Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317, 318, 319, and 381

[Docket No. 97–001P]

RIN 0583–AC35

Elimination of Requirements for Partial Quality Control Programs

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the meat and poultry products inspection regulations by removing the requirements pertaining to partial quality control (PQC) programs except with respect to the irradiation of poultry products. A PQC program controls a single product, operation, or part of an operation in a meat or poultry establishment. The proposal would remove the design requirements for PQC programs and the requirements for establishments to have PQC programs for certain products or processes, other than those that apply to irradiation of poultry products. For example, the proposal would remove the requirements for poultry slaughtering establishments operating under the New Line Speed (NELS) inspection system and the New Turkey Inspection System (NTIS) to have PQC programs and the requirements concerning the design, content, and Agency approval of those programs. The proposal would also remove from the thermal processing regulations the requirements for FSIS prior approval of systems and devices not specified in the regulations and all requirements concerning PQC programs. The proposal would expand the alternatives available to establishments under the thermal processing regulations for ensuring the safety of their products. This proposal is intended to provide inspected establishments with flexibility, to make the regulations more consistent with the Pathogen Reduction (PR)/Hazard Analysis and Critical Control Points (HACCP) regulations, and to encourage establishments to adopt new technologies and methods that will improve food safety and other consumer protections.

DATES: Comments must be received on or before July 19, 1999.

ADDRESSES: Submit one original and two copies of written comments to FSIS Docket Clerk, DOCKET #97–001P, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 112 Cotton Annex Building, 300 12th Street, SW., Washington, DC 20250–3700. All comments submitted in response to this proposed rule will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 4 p.m., Monday through Friday. Those who wish to make oral comments can schedule an appointment with the person whose name appears in **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: Patricia F. Stolfa, Assistant Deputy Administrator, Office of Policy, Program Development, and Evaluation, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700; (202) 205–0699.

SUPPLEMENTARY INFORMATION:

Background

FSIS carries out programs designed to ensure that meat, poultry, and egg products are wholesome, not adulterated, and properly marked, labeled, and packaged. FSIS is implementing the ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems'' final rule published July 25, 1996 (61 FR 38806), to reduce the risk of foodborne illness associated with the consumption of meat and poultry products to the maximum extent possible. The Pathogen Reduction (PR)/HACCP final rule requires establishments to take appropriate and feasible measures to prevent or reduce the likelihood of physical, chemical, and microbiological hazards in the production of meat and poultry products.

FSIS is reviewing its other regulations to determine how they can be made more consistent with the PR/HACCP regulations and the regulatory approach they embody. This approach favors performance-based standards over prescriptive, command-and-control regulations. Command-and-control requirements specify, often in great detail, how a plant is to achieve particular food safety or other regulatory objectives, while performance standards state the objectives or levels of performance to be achieved and give a plant the ability to describe how it will achieve them. Included in the Agency's review are regulations on sanitation, meat and poultry products with visible defects affecting safety or quality, and economic adulteration of meat and poultry products.

FSIS announced its regulatory review in a December 29, 1995, advance notice of proposed rulemaking (ANPR) ''FSIS Agenda for Change'' (60 FR 67469). The Agency said that, by eliminating unnecessary regulations and replacing command-and-control prescriptions with performance standards, inspected establishments would have greater flexibility to adopt innovations that can yield food-safety benefits. Among the regulations FSIS has identified as candidates for modification or elimination are those that delimit processing and treatment methods intended to eliminate specific food safety hazards and requirements concerning quality control programs.

FSIS has already reduced its role of approving and specifying in detail the design and operation of establishment-operated partial quality control (PQC) programs. In 1997, the Agency published a final rule that, among other things, removes the requirement for FSIS prior approval of most PQC programs (62 FR 45016, August 25, 1997). Recognizing that the establishment bears primary responsibility for the control of its own manufacturing processes, FSIS now thinks it appropriate to take the further step of eliminating PQC requirements other than for irradiation of poultry (9 CFR 381.149(b)), so that establishments will have the flexibility they need to be innovative, and consistent with HACCP and the Agency's regulatory policy. (FSIS proposed to remove requirements for quality control programs for poultry-product irradiation in its February 24, 1999, proposal on the irradiation of meat and meat products (64 FR 9809).)

Quality Control

Quality control, in general, is a planned, documented system of activities intended to ensure the

stability of processes and uniformity of products. Quality control programs and systems are based on the assumption that there is normal variation in any process, and that the process is under control if that variation is not exceeded.

In the food industry, quality control systems are used in processing operations to make sure that products from TV dinners to hotdogs will be exactly the same—will have the same content, flavor, color, texture, etc.—no matter how many thousands are made in a production run. Quality control programs can be used to maintain normal process variation within the limits prescribed in a standard, such as the 50-percent-fat limitation in a breakfast sausage. If the expected variation is exceeded, corrective action is taken to restore process stability.

Under FSIS regulations, a company may choose to place all of the processes and products in a plant under a comprehensive, or total, quality control system, or the company may choose to place only individual products or processes under quality control. A quality control program for only one process or product in a plant is known as a partial quality control (PQC) program.

Some PQC programs control product potential health and safety problems; others focus on economic or quality factors. PQC programs controlling for safety factors include those for thermally processed products, which are intended primarily to prevent toxin formation in the processed product. The programs for cooked beef products are intended to ensure that the processing of the products meets the regulatory requirements for handling, processing (time, temperature, and relative humidity), and storage to prevent pathogen formation in the products. PQC programs that control for product safety have been largely superseded by required HACCP plans.

PQC programs that control for economic or non-food-safety factors include those used to control the fat and water content of hotdogs, the number of meatballs in, or pepperoni slices on, a product, and the moisture or protein-fat-free (PFF) content of a product labeled ''ham, water added.'' The quality control program for mechanically separated (species) (MS(S)) is intended to control bone particle size, calcium content, fat and protein content, and protein efficiency ratio (9 CFR 319.5). The programs for pressed ham and spiced ham products are intended to ensure that the products meet the PFF regulatory requirements of § 319.104.

PQC programs to control products for economic factors are intended to prevent the marketing of products that are misbranded or that lack the quality or value that consumers expect. A plant operating under a PQC program for net weight keeps records of its checks and corrective actions to avoid lot inspection. Under PQC programs for fat and water in frankfurters, plants keep ingredient records by lot and results of laboratory tests for verification by FSIS inspectors. A plant operating a PQC program for boneless meat inspection does its own on-line inspection and keeps records. The FSIS inspector randomly selects samples of product that the plant has already inspected to ensure that the records are accurate.

Establishments are required by current regulations to have PQC programs for certain products or processes, such as the one for MS(S), just mentioned. A PQC program for on-line carcass quality control is required for an establishment operating under either the NELS or the NTIS poultry inspection system (9 CFR 381.76(c)).

PQC Programs in Slaughtering Plants

The Agency conducts verification checks on the plant-operated PQC programs required for certain inspection systems. Establishments being considered for implementation of the NELS and NTIS inspection systems (currently, about 10 per year) must meet requirements both for facilities and for PQC programs.

Interested establishments are required to obtain FSIS approval of their PQC programs before the programs can be implemented on a trial basis. Unacceptable PQC programs are returned to the establishment for correction.

Once approved, PQC programs are subject to on-site review by the Agency for six months after implementation. The establishment then submits an updated PQC program to the Agency for final review. If, at that stage, the program is found to be acceptable, full approval is granted, although the establishment remains subject to Agency verification checks. If the program is unacceptable, the trial period may be extended or approval of the program may be withdrawn.

The Agency provides guidelines to help interested establishments prepare for implementation of the NELS and NTIS inspection systems. Instructions for developing PQC programs are included in those guidelines. The Agency also offers instruction on slaughter quality control programs to Government and industry personnel at the FSIS Training Center.

Proposed Changes

FSIS is proposing to eliminate the requirement in 9 CFR 317.21(b) that establishments have, as an alternative to State or local certification of scales, PQC programs or total quality control system provisions for checking the accuracy of scales. The Agency is proposing simply to require that there be a certification of accuracy from State or local authorities or from a State-registered or -licensed scale repair firm or person. Establishments could continue to maintain scale-checking provisions in their QC programs and systems.

The Agency is proposing to remove from the meat and poultry inspection regulations the design requirements for partial quality control programs (9 CFR 318.4(d), 381.145(d)). The provisions outline what is necessary when an establishment is required to have a PQC program. Because the Agency is proposing to revoke the regulatory requirements pertaining to PQC programs, there is no need to describe what is necessary when PQC is required.

FSIS would also remove quality control requirements (9 CFR 318.7) governing the use of nitrites in bacon curing and the use of certain organic acids singly or in combination to delay the discoloration of fresh meat cuts. Such requirements are incompatible with the Agency's regulatory objectives because they specify a manner of compliance rather than simply a performance standard.

Both the nitrite and the organic acid regulations clearly state the maximum limits of use of the substances they concern. The consumer is also informed by product labeling of the presence of the substances in the products. The regulations provide clear limits and adequate consumer protections without the quality control requirements. The Agency is also proposing to improve the accuracy of the regulation by using the term ''production of botulinum toxin'' rather than ''growth of botulinum toxin'' (see 9 CFR 318.7(b)(3)(ii)). FSIS is aware that these food-safety regulations also may be regarded as inconsistent with the PR/HACCP regulations, but the Agency would prefer to address this inconsistency in a future rulemaking.

The Agency proposes to make the meat and poultry canning regulations (9 CFR 318.305 and 381.305) more consistent with the Agency's new, non-command-and-control regulatory approach by eliminating a number of prior-approval requirements. First, the requirement that the Agency prior-approve temperature-indicating devices other than mercury-in-glass

thermometers (at §§ 318.305(a)(1)(ii) and 381.305(a)(1)(ii)) would be replaced. Temperature-indicating devices, such as resistance temperature detectors, could be used and, as is the case currently, they would have to meet known standards of accuracy for such devices, but the frequency of testing for accuracy would not be prescribed.

The Agency is also proposing to remove the requirement for case-by-case evaluation and approval by FSIS of thermal processing systems not specified in the regulations. As amended, 9 CFR 318.305(f) and 381.305(f) would require that such systems be adequate to produce shelf-stable products consistently and uniformly. These requirements reflect the basic purposes of the canning regulations.

FSIS is also proposing to remove from the thermal processing regulations (9 CFR 318.307(b) and 381.307(b)) provisions concerning PQC programs and requirements for FSIS prior approval of thermal processing systems not specified in the regulations, including monitoring and recording devices not specified in the regulations. The Agency tentatively concludes that these regulations will ensure the adequacy of these systems without the requirement that the Agency is proposing to delete, which is inconsistent with the PR/HACCP regulations.

The Agency is also proposing to remove from the thermal processing regulations the requirements (in §§ 318.308 and 309 and §§ 381.308 and 309) concerning partial quality control programs to control process deviations and establishment finished product inspection procedures. The Agency tentatively finds that these requirements are unnecessary. The detailed prescriptions in these sections, which are based on HACCP principles, would remain as acceptable protections against potential microbial contamination.

Under this proposal, a thermal processing establishment would have four alternatives available to control process deviations identified in-process. The establishment could:

(1) Provide for how it will handle the deviations under a HACCP plan; or, until subject to 9 CFR part 417, (2) follow the existing regulations (§§ 318.308(d) and 381.308(d)); (3) handle the deviations under an approved total quality control system until the PR/HACCP rule becomes applicable to it; or (4) use alternative documented procedures for handling process deviations. The alternative documented procedures could be provisions of a HACCP plan, such as corrective actions to be taken, recordkeeping, or monitoring procedures, that would be followed when process deviations occurred. They could also include partial quality control programs, developed by or for the establishment, but not subject to FSIS approval. Such food-safety-related PQC programs would, however, be superseded by or integrated with provisions of the establishment's HACCP plan when that plan is implemented.

Similarly, under this proposal, a thermal processing establishment would have four alternatives for handling finished product inspections. The finished product inspections could be handled under: (1) The existing regulations (§§ 318.309(d) and 381.309(d)); (2) a HACCP plan; (3) the provisions of an approved total quality control system, until the PR/HACCP final rule is applicable to the establishment; or (4) alternative documented procedures for handling finished product inspections. The alternative documented procedures could be PQC programs or the HACCP plan provisions.

In any case, any alternative procedures for handling process deviations or finished product inspections would have to ensure that only safe, stable product is shipped in commerce. This proposed requirement dictates that not only would the procedures have to ensure that the product is free of microorganisms of public health significance, but also that it is not adulterated by other types of microorganisms, such as ''flat-sour'' bacteria or other spoilage organisms. This proposed requirement is consistent with the aims of HACCP and with the statutory prohibitions against the distribution of adulterated and misbranded meat and poultry products in commerce.

The proposed amendments would make the thermal processing regulations more consistent with the PR/HACCP final rule by explicitly providing a HACCP-plan alternative to the prescriptive procedures (consistent with § 417.2(b)(3)) and by including, as an option for handling process deviations or final product inspections, alternative documented procedures that ensure that only safe and stable products are shipped in commerce. This option would provide the establishment with the flexibility to use PQC programs or other procedures that meet a regulatory public health standard.

It should be noted that, under the HACCP regulations, an establishment's HACCP plan does not have to address potential microbial hazards in thermally processed/commercially sterile product if the establishment is following the current regulatory requirements for such product. However, the HACCP plan must address physical and chemical hazards to which the product may be subject.

Besides proposing to remove the requirements pertaining to PQC programs that control food-safety factors, which are inconsistent with PR/HACCP, FSIS is proposing to remove the requirements affecting economic or quality-related PQC programs. FSIS considers these requirements to be too prescriptive. They tend to perpetuate the command-and-control approach to food inspection and regulation. They are not in keeping with the Agency's new regulatory approach, which is oriented more toward monitoring industry compliance with performance-related objectives.

First, the Agency is proposing to remove the QC system requirements from the regulations and requirements governing the identity and composition of MS(S) product and label approval of the product (9 CFR 319.5). The MS(S) regulations specify the maximum calcium content, the minimum protein content, the protein efficiency ratio, the maximum fat content, and the maximum bone particle size for the product. The regulations also specify the elements that the QC system must contain, including a written description of the methods used by the establishment to maintain uniformity of raw materials used in manufacturing product and to control handling and processing of the raw materials and finished product. The regulations also specify the sample size and sampling frequency for food-chemistry analysis of product to determine compliance with the standards. FSIS regards these provisions as overly prescriptive and believes that, to achieve the purposes of the MS(S) regulations, it is sufficient to set the product standards for fat, protein, calcium content, and bone particle size.

The Agency is also proposing to update the provision for finished product samples to be analyzed according to methods of the Association of Official Analytical Chemists (AOAC) or methods listed in the FSIS ''Chemistry Laboratory Guidebook'' to reflect use of the most recent edition of the AOAC compendium. In addition, FSIS is proposing to give establishments the latitude to use validated scientific methods equivalent to, but not listed in, the AOAC and FSIS references. Under this proposed action, the establishments will have flexibility to choose the most appropriate means of ensuring that

MS(S) meets the compositional and labeling identity requirements of the regulations, but they will also have the burden of demonstrating equivalence.

The Agency is aware, however, that some may disagree with the evaluation of the MS(S) QC and analytical requirements as overly prescriptive; their comments on this matter are invited. Others may regard the incorporation by reference of the AOAC methods as unnecessary and such standards as those for fat content and protein efficiency ratio as duplicative of other regulatory requirements. Their comments are invited as well.

Second, consistent with the other changes proposed in this document, FSIS is proposing to eliminate the quality control program requirements from the protein-fat-free (PFF) percentage regulations (§§ 319.104 and 319.105) for various ''finely divided'' cured ham products, such as patties, chopped or pressed ham, and spiced ham. Establishments would still be required to abide by the PFF percentage limits for these products.

Finally, FSIS is proposing to remove the requirement that poultry slaughtering establishments operating under the NELS and NTIS inspection systems have PQC programs for carcass defects. If this proposed change is adopted, the establishments will have the flexibility to adopt quality control programs or other measures for ensuring the quality of their products. Removing the prior-approval aspect of these requirements will contribute to clarifying the respective roles of the inspection service and the regulated industry—a necessary task in making the requirements consistent with HACCP.

FSIS inspectors would continue to check poultry in NELS and NTIS plants for visible contamination and carcass trimming defects.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been determined to be significant, though not economically significant, and was reviewed by the Office of Management and Budget under Executive Order 12866.

FSIS is proposing to eliminate the regulatory requirements pertaining to establishment-operated PQC programs. This action would remove regulatory obstacles to innovation and command-and-control requirements inconsistent with the Agency's new regulatory approach and the objectives of the PR/HACCP regulations. In its August 25, 1997, final rule (62 FR 45016), the requirements for FSIS prior approval of most PQC programs were eliminated. This action was taken to facilitate the transition to HACCP in official establishments producing the greatest portion of meat and poultry products consumed in the United States. FSIS is proposing to take the additional step of eliminating most requirements for establishments to have PQC programs for specific products or processes, as well as design requirements affecting most PQC programs. The only PQC program requirements this proposal would leave in place would be the requirement for QC programs for irradiated chicken. However, as mentioned previously, this requirement is being addressed in another rulemaking proceeding (64 FR 9809).

The alternatives to this proposed rulemaking that FSIS considered were, in addition to the alternative of no rulemaking, those of mandating additional in-plant controls and of mandating general requirements and standards for PQC programs.

The alternative of no rulemaking would impose no additional regulatory burdens on establishments, which would continue to have the assurance that their PQC programs meet basic design criteria. However, the Agency rejected this alternative because not changing the regulations would leave in place a prescriptive regulatory regime for process controls and PQC programs that conflict in a material way with the objectives of the PR/HACCP final rule. Under HACCP, establishments assume responsibility for building science-based, preventive process controls into the food production system to reduce or eliminate food safety hazards. This includes taking responsibility for ensuring that processes conform with sound food safety performance standards. Establishments need to be able to implement better and more innovative food-safety and other consumer-protection strategies. This includes the flexibility to design a PQC program and determine its content and implementation date.

The alternative of mandating additional in-plant controls, whether in addition to or in lieu of PQC requirements, would add regulatory assurances that processes are under control and that products are safe, wholesome, and not misbranded. However, this alternative would add prescriptive, command-and-control requirements and restrict the scope for establishment food-safety initiatives, contradicting the Agency's new regulatory approach. The additional requirements also would probably not result in food-safety improvement.

The alternative of mandating new general requirements or standards for PQC programs would differ little in its effects from the current requirements for PQC programs to have certain features and for process control under the programs to be based on generally accepted statistical principles (9 CFR 318.4(d); 381.145(d)). Even if the current requirements were condensed, they would still be inconsistent with the PR/HACCP regulations and with the Agency's new regulatory approach, establishments would continue to incur a substantial recordkeeping burden, and the Agency would have nearly the same burden as it now does of verifying establishment compliance with the requirements.

FSIS chose the option of eliminating regulatory requirements for all PQC programs except QC programs for the irradiation of poultry products. This option provides establishments with the most flexibility in implementing process control programs in a HACCP environment. FSIS's proposed rule on irradiation of meat and meat products (64 FR 9089, February 24, 1999) would eliminate the requirement for QC programs in facilities where poultry products are irradiated.

Implementation of this proposed rule would enable FSIS to redirect resources from PQC program verification to other activities for ensuring that products are not adulterated or misbranded. FSIS has considered a number of alternatives to PQC program verification, such as finished product sampling for microbiological or food chemistry analysis and market sampling. Market sampling or national surveys can be used in lieu of inspecting lots or evaluating PQC programs for fat and water content of frankfurters. An alternative to FSIS evaluation of PQC programs for basting solutions in poultry products is finished product sampling for chemical analysis.

In-plant sampling of finished products for chemical analysis is a tool that FSIS has used—and will continue to use—to determine whether products are in compliance with regulatory requirements and to verify the effectiveness of in-plant controls. To be most effective, such sampling and analysis would be carried out in conjunction with Agency HACCP-verification and other verification activities.

FSIS also regards market sampling as a potentially useful tool for enforcing the statutes prohibiting the distribution in commerce of adulterated and misbranded meat and poultry products and for checking the effectiveness of establishment process controls.

Marketplace sampling and testing can also help in addressing food safety hazards arising in post-processing distribution of meat and poultry products.

This proposal would affect, overall, as many as 72 poultry slaughtering establishments and about 3,550 establishments that process meat and poultry products beyond slaughtering, dressing, and cut-up. The most far-reaching effect of the rule would be to increase the flexibility establishments have in controlling their processes. This benefit would arise from eliminating the required PQC program elements in §§ 318.4(d) and 381.145(d).

With or without this proposal, establishment HACCP plans will supersede or incorporate the few PQC programs that control food-safety factors. Under the proposal, most establishments that have PQC programs that control for non-food safety factors would continue to use the programs. In all likelihood, in developing new PQC programs, they would continue to include the information now required by FSIS. They would also be free to adopt other methods of process control and different techniques of observation, measurement, documentation, recordkeeping, and evaluation than are prescribed in the current regulations. They could change their PQC-controlled operations to integrate their food quality process control more effectively with their HACCP system operations to improve overall efficiency. For example, raw material control, now a required element in PQC programs, could be handled under an establishment?s HACCP plan, as could process controls for food safety. Similarly, the records requirements for PQC programs could be superseded by more efficient and appropriate establishment-developed systems. Establishments would thus be able to achieve unquantifiable gains in efficiency that would yield food-safety and other consumer-protection benefits.

FSIS-inspected establishments develop about 1,900 PQC programs a year according to regulatory design specifications. Assuming that a PQC program is developed by a QC manager earning about $26 an hour, and that it takes about 20 hours, on average, to develop a PQC program, the cost to an establishment of developing such a program is about $520. FSIS estimates that the cost to the regulated industry of developing such programs is about $1,000,000 per year.

This cost of developing PQC programs according to FSIS requirements, plus $13 million in annual operating costs for about 1,852 mandatory (required by regulation) PQC programs ($26/hr. X 260 hrs./yr./program X 1,852 programs), add up to about $14 million in costs to the regulated industry.

For most establishments, the proposal would not yield immediate, direct savings from removal of burdens associated with developing PQC programs because most PQC programs are voluntarily adopted by establishments. Establishments likely would continue the use of QC methods in their operations, so the removal of the regulatory requirement for establishments to follow the regulatory design specifications would not immediately yield a savings to establishments. Further, a substantial proportion of the costs of complying with this regulation was removed with the publication of the final rule eliminating prior approvals for facilities, equipment, and PQC programs (62 FR 45016; August 25, 1997).

However, FSIS currently requires that if establishments adopt PQC programs, the programs must meet certain design specifications and must contain certain specified information. Some establishments that are required to have PQC programs for certain products and processes would benefit from the removal of burdens associated with developing PQC programs. These establishments, including those involved in producing MS(S), meat cuts treated with organic acids, and other processing, could benefit from shifting some portion of their PQC program development and operation costs into HACCP-related or other activities.

Also, under the proposed regulatory amendments, establishments would have greater freedom to innovate. An indeterminate proportion of the annual burden of developing PQC programs according to FSIS specifications could eventually be channeled into more efficient and effective use of industry resources, especially where PQC programs have been operated.

Thus, although there would not be a direct savings from the removal of the regulatory requirements governing PQC programs, the industry potentially would be able to make more efficient and effective use of the $1 million or so in annual costs of developing the programs.

Finally, the proposed rule would permit FSIS to reallocate field inspection and headquarters resources now used in oversight of establishment-operated PQC programs to higher priority food safety-related activities.

Regulatory Flexibility Act

The Administrator of FSIS has determined that this proposed rule will not have a significant effect on a substantial number of small entities. The proposal would affect about 72 poultry slaughtering establishments, most of which are large business enterprises. It also would affect as many as 3,550 official meat and poultry processing establishments, of which a substantial majority, 3,330, are considered small entities under Small Business Administration criteria (500 or fewer employees per establishment). However, the proposal would not have a significant effect on these establishments. It would impose no new regulatory requirements necessitating investments or other resource commitments by establishments but would, by removing a number of existing regulatory requirements, permit more efficient resource utilization, especially to support establishment HACCP systems.

The proposal would remove most remaining requirements for establishments to have PQC programs for certain products or processes and the general requirement concerning the design of such programs. The proposal would give inspected establishments greater flexibility to innovate and to introduce new processes or products that meet HACCP or other consumer protection objectives. As a result, the proposal would theoretically provide several thousand dollars of regulatory relief annually per establishment.

The proposal would enable establishments to avoid the costs associated with developing and implementing PQC programs that address regulatory requirements for the use of certain substances in preparation of meat and poultry products, such as the use of organic acids to delay discoloration of fresh meat cuts. Thermal processing establishments (of which there are about 130) would avoid the costs associated with developing PQC programs according to Agency specifications and the costs associated with obtaining Agency prior approvals.

As many as 3,330 small establishments would no longer be required to operate PQC programs for certain processes (such as PQC programs for processing cooked beef) and products (such as mechanically separated, or ''deboned,'' product). Small and large establishments would theoretically save about $520 per PQC program in development costs for 320 mandatory PQC programs, or $161,720 total. Out of this total, small establishments would save about $151,320. Small establishments could thus be expected to save about $4,000 each in annual recurring costs associated with developing mandatory PQC programs.

Operating costs of PQC programs vary widely. A simple PQC program to verify the accuracy of scales, for example, may require that tests be performed only several times a year, at little cost in operator time. A PQC program for a complex process, on the other hand, may require daily tests and data collection and recordkeeping tasks lasting up to 4 hours. For the purposes of this document, PQC programs are each assumed to require up to 1 hour's worth of daily attention by the establishment QC specialist. The removal of the PQC requirements would, at least theoretically, relieve small establishments of these burdens.

Assuming, for example, that small establishments incur annual costs of about $12,000,000 in operating mandatory PQC programs (solely in operating the QC evaluation process of such programs, and not including laboratory analysis, and other special facilities that may be required to determine whether products are in compliance with the regulations), each establishment could theoretically save about $4,000 in PQC program operations.

In addition, small establishments would benefit through unquantifiable savings accruing from removal of regulatory design requirements for both mandatory and voluntary PQC programs. They would have additional flexibility, beyond the removal of prior approval requirements effected by FSIS Docket No. 95–032F, to develop and implement HACCP-consistent or other process control systems.

Thus, about $8,000 in recurring savings could theoretically accrue to each small meat and poultry establishment. However, because many, if not most, affected establishments would be likely to continue to operate PQC programs that help in producing products with consistent and uniform characteristics, establishments may not choose to reap the theoretical savings that could result from eliminating their PQC programs. The effect of the proposed rule on the substantial number of affected small establishments would thus not likely be substantial.

Paperwork Requirements

Title: Processing Procedures and Quality Control Systems.

Type of Collection: Revision.

Abstract: FSIS has reviewed the paperwork and recordkeeping requirements in this proposed rule in accordance with the Paperwork Reduction Act. This proposed rule would substantially reduce reporting requirements for official establishments. The proposed rule would remove the design requirements affecting most PQC programs that establishments have and most requirements for establishments to have PQC programs for certain products or processes. Currently, there are 624,465 burden hours associated with the PQC program requirements. FSIS will request OMB to eliminate all these burden hours from the information collection request 0083–0089.

List of Subjects

9 CFR Part 317

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 318

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 319

Food labeling, Meat inspection.

9 CFR Part 381

Poultry and poultry products, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, FSIS is proposing to amend 9 CFR Chapter III, the Federal meat and poultry inspection regulations, as follows:

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

1. The authority citation for part 317 would continue to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§ 317.21 [Amended]

2. Paragraph (b) of § 317.21 would be amended by removing the comma and all words following the word ''person''.

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

3. The authority citation for part 318 would continue to read as follows:

Authority: 7 U.S.C. 138f, 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§ 318.4 [Amended]

4. Paragraph (d) of § 318.4 would be removed.

5. Section 318.7 would be amended to read as follows:

a. Paragraphs (b)(3)(i) and (b)(3)(ii) would be revised;

b. The table in paragraph (c)(4), under the Class of substance ''Miscellaneous,'' the entry for the Substance ''Ascorbic acid, erythorbic acid, citric acid, sodium acetate, and sodium citrate, singly or in combination'' would be revised.

The revisions would read as follows:

§ 318.7 Approval of substances for use in the preparation of products.

* * * * *

(b) * * *

(3) * * *

(i) 100 ppm ingoing (potassium nitrite at 123 ppm ingoing); and 550 ppm sodium ascorbate or sodium erythorbate (isoascorbate) shall be used; or

(ii) A predetermined level between 40 and 80 ppm (potassium nitrite at a level between 49 and 99 ppm); 550 ppm sodium ascorbate or sodium erythorbate (isoascorbate); and additional sucrose or other similar fermentable carbohydrate at a minimum of 0.7 percent and an inoculum of lactic acid producing bacteria such as *Pediococcus acetolactii* or other bacteria demonstrated to be equally effective in preventing the production of botulinum toxin at a level sufficient for the purpose of preventing the production of botulinum toxin.

* * * * *

(c) * * *

(4) * * *

Class of substance	Substance	Purpose	Product	Amount
*	*	*	*	* * *
Miscellaneous	Ascorbic acid, erythorbic acid, citric acid, sodium ascorbate and sodium citrate, singly or in combination.	To delay discoloration.	Fresh beef cuts, fresh lamb cuts, and fresh pork cuts.	Not to exceed, singly or in combination, 500 ppm or 1.8 mg/sq inch of product surface of ascorbic acid (in accordance with 21 CFR 182.3013), erythorbic acid (in accordance with 21 CFR 182.3041), or sodium ascorbate (in accordance with 21 CFR 182.3731); and/or not to exceed, singly or in combination, 250 ppm or 0.9 mg/sq inch of product surface of citric acid (in accordance with 21 CFR 182.6033), or sodium citrate (in accordance with 21 CFR 182.6751).

Class of substance	Substance	Purpose	Product	Amount		
*	*	*	*	*	*	*

* * * * *

6. Paragraphs (a)(1)(ii) and paragraph (f) of § 318.305 would be revised to read as follows:

§ 318.305 Equipment and procedures for heat processing systems.

(a) * * *

(1) * * *

(i) * * *

(ii) *Other devices.* Temperature-indicating devices used in lieu of mercury-in-glass thermometers, such as resistance temperature detectors, shall meet known, accurate standards for such devices when tested for accuracy. The records of such testing shall be available to FSIS program employees.

* * * * *

(f) *Other systems.* All other systems not specifically delineated in this section and used for the thermal processing of canned product shall be adequate to produce shelf-stable products consistently and uniformly.

* * * * *

7. Paragraph (b) of § 318.307 would be revised to read as follows:

§ 318.307 Record review and maintenance.

* * * * *

(b) *Automated process monitoring and recordkeeping.* Automated process monitoring and recordkeeping systems shall be designed and operated in a manner which will ensure compliance with the applicable requirements of § 318.306.

* * * * *

8. In § 318.308, paragraph (b) would be revised, paragraph (c) would be removed and reserved, and paragraph (d) introductory text would be revised to read as follows:

§ 318.308 Deviations in processing.

* * * * *

(b) Deviations in processing (or process deviations) shall be handled:

(1) Under a HACCP plan for thermally processed/commercially sterile product that addresses hazards associated with microbial contamination; or

(i) Under the provisions of paragraph (d) of this section; or

(2) Until the establishment is subject to part 417 of this chapter,

(i) Under an FSIS-approved total quality control system; or

(ii) Under alternative documented procedures for handling process deviations that will ensure that only product that is safe and stable is shipped in commerce.

(c) [Reserved]

(d) Procedures for handling process deviations where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented procedures for handling process deviations.

* * * * *

9. In § 318.309, paragraph (a) would be revised, paragraphs (b) and (c) would be removed and reserved, and paragraph (d) introductory text would be revised, to read as follows:

§ 318.309 Finished product inspection.

(a) Finished product inspections shall be handled:

(1) Under the provisions of paragraph (d) of this section;

(2) Under a HACCP plan for thermally processed/commercially sterile products that addresses hazards associated with microbiological contamination;

(3) Under an FSIS-approved total quality control system; or

(4) Under alternative documented procedures that will ensure that only safe and stable product is shipped in commerce.

(b) [Reserved]

(c) [Reserved]

(d) Procedures for handling finished product inspections where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented procedures for handling finished product inspections.

* * * * *

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

10. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

11. Paragraph (e)(2) of § 319.5 would be revised to read as follows:

§ 319.5 Mechanically Separated (Species).

* * * * *

(e) * * *

(2) Analytical methods used by establishments in verifying the fat, protein, and calcium content of product consisting of or containing Mechanically Separated (Species) shall be among those listed in ''Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC),'' 16th edition, 1995, §§ 960.39, 976.21, 928.08 (Chapter 39), and 940.33 (Chapter 45), which is incorporated by reference, or, if no AOAC method is available, in the ''Chemistry Laboratory Guidebook,'' U.S. Department of Agriculture, Washington, DC, March 1986 edition, sections 6.011–6.013, Revised June 1987 (pages 6–35 through 6–65), or by appropriate methods validated by scientific bodies in collaborative trials. The ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 16th edition, 1995, is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51.

§ 319.104 [Amended]

12. Section 319.104 would be amended in paragraph (a) by removing the last sentence of footnote 3 to the chart.

§ 319.105 [Amended]

13. Section 319.105 would be amended in paragraph (a) by removing the last sentence of footnote 2 to the chart.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

14. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.18, 2.53.

15. Section 381.76 would be amended to read as follows:

a. Paragraph (b)(1)(ii)(*b*) would be revised.

b. Paragraph (b)(1)(iii)(*b*) would be revised.

c. Paragraph (b)(4)(i)(*a*), introductory text, would be revised.

d. Paragraph (b)(4)(i)(*b*) would be revised.

e. Paragraph (b)(4)(ii) would be removed and reserved.

f. Paragraph (b)(4)(iii) would be removed and reserved.

g. Paragraph (b)(5)(i)(*a*) introductory text, would be revised.

h. Paragraph (b)(5)(i)(*b*) would be revised.

i. Paragraph (b)(5)(ii) would be removed and reserved.

j. Paragraph (b)(5)(iii) would be removed and reserved.

k. Paragraph (c) would be removed.

The revisions would read as follows:

§ 381.76 Post-mortem inspection, when required; extent; traditional, Streamlined Inspection System (SIS), New Line Speed (NELS) Inspection System and the New Turkey Inspection (NTI) System; rate of inspection.

* * * * *

(b)(1) * * *

(ii) * * *

(*b*) The Administrator determines that the establishment has the intent and capability to operate at line speeds greater than 70 birds per minute, and meets all the facility requirements in § 381.36(d).

(iii) * * *

(*b*) The Administrator determines that the establishment meets all the facility requirements in § 381.36(e).

* * * * *

(4) * * *

(i) * * *

(*a*) Post-mortem inspection. The establishment shall provide three inspection stations on each eviscerating line in compliance with the facility requirements § 381.36(d)(1). The three inspectors shall inspect the inside, viscera, and outside of all birds presented. Each inspector shall be flanked by two establishment employees—the presenter and the helper. The presenter shall ensure that the bird is properly eviscerated and presented for inspection and the viscera uniformly trailing or leading. The inspector shall determine which birds shall be salvaged, reprocessed, condemned, retained for disposition by the veterinarian, or allowed to proceed down the line as a passed bird subject to reinspection. Poultry carcasses with certain defects not requiring condemnation of the entire carcass shall be passed by the inspector, but shall be subject to reinspection to ensure the physical removal of the specified defects. The helper, under the supervision of the inspector, shall mark such carcasses for trim when the defects are not readily observable. Trimming or birds passed subject to reinspection shall be performed by:

* * * * *

(*b*) A reinspection station shall be located at the end of each line. This station shall comply with the facility requirements in § 381.36(d)(2). The inspector shall ensure that the establishment has performed the indicated trimming of carcasses passed subject to reinspection by visually monitoring, checking data, and/or gathering samples at the station or at other critical points on the line.

(ii) [Reserved]

(iii) [Reserved]

(5) * * *

(i) * * *

(*a*) *Post-mortem inspection.* Each inspection station must comply with the facility requirements in § 381.36(e)(1). Each inspector shall be flanked by and establishment employee assigned to be the inspector's helper. The one inspector on an NTI–1 Inspection System shall be presented every bird. Each inspector on an NTI–2 Inspection System line shall be presented every other bird on the line. An establishment employee shall present each bird to the inspector properly eviscerated with the back side toward the inspector and the viscera uniformly trailing or leading. Each inspector shall inspect the inside, viscera, and outside of all birds presented. The inspector shall determine which bird shall be salvaged, reprocessed, condemned, retained for disposition by a veterinarian, or allowed to proceed down the line as a passed bird subject to reinspection. Turkey carcasses with certain defects not requiring condemnation of the entire carcass shall be passed by the inspector, but shall be subject to reinspection to ensure the physical removal of the specified defects. The helper, under the supervision of the inspector, shall mark such carcasses for trim when the defects of birds passed subject to reinspection shall be performed by:

* * * * *

(*b*) *Reinspection.* A reinspection station shall be located at the end of the lines. This station shall comply with the facility requirements in § 381.36(e)(2). The inspector shall ensure that establishments have performed the indicated trimming of each carcass passed subject to reinspection by visually monitoring, checking data, and/or sampling product at the reinspection station and, if necessary, at other points, critical to the wholesomeness of product, on the eviscerating line.

(ii) [Reserved]

(iii) [Reserved]

§ 381.121d [Amended]

16. Paragraph (b) of § 381.121d would be amended by removing the comma and all words following the word ''person.''

§ 381.145 [Amended]

17. Paragraphs (d) and (e) of § 381.145 would be removed.

18. Paragraphs (a)(1)(ii) and (f) of § 381.305 would be revised to read as follows:

§ 381.305 Equipment and procedures for heat processing systems.

(a) * * *

(1) * * *

(ii) *Other devices.* Temperature-indicating devices used in lieu of mercury-in-glass thermometers, such as resistance temperature detectors, shall meet known, accurate standards for such devices when tested for accuracy. The records of such testing shall be available to FSIS program employees.

* * * * *

(f) *Other systems.* All other systems not specifically delineated in this section and used for the thermal processing of canned product shall be adequate to produce shelf-stable products consistently and uniformly.

* * * * *

19. Paragraph (b) of § 381.307 would be revised to read as follows:

§ 381.307 Record review and maintenance.

* * * * *

(b) *Automated process monitoring and recordkeeping.* Automated process monitoring and recordkeeping systems shall be designed and operated in a manner which will ensure compliance with the applicable requirements of § 381.306.

* * * * *

20. In § 381.308, paragraphs (b) would be revised, paragraph (c) would be removed and reserved, and paragraph (d) introductory text would be revised to read as follows:

§ 381.308 Deviations in processing.

* * * * *

(b) Deviations in processing (or process deviations) shall be handled:

(1) Under a HACCP plan for thermally processed/commercially sterile product that addresses hazards associated with microbial contamination; or

(i) Under the provisions of paragraph (d) of this section; or,

(ii) Under a HACCP plan for thermally processed/commercially sterile product that addresses hazards associated with microbial contamination; or

(2) Until the establishment is subject to part 417 of this chapter,

(i) Under an FSIS-approved total quality control system; or

(ii) Under alternative documented procedures for handling process deviations that will ensure that only product that is safe and stable is shipped in commerce.

(c) [Reserved]

(d) Procedures for handling process deviations where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented system or procedures for handling process deviations.

* * * * *

21. In § 381.309, paragraph (a) would be revised, paragraphs (b) and (c) would be removed and reserved, and paragraph (d) introductory text would be revised, to read as follows:

§ 381.309 Finished product inspection.

(a) Finished product inspections shall be handled:

(1) Under the provisions of paragraph (d) of this section;

(2) Under a HACCP plan for thermally processed/commercially sterile products that addresses hazards associated with microbiological contamination;

(3) Under an FSIS-approved total quality control system; or

(4) Under alternative documented procedures that will ensure that only product that is safe and stable is shipped in commerce.

(b) [Reserved]

(c) [Reserved]

(d) Procedures for handling finished product inspections where the HACCP plan for thermally processed/ commercially sterile product does not address food safety hazards associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative procedures for handling finished product inspections.

* * * * *

Done at Washington, DC, on May 11, 1999.

Thomas J. Billy,

Administrator.

[FR Doc. 99–12352 Filed 5–17–99; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM156, Notice No. 25–99–04–SC]

Special Conditions: McDonnell Douglas Corporation (MDC) Model MD–17 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: The FAA proposes to issue special conditions for the McDonnell Douglas Corporation Model MD–17 airplane. This airplane will have novel and unusual design features, including the use of power-augmented-lift from externally blown flaps, for which the applicable airworthiness standards for transport category airplanes do not contain adequate or appropriate safety standards. This document contains the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that provided by the existing airworthiness standards.

DATES: Comments must be received on or before July 2, 1999.

ADDRESSES: Comments on this document may be mailed in duplicate to: Federal Aviation Administration, Transport Airplane Directorate, Program Management Branch, Attention: Rules Docket (ANM–114), Docket No. NM156, 1601 Lind Avenue SW., Renton, WA 98055–4056; or delivered in duplicate to the Transport Airplane Directorate at the above address. Comments delivered must be marked Docket No. NM156. Comments may be examined in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Gerry Lakin, Project Officer, FAA Transport Airplane Directorate, Standardization Branch, ANM–113, 1601 Lind Avenue SW., Renton, WA 98055–4056; telephone (425) 227–1187; facsimile (425) 227–1149; Email: gerald.lakin@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of these proposed special conditions by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket or notice number and be submitted in duplicate to the Rules Docket address specified above. All communications received on or before the closing date for comments will be considered by the Administrator. The proposals described in this notice may be changed in light of the comments received. All comments received will be available in the Rules Docket for examination by interested persons, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Persons wishing the FAA to acknowledge receipt of their comments must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. NM156.'' The postcard will be date stamped and returned to the commenter.

Background

On July 7, 1996, McDonnell Douglas Corporation, 2401 E. Wardlow Rd., Long Beach, CA 90807–5309, a wholly owned subsidiary of The Boeing Company, submitted an application for type certification of a commercial version of the Model C–17 military airplane, designated as the MDC Model MD–17. The MD–17 is a long range, transport category airplane powered by four Pratt & Whitney F–117–PW–100 engines, which are a military version of the PW2040 engines used on other civil transport category airplane types. The airplane will be offered in a cargo configuration only and is designed for carriage of outsized cargo into short runways.

The MD–17 airplane will be certified as a part 25 transport category airplane and, as such, pilots and flight instructors who operate it will have a standard airplane multiengine rating.

Type Certification Basis

Under the provisions of § 21.17, McDonnell Douglas must show that the MD–17 complies with the applicable provisions of 14 CFR part 25, as amended by Amendments 25–1 through 25–87. In addition, the certification basis includes part 36, as amended at the time of certification; part 34, as amended at the time of certification; any subsequent amendments to part 25 that are required for operation under part 121; and the special conditions resulting from the proposals specified in this notice.

If the Administrator finds that the applicable airworthiness regulations (i.e., part 25) do not contain adequate or appropriate safety standards for the MD–17 because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the MD–17 must comply with the fuel vent and exhaust emission requirements of part 34 and the noise certification requirements of part 36, and the FAA must issue a finding of regulatory adequacy pursuant to § 611 of Pub. L. 92–574, the ''Noise Control Act of 1972.''