plan. Table 7. FSIS Recommendations for Product Sampling and Testing After Each Type of Cooking Deviation to Determine Product Disposition

Type of Heating Deviation*	Vegetative Pathogens	Heat-stable Enterotoxins	Salmonella	Lm E. coli O157:H7	** <i>S. aureus</i> Enterotoxins A, B, C, D, and E
1 - Missed Time-Temperature	X X X	2 - Insufficient Humidity	X X X	3 - Long CUT	X Multiple Types in Combination (i.e., missed time-temperature AND long CUT)

Contact a processing authority for assistance evaluating product disposition in a complex deviation which combined multiple types of heating deviation. May need to consider *C. perfringens* and *C. botulinum* in addition to the hazards listed in this table.

\*Cooking deviation Types 1-3 are described on page 66. \*\*E. coli O157:H7 testing recommended only for products containing beef. Establishments may also choose to test for other STEC; however, testing for E. coli O157:H7 alone is sufficient. Sampling in Response to a Cooking Deviation \u2022 The establishment should test a statistically representative number of samples per lot depending on the bacterial pathogen. FSIS recommends testing at least 10-15 products per lot as outlined by the two-class sampling plan (Case 11 and Case 13, respectively) per the International Commission on Microbiological Specifications for Foods (ICMSF, 2002). \u2022 If the product contains non-meat ingredients previously associated with *B. cereus* associated illnesses (e.g., rice, or pasta) and microbial modeling estimates >3Log growth of *S. aureus*, then establishments may also want to consider testing for *B. cereus* emetic toxin.","78 NOTE: FSIS does not recommend all products to be tested for *B. cereus* emetic toxin due to the low incidence of *B. cereus* in raw meat and poultry. If you are uncertain if the

formulation of product affected by a cooking deviation may need to address *B. cereus* emetic toxin as a potential hazard, please contact askFSIS (page 9). Key Question Question: Can samples be composited for lab testing? Answer: It depends on what the sample is being tested for: \u2022 Enterotoxins? No. FSIS does not recommend compositing samples to be tested for enterotoxins. Combining multiple samples for a single test (i.e., compositing) could prevent the test from detecting enterotoxins in the product. \u2022 Vegetative pathogens? Yes. However, the number of samples that can be combined depends on the pathogen. Additionally, establishments should ensure the lab method has been validated for the larger test portion. o *Salmonella* and *E. coli* O157:H7: FSIS recommends compositing up to 3 samples (total 75g) for a total of 5 analyses although establishments may also be able to support compositing up to 15 \u2013 25-g samples (total 375 grams). The establishment would collect 15 samples from different pieces of product. The lab would combine the 25g sample from each of 3 different pieces, to make a 75g composited sample for analysis. The lab analyzes 5 composited samples. When compositing, establishments should ensure the method has been validated for the larger test portion. FSIS has validated a 325g test portion size for its analysis of RTE product samples collected under the RTEPROD program (see the FSIS\u2019 Microbiology Laboratory Guideline *Salmonella* Chapter). o Lm: FSIS recommends compositing up to 5 samples (total 125g) and 3 lab tests total. The establishment would collect 15 samples from different pieces of product. The lab would combine the 25g test sample from each of 5 different pieces, to make a 125g composited sample for analysis. The lab analyzes 3 composited samples. When compositing, establishments should ensure the method has been validated for the larger test portion. FSIS has validated a 25g and 125g test portion size for its analysis of RTE product samples collected under the RTEPROD and RLm programs, respectively (see the FSIS\u2019 Microbiology Laboratory Guideline *Listeria monocytogenes* Chapter).", "79 Disposition after Testing Results: To support the safe release of the product, every hazard associated with the type of heating deviation identified (see Table 7) must be controlled for the safe release of product. If any single hazard is not controlled, then product should be destroyed (renderer or landfill). \u2022 Enterotoxins: o If the product tests negative for enterotoxins, product can be released, unless insanitary (or other) conditions exist that could adulterate the product (e.g., vegetative pathogens). o If any enterotoxin is found, the lot is adulterated, and product should be destroyed (renderer or landfill).) \u2022 Vegetative Pathogens: o If the product tests negative for vegetative pathogens, product can be released, unless insanitary (or other) conditions exist that could adulterate the product (e.g., enterotoxins). NOTE: It would be inappropriate to test for live *S. aureus* instead of enterotoxin because it is possible for *S. aureus* to produce enterotoxins prior to the death of the bacteria (e.g., during cooking). The food product would still cause illness even though no vegetative bacteria were found. o If any vegetative pathogens are found, the lot is adulterated. Product may be: \uf0a7 Recooked per Type 1 or Type 2 recommendations (pages 67-69); or \uf0a7 Destroyed (rendered or denatured per 9 CFR 314.3(a), 9 CFR 325.11(a), 9 CFR 325.13(a)(1) through 325.13(a)(7), or 9 CFR 381.95 and sent to a landfill).", "80 Common Mistakes made by Establishments when Evaluating Heating Deviations\u2014and the Recommended Solutions 1) The establishment did not input an accurate internal time-temperature profile into the model. The establishment should be using a data logger or collecting time and temperature data at regular intervals during cooking. The establishment should take into account all parts of the process and temperatures at both the

center and surface of the product (Monitoring Endpoint Temperature page 21 and Monitoring Surface Temperature page 24). 2) In Type 1 or 3 deviations with a missed time-temperature parameter, the establishment failed to take into consideration the amount of bacterial growth that could occur during the cooking come-up-time when the cooking cycle was restarted. To address this issue, the establishment should consider both the original come-up-time, the initial cooling, and second come-up-time when the cooking is restarted as part of its modeling. 3) The establishment did not address whether additional growth of *Salmonella*, *E. coli* O157:H7 and Lm could have occurred during the Type 1 heating deviation and whether heat tolerance could have developed. To address this issue, when re-cooking the product, the establishment should increase endpoint temperature and apply sufficient humidity (FSIS Relative Humidity Options page 26). 4) The establishment failed to address the amount of growth of *S. aureus* and other bacterial pathogens that could occur on the product's surface. Measuring the temperature both at the product center and at the surface (wet bulb) temperature would address this issue. 5) The establishment failed to take into account the initial levels of *S. aureus* commonly found in raw meat and poultry. Levels of pathogens in raw product are approximately 2-Log. Increases of 3-Log or more could result in conditions where enterotoxin could be formed. Establishments should limit *S. aureus* growth to 2Log or less, to support safe release of product based on microbial modeling. See Biological Hazards of Concern During Cooking subsection: *Staphylococcus aureus* (page 14) for more information.", "81 Attachment A3. When can Products be Labeled as Pasteurized? FSIS defines pasteurization as any process, treatment, or combination thereof, that eliminates or reduces the number of pathogenic microorganisms to achieve at least a 5Log reduction of either *Salmonella* or Lm, on or in ready-to-eat (RTE) meat or poultry products in the final finished package. With adequate validation, pasteurization processes may include alternative technologies other than traditional cooking (e.g., high pressure processing (HPP)). FSIS considers products with a raw appearance that have been treated with a lethality process that renders the product RTE, and that are not post-lethality exposed (e.g., \u201csteak tartare\u201d subjected to a HPP treatment) as pasteurized. For the product to be labeled \u201cpasteurized,\u201d the treatment needs to: 1) Be applied in the final package (product is not post-lethality exposed); 2) Be sufficient to eliminate the number of pathogenic microorganisms to make the product safe for human consumption (so there are no detectable pathogens; RTE), and 3) Be effective for at least as long as the product shelf life. Establishments may label products as \u201cpasteurized.\u201d However, the term \u201cpasteurized\u201d is a special statement and claim that needs to be submitted to the Agency for label approval under 9 CFR 412.1(c)(3). The request for label approval needs to include supporting documentation providing evidence that the process achieves a 5-Log reduction of *Salmonella* or Lm. For more information see the FSIS Compliance Guidance for Label Approval. Irradiation is not a pasteurization process. Although the effect is similar to pasteurization, FSIS considers ionizing radiation a food additive under 9 CFR 424.22.", "82 Attachment A4. Sources of *Salmonella* Contamination in RTE Products and Best Practices to Address It Although the *Salmonella* percent positive found in ready-to-eat (RTE) products is low, the presence of *Salmonella* in RTE products may indicate a serious processing and public health problem. Common sources of *Salmonella* in RTE products include: \u2022 Under processing. \u2022 Cross-contamination. o Product contact surfaces that are contaminated with *Salmonella*; or, o Raw product contact with RTE product. \u2022 Ingredients

added to the product or the sauce after the cooking step. \u2022 Improper handling by establishment employees. \u2022 Insect or animal vectors. Each common source of Salmonella contamination on RTE products and best practices to prevent the hazard are discussed in detail below. Under-Processing Under-processing occurs when the lethality treatment is not adequate to eliminate the pathogens of concern. For heat-treated product, under-processing may result from inadequate cooking or the development of bacterial heat tolerance due to drying of the product\u2019s surface before completion of the lethality step because of inadequate humidity (see FSIS Critical Operating Parameters for Cooking (Time-Temperature Tables) page 23). Cross-Contamination Cross-contamination of product can occur from situations such as the following:

- \u2022 Using the same equipment (e.g., slicers) for both raw and cooked products without complete cleaning and sanitizing of the equipment (as should be addressed in the establishment\u2019s Sanitation Standard Operating Procedure (SOP)) after raw production and prior to RTE production.
  - o In a for-cause Food Safety Assessment (FSA) in response to a Salmonella positive in a RTE head cheese product, FSIS identified equipment used to grind both raw and cooked ingredients for head cheese was not cleaned and sanitized between use for raw and cooked meat potentially resulting in Salmonella cross-contamination.
- \u2022 Placing cooked product on the same surface (e.g., cutting table) as raw product without complete cleaning and sanitizing of the surface before reuse.", "83
- \u2022 Using the same utensils or containers (e.g., scoops or buckets) for both raw and cooked product.
  - o In two FSAs, popped pork skins were most likely contaminated with Salmonella when the same buckets and tongs were used for handling both raw and RTE product.

\u2022 Condensation or aerosolization in the processing environment. Best Practices to Prevent Cross-Contamination Under the HACCP regulations, establishments are required to prevent contamination of product with pathogens after the lethality step. Establishments are required to maintain sanitation in the RTE area to ensure that food contact surfaces are free of contamination from pathogens such as Lm and Salmonella. Best practices include:

- \u2022 Completely separating the processing areas by time or space (e.g., scheduling raw and RTE processing on different days).
- \u2022 Installing separate air ventilation systems that are designed to prevent or minimize condensation and other potential air contaminants. If separate ventilation systems are not feasible, ensure that airflow is directed from the RTE areas to the raw areas.
- \u2022 Using separate equipment for RTE and raw processing. If this is not possible, schedule use of equipment first for RTE processing and then for raw processing.
- \u2022 Restricting travel of personnel from the non-RTE area to the RTE area during processing.
- \u2022 Establishing proper sanitation procedures for equipment that is moved from a non-processing area to an RTE processing area to prevent product contamination from the equipment during operation.
- \u2022 Avoiding passing raw product through RTE areas and passing RTE product through raw production areas.
- \u2022 Not allowing RTE product in coolers to come into contact with raw products or surfaces that may be contaminated.
- \u2022 Discarding products that touch environmental surfaces (e.g., product that has fallen on the floor) if the product cannot be properly reconditioned to ensure that any possible contamination is eliminated.
- \u2022 During cleaning and sanitizing, following proper sanitation procedures to ensure that no food residue is left on the equipment."

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\u2022 When adding ingredients to a second container, avoiding any contact between the ingredient container and the interior of the second container. Ingredients Added After the Lethality Treatment Salmonella contamination may occur from the addition of uncooked vegetables

(e.g., tomatoes and onions), fresh herbs, eggs, spices (that may or may not have been treated to eliminate Salmonella), or other ingredients (e.g., nuts, hydrolyzed vegetable protein (HVP)) to processed meat and poultry products after the primary lethality treatment. Sauce that has not undergone a lethality treatment may also be a source of contamination of the finished product, even if the pH is low. The safety of all ingredients added to the product after the lethality step should be considered, even if they are normally considered RTE. In some cases, FSAs determined the addition of seasonings or other ingredients after the cooking step resulted in the contamination of RTE product with Salmonella. Failure to identify all steps in a process, including the addition of contaminated ingredients and sauces, can result in an inadequate food safety system. Outbreaks related to ingredients added after lethality treatment An outbreak and several recalls of meat and poultry products that were prepared using Salmonella-contaminated ingredients exemplify the need to ensure the safety of all ingredients added to the product after the lethality treatment. Examples include a 2010 outbreak-related recall of salami products coated with contaminated pepper (RC-0062010) and recalls involving products containing HVP that was the subject of an FDA recall (i.e., bacon base, RC-015-2010; beef tornados, RC-016-2010, and beef taquitos and chicken quesadillas, RC-017-2010). RC-055-2010 may have been due to contaminated sauce added to the product after the lethality step. There have also been two recalls of meat and poultry salads containing Salmonella contaminated tomatoes recalled by the supplier (RC-033-2011 and RC-79-2011), and Caesar salad containing contaminated cilantro that was the subject of an FDA recall (RC-059-2012). In 2018, there were 12 recalls due to potential vegetable contamination with Salmonella and Lm that were triggered by an FDA investigation and subsequent recall from the same supplier (RC-092-2018, RC-093-2018, RC-094-2018, RC-095-2018, RC-096-2018, RC-097-2018, RC-098-2018, RC-099-2018, RC-100-2018, RC-1012018, RC-102-2018, and RC-103-2018).", "85 Requirements and Best Practices to Prevent Hazards from Ingredients Added Post-Lethality Establishments are required to:

- \u2022 Ensure all ingredients and other articles used in the preparation of any meat or poultry product are clean, sound, healthful, wholesome and otherwise such as will not result in the product being adulterated (9 CFR 318.6 and 9 CFR 424.21).
- \u2022 Consider any potential food safety hazards at the step in the process where the non-meat ingredient is received into the food safety system (9 CFR 417.2(a)(1)) and document any controls it needs to support its decisions (9 CFR 417.5(a)(1)) about those hazards.

o Establishments may choose to use COAs that include negative test results for each lot of the non-meat ingredient as support or may test each lot of non-meat ingredients upon receipt; however, establishments have flexibility and do not have to only rely on testing.

- o Alternatively, establishments may maintain supporting documentation demonstrating that the ingredients such as spices, have been treated by processes to kill pathogens (e.g., irradiation, ethylene dioxide, steam treatment of spices), or they can apply a lethality treatment to the ingredients (e.g., cook the sauce of a pork BBQ).
- o In most cases, a LOG alone would not be sufficient to support the safety of non-meat ingredients added to a product unless they indicate how each lot of ingredients is processed, tested, treated, or otherwise processed to ensure its safety as described in the bullet above.
- o A LOG can be used to support the safety of pre-packaged ingredients (e.g., ketchup or mustard) that have not been associated with previous outbreaks or recalls.

NOTE: Many frozen vegetables are considered NRTE by the producing facility. FSIS recommends establishments that do not receive a COA or LOG as described in the bullets

above, treat all frozen vegetables as NRTE and address potential hazards from this ingredient (e.g., by testing each lot of non-meat ingredients upon receipt or applying a validated lethality treatment). Additionally, any vegetables labeled with cooking instructions are to be treated as NRTE. \u2022 Developing procedures to ensure that spices or other source materials are maintained under sanitary conditions and are not contaminated by the introduction of pathogens during repeated opening of the container and removal of the ingredient for use in multiple production lots.", "86 \u2022 Taking steps to ensure sauce used for RTE products is also not contaminated by exposure to unclean surfaces, untreated ingredients, or contact with raw products. Food Handlers There is a high incidence of salmonellosis in the US. Additionally, some people can be asymptomatic carriers that spread Salmonella without appearing ill. Establishment employees that are asymptomatic carriers may be a source of Salmonella in RTE products. Best Practices to Prevent Hazards from Food Handlers Food handlers, employees, and supervisors at food preparation facilities should: \u2022 Stay home from work when having symptoms of vomiting or diarrhea and wait to resume work until at least 24 hours have passed since the vomiting and diarrhea symptoms ended. \u2022 Wash hands upon resuming duties after breaks and before putting on gloves. \u2022 Wear separate or color-coded frocks in RTE areas of the establishment and control employee traffic between raw and RTE production areas. \u2022 Train employees in proper hygiene practices, and regularly monitor those practices, and retrain employees at least annually. \u2022 Develop and maintain procedures to ensure that sanitizer concentrations in footbaths are monitored and maintained adequately. Animals Animals (e.g., birds and rodents) and insects may also contaminate food products with Salmonella. It is possible for animal fecal contamination within and outside the establishment to be introduced into the RTE production area. Best Practices to Prevent Hazards from Animals \u2022 Maintaining an effective pest control program to maintain sanitary conditions and ensure that product is not adulterated (9 CFR 416.2(a)). Rats, mice, birds, and insects are sources of pathogen contamination. \u2022 Product and ingredients should always be protected from contamination and adulteration during processing, handling, and storage (9 CFR 416.14)." "87 Attachment A5. RTE Salmonella Self-Assessment Tool FSIS recommends that establishments use this tool to determine whether they have adopted the appropriate procedures to control Salmonella, or whether they should adopt new procedures. If establishments find that they are not meeting the recommendations in this guideline, FSIS recommends they consider changing practices to better control Salmonella in the product. The questions are related to evaluating the following: \u2022 Hazard Analysis\HACCP Plan \u2022 Ingredients \u2022 Corrective Actions in Response to Salmonella Positives Hazard Analysis\HACCP Plan YES NO N/A 1. Have you considered whether Salmonella is a hazard reasonably likely to occur (RLTO) in your Hazard Analysis? \u25a1 \u25a1 \u25a1 2. If you determined that Salmonella was RLTO, did you establish CCPs to control or prevent it? \u25a1 \u25a1 \u25a1 3. If you established CCPs, do you have sufficient supporting documentation to support the effectiveness of the measures you are taking? \u25a1 \u25a1 \u25a1 4. If you produce roast, cooked, or corned beef, does your process achieve at least a 6.5-Log or other supportable (e.g., 5-Log) reduction of Salmonella? \u25a1 \u25a1 \u25a1 5. If you produce cooked uncured meat patties, does your process achieve at least a 5-Log reduction of Salmonella? \u25a1 \u25a1 \u25a1 6. If you produce cooked poultry, does your process achieve at least a 7-Log reduction of Salmonella? \u25a1 \u25a1 \u25a1 7. If you produce other cooked

RTE meat products, does your process achieve at least a 6.5-Log or other supportable (e.g., 5-Log) reduction of Salmonella in the product? \u25a1 \u25a1 \u25a1 8. If you are using an alternative lethality Log reduction target (e.g., 5-Log reduction) do you have additional support such as COA, LOG, combined interventions, or baseline testing? \u25a1 \u25a1 \u25a1 9. As part of your critical limits, have you identified the target or performance standard that your \u25a1 \u25a1 \u25a1,"88 process is designed to achieve (9 CFR 417.2(c)(3))? 10. If you produce cooked products and use a time- temperature table, are you applying humidity during the cooking process? \u25a1 \u25a1 \u25a1 11. If \u201cno\u201d to the question above, do you have support for why relative humidity is not a critical operating parameter? \u25a1 \u25a1 \u25a1 12. If \u201cno\u201d to the question above, are you applying a scientific gap for lack of relative humidity? Which one? (fill in here) \_\_\_\_\_ \u25a1 \u25a1 \u25a1 13. If you produce cooked products and use a FSIS time-temperature table, have you limited product heating come-up-time (50 to 130\u00b0F) to 6 hours or less? \u25a1 \u25a1 \u25a1 14. If \u201cno\u201d to the question above, do you have alternative support for applying a long come-up-time? \u25a1 \u25a1 \u25a1 15. If \u201cno\u201d to the question above, are you applying a scientific gap for long come-up-time? \u25a1 \u25a1 \u25a1 Ingredients YES NO N\A 16. Do you add ingredients to the product after the lethality treatment? (if \u201cno,\u201d move to the next section) \u25a1 \u25a1 \u25a1 17. Do you maintain COAs, LOGs, or other information (e.g., sampling data) to support the safety of the ingredients? \u25a1 \u25a1 \u25a1 18. If you use LOGs, do they indicate how each lot of ingredients is processed, tested, or otherwise treated to ensure its safety? \u25a1 \u25a1 \u25a1 19. Are the ingredients that you add to the product included in your flow chart or hazard analysis? \u25a1 \u25a1 \u25a1 20. If you use pre-packaged ingredients that are included in the final package with the finished product do you have LOGs or other information to support their safety? \u25a1 \u25a1 \u25a1,"89 Corrective Actions in Response to Salmonella Positives YES NO N\A 21. Has a RTE product sample tested positive for Salmonella from FSIS or establishment testing? (If \u201cno\u201d the assessment is complete). \u25a1 \u25a1 \u25a1 22. If you control Salmonella in your HACCP plan, did you take corrective actions according to 9 CFR 417.3(a)? (If you prevent Salmonella through a Sanitation SOP or other prerequisite program, skip to #26). \u25a1 \u25a1 \u25a1 23. Did you take steps to identify and eliminate the cause of the deviation, according to 9 CFR 417.3(a)(1)? \u25a1 \u25a1 \u25a1 24. If the cause of the positive result is under- processing, did you immediately review your processing system and bring the process back into compliance? \u25a1 \u25a1 \u25a1 25. If the cause of the positive result is lack of support for your lethality process, did you change your process or provide additional support for the safety of the process, in light of the positive result? \u25a1 \u25a1 \u25a1 26. If you prevent Salmonella through a Sanitation SOP or another prerequisite program, did you take corrective actions according to 9 CFR 417.3(b)? \u25a1 \u25a1 \u25a1 27. As part of your corrective actions, did you reassess your HACCP plan according to 9 CFR 417.3(b)(4)? \u25a1 \u25a1 \u25a1 28. As a result of your reassessment, did you address the pathogen in a CCP or make substantive changes to your prerequisite program? \u25a1 \u25a1 \u25a1,"90 Attachment A6. Cooking Country-Cured Hams In October 2018, an establishment recalled cooked country-cured ham product that was associated with a listeriosis outbreak (Recall 084-2018; CDC: Outbreak of Listeria Infections Linked to Deli Ham). FSIS\u2019s investigation at the establishment found that the country-cured hams were

cooked in a sealed bag multiple times. Before being cooked multiple times, the ham was salt-cured and dried, thus reducing its water activity. Additionally, after an initial cooking step in a sealed bag, the ham was removed, drained of its juices, and placed into a second bag; during this process, the ham may have been cross-contaminated from the processing environment. Additionally, the draining of juices may have resulted in drier conditions during cooking. The establishment used FSIS cooking guidance (Appendix A) as scientific support that cooking achieved lethality of pathogens, including Lm. However, as discussed on page 12, Appendix A guidance was not intended for lower water activity products cooked under dry conditions or for dried products cooked multiple times. Hence the process may not have been lethal to Lm (USDA/FSIS, 2020). Establishments that apply these types of processes must identify other support for their HACCP System (9 CFR 417.5(a)(1) and 9 CFR 417.4(a)(1)). During the outbreak investigation, FSIS also discovered that several establishments cook country-cured hams once under moist conditions using FSIS cooking guidance as support. FSIS cooking guidance was also not intended for lower water activity products cooked even under moist conditions; however, FSIS is not aware of any imminent food safety issues with this practice. Therefore, page 47 (Table 5), includes critical operating parameters that may be applied to cook dried products like country cured hams if they are cooked once under moist conditions to rehydrate the surface. While cooking under moist conditions should rehydrate the surface, there is no research validating this process so it is considered a scientific gap. As with other scientific gaps, there is a vulnerability because FSIS's lethality guidance is not designed for processes where the drying step comes before the moist cooking step. This is because cooking under low moisture conditions results in product with a lower water activity. These conditions lead to pathogens, such as Lm, becoming more heat-tolerant and the organism could survive the cooking process. To minimize this vulnerability, FSIS recommends: If the product is cooked once: Establishments should gather support such as water activity measurements after drying (before cooking), then again after cooking to demonstrate that the water activity increased, and product surface was rehydrated during cooking. This recommendation applies even if the product is cooked-in bag, because the water activity may not be high enough to ensure that pathogens are killed on the product without addition of moisture. Establishments should achieve the highest water activity possible during cooking. Values 0.96 have been shown to prevent bacterial heat tolerance", "91 (Kieboom, et al. 2006), but this water activity may not be possible for all processes to achieve. Establishments conduct finished product testing for Salmonella and Lm as part of on-going verification. Establishments should also ensure that the cooking bag is completely sealed, so that moisture is contained in the bag and the product is not exposed to the environment or contaminants. Cooking bags may be compromised during steps such as molding or shaping. The establishment should have a process to verify the package integrity, and if leaks are observed, the establishment should reprocess/recook the product, using a supported process.", "92 https://www.fsis.usda.gov/contact-us/askfsis FSIS/USDA www.fsis.usda.gov 2021"]}, {"file\_name": "FSIS\_GD\_2021\_0015", "title": "HACCP Model for Raw Intact Beef", "num": "FSIS-GD-2021-0015", "id": "80b3ddb50c6f044e66fac42d74ca38b17faf021000fe72ee12d73399d2f33f30", "corp\_us": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2021-"}]

12\FSIS-GD-2021-0015.pdf","type":"pdf","n\_pages":11,"word\_count":3352,"text\_by\_page":["Page 1 of 11 HACCP Model for Raw Intact Beef The United States Department of Agriculture (USDA) published the Pathogen Reduction\Hazard Analysis Critical Control Point (HACCP) Systems Final Rule in July 1996 mandating all USDA inspected meat and poultry establishments implement a HACCP system. Hazard Analysis Critical Control Point (HACCP) is a systematic and scientific method of process control for the production of safe food products. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to improve the safety of their products. The HACCP models\u2019 focus is on product safety, not product quality characteristics. With the rule, FSIS made available a guidebook for the preparation of HACCP plans and a generic model for each food processing category defined in the regulation (9 CFR 417.2(b)(1)). The guidebook and the generic models have been revised since their initial publication to be consistent with current science and policy. FSIS recommends you use the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan. Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used as is. Establishments are to tailor the model(s) to fit the establishment\u2019s operation. The raw intact1 beef model\u2019s critical control points (CCPs) do not necessarily apply to all operations or products. Products or operations may require fewer or more CCPs depending on the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. The food safety critical limits selected must come from scientific documents or other reliable sources. Each model includes references for guidance on the selection of critical limits. This model illustrates how establishments might include beef intended for intact use in the production of steaks and roasts. The sources of beef in this model are purchased product intended for intact use and product from in-house slaughter operations. The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis, are HACCP records (CFR 417.5(a)). The selection of processing categories and HACCP models are preliminary steps to completing a hazard analysis. The documents produced during the selection process are HACCP records. Ensure you maintain the documents produced while developing a HACCP plan. For further assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP webpage.<sup>2</sup> 1 FSIS considers raw products to be intact unless they have undergone any of the processes associated with the raw non-intact process category. Processes common to the non-intact category include grinding, comminuting, injecting product with solutions, or mechanical tenderization by needling, cubing, pounding devices or other means of creating non-intact product. 2 This information is best suited for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products."],"Page 2 of 11 EXAMPLE PRODUCT DESCRIPTION3 Process Type and Product Name: Raw Intact Beef Process

Type and Product Name Raw Intact Beef: steaks and roasts. Important product characteristics (Aw, pH, preservatives, etc.) None How it is to be used4 The products are to be cooked intact while using the validated cooking instructions.5 Packaging (durability and storage conditions) Tray packages, vacuum sealed packages or in butcher paper. Shelf Life and at what temperature6 Shelf life is 7 days when held at \u226440\u00b0F and paper wrapped; 60 days when held at \u226440\u00b0F and vacuum packed.7 Vacuum packed product can be held for 180 days at \u226410\u00b0F. Where it will be sold (specify intended consumers, especially at-risk populations8) Sold to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI). Labeling Instructions Product name, inspection legend and establishment number, handling statement, net weight statement, address line, nutrition facts, and safe handling instructions. Validated cooking instructions.9 What special distribution controls are required? None DATE: APPROVED BY: 3 Prior to developing the HACCP plan please read the FSIS Guidebook for the Preparation of HACCP Plans for detailed descriptions of the worksheets and hazard analysis. The FSIS Guidebook for the Preparation of HACCP Plans and the generic HACCP models are intended for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP models are for demonstration purposes only. The models do not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products. 4 The intended use or consumer of the product must be identified in accordance with 9 CFR 417.2(a)(2). Identifying the product\u2019s intended use in the product description is one way to meet the regulatory requirements specific to 417.2(a)(2). 5 Establishments are required to identify the intended use of the product (9 CFR 417.2(a)(2)); they are also required to maintain decisionmaking documents associated with the HACCP plan (9 CFR 417.5(a)(2)). See the Adequate Support for the Intended Use of Beef Primal and Subprimal Cuts FSIS knowledge article for additional information. 6 Each establishment\u2019s products may have their own defined shelf life. 7 See Beef Shelf-life. 8 At-risk populations include young children, the elderly and immunocompromised persons. 9 See the FSIS Labeling Overview and Generic Label Approval guideline for information on required labeling features.", "Page 3 of 11 EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL10 Process Type and Product Name: Raw Intact Beef Meat and Meat by-products In-house slaughtered beef primals and sub-primals intended for intact use. Purchased beef sub-primals intended for intact use. Non-meat food ingredients None Antimicrobial11 Interventions and processing aids None Packaging Material Plastic, foam, or paper. Restricted Ingredients and Allergens None Other None DATE: APPROVED BY: 10 List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. See the FSIS Compliance Guideline Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling for detailed information on allergens. To review restrictions on the use of nitrite and sodium ascorbate or sodium erythorbate, see 9 CFR 424.22(b). 11 FSIS and the Food and Drug Administration (FDA) have a memorandum of understanding (MOU) that establishes the working relationship followed when responding to notifications for the use of food additives (including ingredients) intended for use in the production of FSIS regulated products. FSIS determines the suitability of

the use of food ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDA on the requirements under the Federal Food, Drug & Cosmetic Act and its implementing regulations. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products for the list of suitable ingredients." , "Page 4 of 11

EXAMPLE PROCESS FLOW DIAGRAM12 Process Type and Product Name: Raw Intact Beef 12 This is an example flow diagram. Establishments\u2019 flow diagrams for the same product may be different. Establishments determine which steps are included in their process. The steps must represent all relevant hazards in the hazard analysis. 13 The flow diagram and hazard analysis demonstrate the use of two differently sourced beef products. They are from in-house slaughter production (step 1a) that underwent interventions as part of the slaughter HACCP plan, and purchased product intended for intact use (without a COA) (step 1b). 14 The Returned Product step (9) is shown connected to the Finished Product Cold Storage step. Returned product may re-enter the production system at different process steps depending on condition or food safety concerns. Returned product may be relabeled, repackaged, or discarded. 1a.

Meat Receiving: beef from in-house slaughter intended for intact use13 8. Returned Product14 1c. Packaging Materials Receiving and Storage 1b. Meat Receiving: purchased beef intended for intact use 3. Fabrication and Cutting 2. Cold Storage 5. Packaging and Labeling CCP 1 Product Temperature 4. Rework and Work in Progress 9. Distribution 6. Finished Product Cold Storage 7. Trimmings from Fabrication and Cutting", "Page 5 of 11 15 STEC is an adulterant in raw non-intact beef products. When STEC is present on the meat\u2019s exterior, the pathogen may be translocated to the interior of the product during processing (e.g., grinding, tenderizing). In such cases, normal cooking to a rare or medium-rare internal state may not be sufficient to destroy STEC that is present throughout the product. See the Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli(STEC) in Raw Beef (including Veal) Processing Operations (page 8) for additional information. EXAMPLE HAZARD ANALYSIS Process Type and Product Name: Raw Intact Beef Column 1 Column 2 Column 3 Column 4 Column 5 Column 6

Ingredient \ Process Step Potential Hazards (introduced or controlled) at this Step i Is the Potential Food Safety Hazard Reasonably Likely to Occur (RLTO)? (Yes or No) ii Justification \ Basis for Decision iii If yes in Column 3 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels iv Is this Step a Critical Control Point (CCP)? 1a. Meat Receiving: beef from inhouse slaughter intended for intact use B:

Presence of pathogens: Shiga-toxin producing Escherichia coli (STEC) (E. coli O157:H7, O26, O45, O103, O111, O121 and O145), and Salmonella B: Outgrowth of pathogens: STEC and Salmonella. No No STEC and Salmonella are known to be present and may cause illness if not controlled. In-house product from slaughter operations was subjected to slaughter sanitary dressing procedures, a Zero Tolerance CCP, and an Organic Acid CCP. STEC is not an adulterant on intact products intended for intact use as the contamination is limited to the exterior of the product whereby customary consumer cooking practices will destroy the pathogen on the exterior surface even if the interior of the product is consumed in a rare or medium rare state. 15 Temperature Control Standard Operating Procedure (SOP) for maintenance of cold storage room temperature.", "Step Potential Hazard RLTO Justification \ Basis Controls CCP

Page 6 of 11 16 The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50\u00b0F (Tompkin, R.B. 1996) 17 If an establishment implements a process consistent with the process specifications described in the scientific support, and the

scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. However, if an establishment implements different critical operational parameters in the process from the scientific support, or the scientific support identified does not contain microbiological data, then the establishment should collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological validation data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameters (FSIS Compliance Guideline HACCP Systems Validation, page 27).<sup>18</sup> A LOG is a document that provides details for components that are used in the areas of food processing, handling, and storage. Generally, a LOG contains: supplier name and address, brand name, statement that the material is safe and effective under intended conditions of use and will not adulterate the food product, and signature of an official of the supplier. The LOG may be attached to an invoice or may be a continuing LOG that does not accompany each shipment. An annual update for Letters of Guarantee (LOG) is not a regulatory requirement. Each establishment must determine the frequency at which the LOG are updated. The frequency should be sufficient to adequately describe the supplier's process to support the decision(s) made. B: Bovine Spongiform Encephalopathy (BSE) Prions associated with Specified Risk Materials (SRM) (9 CFR 310.22). No Written Cold Storage Program to receive product \u226444.6\u00b0F to prevent outgrowth (Tompkin, R.B. 1996).<sup>16,17</sup> Written SRM Program to remove, segregate and dispose of SRMs (9 CFR 310.22). C: None P: None 1b. Meat Receiving: purchased beef intended for intact use B: Presence of pathogens: STEC and Salmonella. B: Outgrowth of pathogens STEC and Salmonella. B: BSE ✓ SRMs No No No An annual Letter of Guarantee<sup>18</sup> (LOG) from each supplier indicating the STEC and Salmonella controls were applied, and the products are intended for intact use. Written Receiving Program to receive product \u226444.6\u00b0F to prevent outgrowth (Tompkin, R.B. 1996). SRMs are required to be removed by supplier prior to receipt. Only boneless beef received and supplier LOG on file." "Step Potential Hazard RLTO Justification ✓ Basis Controls CCP Page 7 of 11 4. Rework and Work in Progress B: Outgrowth of pathogens, STEC and Salmonella. No Temperature Control SOP for production room temperature. C: None P: None 19 This Foreign Material SOP (prerequisite program) should have details on how this procedure (such as metal prevention controls) is preventing the hazard from occurring as well as the on-going verification procedures. These controls should be evident within the written document upon review. The Foreign Material SOP and plant data related to on-going verification activities then become part of recordkeeping and historical data. 20 Establishments may decide to add an organic acid treatment to be applied during fabrication. The organic acid treatment functions as a component of a multi-hurdle approach to pathogen control in ground product because trimmings are frequently used in ground beef production. C: None P: None 1c. Packaging Materials Receiving and Storage B: Contamination with Pathogens No Procedure to protect packaging materials from pests and environmental contamination. C: Non-food grade materials No LOG for packaging materials (9 CFR 317.24) and the materials are safely stored. P: Foreign materials No Foreign Material SOP with visual evaluation for foreign material.<sup>19</sup> Protect

packaging materials from environment. 2. Cold Storage B: Outgrowth of pathogens: STEC and Salmonella No Written Cold Storage Program to maintain product  $\leq 44.6^{\circ}\text{F}$  to prevent outgrowth (Tompkin, R.B. 1996). C: None P: None 3. Fabrication and Cutting B: Outgrowth of pathogens: STEC and Salmonella. No Temperature Control SOP for maintenance of production room temperature. 20 C: None P: None", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 8 of 11 5. Packaging and Labeling CCP 1 Product Temperature B: Outgrowth of pathogens: STEC and Salmonella. Yes Processing activities may result in product temperatures  $>44.6^{\circ}\text{F}$ . Product temperatures  $>44.6^{\circ}\text{F}$  may facilitate pathogen outgrowth. Product temperature taken at packaging. CCP 1 Product Temperature at Packaging and Labeling. Temperature Control SOP for production room temperature. CCP 1 Product Temperature at Packaging and Labeling C: None P: None 6. Finished Product Cold Storage B: Outgrowth of pathogens, STEC and Salmonella. No Written (and implemented) Cold Storage Program to maintain product  $\leq 44.6^{\circ}\text{F}$  to prevent outgrowth (Tompkin, R.B. 1996). C: None P: None 7. Trimmings from Fabrication and Cutting B: Outgrowth of pathogens: STEC and Salmonella. No Trimmings are processed into ground beef. Steaks and roasts may be mechanically tenderized, or needle injected. Mechanically tenderized, needle injected products and beef trimmings are packaged and then further processed under the Raw Non-Intact Beef HACCP plan which contains a Written Raw Beef Testing SOP for verification of STEC and Salmonella controls. Temperature Control SOP for production room temperature. . C: None P: None 8. Returned Product B: None Returned Product Evaluation SOP implemented before accepting returned product. Person(s) or", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Page 9 of 11 business returning the product must demonstrate the product was held in the appropriate temperature range and in a sanitary manner. When such assurance is not available, returned product is rejected or destroyed. Opened packages are not accepted. Accepted product enters the appropriate step of the production system based on findings of product evaluation. Notify FSIS personnel when returned product has been accepted. C: None P: None 9. Distribution B: None C: None P: None DATE: APPROVED BY:

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" , "Page 10 of 11 EXAMPLE HACCP PLAN for Raw Intact Beef Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who Packaging and Labeling CCP 1 Product Temperature Pathogen outgrowth: STEC (E. coli O157:H7, O26, O45, O103, O111, O121 and O145), and Salmonella. Internal product temperature is  $\leq 44.6^{\circ}\text{F}$  at packaging. Internal product temperature is measured after the product is placed in its packaging and before the package is closed. Observations documented. Employee measures product internal temperature at the thickest part of 5 pieces with a handheld digital thermometer. Record results on the Product Temperature Form. To be performed one time during each 2 hours of production. Designee If a deviation from the critical limit occurs, a supervisor will: 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence 9 CFR 417.3 Once per week, a supervisor will directly observe the monitoring activity, conduct the records review and calibrate the thermometer (per manufacturer's calibration instructions). Product Temperature Form Verification Form Corrective Action Form Pre-shipment Review Form Thermometer Calibration Form DATE: APPROVED BY:

","Page 11 of 11 i Hazards are grouped into three categories: Biological (B), Chemical (C), and Physical (P). Biological hazards are living organisms. Chemical hazards may be naturally occurring in foods, used or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification. ii Place the justification for your decision in column 4. Control measures for hazards not reasonably likely to occur are entered in column 4. Control measures for hazards reasonably likely to occur are entered in column 5. If a hazard is reasonable likely to occur, then a CCP must be addressed at this step or a later step. See the Meat and Poultry Hazards and Controls Guide for a list of frequently used controls. iii Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced article must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from an FSIS source, then HACCP system design must be supported by documentary evidence \u2013 that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan. iv Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation, page 5."}],{"file\_name":"FSIS\_GD\_2022\_0002","title":"HACCP Model for Full Cooked-Not Shelf Stable Roast Beef","num":"FSIS-GD-2022-0002","id":"a3b881ae60480d147c8f73ad473db7713e7d8d0b6716726748541a0cbc72f319","corpus":"fsis\_guidelines","source\_page\_url":"https://www.fsis.usda.gov/policy/fsis-guidelines","url":"https://www.fsis.usda.gov/sites/default/files/media\_file/2022-04/FSIS-GD-2022-0002.pdf","type":"pdf","n\_pages":13,"word\_count":4595,"text\_by\_page":["HACCP Model for Fully Cooked\u2014Not Shelf Stable Roast Beef The United States Department of Agriculture (USDA) published the Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule in July 1996 mandating all USDA inspected meat and poultry establishments implement a HACCP system. HACCP is a systematic and scientific method of process control for the production of safe food products. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to improve the safety

of their products. The HACCP models' focus is on product safety, not product quality characteristics. With the rule, FSIS made available a guidebook for the preparation of HACCP plans and a generic model for each food processing category defined in the regulation (9 CFR 417.2(b)(1)). The guidebook and the generic models have been revised since their initial publication to be consistent with current science and policy. FSIS recommends you use the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan. Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used *in* an establishment's operation. This Fully Cooked/Not Shelf Stable HACCP model applies to products that receive a full lethality heat process step to achieve food safety. The full lethality heat process step makes these products safe to eat with no further preparation required by the consumer. However, these products are not shelf stable. Therefore, these products must be frozen or refrigerated throughout their shelf-life to maintain product safety. These products also meet the definition of ready-to-eat (RTE) product, as defined in 9 CFR 430.1. The Fully Cooked/Not Shelf Stable model's critical control points (CCPs) do not necessarily apply to all operations or products. Products or operations may require fewer or more CCPs depending on the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. The food safety critical limits selected must come from scientific documents or other reliable sources. Each model includes references for guidance on the selection of critical limits. The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis, are HACCP decisionmaking records (CFR 417.5(a)). The selection of a HACCP model is a preliminary step to completing a hazard analysis. The documents produced during the selection process are HACCP records. Ensure you maintain the documents produced while developing a HACCP plan. For further assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP webpage.<sup>1</sup> This information is best suited for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products. Page 1 of 13", "EXAMPLE PRODUCT DESCRIPTION Process Type and Product Name: Fully Cooked/Not Shelf Stable Roast Beef Process Type and Product Name<sup>2</sup> Fully Cooked/Not Shelf Stable, Roast Beef Important product characteristics (Aw, pH, Preservatives, etc.) None How it is to be used<sup>3</sup> Ready-to-eat Packaging (durability and storage conditions) Vacuum package, Catch weights < 8 lbs. Shelf Life and at what temperature<sup>4</sup> 21 days at 40°F Where it will be sold (specify intended consumers, especially at-risk populations)<sup>5</sup> Sold to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI). Labeling instruction and requirements Product name, inspection legend and establishment number, handling statement, net weight statement, ingredients statement, address line, and nutrition facts.<sup>6</sup> Special distribution control Keep

refrigerated DATE: APPROVED BY: 2Prior to developing the HACCPplan, please read the FSIS Guidebook for the Preparation of HACCPPlans for detailed descriptions of the worksheets and hazard analysis. The Guidebookisintended for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. 3Theintended use or consumer of the product must be identified in accordance with 9 CFR417.2(a)(2). Identifying the product\u2019sintended use in the product description is one way to meet the regulatory requirements specific to 417.2(a)(2). 4Each establishment may have their own defined shelf life. 5At-risk populations include young children, pregnant women, the elderly, and immunocompromised persons. 6See the FSIS Labeling Overview and Generic Label Approval guideline for information on required labeling features. Page 2 of 13", "EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL Process Type and Product Name: Fully Cooked\u2014Not Shelf Stable Roast Beef Meat and meat byproducts7 Fresh beef (beef eye rounds) Non-meat food ingredients Spice mixture (Sea Salt, Black Pepper, Natural Beef Stock & Flavor (Contains Smoke)) Antimicrobial interventions and processing aids8 None Packaging material Plastic vacuum bags Restricted ingredients and allergens None9 Other None DATE:

\_\_\_\_\_ APPROVED BY: 7List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCPplan. See the FSIS Compliance Guideline Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling for detailed information on allergens. To review restrictions on the use of nitrite and sodium ascorbate or sodium erythorbate, see 9 CFR 424.22(b). 8FSIS and the Food and Drug Administration (FDA) have a memorandum of understanding (MOU) that establishes the working relationship followed when responding to notifications for the use of food additives(including ingredients)intended for use in the production of FSIS regulated products. FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDA on the requirements under the Federal Food, Drug & Cosmetic Act and its implementing regulations. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products for the list of suitable ingredients. 9With this model, the establishment does not incorporate allergenic compounds or restricted ingredients into any products and so these ingredients are not present in the facility. For that reason, this model\u2019s hazard analysis does not demonstrate controls for allergenic compounds or restricted ingredients. Review the HACCP Model for Ready-to-Eat, Heat-Treated, Shelf-Stable (Beef Jerky) to see how allergen controls might be included in a hazard analysis. Page 3 of 13", "EXAMPLE PROCESS FLOW DIAGRAM10 Process Type and Product Name: Fully Cooked\u2014Not Shelf Stable Roast Beef11 1a. Receiving Raw Meat (eye rounds) 2.Cold Storage 1b. Non-Meat Ingredients Receiving and Storage 1c. Packaging Materials Receiving and Storage 3.Trim, Size Eye Rounds 4.Rub Beef with Seasoning 5.Racking \u2013 Seal Roasts in Cook-in Bags and Place on Rolling Oven Racks 7. Cooking CCP 1 8. Chilling CCP 2 6. Rework 9. Cold Storage (Cooked Roasts) 10. Packaging and Labeling 10This is an example flow diagram. Establishments\u2019 flow diagrams for the same product may be different. Establishments determine which steps are included in their process. The steps must represent all relevant hazards in the hazard analysis. 11See FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) and FSIS Stabilization Guideline for Meat and Poultry Products (Revised

Appendix B) for guidance on the production of products in the Fully Cooked\Not Shelf Stable processing category. 11. Storage\Distribution 12. Returned Product Page 4 of 13", "EXAMPLE HAZARD ANALYSIS12 Process Type and Product Name: Fully Cooked\Not Shelf Stable Roast Beef (Eye Rounds) Column 1 Column 2 Column 3 Column 4 Column 5 Column 6 Ingredient \ Process Step Potential Hazards (introduced or controlled) at this Step13 Is the Potential Food Safety Hazard Reasonably Likely to Occur? (Yes or No)14 Justification for Decision15 What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce to Acceptable Levels16 Is this Step a Critical Control Point (CCP)? 1a. Receiving Raw Meat (eye rounds) B: Presence of pathogens: Salmonella, Shigatoxin producing Escherichia coli (STEC) (E. coli O157:H7, O26, O45, Yes STEC and Salmonella are known to be present and may cause illness if not controlled. An annual Letter of Guarantee17 (LOG) from each supplier indicating the STEC and Salmonella controls were applied. Hazards controlled at step 7 CCP 1 Cooking No 12See Meat and Poultry Hazards and Controls Guide for lists of potential biological, physical, and chemical hazards and frequently used controls and preventive measures. 13Hazards are grouped into three categories: Biological (B), Chemical (C), and Physical (P). Biological hazards are living organisms. Chemical hazards may be naturally occurring in foods, used or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification. 14Place the justification for your decision in column 4. Control measures either go in column 4 for hazards not reasonably likely to occur or go in column 5 for hazards reasonably likely to occur. If a hazard is reasonable likely to occur, then a CCP must be addressed at this step or a later step. See FSIS Meat and Poultry Hazards and Controls Guide for a list of frequently used controls. 15Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced article must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from an FSIS source, then HACCP system design must be supported by documentary evidence \u2013 that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan. 16Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation, page 5). 17 An annual update for a LOG is

nota regulatoryrequirement. Eacheestablishmentmust determine the frequencyat whichthe LOG are updated. The frequency should be sufficient to adequately describe the supplier\u2019s process to support the decision(s) made. Page 5 of 13", "Step Potential Hazard RLTO Justification \ Basis Controls CCP O103, O111, O121 and O145). B: Outgrowth of pathogens: STEC and Salmonella. B: Bovine Spongiform Encephalopathy (BS E) Prions associated with Specified Risk Materials (SRMs). No No Written Sanitation standard operating procedure (Sanitation SOPs) for procedures used to protect ingredients from environmental contamination. Written Receiving SOP to ensure product is received at \u226445\u00b0F to prevent outgrowth (Tompkin, R.B. 1996).18 SRMs are required to be removed by supplier prior to receipt. Only boneless beef received and supplier LOG on file. C: None P: Foreign Materials No Written Incoming Material SOP for procedures to visually evaluate incoming packaged product for foreign material contamination.19 Records demonstrate no incidents of foreign materials detected in products received. 20 1b. Non-Meat B: Pathogens: Yes Spices and flavorings may introduce pathogens. Hazards controlled at No Ingredients Receiving and Storage Salmonella LOG from suppliers describing quality controls and prevention procedures. Written Incoming Material SOP for procedures to examine incoming non-meat ingredients for package integrity and sanitary conditions. Written Sanitation SOP for procedures used to protect ingredients from environmental contamination. step 7 CCP 1 Cooking 18Tompkin, R.B. 1996: The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50\u00b0F. Presented during the Joint FSIS\FDAConference on Time\Temperature. November 18, Washington,DC). 19ThisForeign MaterialSOP(prerequisite program) should have details on how this procedure is preventing the hazard from occurring (such as metal prevention controls) as well as the on-going verification procedures. These controls should be evident within the written documentupon review. The Foreign MaterialSOPand plant data related to on-going verification activities then become part of recordkeeping and historic data. 20Note: The establishmentmustmaintain copies of all the documents referenced in the hazard analysis that are designated as support for the decisions(9 CFR417.5(a)(1) including establishment historicalrecords. Such historical records are often gathered as partof in-plant validation (9 CFR417.4(a)(1). When historicalrecords are not available (for example,aHACCP plan for anew process or product), then system design must besupported by other documentary evidencesuch as the FSISMeat and Poultry Hazards and Controls Guide. See the guide forfrequently usedhazard controls. Page 6 of 13", "Step Potential Hazard RLTO Justification \ Basis Controls CCP C: Undeclared allergens No LOG from suppliers describing quality controls and prevention procedures. Written Incoming Material SOP for procedures to verify that each lot of incoming materials does not contain allergenic ingredients. Approved supplier program and ongoing communication with suppliers to verify LOG. P: None 1c. Packaging Materials B: Contamination with pathogens Procedure to protect packaging materials from environment. C: Non-food grade No Packaging materials may introduce chemical hazards. Receiving and Storage materials. LOG for all packaging materials describing quality controls and prevention procedures. Written Incoming Material SOP for procedures to examine incoming materials including sanitary conditions. Written Sanitation SOP for procedures used to protect packaging materials from environmental contamination. P: None 2. Cold Storage B: Pathogen outgrowth: Salmonella, STEC, No Written Temperature Control SOP for maintaining product at temperatures that preclude Salmonella and STEC growth

(<45°F, (Tompkin, R.B. 1996). C: None P: None 3. Trim, Size Eye Rounds B: Pathogen outgrowth: Salmonella, STEC, No Written Temperature Control SOP for maintaining product work area at temperatures that prevent outgrowth of microorganisms. Duration of this step (Trimming) is short enough that outgrowth is not reasonably likely to occur. According to Tompkin, R.B. 1996 Table 2, Salmonella and STEC growth is limited to < 1-log if product temperatures 21 are no more than 70°F for up to 9 hours. Nine hours is 21The University of Wisconsin Center for Meat Process Validation hosts a pathogen modeling tool (THERM 2.0) designed for evaluating the safety of meat or poultry held at temperatures between 50°F and 115°F. See THERM 2.0 for alternative time and temperature combinations that support the production of safe products. Page 7 of 13", "Step Potential Hazard RLTO Justification √ Basis Controls CCP longer than a shift, so outgrowth is not reasonably likely to occur. Written Good Manufacturing Practices to prevent or minimize cross-contamination. C: None P: None 4. Rub Beef with Seasoning B: Pathogen outgrowth: Salmonella, STEC No Written Temperature Control SOP for maintaining product work area at temperatures that prevent outgrowth of microorganisms. Duration of this step (Rub Beef with Seasoning) is short enough that outgrowth is not reasonably likely to occur. According to Tompkin, R.B. 1996 Table 2, Salmonella and STEC growth is limited to < 1-log if product temperatures are no more than 70°F for up to 9 hours. Nine hours is longer than a shift, so outgrowth is not reasonably likely to occur. Proper employee handling through Written Sanitation SOPs. C: Undeclared No This product does not contain allergenic ingredients. Allergens LOG from suppliers describing quality controls and prevention procedures. Written Incoming Material SOP for procedures to verify that each lot of incoming materials does not contain allergenic ingredients. Approved supplier program and ongoing communication with suppliers to verify LOG. P: None 5.

Racking 2014 Seal Roasts in Cook-in Bags and Place on Rolling Oven Racks B: None C: None P: None Page 8 of 13", "Step Potential Hazard RLTO Justification √ Basis Controls CCP 6. Rework B: Pathogen outgrowth: Salmonella, STEC No Written Rework Procedures SOP for handling product, including bags punctured for temperature monitoring to be reworked. C: None P: None 7. Cooking B: Pathogen outgrowth: Staphylococcus aureus Pathogen presence: Salmonella, STEC Yes Yes Extended heating come-up time could allow excessive S. aureus outgrowth and toxin formation. Improper cooking times and temperatures could result in bacterial survival and growth. Relative humidity is addressed through the cook-in-bag process. While monitoring product temperature with a probe thermometer, the bag is punctured which exposes the product to the environment (i.e., post-lethality exposed). Product monitored with a probe thermometer is reworked and recooked before distribution per Written Rework Procedures SOP to ensure no post-lethality exposed product is in commerce. Limit heating come-up time (50°F to 130°F) to less than 6 hours to ensure S. aureus outgrowth is limited to 2 logs or less (see FSIS Revised Appendix 23, 24 A). Cook to appropriate time and temperature found in FSIS Revised Appendix A to achieve a 6.5 log<sub>10</sub> reduction of Salmonella as per performance standards in 9 CFR 318.17. 25 CCP 1 C: None 22 If the product is not cook-in-bag and the establishment uses FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) as support for the lethality treatment/ cooking step, relative humidity must be addressed using one of the options on page 26 of the Revised Appendix A or the establishment must provide support for why relative humidity does not need to be addressed (9 CFR 417.5(a)(1)). For a model HACCP plan that addresses relative humidity following

one of the options in the Revised Appendix A, see the HACCP Model for Ready-to-Eat, Heat-treated, Shelf-stable (Beef Jerky).<sup>23</sup> If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. However, if an establishment implements different critical operational parameters in the process from the scientific support, or the scientific support identified does not contain microbiological data, then the establishment must collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameters (FSIS Compliance Guideline HACCP Systems Validation, page 27).<sup>24</sup> Establishments producing products with long heating come-up-times due to product size, such as ham and beef brisket, can use the critical operating parameters found on page 48 of the FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A). This reference can be used as support for applying FSIS<sup>u2019</sup> applicable time-temperature combinations and relative humidity, without considering heating come-up-time as a critical operating parameter.<sup>25</sup> See FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) for validated times and temperatures. If alternative methods are used, refer to the validation and scientific support for the alternative lethality step as described in the FSIS Compliance Guideline HACCP Systems Validation. Include critical operational parameters for lethality and stabilization in the HACCP plan. Page 9 of 13", "Step Potential Hazard RL TO Justification \ Basis Controls CCP P: None 8. Chilling B: Clostridium perfringens and Clostridium botulinum Yes Spores can survive the Cooking step (#7), germinate, and grow if not cooled quickly. Product is cook-in-bag and therefore not post-lethality exposed so Listeria monocytogenes is not a hazard of concern.<sup>26</sup> Bags that are punctured with a thermometer for monitoring are reworked and recooked before distribution per Written Rework Procedures SOP to ensure no post-lethality exposure. Chill roasts following appropriate time and temperature in FSIS Revised Appendix B to prevent multiplication of toxigenic microorganisms such as Clostridium botulinum and no more than 1 log<sub>10</sub> multiplication of Clostridium perfringens to comply with the performance standard in 27 9 CFR 318.17(a)(2). CCP 2 C: None P: None 9. Cold Storage Cooked Roasts B: Pathogen outgrowth: Clostridium perfringens and Clostridium botulinum No Written Temperature Control SOP for monitoring product temperature to prevent outgrowth of microorganisms. Product is stored at temperatures that preclude spore formation growth <50\u00b0F, Revised Appendix B. C: None P: None 10. Packaging and Labeling B: None C: Undeclared allergens This product does not contain allergenic ingredients. LOG from suppliers describing quality controls and prevention procedures. 26 Product is cooked in a bag and remains in the bag after the cooking step. Therefore, the product is not exposed to the environment after cooking (i.e., not post-lethality exposed) and not covered by 9 CFR 430.4. 27 See FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B) for optional validated time and temperature reported in literature for stabilization processes. If alternative methods are used, validation and scientific support for the alternative lethality step as described in the

FSISCompliance Guideline HACCPSystems Validation. Include critical operational parameters for stabilization in HACCPplan. Page 10 of 13","Step Potential Hazard RLTO Justification \ Basis Controls CCP Written Incoming Material SOP for procedures to verify each lot of incoming packaging material does not contain allergenic compounds. Approved supplier program and ongoing communication with suppliers to verify LOG. Allergen Control SOP ensures ingredient statements on finished product labels match ingredient formulation. P: None 11. Storage and Distribution B: Pathogen outgrowth: Clostridium perfringens and Clostridium botulinum No Product stored at improper temperatures can result in outgrowth of pathogens. Product is stored at temperatures that preclude spore germination and Clostridium growth (<50\u00b0F, Revised Appendix B). Written Final Product SOP for procedures to examine outgoing packaged product. Includes verifying the sanitary condition of the truck, functioning refrigeration unit, and package integrity. C: None P: None 12. Returned Product B: None Returned Product Evaluation SOP implemented before accepting returned product. Entity returning the product must demonstrate the product was held in the appropriate temperature range and in a sanitary manner. When such assurance is not available, returned product is rejected or destroyed. Opened packages are not accepted. Accepted product enters the appropriate step of the production system at process flow steps 10 or 11 based on findings of product evaluation. Notify FSIS personnel when returned product has been accepted. C: None P: None DATE: APPROVED BY: Page 11 of 13","EXAMPLE ROAST BEEF HACCP PLAN Critical Critical Limits Monitoring Procedures Corrective Action Verification Records Control Point (CCP) Significant Hazard(s) for Each Control Measure What How Frequency Who CCP 1 Cooking (1) Pathogen outgrowth: Staphylococcus aureus (2) Pathogen presence: Salmonella, STECs, (1) Product temperature come-up-time, from 50\u00b0Fto 130\u00baF, in less than 6 hours. 28, (2) Roasts held for 36 minutes at 135\u00b0Finternal product 29, temperature. 30 Internal product temperature and dwell time during heating come-uptime and internal product temperature and dwell time at endpoint. Designee sets up continuous monitoring device. Designee places product temperature probe in center of largest piece in the batch and held in the oven\u2019s coldest spot. Designee will review records from continuous monitoring device at completion of cooking cycle to determine the critical limits are met.31 Continuous for each oven load (lot) Designee If a deviation from the critical limit occurs, the designee will immediately report to a supervisor. The supervisor will: 1. Hold all product produced since the last acceptable check until appropriate disposition taken (no product injurious to health enters commerce)32; 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence. 9 CFR 417.3 Once per week, a manager will observe the designee setting up the continuous monitoring device. Once per week, a manager will observe the designee placing the product temperature probe in center of largest piece in the batch and held in the oven\u2019s coldest spot. Once per week, a manager or designee will observe the designee reviewing records from continuous monitoring device. Once per week, a manager or designee calibrates product thermometers per manufacturer\u2019s instructions. Once per week a manager or designee will review all records maintained. Roast Beef Cooking Log from computerized continuous monitoring device Thermometer Calibration Log Direct Observation Log Records Review Log Corrective Action Log 28The cooking critical limits used in this plan are derived fromthe FSISCooking Guideline for Meatand Poultry Products (Revised Appendix A). See Appendix Afor guidance on implementing this safe harbor and foradditionalvalidated time and

temperature parameters for lethality cooking processes including parameters for products with heating come-up times (50°F to 130°F) longer than 6 hours. For general guidance on establishing critical limits, see the Guidebook for the Preparation of HACCP plans (page 27).

29 The critical limits in this model assume a thermometer with an accuracy of less than 0.1°F. Establishments producing cooked meat and poultry products should have sufficient monitoring equipment, including recording devices, to assure that the time, temperature, and relative humidity operating parameters of their processes are being met. With any monitoring equipment, the establishment should take the normal variation of the monitoring equipment into account when designing the critical limits. 30 Relative humidity is not addressed because moisture is inherently maintained around the product due to cooking in a sealed, moisture impermeable bag. 31 Establishments may also determine during the initial validation period that the worst-case scenario is the largest roast regardless of location in the oven. In that case, establishments may choose to monitor the internal temperature in the largest roast rather than a roast in the coldest spot in the oven. 32 See Revised Appendix A guidance on corrective actions to perform when a cooking deviation occurs (page 66). Page 12 of 13, "EXAMPLE ROAST BEEF HACCP PLAN Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 2 Chilling Clostridium perfringens and Clostridium botulinum Chill product from 130°F to 80°F in 1.5 hours or less. Chill product from 80°F to 40°F in 5 hours or less. 33 Internal product temperature and time. Designee sets up continuous monitoring device. Designee places product temperature probe in center of largest piece in the batch and held in the cooler's warmest spot. Designee will review records from continuous monitoring device at completion of chilling cycle to determine the critical limits are met. 34 Each batch (lot) Designee If a deviation from the critical limit occurs, the supervisor will:

1. Hold all product produced since the last acceptable check until appropriate disposition taken (no product injurious to health enters commerce);
2. Determine and eliminate the cause of the deviation;
3. Bring the CCP under control;
4. Take measures to prevent recurrence.

9 CFR 417.3 Once per week, a manager will observe the designee setting up the continuous monitoring device. Once per week, a manager will observe the designee placing the product temperature probe in center of largest piece in the batch and held in the cooler's warmest spot. Once per week, a manager or designee will observe the designee reviewing records from continuous monitoring device. Once per week, a manager or designee calibrates product thermometers per manufacturer's instructions. Once per week a manager or designee will review all records maintained. Roast Beef Chilling Log from computerized continuous monitoring device 36 Thermometer Calibration Log Direct Observation Log Records Review Log Corrective Action Log DATE: \_\_\_\_\_

APPROVED: \_\_\_\_\_ 33 The chilling critical limits used in this plan are Option 1.1 found in the FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B) (page 50). See Appendix B for additional guidance on implementing this safe harbor. Appendix B also contains additional validated chilling time and temperature stabilization methods. For general guidance on establishing critical limits see the Guidebook for the Preparation of HACCP plans (page 27). 34 Establishments may determine during the initial validation period that the worst-case scenario is the largest roast regardless of location in the cooler. In that case, establishments may choose to monitor the internal

temperature of the largest roast rather than a roast in the warmest spot in the cooler. 35 See Revised Appendix B guidance on corrective actions to perform when a cooling deviation occurs (page 71). 36 The Roast Beef Temperature Cooking and Chilling recordkeeping logs must include monitoring the interim steps for cooling (for this example: record the time required for the product to drop from 130°F to 80°F, and the time required for the product temperature to drop from 80°F to 40°F). Page 13 of

13"]}, {"file\_name": "FSIS\_GD\_2022\_0003", "title": "Self-Reporting Tool (v2022-001)", "num": "FSIS-GD-2022-0003", "id": "d4827534ed64293053c814624ab7d972bfe987b6e7a6e7fe4dc06a9817b7e395", "co\_rpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2022-03/Self-Reporting-Tool\_v2022-001.pdf", "type": "pdf", "n\_pages": 27, "word\_count": 14936, "text\_by\_page": ["Self-Reporting Tool (SRT; v2022-001) Self-Reporting Tool To be eligible to export meat, poultry, or egg products to the United States, countries must maintain inspection systems that achieve an equivalent level of public health protection to FSIS\u2019 inspection system. The Codex standard Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003) defines equivalence as \u201cthe state wherein sanitary measures applied in an exporting country, though different from the measures applied in an importing country, achieve, as demonstrated by the exporting country, the importing country\u2019s appropriate level of sanitary protection.\u201d This definition is consistent with the principle of equivalence as provided in the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization. Furthermore, the definition of sanitary measure in the Codex standard includes \u201call relevant laws, decrees, regulations, requirements, and procedures.\u201d Therefore, a country that wishes to export meat, poultry and egg products to the United States must provide objective data that the country\u2019s laws, regulations, requirements, and procedures provide a level of public health protection equivalent to the FSIS inspection system. If the exporting country does not have this objective data, FSIS would consider implementation of U.S. sanitary measures as a reasonable alternative to assure the eligibility of products for export to the United States. To determine whether a country\u2019s documented food safety inspection system achieves an appropriate level of public health protection, FSIS assesses the Self-Reporting Tool (SRT) responses and supporting documentation provided by the country\u2019s national government authority responsible for ensuring the safety, wholesomeness, and accurate labeling of meat, poultry, and egg products (i.e., the Central Competent Authority (CCA)). The SRT questions are based on regulatory-focused food safety objectives and reflect the equivalence criteria used by FSIS to determine whether a country\u2019s documented food safety inspection system is equivalent to the FSIS inspection system. The SRT is designed for countries that want to export the following products to the United States: meat (including beef, veal, pork, sheep including lamb and mutton, goat, and Siluriformes fish); poultry (including chickens, turkeys, ducks, geese, guineas, squabs, emu, rhea, and ostrich); or egg products (i.e., dried, frozen, or liquid eggs, with or without added ingredients). The SRT questions are arranged into six (6) components: 1. Government Oversight (e.g., Organization and Administration, Enforcement Authority, Government Inspection Personnel\u2013Training/Staffing) 2. Government Verification of Food Safety and Other

Consumer Protection Requirements (e.g., Humane Handling, Ante-mortem Inspection, Post-mortem Inspection, Product Standards and Labeling) 3. Government Sanitation Verification 4. Government Hazard Analysis and Critical Control Point (HACCP) System Verification 5. Government Chemical Residue Program 6. Government Microbiological Pathogen and Process Control Programs For FSIS to determine equivalence, the CCA must provide complete responses to all SRT questions applicable to its food safety inspection system governing the meat, poultry, or egg products the country intends to export to the United States. Complete responses include a narrative, accompanied by supporting documentation, describing how the country's food safety inspection system is implemented. In addition, SRT responses need to cite where in the supporting documentation the information can be found. For example, answers should include the page number, section number, or chapter from the relevant supporting documentation. Types of supporting documentation the CCA should provide include, but are not limited to, the following: a. Food safety and inspection laws and legislation; b. Regulations, policies, standards, decisions, annexes, and decrees; c. Inspection procedures, manuals, and directives; d. Control programs; e. Inspection training programs; f. Mechanisms for documenting compliance/noncompliance; g. Enforcement and compliance programs; and h. Government chemical residue and microbiological sampling and testing programs, and test results.", "Self-Reporting Tool (SRT; v2022-001) The following chart identifies which SRT questions the CCA needs to provide answers and supporting documentation for based on the specific products the country is eligible to export or interested in exporting to the United States. To view which products your country is currently eligible to export to the United States, refer to FSIS Import & Export Library. For more information on product categorization, refer to the FSIS Product Categorization (Import) guide. Products SRT Question Numbers Standard SRT questions to be answered for all products 1, 2, 3, 4, 5, 6, 7, 9, 13, 14, 15, 16, 18, 23, 24, 25, 26, 34 Raw-Intact and Raw-Non Intact Beef and Veal 10, 11, 12, 17, 22, 27, 28, 29 Raw-Intact and Raw-Non Intact Pork 10, 11, 12, 22, 27, 28 Raw-Intact and Raw-Non Intact Lamb, Mutton, or Goat 10, 11, 12, 17, 22, 27, 28 Raw-Intact and Raw-Non Intact Poultry and Ratites 10, 11, 12, 22, 27, 28 Raw-Intact and Raw-Non Intact Siluriformes Fish 20, 21 Thermally Processed/Commercially Sterile Meat and Poultry Products 33 Not Heat Treated-Shelf Stable Meat and Poultry Products 30, 31, 32 Heat Treated-Shelf Stable Meat and Poultry Products 30, 31, 32 Fully Cooked-Not Shelf Stable Meat and Poultry Products 30 Heat Treated-Not Fully Cooked-Not Shelf Stable Meat and Poultry Products 32 Product with Secondary Inhibitors-Not Shelf Stable Meat and Poultry Products 30, 32 Egg Products 30 The SRT provides bulleted guidance under each SRT question to aid CCAs in providing complete SRT responses that adequately demonstrate that the country's documented food safety inspection system achieves an equivalent level of public health protection to the U.S. inspection system. The bulleted information is not intended to be prescriptive in nature but rather guidance to foreign countries on the type of information CCAs should include in their responses to each individual SRT question. When responding to SRT questions, the CCA can provide responses that demonstrate that the CCA implements regulations and procedures consistent with FSIS regulations and procedures or implements alternative measures that achieve an equivalent level of public health protection. Submission of the SRT To submit the SRT and supporting documentation, the CCA can either upload the information into FSIS' webbased Public Health Information System (PHIS), or submit the SRT, including supporting documentation, to

the FSIS Office of International Coordination through e-mail at internationalcoordination@usda.gov or regular mail (1400 Independence Avenue SW, Room 3143-South Building, Washington, DC 20250). FSIS uploads and maintains all SRT answers and supporting documentation in PHIS. It is important for countries to verify the accuracy and completeness of the English translated documents in PHIS because FSIS uses the English translated version of the SRT answers and supporting documentation in PHIS when making equivalence determinations. If issues are identified during FSIS\u2019 review of the country\u2019s submitted SRT answers and supporting documentation, FSIS will send the CCA requests for information and may propose a technical call between FSIS and the CCA. Ongoing Equivalence Verification No later than May 18th of each year, the CCAs of countries wishing to maintain ongoing equivalence and 2", "Self-Reporting Tool (SRT; v2022-001) continue exporting meat, poultry, or egg products to the United States must either provide updated SRT answers, or communicate to FSIS that the SRT answers in PHIS are accurate and complete by providing an answer to SRT Question 34. Also, no later than May 18th of each year, the CCA should verify in PHIS whether the translated documents were translated correctly into English by providing an answer in SRT Question 34. Updates to the SRT are expected whenever the CCA makes changes to its food safety inspection system, including changes implemented because of new or revised FSIS policies, or in response to FSIS requests for information. In addition, the CCA must provide the following no later than May 18th of each year: 1. An up-to-date list of all certified establishments eligible to export to the United States. \u2022 For more information on how to complete and submit an up-to-date list of all establishments used in the production of products eligible to export to the United States, refer to FSIS Guidance for a Suggested Reporting Table for the Certified Establishment List. 2. An updated official government chemical residue sampling and testing program, including the previous year\u2019s chemical residue test results. \u2022 For more information on how to submit annual official government chemical residue sampling and testing plans and results and for an example of the information FSIS needs to evaluate foreign official government chemical residue sampling programs, refer to guidance documents on the Equivalence page of the FSIS website under \u201cAdditional Resources.\u201d 3. An updated official government microbiological sampling and testing program, including the previous year\u2019s test results for the following: (A) Salmonella and Campylobacter in raw meat and poultry products; (B) Listeria monocytogenes (Lm) and Salmonella in ready-to-eat (RTE) meat, poultry, and egg products; (C) food contact surfaces for Lm in certified establishments that produce post-lethality exposed RTE meat and poultry products; and (D) Shiga toxin-producing Escherichia coli (STEC) in raw beef products. NOTE: The CCA should provide indicator organism results for intestinal or fecal contamination if the official government sampling and testing program includes monitoring for indicator organisms. \u2022 For more information on how to submit annual official government microbiological sampling and testing plans and results and for an example of the information FSIS needs to evaluate foreign official microbiological sampling programs, refer to guidance documents on the Equivalence page of the FSIS website under \u201cAdditional Resources.\u201d Annually, FSIS will notify the CCAs of countries wishing to maintain ongoing equivalence and continue exporting meat, poultry, or egg products to the United States of the following: issues identified during our review of the SRT and official government microbiological and chemical residue sampling and testing programs; a summary of the previous year\u2019s point-of-entry (POE)

results; and any new FSIS policies that CCAs need to address, or information that CCAs need to include, as part of their annual update by May 18th of the following year. Additionally, at this time, FSIS will also inform CCAs which process categories, product categories, and product groups of meat, poultry, or egg products their country is eligible to export to the United States.

3", "Self-Reporting Tool (SRT; v2022-001) Component 1 Government Oversight

1. How does the CCA ensure that the laws and regulations governing meat (including beef, veal, pork, sheep, goat, and Siluriformes fish); poultry (including chickens, turkeys, ducks, geese, guineas, squabs, emu, rhea, and ostrich); and egg products inspection are enforced? To respond to this question sufficiently, the CCA must:
  - \u2022 Describe the legal framework that gives the CCA the authority and ability to administer the inspection system. Include the name of the CCA and a brief explanation of the CCA\u2019s organizational structure.
  - \u2022 Provide an organizational chart and a description of how to trace the linkage of authority from the CCA to local government inspection personnel.
  - \u2022 Describe the CCA\u2019s authority and responsibility to enforce the laws and regulations governing meat, poultry, and egg products inspection. In addition, describe the CCA\u2019s authority to require corrective actions in certified establishments and to take additional enforcement measures as appropriate.
    - o Include supporting documentation demonstrating that the CCA has an effective enforcement program that requires that certified establishments perform the following: take action to prevent product contamination, take corrective actions when insanitary conditions or contaminated products are found, and take effective preventive measures after instances of noncompliance.
    - o Include how (i.e., actions taken) and under what circumstances the CCA implements additional enforcement measures in certified establishments (e.g., withdrawal of inspection for failure to maintain a HACCP plan).
2. How does the CCA ensure that no meat, poultry, or egg products intended for export to the United States are adulterated or misbranded (i.e., properly labeled and packaged), and only eligible meat, poultry, and egg products are certified for export to the United States? To respond to this question sufficiently, the CCA must:
  - \u2022 Describe the CCA\u2019s legal authority and responsibility to ensure that adulterated or misbranded product is not prepared for export to the United States.
  - o Define adulterated and misbranded as it relates to meat, poultry, and egg products (i.e., statutory or regulatory definition).
  - o Describe how the CCA identifies misbranded or adulterated products and provide information on the enforcement activities the CCA takes when it identifies adulterated or misbranded product.
  - \u2022 Describe the CCA\u2019s authority and inspection procedures for certifying meat, poultry, or egg products for export to the United States, including evidence of a certificate procedure to meet U.S. import requirements. Furthermore, identify which type of government inspection personnel (i.e., government inspector, licensee, or contract employee)<sup>1</sup> is performing export certification procedures for product intended for export to the United States, including signing the export certificate.
  - Lastly, describe how the CCA maintains control over export certificates, stamps, and seals.
  - \u2022 Describe how and at what frequency government inspection personnel are verifying during export certification that adulterated or misbranded product is not being exported to the United States.
  - \u2022 Describe how and at what frequency government inspection personnel review and confirm acceptable testing results from all samples of products (i.e., establishment testing and government verification testing) tested for adulterants as defined by FSIS prior to signing the export certificate.

NOTE: This applies to confirmation of acceptable testing results for the following sampled products:

raw non-intact beef product or raw intact beef product intended for raw non-intact use (or where intended use is unknown) that is tested for STEC; RTE meat, poultry, and egg products tested for Lm or Salmonella, or STEC (relative to RTE beef products); RTE product that passed over food contact 1 For definitions of these terms, please refer to SRT Question 5. 4", "Self-Reporting Tool (SRT; v2022-001) surfaces that have been tested for the presence of Lm or Salmonella; and livestock carcasses and parts subjected to both routine and suspect chemical residue testing for veterinary drugs, pesticides, and environmental contaminants. \u2022 Describe the CCA\u2019s authority to recall adulterated or misbranded product. Identify whether recalls of adulterated or misbranded product are carried out by the CCA or the establishment, and identify whether the CCA maintains the authority and ability to take action if the recall is ineffective (e.g., the authority to seize product). \u2022 Describe whether recalls are carried out on adulterated or misbranded product in the distribution phase or in commerce. Additionally, describe whether the CCA requires certified establishments to notify the CCA of the production of or shipment of adulterated products within a certain time (e.g., within 24-hours). Furthermore, in the event adulterated or misbranded products are shipped to the United States, describe the CCA\u2019s procedures for informing FSIS and include a timeframe of when FSIS will be notified. 3. How does the CCA ensure that source meat, poultry, or egg products used in processing operations originate from certified establishments in countries that the United States has determined have an equivalent meat, poultry, or egg products inspection system (i.e., eligible countries)? NOTE: Source is defined as materials that originate from a certified establishment in an eligible country. To respond to this question sufficiently, the CCA must: \u2022 Describe how and at what frequency government inspection personnel verify source materials originate from a certified establishment in a country eligible to ship meat, poultry, or egg products to the United States. \u2022 Identify the source country for shell eggs used to produce egg products for export to the United States. In addition, describe the CCA\u2019s requirements for the quality and appearance of shell eggs used to produce egg products for export to the United States. 4. How does the CCA ensure that the same set of laws, regulations, and policies are applied consistently to all establishments certified to export meat, poultry, or egg products to the United States? NOTE: By May 18th of each year, the CCAs of countries wishing to maintain ongoing equivalence and continue actively exporting meat, poultry, or egg products to the United States are required to provide FSIS an up-to-date list of all certified establishments used to produce or export products to the United States. Therefore, if the production chain involves more than one establishment (e.g., beef is slaughtered at one establishment, further processed at a different establishment, packaged and labeled at yet another establishment, and then exported to the United States from a different establishment), each establishment in the production chain, including the storage facility from where the product is exported, must be listed on the certified establishment list. Furthermore, countries that are not eligible to export raw product directly to the United States (e.g., due to animal disease restrictions), but are eligible to use their own raw source materials for further processing are required to certify and list the establishments providing the raw source materials. NOTE: FSIS requests that the CCA inform FSIS of any establishment delistment within 90 days. \u2022 For more information on how to complete and submit an up-to-date list of all establishments used in the production of products eligible for export to the United States, refer to FSIS Guidance for a Suggested Reporting Table for the Certified Establishment List. NOTE: A

certified establishment is an establishment that the CCA determines as meeting U.S. requirements and, therefore, eligible to export meat, poultry, or egg products to the United States. NOTE: A decertified establishment is an establishment that the CCA determines as not meeting U.S. requirements and, therefore, not eligible to export meat, poultry, or egg products to the United States. NOTE: A source establishment is an establishment that provides raw materials to certified establishments for the production of processed products intended for export to the United States. Product from establishments that are not eligible to export product directly to the United States due to disease restrictions, regionalization, product ineligibility, or other reasons may be able to be used as a source 5", "Self-Reporting Tool (SRT; v2022-001) establishment for processed products (e.g., when product will be fully cooked to destroy causative agents related to restricted animal diseases). However, source establishments must meet all U.S. requirements, be from an equivalent country, be certified by the CCA, and be identified as a source establishment on the certified establishment list. To respond to this question sufficiently, the CCA must: \u2022 Describe how and at what frequency CCA supervisory personnel verify that certified establishments meet U.S. requirements. \u2022 Describe the processes that the CCA follows to certify establishments as meeting U.S. requirements, and to decertify establishments that no longer meet U.S. requirements. \u2022 Describe how and at what frequency the CCA disseminates information regarding U.S. requirements from headquarters to government inspection personnel and certified establishments, including how the CCA communicates any changes to U.S. requirements in a timely manner. Further, describe how the CCA remains aware of FSIS requirements as they change over time.

5. How does the CCA ensure that government inspection personnel assigned to certified establishments exporting meat, poultry, or egg products to the United States are employees of and paid by the government? NOTE: The term \u201cgovernment inspection personnel\u201d (referenced throughout this SRT) refers to inspectors meeting the criteria in a, b, or c. When responding to this SRT question, use the terms and definitions below to identify the type of government inspection personnel used in your country\u2019s certified establishments when producing product for export to the United States.

a. Government Inspector: A government inspector is a permanent or intermittent employee of the CCA of a foreign government, eligible to perform all applicable inspection duties, including: \u2022 ante-mortem inspection of livestock and poultry; \u2022 post-mortem inspection of every livestock carcass, head, and viscera and every poultry carcass and viscera; 2 \u2022 sanitation and HACCP verification activities in all meat, poultry, and egg product establishments; \u2022 export verification activities; and \u2022 official government verification sample collection activities in meat, poultry, and egg product establishments. NOTE: FSIS would recognize as government inspectors those inspectors that work for another part of the foreign government outside the CCA, but under delegated authority from the CCA, provided the CCA has authority and oversight over the inspection.

b. Licensee (Limited Government Inspector): An inspector employed under individual contract by the government and who is eligible to perform all applicable inspection duties, including: \u2022 ante-mortem inspection of livestock and poultry; \u2022 post-mortem inspection of every livestock carcass, head, and viscera and every poultry carcass and viscera; \u2022 sanitation and HACCP verification activities in all meat, poultry, and egg product establishments; 2 Under alternative poultry inspection systems, similar to FSIS\u2019 New Poultry Inspection System (NPIS), the government inspection

personnels\u2019 visual inspection of each carcass also serves as the inspection of the viscera if the inspector\u2019s condemnation of a carcass also requires condemnation of the corresponding viscera. For countries that implement an alternative poultry inspection system, provide a response that describes the requirements and procedures of your alternative poultry inspection system under Question 12. 6", "Self-Reporting Tool (SRT; v2022-001) \u2022 export verification activities; and \u2022 official government verification sample collection activities in meat, poultry, and egg product establishments. NOTE: Typically in this situation, the licensee (limited government inspector) is under direct supervision of the government, meaning that a government inspector is on the premises while licensees (limited government inspectors) are performing inspection duties (other than official government verification sample collection activities) for product intended for export to the United States continuously throughout slaughter operations and at least once per shift during processing (i.e., non-slaughter) operations and are ensuring licensees are effectively performing inspection duties. Typically, criterion b is not equivalent when a limited government inspector performs inspection activities (other than official government verification sample collection activities) without direct supervision from an onsite government inspector continuously during slaughter operations and at least once per shift during processing operations. c. Contract Employee (Private Contractor): An employee employed by a third-party organization contracted to conduct inspection activities on behalf of the government. The operator is authorized by the government to perform all applicable inspection duties, including: \u2022 ante-mortem inspection of livestock and poultry; \u2022 post-mortem inspection of every livestock carcass, head, and viscera and every poultry carcass and viscera; \u2022 sanitation and HACCP verification activities in all meat, poultry, and egg product establishments; \u2022 export verification activities; and \u2022 official government verification sample collection activities in meat, poultry, and egg product establishments. NOTE: Typically in this situation, the contract employee (private contractor) is under direct supervision of the government, meaning that a government inspector is on the premises while contract employees are performing inspection duties (other than official government verification sample collection activities) for product intended for export to the United States continuously during slaughter operations and at least once per shift during processing (i.e., non-slaughter) operations, and are ensuring contract employees are effectively performing inspection duties. Typically, criterion c is not equivalent when a contract employee performs inspection activities (other than official government verification sample collection activities) without direct supervision from an onsite government inspector continuously during slaughter operations and at least once per shift during processing operations. To respond to this question sufficiently, the CCA must: \u2022 Identify which criterion (or criteria) above applies to the government inspection personnel provided for meat, poultry, or egg products intended for export to the United States. o For countries utilizing licensees or contract employees, describe how and at what frequency the CCA ensures that inspection activities (other than official government verification sample collection activities) are being conducted under the direct authority of a government agency when producing product for export to the United States \u2022 Describe how all government inspection personnel are paid. This may include direct or indirect payment by the government, such as payment through a third party. \u2022 Describe the CCA\u2019s conflict-of-interest controls to ensure that government inspection personnel act in the public\u2019s interest. 7", "Self-Reporting Tool (SRT; v2022-001)

6. How does the CCA ensure that government inspection occurs continuously during slaughter operations, and at least once per production shift during the processing of meat, poultry, or egg products intended for export to the United States? NOTE: Processing operations include all non-slaughter activities, including but not limited to, boning, cutting, slicing, grinding, injecting, pumping, filleting, breading, adding ingredients through other mechanical means, formulating, assembling, packaging, and labeling meat or poultry food products. For egg products, processing operations include the manufacturing of egg products, including but not limited to, breaking eggs, filtering, blending, mixing, pasteurizing, stabilizing, storing, cooling, freezing, drying, packaging, labeling, and final product examination. NOTE: In slaughter operations, FSIS requires continuous government inspection during slaughter activities to ensure that every livestock carcass, head, and viscera and every poultry carcass and viscera<sup>3</sup> are inspected. NOTE: In processing operations (i.e., non-slaughter), FSIS typically requires that government inspection personnel (i.e., government inspector, licensee, or contract employee) be on the premises and performing inspection activities at least once per production shift during processing operations. The requirement for government inspection once per production shift during processing operations is not the same as inspection once daily. In processing establishments, if an establishment has more than one production shift per day during which it produces product for export to the United States, typically government inspection personnel (i.e., government inspector, licensee, or contract employee) must be present at least once during each production shift. To respond to this question sufficiently, the CCA must: \u2022 Describe how the CCA ensures that there will be enough qualified government inspection personnel to provide inspection coverage at each of the certified establishments continuously during slaughter operations, and at least once per production shift during processing operations when producing meat, poultry, or egg products for export to the United States, including during planned or unplanned government inspection personnel absences.

7. How does the CCA ensure that government inspection personnel have appropriate educational credentials, disciplinary backgrounds, and training to carry out their inspection tasks? To respond to this question sufficiently, the CCA must:

\u2022 Describe the minimum qualifications for government inspection personnel (e.g., educational credentials, training, and experience requirements), including whether official veterinarians in certified establishments are required to possess a Doctor of Veterinary Medicine or equivalent degree.

\u2022 Describe how and at what frequency government inspection personnel are trained on requirements consistent with U.S. requirements.

8. RESERVED

9. How does the CCA ensure adequate oversight of laboratories that perform analyses for official government sampling and testing programs for meat, poultry, or egg products that are exported to the United States, including oversight to ensure that laboratories conducting official government analyses comply with the general quality assurance and control criteria provided in International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 17025? NOTE: The CCA must provide information for laboratories that perform analyses for the official government chemical residue and the official government microbiological sampling and testing programs.

3 See footnote 2 8", "Self-Reporting Tool (SRT; v2022-001)

To respond to this question sufficiently, the CCA must:

\u2022 Describe the CCA\u2019s oversight of laboratories responsible for analyzing official government samples, including whether the CCA has the legal authority and responsibility to approve and disapprove laboratories conducting testing of official government

samples of product destined for the United States. \u2022 Provide a list of laboratories that perform official government chemical residue or microbiological analyses. Identify whether laboratories conducting official government analyses are official government laboratories or third-party laboratories (e.g., international (foreign), private, or establishment laboratories) and which type of analyses are performed at each laboratory (i.e., chemical residue or microbiological). If a third-party laboratory is used, briefly describe the interaction and oversight by the government. Include documentation demonstrating that the third-party laboratory reports test results directly to the government, as well as documentation demonstrating the degree of oversight by the government, such as annual audits, to ensure laboratory procedures are followed in accordance with ISO\IEC 17025 standards. \u2022 Describe the CCA\u2019s requirements for ensuring that official laboratories implement procedures consistent with ISO\IEC 17025 standards.

- o If official laboratories are required to be accredited to ISO\IEC 17025 standards, provide accreditation certificates and scopes of accreditation for all official laboratories. \u2022 Describe the CCA\u2019s requirements for ensuring that laboratory personnel are properly trained in the chemical residue and microbiological analyses performed (ISO\IEC 17025:2017(E), Section 6.2).
- o Indicate whether official laboratories are required to monitor laboratory performance through proficiency testing or other interlaboratory comparisons (ISO\IEC 17025:2017(E), Section 7.7). \u2022 If the laboratory is not ISO-accredited, describe how laboratory management and technical requirements comply with ISO\IEC 17025 standards including the following:

- o Sample handling after collection and during transport to official laboratories;
- o Sample receipt and storage prior to analyses at the laboratory;
- o Calibration and maintenance of laboratory equipment necessary for chemical residue and microbiological analyses (ISO\IEC 17025:2017(E), Section 6.4);
- o Internal quality control parameters, including positive and negative assay controls where appropriate, to assure the quality of the results for the analyses performed (ISO\IEC 17025:2017(E), Section 7.7); and
- o Reporting and recordkeeping capabilities that can clearly track and link a test result to the correct establishment, including traceability from sample collection, to receipt by the laboratory, through reporting back to the CCA (ISO\IEC 17025:2017(E), Sections 7.5 and 8.4).

\u2022 Describe how official government test results are reported directly from the laboratory performing the analysis to the CCA in a timely manner. In addition, describe how the CCA notifies establishments when official government test results are found positive for microbiological pathogens or violative for chemical residues. \u2022 Describe how the CCA ensures that samples with violative or unacceptable test results are not resampled or retested.

Component 2 Government Verification of Food Safety and Other Consumer Protection Requirements 10. How does the CCA ensure that animals are handled and slaughtered humanely? To respond to this question sufficiently, the CCA must:

- \u2022 Identify and describe the CCA\u2019s laws and regulations requiring that livestock and poultry are handled and slaughtered humanely.
- \u2022 Describe how and at what frequency government inspection personnel verify that livestock and poultry are handled and slaughtered humanely, including how livestock are rendered insensible to pain (e.g., 9", "Self-Reporting Tool (SRT; v2022-001) stunning by captive bolt, gunshot) prior to shackling, hoisting, and cutting the animal and how and at what frequency government inspection personnel verify that birds are thoroughly bled and not breathing prior to entering the scalding.
- \u2022 Describe the enforcement actions the CCA takes when certified establishments do not comply with humane

handling and slaughter requirements. \u2022 Describe how and at what frequency the CCA verifies that certified establishments take effective corrective actions after instances of noncompliance.

11. How does the CCA ensure that government inspection personnel perform ante-mortem inspection of livestock and poultry prior to slaughter? To respond to this question sufficiently, the CCA must:

- \u2022 Identify and describe the CCA\u2019s laws and regulations for ante-mortem inspection of livestock and poultry.
- \u2022 Identify which type of government inspection personnel (i.e., government veterinarian, government inspector, licensee, or contract employee) is performing ante-mortem inspection of livestock and poultry in certified establishments, and how and at what frequency government inspection personnel verify antemortem requirements are met. Furthermore, identify whether a government veterinarian oversees antemortem verification activities.
- \u2022 Identify which ante-mortem disease conditions are condemnable.
- \u2022 Describe how and at what frequency government inspection personnel verify that dead, dying, and diseased animals, or non-ambulatory disabled cattle (including calves), are condemned and not used to manufacture meat and poultry products eligible for export to the United States.
- \u2022 Describe how and at what frequency government inspection personnel verify that cattle displaying clinical signs of central nervous system disorders or bovine spongiform encephalopathy (BSE) are condemned and not used to manufacture meat products eligible for export to the United States.

\u2022 For swine, identify whether the CCA utilizes an alternative swine slaughter inspection system similar to FSIS\u2019 New Swine Slaughter Inspection System (NSIS). If using an alternative swine slaughter inspection system, describe how and at what frequency government inspection personnel verify that certified establishments:

- o Sort fit from unfit animals prior to government ante-mortem inspection;
- o Dispose of carcasses and parts with condemnable conditions;
- o Identify animals or carcasses, that they have sorted and removed for disposal before government inspection, with a unique tag, tattoo, or similar device; and
- o Maintain records documenting the total number of animals and carcasses sorted and removed per day and the reasons for their removal.

12. How does the CCA ensure that government inspection personnel perform post-mortem inspection of every livestock carcass, head, and viscera and every poultry carcass and viscera during and after the slaughter of livestock and poultry? NOTE: In this SRT question, the term \u201con-line\u201d refers to government inspection personnel working on the production line and performing post-mortem inspection procedures on every livestock carcass, head, and viscera and every poultry carcass and viscera.<sup>4</sup> The term \u201coff-line\u201d refers to government inspection personnel performing verification activities throughout the establishment (e.g., HACCP, sanitation, zero tolerance). Off-line government inspection personnel do not remain on the production line performing inspection activities throughout the day. Off-line government inspection personnel are also referenced in SRT Question 22. To respond to this question sufficiently, the CCA must:

- 4 See footnote 2 10", "Self-Reporting Tool (SRT; v2022-001)
- \u2022 Identify and describe the CCA\u2019s laws and regulations for post-mortem inspection of every livestock carcass, head, and viscera and every poultry carcass and viscera<sup>5</sup> at the time of slaughter. Furthermore, identify which type of government inspection personnel (i.e., government inspector, licensee, or contract employee) is performing post-mortem inspection of livestock and poultry in certified establishments.
- \u2022 For livestock, describe how on-line government inspection personnel perform post-mortem inspection of every livestock carcass, head, and viscera and the point in the slaughter process where

government inspection personnel examine each carcass, head, and viscera. Include how on-line government inspection personnel perform post-mortem inspection activities to ensure that every livestock carcass, head, and viscera are free of visible fecal material, ingesta, and milk; and the actions taken when on-line government inspection personnel observe contamination (fecal, ingesta, or milk) on livestock carcasses, heads, or viscera. \u2022 For poultry, describe how on-line government inspection personnel perform post-mortem inspection of every poultry carcass and viscera.<sup>6</sup> Describe how on-line government inspection personnel verify that poultry carcasses with visible fecal contamination do not enter the chiller; and the actions taken when online government inspection personnel observe fecal contamination on poultry carcasses. \u2022 For poultry, identify whether the CCA utilizes an alternative poultry slaughter inspection system similar to FSIS\u2019 New Poultry Inspection System (NPIS). If using an alternative poultry slaughter inspection system, describe how and at what frequency government inspection personnel verify that certified establishments 1) conduct carcass and viscera sorting activities, 2) dispose of carcasses and parts with condemnable conditions, and 3) perform appropriate trimming and reprocessing tasks before carcasses are presented for government inspection. \u2022 For swine, identify whether the CCA utilizes an alternative swine slaughter inspection system similar to FSIS\u2019 New Swine Slaughter Inspection System (NSIS). If using an alternative swine slaughter inspection system, describe how and at what frequency government inspection personnel verify that certified establishments 1) prepare carcasses and parts for government post-mortem inspection (e.g., incise mandibular lymph nodes and palpate the viscera to detect the presence of animal diseases (e.g., *Mycobacterium avium*); and 2) maintain records documenting that products resulting from their slaughter operations meet the new definition of ready-to-cook (RTC) pork product, which is any slaughtered pork product sufficiently free from bile, hair, scurf, dirt, hooves, toenails, claws, bruises, edema, scabs, skin lesions, icterus, foreign material, and odor that is suitable for cooking without need of further processing. \u2022 Identify which post-mortem disease conditions are condemnable. In addition, describe how and at what frequency government inspection personnel verify the proper disposition of livestock and poultry identified with these conditions. \u2022 Describe the maximum line speed rate and government staffing standards for on-line government inspection personnel in meat and poultry slaughter establishments.

13. How does the CCA ensure that a representative of the government inspection system makes periodic supervisory visits to each certified establishment to evaluate the performance of inspection personnel? To respond to this question sufficiently, the CCA must:

\u2022 Describe how and at what frequency the CCA evaluates the performance of government inspection personnel in certified establishments, including who (level of government) conducts the performance reviews of government inspection personnel.

\u2022 Identify the inspection topics evaluated during these supervisory review visits. These visits should include reviews of government inspection personnel\u2019s knowledge of U.S. import requirements and verification of the following: animal welfare, ante-mortem, post-mortem, Sanitation Standard Operating Procedure (Sanitation SOP) and sanitation performance standards (SPS), HACCP, labeling verification, export <sup>5</sup> See footnote 2 <sup>6</sup> See footnote 2 <sup>11</sup>,"Self-Reporting Tool (SRT; v2022-001) certification, import inspection to ensure source materials originate from certified establishments in eligible countries, separation from non-certified establishments, control over condemned materials, official government sample collection practices, and enforcement of U.S.

import requirements.

14. How does the CCA ensure complete separation of certified meat, poultry, or eggs products from noncertified meat, poultry, or egg products? NOTE: Any meat, poultry, or egg products intended to be exported to the United States cannot be produced in an establishment (or part of an establishment) that is not eligible to export to the United States.

NOTE: If a certified establishment also produces meat, poultry, or egg products not intended for export to the United States, the products not intended for export to the United States must be produced separately by either time or space. To respond to this question sufficiently, the CCA must:

\u2022 Describe how the CCA ensures that meat, poultry, or egg products intended for export to the United States are produced separately (by time or space) from products not intended for export to the United States.

\u2022 Describe how and at what frequency government inspection personnel verify the separation of eligible meat, poultry, and egg products from ineligible products.

15. How does the CCA ensure that meat, poultry, and egg products intended for export to the United States meet U.S. labeling requirements?

NOTE: For labels that require FSIS approval, applications can be submitted for FSIS approval electronically through FSIS\u2019 Label Submission and Approval System (LSAS), or by completing FSIS Form 7234-1, Application for Approval of Labels, Marking or Device, and then mailing the paper form. Mailing instructions are located under Label Application Guidance on the FSIS website. For more information on U.S. labeling requirements, please refer to FSIS Compliance Guidance for Label Approval and Check List for Mandatory Features on a Label.

To respond to this question sufficiently, the CCA must:

\u2022 Describe how and at what frequency government inspection personnel perform labeling verification activities to ensure that U.S. labeling requirements are met, and all labels are accurate and truthful (e.g., verification of accurate net weights and product formulation).

\u2022 Describe how and at what frequency government inspection personnel verify that all ingredients and processing aids used in the production of product intended for export to the United States are safe and suitable for the intended use.

\u2022 Describe how and at what frequency government inspection personnel perform verification activities to ensure that allergens are clearly controlled, identified, and labeled.

NOTE: FSIS recognizes the major food allergens designated by the U.S. Food and Drug Administration\u2019s (FDA) Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). These allergens include wheat; crustacean shellfish (e.g., crab, lobster, shrimp); eggs; fish; peanuts; milk; tree nuts (e.g., almonds, pecans, walnuts); and soybeans.

\u2022 Describe how and at what frequency government inspection personnel perform species verification activities (e.g., species verification testing or verification of product formulation).

\u2022 Describe how and at what frequency the CCA ensures that labels with special statements and claims (9 CFR 412.1(c)(3)) have been approved by FSIS before exporting products to the United States.

\u2022 Describe how the CCA ensures that meat and poultry products with a U.S. standard of identity are accurately labeled.

NOTE: For more information on the U.S. labeling requirements for standards of identity, please refer to 9 CFR 319 (meat products) and 9 CFR 381 Subpart P (poultry products), and to the FSIS Food 12", "Self-Reporting Tool (SRT; v2022-001) Standards and Labeling Policy Book.

\u2022 Describe the enforcement actions the CCA takes when certified establishments do not comply with labeling requirements.

16. How does the CCA ensure that meat, poultry, and egg products designated for export to the United States are not restricted by the USDA Animal and Plant Health Inspection Service (APHIS)?

To respond to this question sufficiently, the CCA must:

\u2022 Identify and describe any APHIS disease restrictions

for meat, poultry, or egg products that the country is currently exporting to the United States or intends to export to the United States. \u2022 Describe how the CCA is notified of updates or changes to APHIS restrictions, and how these changes are communicated to government inspection personnel in certified establishments. \u2022 Describe how government inspection personnel verify during the export certification process that APHISrestricted products are not shipped to the United States. 17. How does the CCA ensure that beef products are not contaminated with specified risk materials (SRMs) associatedwith bovine spongiform encephalopathy (BSE)? To respond to this question sufficiently, the CCA must: \u2022 Describe how the CCA defines SRMs, and identify the affected tissues. \u2022 Describe the CCA\u2019s requirements concerning the identification, removal, and disposal of SRMs. \u2022 Describe how and at what frequency government inspection personnel verify adequate identification, removal, and disposal of SRMs. 18. How does the CCA ensure control over condemned animals, which can include portions of inspected carcasses and parts, and inedible material, until destroyedor otherwise denatured? NOTE: Condemned means any animal carcass, part of an animal carcass, or animal-based product inspected and determined to be unfit for human food. NOTE: Inediblematerial includes animals condemned either at ante-mortem or post-mortem inspection, SRMs, diseased parts, tissues that are inedible by definition (e.g., tonsils and lungs), and inedible shell eggs and egg products. NOTE: The denaturing of meat, poultry, or egg products includes the addition of a chemical substance (e.g., charcoal or dye) to ensure that the products cannot be used for human food. To respond to this question sufficiently, the CCA must: \u2022 Identify and describe the CCA\u2019s laws and regulations for identifying, handling, and controlling inedible material to ensure that it is not used to manufacture meat, poultry, or egg products destined for export to the United States. \u2022 Describe how and at what frequency government inspection personnel verify that condemned and inedible material is destroyed or denatured before leaving the establishment. 19. RESERVED Component 3 Government Sanitation Verification 20. How does the CCA ensure that Siluriformes fish are raised and transported under sanitary conditions? To respond to this question sufficiently, the CCA must: 13", "Self-Reporting Tool (SRT; v2022-001) \u2022 Describe how and at what frequency the CCA verifies that Siluriformes fish intended for export to the United States are raised in a sanitary manner. Include how the CCA ensures that Siluriformes fish do not grow or live under conditions that would render the fish unsound, unwholesome, unhealthful, or otherwise inedible (e.g., pre-harvest standards). \u2022 Identify whether the CCA collects either routine or \u201cfor cause\u201d official government samples of feed, Siluriformes fish, or source water to verify that Siluriformes fish are being raised under sanitary conditions. Additionally, describe the official government sample collection procedures and sampling frequencies. If samples are not collected by the CCA (e.g., by producers or establishments), describe how and at what frequency the CCA ensures that samples are collected appropriately. Furthermore, if product sampling results indicate the conditions in which the fish were raised as the source of contamination, describe how the CCA ensures contaminated or adulterated Siluriformes fish is not used in the production of Siluriformes fish product for export to the United States. \u2022 Describe the CCA\u2019s requirements for ensuring that Siluriformes fish are transported from the point of harvest to the processing establishment in a sanitary manner, including requirements for the sanitation of containers used to transport Siluriformes fish to the establishments (e.g., a holding tank in a boat transporting live fish). \u2022 Describe

how and at what frequency the CCA verifies that Siluriformes fish are transported to the establishment in a sanitary manner. 21. How does the CCA ensure that Siluriformes fish that have died from circumstances other than under the controlled circumstances of commercial fishing are separated from eligible Siluriformes fish and fish products? To respond to this question sufficiently, the CCA must: \u2022 Describe the CCA\u2019s requirements to ensure separation between slaughtered Siluriformes fish and fish products and any fish that have died other than by slaughter. \u2022 Describe how and at what frequency government inspection personnel verify that establishments are properly identifying, sorting, and disposing of Siluriformes fish that have died from circumstances other than under the controlled circumstances of commercial fishing (e.g., dead Siluriformes fish that exhibit signs of spoilage or decomposition). 22. How does the CCA ensure that livestock and poultry are slaughtered and processed in a sanitary manner? To respond to this question sufficiently, the CCA must: \u2022 Describe the CCA\u2019s requirements for sanitary dressing of livestock and poultry throughout slaughter operations, include whether establishments are required to develop, implement, and maintain written procedures in their HACCP plans, Sanitation SOPs, or other prerequisite programs to prevent contamination of livestock carcasses and parts by enteric pathogens, fecal matter, ingesta, and milk; and poultry carcasses by enteric pathogens and fecal matter. NOTE: The term \u201csanitary dressing\u201d refers to the practice of handling carcasses by establishment employees and machinery, throughout the slaughter process, in a manner that produces a clean, safe, wholesome meat or poultry food product in a sanitary manner. \u2022 Describe how and at what frequency government inspection personnel perform sanitary dressing verification activities. \u2022 Describe how and at what frequency off-line government inspection personnel perform zero tolerance verification activities to ensure the following: livestock carcasses are free of visible fecal material, ingesta, and milk at or immediately after the final rail; head, cheek, and weasand meat are free of visible fecal material, ingesta, and milk at the end of the harvesting process (e.g., at the packaging step or when 14", "Self-Reporting Tool (SRT; v2022-001) the product is placed into a container for storage); and poultry carcasses are free of visible fecal material prior to entering the chiller. Include the point in the slaughter process where the off-line government zero tolerance verification activity is performed and the actions taken when government inspection personnel observe fecal material, ingesta, or milk on livestock carcasses, heads, or viscera; or fecal material on poultry carcasses or viscera. 23. How does the CCA ensure that the condition of certified establishments\u2019 construction, facilities, and equipment is adequate to prevent the contamination or adulteration of meat, poultry, or egg products designated for export to the United States? To respond to this question sufficiently, the CCA must: \u2022 Describe the CCA\u2019s requirements for certified establishments\u2019 construction, facilities, and equipment, including how and at what frequency government inspection personnel verify that conditions in certified establishments are sufficient to prevent product contamination or adulteration (e.g., pest management program; construction; separation of edible materials from inedible materials; employee hygiene; sanitation of equipment and utensils; adequate lighting, drainage, and ventilation; and water potability). \u2022 Describe the enforcement actions the CCA takes when certified establishments do not comply with the requirements. \u2022 Describe how and at what frequency the CCA verifies that certified establishments take effective corrective actions after instances of noncompliance. 24. How does the CCA ensure

that certified establishments develop, implement, and maintain daily preoperational and operational sanitation procedures sufficient to prevent the direct contamination or adulteration of meat, poultry, and egg products designated for export to the United States? To respond to this question sufficiently, the CCA must:

- \u2022 Describe the CCA\u2019s requirements for daily sanitation procedures sufficient to prevent direct contamination or adulteration of product, including how and at what frequency government inspection personnel verify that certified establishments develop, implement, and maintain daily pre-operational and operational sanitation procedures.
- \u2022 Identify which type of government inspection personnel (i.e., government inspector, licensee, or contract employee) is performing sanitation verification activities in certified establishments.
- \u2022 Describe the CCA\u2019s sanitation recordkeeping requirements, including a description of the records certified establishments are required to maintain to demonstrate adequate implementation of their sanitation procedures (e.g., sanitation monitoring records and corrective action records).

Furthermore, describe how and at what frequency government inspection personnel review sanitation records.

- \u2022 Describe the enforcement actions the CCA takes when certified establishments do not comply with the sanitation requirements.
- \u2022 Describe how and at what frequency the CCA verifies that certified establishments take effective corrective actions and preventive measures, as applicable, after instances of noncompliance to restore sanitary conditions.

Component 4 Government HACCP System Verification 25. How does the CCA ensure that certified establishments develop, implement, and maintain a HACCP system to ensure that food safety hazards are identified, and prevented or controlled when producing meat, poultry, or egg products for export to the United States? NOTE: For countries using HACCP to address microbiological food safety hazards when producing thermally processed\commercially sterile (TP\CS) meat and poultry products, discuss food safety controls 15", "Self-Reporting Tool (SRT; v2022-001) under this question. To respond to this question sufficiently, the CCA must:

- \u2022 Identify whether the CCA requires that each certified establishment develop, implement, and maintain a HACCP system which incorporates the seven principles of HACCP to identify, prevent, and control hazards.
  - o The seven principles of HACCP include: (1) conduct a hazard analysis; (2) identify critical control points; (3) establish critical limits for each critical control point; (4) establish critical control point monitoring requirements; (5) establish corrective actions; (6) establish record keeping procedures; and (7) establish procedures for verifying the HACCP system is working as intended.
- \u2022 Identify whether the CCA requires specific controls for relevant hazards to be incorporated in the HACCP plan as a critical control point (CCP), for example, requiring certified establishments to incorporate into their HACCP plan a post-lethality treatment used to reduce or eliminate Lm.
- \u2022 Identify whether the CCA requires certified establishments to identify and evaluate the food safety hazards that can affect the safety of their products, institute controls necessary to prevent those hazards from occurring or keep them within acceptable limits, monitor the performance of controls, and maintain records routinely.
- \u2022 Describe how and at what frequency the CCA verifies that certified establishments properly identify hazards reasonably likely to occur and develop CCPs.
- \u2022 Describe how the CCA requires and verifies that certified establishments maintain in-plant implementation data, and scientific or technical support to validate the adequacy of their HACCP systems in controlling the food safety hazards identified in the hazard analysis.
- \u2022 Describe how the CCA requires and verifies that certified establishments perform ongoing

verification activities (e.g., calibration of process monitoring equipment, direct observation of monitoring activities and corrective actions, and review of records) to ensure the adequacy of their HACCP systems. \u2022 Describe how and at what frequency the CCA conducts an ongoing review of HACCP plans and verifies the effectiveness of the HACCP plans. \u2022 Describe whether the CCA has the regulatory authority to require that certified establishments take corrective actions when a CCP does not control an identified hazard. Furthermore, describe the corrective action requirements when establishment monitoring or verification, or government verification, shows that a deviation has occurred (e.g., identify and eliminate the cause of the deviation, determine that the CCP is under control after taking corrective actions, establish measures to prevent recurrence, and ensure appropriate product disposition). \u2022 Describe how often certified establishments are required to reassess their HACCP plans and under what circumstances reassessment is required. \u2022 Describe the CCA\u2019s HACCP recordkeeping requirements, including a description of the records certified establishments are required to maintain to demonstrate adequate implementation of their HACCP systems. \u2022 Identify which type of government inspection personnel (i.e., government inspector, licensee, or contract employee) is performing HACCP verification activities in certified establishments. \u2022 Describe how and at what frequency government inspection personnel verify that certified establishments review records associated with the production of product for export to the United States to ensure that all HACCP requirements are met (e.g., all critical limits at all CCPs have been met, and any required corrective actions have been taken) prior to shipping the product into commerce (i.e., establishments conduct pre-shipment review). \u2022 Describe how and at what frequency government inspection personnel verify that certified establishments are receiving and confirming acceptable testing results from all samples (i.e., establishment testing and government verification testing) of products tested for adulterants as defined by FSIS prior to completing and signing the pre-shipment review record. NOTE: This applies to confirmation of acceptable testing results for the following sampled products: 16", "Self-Reporting Tool (SRT; v2022-001) raw non-intact beef product or raw intact beef product intended for raw non-intact use (or where intended use is unknown) that is tested for STEC; RTE meat, poultry, and egg products tested for Lm, Salmonella, or STEC (relative to RTE beef products); RTE product that passed over food contact surfaces that have been tested for the presence of Lm or Salmonella; and livestock carcasses and parts subjected to both routine and suspect chemical residue testing for veterinary drugs, pesticides, and environmental contaminants. \u2022 Describe how and at what frequency government inspection personnel perform HACCP verification activities in certified establishments (e.g., monitoring, verification, recordkeeping, corrective actions). \u2022 Describe the enforcement actions the CCA takes when certified establishments do not comply with the HACCP requirements. Component 5 Government Chemical Residue Program 26. How does the CCA ensure the implementation and maintenance of an official government chemical residue control program that prevents and controls all specific compounds of concern in the foreign country and in the United States? NOTE: The CCAs of countries wishing to maintain ongoing equivalence and continue actively exporting meat, poultry, or egg products to the United States must submit an updated official government chemical residue sampling and testing program, the previous year\u2019s residue test results, and the actions taken in response to violative findings by May 18th of each year. \u2022 For more information on how to submit annual official government chemical residue

sampling and testing plans and results and for an example of the information FSIS needs to evaluate foreign official government chemical residue sampling programs, refer to guidance documents on the Equivalence page of the FSIS website under \u201cAdditional Resources.\u201d To respond to this question sufficiently, the CCA must: \u2022 Identify and describe the CCA\u2019s official government chemical residue sampling program. Include the following: o Proposed number of samples for each production class and compound tested; o Type of tissue (e.g., muscle, liver, or kidney) and sample collection procedures for each production class and compound tested; and o Established tolerances used to take regulatory action (e.g., maximum residue limit (MRL)) for each chemical compound tested. \u2022 Describe the process and frequency of reassessment of the official government chemical residue sampling program to determine whether the production classes and compounds tested should be modified. Include the following: o Indicate whether the results from previous sampling programs are evaluated to determine when changes are required; o The rationale or criteria used to develop the proposed number of samples for each production class (e.g., statistical basis, etc.); and o The rationale or criteria used to determine whether a compound is included or removed from the testing program. \u2022 Provide the analytical methodology for each of the compounds tested as part of the official government chemical residue sampling program. For reference, current FSIS analytical methods can be found in the FSIS Chemistry Laboratory Guidebook (FSIS CLG). Include the following: o The screen method and confirmation method for each compound tested. o If a single method is used to analyze multiple compounds, provide the analytical method and the list of compounds detected by that method. \u2022 Identify whether all official government chemical residue sampling is done by government inspection personnel (i.e., government inspector, licensee, or contract employee). If official government chemical 17", "Self-Reporting Tool (SRT; v2022-001) residue sampling is performed by the establishment, please include a description of how and at what frequency the CCA verifies that samples are collected appropriately. \u2022 Describe how the CCA ensures that lotting procedures are defined so that if there is a violative sample result, all affected product can be identified. \u2022 Confirm whether the CCA requires individual livestock carcasses subjected to routine official government chemical residue testing to be held pending acceptable test results when used for product intended for export to the United States. \u2022 Describe how the CCA reviews official government chemical test results to ensure that product intended for export to the United States does not contain a chemical residue that exceeds an established U.S. tolerance, or contain a chemical compound with no approved use in the production class tested. For reference, information regarding FSIS\u2019 current sampling and testing plan for chemical residues can be found on the FSIS Sampling Program web page under the \u201cAnnual Sampling Reports\u201d section; the acceptable tolerance levels set by the United States Food and Drug Administration for veterinary drugs can be found at Title 21 CFR 556; and the acceptable tolerance levels set by the United States Environmental Protection Agency for pesticides can be found at 40 CFR 180. NOTE: Generally, if there is no U.S. tolerance set for a specific chemical residue, FSIS would consider the product adulterated if any level is detected. However, there are some chemical residues, such as environmental or industrial contaminants including heavy metals, where no tolerances are set, but FSIS evaluates detection of the chemical residue on a case-by-case basis to determine if the level of contaminant in the product may render it injurious to health and thus adulterated. \u2022 Describe how the CCA

notifies establishments when an official government chemical residue result exceeds established criteria, including when the result for product intended for export to the United States exceeds an established U.S. tolerance, or contains a chemical compound with no approved use in the production class tested. \u2022 Describe the enforcement actions the CCA takes when an official government chemical residue result exceeds established criteria, including when the result for product intended for export to the United States exceeds an established U.S. tolerance or contains a chemical compound with no approved use in the production class tested. \u2022 Describe how and at what frequency the CCA verifies that certified establishments take effective corrective actions when established chemical residue criteria are not met.

Component 6 Government Microbiological Pathogen and Process Control Programs

27. How does the CCA ensure that a slaughter establishment\u2019s microbiological sampling and testing program for meat and poultry verifies process control using microbiological analyses for indicators of intestinal and fecal contamination? NOTE: The CCAs of countries wishing to maintain ongoing equivalence and continue actively exporting meat or poultry products to the United States should provide indicator organism results for intestinal or fecal contamination if the official government sampling and testing program includes monitoring for indicator organisms. If applicable, submit your updated official government microbiological sampling and testing program for indicator organisms and the previous year\u2019s test results by May 18th of each year.

\u2022 For more information on how to submit annual official government microbiological sampling and testing plans and results and for an example of the information FSIS needs to evaluate foreign official microbiological sampling programs, refer to guidance documents on the Equivalence page of the FSIS website under \u201cAdditional Resources.\u201d To respond to this question sufficiently, the CCA must:

\u2022 Describe how the CCA requires and verifies process control in certified slaughter establishments.

\u2022 Identify whether sampling for microbiological indicators of process control is done by government inspection personnel (i.e., government inspector, licensee, or contract employee). If official government 18", "Self-Reporting Tool (SRT; v2022-001) sampling is performed by the establishment, include a description of how and at what frequency the CCA verifies that samples are collected appropriately.

\u2022 Identify and describe the CCA\u2019s testing requirements for using indicator organisms to monitor process control in certified establishments. Include the following:

- o Microbiological indicator chosen;
- o Frequency of sampling;
- o Points in the process where sampling will occur (e.g., pre-evisceration, pre-chill, or post-chill);
- o Sampling methodology; and
- o Process control criteria used to evaluate the results.

\u2022 Identify whether the microbiological methods of analysis used for official government samples of indicator organisms conform to FSIS Microbiology Laboratory Guidebook (FSIS MLG) methods or internationally recognized method standards (e.g., ISO methods for Enterobacteriaceae or generic E. coli).

NOTE: If the official method includes the use of a commercial detection kit, the commercial detection kit must have been validated by an external validating organization such as Association of Analytical Communities (AOAC), Association Fran\u00e7aise de Normalisation (AFNOR), NordVal, Microval, or Spanish Association for Standardization and Certification (AENOR).

\u2022 Describe the CCA\u2019s requirements for maintaining process control records for monitoring of indicators of intestinal and fecal contamination.

\u2022 Describe how and at what frequency government inspection personnel verify that certified establishments restore process control when performance

criteria are exceeded. \u2022 Describe the enforcement actions the CCA takes when established microbiological criteria are not met. \u2022 Describe how and at what frequency the CCA verifies that certified establishments take effective corrective actions when established microbiological criteria are not met.

28. How does the CCA ensure the reduction of Salmonella in raw meat and poultry products, and Campylobacter in raw poultry products through sampling and other verification activities? NOTE: The CCAs of countries wishing to maintain ongoing equivalence and continue actively exporting meat or poultry products to the United States must submit an updated official government microbiological sampling and testing program for Salmonella and Campylobacter in raw meat and poultry products, and the previous year\u2019s test results by May 18th of each year. \u2022 For more information on how to submit annual official government microbiological sampling and testing plans and results and for an example of the information FSIS needs to evaluate foreign official microbiological sampling programs, refer to guidance documents on the Equivalence page of the FSIS website under \u201cAdditional Resources.\u201d To respond to this question sufficiently, the CCA must:

\u2022 Describe how and at what frequency the CCA verifies that establishments reduce and control Salmonella in raw meat and poultry, and Campylobacter in raw poultry.

\u2022 Describe the CCA\u2019s requirements for poultry on-line reprocessing (OLR) and poultry off-line reprocessing (OFLR). Furthermore, if antimicrobial interventions are used during poultry reprocessing, describe the antimicrobial interventions used, and explain how the CCA ensures that these antimicrobial interventions are suitable for purpose, safe, and effective.

\u2022 Describe how and at what frequency the CCA verifies that all poultry carcasses, parts, and giblets are chilled immediately after slaughter operations so that there is no outgrowth of pathogens, unless such poultry is frozen or cooked immediately at the establishment.

\u2022 For poultry, identify whether the CCA requires establishments to develop, implement, and maintain written procedures for chilling in their HACCP plans, Sanitation SOPs, or other prerequisite programs that address the potential for pathogen outgrowth, the conditions affecting carcass chilling, and the length of time necessary for adequate chilling. In addition, describe how and at what frequency government inspection personnel verify that certified establishments develop, implement, and maintain these procedures in their HACCP plans, Sanitation SOPs, or other prerequisite programs.

19", "Self-Reporting Tool (SRT; v2022-001)

\u2022 Describe how the CCA provides for an official government microbiological sampling and testing program for Salmonella in raw meat and poultry, and for Campylobacter in raw poultry. Include the following:

- o Provide a written sampling plan with instructions for sample collection and testing. When describing the sampling program for Salmonella and Campylobacter in raw meat and/or poultry products, describe the following: \uf0a7 Frequency of sampling; \uf0a7 Points in the process where sampling will occur; and \uf0a7 Sampling methodology.
- o Describe the CCA\u2019s performance standard criteria for evaluation of Salmonella and Campylobacter results, including how the CCA assesses on an ongoing basis whether certified establishments meet such performance standards for poultry: carcasses (young chicken and turkey), chicken parts, and comminuted poultry (from chicken and turkey).
- o Describe the CCA\u2019s performance standard criteria for evaluation of Salmonella results, including how the CCA assesses on an ongoing basis whether certified establishments meet such performance standards for raw meat: carcasses (cow/bull, steer/heifer) and raw ground beef.

\u2022 Identify whether official government sampling for Salmonella and/or Campylobacter in raw

meat and poultry products is done by government inspection personnel (i.e., government inspector, licensee, or contract employee). If official government sampling is performed by the establishment, include a description of how and at what frequency the CCA verifies that samples are collected appropriately. \u2022 Identify whether the microbiological methods of analysis used for official government samples of *Salmonella* and *Campylobacter* conform to FSIS MLG methods or internationally recognized method standards (e.g., ISO methods). Additionally, identify any circumstances where culture confirmation is not performed on screen positive results from samples collected as part of official government microbiological sampling, and how the CCA will respond to a screen positive result if culture confirmation is not performed. NOTE: If the official method includes the use of a commercial detection kit, the commercial detection kit must have been validated by an external validating organization such as AOAC, AFNOR, NordVal, Microval, or AENOR. \u2022 Describe the enforcement actions the CCA takes when performance standard criteria are not met. \u2022 Describe how and at what frequency the CCA verifies that certified establishments take effective corrective actions when performance standard criteria are not met, including whether the CCA conducts follow-up sampling.

29. How does the CCA ensure through sampling and other verification activities that raw beef products are free of STEC at the end of the production process? NOTE: The CCAs of countries wishing to maintain ongoing equivalence and continue actively exporting beef products to the United States must submit an updated official government microbiological sampling and testing program for STEC, and the previous year\u2019s STEC test results by May 18th of each year.

\u2022 For more information on how to submit annual official government microbiological sampling and testing plans and results and for an example of the information FSIS needs to evaluate foreign official microbiological sampling programs, refer to guidance documents on the Equivalence page of the FSIS website under \u201cAdditional Resources.\u201d To respond to this question sufficiently, the CCA must:

- \u2022 Identify whether the CCA considers STEC an adulterant in raw non-intact beef products (e.g., raw ground beef products) or raw beef products intended for raw non-intact use (e.g., beef manufacturing trimmings and other raw ground beef components such as head meat, cheek meat, weasand meat, heart meat, and product from advanced meat recovery systems (AMR)).
- \u2022 Describe how and at what frequency government inspection personnel verify that certified establishments producing raw beef products adequately address STEC in their HACCP plans, Sanitation SOPs, or prerequisite programs.

20", "Self-Reporting Tool (SRT; v2022-001)

\u2022 Describe the official government microbiological sampling and testing programs for (1) *Escherichia coli* (*E. coli*) O157:H7 and non-O157 STEC (O26, O45, O103, O111, O121, and O145) in beef manufacturing trimmings, and (2) *E. coli* O157:H7 in raw ground beef products and other raw ground beef components.

Include the following:

- o Provide a written official government sampling plan with instructions for sample collection and testing. When describing the official government STEC sampling verification program, describe the following: \uf0a7 Frequency of sampling; \uf0a7 Points in the process where sampling will occur; \uf0a7 Sampling methodology; NOTE: For analyses of raw beef products using an N60 sampling method, confirm that the entire sample is analyzed, not just a portion of the N60 trim pieces equaling a specific weight (e.g., 325g or 375g).
- \uf0a7 Target pathogens for each analysis; and \uf0a7 Criteria used to evaluate the results.

\u2022 Identify whether official government sampling for (1) *E. coli* O157:H7 and non-O157 STEC (O26, O45, O103, O111, O121, and O145) in beef manufacturing trimmings, and (2) *E. coli* O157:H7 in

raw ground beef products and other raw ground beef components is done by government inspection personnel (i.e., government inspector, licensee, or contract employee). If official government sampling is performed by the establishment, include a description of how and at what frequency the CCA verifies that samples are collected appropriately. \u2022 Identify whether the microbiological methods of analysis used for official government samples of *E. coli* O157:H7 or non-O157 STEC conform to FSIS MLG methods or internationally recognized method standards. Additionally, identify any circumstances where culture confirmation is not performed on screen positive results from samples collected as part of official government microbiological sampling, and how the CCA will respond to a screen positive result if culture confirmation is not performed. NOTE: If the official method includes the use of a commercial detection kit, the commercial detection kit must have been validated by an external validating organization such as AOAC, AFNOR, NordVal, Microval, or AENOR.

- o Describe which STEC characteristics are used to define adulterants (e.g., presence\absence of virulence genes (stx, eae), O-antigens).
- \u2022 Describe how the CCA ensures that lots are defined to establish microbiological independence so that if there is a positive sample result, all affected product can be identified.
- \u2022 Indicate whether the CCA requires establishments to sample and test raw beef products for STEC. If so, describe how and what frequency government inspection personnel verify that establishments collect samples appropriately.
- \u2022 Describe the enforcement actions the CCA takes when *E. coli* O157:H7 and non-O157 STEC positive test results are found through official government or establishment microbiological sampling programs.
- o Identify whether the CCA verifies that establishments define, investigate, and respond to recurring positives (i.e. periods of time in which slaughter establishments experience a high rate of positive results for STEC in production lots containing the same source materials).
- \u2022 Describe how and at what frequency the CCA verifies that certified establishments take effective corrective actions to prevent recurrence of STEC in response to positive samples from official government or establishment testing. For example, verification activities can include: increased frequencies of inspector verification tasks (e.g., increased sanitary dressing verification); follow-up sampling and testing; or routine sampling and testing of every lot for the presence of STEC.
- o If the CCA requires follow-up sampling, provide the frequency and duration of the follow-up sampling, and identify whether the CCA or the establishment conducts the follow-up sampling. If the CCA requires the establishment to collect follow-up samples, describe how and at what frequency the CCA verifies that the establishment conducts sampling and that results are acceptable.
- \u2022 Identify any additional STEC controls required and verified by the CCA in establishments producing raw 21", "Self-Reporting Tool (SRT; v2022-001) beef products intended for export to the United States.

30. How does the CCA ensure through sampling and other verification activities that RTE meat, poultry, and egg products are not contaminated with microbiological pathogens or their toxins, including *Lm* and *Salmonella*? NOTE: RTE products are meat, poultry, or egg products that are edible without further preparation to achieve food safety. NOTE: RTE products may include products produced under the following HACCP categories: Not Heat Treated-Shelf Stable; Heat Treated-Shelf Stable; Fully Cooked-Not Shelf Stable; Products with Secondary Inhibitors-Not Shelf Stable. For more information on how FSIS defines these HACCP process categories, refer to the FSIS Product Categorization (Import) guide. NOTE: The CCAs of countries wishing to maintain ongoing equivalence and continue actively exporting meat, poultry, or egg products to the

United States must submit an updated official government microbiological sampling and testing program for Lm, Salmonella, and other pathogens of concern in RTE product, and the previous year's residue test results by May 18th of each year. For more information on how to submit annual official government microbiological sampling and testing plans and results and for an example of the information FSIS needs to evaluate foreign official microbiological sampling programs, refer to guidance documents on the Equivalence page of the FSIS website under Additional Resources.

To respond to this question sufficiently, the CCA must:

- \u2022 Identify whether the CCA considers RTE product containing Lm, Salmonella, or other pathogens (e.g., STEC in dry, semi-dry, or fermented beef products); and RTE product that comes into direct contact with a food contact surface (FCS) contaminated with Lm or Salmonella, to be adulterated.
- \u2022 Describe how the CCA enforces a zero tolerance approach to control Lm, Salmonella, and other pathogens in RTE product destined for export to the United States. NOTE: FSIS considers all RTE products to be adulterated if they contain pathogens of public health concern (depending on the type and level) or their toxins that can cause illness in humans. There are some pathogens where any level would make the product adulterated (e.g., Lm, Salmonella, and STEC) because it would be injurious to health. Other pathogens are only a public health concern when multiplication occurs at levels that could lead to toxin formation (e.g., Clostridium perfringens (*C. perfringens*), and Clostridium botulinum (*C. botulinum*)).
- \u2022 Identify whether the CCA maintains laws, regulations, or inspection procedures regarding high pressure processing (HPP) operations that apply lethality treatments to products intended for export to the United States. For reference, HPP is an antimicrobial treatment that is capable of either reducing or eliminating biological food safety hazards on meat, poultry, or egg products. For meat and poultry products:

\u2022 Describe the CCA's government verification activities for certified establishments producing RTE meat and poultry products, including the following:

- o Describe how and at what frequency government inspection personnel verify that certified establishments adopt Listeria control measures.
- o Describe how and at what frequency government inspection personnel review and verify that certified establishments implement testing for Lm or Listeria species as an indicator for Lm based on risk, including verifying sampling procedures, testing methods, and testing results.
- o Describe how and at what frequency government inspection personnel verify that certified establishments producing RTE meat and poultry products implement control measures to prevent adulteration of both post-lethality exposed RTE products and non-post-lethality exposed RTE products. Include how and at what frequency government inspection personnel verify that certified establishments identify and implement procedures in their HACCP plans, Sanitation SOPs, or other prerequisite programs to control pathogens of concern in RTE product.
- o Describe how and at what frequency government inspection personnel verify that certified establishments are meeting lethality and stabilization requirements for RTE products. Include whether the CCA maintains performance standard requirements for pathogens or their toxins in RTE meat and poultry products (e.g., at least a 6.5-log reduction in Salmonella in cooked beef products, at least a 7-log reduction in Salmonella in cooked poultry products, and no more than a 1-log multiplication of *C. perfringens* and no multiplication of *C. botulinum* in RTE meat and poultry products).

\u2022 Describe the CCA's official government sampling verification activities for Lm and Salmonella in RTE products exported to the United States. Include the following:

- o Provide a

written sampling plan with instructions for sample collection and testing. When describing the sampling program for RTE products describe the following: \uf0a7 Frequency of sampling; \uf0a7 Points in the process where sampling will occur; \uf0a7 Sampling methodology; \uf0a7 Target pathogens for each analysis; and \uf0a7 Criteria used to evaluate the results. \u2022 Describe official government sampling verification procedures for Lm on food contact and environmental (non-food contact) surfaces in certified establishments producing post-lethality exposed RTE meat and poultry products. Include the frequency of sampling and the sampling methodology. \u2022 Describe how the CCA ensures that both post-lethality exposed and non-post-lethality exposed (e.g., cook-in-bag) RTE meat and poultry products are included in its official government sampling program. \u2022 Describe how the CCA ensures that lots are defined to establish microbiological independence so that if there is a positive sample result, all affected product can be identified. \u2022 Identify whether official government sampling for Lm and Salmonella in RTE products or the RTE production environment is done by government inspection personnel (i.e., government inspector, licensee, or contract employee). If official government sampling is performed by the establishment, include a description of how and at what frequency the CCA verifies that samples are collected appropriately. \u2022 Identify whether the microbiological methods of analysis used for official government samples of Lm and Salmonella conform to FSIS MLG methods or internationally recognized method standards. Additionally, identify any circumstances where culture confirmation is not performed on screen positive results from samples collected as part of official government microbiological sampling, and how the CCA will respond to a screen positive result if culture confirmation is not performed. NOTE: If the official method includes the use of a commercial detection kit, the commercial detection kit must have been validated by an external validating organization such as AOAC, AFNOR, NordVal, Microval, or AENOR. \u2022 Describe the enforcement actions the CCA takes when insanitary conditions or Lm, Salmonella, or other pathogens of public health concern are found through official government or establishment microbiological sampling programs. \u2022 Describe how and at what frequency the CCA verifies that certified establishments take effective corrective actions when insanitary conditions or Lm, Salmonella, or other pathogens of public health concern are found through official government or establishment microbiological sampling programs. For example, verification activities can include: increased frequencies of inspector verification tasks (e.g., increased sanitation or HACCP verification); follow-up sampling and testing; and routine sampling and testing of every lot for the presence of Lm and Salmonella. o If the CCA requires follow-up sampling, provide the frequency and duration of the follow-up sampling, and identify whether the CCA or the establishment conducts the follow-up sampling. If the CCA requires the establishment to collect follow-up samples, describe how and at what frequency the CCA verifies that the establishment conducts sampling and that results are acceptable. For egg products: \u2022 Describe how the CCA ensures that establishments implement time and temperature parameters for 23", "Self-Reporting Tool (SRT; v2022-001) cooling, pasteurization, or other heat treatments that are effective in eliminating microbiological hazards in egg products intended for export to the United States. \u2022 Describe the official government microbiological sampling and testing program for Salmonella and Lm in pasteurized liquid, frozen, and dried egg products in certified egg product establishments. Include the following: o Provide a written sampling plan with instructions for sample collection and testing. When describing the sampling program for egg

products, describe the following: \uf0a7 Frequency of sampling; \uf0a7 Points in the process where sampling will occur; \uf0a7 Sampling methodology; \uf0a7 Target pathogens for each analysis; and \uf0a7 Criteria used to evaluate the results. \u2022 Identify whether official government sampling for Salmonella and Lm in pasteurized liquid, frozen, and dried egg products is done by government inspection personnel (i.e., government inspector, licensee, or contract employee). If official government sampling is performed by the establishment, include a description of how and at what frequency the CCA verifies that samples are collected appropriately. \u2022 Identify whether the microbiological methods of analysis used for official government samples of Lm and Salmonella conform to FSIS MLG methods or internationally recognized method standards. Additionally, identify any circumstances where culture confirmation is not performed on screen positive results from samples collected as part of official government microbiological sampling, and how the CCA will respond to a screen positive result if culture confirmation is not performed. NOTE: If the official method includes the use of a commercial detection kit, the commercial detection kit must have been validated by an external validating organization such as AOAC, AFNOR, NordVal, Microval, or AENOR. \u2022 Describe whether the CCA requires certified egg product establishments to develop and implement Salmonella sampling programs for pasteurized liquid, frozen, and dried egg products. Describe how and at what frequency the CCA verifies establishment sampling and testing procedures and results. \u2022 Describe how the CCA ensures that lotting procedures are defined to establish microbiological independence of production lots so that if there is a positive sample result, all affected product can be identified. \u2022 Describe the enforcement actions the CCA takes when Lm or Salmonella positive test results are found through results are found through official government or establishment microbiological testing programs. \u2022 Describe how and at what frequency the CCA verifies that certified establishments take effective corrective actions to prevent recurrence of Lm or Salmonella in response to positive samples from official government or establishment testing.

31. How does the CCA ensure that RTE shelf-stable meat and poultry products that do not rely on cooking alone to achieve lethality, such as fermented, acidified, salt-cured or dried meat and poultry products, achieve adequate lethality and shelf-stability to prevent contamination with microbiological pathogens or their toxins (e.g., Salmonella, Lm and STEC (in beef products), C. perfringens, C. botulinum, and *Staphylococcus aureus* (*S. aureus*))?

NOTE: This question applies to products produced under the Heat Treated-Shelf Stable or Not Heat Treated-Shelf-Stable HACCP categories. For more information on how FSIS defines these HACCP process categories, refer to the FSIS Product Categorization (Import) guide. To respond to this question sufficiently, the CCA must:

\u2022 Provide all supporting documentation, including inspection procedures and frequencies, used by the CCA to verify the following:

- o At least a 5-log reduction in Salmonella and STEC (for products containing beef), and sufficient reductions in Lm during lethality;
- o The prevention of the growth of spore-forming bacteria (i.e., C. perfringens and C. botulinum) by 24", "Self-Reporting Tool (SRT; v2022-001) maintaining critical operational parameters (low pH, relatively low water activity); and
- o The prevention of the growth of *S. aureus* during the processing and no growth of *S. aureus* during the storage of shelf stable product (pH, water activity, etc.).

32. How does the CCA ensure that heat-treated NRTE meat and poultry products are properly stabilized to prevent outgrowth of microbiological pathogens or their toxins (i.e., C. perfringens and C. botulinum), and properly labeled to ensure adequate cooking by the consumer?

NOTE:

NRTE products are meat and poultry products that may or may not have received an adequate lethality treatment for *Salmonella*, and may appear RTE (e.g., chicken kiev). Furthermore, products that receive a full lethality treatment may be classified as NRTE product if they are not defined by a standard of identity to be fully cooked (e.g., hotdogs or barbecue) and are not edible without further preparation to achieve food safety. NOTE: NRTE products may include products produced under the following HACCP categories: Not Heat Treated-Shelf Stable; Heat Treated-Shelf Stable; Heat Treated but not Fully Cooked-Not Shelf Stable; Products with Secondary Inhibitors-Not Shelf Stable. For more information on how FSIS defines these HACCP process categories, refer to the FSIS Product Categorization (Import) guide. To respond to this question sufficiently, the CCA must:

\u2022 Describe how and at what frequency the CCA verifies that certified establishments are properly stabilizing and preventing the growth of spore-forming bacteria (i.e., *C. perfringens* and *C. botulinum*) in NRTE product intended for export to the United States.

\u2022 Describe how and at what frequency the CCA verifies that NRTE products are labeled with safe handling instructions and NRTE products that are not shelf-stable are labeled with special handling statements, such as keep refrigerated or keep frozen.

NOTE: For more information on the U.S. labeling requirements for safe handling instructions and special handling statements, refer to 9 CFR 317.2(k) and (l) (meat products) and 9 CFR 381.125(a) and (b) (poultry products).

33. How does the CCA ensure that the processing of canned meat and poultry products addresses *C. botulinum* and the finished products are commercially sterile? NOTE: Address the types of processing systems your country uses to produce thermally processed\commercially sterile (TP\CS) meat or poultry products for export to the United States (e.g., batch steam still, batch steam agitating, continuous rotary, hydrostatic, batch still pressure processing in water, batch agitating pressure processing in water, pressure processing with steam\air mixture in batch retorts, atmospheric cookers, and other systems such as cascading water or aseptic systems). NOTE: FSIS considers the implementation of requirements consistent with the FSIS canning regulations (see 9 CFR 431) as providing an equivalent level of sanitary protection when producing TP\CS meat and poultry products for export to the United States. NOTE: For countries using HACCP to address all food safety hazards during thermal processing\ commercial sterilization, describe your country\u2019s food safety controls under SRT Question 25. To respond to this question sufficiently, the CCA must:

\u2022 Describe how and at what frequency the CCA ensures that certified establishments producing TP\CS products for export to the United States address *C. botulinum*, incipient spoilage (i.e., spoilage occurring before the thermal process is initiated), post-processing contamination, and non-pathogenic spores (e.g., thermophilic spoilage) that are a source of abnormal containers. Furthermore, include any strategies for reducing or eliminating these hazards.

\u2022 Describe how and at what frequency the CCA verifies adequate thermal processing and commercial sterility of containers for the following:

- o For low-acid products (i.e., a canned product in which any component has a pH value above 4.6), 25", "Self-Reporting Tool (SRT; v2022-001) the process achieves a probability of  $10^{-9}$  that there are spores of *C. botulinum* in a container of the product that are capable of growing, or, a 12D reduction of *C. botulinum*, assuming an initial load of \u2264 1000 spores per container.
- o For acidified low-acid products (i.e., a canned product which has been formulated or treated so that every component of the finished product has a pH of 4.6 or lower within 24 hours after the completion of the thermal process) or products in which pathogen growth is controlled by

factors other than thermal or other sporicidal processing, the process prevents multiplication of C. botulinum in the food under the conditions in which the food is stored, distributed, and held.

- o All products are rendered free of microorganisms capable of growing in the product at nonrefrigerated conditions (over 50°F or 10°C) at which the product is intended to be held during distribution and storage (e.g., process schedules ensure at least a 5D reduction of C. sporogenes). \u2022 Describe how and at what frequency the CCA verifies that establishments certified to export TP\CS meat and poultry products to the United States address the following:

  - o Containers are airtight (hermetically sealed) and protect the contents of the container against the entry of microorganisms during and after processing;
  - o Containers and closures are cleaned and examined prior to filling; stored and handled in a sanitary manner; and examined prior to closure (e.g., visual, teardown, or physical examination) by trained closure technicians;
  - o Process schedules are developed by a processing authority prior to the processing of canned product for export to the United States;
  - o Critical factors specified in the process schedule are measured, controlled, and recorded (e.g., initial temperature, retort processing time and temperature);
  - o Operations in thermal processing areas include the posting of process schedules; development of a retort traffic control system to prevent product from bypassing the retort, along with placement of heat sensitive indicators to indicate adequate thermal processing; determination and recording of initial temperature at the start of the processing cycle; accuracy of timing devices (e.g., analog and digital clocks); and measurement of pH with a pH meter;
  - o Equipment and procedures for heat processing systems include:

    - \uf0a7 Instruments and controls common to different thermal processing systems (e.g., indicating temperature devices, temperature\time recording devices, steam controllers, air valves, and water valves);
    - \uf0a7 Engineering design standards for each retort used (e.g., batch steam still, batch steam agitating, continuous rotary, hydrostatic, batch still pressure processing in water, batch agitating pressure processing in water, pressure processing with steam\air mixture in batch retorts, atmospheric cookers, and other systems such as cascading water or aseptic systems);
    - \uf0a7 Examinations of all instrumentation and controls upon installation, on an annual basis, and following an extended shutdown to ensure the design of all equipment, instrumentation, and controls is sound, and that equipment maintenance is up-to-date;
    - \uf0a7 The recording and retention of maintenance records;
    - \uf0a7 Requirements for container cooling and cooling water, both single pass and recycled or reused cooling water (e.g., potable, chlorinated, cooling canals cleaned at an adequate frequency to prevent insanitary conditions); and
    - \uf0a7 Handling processed containers in a manner that will prevent damage to the hermetic seal area.

- o Processing and production records include, at a minimum, the date of production; product name and style; container code; container size and type; the process schedule, including the minimum initial temperature; measurement of critical factors, and record requirements specific to each retort type;
- o Certified establishments maintain records, including but not limited to, thermal process records, critical factor control records, closure evaluation records, and records associated with the development of the process schedule (e.g., venting schedules, heat distribution data, heat penetration data); 26", "Self-Reporting Tool (SRT; v2022-001)
- o Records review and maintenance includes reviewing processing records and container closure records; maintaining records identifying initial distribution of the product; and retaining processing and production records;
- o Processing deviations identified in-process or through record review are handled according to the

establishment\u2019s HACCP plan, or alternative documented procedures to ensure that TP\CS product being exported to the United States is safe for human consumption and shelf-stable; o Finished product inspections are conducted to ensure that only normal appearing containers are exported to the United States; and o Direct supervisors of thermal processing operators and closure technicians possess knowledge and training specific to canning operations. \u2022 Describe the enforcement actions taken by the CCA in response to processing deviations (i.e., deviation identified in process or through records review), including how the CCA controls TP\CS products identified to be abnormal, under-processed, or contaminated post-processing. In addition, describe how the CCA verifies corrective actions. 34. Has the CCA reviewed the SRT responses and supporting documentation in PHIS for accuracy and completeness, including all English translated documents, as part of its annual update by May 18th of each year? NOTE: In the SRT response to this question, verify whether your country\u2019s current SRT responses and supporting documentation in PHIS are accurate and up-to-date, including whether translated documents were correctly translated into English. Countries unable to access PHIS can contact the FSIS Office of International Coordination through e-mail at [internationalcoordination@usda.gov](mailto:internationalcoordination@usda.gov) to obtain copies of English translated documents for review. NOTE: All translated documents will be uploaded for review in the document section of PHIS with the word TRANSLATED in all capital letters at the beginning of the title. 35. For countries requesting a reinstatement of equivalence, initial equivalence, or expansion of equivalence, identify the process category, product category, product group, and species that your country intends to export to the United States. NOTE: For more information, refer to FSIS Product Categorization (Import) guide.

27"]}, {"file\_name": "FSIS\_GD\_2022\_0004", "title": "HACCP Model for Raw Non-Intact Egg Products", "num": "FSIS-GD-2022-0004", "id": "a9bf2768d222d60124de42692261a8f988f6690a2816e937a73b8756b8aada7e", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/2022-06/FSIS-GD-2022-0004.pdf", "type": "pdf", "n\_pages": 14, "word\_count": 3537, "text\_by\_page": ["HACCP Model for Unpasteurized Liquid Egg (Raw Non-Intact Processing Category) The United States Department of Agriculture (USDA) published the Pathogen Reduction\Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule (PR\HACCP rule) in July 1996, mandating all USDA inspected meat and poultry establishments implement a HACCP system. Hazard Analysis and Critical Control Point (HACCP) is a systematic and scientific method of process control for the production of safe food products. The HACCP regulations (9 CFR Part 417) required meat and poultry establishments to develop and implement a system of controls designed to improve the safety of their products. The HACCP models\u2019 focus is on product safety, not product quality characteristics. On October 29, 2020, the USDA published a final rule that updated the egg products inspection regulations. The USDA amended the egg products inspection regulations to require official plants that process egg products to develop and implement Sanitation Standard Operating Procedures (Sanitation SOPs) to meet other sanitation requirements consistent with USDA\u2019s meat and poultry regulations (effective date: October 29, 2021) and develop and implement HACCP Systems (effective date: October 31, 2022). With the PR\HACCP rule, FSIS made available a guidebook for the preparation of HACCP

plans and a generic model for each food processing category defined in the regulation (9 CFR 417.2(b)(1)). The guidebook and the generic models have been revised since their initial publication to be consistent with current science and policy. FSIS recommends you use the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan. Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used as is. Establishments are to tailor the model(s) to fit the establishment's operation. This generic HACCP model illustrates the Raw Non-Intact processing category with an unpasteurized liquid egg product. The model's critical control points (CCPs) do not necessarily apply to all egg products operations or products. Products or operations may require fewer or more CCPs depending on the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. The food safety critical limits selected must come from scientific documents or other reliable sources. This model includes references for guidance on the selection of critical limits. The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis are HACCP decisionmaking records (9 CFR 417.5(a)). Ensure you maintain the documents produced while developing a HACCP plan. For further assistance with developing HACCP plans, see the Egg Products Hazards and Controls Guide, the FSIS Food Safety Guideline for Egg Products, the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP Guidance webpage. Visit the State HACCP Contacts and Coordinators webpage for a list of contacts who provide technical advice, assistance, resources and conduct activities to support HACCP implementation in small and very small plants.<sup>1</sup> This information is best suited for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products."

"EXAMPLE PRODUCT DESCRIPTION

Product Name and Process Type: Unpasteurized Liquid Egg (Raw Non-Intact Processing Category) Process Type and Product Name Raw Non-Intact Liquid Egg Product (Whole Egg, Yolk, Whites) Important product characteristics (Aw, pH, Preservatives, etc.) None How it is to be used<sup>3</sup> Further processed into pasteurized liquid or dried egg product. Packaging (durability and storage conditions) Bulk container (e.g., tanker, totes) Storage condition and at what temperature<sup>4</sup> Perishable, not shelf stable -Keep refrigerated (\u226445\u00b0F) Where it will be sold (specify intended consumers, especially at-risk populations)<sup>5</sup> Official egg products plants for further processing. Labeling instructions and requirements \u201cDate of loading\u201d is displayed, indicating the date the container, tanker truck, or portable tank is loaded, along with product name, the statement \u201cFor Further Processing in an Official USDA Plant\u201d and the producing establishment number. What special distribution controls are required? Controls are in place to secure the product during transportation. Prior to developing the HACCP plan, please read the FSIS Guidebook for the Preparation of HACCP Plans for detailed descriptions of the worksheets and hazard analysis. The FSIS Guidebook for the Preparation of HACCP Plans and the generic HACCP models are intended

for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP models are for demonstration purposes only. The models do not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products.

3The intended use or consumer of the product must be identified in accordance with 9 CFR 417.2(a)(2). Identifying the product's intended use in the product description is one way to meet the regulatory requirements specific to 9 CFR 417.2(a)(2).

4 Each establishment's products may have their own defined shelf life. A specific shelf life may not be applicable for intermediate products.

5At-risk populations include young children, the elderly and immunocompromised persons.

6See the FSIS Labeling Overview and Generic Label Approval guideline for information on required labeling features. Not all labeling features are required for products moving between official establishments under company control.", "EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIALS

7 Product Name and Process Type: Unpasteurized Liquid Egg (Raw Non-Intact Processing Category)

Eggs Shell eggs Non-Egg food ingredients Salt, sugar Antimicrobials

8 or processing aids None

Packaging material Product transported with tanker trucks or plastic portable totes

Restricted Ingredients\Allergens Allergens -Egg Other None

DATE: APPROVED BY: 7List all egg, non-egg ingredients, restricted ingredients (for example, nitrites), processing aids, and packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. See the FSIS Compliance Guideline Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling for detailed information on allergens. To review restrictions on the use of nitrite and sodium ascorbate or sodium erythorbate, see 9 CFR 424.22(b).

8FSIS and the Food and Drug Administration (FDA) have a memorandum of understanding (MOU) that establishes the working relationship followed when responding to notifications for the use of food additives (including ingredients) intended for use in the production of FSIS regulated products. FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDA on the requirements under the Federal Food, Drug & Cosmetic Act and its implementing regulations. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products for the list of suitable ingredients.", "t -----.\u25a1 EXAMPLE PROCESS FLOW CHART

9 Product Name and Process Type: Unpasteurized Liquid Egg (Raw Non-Intact Processing Category)

2. Classification, Sorting, Transfer (temper) of Shell Eggs

3. Washing Shell Eggs

4. Sanitizing Shell Eggs

1. Receiving Shell Eggs

5. Candling

1 a. Storage of Shell Eggs

1 b. Unpacking Shell Eggs

5 a. Removing Eggs Unfit for Human Consumption

5 b. Waste By-products

7. Filtration

6. Breaking Eggs, Separating

5 c. Egg Shell Waste

8. Liquid Egg Cooling and Holding CCP

10. Returned Product

10. Loading, Shipping CCP

2 9This is an example flow diagram. Establishments' flow diagrams for the same product may be different. Establishments determine which steps are included in their process. The steps must represent all relevant hazards in the hazard analysis.

10The Returned Product step (10) is shown as not connected to another process step. Returned product may re-enter the production system at different process steps depending on condition or problem. Returned product may be re-processed, discarded, etc.", "EXAMPLE HAZARD ANALYSIS

11 Product Name and Process Type:

Unpasteurized Liquid Egg (Raw Non-Intact Processing Category)

Column 1 Column 2 Column 3

Column 4 Column 5 Column 6 Ingredient\ Potential Is the Justification \ Basis for Decisionii If yes in Column 3, Is this Process Step Hazards (introduced or controlled) at this stepi Potential Food Safety Hazard Reasonably Likely to (RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the step a Critical Control Point Occur Hazard to Acceptable (CCP)? (RLTO) Levelsiv (Yes or No)ii 1. Receiving Shell Eggs B: Presence of pathogens: (e.g., Salmonella) No Pre-harvest measures, ambient temperature compliance, proper sanitation of equipment. Subsequent steps ensure final packaged unpasteurized liquid egg product is appropriately labeled and will be shipped and maintained under company control to FSISregulated official egg products plant for pasteurization or heat treatment. C: Residues (pesticides, antibiotics) No Residue control program or approved supplier program. P: None 1 a. Storage B: Presence of pathogens: (e.g., No Pre-harvest measures, ambient temperature compliance, proper sanitation of equipment. 11This is an example hazard analysis. Each establishment\u2019s flow chart, hazards analysis, hazards, decision-making, and support may be different. An establishment can determine what \u201ccsteps\u201d are included in the overall process if all of the hazards are considered in the hazard analysis. The FSISEgg Products Hazards and Controls Guide (starting on page 5) describes the usual process steps for egg product processing.", "Step Potential Hazard RLTO Justification \ Basis Controls CCP of Shell Eggs Salmonella) Subsequent steps ensure final packaged unpasteurized liquid egg product is appropriately labeled and will be shipped and maintained under company control to FSISregulated official egg products plant for pasteurization or heat treatment. C: Residues (pesticides, antibiotics) No Residue control program or approved supplier program. P: None 1 b. Unpacking Shell Eggs B: Presence of pathogens: (e.g., Salmonella) No Proper handling and employee hygiene. C: None P: Foreign material (plastic, wood) No Proper handling and employee hygiene. Foreign Material SOP.12 2. Classification, Sorting, Transfer (temper) of Shell Eggs B: Presence of pathogens: (e.g., Salmonella) No Restricted or ineligible eggs are properly segregated. Eggs with strong odors are segregated and processed separately. Soiled eggs are segregated for washing. C: None P: None 12ThisForeign MaterialSOP (prerequisite program) should have details on how this procedure (such as metal prevention controls) is preventing the hazard from occurring as well as the on-going verification procedures. These controls should be evident within the written document upon review. The Foreign MaterialSOPand plant data related to on-going verification activities then become part of recordkeeping and historicaldata. 6", "Step Potential Hazard RLTO Justification \ Basis Controls CCP 3. Washing Shell Eggs B: Presence of pathogens: (e.g., Salmonella) No Maintain wash water temperature, monitor water quality to minimize cross contamination, monitor pH and concentration. C: Washing No Written Chemical Receiving, Storage, and Use compounds SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer\u2019s instructions and is within the allowable limits identified in Directive 7120.1 (FCN# [insert number]).13 P: None 4. Sanitizing Shell Eggs B: Presence of pathogens: (e.g., Salmonella) No Maintain wash water temperature, monitor water quality to minimize cross contamination, monitor pH and concentration. C: Washing No Written Chemical Receiving, Storage, and Use compounds SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer\u2019s instructions and is within the allowable limits identified in Directive 7120.1 (FCN# [insert number]). P: None 5. Candling B: Presence of pathogens: (e.g., Salmonella) No Proper segregation and sorting of ineligible eggs. Soiled eggs are segregated for

resorting and rewashing. Proper cleaning of 13Provide reference for scientific support and validation for effective concentrations and support for critical operational parameters that reduce biologicalhazards. FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat,Poultry and Egg Products contains the list of substances that maybe used in the production of egg products. The list contains the allowable amounts and the intended use of the approved antimicrobials. The list (Directive 7120.1) can be used as supporting documentation for chemical hazard controls (safety and suitability). Directive 7120.1 cannot be used assupport for the control of biological hazards because the antimicrobial concentration needed to control bacteria is different from the concentrations required for safety and suitability. 7", "Step Potential Hazard RLTO Justification \ Basis Controls CCP equipment and effective Sanitation SOP\u2019s. C: None P: None 5 a. Removing Eggs Unfit for Human Consumption B: Presence of pathogens: (e.g., Salmonella) No Proper disposal, denaturing, and labeling and segregation of inedible product. C: None P: None 5 b. Waste By-products B: Presence of pathogens: e.g., Salmonella) No Proper disposal, segregation, and labeling of waste products. C: None P: None 5 c. Egg Shell Waste B. Presence of pathogens: (e.g., Salmonella) (exterior of egg) No Proper disposal, segregation, and labeling. C: None P: None 6. Breaking Eggs, Separating B: Presence and outgrowth of Salmonella No Sanitation SOPs address proper cleaning and sanitation of rooms and equipment. Proper hygienic practices in place. Adequate air movement to ensure organoleptic examination for product wholesomeness. Use of sanitizers, frequency of equipment cleaning, and control of room temperature adequate to inhibit 8", "Step Potential Hazard RLTO Justification \ Basis Controls CCP growth of pathogenic bacteria on food contact surfaces. Proper candling to prevent ineligible eggs from entering breaking room; line speed adjusted to maintain process control. C: Cleaning chemicals and sanitizers No Sanitation SOPs address proper cleaning, sanitation, and use of cleaning chemicals\compounds. P: Foreign material (eggshell fragments) No Maintain liquid egg pumps and shell egg filters for effective performance. Adjustments to breaking equipment to minimize shell fragmentation. Lack of historical findings from visual inspection during egg processing.14  
7. Filtration B: Outgrowth of pathogens (e.g., Salmonella) No Proper sanitation and maintenance of pipes, liquid egg pumps, and shell egg filters for effective removal of fragments. C: None P: Foreign material (eggshell fragments) No Proper sanitation and maintenance of equipment. 8. Liquid Egg Cooling and B: Outgrowth of pathogens (e.g., Yes Improper cooling of product may lead to pathogen growth. Cooling occurs in a period of time which precludes pathogen outgrowth. Monitor time and temperature to ensure proper cooling of product Yes CCP 1 14Note:this \u201chistorical data\u201d must be supported with evidence from the establishment through the establishment\u2019s history or validation data with reference to the actual SOP or prerequisite program. When historical data is not available (for example, a HACCPplan for anew process or product), then system design must be supported by other documentary evidence, such as the FSIS Egg Products Hazards and Controls Guide which states \u201cliquid egg pumpsand shell filters working properly\u201d is a frequently used control for foreign material hazards in egg breaking. 9", "Step Potential Hazard RLTO Justification \ Basis Controls CCP Holding CCP 1 Salmonella) is attained. CCP #1 \u2013 Cold Storage\Silo Temperature Log.15 Maintain product at Safe Harbor holding time and temperature combination to minimize pathogen outgrowth (Table 2 \u2013 Cooling Operations within FSIS Food Safety Guideline for Egg Products, 9\9\2020) C: None P: None 9. Loading, B: Outgrowth

of Yes Improper product temperature during loading Monitor temperature upon Yes Shipping CCP 2 pathogens (e.g., Salmonella) or transport may lead to pathogen growth. completion of loading product prior to shipping. CCP #2 Bulk Container Shipping Temperature Log. Maintain product at Safe Harbor holding time and CCP 2 15If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. However, if an establishment implements different critical operational parameters in the process from the scientific support, or the scientific support identified does not contain microbiological data, then the establishment should collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameter(FSIS Compliance Guideline HACCP Systems Validation, page 27).

10", "Step Potential Hazard RLTO Justification \ Basis Controls CCP temperature combination to minimize pathogen outgrowth (Table 2 \u2013 Cooling Operations within FSIS Food Safety Guideline for Egg Products, 9/9/2020) C: None P: None 10. Returned Products B. Outgrowth of pathogens (e.g., Salmonella) No Reinspection SOP implemented before accepting returned product. Person(s) or business returning the product must demonstrate the product was held in the appropriate temperature range and in a sanitary manner. When such assurance is not available, returned product is rejected or destroyed. Opened packages are not accepted. Accepted product enters the appropriate step of the production system based on findings of product evaluation. Notify FSIS personnel when returned product has been accepted. C: None P: None DATE: APPROVED BY: 11", "EXAMPLE HACCP PLAN Unpasteurized Liquid Egg (Raw Non-Intact Processing Category) Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency Who CCP 1 Liquid Egg Cooling and Holding B: Outgrowth of pathogens, Salmonella \u226445\u00b0F for product held less than 8 hours.\* \u226440\u00b0F for product held more than 8 hours.\* \*Product temperature must be met within two hours of breaking Product temperature is measured via temperature gauge on silo continuous monitoring log.

Observations documented. Read thermometer and verify on continuous monitoring log sheet. Record results on Silo Storage Temperature CCP Form. Every cold storage unit (each silo container) Designee If a deviation from the critical limit occurs, the supervisor will: 1. Hold product in cold storage unit until appropriate disposition taken (no product injurious to health will be shipped into commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence (9 CFR 417.3). Once per week, a supervisor will directly observe the monitoring activity, conduct the records review, and calibrate the thermometers (per manufacturer\u2019s instructions). Silo Storage Temperature Form Verification Form Corrective Action Form Pre-Shipment Form Thermometer Calibration Form 12", "EXAMPLE HACCP PLAN Unpasteurized Liquid Egg (Raw Non-Intact Processing Category) Critical Control Point (CCP) Significant Hazard(s) Critical Limits for Each Control Measure Monitoring Procedures Corrective Action Verification Records What How Frequency

Who CCP2 Loading, Shipping B: Outgrowth of pathogens, Salmonella Internal product temperature is \u226445\u00b0F (for product held less than 8 hours) \u226440\u00b0F (for product held more than 8 hours) at packaging Product temperature is measured at packaging prior to shipping. Measure product temperature with handheld probe thermometer. Each bulk container of unpasteurized liquid egg product intended for further processing into edible product (e.g., tanker). Designee If a deviation from the critical limit occurs, the supervisor will:

1. Hold product in cold storage unit until appropriate disposition taken (no product injurious to health will be shipped into commerce);
2. Determine and eliminate the cause of the deviation;
3. Bring the CCP under control;
4. Take measures to prevent recurrence (9 CFR 417.3).

Once per week, a supervisor will directly observe the monitoring activity, conduct the records review, and calibrate the thermometers (per manufacturer\u2019s instructions). Bulk Container Shipping Temperature Log Verification Form Corrective Action Form Pre-Shipment Form Thermometer Calibration Form DATE: APPROVED BY: 13", "i Hazards are grouped into three categories: Biological (B), Chemical (C), and Physical (P). Biological hazards are living organisms. Chemical hazards may be naturally occurring in foods, used or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification.

ii Place the justification for your decision in column 4. Control measures for hazards not reasonably likely to occur are entered in column 4. Control measures for hazards reasonably likely to occur are entered in column 5. If a hazard is reasonable likely to occur, then a CCP must be addressed at this step or a later step. See FSIS Egg Products Hazards and Controls Guide for a list of frequently used controls.

iii Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced article must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from an FSIS document, then HACCP system design must be supported by documentary evidence \u2013 that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan.

iv Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur (NRLTO) because the implementation of a prerequisite program (e.g., Sanitation Standard Operating Procedure (Sanitation SOP), written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation). 14"]}, {"file\_name": "FSIS\_GD\_2022\_0005", "title": "Label Application"}]

Guidance", "num": "FSIS-GD-2022-0005", "id": "2c2c8504481a85ba10281358ff5b09d50f33d131d959d3493a1fe869394ec4be", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/documents/FSIS-GD-2022-0005.pdf", "type": "pdf", "n\_pages": 1, "word\_count": 261, "text\_by\_page": ["Label Application Guidance The Labeling and Program Delivery Staff (LPDS) serves as the Agency\u2019s expert group on the composition of meat, poultry, and egg products, including safe and suitable ingredients. The Staff ensures that all labels are truthful and not misleading. Labeling includes all forms of product identification, claims, net weight, species identification and nutrition as related to meat, poultry, and egg products. The following label application guidance is relevant only to applications submitted in paper form and mailed to LPDS for evaluation. Label Applications sent via U.S. Postal Service (including regular mail, U.S. Priority Mail and U.S. Overnight Mail) should be mailed to: USDA, FSIS, OPPD, LPDS Labeling Distribution Unit Stop Code 3786, Room 1255 1400 Independence Avenue, SW Washington, DC 20250-3876 Label Applications sent via UPS, FedEx, or courier should be shipped to (delivered by courier to Room 1255): USDA, FSIS, OPPD, LPDS Labeling Distribution Unit Room 1255 1400 Independence Avenue, SW Washington, DC 20250-3876 Note: FAXED label applications are no longer accepted. Label Applications received in paper form are being integrated into the electronic LabelSubmissionandApprovalSystem(LSAS) for evaluation. To facilitate this process the following guidance, Integration of Paper Label Applications into the Label Submission and Approval System (LSAS) is essential for applicants to consider when submitting Label Applications in paper form. To confirm receipt or to check the status of Label Applications, contact our Distribution Team at (301)504-0883 for assistance. Questions concerning labeling regulations or policies, can be submitted through askFSIS: askFSIS or mailed to the address above for label applications. For additional assistance, contact our office at (301) 504-0878."]}, {"file\_name": "FSIS\_GD\_2022\_0006", "title": "HACCP Model for Raw Intact Farm-raised Catfish Products", "num": "FSIS-GD-2022-0006", "id": "3ed6229ecc6784ed452996e19c4e1720aa2f4aa5cd42d6e5495bdd795d40c1a", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/documents/FSIS-GD-2022-0006.pdf", "type": "pdf", "n\_pages": 14, "word\_count": 4230, "text\_by\_page": ["A Generic HACCP Model for a Raw Intact Farm-raised Catfish Product The United States Department of Agriculture (USDA) published the Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) Systems Final Rule in July 1996. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to address safety hazards reasonably likely to occur in their production process. Therefore, this HACCP model\u2019s focus, and the focus of the other HACCP models, is on product safety, not product quality characteristics. With the rule, FSIS made available a guidebook for the preparation of HACCP plans and a generic model for each food processing category defined in regulation 9 CFR 417.2(b)(1). The guidebook and the generic models have been updated since their initial publication to be consistent with current science and policy. FSIS recommends you use the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan. Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category."]}]

Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used as is. FSIS recommends that establishment tailor the model(s) to fit the establishment's operations. On December 2, 2015, FSIS published the final rule Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish (80 Federal Register 75590). The final rule amended the Agency's regulations to establish a mandatory inspection program for catfish and for products derived from catfish.<sup>1</sup> The final rule explains that, because catfish are an amenable species under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601(w)(2)), the catfish inspection program is part of the FSIS meat inspection program.<sup>2</sup> Generally, live catfish are processed into whole fish, fillets, steaks, strips, and nuggets. These products are typically sold raw. Raw products may be marinated, vacuum-tumbled, injected, or single-ingredient. Catfish fillets are also shipped frozen. Frozen products may contain a preservative (polyphosphate) which is used to minimize excessive water loss during freezing. Polyphosphates are added to the product in a (non-vacuum) tumbler. Little if any U.S. farm-raised catfish undergoes further processing into multi-ingredient ready-to-eat meals (e.g., gumbo, patties, surimi). This model illustrates the raw intact processing of farm-raised catfish into whole fish, fillets, steaks, strips, and nuggets. The model may not necessarily apply to all operations or products. Products or operations may require fewer or more Critical Control Points (CCPs) depending on the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. For additional guidance see the FSIS Compliance Guideline for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products. The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis, are HACCP decisionmaking records (9 CFR 417.5(a)). Ensure you maintain the documents produced while developing a HACCP plan.<sup>3</sup> For further assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP webpage.<sup>4</sup> For purposes of convenience, the term "catfish" is used in this HACCP model. Other FSIS documents may use "fish of the order Siluriformes," "Siluriformes fish," or simply "fish" in addition to "catfish." See the Executive Summary of the final rule Mandatory Inspection of Fish of the Order Siluriformes and Products Derived From Such Fish (page 75590). Prior to developing the HACCP plan, please read the Guidebook for the Preparation of HACCP Plans for detailed descriptions of the worksheets and hazard analysis. The FSIS Guidebook for the Preparation of HACCP Plans and the generic HACCP models are intended for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products.

**EXAMPLE PRODUCT DESCRIPTION**

Raw Intact Catfish

Raw intact farm-raised fresh catfish (whole fish, Process or Product name fillets, steaks, strips, nuggets)

Important product characteristics

None (Aw, pH, Preservatives, etc.)

To be fully cooked prior to consumption. For further processing at this facility or another Intended use<sup>4</sup> establishment or intended for cooking by end consumer

Packaging (durability and storage Vacuum-packaged, tray packs or bulk pack conditions) boxes

with liners. Refrigerated -5 days when held at 40°F. Shelf life and at what temperature5  
Frozen -4 months when held at 0°F. Where it will be sold (specify Sold to household  
consumers through retail intended consumers, especially at outlets or distributed to hotels,  
restaurants, and risk populations)6 institutions (HRI). Product name, inspection legend and  
establishment number, handling statement, safe Labeling instructions and handling  
instructions, net weight statement, requirements address line, nutrition facts panel, and  
ingredients list.7 Special distribution control None DATE: APPROVED

BY: \_\_\_\_\_ 4The intended use or consumer of the product must be  
identified in accordance with 9 CFR417.2(a)(2). Identifying the product's intended use in  
the product description is one way to meet the regulatory requirements specific to 417.2(a)(2).  
5Each establishment's products may have their own defined shelf life. 6At-risk  
populations include young children, the elderly, and immunocompromised persons. 7See the  
Labeling and Label Approval webpage for information on required labeling features and other  
labeling resources. Page 2 of 14", "EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING  
MATERIAL8 Raw Intact Catfish Meat Live farm-raised catfish Non-meat food ingredients  
Polyphosphate mixture Antimicrobial interventions9 and None processing aids Packaging  
material Plastic wrap and trays Restricted ingredients or Allergens Catfish contains allergenic  
proteins Other None DATE: APPROVED BY: \_\_\_\_\_ 8List all meat, non-  
meat ingredients, restricted ingredients (for example, nitrites), processing aids, and packaging  
material used in production of this product. This is important to help identify any special  
ingredients or processes to address in the HACCP plan. See the FSIS Compliance Guideline  
Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and  
Declaration through Labeling for detailed information on allergens. 9FSIS and the Food and Drug  
Administration (FDA) have a memorandum of understanding (MOU) that establishes the working  
relationship followed when responding to notifications for the use of food additives (including  
ingredients) intended for use in the production of FSIS regulated products. FSIS determines the  
suitability of the use of food ingredients used in the production of meat, poultry, and egg  
products. FSIS consults, as necessary, with FDA on the requirements under the Federal Food,  
Drug & Cosmetic Act (FD&C Act) and its implementing regulations. See FSIS Directive  
7120.1, Safe and Suitable Ingredients Used in Meat Poultry and Egg Products for the list of  
suitable ingredients. Page 3 of 14", "b 11 2022 b ~ ~ EXAMPLE PROCESS FLOW  
DIAGRAM10 Raw Intact Catfish 1. Receiving Farm-raised Catfish 3a. Manual -Deheaded and  
Eviscerated 3b. Automated -Deheaded and Eviscerated 2. Stunned 4. Remove Skin 5. Fillet  
Fillet line Whole Dressed fish 4. Remove Skin 6. Sizing 11 10. Rework and Work in 7. Chill 6.  
Sizing Progress 19. Receiving and 8. Ice 7. Chill Storage Non-Meat Ingredients 8. Ice 18.  
Returned Product12 11. Tumble Marination 9. Cooler 12. Individually Quick 17. Receiving and  
Frozen and Ice Glaze 14. Freezer Storage of Packaging 16. Ship (with or without ice) Materials  
15. Ship Frozen 13. Pack DATE: APPROVED BY: \_\_\_\_\_ 10 This is an example  
flow diagram. Establishments' flow diagrams for the same product may be different.  
Establishments determine which steps are included in their process. The steps must represent  
all relevant hazards in the hazard analysis. 11 Step 7 represents the manual  
processing procedures used to produce fillets, steaks, strips, and nuggets. 12 The Returned  
Product step (18) is shown not connected to another step. Returned product may re-enter the  
production system at different process steps depending on condition or food safety concerns.

Returned product may be relabeled, repackaged, or discarded. Page 4 of 14", "EXAMPLE HAZARD ANALYSIS Raw Intact Catfish Potential Hazard13 Is the Hazard Reasonably Likely to occur (RLTO)? Justification or Basis for Decision14 If yes in Column 2 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels15 Is this Step a Critical Control Point (CCP)? 1. Receiving Farm-raised Catfish B: Salmonella No A hazard identification study identified Salmonella as one of the few potential hazards. There is evidence that at least one outbreak of human salmonellosis may have been related to catfish consumption. Although Salmonella has been isolated from farm-raised catfish fillets, Salmonella contamination is a hazard not reasonably likely to occur when processing catfish. Product is to be fully cooked prior to consumption. 13Hazards are grouped into three categories: Biological (B), Chemical (C), and Physical (P). Biological hazards are living organisms. Chemical hazards may be naturally occurring in foods, used or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification. 14Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced articles must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from an FSIS program, then HACCP system design must be supported by documentary evidence \u2013 that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan. 15Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, or antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation, page 5). Page 5 of 14", "1111111111\u00b7-----

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-----+-----\u00b7||||| Potential Hazard RLTO Justification or Basis Controls CCP C: Allergenic proteins No Catfish is a food allergen. Products are properly labeled. P: None 2. Stunned B: None C: None P: None 3a. Manual \u2013 Deheaded and Eviscerated B: Salmonella Outgrowth No Written Sanitation Standard Operating Procedures (Sanitation SOPs) to prevent or minimize cross-contamination. Temperature Control Standard Operating Procedures (SOPs) for the processing area to aid in the control of Salmonella outgrowth. The total time required to remove heads, eviscerate, and prepare products for packaging is short enough to preclude the outgrowth of Salmonella and meets the time and temperature parameters in the Federal Food and Drug Administration\u2019s (FDA\u2019s) guidance.16 C: Sanitizers No Written Chemical Receiving, Storage, and Use SOP. P: None 16 See the FDA\u2019s Fish and Fishery Products Hazards and Controls Guidance (Table A-2 page 421).

Page 6 of 14", "-----~-----1-----

-----+-----\u00b7||||| Potential Hazard RLTO Justification or Basis Controls CCP 3b. Automated \u2013 Deheaded and Eviscerated B: Salmonella No Written Sanitation SOPs to prevent or minimize cross-contamination. Outgrowth Temperature Control SOP for the processing area to aid in the control of Salmonella outgrowth. The total time required to remove heads, eviscerate, and prepare products for packaging is short enough to preclude the outgrowth of Salmonella and meets the time and temperature parameters in the FDA guidance.17 No Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer\u2019s instructions and is within the allowable limits identified in Directive 7120.1 (FCN# [insert number]).18 Yes Metal fragments could come from processing equipment. No historical findings of foreign material contamination.19 C: Sanitizers P: Foreign Written Foreign Foreign Materials Material SOP requires Material daily equipment CCP 1 examination and preventive maintenance to prevent foreign materials (e.g., metal, rubber, plastic) from contaminating the product.20 17 See the Federal Food and Drug Administration\u2019s Fish and Fishery Products Hazards and Controls Guidance (Table A-2 page 421). 18 Provide reference for scientific support and validation for effective concentrations and support for critical operational parameters that reduce biological hazards. FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products contains the list of substances that maybe used in the production of meat and poultry products. The list contains the allowable amounts and the intended use of the approved antimicrobials. The list (Directive 7120.1) can be used as supporting documentation for chemical hazard controls (safety and suitability). Directive 7120.1 cannot be used as support for the control of biological hazards because the antimicrobial concentration needed to control bacteria is different from the concentrations required for safety and suitability. 19 Note: this \u201chistorical data\u201d must be supported with evidence from the establishment through the establishment\u2019s history or validation data with reference to the actual SOP or prerequisite program. When historical data is not available (for example, a HACCP plan for a new process or product), then system design must be supported by Page 7 of 14", "-----r-----\""\u201cT'\u201d-----

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----- Potential Hazard RLTO Justification or Basis Controls CCP Outgrowth likely to occur. Product internal temperature is lowered to  $\leq 40^{\circ}\text{F}$  during processing. 21 Product temperature during processing is not to exceed the time and temperature parameters in the FDA's Fish and Fishery Products Hazards and Control Guidance (Table A-2, page 421). 22 Written Processing SOP for maintenance of ice and water solution temperature. C: None P: None 8. Ice B:None C:None P: Foreign Material No Written Ice Machine Maintenance SOP to ensure the ice produced is free of foreign materials. 9. Cooler B:Salmonella Outgrowth No Cooler ambient temperature is  $\leq 40^{\circ}\text{F}$ . Written Cooler Temperature Monitoring SOP. 21 Establishments may be able to safely process catfish without an ice and water chilling process, relying instead on the coolers and freezers to bring down product temperatures. 22 If

an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. However, if an establishment implements different critical operational parameters in the process from the scientific support, or the scientific support identified does not contain microbiological data, then the establishment should collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameter (FSIS Compliance Guideline HACCP Systems Validation, page 27). Page 9 of 14","-----r-----r-----\u202211111111-----

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None P: None 10. Rework and Work in Progress B: Salmonella Outgrowth No Catfish products  
have been chilled to, and maintained at or below \u2264 40\u00b0F. C: None P: None 11.  
Tumble Marination B: Salmonella Outgrowth No Product temperature during the tumble  
marination process does not exceed the time and temperature parameters in the FDA\u2019s  
Fish and Fishery Products Hazards and Control Guidance (Table A-2, page 421). C: Chemicals No  
Polyphosphate mixture received, stored, and handled according to Written Receiving, Storage,  
and Use SOP to prevent chemical contamination. The polyphosphate mixture is used within the  
allowable limits identified in Directive 7120.1- Table of Safe and Suitable Ingredients for Fish in  
the Order of Siluriformes(FCN# [insert number]).23 P: None 12. Individually Quick Frozen and  
Ice Glaze 23FSIS Directive 7120.1, Safe and Suitable Ingredients for Fish in the Order of  
Siluriformes contains the list of substances that may be used in the production of catfish  
products. The list contains the allowable amounts and the intended use of the approved  
compounds. The list (Directive 7120.1) can be used as supporting documentation for chemical  
hazard controls (safety and suitability). Page 10 of 14","-----r-----r-----\u20221111111111111111-----

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||||| Potential Hazard RLTO Justification or Basis Controls CCP B:None C: None P: None 13.  
Pack B:None C: Allergens Product does not contain non-meatallergenic ingredients. Allergen  
Control SOP ensures ingredient statements on finished product labels match ingredient  
formulation.Catfishcontains allergenic proteins. P: None 14. Freezer B:Salmonella Outgrowth  
No Freezer ambient temperature is \u2264 0\u00b0F. Written FreezerTemperature Monitoring  
SOP. C: None P: None 15. Ship Frozen B:Salmonella Outgrowth No Frozen products are  
transported \u2264 0\u00baF. Product Transport SOP to ensure product temperatures are  
maintained when transported via company owned or contracted carriers. C:None P:None 16.  
Ship (with or without ice) Page 11 of 14","-----r-----r-----  
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Potential Hazard RLTO Justification or Basis Controls CCP B:Salmonella Outgrowth No  
Catfishproducts are transported in ice and \u2264 40\u00b0F. Product Transport SOP to ensure  
product temperatures are maintained when transported via company owned or contracted  
carriers. C: None P: None 17. Receiving and Storage of Packaging Materials B: None C: Chemical  
Contamination No Packaging materials are received, stored, and handledaccording to Written  
Receiving, Storage, and Use SOP to prevent contamination of products. LOG for all packaging  
materials describing quality controls and prevention procedures. Written Sanitation SOP for  
procedures used to protect packaging materials from environmental contamination. P:None 18.  
Returned Product B: Outgrowth of Pathogens No Returned Product Evaluation SOP  
implemented before accepting returned product. Person(s) or business returning the product  
must demonstrate the product was held in the appropriate temperature range and in a sanitary

manner. When such assurance is not available, returned product is rejected or destroyed. Opened packages are not accepted. Accepted product enters the appropriate step of the production system based on findings of product evaluation. Notify FSIS personnel when returned product has been accepted. C: None Page 12 of 14", -----r-----

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-----1-----1-----| Potential Hazard

RLTO Justification or Basis Controls CCP P: None 19.Receiving and Storage of Non-Meat Ingredients B: Presence of No Salmonella C:Undeclared No allergens Polyphosphate mixture is received, stored, and handled according to Written Receiving, Storage, and Use SOP to ensure non-meat ingredients are not contaminated and otherwise, suitable for use. LOG from suppliers describing quality controls and prevention procedures. Written Sanitation SOP for procedures used to protect ingredients from environmental contamination. LOG from suppliers describing quality controls and prevention procedures. Written Receiving, Storage and Use SOP with procedures to verify for each lot of incoming ingredients does not contain allergenic ingredients. Approved supplier program and ongoing communication with suppliers to verify LOG. P: None DATE: APPROVED BY: Page 13 of 14", "Page 14 of 14 Example Raw Intact Catfish HACCP Plan Automated \u2013 Deheaded and Eviscerated CCP 1 Hazard(s) Foreign Materials Critical Limits Visible metal fragments Monitoring procedures What Metal detection device used for all products. How Packaged product passes through a metal detector. Frequency Each. Who Designated employee. Corrective Action If a deviation from the critical limit occurs, the designated employee will immediately report to the manager. The manager will: 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence. 9 CFR 417.3 Verification Randomly, once each week, the supervisor will directly observe the designated employee monitor the metal detector. Once every week, the supervisor will review records. Records Corrective Action Log, Lab Results Form, Records Review Form, Preshipment Records"]}, {"file\_name": "FSIS\_GD\_2022\_0007", "title": "HACCP Model for Raw Intact Wild-caught Catfish Products", "num": "FSIS-GD-2022-0007", "id": "153afca7a3aee4bb17b8d1ecd2436b05386c98becf0a8e2512d8c9a69ce4d825", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/documents/FSIS-GD-2022-0007.pdf", "type": "pdf", "n\_pages": 13, "word\_count": 4109, "text\_by\_page": ["A Generic HACCP Model for a Raw Intact Wild-caught Catfish Product The United States Department of Agriculture (USDA) published the Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) Systems Final Rule in July 1996. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to address safety hazards reasonably likely to occur in their production process. Therefore, this HACCP model\u2019s focus, and the focus of the other HACCP models, is on product safety, not product quality characteristics. With the rule, FSIS made available a guidebook for the preparation of HACCP plans and a generic model for each food processing category defined in regulation 9 CFR 417.2(b)(1). The guidebook and the generic models have been updated since their initial publication to be consistent with current science and policy. FSIS"]}

recommends you use the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan. Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used as is. FSIS recommends that establishment tailor the model(s) to fit the establishment's operations. On December 2, 2015, FSIS published the final rule Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish (80 Federal Register 75590). The final rule amended the Agency's regulations to establish a mandatory inspection program for catfish and for products derived from catfish.<sup>1</sup> The final rule explains that, because catfish are an amenable species under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601(w)(2)), the catfish inspection program is part of the FSIS meat inspection program.<sup>2</sup> Generally, live catfish are processed into whole fish, fillets, steaks, strips, and nuggets. These products are typically sold raw. Raw products may be marinated, vacuum-tumbled, injected, or single-ingredient. This model illustrates the raw intact processing of wild-caught catfish into whole fish, fillets, steaks, strips, and nuggets. The model may not necessarily apply to all operations or products.

Products or operations may require fewer or more Critical Control Points (CCPs) depending on the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. For additional guidance see the FSIS Compliance Guideline for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products. The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis, are HACCP decisionmaking records (9 CFR 417.5(a)). Ensure you maintain the documents produced while developing a HACCP plan.<sup>3</sup> For further assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP webpage. <sup>4</sup> For purposes of convenience, the term "catfish" is used in this HACCP model. Other FSIS documents may use "fish of the order Siluriformes" or simply "fish" in addition to "catfish". <sup>5</sup> See the Executive Summary of the final rule Mandatory Inspection of Fish of the Order Siluriformes and Products Derived From Such Fish (page 75590). <sup>6</sup> Prior to developing the HACCP plan, please read the Guidebook for the Preparation of HACCP Plans for detailed descriptions of the worksheets and hazard analysis. The FSIS Guidebook for the Preparation of HACCP Plans and the generic HACCP models are intended for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products. <sup>7</sup> Page 1 of 13, "EXAMPLE PRODUCT DESCRIPTION" Raw Intact Catfish Process or Product name Important product characteristics (Aw, pH, Preservatives, etc.) Intended use<sup>8</sup> Packaging (durability and storage conditions) Shelf life and at what temperature<sup>9</sup> Where it will be sold (specify intended consumers, especially at-risk populations)<sup>10</sup> Labeling instructions and requirements Special distribution control DATE: Raw intact wild-caught fresh catfish (whole fish, fillets, steaks, strips, nuggets) None To be fully cooked prior to consumption. For further processing at this facility or another establishment or

intended for cooking by end consumer Vacuum-packaged, tray packs or bulk pack boxes with liners. Refrigerated -5 days when held at 40°F. Sold to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI). Product name, inspection legend and establishment number, handling statement, safe handling instructions, net weight statement, address line, nutrition facts panel, and ingredients list. 8 None APPROVED BY: 4 Prior to developing the HACCP plan please read the FSIS Guidebook for the Preparation of HACCP Plans for detailed descriptions of the worksheets and hazard analysis. The FSIS Guidebook for the Preparation of HACCP Plans and the generic HACCP models are intended for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP models are for demonstration purposes only. The models do not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products. 5 The intended use or consumer of the product must be identified in accordance with 9 CFR 417.2(a)(2). Identifying the product's intended use in the product description is one way to meet the regulatory requirements specific to 417.2(a)(2). 6 Each establishment's products may have their own defined shelf life. 7 At-risk populations include young children, the elderly, and immunocompromised persons. 8 See the Labeling and Label Approval webpage for information on required labeling features and other labeling resources. Page 2 of 13, "EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL" 9 Raw Intact Catfish Meat Live wild-caught catfish Non-meat food ingredients None Antimicrobial interventions 10 and None processing aids Packaging material Plastic wrap and trays, boxes and liners Restricted ingredients or Allergens Catfish contains allergenic proteins Other None DATE: APPROVED BY: \_\_\_\_\_ 9 List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, and packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. See the FSIS Compliance Guideline Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling for detailed information on allergens. 10 FSIS and the Food and Drug Administration (FDA) have a memorandum of understanding (MOU) that establishes the working relationship followed when responding to notifications for the use of food additives (including ingredients) intended for use in the production of FSIS regulated products. FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDA on the requirements under the Federal Food, Drug & Cosmetic Act (FD&C Act) and its implementing regulations. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat Poultry and Egg Products for the list of suitable ingredients. Page 3 of 13, "t, It II \u00a2 ...---~---. 11 EXAMPLE PROCESS FLOW DIAGRAM" 11 Raw Intact Catfish 2. S t unned 3. Manual -Deheaded and Eviscerated 1. Receiving Wild-caught Catfish CCP 1 5. Remove Skin 6. Sizing 12 7. Chill 8. Pack 4. Whole Dressed Fish 11. Rework and Work in Progress 12. Receiving and Storage of Packaging Materials 9. Cooler 10. Ship Fresh 13. Returned Product 13 DATE:

\_\_\_\_ APPROVED BY: \_\_\_\_\_ 11 This is an example flow diagram. Establishments' flow diagrams for the same product may be different. Establishments determine which steps are included in their process. The steps must represent all relevant hazards in the hazard analysis. 12 Step 7 \u201c Sizing \u201d represents the manual processing procedures used to produce fillets, steaks, strips, and nuggets. 13 The Returned Product step (18)

is shown not connected to another step. Returned product may re-enter the production system at different process steps depending on condition or food safety concerns. Returned product may be relabeled, repackaged, or discarded. Page 4 of 13", "----- L

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.1 ----- EXAMPLE HAZARD ANALYSIS

Raw Intact Catfish Potential Hazard<sup>14</sup> Is the Hazard Reasonably Likely to occur (RLTO)?

Justification or Basis for Decision<sup>15</sup> If yes in Column 2 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels<sup>16</sup> Is this Step a Critical Control Point (CCP)? 1. Receiving Wild-caught Catfish CCP 1 B: Salmonella No A hazard identification study identified Salmonella as one of the few potential hazards.<sup>17</sup> There is evidence that at least one outbreak of human salmonellosis may have been related to catfish consumption. Although Salmonella has been isolated from wild-caught catfish product, Salmonella is considered not reasonably likely to occur when processing wild-caught catfish.<sup>18</sup>

<sup>14</sup>Hazards are grouped into three categories: Biological (B), Chemical (C), and Physical (P).

Biological hazards are living organisms. Chemical hazards may be naturally occurring in foods, used or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification. <sup>15</sup>Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced articles must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from an FSIS program, then HACCP system design must be supported by documentary evidence \u2013 that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan. <sup>16</sup>Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, or antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation, page 5). <sup>17</sup>See the Assessment of the Potential Change in Human Health Risk associated with Applying Inspection to Fish of the order Siluriformes. <sup>18</sup>Abstract: Effect of Federal Inspection on Louisiana Wild-Caught Catfish Industry, Prevalence of Salmonella, and Microbial Characteristics of Raw Wild-Caught Catfish Fillets Page 5 of 13", "\u00b7-----;-----1-----

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||||||||| Potential Hazard RLTO Justification or Basis Controls CCP P:None 2. Stunned B: None C: None P: None 3. Manual \u2013 Deheaded and Eviscerated B: Salmonella Outgrowth No Written Sanitation Standard Operating Procedures (Sanitation SOPs) to prevent or minimize cross-contamination. Temperature Control Standard Operating Procedures (SOPs) for the processing area to aid in the control of Salmonella outgrowth. The total time required to remove heads, eviscerate, and prepare products for packaging is short enough to preclude the outgrowth of Salmonella and meets the time and temperature parameters in the Federal Food and Drug Administration\u2019s (FDA\u2019s) guidance.<sup>25</sup> C: Sanitizers No Written Chemical Receiving, Storage, and Use SOP. P: None 25 See the FDA\u2019s Fish and Fishery Products Hazards and Controls Guidance (Table A-2 page 421). Page 7 of 13", "-----~-----

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RLTO Justification or Basis Controls CCP 4. Whole Dressed Fish B: Salmonella No Outgrowth C: Sanitizers No P: Foreign No Materials Written Sanitation SOPs to prevent or minimize cross-contamination. Temperature Control SOP for the processing area to aid in the control of Salmonella outgrowth. The total time required to remove heads, eviscerate, and prepare products for packaging is short enough to preclude the outgrowth of Salmonella and meets the time and temperature parameters in the FDA guidance.<sup>26</sup> Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer's instructions and is within the allowable limits identified in Directive 7120.1 (FCN# [insert number]).<sup>27</sup> Written Foreign Material SOP requires daily equipment examination and preventive maintenance to prevent foreign materials (e.g., metal, rubber, plastic) from contaminating the product.<sup>28</sup> No historical findings of foreign material contamination.<sup>29</sup> See the Federal Food and Drug Administration's Fish and Fishery Products Hazards and Controls Guidance (Table A-2 page 421). Provide reference for scientific support and validation for effective concentrations and support for critical operational parameters that reduce biological hazards. FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products contains the list of substances that may be used in the production of meat and poultry products. The list contains the allowable amounts and the intended use of the approved antimicrobials. The list (Directive 7120.1) can be used as supporting documentation for chemical hazard controls (safety and suitability). Directive 7120.1 cannot be used as support for the control of biological hazards because the antimicrobial

concentration needed to control bacteria is different from the concentrations required for safety and suitability. 28This Foreign Material SOP(prerequisite program) should have details on how this procedure(such as metal prevention controls)is preventing the hazard from occurring as well as the on-going verification procedures. These controls should be evident within the written document upon review. The Foreign Material SOP and plant data related to on-going verification activities then become part of recordkeeping and historical data. 29Note:this \u201chistorical data\u201d must be supported with evidence from the establishment through the establishment\u2019s history or validation data with reference to the actual SOP or prerequisite program. When historical data is not available (for example,a HACCP plan for a new process or product), then system design must be supported by other documentary evidence. Such as the Fish and Fishery Products Hazards and Controls Guidance which states \u201cpreventive measures for metal inclusion can include periodically checking equipment for damaged or missing parts\u201d (page 386). Page 8 of 13","-----r-----\"T\"-----

P-----t----- Potential Hazard RLTO Justification or Basis Controls CCP 5.  
Remove Skin B:None C: None P: None 6. Sizing B: None C: None P: None 7. Chill B:Salmonella  
No Salmonellaoutgrowthduring catfish processing is not reasonably Outgrowth likely to occur.  
Product internal temperature is lowered to \u2264 40\u00b0F during processing.30 Product  
temperature during processing is not to exceed the time and temperature parameters in the  
FDA\u2019s Fish and Fishery Products Hazards and Control Guidance (Table A-2,page 421).31  
Written Processing SOP for maintenance of ice and water solution 30 Establishments may be  
able to safely process catfish without an ice and water chilling process, relying instead on the  
coolers and freezers to bring down product temperatures. 31 If an establishment implements a  
process consistent with the process specifications described in the scientific support, and the  
scientific support contains microbiological data specifying the level of pathogen reduction  
achieved by the intervention strategy for the target pathogen identified in the hazard analysis,  
the in-plant data collected during the 90 day initial validation period will consist of data on  
quantifiable characteristics of the critical operational parameters, such as pressure,  
temperature, and concentration. However, if an establishment implements different critical  
operational parameters in the process from the scientific support, or the scientific support  
identified does not contain microbiological data, then the establishment should collect in-plant  
data demonstrating the critical operational parameters that it has implemented can all be met  
AND should collect in-plant microbiological data or identify scientific support with  
microbiological data that demonstrates the effectiveness of those implemented critical  
operational parameter (FSIS Compliance Guideline HACCP Systems Validation, page 27). Page 9  
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FSIS personnel when returned product has been accepted. Page 11 of 13",-----r-----  
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Potential Hazard RLTO Justification or Basis Controls CCP C: None P: None DATE: APPROVED BY: Page 12 of 13", "Page 13 of 13 32 This critical limit reflects the consumption advisory for catfish harvested from the Potomac River Basin (2022), it would not apply to all sources of wild-caught catfish. Different regions may include reports for different chemicals. Consumption advisories for a region may change over time. Example Raw Intact Catfish HACCP Plan Receiving Wild-caught Catfish CCP 1 Hazard(s) Environmental Chemicals - PCBs Critical Limits Channel catfish harvested from the Potomac River Basin which are \u2265 18 inches in length are not processed.32 Monitoring procedures What Sort catfish \u2265 18 inches in length How Identify catfish that approach 18 inches in length and measure the sorted fish. Frequency Each fish that \u2265 18 inches in length. Who Designated employee. Corrective Action If a deviation from the critical limit occurs, a supervisor will: - 1. Hold the product lot until appropriate disposition is taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence (9 CFR 417.3) Verification Randomly, once per week, the supervisor will directly observe designated employee sorting and measuring the fish. Once every three months, the supervisor will review records. Records Corrective Action Log, Lab Results Form, Records Review Form, Preshipment Records"]}, {"file\_name": "FSIS\_GD\_2023\_0001", "title": "FSIS Guideline for Label Approval", "num": "FSIS-GD-2023-0001", "id": "f3fc42eeecf0880230b784fa2c7670cbb85a085f9afad8050af5b96b55cdd03b", "corpus": "fsis\_guidelines", "source\_page\_url": "https://www.fsis.usda.gov/policy/fsis-guidelines", "url": "https://www.fsis.usda.gov/sites/default/files/media\_file/documents/FSIS-GD-2023-0001.pdf", "type": "pdf", "n\_pages": 37, "word\_count": 13012, "text\_by\_page": ["FSIS Guideline for Label Approval January 2023 FSIS-GD-2023-0001 This guideline is designed to help establishments determine whether their labels must be submitted to FSIS Labeling and Program Delivery Staff (LPDS) for approval. 1", "Table of Contents", "Preface..... 3", "Congressional Review Act ..... 3", "Purpose..... 3", "Reason for Reissuing the Guideline..... 4", "Changes from the Previous Version of the Guideline", "..... 4 How to Effectively Use the Guideline", "..... 5 How to Comment on the Guideline", "..... 5 Questions Regarding Topics in this Guideline ..... 6", "Background..... 7", "Special Statements and Claims (9 CFR 412.1 (c) (3)) .....", "8 Factual Statements and Claims Generically Approved (9 CFR 412.2)", "..... 8 Changes to Labels with Approved Special Statements and Claims That Do Not Require Additional LPDS Review..... 9"]}

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Preface This is a revised version of the FSIS Guideline for Label Approval. It replaces the July 2020 version of the guideline. The previous version of the guideline was titled the \u201cFSIS Compliance Guideline for Label Approval.\u201d The Food Safety and Inspection Service (FSIS) has renamed the guideline the \u201cFSIS Guideline for Label Approval,\u201d so asnotto give the impression thatthe documenthasforce and effectof law. This guideline represents FSIS\u2019 current thinking on these topics and should be considered effectiveas ofits issuance. Establishments that used previous versions of the FSIS Guideline for Label Approval should update their procedures as necessary based on this guideline. For purposes of this document, the term \u201cestablishment(s)\u201d includes official meat and poultry establishments and egg products plants, unless otherwise indicated. The information in this guideline is provided to assist establishments in meeting regulatory requirements. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to industry regarding existing requirements under the regulations. This guideline is focused on small and very small establishments, in support of the Small Business Administration\u2019s initiative to provide small businesses with compliance assistance under the Small Business Regulatory Fairness Act. However, all establishments may apply the recommendations in this guideline. It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to label products in compliance with FSIS regulations. Although large establishments can benefit from the information provided, focusing the guideline on the needs of small and very small establishments provides them with assistance that may be otherwise unavailable to them. Congressional Review Act Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq, the Office of Information and Regulatory Affairs .....	35

has determined that this guideline is not a major rule, as defined by 5 U.S.C. 804(2). Key Point Purpose LPDS only needs to evaluate three types of labels prior to use in commerce (9 CFR 412.1 (c)): This guideline provides information about 1) Labels for religious exempt products 9 CFR the types of labels that must be submitted 412.1 (c) (1). 2) Labels with special statements and claims to LPDS for approval. Specifically, LPDS 9 CFR 412.1 (c) (3). must review three categories of labels 3) Labels for temporary approval 9 CFR 412.1 before they may be used in commerce: (c) (4). labels for religious exempt products (9 CFR 412.1(c)(1)), labels with special statements and claims (9 CFR 412.1(c)(3)), and labels for temporary approval 9 CFR 412.1(c)(4). All other categories of labels are considered generically approved, meaning they may be used in commerce without prior review by LPDS provided that they meet all applicable labeling requirements. All labels, including 3", "generically approved labels, are, subject to routine verification by FSIS field inspectors to ensure ongoing compliance with FSIS labeling requirements. All labels, whether submitted to LPDS for approval or generically approved, are required to comply with all FSIS labeling requirements. To assist establishments with the design and modification of their product labels, this guideline includes specific examples of special statements and claims that must be submitted to LPDS for approval. This guideline also provides examples of: (1) factual statements and claims that are eligible for generic approval, (2) changes that can be made to labels approved with special statements and claims without additional LPDS review, (3) changes that cannot be made to labels approved with special statements and claims without additional LPDS review, (4) blanket label approvals (labels for product line or multiple product lines with identical claims), (5) information about negative claims, (6) information about export labels with deviations from domestic requirements, and ( geographic landmark claims on labels and additional information about label approval. Reason for Reissuing the Guideline FSIS reissued this guideline in response to comments received on the previous version and to improve clarity. This revision also reflects changes to generic labelling approval eligibility established by the final rule, Prior Label Approval System: Expansion of Generic Label Approval (88 FR 2798). The final rule expanded generic approval to products only intended for export that deviate from domestic labeling requirements and permitted generic approval of the labels of products that receive voluntary FSIS inspection. It also expanded generic approval to: (1) organic claims that appear in a product label\u2019s ingredients statement; (2) geographic landmarks\u201d displayed on a product label; (3) negative\u201d claims made on product labels that identify the absence of certain ingredients or types of ingredients. In addition, the final rule announced that LPDS will no longer evaluate generically approved labels voluntarily submitted to LPDS for review. Changes from the Previous Version of the Guideline This guideline, dated January 2023, is final. FSIS will update this guideline, as necessary, should new information become available. This version incorporates the following changes: The guideline\u2019s title was shortened from the FSIS Compliance Guideline for Label Approval to the FSIS Guideline for Label Approval. In the appendices, A bold red asterisk (\*) marks new or updated entries to the appendix. Items previously on the list not marked by a bold red asterisk (\*) may have been rearranged for ease of readability. A bold plus (+) marks claims that reference a guideline that is hyperlinked at the end of the appendix. A red bold hash (#) marks reference that there is additional information about this factual negative statement in Appendix 7. Appendix 1 now includes new

examples of special statements and claims that require LPDS approval before they can be used on labels of product in commerce 4", "(e.g., \u201cnatural\u201d and \u201cno animal by-products\u201d claims). Some other types of claims were moved from Appendix 1 to Appendix 2, given they are now eligible for generic approval (e.g., certain negative claims and state endorsement programs that have geographic emblematic design). \u2022 Appendix 2 now includes several new factual statements and claims that do not require LPDS approval before they can be used on labels of product in commerce (e.g., \u201cAuthentic,\u201d and \u201cDouble Smoked\u201d). \u2022 Appendix 3 no longer references export labels that deviate from domestic requirements, as those labels are no longer required to be submitted to LPDS for approval. \u2022 Appendix 4 no longer includes two examples of export labels, given they are now eligible for generic label approval. \u2022 Appendix 5 includes new examples of labels that can be approved as a blanket approval. \u2022 Appendix 6 includes new examples of special statements and claims that can be generically approved after receiving the first approval from LPDS. \u2022 Appendix 7 has been added to provide information and examples about the types of negative claims that are generically approved. \u2022 Appendix 8 has been added to provide information about the generic approval of export labels that deviate from domestic requirements and geographic landmark claims. \u2022 Appendix 9 is now entitled \u201cAdditional Information for Label Approval,\u201d which was the previous title of Appendix 7.

**How to Effectively Use the Guideline**

This guideline is organized to provide users with FSIS\u2019s current thinking on its labeling regulations. To use this guideline, LPDS recommends that readers use the navigation headings to move efficiently through the document sections of interest. Hyperlinks, where provided, will quickly take you to the correct place in the document electronically and are also provided for other complementary documents. The Resources section of this guideline provides resource material used in the revision of this guidance.

**How to Comment on the Guideline**

FSIS is seeking public comment on this guideline as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to content, readability, applicability, and accessibility. The comment period will be 60 days from publication of the Federal Register Notice (88 FR 2798) and, as appropriate, the 5", "Agency may update this guideline in response to comments.

Although FSIS may make changes to future iterations of this guideline in response to comments, this document reflects current thinking. FSIS encourages establishments producing products discussed in this document to review it. Comments may be submitted by either of the following methods:

- \u2022 Federal eRulemaking Portal Online submission at [Regulations.gov](https://www.regulations.gov). This website provides a way to type short comments directly into the comment field on the webpage or attach a file to submit lengthier comments. Follow the online instructions at that site to submit comments.
- \u2022 Mail and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, 1400 Independence Avenue SW, Washington, D.C. 20250-3700. All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title: FSIS GUIDELINE FOR LABEL APPROVAL. Comments received will be made available for public inspection and posted without change, including any personal information, on <https://www.regulations.gov>.

**Questions Regarding Topics in this Guideline**

If after reading this guideline you still have questions, FSIS recommends searching the publicly posted Knowledge Articles (\u201cPublic Q&As\u201d) in the askFSIS database. If after

searching the database, you still have questions, refer them to the Office of Policy and Program Development through askFSIS and select Labeling as the Inquiry type or by telephone at 1-800-233-3935. Documenting these questions helps FSIS improve and refine present and future versions of the guideline and associated issuances.

6", "FSIS Guideline for Label Approval Background FSIS is publishing this guideline to provide information about the types of labels that must be submitted to the Agency for approval, including specific examples of special statements and claims. To prevent the introduction of adulterated or misbranded products into commerce, LPDS implements a prior label approval system for labels intended to be used on federally inspected meat, poultry, and egg products, including imported products (9 CFR 412). Without approved labels, meat, poultry, and egg products may not be sold, offered for sale, or otherwise distributed in commerce. Under LPDS\u2019 prior label approval system, there are two types of label approval. First, certain categories of labels must receive \u201ckscketch approval\u201d (9 CFR 412.1). To receive sketch approval, establishments must submit a rendering of their label (i.e., a \u201ckscketch label) to LPDS for evaluation prior to use in commerce. The sketch label must reasonably represent what the label will ultimately look like but need not be the actual final label applied to the product. Other categories of labels are \u201cgenerically approved,\u201d meaning they are approved for use in commerce without LPDS evaluation so long as they are consistent with FSIS regulations (9 CFR 412.2).

Establishments do not need to submit generically approved labels to LPDS for evaluation prior to use so long as they meet all applicable labeling requirements. However, all labels, including generically approved labels are subject to routine verification by FSIS field inspectors. The categories of labels that require sketch approval and, therefore, need to be submitted to LPDS for evaluation are: 1) Labels for religious exempt products 9 CFR 412.1(c) (1); 2) Labels with special statements and claims 9 CFR 412.1 (c) (3); and 3) Labels for temporary approval 9 CFR 412.1(c) (4). Below, there is further discussion about special statements and claims that require submission to LPDS for approval and additional information about generic approval, including:

\u2022 Special statements and claims that require submission to LPDS;

\u2022 Factual statements and claims that are generically approved;

\u2022 Changes that can be made to labels approved with special statements and claims without additional LPDS review;

\u2022 Changes that cannot be made to labels approved with special statements and claims without additional LPDS review;

7", "\u2022 Blanket label approvals (labels for product line or multiple product lines with identical claims);

\u2022 Special statements and claims that can be generically approved after first approval by LPDS;

\u2022 Information about negative claims;

\u2022 Information about export labels with deviations from domestic requirements and geographic landmark claims on labels and;

\u2022 Additional information about label approval.

More information can also be found in each of the appendices summarized below.

Special Statements and Claims (9 CFR 412.1 (c) (3))

\u201cSpecial statements and claims\u201d are claims, logos, trademarks, and other symbols on labels that are generally not defined in FSIS regulations or in the Food Standards and Labeling Policy Book.

\u2022 An example of a logo or symbol is a graphic representation of a heart.

Special statements and claims include

\u201cnatural\u201d claims, \u201ccertified gluten free\u201d claims (e.g., Certified Gluten Free by XYZ entity), health claims, ingredient and processing method claims (e.g., high-pressure processing), claims regarding the raising of animals, organic claims, and instructional or disclaimer statements concerning pathogens (e.g., \u201cfor cooking only\u201d or \u201cnot

tested for E-coli O157:H7\u201d). See Appendix 1 for an expanded list of examples of special statements and claims. Factual Statements and Claims Generically Approved (9 CFR 412.2) FSIS does not consider some factual statements applied to labels to be special statements or claims that require submission to LPDS for approval. Rather, they are statements offactthat mustbe supported in the labeling record.These factual statements are generically approved. \u2022 Examples of factual statements in this category include defined geographic styles (e.g., \u201cItalian Style\u201d), \u201cextra\u201d or \u201cmore\u201d statements (e.g., \u201c10% more cheese\u201d), geographic landmarks (e.g., Statue of Liberty, maps, flags), organic ingredients listed in the ingredients statement (e.g., organic sugar or organic garlic), and allergen statements (e.g., \u201ccontains milk\u201d) consistent with the Food Allergen Labeling and Consumer Protection Act. Most negative claims (e.g., \u201cNo Pork\u201d) are also generically approved, including \u201cgluten free\u201d (without an accompanying certification statement) and \u201cno monosodium glutamate (MSG)\u201d or \u201cno MSG added\u201d with appropriate disclaimer statement. However, LPDS evaluation continues to be required for labels that bear negative claims relating to the raising of the animal from which the product is derived (e.g., \u201cno antibiotics administered\u201d) or negative claims relating to the use of genetically modified ingredients. For more information about animal raising claims, see the Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submissions (2019). For more information about negative claims related to the use of genetically modified ingredients, see the Labeling Guideline on 8", "Statements that Bioengineered or Genetically-Modified Ingredients or Animal Feed were not used in Meat, Poultry or Egg Products. See Appendix 2 for an expanded list of examples of factual statements that are generically approved. Changes to Labels with Approved Special Statements and Claims That Do Not Require Additional LPDS Review Once a label is approved by LPDS for compliance with 9 CFR 412.1, there are several changes that can be made to the label that do not require resubmission to LPDS. These changes are generically approved under 9 CFR 412.2. For such a change to be made, it must be unrelated to the special statement or claim. Some common examples include: \u2022 The removal of an ingredient or change in order of predominance of an ingredient in a product formula for a label that was previously approved with a negative claim (e.g., \u201ccertified gluten free\u201d). In this case, the removal of an ingredient or change in its order of predominance will not affectthe special statement or claim. \u2022 Changing the name of the cut of meat or poultry for a label previously approved with an animal-raising claim (e.g., raised without antibiotics). An example would include changing the name from chicken breast to chicken thigh. The change is generically approved provided the supporting documentation for the chicken is the same as documented in the previously approved label. In this case, changing the name ofthe cutofpoultry willnotaffectthe special statement or claim. \u2022 Changing information such as the establishment number (except for products labeled as organic), signature line, preparation instructions, Hazard Analysis and Critical Control Points Category, or vignette for a label that was previously approved with a special statement or claim. These changes are generically approved as they will not affectthe special statement or claim. See Appendix 3 for a list of changes to labels with special statements and claims that can be generically approved. Changes to Labels with Approved Special Statements and Claims that Require Additional LPDS Review Sometimes, changes made to a previously approved label with special statements and claims

require LPDS approval before the updated label may be used in commerce. Such changes include those that affect the special statement or claim and require LPDS to reevaluate the product formula or other relevant information. Examples include: \u2022 A label with a negative claim (e.g., \u201ccertified gluten free\u201d) that was previously approved by LPDS. Now, the establishment wants to update its label to reflect the use of a new seasoning mix, which includes ingredients that were not in the product formula for the previously approved label. In this case, the establishment is required to resubmit the label to LPDS for approval, so the Agency can verify that the new ingredients do not contain any sources of gluten. \u2022 If a company adds an uncured claim to a previously approved label with a \u201cnatural\u201d and \u201ccertified gluten free\u201d claim, the company must resubmit the label to LPDS for approval because it contains a new special statement or claim not included as part of the previous approval. See Appendix 4 for a list of examples of changes to labels with special statements and claims that need to be resubmitted to LPDS. Blanket Label Approvals (Labels for product line or multiple products with identical claims) In some cases, the addition of a special statement or claim to an entire line of products or multiple products will not require every single label to be submitted to LPDS for approval. Instead, establishments may submit a \u201cblanket approval\u201d application to LPDS along with a label for one of the products. The establishment should also include supporting documentation with its application indicating that the establishment is requesting approval for the use of the special statement or claim on multiple product labels. The label application should indicate that the special statement or claim will be added to an entire product line and should specify the product line, or, in the case of only certain labels, the application should list the product labels to which the approval would apply. Some examples include: \u2022 An establishment produces 50 different frozen meals. The establishment intends to add a Front of Pack (FOP) statement for all 50 products that will identify the number of calories and grams of protein. In this case, the establishment should not submit 50 applications for different products in a product line for approval. Instead, the establishment should submit an application for blanket approval to LPDS, along with a label for one of the products. The label application should indicate that the FOP statement will be added to all frozen product meals produced at the establishment. The blanket approval will cover products to which the FOP statement is applied so there is no need for each individual label bearing the FOP information to be submitted for approval. The establishment should update the individual nutrient values within the FOP statement generically to match the nutrient values displayed in the nutrition facts panel for each of the meals. However, when a new nutrient is added to the FOP statement, the label can no longer be generically approved (e.g., adding sodium to the statement that already displays the calories and grams of protein). Adding a new nutrient to the FOP statement will require the revised label to be resubmitted to LPDS for evaluation and approval. \u2022 An establishment produces X number of organic chicken parts. To obtain approval to label all organic chicken parts with a new claim, such as \u201cno antibiotics,\u201d the establishment should submit one organic chicken breast package with the new \u201cno antibiotic\u201d claim to LPDS. The label application should also include a list of other chicken parts that will also use the new claim. This is a blanket approval because all the parts of the chicken listed in the application will be approved through one label submission. \u2022 An establishment has an entire line of beef sausages that LPDS approved with a \u201ccertified gluten free\u201d claim. The establishment wants to add a \u201cmade with

grass fed beef\u201d claim to all the other product labels in the beef sausage product line. Instead of submitting separate applications for each of the individual products, the establishment should submit a request for blanket approval with the 10", "necessary supporting documentation for the \u201cmade with grass-fed beef\u201d claim and a list of all the products in the line. The addition of a \u201cmade with grass-fed beef\u201d claim does not affect the previously approved \u201ccertified gluten free\u201d claim because there is no change to the ingredients. The addition of the \u201cmade with grass-fed beef\u201d claim for products formulated with grass fed beef is a type of claim that can be approved through a request for blanket approval. See Appendix 5 for additional types of special statements and claims that can be approved through a blanket approval. Special Statements and Claims Generically Approved After the First Approval from LPDS There are certain types of special statements and claims that LPDS only needs to see once to ensure compliance with the regulations. After this initial review, the special statements and claims are generically approved for use on any other product produced by the establishment on the condition that future labels using the special statements and claims follow all FSIS requirements and that the special statements and claims are not changed in any way from the initial LPDS approval. Some examples include: \u2022 A label that displays a USDA Food Shield was approved for a Chicken Cordon Bleu product. The establishment wants to add the shield to a Chicken Parmesan product as well. Because the establishment has the prior approval from LPDS for the USDA Food shield and has the supporting documentation from the USDA Agricultural Marketing Service (AMS) on file, the Chicken Parmesan label can be generically approved. This label can be generically approved because the shield was previously approved by LPDS and the label application has the documentation from AMS to support the use of the claim on the label. \u2022 A label for chicken hot dogs was approved with a \u201ccertified halal\u201d claim. The establishment now wants to make a certified halal chicken sausage. The establishment has the prior approval from LPDS for the certified halal claim and the supporting documentation from the certified Halal organization. This label can be generically approved because the establishment has the certification from the Halal organization that supports the use of the claim on the label. The establishment would need to ensure that the documentation is kept current per FSIS requirements. See Appendix 6 for additional examples. Negative Claims The \u201cnegative\u201d claims section provides label examples of ingredient-based claims (e.g., \u201cgluten free without the accompanying certification statement,\u201d \u201cNo MSG\u201d/No MSG Added [with the accompanying disclaimer statement],\u201d and \u201cno preservatives\u201d that can be generically approved. \u201cNegative\u201d claims are claims made on product labels that identify the absence of certain ingredients or types of ingredients and are generically approved. Negative claims labeling is allowed to indicate the absence of an ingredient when that ingredient is expected or permitted by regulation or policy. This could also apply to ingredients which are not expected or permitted by regulation or policy if the 11", "ingredients could find their way into the product through a component. For example, the use of \u201cno preservatives\u201d on the label of \u201cspaghetti with meat and sauce\u201d (where regulations do not permit the direct addition of preservatives) would be acceptable if the product contained an ingredient, such as cooking oil, which could contain preservatives but do not. The claims are truthful and not misleading because the ingredients statement provides support that the product does not contain the ingredient. Also in this

section are definitions of certain claims such as \u201cNo Artificial Flavors,\u201d \u201cNo Artificial Colors,\u201d \u201cNo Artificial Colors and Flavors,\u201d and \u201cNo Artificial Preservatives.\u201d There are sample labels to provide further explanation as to what is allowed on the label with these claims. Labels with negative claims that have animal-raising claims and/or nongenetically modified organisms (non-GMO) claims are not eligible for generic approval. An example of a negative claim that can be generically approved includes: \u2022 A label with a gluten free claim. Gluten free highlights the absence of gluten containing ingredients. A claim such as gluten free can be verified by examining the ingredients statement for any gluten-containing ingredients. If the product does contain any gluten containing ingredients, the claim would not be permitted on the label. See Appendix 7 for additional types of negative claims and label examples that can be generically approved. Export Labels that Deviate from Domestic Requirements and Geographic Landmark Claims on Labels The export labels with deviations from domestic requirements section provides information about the documentation and support needed for labels on products that are exported outside of the United States and have deviations from domestic requirements. Such labels must meet the requirements of the importing country, as indicated in the FSIS Export Library. An example of an export label that can be generically approved includes: \u2022 A label for Abratwurst that has a nutrition facts panel that deviates from United States domestic requirements and the ingredients statement contains incomplete sublists of the ingredients. The label would be acceptable to generically approve as the label complies with the foreign country's labeling requirements. Documentation supporting the acceptability of the deviation should be kept in the establishment's labeling records to comply with 9 CFR 320.1(b)(10) and 381.175(b)(6). FSIS inspection program personnel (IPP) verify whether product for export meets requirements listed in the Export Library, including labeling, when certifying products for export. In addition to the information from the Export Library, additional documentation, such as a letter from the importer of record on letterhead, can be used to support that the label is in compliance with importing countries labeling requirements for verification purposes. The geographic landmark claim on labels section provides information about labels that comply with 9 CFR 317.8 (b) (1) or 9 CFR 381.129 (b) (2), the state endorsement programs that have a geographic emblematic design, state endorsement programs that do not have a geographic emblematic design, and geographic style documentation by 12", "third-party authority claims on labels. There is also a list of the geographic claims on labels that are found in the Food Standards and Labeling Policy Book. An example of a geographic landmark claim that can be generically approved includes: \u2022 A label with a Go Texan with a map of Texas on the label can be generically approved and there needs to be support in the labeling record that the product complies with the Go Texan requirements. The support can be a certificate for being a member of the Go Texan program or a letter from the certifying entity stating the label is compliant with their requirements. The documentation should be updated once a year to remain compliant. See Appendix 8 for additional information about export labels that deviate from domestic requirements and geographic landmark claims that can be generically approved. Additional Information for Label Approval Appendix 9 provides general information about label approval and information about the other categories of labels (i.e., labels for temporary approval, including label transfers, and labels for product produced under religious exemption) that must be evaluated by LPDS prior to entering commerce. Resources \u2022 General

Labeling Information o Label Submission and Approval System (LSAS) o A Guide to Federal Food Labeling Requirements for Meat, Poultry, and Egg Products o Allergens- Voluntary Labeling Statements o askFSIS o Check List for Mandatory Features on a Label o Descriptive Designation for Needle-or Blade-tenderized Raw Beef Products as Required by 9 CFR 317.2(e)(3) o Descriptive Designation for Raw Meat and Poultry Products Containing Added Solutions o FSIS Directive 7000.2- Experimental and Sample Products Policy o Extraordinary Circumstances- Procedures for Evaluating Labels o FSIS Guideline on Kit Product Labeling o Food Standards and Labeling Policy Book o FSIS Directive 7221.1- Prior Labeling Approval o FSIS Directive 7120.1- Safe and Suitable Ingredients Used in the Production of Meat, Poultry and Egg Products o FSIS Form 7234-1- Application for Approval of Labels, Marking or Device o Information Required for Requesting a Temporary Label Approval o Labeling and Establishment Responsibilities o Labeling and Consumer Protection: Proprietary Mixture Suppliers and Manufacturers Questions and Answers 13", "o Labeling Policies o Labeling Procedures o Labeling Situations that Cannot Have a Temporary Approval o Nutrition Facts Label Compliance: Voluntary use of FDA panel on USDA products prior to a FSIS final rule o FSIS Directive 6030.1- Religious Exemption for the Slaughter and Processing of Poultry o FSIS Directive 7000.4- Verifying Certain Transferred Labeling \u2022 Generic Labeling o askFSIS Public Q&As: FSIS Labeling Records o askFSIS Public Q&As: Generic Label Advisor 9 CFR Part 412.2 o askFSIS Public Q&As: Generic Label Advisor Certificate o askFSIS Public Q&As: Generic Label Advisor Information o Generic Label Approval Final Rule (January 18, 2023) \u2022 Claims Guidance o Carbohydrate Labeling Statements Interim Policy Statement o FSIS Guidance on the Labeling of Omega Fatty Acids Claims on Meat, Poultry and Egg Products o FSIS Guideline on Whole Grain Statements on the Labeling of Meat and Poultry Products \u2022 Animal-Raising Claims and Non-GMO Claims o Animal-Raising Claims Labeling Guidelines Updates o FSIS Labeling Guideline on Documentation needed to substantiate AnimalRaising Claims for Label Submissions o Statements that Bioengineered or Genetically Modified Ingredients or Animal Feed were not used in Meat, Poultry, or Egg products \u2022 Other Labeling Information o Compliance Guidelines for Shiga Toxin Escherichia Coli (STEC) Organisms Sampled and Tested Labeling Claims for Boneless Beef Manufacturing Trimmings ("Beef Trim") o Label Verification of Imported Raw Beef Products Labeled "For Cooking Only\u201d or "For Full Lethality Treatment" Appendix 1: Special Statements and Claims LPDS must preapprove labels bearing the following special statements and claims prior to entering commerce. The label bearing a special statement or claim must be submitted to LPDS for sketch approval. Supporting documentation for the special statement or claim must be included as part of the labeling record. 14", "\u2022 Allergen warning statement from processing in a meat and poultry plant (e.g., \u201cmade in a facility that also processes tree nuts and soy,\u201d and \u201cmay contain soy.\u201d) \u2022 American Heart Association Logo \u2022 AMS \u201ccertified compliantdocument\u201d asrelated to ChildNutrition(CN)Labels \u2022 AMS processing, AMSprocessing extra regulatory marking or verification programs\*, AMS extra regulatory marking or verification programs + \u2022 Animal-raising claims (e.g., no animal byproducts\*, no added antibiotics, no gestation crates\*, no growth promotants including ractopamine\*, no hormones added, no ractopamine a beta agonist growth promotant\*, raised without antibiotics, vegetarian fed). + \u2022 Best Aqua Practice symbol \u2022 Breed claims (e.g., Angus, Berkshire, Certified Angus, Hereford, British Quality Assured Pork\*). + \u2022 Browned in Cottonseed oil (implied nutrition claim that must

meet the regulatory definition for low in saturated fat) \u2022 Cage Free+ \u2022 Certified Claims (e.g., certified organic, certified gluten free, certified halal, certified select ingredients, CrossFit Certified, Certified Women\u2019s Business Enterprise, Employee Owned Certified) + \u2022 Certified State programs (e.g., certified product of Louisiana). \u2022 Certified tender \u2022 Environmentally Raised \u2022 Extra Trim \u2022 Family Farmed Raised+ \u2022 Farm Raised (livestock and poultry)+ \u2022 Fight climate change with your fork\* \u2022 Food and Drug Administration (FDA) nutrition panel, for more information see: Nutrition Facts Label Compliance: Voluntary use of FDA Panel on USDA Products Prior to an FSIS Final Rule \u2022 Free from\// Certified free from (major food allergens and ingredients of public health concern) e.g., free of all major food allergens (milk, eggs, fish, Crustacean, shellfish, tree nuts, peanuts, wheat, soybeans, and\u2014effective January 1, 2023\u2014 sesame.) \* \u2022 Free Range+ \u2022 Fruit Claims (e.g., made with real fruit, made with fruit, made with cranberries) \u2022 Gluten free (certified) \u2022 Great for You program \u2022 Health claims defined in 21 CFR 101.14 and 101.70-83 \u2022 Hydroponically Grown\* \u2022 Humanely Raised+ \u2022 Implied nutrition claims (e.g., any version of a nutrition statement that does not follow the regulations in 9 CFR 317.313 (b) (2) or 9 CFR 381.413 (b) (2), including, baked not fried, heart smart, made with vegetable oil, made with olive oil, made without butter, no tropical oils, non-fried, protein life\*, protein pals, protein snack, protein snack box, rubbed with olive oil, reduced guilt\// guilt free\*, statements about specific types of oil, thin battered, and breaded) \u2022 Instructional or disclaimer statements addressing pathogens on products going to another Federal establishment, (e.g., for cooking only, for full lethality treatment, for 15", "high pressure processing at establishment XXX ) \u2022 Labels for religious exempt poultry product not produced under Federal inspection (e.g., Buddhist, Confucius, Halal product not receiving the mark of inspection and Kosher product not receiving the mark of inspection) \u2022 Labels for sample product (i.e., products not for sale that are for consumer testing within commerce facilities) with special statements and claims \u2022 Local, Locally Raised, Grown Locally, Locally Sourced in geographic location (e.g., Locally Sourced in New York)+ \u2022 Made without genetically engineered ingredients claim (that do not have USDA organic certification on the label+) \u2022 Milk from cows not treated with rBST-no significant difference has been shown between milk derived from rBST treated and non rBST treated cow\u2019s statements on FDA products incorporated into USDA products+ \u2022 Minimally Processed \u2022 MyPlate icon \u2022 Natural claims (e.g., all natural, 100% natural, made with natural ingredients) \u2022 Non-GMO or other statements from the guideline: Statements that Bioengineered or Genetically Modified Ingredients or Animal Feed Were Not Used in Meat, Poultry or Egg products )+ \u2022 Nutrition factual statements (e.g., 0 grams carbohydrates per serving, check marks associated with nutrition claim, nutritional facts up front(FOP), 0 grams trans-fat per serving) \u2022 Omega3 factual statements, (e.g., 200mg omega3 fatty acids per serving or any other use of the word omega 3, synonym for omega 3, or type of omega 3 fatty acid-alpha linoleic acid). For more information see: Food Safety and Inspection Service Guidance on the Labeling of Omega Fatty Acids Claims on Meat, Poultry and Egg products \u2022 Organic Claims (e.g., organic, certified organic, made with organic ingredients)+ \u2022 Paleo, Paleo Certified, Paleo Friendly \u2022 Pasture Raised+ \u2022 Pasteurized \u2022 Quality Control, USDA Approved\* \u2022 Raised with care\* \u2022 Raised with care in the USA\* \u2022 Real Ingredients \u2022 Regenerative claims\* \u2022 Sampled and tested claims

for STEC organisms Compliance Guidelines for Shiga toxin Escherichia coli (STEC) Organisms Sampled and Tested Labeling Claims for Boneless Beef Manufacturing Trimmings ("Beef Trim") \u2022 Safety claims (e.g., #1 Food Safety Priority, High pressure processing was used in the manufacturing of this product) \u2022 Serving sizes in the nutrition facts panel that deviate from 9 CFR 317.309 (b) and 9 CFR 381.409 (b) or Guideline documents (e.g., \u201cmeal for 2\u201d with the serving size of \u201c\u00bd package (300 g).\u201d This is not in accordance with the RACC in 9 CFR 317.312 or 9 CFR 381.412 or the serving size rules in 9 CFR 317.309 (b) or 9 CFR 381.409 (b). \u2022 State proposition statements (e.g., California Proposition 12+\* and Massachusetts Question 3 statements+\*) \u2022 Sustainable, Sustainable Farming, Sustainably Raised+ 16", "\u2022 Sustainable Forestry Initiative Certified Sourcing \u2022 Super Trim \u2022 Symbols on the label (e.g., arrows or check marks) \u2022 Third-party raising claim programs (e.g., Audubon Certified\*, AMS Processed Verified or Certified programs, American Grass-fed Association, Animal Welfare Association, and Global Animal Partnership) + \u2022 Trans fat in the nutrition facts panel for the first time \u2022 USDA Contract Compliance (AMS program)\* \u2022 USDA Food shield (AMS program)\* \u2022 USDA Further Processed Certification Program (AMS program)\* \u2022 U.S. Farm Fresh+ \u2022 Uncured in the product name\Uncured in the ingredients statement+ \u2022 Vegetable claims (e.g., made with premium vegetables, made with vegetables, 40% daily value of vegetables, made with Grade A Vegetables) \u2022 Whole grain claims (e.g., made with whole grain, whole grain stamp, whole grain seal, whole grain in the product name, whole grain claims on CN labels, Whole wheat in the product name, whole grain). For more information see: Food Safety and Inspection Service Guideline on Whole Grain Statements on the Labeling of Meat and Poultry Products. \u2022 WHOLE30 + For more information see: Food Safety and Inspection Service Labeling Guideline on Documentation Needed to Substantiate Animal-Raising Claims for Label Submissions Appendix 2: Factual Statements and Claims The following statements and claims do not require LPDS approval prior to use in commerce. Labels withthese factualstatements andclaimsare generically approvedif the label complies with all regulatory requirements and the statement or claim is truthful and not misleading. Supporting documentation for the statement or claim must be part of the labeling record. LPDS is ceasing evaluating voluntarily submitted generic labels. Generic labels that are submitted to LPDS for evaluation will be returned with a comment stating that the labels are generically approved and does not qualify for sketch approval. \u2022 Any label for non-amenable product produced under FSIS voluntary inspection (e.g., closed-facesandwiches and exotic species products (e.g., buffalo, bison, venison)) \* \u2022 100% American Farmed \u2022 100% Steer\ Made with 100% steer\* \u2022 All, 100%, pure \u2022 Aged\dry aged \u2022 Air Chilled \u2022 Allergen or \u201cccontains\u201d statements at the end of ingredients statement. \u2022 Allergen statements (e.g., \u201cNo: milk, eggs, shellfish, tree nuts, peanuts, wheat or soy,\u201d \u201cTop allergen free: no milk, no eggs, no fish, no shellfish, no tree nuts, no wheat or gluten or no soy and\u2014effective January 1, 2023\u2014sesame.\u201d \*) \u2022 Allergen warning statements carried over from FDA products and listed at the 17", "end of the FDA component sublisting in the ingredients statement. \u2022 Amish \u2022 AMS Grading for(e.g., prime,choice, selectandgradeA). \u2022 Ancient grain, made with \u2022 Artisanal \u2022 Authentic\* \u2022 Awards (e.g., Good Housekeeping Seal) \u2022 Baby food and\or toddler food stages e.g., stage 1, step 1 and stage 2, step 1 \u2022 Big Agriculture, Factory Farming,

Factory Agriculture\* \u2022 Beef is the main ingredient\* \u2022 Better is Possible \u2022 Certified by SQF Quality Supplier \u2022 Chicken is the main ingredient\* \u2022 CN box. \u2022 Cold Smoked\* \u2022 Contains: a certain ingredient (states the presence of certain ingredients) e.g., contains: MSG, contains honey \u2022 Containers of products sold under contract specifications to Federal government agencies \u2022 Country-of-origin labeling statements per 9 CFR 317.8 (b) \u2022 Craft Sausage\* \u2022 Double Smoked\* \u2022 Egg labels that comply with 9 CFR 412.2 \u2022 Exotic Species\ products under voluntary FSIS inspection services \u2022 Experimental Products \u2022 Extra and more than statements (e.g., cheesier macaroni and cheese, more chicken less breading) \u2022 Family-owned ranches\* \u2022 Farm raised on labels for Siluriformes \u2022 Farm to Fork \u2022 Farm to Table\* \u2022 Flexitarian\* \u2022 Free \u2022 Fresh \u2022 Fresh in conjunction with other descriptors (e.g., Deli Fresh, Valley Fresh, Fresh Slice, Premium Fresh, Premium Fresh Deli, Deli Fresh Meats, Farm Fresh, Farm Fresh Meats and Poultry Logo, Fresh Ideas, Fresh from the Heartland, Freshly Prepared and Fresh Selects) \u2022 Flavor profiles (e.g., cheesy\*, drizzled with olive oil, made with any type of cheese, BBQ flavored, chipotle flavored, made with fennel, made with fresh tomatoes, garlic flavored, made with Italian cheese, made with only white meat chicken, made with real cheese\made with 100%-real cheese, made with real chicken, made with real maple, made with real cr\u00e8me\*, made with Spanish pimento, meaty\*, teriyaki flavored, made with tomatoes) \u2022 Flavors and reaction flavors \u2022 Foreign language on domestic products or exported products that deviate from domestic requirements \u2022 From the land for the land\* \u2022 Geographic claims on labels that comply with 9 CFR 317.8 (b)(1) and 9 CFR 18", "381.129 (b) (2) \u2022 Geographic flag with corresponding statement, (e.g., Foreign Country Flag) Accompanied by statement Made in USA) \u2022 Geographic logo orFlag(e.g., Eiffeltower, flag.map, MountRushmore,outline of a specific region (State or Country)) \u2022 Geographic style defined in 9 CFR 317.8 (b) (1) and 9 CFR 381. 129 (b) (2) and the Food Standards and Labeling Policy Book (e.g., country style, Italian style, Mexican style) \u2022 Geographic styles undefined (e.g., German Style and Tuscan style) Labels making this type of claim must have documentation of the approval of a thirdparty authority in their labeling record in support of the use of the undefined style. \u2022 Goodness within \u2022 Green claims or environmental claims (e.g., BPA Free (packaging), Made with recycled materials and made with soy ink) \u2022 Guarantees \u2022 Hand hung, hand pulled style, hand pinched style, and hand tossed style\* \u2022 Handcrafted, handmade, hand slaughtered, hand-crafted style \u2022 Healthy Ideas logo \u2022 Home style \u2022 \u201cHomegrown by Heroes\u201d logo \u2022 Julian Date \u2022 Ice glazed \u2022 Inserts, tags, liners, pasters, and like devices \u2022 International trade membership organization (e.g., USA Poultry and Egg Export Council) \u2022 Irradiation, irradiation symbol \u2022 Kosher claims on products \u2022 Labels for amenable products containing exotic species \u2022 Labels for containers of products sold under contract specifications to Federal Government agencies \u2022 Labels for experimental product \u2022 Labels for inedible product \u2022 Labels for non-certified pet food \u2022 Labels for Sample product without special statements and claims \u2022 Lightly Seasoned \u2022 Made by or made with statements (e.g., Made by Native Americans, made with rice from cooperatives in geographic area, veteran owned\*, women owned) \u2022 Made in USA \u2022 Multi grain \u2022 No additives (only permitted on single ingredient items)\No meat additives (must have meat component that is single ingredient item)\* \u2022 Negative or

Free Claims (e.g. Casein Free, Egg Free, Free of Preservatives, Gluten Free#, Lactose Free, Milk Free, Nut Free, Peanut Free, Preservative Free\*, Tree Nut Free, No Alcohol, No artificial colors#, no artificial flavors#, no artificial preservatives with statement under claim \u201csee back panel for ingredients to preserve quality\u201d#, no binders or fillers \*, no breading, no butter, no certified colors, certified synthetic colors, no corn syrup, no extenders\*, no fillers or dyes, no gluten ingredients, no high fructose corn syrup, no imitation anything, no lard, no liquid smoke, no mechanically separated chicken, no mechanically separated pork, 19", "chicken or turkey, No MSG#, No MSG added\* with disclaimer statement \*\u201cexcept for that naturally occurring in [natural sources of MSG]\u201d#, no nitrites#, no nitrates#, no nitrites and nitrates#, no nitrites and nitrates added\* with disclaimer statement\* \u201cexcept for that naturally occurring in [natural sources of nitrites and nitrates]\u201d#, no pork\|no pork added, no poultry\|no poultry added, no preservatives#, no preservatives added, not preserved, no sodium nitrite added\* with disclaimer statement\*\u201cexcept for that naturally occurring in [natural sources of nitrites]\u201d\*, no sodium nitrate added \* with disclaimer statement\*\u201cexcept for the naturally occurring in [natural sources of nitrate])\u201d\*, no sodium phosphate \*, no solutions added, no synthetic colors, no water added. \u2022 New, new and improved, new flavor, new look\* \u2022 Noncertified religious exempt product (Halal guarantee, Halal on products receiving the mark of inspection, Halal Style, Halal symbol with trademark, Kosher) \u2022 Not stunned\* \u2022 Number 1 brand (would need to have support in the labeling record for the claim) \u2022 Nutrition claim defined in 9 CFR 317.313 -317.380 and 9 CFR 381.413 -381.480 \u2022 Organic ingredients in the ingredients statement\* (e.g., organic tomatoes- would need to have support in the labeling record for the claim) \u2022 Oven Roasted or similar statements \u2022 Piece count \u2022 Premium \u2022 Processed in the USA 100% \u2022 Product of USA \u2022 Product received high pressure processing \u2022 Products not intended for human consumption \u2022 Products with standard of identity (e.g., meatloaf) \u2022 Products without standard of identity (e.g., Wyngz- white chicken fritters) \u2022 Promotions or other similar statements on the label (e.g., charity, holiday, kid tested, kid approved) \u2022 Ready in\|cooks in (number of seconds or minutes) \u2022 Retained water statements \u2022 Shipping containers \u2022 Simple ingredients\* \u2022 Single ingredient products without claims (single cuts of meat and poultry) \u2022 Small batch (would need to have support in the labeling record for the claim)\* \u2022 State endorsement programs that have a geographic emblematic design (e.g., \u201cGo Texan- with map of Texas, Pride of New York- with map of New York, Made in Wisconsin- with map of Wisconsin, Nevada Grown-with map of Nevada)\| Third party State Certification Programs (e.g., 100% Made in Puerto Rico, Arizona Grown, Arkansas Grown, California Grown, Fresh from Florida, Missouri Grown, New York State Grown and Certified, Virginia\u2019s Finest- need to have certificate in the labeling record to support the use of the logo on the label current within the last year)\* \u2022 State endorsement programs that do not have a geographic emblematic design, (e.g., Kentucky Proud, made with Wisconsin Cheese- need to have certificate in the labeling record to support the use of the logo on the label current within the last year) \u2022 Statements of limited use (e.g., for further processing, for HRI, institutional use only, for food service use only) 20", "\u2022 Statements relating to free components (e.g., free packet of hot sauce included) \u2022 Substitution of any unit of measurement with its abbreviation or any abbreviation with its unit of measurement \u2022 Super marbling for rich taste and

unbelievable juiciness\* \u2022 TG enzyme (transglutaminase enzyme) (products containing this ingredient) \u2022 Trademark\* \u2022 Value size\* \u2022 Wet aged\* \u2022 Wholesome from the beginning \u2022 \u201cWild caught\u201d on labels for Siluriformes \u2022 Wrappers or other covers bearing pictorial designs, non-geographic emblematic designs or illustrations (e.g., floral arrangements, illustrations of animals, fireworks, etc.) \u2022 X-rayed for bone detection \u2022 Your journey begins here\* Appendix 3: Changes to labels approved with special statements and claims not requiring additional LPDS review 9 CFR 412.2 allows for labels to be generically approved provided they do not fall into any of the categories of the labels that must be evaluated by LPDS. Included in that group of labels are those labels that have a special statement or claim that were previously approved by LPDS. Thus, once a label is approved there are several changes that can be made to the label that do not impact the previously approved claims. These revisions do not impact the previously approved special statement or claim. In addition, for the additional changes to be generically approved, there cannot be any formulation changes or addition of ingredients that were not part of the previously approved label. For more in-depth explanation see discussion on page 9. Examples of the types of label changes permitted are: \u2022 Additional cooking instructions, e.g., the label originally includes cooking instructions for a conventional oven but now the establishment is adding instructions for a microwave. \u2022 Addition of a bar code \u2022 Addition of a brand name or changes to a brand name that do not include a new claim \u2022 Addition of defined nutrition claim \u2022 Addition of Julian date \u2022 Adding new establishments for certification claims that cover multiple establishments \u2022 Addition of a flag that would have to be associated with \u201cmade in USA,\u201d or \u201cproduct of USA\u201d. However, this change must follow the requirements of 9 CFR 317.8 (b) (2). \u2022 Addition of a flag, map, or geographic emblem without including emblem \u201cbrand 21","made in\u201d \u2022 Addition of e-mail address or website information \u2022 Addition of a logo or changes to a logo that does not include a new claim\* \u2022 Addition of a \u201cnon-GMO or \u201cnon-GE\u201d claim to a certified organic label. For more information see Labeling Guideline on Statements that Bioengineered or Genetically Modified Ingredients or Animal Feed Were Not Used in Meat, Poultry or Egg Products. \u2022 Addition of a nutrition facts panel \u2022 Addition of a scan code app or QR (quick response) code \u2022 Addition of geographic style to product names, e.g., Tuscan Style to a previously approved Italian Sausage label. When not an established style in the regulations or Food Standards and Labeling Policy Book, the third-party authority documentation must be included as part of the labeling record. \u2022 Addition of a universal product code (UPC code) \u2022 Additional meat or poultry cut not on the previous list of cuts approved except for organic claims \u2022 Addition of trademark that does not impact previously approved special statement or claim and does not add a new special statement or claim\* \u2022 Changes to the ad copy that does not include an additional claim that was not present on the previously approved label and does not conflict with the current claims on the label \u2022 Changing an approved claim to a synonymous claim (e.g., changing from \u201cno antibiotics used\u201d to \u201craised without antibiotics\u201d) \u2022 Changes to comply with Descriptive Designation for Raw Meat and Poultry Products Containing Added Solutions (9 CFR 317.2(e)(2) and 9 CFR 381.117(h)) \u2022 Changes to comply with Descriptive Designation for Needle-or Blade-tenderized Beef Products(9 CFR 317.2(e)(3)) \u2022 Changes to the cooking instructions provided it still complies with the requirements of

the corresponding HACCP category \u2022 Changes to the descriptive name \u2022 Changes to the design of the label including layout. The establishment has the responsibility to ensure that all mandatory features are still in the required location. \u2022 Changes to the design of the label including the layout to labels for export with deviations from domestic requirements. The establishment has the responsibility to ensure that all mandatory features are still in the required location and no new label deviations were created. \u2022 Changes to an e-mail address or website that was on previously approved label \u2022 Changes to the establishment number or legend except for organic product. (Changes to the establishment number for organic product must be evaluated by LPDS.) \u2022 Changes to the form of the product (e.g., changing from link sausage to bulk sausage or changing from sausage patties to sausage links)\* \u2022 Changes to the HACCP category (e.g., change from raw product ground to fully cooked not shelf stable) \u2022 Changes to the handling statement (e.g., keep refrigerated) 22", "\u2022 Changes to the label for compliance with the added solutions regulations (9 CFR 317.2 (e) and 9 CFR 381.117). \u2022 Changes to names of ingredients in the ingredients statement provided the addition complies with FDA or FSIS labeling policies \u2022 Changes to the net weight, including the addition of net weight labels (e.g., a label was approved for 1 pound (lb.) and the new label is for 2 pounds (lbs.) \u2022 Changes to the order of predominance or product formula without the addition of new ingredients \u2022 Changes to the packaging (e.g., going from plastic container to plastic bag) \u2022 Changes to the placement or location of the legend \u2022 Changes to the product name (e.g., changing the product name from sausage to Italian sausage provided it meets the regulation and/or standards) \u2022 Changes to the signature line (e.g., manufactured for or distributed by) \u2022 Changes to values in the nutrition facts panel \u2022 Changing from \u201cGE to \u201cGMO\u201d on certified organic or other third-party certified labels. For more information see Labeling Guideline on Statements that Bioengineered or Genetically Modified Ingredients or Animal Feed Were Not Used in Meat, Poultry or Egg Products \u2022 Removal of ingredients in product without the addition of new ingredients \u2022 Removal of nutrition front of pack icon. The addition of an icon that was not previously evaluated by LPDS would need to be submitted for approval. \u2022 Removal of previously approved claim. Appendix 4: Changes to labels with special statements and claims that require LPDS review 9 CFR 412.1 states that certain changes to labels are not permitted to be made generically. The labels must be submitted to LPDS for approval. For more in-depth explanation see discussion on page 9. Examples on the types of label changes that cannot be made generically include: \u2022 Addition of additional nutrients to the labels with nutrition front of pack (FOP) statement \u2022 Addition of an animal-raising claim \u2022 Addition of ingredients to labels with special statement and claims such as \u201cNatural,\u201d \u201cOrganic,\u201d and \u201cCertified Gluten Free\u201d \u2022 Change to the establishment number on labels with an organic claim \u2022 Change to the ingredients without changing the label. That would require a temporary approval from LPDS \u2022 Changing the organic certifier on an approved label 23", "Appendix 5: Blanket Label Approvals (Product Line or Multiple Products with Identical Claims) A Blanket Approval refers to an approval that would cover multiple products or product lines that is submitted to LPDS for approval because it falls under one or more of the four categories of labels described in 9 CFR 412.1. For more in-depth explanation see discussion on page 10. Examples of labels that can be approved as a blanket approval: \u2022 Addition of

animal-production claim to line that also bears an ingredient-related claim \u2022 Addition of FOP statements to multiple products in the same product line or company \u2022 Addition of a new supplier for an approved animal- production claim \u2022 AMS processing extra regulatory marking or verification programs\* \u2022 Changing the organic certifier on an approved label \u2022 Changing the source of meat from a previously approved label when the claims and ingredients have not changed from the prior approval \u2022 High pressure processed at establishment ABC \u2022 Religious exempt products\* \u2022 USDA Contract Compliance (AMS program)\* \u2022 USDA Food Shield (AMS program)\* \u2022 USDA Further Processed Certification Program (AMS Program)\* Appendix 6: Special Statements and Claims Generically Approved After the First Approval from LPDS There are certain types of special statements and claims for which LPDS only needs to see one label to ensure compliance with the regulations and after that initial approval, the label can be generically approved for additional products. This is provided that any future labels follow all FSIS rules, policies, and regulations. The establishment would also have to include a copy of the initial approval in their labeling record to provide assurance that the special statement or claim did initially receive approval from LPDS. If the special statement or claim has changed at all from the initial LPDS approval, the new label must be submitted to LPDS for evaluation. For more in-depth explanation see discussion on page 11. A bold red asterisk (\*) marks new or updated entries to the appendix. Items previously on the list not marked by a bold red asterisk (\*) may have been rearranged for ease of readability. Examples of labels that can be generically approved after initial LPDS approval: \u2022 AMS processing extra regulatory marking or verification programs\* 24", "\u2022 Nutrition FOP\u2014provided the format, location and nutrients remain identical to the initial approval. If the establishment changes the format, location, or nutrients, then the new label must be evaluated by LPDS \u2022 Certified Halal/\u2022 Certified Zabihah Halal- must have documentation in the labeling record current within the last year to support the use of the claim \u2022 Certified Kosher- must have documentation in the labeling record current within the last year to support the use of the claim \u2022 Certified Women\u2019s Business Enterprise \u2022 Employee Owned Certified \u2022 FDA nutrition facts panel- one approval from LPDS per format (e.g., full format, simplified, linear, tabular, dual column, or aggregate format) \u2022 For cooking only at establishment xyz- must have documentation in the labeling record to support that the product is being sent to another establishment for cooking \u2022 High pressure processed at establishment ABC \u2022 Sustainable Forestry Initiative Certified Sourcing \u2022 USDA Contract Compliance (AMS program)\* \u2022 USDA Food Shield (AMS program)\* \u2022 USDA Further Processed Certification Program (AMS Program)\* Appendix 7: Negative Claims Negative claims are claims that state a product does not contain a certain ingredient . Negative claims can be generically approved per 9 CFR 412.2 (b). Examples of negative claims include gluten free, no artificial colors, no artificial flavors, no artificial preservatives, no MSG, no MSG added, no nitrites and nitrates, no nitrites and nitrates added and no preservatives. \u2022 Gluten Free is a negative claim that highlights the absence of certain gluten-containing ingredients in the ingredients statement. FSIS does not define gluten free in its regulations but applies FDA\u2019s requirements for the voluntary use of the claim in 21 CFR 101.91. A claim of \u201cgf\u201d is generically approved unless it is a certified claim, e.g., \u201cCertified Gluten Free by (XYZ entity).\u201d Certified gluten-free claims need to be submitted to LPDS for approval with support for the claim. See the sample

label below for a gluten-free label claim that can be generically approved. 25", "Made with beef, pork and chicken Ingredient": Beef, pork, chicken, salt, spices, flavors, sodium nitrate, sodium phosphate, sea salt. NET WT. 7 oz (198g) Gluten Free \u2022 No Artificial Colors is a negative claim that follows the entry in the Food Standards and Labeling Policy Book that the product doesn't contain any artificial colors as defined therein: Labels of products that are artificially colored either by artificial colors or natural colors must bear a statement to indicate the presence of the coloring, for example, \u201cartificially colored\u201d or \u201ccolored with annatto.\u201d Products whose true color is disguised by packing media, for example, colored pickling solutions, must also have labels that include a statement that indicates the presence of the color. The statement must appear in a prominent and conspicuous manner contiguous to the product name. When a component within a product is artificially colored, for example, breading, sauce, and sausage, a qualifying statement is not necessary. However, in all cases, the presence of the coloring must appear in the ingredients statement. Common artificial colors are FD&C Yellow No. 5 or Yellow No. 5, Red Dye No. 40, FD&C Red No. 3, FD&C Green No. 3, and FD&C Blue No. 2. 21 CFR Part 73 lists color additives that are exempt from certification. Colors that are exempt from certification are not required to be declared by common or usual name on labels and may be declared as \u201ccolorings\u201d or \u201ccolor added.\u201d Examples of exempt colors include Annatto extract, Caramel, and Paprika oleoresin. In comparison, certified colors are listed in 21 CFR Part 74 and are required to be declared by common or usual name, e.g., FD&C Blue No. 1, FD&C Blue No 2, FD&C Green No. 3, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 5, FD&C Yellow No. 6, Orange B, Citrus Red No. 2. \u2022 No Artificial Flavors is a negative claim that describes a product that contains no ingredients labeled as artificial flavors (e.g., Artificial Maple Flavor). Acceptable ingredients can include MSG, smoke flavor, flavors, natural flavors, disodium 26", "Skinless Chicken Breast No Artificial Colors or Flavors KEEP REFRIGERATED NET WT. 48 OZ (3 LB) Safe Handling Instructions This product was prepared from inspected and passed meat and/or poultry. Some products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions. Keep refrigerated or frozen. Thaw in refrigerator or microwave. Keep raw meat and poultry separate from other foods. Wash hands after touching raw meat or poultry. Cook thoroughly. ~ Keep hot foods hot. Refrigerate leftovers immediately or discard. Distributed by 1MB Ranch, Inc. 1234 Special Rd., Elsewhere, VA 54321 inosinate, disodium guanylate, hydrolyzed vegetable proteins, and yeast extracts. See the sample label below for a no artificial colors or flavors label that can be generically approved. \u2022 No artificial preservatives mean the product would not contain any source of artificial preservative. LPDS has allowed the claim of no artificial preservatives under the following conditions so the consumer is not misled about whether the products are preserved or not. The labeling claim would consist of: 1. A statement \u201cSee back panel for ingredients used to preserve quality\u201d would appear on the front panel in immediate proximity to the \u201cNo Artificial Preservatives\u201d claim. This will provide consumers with details about the claim-namely, the fact that the product has added ingredients that will help preserve product quality. 2. Each ingredient added to preserve the product would be declared with an asterisk in the ingredient line. The asterisk would lead to the following explanatory statement below the ingredient line: \u201cIngredient to preserve quality\u201d or perhaps a shortened

form like \u201cto preserve quality.\u201d See sample label below for no artificial preservatives claim that can be generically approved. 27", "FULLY COOKED No Artificial Preservatives See back panel for ingredients used to preserve quality Chicken Nuggets BREADED STAR SHAPED CHICKEN BREAST WITH RIB MEAT KEEP FROZEN NET WT. 5 LBS (2.26kg) Pepperoni Ingredients: Beef, pork, chicken, salt, spices, flavors, sodium phosphate, sea salt. NET WT. 7 oz (198g) Nutrition Facts About 25 servings per container Serving size 5 pieces (88g) Amount per serving 230 Calories %Daily Value\u2022 Total Fat 13g 20% Saturated Fat 3g 15% Trans Fat 0g Cholesterol 140mg 13% Sodium 480mg 20% Total Carbohydrate 14g 5% Dietary Fiber 3g 16% Total Sugars 0g Includes 0g Added Sugars 0% Protein 12g 24% Vitamin D 0mcg 0% Calcium 100mg 0% Iron 0.5mg 4% Potassium 0mg 0% The % Daily Value (DV) tells You how much of a nutrient is in a serving based on a 2,000 calorie diet. A day's calorie needs may be higher or lower depending on your age, sex, weight, and activity level.

INGREDIENTS: Chicken breast with rib meat, water, whole wheat flour, contains 2% or less of the following: dried garlic, corn flour, salt, spices, natural flavoring, lemon juice.\u2022

CONTAINS: Wheat. \u2022 To preserve quality Breading set in vegetable oil. No MSG \u2022 No MSG is a negative claim that means the product does not contain any sources of MSG. Common sources of MSG include any ingredient that is hydrolyzed or autolyzed such as autolyzed yeast extract. Other common sources of MSG are Worcestershire sauce and soy sauce. For a label that claims No MSG and does have a natural source of MSG, the claim would need to be changed to No MSG added with a disclaimer statement (see the next section for additional information). See sample label below for No MSG claims that can be generically approved.

28", "Made with beef, pork and chicken Ingredients: Beef, pork, chicken, salt, spices, flavors, sodium nitrate, sodium phosphate, sea salt, autolyzed yeast extract. No MSG Added\* NET WT. 7 oz (198g) \*Except for that naturally occurring in autolyzed yeast extract. \u2022 No MSG Added is a negative claim that means the product does not have any sources of MSG added but it does contain naturally occurring sources of MSG such as soy sauce or Worcestershire sauce. Other common ingredients include any ingredient that is hydrolyzed or autolyzed such as autolyzed yeast extract. For labels with this claim, it would need to state No MSG Added\* and then have a corresponding asterisk on the same panel with the \*except for that naturally occurring and identify the ingredients in the product that are the naturally occurring sources of MSG, e.g., \u201cNo MSG Added\* \*except for that naturally occurring in autolyzed yeast extract and Worcestershire sauce.\u201d The disclaimer statement must be on the same panel as the claim. See sample label below for no MSG added claim that can be generically approved.

\u2022 No Nitrites and Nitrates is a negative claim that means that the product would have no natural sources of nitrites, nitrates, or nitrites and nitrates (e.g., sea salt, cultured celery powder, celery powder, cultured celery juice or celery juice). Products labeled as uncured would need to follow the 9 CFR 317.17 requirements. See sample label for no nitrites and nitrates claim that can be generically approved.: 29", "Andouille Sausage Ingredients: Pork, beef, salt, sugar, garlic, spices, flavors. Keep Refrigerated NET WT. 7 oz (198g) \u2022 No Nitrites and Nitrates Added is a negative claim that means that the product would have natural sources of nitrites, nitrates, or nitrites and nitrates (e.g., sea salt, cultured celery powder, celery powder, cultured celery juice or celery juice). For products with this claim, sea salt and salt cannot be combined into one ingredient, those ingredients must be declared separately. For products that declare those natural sources of cure, the label would need to have a disclaimer statement.

\u201cNo Nitrites or No Nitrates Added\* \*except for that naturally occurring in sea salt and celery powder\u201d on the same panel as the claim For the ingredients cultured celery powder and cultured celery juice, they must be sublisted in the ingredients statement (e.g., cultured celery powder (celery powder, sea salt, silicon dioxide)). The disclaimer statement must be on the same panel as the claim. Products labeled as uncured would need to follow the 9 CFR 317.17 requirements. See sample label for no nitrites and nitrates added claim that can be generically approved. 30", "Sausage No nitrates or nitrites added\u2022 Ingredients: Pork, salt, sugar, garlic, spices, flavors, sodium phosphate, sea salt, celery powder. Keep Refrigerated NET WT. 7 oz (198g) \u2022 Except for those naturally occurring in sea salt and celery powder. \u2022 No preservatives is a negative claim that means the product would not contain any source of preservatives in the product. Per 21 CFR 101.22 (a) (5) \u201cChemical Preservatives\u201d means any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties. Some common chemical preservatives include BHA, BHT, calcium propionate, citric acid, natamycin and sodium propionate. For more information about chemical preservatives, please see 9 CFR 424.21 and FSIS Directive 7120.1- Safe and Suitable Ingredients Used in the Production of Meat, Poultry and Egg Products. See sample label below for no preservative label claims that can be generically approved. 31", "Skinless Chick.en Breast No preservatives KEEP REFRIGERATED NET WT. 48 OZ (3 LB) Ingredients: Chicken, salt, spices. Safe Handling Instructions This product was prepared from inspected and passed meat and/\u00b3 or poultry. Some food products may contain bacteria that coukt cause illness if the product is mishandled or cooked improperly. fol' your protection.follow these safe handling instructions. El Keep refrigerated\u00b3 frozen. Thaw in refrigerator or microwave. a;,\_... Keep raw meat and poultry separate from other foods. ~ :=~~=f=~~~~ltry. ~ Cook thomughly. Cl Keep hol foods hot Refrigerate klfovers ~ immediately Of discard. Distributed by 1MB Ranch, Inc. 1234 Special Rd., Elsewhere, VA 54321 Appendix 8: Export Labels with deviations from domestic requirements and Geographic Claims on Labels Export Labels that Deviate from Domestic Requirements: A labeling deviation is a feature on labeling that is not permitted on labeling domestically but is required or permitted by the importing country. FSIS regulations provide for deviations from domestic labeling requirements for products for export with deviations from domestic requirements under 9 CFR 317.7 and 9 CFR 381.128. Export labels that deviate from U.S. domestic requirements are approved generically provided the labeling deviations comply with the importing country\u2019s labeling requirements. Documentation supporting the acceptability of the deviation should be kept in the establishment\u2019s labeling records under 9 CFR 320.1(b)(11) and 381.175(b)(6). FSIS maintains an Export Library that lists requirements for exported products that foreign authorities have officially communicated to FSIS, including labeling requirements. At times, foreign country labeling requirements conflict with domestic requirements. FSIS regulations (9 CFR 317.7 and 9 CFR 381.128) permit export product labels to deviate from FSIS\u2019 domestic labeling requirements to comply with foreign country requirements or to be marketed more easily in a foreign country. Although there is no specific equivalent regulation for egg products, FSIS follows the same policy because such products, intended exclusively for export, must comply with foreign countries\u2019 requirements and are therefore not

considered misbranded. FSIS IPP verify whether product for export meets requirements listed in the Export Library, including labeling, when certifying products for export. 32", "The FSIS Export Library is a resource published by the agency for information on various countries importing requirements. In addition to the information in the Export Library, types of documentation typically used to support labeling deviations include a letter from the importer on its official letterhead, a letter from the government of the importing country, and excerpts from the importing country's regulations or laws, provided the source of the information can be verified by IPP e.g., a link to a government site listing official regulations. The information in the label record helps verify that the label complies with the importing country's requirements. Geographic Landmark Claims on Labels: \u201cGeographic landmarks\u201d are claims displayed on a product label, such as a foreign country's flag, monument, or map. For example, the following claims displayed on a product label no longer require LPDS review prior to entering commerce:a Polish flag depicted on a Polish sausage product label, or an outline of the State of Nevada depicted on a product label for beef produced in Nevada. There are several types of geographic landmark claims, including labels that comply with 9 CFR 317.8(b)(1) or 9 CFR 381.129(b), other options for geographic naming, state endorsement programs that have a geographic emblematic design, state endorsement programs that do not have a geographic emblematic design, and geographic style documentation by third-party authority. Labels that comply with 9 CFR 317.8 (b) (1) or 9 CFR 381.129 (b) (2) requirements: For labels that comply with 9 CFR 317.8 (b) (1) or 9 CFR 381.129 (b) (2), the product would need to be labeled as e.g., \u201cTuscan Brand Made in USA\u201d or follow one of the established styles in the Food Standards and Labeling Policy Book (e.g., \u201cItalian Style\u201d). Other options for geographic naming to comply with 9 CFR 317.8 (b) (1) or 9 CFR 381.129 (b) (2) include e.g., \u201cTuscan Inspired,\u201d \u201cTuscan Recipe Chicken,\u201d or \u201cChicken Tuscan.\u201d For a list of the established styles in the Food Standards and Labeling Policy Book, see the end of this appendix, if the style in question is not in this list, the label would need to comply with the requirements in 9 CFR 317.8 (b) (1), 9 CFR 381.129 (b) (2) or follow the third-party authority documentation requirement State endorsement programs that have a geographic emblematic design (e.g., Wisconsin Cheese with a map of Wisconsin or use of flag): State endorsement programs that have a geographic emblematic design (e.g., Go Texan with the map of Texas or Nevada Made with the map of Nevada) and a geographic logo, map or flag are generically approved per 9 CFR 412.2 (b). The label must comply with 9 CFR 317.8 (b) (1), 9 CFR 381.129 (b) (2) or an established style in the Food Standards and Labeling Policy Book. In addition, there must be support in the labeling record for the claim. The support can be a certificate from the agency running the certification program or a letter stating the label complies with the requirements. The supporting documentation needs to be updated yearly. 33", "State Endorsement Programs that do not have a geographic emblematic design: For the state endorsement programs that do not have a geographic emblematic design (e.g., \u201cPride of New York,\u201d \u201cKentucky Proud\u201d), there needs to be support in the labeling record for the claim. The support can be a certificate from the agency running the certification program or a letter stating the label complies with the requirements. The supporting documentation needs to be updated yearly. Geographic Style Documentation by Third-Party Authority: New geographic styles, not listed in the Food Standards or Labeling Policy Book, for example, \u201cLaos Style,\u201d must be supported by a third-party authority. The

third-party authority could be a chef or other culinary authority providing a definition for the style and stating how the product meets that definition. The geographic style documentation by a third-party authority must:

- \u2022 Indicate the type of product as identified with and peculiar to the area represented by the geographical term.
- \u2022 Indicate the characteristics of the X style in a manner that is quick and easy to understand. It may be a method of preparation and/or certain ingredients that are used.
- \u2022 Have characteristics that are unique to the geographical style for which the documentation is being provided; and
- \u2022 Provide the credentials of the person who is claiming to be the third-party authority. Further, unless the new style is documented in the Food Standards and Labeling Policy Book, the company needs to include supporting information in every labeling record that is generically approved and with every label that is submitted for approval.

Documentation requirements for Geographic Landmark Claims: The documentation for a geographic claim on a label must be updated once a year and be current for that year. The documentation to support the claim for a state endorsement program and state endorsement program with geographic emblematic design can be a certificate from a state agency. For the third-party authority, you need to have the supporting documentation and/or certificate updated once a year from the third-party authority to support the claim. Styles defined in the Food Standards and Labeling Policy Book

- \u2022 Asian Style
- \u2022 Country Style
- \u2022 Buffalo Style
- \u2022 Cajun Style/Cajun Recipe
- \u2022 Cantonese Style Spices
- \u2022 Creole Style
- \u2022 Italian Style (please note- Italian Style sausage must meet 9 CFR 319.145) 34",
- \u2022 Jamaican Style
- \u2022 Jerk or Jerk Style
- \u2022 Hawaiian Style
- \u2022 Mediterranean Style
- \u2022 Mexican Style
- \u2022 Nacho Style, Nacho Flavor and Similar Terms
- \u2022 New Orleans Style
- \u2022 Oriental Style
- \u2022 Santa Fe Style
- \u2022 Southwestern Style
- \u2022 Szechwan Style
- \u2022 Thai Style

Appendix 9: Additional Information for Label Approval This section provides additional information about the two other categories of labels that LPDS must evaluate. Also, the following provides some general information about label requirements. Labels for religious exempt products (9 CFR 412.1 (c)(1)): Poultry slaughtered under Buddhist, Confucian, Halal, or Kosher religious exemptions may not bear the mark of inspection. Because of this, the labels deviate from labeling requirements and must be approved by LPDS. For more information see Religious Exemption for the Slaughter and Processing of Poultry. Labels for temporary approval (9 CFR 412.1 (c)(4)): A temporary label approval may be granted for labels with a regulatory deviation that does not pose any potential health, safety, or dietary problems to the consumer. Temporary approvals will be granted for up to 180 days, and establishments can apply for one extension of up to an additional 180 days. Label transfers are a special type of temporary approval which is granted for 60 days with one additional extension. Temporary label approval is granted on a case-by-case basis. Example: A supplier changes ingredients and fails to inform the establishment, and the establishment needs to make a minor correction to the ingredients statement. The establishment can apply for a temporary approval to use the existing label, even though it does not have the correct ingredients statement. Only LPDS can grant temporary approvals for labels with deficiencies. The submitter must address the four conditions for temporary approval listed in 9 CFR 412.1(f) and explain how they meet each condition. As part of their label application, they must also explain exactly what is wrong with their label. Example: A change in the ingredients statement from what was approved in the past. The submitter would submit both ingredients statements and highlight the differences between them.

FSIS Verification Activities at Establishments

35","FSIS IPP perform routine and directed General Labeling Tasks as assigned by the Public Health Inspection System as part of their regular label verification activities under FSIS Directive 7221.1, Prior Label Approval. FSIS IPP verify that final labels applied to final product follow applicable regulations by evaluating information in the establishment\u2019s labeling record and the label that is applied to the product (e.g., to verify that the ingredients statement on the label matches the product formula). Neither establishments, LPDS, nor FSIS inspectors generically approve labels. Rather, such labels are approved by the regulations provided they follow applicable requirements in 9 CFR 412.2 (b). For additional information, see FSIS Directive 7221.1, Prior Labeling Approval. Labeling and Establishment Responsibilities concerning Label Approval Establishments are required to keep records of all labeling, both generically approved, and sketch approved by LPDS, along with the product formulation and processing procedures, as prescribed in 9 CFR 320.1(b)(11), 9 CFR 381.175(b)(6), and 9 CFR 412.1. For labels that are sketch modified by LPDS, the establishment is responsible for making the changes on the label as noted by LPDS, prior to the final generic label approval and printing. For establishments that are making changes to labels previously approved by LPDS, they must update the labeling records and label to reflect the changes made. If the label has claims that are impacted by the ingredients, then the label would need to be resubmitted to LPDS for approval prior to use. 9 CFR 412.1(a) added the requirement that any additional documentation needed to support that the labels are consistent with the Federal meat and poultry regulations on labeling also be kept. For example, in a situation where an establishment is making an undefined geographic claim on a label (\u201cTuscan style\u201d), documentation should be included to support that the style meets 9 CFR 317.8 (b). Companies must provide labeling records to FSIS personnel upon request as described in 9 CFR 412.1(a). For additional information see: Labeling and Establishment Responsibilities. 36","SMALL PLANT HELP DESK i'h!JHIW.:~ sm lt1nil'frH'7:!!&J.II fil~ -L 12-17~Z.OJ 0 ;\~-fm~1MLUI La. r,um lup il'h.'r'b.luu U~iu .I 11tnil11\u2022 nil \u2022u..d , .. ,hnlh l~,c,i,r. ASKFSIS USDA FSIS www.fsis.usda.gov 2023 37"]}]