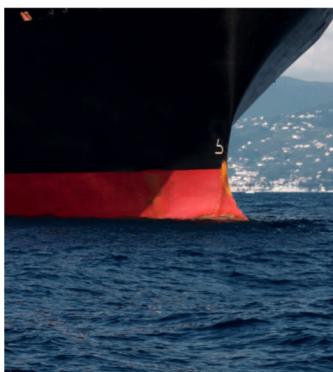




FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Foreign Supplier Verification Programs

Version 1.1 – 2017



Participant Manual

**FSPCA FOREIGN SUPPLIER VERIFICATION PROGRAMS
TRAINING CURRICULUM**

Version 1.1 – 2017

Copyright Notice

The Foreign Supplier Verification Programs (FSVP) training curriculum was developed by the Food Safety Preventive Controls Alliance (FSPCA).

The FSPCA is a broad-based public-private alliance of key industry, academia and government stakeholders. It was established in late 2011 by grants from U.S. Food and Drug Administration (FDA) to Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH) (U01FD003801, U19FD005322, U01FD005661).

© 2017 Illinois Institute of Technology Institute for Food Safety and Health (IIT IFSH). All rights reserved.

FSPCA FOREIGN SUPPLIER VERIFICATION PROGRAMS

TRAINING CURRICULUM

Version 1.1 – 2017

Disclaimer

The information provided by the Food Safety Preventive Controls Alliance (FSPCA) is for training purposes only. The FSPCA is not your attorney and cannot provide you with legal advice. The FSPCA curriculum is intended as a training tool to assist companies in complying with the FDA Food Safety Modernization Act (FSMA) foreign supplier verification programs regulation; however, following this curriculum does not ensure compliance with the law or FDA's regulations. For advice regarding the legal compliance with FSMA, please consult your legal counsel.

The information provided by the FSPCA will vary in applicability to each food importer. It is not possible for the FSPCA training curriculum to address every situation. Importers should implement the practices and programs that will function best to import safe foods based on the nature of their individual operations. FSPCA materials do not outline the only approach to developing and implementing a foreign supplier verification program. Importers can follow any approach that satisfies the requirements of the applicable statutes and regulations related to FSMA. The information provided by FSPCA does not create binding obligations for the Food and Drug Administration or industry.

FSPCA does not guarantee the accuracy, adequacy, completeness or availability of any information provided in its curriculum and is not responsible for any errors or omissions or for any results obtained from the use of such information. FSPCA gives no express or implied warranties, including but not limited to, any warranties of merchantability or fitness for a particular purpose or use. In no event shall FSPCA be liable for any indirect, special or consequential damages in connection with any use of this training curriculum.

Developed by the



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Foreign Supplier Verification Programs Work Group

Betsy Bihm, Cornell University, Ithaca, NY
Robert Brackett, Institute for Food Safety and Health – Illinois Institute of Technology (IFSH-IIT), Chicago, IL
Catherine Carnevale (Editor), FSVP Subject Matter Expert and Consultant to FSPCA/IFSH/IIT, Cold Spring, NY
Virginia Darenkamp, FDA, San Diego, CA
Daniel C. Geffin, FDA-CFSAN, College Park, MD
Wanda Y. Honeyblue, FDA-CFSAN, College Park, MD
Daria Kleinmeier, FDA-CFSAN, College Park, MD
Cindy Koschetz, Institute for Food Safety and Health – Illinois Institute of Technology (IFSH-IIT), Chicago, IL

L. Robert (Bob) Lake (Editor), FSVP Subject Matter Expert and Consultant to FSPCA/IFSH/IIT, Bristow, VA
Wesley Long, FDA-CFSAN, College Park, MD
Sharon L. Mayl, FDA, Silver Spring, MD
Kelly Morin, FDA-CFSAN, College Park, MD
Trudy Perry, FDA, Silver Spring, MD
Brian Ravitch, FDA, San Diego, CA
Gretchen Wall, Cornell University, Ithaca, NY
Jason Wan, Institute for Food Safety and Health – Illinois Institute of Technology (IFSH-IIT), Chicago, IL
Gerald Wojtala, International Food Protection Training Institute (IFPTI), Battle Creek, MI

Importer Group

Bob Bauer, Association of Food Industries (AFI), Neptune, NJ
Roger Clarke, Williams Clarke Company, Wilmington, CA
Chris Epstein, American Association of Exporters and Importers (AAEI), Washington, DC
Michael E. Lahar, A.N. Deringer, Inc., St. Albans, VT
Roger Lawrence, McCormick and Company, Sparks, MD
Alexander Lesser, InXpress, Rochdale, United Kingdom
Erik Lieberman, U.S. Food Imports, Washington, DC
Kellee Poole, American Spice Trade Association (ASTA), Washington, DC

Barbara Reilly, National Customs Brokers and Forwarders Association of America (NCBFAA), Washington, DC
Mike Robach, Cargill, Minneapolis, MN
Michael Roberson, Publix Super Markets, Inc., Lakeland, FL
Marianne Rowden, American Association of Exporters and Importers (AAEI), Washington, DC
Nancy Seaquist, Sweet Harvest Foods, Inc., Rosemount, MN
Hilary Thesmar, Food Marketing Institute (FMI), Arlington, VA

Editors and Contributors

Catherine Carnevale (Editor), FSVP Subject Matter Expert and Consultant to FSPCA/IFSH/IIT, Cold Spring, NY
L. Robert (Bob) Lake (Editor), FSVP Subject Matter Expert and Consultant to FSPCA/IFSH/IIT, Bristow, VA
Bob Bauer, Association of Food Industries (AFI), Neptune, NJ
Robert Brackett, Institute for Food Safety and Health – Illinois Institute of Technology (IFSH-IIT), Chicago, IL
Virginia Darenkamp, FDA, San Diego, CA
David Gombas, Consultant to FSPCA/IFSH/IIT, Silver Spring, MD
Kathy Gombas, Consultant to FSPCA/IFSH/IIT, Silver Spring, MD

Daria Kleinmeier, FDA-CFSAN, College Park, MD
Erik Lieberman, U.S. Food Imports, Washington, DC
Sharon L. Mayl, FDA, Silver Spring, MD
Kelly Morin, FDA-CFSAN, College Park, MD
Brian Pendleton, FDA, Silver Spring, MD
Brian Ravitch, FDA, San Diego, CA
Michael Roberson, Publix Super Markets, Inc., Lakeland, FL
Nancy Seaquist, Sweet Harvest Foods, Inc., Rosemount, MN
Hilary Thesmar, Food Marketing Institute (FMI), Arlington, VA
Jason Wan, Institute for Food Safety and Health – Illinois Institute of Technology (IFSH-IIT), Chicago, IL

FSPCA Executive Committee (October 2016)

Benjamin Chapman, North Carolina State University, Raleigh, NC (*Chair*)
Claudia Coles, Washington State Department of Agriculture, Olympia, WA
Donna Garren, AFFL, Washington, DC
Donald Schaffner, Rutgers University, New Brunswick, NJ

Katherine M.J. Swanson, KMJ Swanson Food Safety, Inc., Mendota Heights, MN (*FSPCA Project Manager, Curriculum Development*)
Purnendu C. Vasavada, PCV & Associates LLC, River Falls, WI (*FSPCA Project Manager, Outreach*)

Foreign Supplier Verification Programs Training

The Food Safety Preventive Controls Alliance developed this training curriculum in Foreign Supplier Verification Programs compliant with the FDA's *Foreign Supplier Verification Programs (FSVP) for Importers of Food for Human and Animal* regulations. For the most current course information, please consult: <http://www.iit.edu/ifsh/alliance/>



This publication was developed by the Food Safety Preventive Controls Alliance (FSPCA) and was supported, in part, by a grant from the Food and Drug Administration to the Illinois Institute of Technology's Institute for Food Safety and Health. The views expressed herein do not necessarily reflect the views of these organizations. Direct all inquiries to the FSPCA at fspca@iit.edu

TABLE OF CONTENTS

| | |
|--|--------|
| Preface | P-1 |
| Chapter 1: Context: FSMA and FSVP | 1-1 |
| Chapter 2: Setting the Stage: Building the Foundation for the FSVP Process..... | 2-1 |
| Chapter 3: Overview of the Requirements..... | 3-1 |
| PCPS: Preventive Controls and Produce Safety Session | PCPS-1 |
| Chapter 4: Hazard Analysis | 4-1 |
| Chapter 5: Evaluation and Approval of Foreign Supplier..... | 5-1 |
| Chapter 6: Foreign Supplier Verification | 6-1 |
| Chapter 7: Reevaluation of Foreign Supplier Performance and Food Risk, and Corrective Actions | 7-1 |
| Chapter 8: Importer Identification at Entry | 8-1 |
| Chapter 9: Importance of Records..... | 9-1 |
| Chapter 10: FDA Oversight..... | 10-1 |
| Appendix 1: FSVP Summary, Rule, and Guidance..... | A1-1 |
| Appendix 2: Compliance Dates | A2-1 |
| Appendix 3: Workaids | A3-1 |
| Appendix 4: Dietary Supplements | A4-1 |
| Appendix 5: Modified Requirements | A5-1 |
| Appendix 6: Preventive Controls and Produce Safety | A6-1 |
| 6a: Preventive Controls Rules Overview | A6a-1 |
| 6b: Produce Safety Rule Overview | A6b-1 |
| Appendix 7: Technical Assistance and Resources | A7-1 |
| Appendix 8: Sections 402 and 403 of the FD&C Act | A8-1 |
| Appendix 9: FSMA Fact Sheets | A9-1 |
| Appendix 10: Definitions and Acronyms | A10-1 |

Blank Colored Insert-Front

Blank Colored Insert-Back

PREFACE. Introduction to the FSVP Course

Preface: Introduction to the FSVP Course

FOREIGN SUPPLIER VERIFICATION PROGRAMS (FSVP)



Welcome and Introductions

Welcome to the Foreign Supplier
Verification Programs (FSVP) course!



ICONS USED IN THE PARTICIPANT MANUAL

The Participant Manual uses the following icons—

Key Point: A key icon indicates a key point that may help explain or highlight a particular term or phrase, or give additional information.

Resources: A book icon indicates helpful resources available in the Appendices.

This course is designed to provide an understanding of the new role that the U.S. Congress has defined for food importers under the FDA Food Safety Modernization Act of 2011 (FSMA). FSMA adds many new requirements to improve the safety of human and animal food, and FDA has published several regulations to implement the new

requirements. The most important regulation for food importers is the Foreign Supplier Verification Programs regulation (FSVP rule) that FDA published on November 27, 2015.

This course will focus on explaining the requirements of the FSVP rule, and how you as importers can go about complying with those requirements. The course materials include all slides, lesson content, resource materials and exercises. The materials are yours to keep, so please feel free to take notes in your manual as you go along.

Introductions

- Instructor introductions
- Participant introductions—introduce yourself to the group by providing your:
 - Name
 - Employer
 - Products you import
 - What you hope to get out of the course



The FSVP contains a new set of requirements for importers. It is possible that some persons, who have not previously considered themselves to be food importers per se, nor directly subject to FDA food safety requirements, may now fall under the new FSVP definition of a food “importer.” Thus, these people may be here to learn how this rule potentially pertains to them. Others in this class may be brokers, exporters, or auditors or persons who wish to advise importers on FSVP. For whatever reason that you are attending this class, we would like to know why you are here so we can meet your training needs. You may also want to get to know some of your classmates as well, as they may be of use to you in the future.

Food Safety Preventive Controls Alliance (FSPCA)

Food Safety Preventive Controls Alliance (FSPCA)

- Background:
 - FDA recognized the need to assist the regulated industry to comply with the Food Safety Modernization Act (FSMA)
 - Food Safety Preventive Controls Alliance (FSPCA) is a public/private partnership funded by FDA
 - FSPCA's mission is to develop training curricula, outreach programs, and technical assistance to assist the regulated industry in complying with FSMA



The FSPCA was established in 2011 as part of a grant from FDA to the Illinois Institute of Technology's Institute of Food Safety and Health. The purpose of this broad-based alliance is to develop and maintain a cost-effective education and training program to assist the food industry with understanding and achieving compliance with certain aspects of FSMA.

FSPCA's mission is to support safe food production by developing a standardized curriculum and technical educational materials on FSMA regulations and providing technical assistance outreach to the food industry.

Disclosure

Disclosure

Although I attended the FSPCA FSVP Lead Instructor training:

- a) Lead Instructors are not certified, licensed, accredited, qualified, registered, sanctioned, authorized, recognized, endorsed, or approved by the FSPCA;
- b) I do not represent, speak for, or act on behalf of the FSPCA;
- c) The FSPCA cannot provide legal advice;
- d) The FSPCA does not guarantee the accuracy, adequacy, completeness or availability of any information provided and is not responsible for any errors or omissions or for any results obtained from the use of such information;
- e) Following the FSPCA curriculum does not ensure compliance with FDA's regulations or any other law or legal requirement; and
- f) The FSPCA gives no express or implied warranties, including but not limited to, any warranties of merchantability or fitness for a particular purpose or use



It should be noted that the instructors of this course have attended the FSPCA Lead Instructor training, but:

1. Lead Instructors are not certified, licensed, accredited, qualified, registered, sanctioned, authorized, recognized, endorsed, or approved by the FSPCA;
2. I do not represent, speak for, or act on behalf of the FSPCA;
3. The FSPCA cannot provide legal advice;
4. The FSPCA does not guarantee the accuracy, adequacy, completeness or availability of any information provided and is not responsible for any errors or omissions or for any results obtained from the use of such information;
5. Following the FSPCA curriculum does not ensure compliance with FDA's regulations or any other law or legal requirement; and
6. The FSPCA gives no express or implied warranties, including but not limited to, any warranties of merchantability or fitness for a particular purpose or use.

FSPCA FSVP Curriculum

FSPCA FSVP Curriculum

- This curriculum was designed by regulatory, academic, and industry professionals and developed with funding from FDA as part of the FSPCA.
- Taking this course is not required.
- Successfully completing this course will:
 - Help you to understand the FSVP requirements, and
 - How those requirements can be met in your particular circumstances.



This curriculum was designed by regulatory, academic, and industry professionals and developed with funding from FDA as part of the FSPCA. While FDA assisted in the preparation of the course materials, the materials have been written and produced by the Alliance and are not official FDA materials.

The FSVP rule does not require you to attend a training program following a “standardized curriculum” recognized by FDA. Therefore, completing this course is **NOT** mandatory. Attending this course, however, will help you understand the FSVP requirements and how those requirements can be met in your particular circumstance.

Note: The FSVP rule does require a “qualified individual” to perform each of the activities under the rule and specifies that a “qualified individual” is a person who has the education, training, or experience (or combination thereof) necessary to perform each of the required activities.

Course Description and Target Audience

Course Description and Target Audience

- **Course Description:** This course is a training curriculum that will provide participants with an understanding of the requirements of the “Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals” regulation.
- **Target Audience:** This course is designed for the FSVP importer who will be taking responsibility for fulfilling the requirements of the FSVP rule.



This course will provide participants with a thorough understanding of the requirements of the “Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals” regulation of the U.S. Food and Drug Administration (FDA). This regulation is one of a number of regulations and guidance that implement the provisions of the 2011 Food Safety Modernization Act (FSMA), which focuses on safe food practices.

This course is designed for:

1. U.S.-based importers who meet the definition of “importer” in the FSVP rule, which includes those who own or are the consignee of food at the time of entry, or, if no owner or consignee exists, the U.S. agent or representative of the foreign owner.
2. Others who have an interest in ensuring that the requirements of the FSVP rule are met, including brokers, exporters, foreign suppliers of food that will be exported to the U.S., persons/business owners who currently buy food from foreign sources, and representatives of foreign governments.

Course Goal and Objectives

Course Goal and Objectives

Goal: Participants should be able to determine how to comply with FSVP requirements.

Learning Objectives:

- By the end of this course, participants will be able to:
 1. Explain the underlying purpose(s) of the FSVP rule.
 2. Explain how to develop an FSVP.
 3. Describe how to implement an FSVP.
 4. Describe how to implement an FSVP recordkeeping system.
 5. Summarize FDA oversight.



This course is intended for importers of food and others who want to understand the FSVP rule requirements. The overall objectives of the course are to help you understand:

1. The underlying purpose of the FSVP rule;
2. How to develop an FSVP, i.e., what's needed in your FSVP;
3. How to implement your FSVP;
4. How to implement a recordkeeping system; and
5. How FDA will oversee your FSVP.

What Will the FSVP Course Not Do?

What Will the FSVP Course Not Do?

- This FSVP course is **NOT** intended to be a comprehensive course on anything other than FSVP, including:
 - Preventive Controls (FSPCA courses, PC for Human Food and PC for Animal food, are available)
 - Produce Safety (Produce Safety Alliance course is available)
 - All FDA food safety regulations, all labeling, and other requirements for foods
 - Answering all questions about how FSVP applies to individual import arrangements
 - FDA facility registration, prior notice



Resources:

FDA's Technical Assistance Network (TAN) is available to answer regulatory or rule interpretation questions. TAN can be accessed at:

<http://www.fda.gov/fsma>

The FSPCA TAN is available to answer scientific/technical questions about the rule. The FSPCA TAN can be accessed at:

<https://www.ifsh.iit.edu/fspca/fspca-technical-assistance-network>

More information about these and other resources are available in Appendix 7.

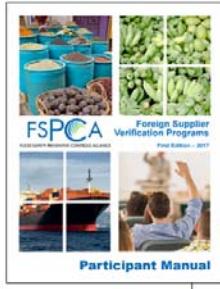
This course will not provide you with enough information to comply with the PC rules for either human or animal food. If you must implement either or both of those two rules, you will need to take courses that teach those rules, as appropriate for your purposes. The same applies to the Produce Safety rule. This course should, however, provide you with enough information to grasp the concepts and some details on what your foreign suppliers are expected to do in implementing these rules.

The course also will give you the tools to determine how FSVP applies to you. Nevertheless, given that there are a multitude of unique existing import operations and arrangements, the course will lead you in the right direction but will not have the time to consider individual situations. You will need to figure out how FSVP affects you and your particular arrangements based on the rule and course information provided. The course will provide some worksheets and exercises that will aid you in this process.

Course Materials

Course Materials

- Agenda
- Participant Manual
 - The book that participants will need for reference and knowledge
 - Exercise Workbook



FSPCA FOREIGN SUPPLIER
VERIFICATION PROGRAMS
(FSVP)
Exercise Workbook
Downloaded by The
FSPCA

The FSVP training materials includes an agenda (located at the end of the Preface), a participant manual, and an exercise workbook.

The manual and exercise workbook are yours. Become familiar with them and use them as a reference. The manual contains references and forms that can help you develop an FSVP and resources to locate other basic information. Make as many notes and marks in the manual as needed to assist you in creating an understanding of FSVP. This manual does not have a copyright. Make as many copies of the forms as necessary or copy the whole manual to share with others in your company.

Course Format



The course is divided into 10 chapters, not including the Preface and Appendices. It also includes a brief Preventive Controls and Produce Safety Session between Chapters 3 and 4.

Chapters 1, 2, and 3 will help to explain WHY and HOW the FSVP rule came about; WHO it applies to, i.e., who is an FSVP “importer;” WHAT are the requirements, i.e., standard and modified, and HOW they apply to a particular situation.

Chapters 4 through 9, focus on explaining the core elements of an FSVP, i.e., hazard analysis, evaluation and approval of foreign supplier, verification and corrective actions, reevaluation, importer identification at entry, and records and documentation.

The final chapter, Chapter 10, focuses on FDA oversight of FSVP importers and their implementation of the FSVP requirements.

There are ten appendices located at the end of this manual. They are included as a resource to provide you with more information and to help you develop your FSVP. We will review the appendices in more detail in the next slide.

Preview of Appendices

| Preview of Appendices | | |
|-----------------------|---|-----------------|
| Appendix | Name | Page # |
| 1 | FSVP Summary, Rule, and Guidance | A1-1 to A-1-32 |
| 2 | Compliance Dates | A2-1 to A2-4 |
| 3 | Workaids | A3-1 to A3-12 |
| 4 | Dietary Supplements | A4-1 to A4-16 |
| 5 | Modified Requirements | A5-1 to A5-25 |
| 6 | Preventive Controls and Produce Safety | |
| | Preventive Controls (for human and animal food) | A6a-1 to A6a-18 |
| | Produce Safety | A6b-1 to A6b-13 |
| 7 | Technical Assistance and Resources | A7-1 to A7-17 |
| 8 | Sections 402 and 403 of the FD&C Act | A8-1 to A8-6 |
| 9 | FSMA Fact Sheets | A9-1 to A9-31 |
| 10 | Definitions and Acronyms | A10-1 to A10-10 |

As you learn more about developing an FSVP, there are many definitions that you need to understand. Refer to Appendix 10 as needed. You may also want to add other terms that you may need in developing and implementing your own FSVP.

Participation and Engagement

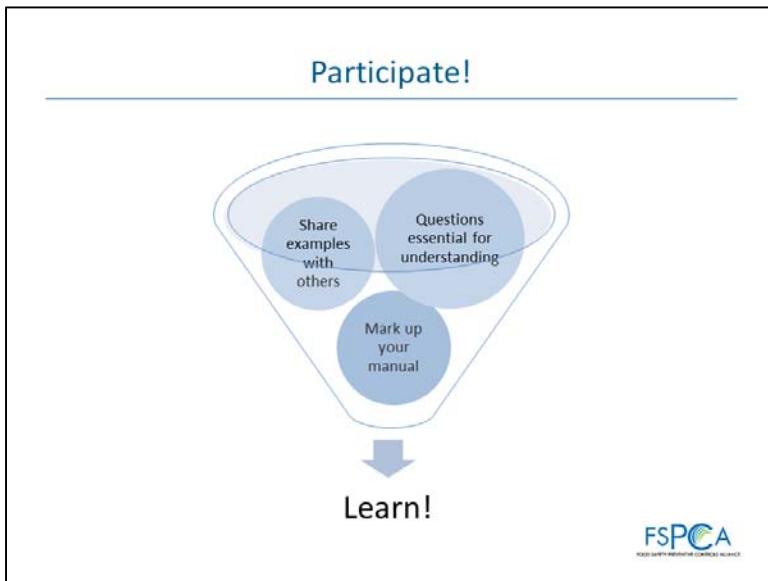
Participation and Engagement

- We plan to keep you engaged by asking questions, presenting scenarios, and giving you exercises to supplement the course content.
- There will be time for questions at the end of every chapter. Raise your hand at anytime if you are lost or something does not make sense.
- Resources are listed in the slides and manual.



Exercises and scenarios will keep you engaged and be helpful for the entire class by raising issues and questions that might not otherwise come up.

Please do not be shy about asking questions throughout the course. This rule is new, the role of importers as verifiers of food safety is new, and if you do not understand something, it is likely that others in the class do not as well. There will be an opportunity for questions at the end of each chapter, but raise your hand to interrupt if a concept is fuzzy or you need clarification.



To get the most out of this course, you will want to participate through sharing examples with others, marking up your manual, and asking questions.

FSPCA Contact Information

FSPCA Contact Information

If you have any questions,
please contact the FSPCA at

fspca@iit.edu

or visit the FSPCA website at

<http://www.iit.edu/ifsh/alliance>

for resources on FSVP and information on FSPCA activities,
including FSPCA's Technical Assistance Network, visit

<https://www.ifsh.iit.edu/fspca/fspca-technical-assistance-network>



Resources:

FSPCA's Technical Assistance Network is available to answer scientific/technical questions:

<https://www.ifsh.iit.edu/fspca/fspca-technical-assistance-network>

For more information about FSPCA, FSPCA's Technical Assistance Network and other resources see Appendix 7.

If you have questions, you can contact the Food Safety Preventive Controls Alliance at FSPCA@iit.edu or visit the website at the address listed on the slide. This website has a number of resources on FSVP and FSPCA activities. Of course, FDA's website contains all the FSVP regulation and related documents at FDA.gov.

Participant Course Agenda

The participant course agenda is intended to be covered as a 2-day (16 hours) course, which includes frequent opportunities for review and classroom exercises designed to provide learning opportunities to thoroughly understand the FSVP rule. The time allotted to each section will vary based on the audience and level of familiarity with the FSVP rule. A typical agenda appears on the next page.

AGENDA

Participants must attend the entire course to receive a certificate

| Day One | Registration, Sign-in, Book Distribution, Coffee |
|----------------|---|
| | Welcome, Introductions |
| Preface | Introduction to the FSVP Course |
| Chapter 1 | Context: FSMA and FSVP |
| Chapter 2 | Setting the State: Building the Foundation for the FSVP Process and Chapter 2 Exercise |
| Chapter 3 | Overview of the Requirements |
| | Lunch |
| Chapter 3 | Overview of Requirements (continued) and Chapter 3 Exercise |
| PCPS | Preventive Controls and Produce Safety Session |
| | Questions, Expectations for Day 2, and Adjourn |
| Day Two | Registration, Sign-in, Questions from Previous Day, Coffee |
| Chapter 4 | Hazard Analysis and Chapter 4 Exercise |
| Chapter 5 | Evaluation and Approval of Foreign Supplier |
| Chapter 6 | Foreign Supplier Verification |
| Chapter 7 | Reevaluation of Foreign Supplier Performance and Food Risk, and Taking Corrective Actions |
| | Lunch |
| Chapter 8 | Importer Identification at Entry |
| Chapter 9 | Importance of Records and Chapter 9 Exercise |
| Chapter 10 | FDA Oversight |
| | Questions and Closing Remarks, Course Evaluations/Certificates |

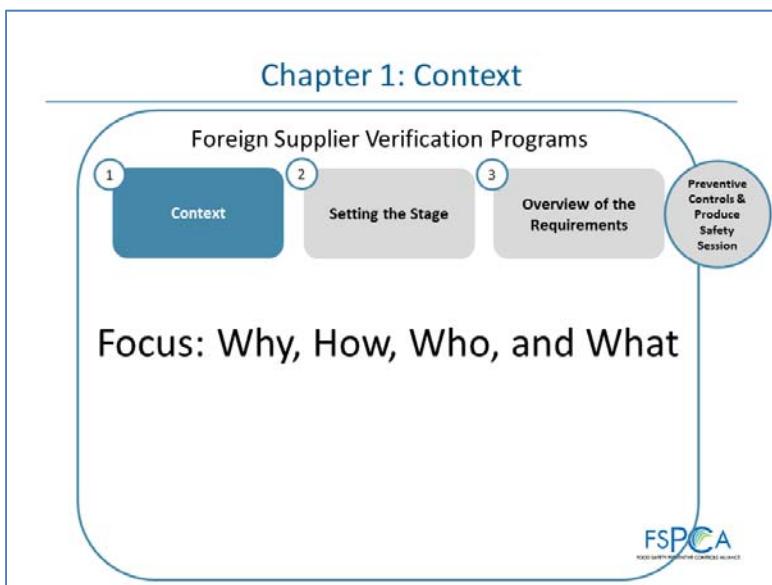
Blank Colored Insert-Front

Blank Colored Insert-Back

CHAPTER 1. Context



The FSVP rule fits into a broad food safety regulatory context, much of which existed prior to the 2011 Food Safety Modernization Act (FSMA) and the rest as a result of the new FSMA law.



Chapter 1 briefly describes that context with a focus on explaining WHY and HOW the FSVP rule came about. Additionally, it notes that food producers have always been responsible for food safety and that FDA has a long history of taking action against unsafe food and against those who cause the food to be unsafe or introduce or receive it in commerce.

This chapter also describes the purpose of the FSMA amendments to the Food, Drug, and Cosmetic Act (FD&C Act) as changing the emphasis of the food regulatory system to one of **preventing food safety problems before they occur**. The chapter also explains why these changes were needed. It will also identify some of the other FSMA requirements that are relevant to the FSVP rule. It then focuses on the important role that importers have in ensuring the safety of imported food.

Chapter 1: Goal and Objectives

Chapter 1: Goal and Objectives

Goal: Participants will be able to convey why importers' new FSVP role must be taken seriously.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Identify who is responsible for food safety.
 2. Explain the rise of the FSMA preventive food safety paradigm.
 3. Identify FSMA's new rules that pertain to you and your suppliers.
 4. Describe FDA's role in ensuring the safety of imported food.
 5. Describe your role in ensuring the safety of imported food.



Key Point:

The FSVP rule is about ensuring that imported foods meet the same level of food safety standards that are required of foods produced in the U.S. And, you, as a U.S. importer of food, have the responsibility of ensuring that your foreign suppliers are doing what they need to do in order to meet those requirements.

The goal of Chapter 1 is to convey why importers' FSVP role must be taken seriously. By the end of this chapter, you will be able to:

1. Identify who is responsible for food safety,
2. Explain the rise of the FSMA preventive food safety paradigm,
3. Identify FSMA's new rules that pertain to you and your suppliers,
4. Describe FDA's role in ensuring the safety of imported food, and
5. Describe your role in ensuring the safety of imported food.

Before We Get Started...

Before We Get Started....

- Please take a moment to look at the **Definitions and Acronyms** section in Appendix 10 at the very back of the manual.
- Although we will present the most important definitions specific to FSVP during the course, you may have need to refer to this section occasionally during the course.



Please take a moment to look at the Definitions and Acronyms section in Appendix 10 at the back of the manual. Although we will present the most important definitions specific to the FSVP rule during the course, you may need to refer to this section occasionally throughout the course.

Who Is Responsible for Food Safety?

Who Is Responsible for Food Safety?

Food Drug and Cosmetic Act (FD&C Act)

- Places primary responsibility for human and animal food safety on the food industry.
- Assigns responsibility of regulating food safety to the FDA (with the exception of meat, poultry, processed egg products, and recently catfish (Siluriformes), which are regulated by U.S. Department of Agriculture (USDA)).



The FD&C Act of 1938 placed primary responsibility for food safety on the food industry. So, the entity that produces a hazardous food (i.e., a food containing any biological, chemical, or physical agent that is reasonably likely to cause illness or injury) can be held accountable.

Also, anyone who introduces or receives an **unsafe food** in interstate commerce (including importing food into the U.S.) may also be held accountable.

The FD&C Act gives the responsibility for regulating food safety (other than meat, poultry and processed egg products regulated by the U.S. Department of Agriculture (USDA)) to FDA. FDA partners with USDA, the 50 states, and others in overseeing the food industry to help ensure the safety of food.

Traditional FDA Food Safety Responsibilities

Traditional FDA Food Safety Responsibilities

- Issuing regulations and guidance that establish food safety standards that help ensure food is safe to eat.
- Inspecting industry to ensure compliance with FDA requirements.
- Taking action to protect U.S. consumers from unsafe products, including:
 - Removing unsafe foods from the U.S. marketplace.
 - Refusing entry of unsafe foods into the U.S.
 - Pursuing regulatory actions against food companies that are not in compliance with the FD&C Act and FDA's implementing regulations.



Traditional FDA food authorities include issuing regulations and guidance that establish food safety standards that help ensure food is safe to eat, inspecting the food industry and food itself to ensure compliance with food safety standards, and taking regulatory action to protect consumers from hazardous foods. FDA has the authority to remove unsafe foods from the U.S. marketplace and to refuse entry into the U.S. of food that may be unsafe. FDA has always performed inspections of food facilities, as well as examining and testing both domestically produced and imported foods to look for contaminants and other food hazards. FSMA has provided FDA with additional tools to help protect food safety. For example, FSMA provided FDA with the legal authority to gain access to food safety records, thus enhancing FDA's ability to determine whether a food may be hazardous **or whether those responsible for the food are complying with food safety requirements.**

In addition to jurisdiction over the food itself, FDA has long had the authority to pursue enforcement actions against food companies or individuals that violate the FD&C Act and FDA's implementing regulations. FDA has exercised its authority through traditional FDA

activities. As mentioned earlier, these activities have focused on inspecting food facilities, as well as testing foods, both in the U.S. and other countries, to determine whether such facilities and foods were in compliance with U.S. laws.

Traditional FDA Food Safety Responsibilities (continued)

- The FD&C Act requires imported foods to meet the same public health requirements as foods produced in the U.S.
- FDA collects and analyzes samples of imported foods to determine whether they are in compliance with the U.S. food safety requirements.
- FDA has conducted inspections of foreign facilities and worked with food safety authorities in other countries to improve food safety.



Food manufacturers/processors/growers in other countries must produce food exported to the U.S. in a manner that will comply with U.S. food safety standards. Traditionally, FDA has enforced these standards through inspection of facilities and collecting samples of human and animal food, both in the U.S. and those offered for import, which are analyzed in FDA laboratories to determine if they contain something that could be hazardous to consumers. When problems are found, FDA takes appropriate action to ensure that consumers are protected from further exposure to potentially hazardous food.

Some facility inspections and testing of food products will still be appropriate as FDA adjusts to the FSMA prevention paradigm. FSMA provides robust and comprehensive tools to **prevent** food safety problems **before** they occur, rather than trying to identify and react to food safety hazards that have already occurred.

For example, the new human and animal food Preventive Controls rules, established as a result of FSMA, require the food industry to systematically identify food hazards needing controls and systematically control those hazards. Similarly, the Produce Safety rule provides requirements for best practices to prevent microbiological contamination of fruits and vegetables.

As noted earlier, the FSVP rule is about ensuring that imported foods meet the same level of food safety standards that are required of food produced in the U.S. And, the U.S. importer now has the responsibility of ensuring that its foreign suppliers are doing what they need to do in order to meet those requirements.

Food Safety Modernization Act (FSMA)

Food Safety Modernization Act (FSMA)

- U.S. Congress passed the FSMA law that amends the FD&C Act; the President signed it on January 4, 2011.
- FSMA builds on the food safety foundation of the FD&C Act, the main law that FDA enforces.
- FSMA contains **the most significant food safety amendments to the FD&C Act since 1938.**



The U.S. Congress passed FSMA, a law that now amends the FD&C Act, which the President signed in 2011. FSMA builds on the food safety foundation of the FD&C Act, the main law that FDA enforces and contains some of the most significant food safety amendments to the FD&C Act since 1938.

Purpose of FSMA

Purpose of FSMA

- FSMA is intended to better protect public health by:
 - Adopting a **modern, preventive, and risk-based approach** to food safety regulation, and
 - Providing FDA with additional regulatory tools (including greater access to food safety records).



Protecting the public has always been the main purpose of the FD&C Act. The FD&C Act has always prohibited the sale of human or animal food that can cause illness or death, whether the food is produced in the U.S. or imported from another country.

FSMA is intended to better protect public health by, among other things, adopting a **modern, preventive, and risk-based approach** to food safety regulation. FSMA creates new responsibilities for many parts of the food industry, including those who import human and animal food.

Why Was FSMA Needed?

Why Was FSMA Needed?

- The Centers for Disease Control and Prevention (CDC) estimates that each year, foodborne diseases cause¹:
 - 48 million Americans to get sick
 - 128,000 to be hospitalized
 - 3,000 to die
- Foodborne diseases have been caused by both domestically produced foods and imported foods.
- Many foodborne illnesses could be prevented if everyone in the global food chain was held accountable for controlling food hazards.

¹Schaffner, E., Griffin, P. M., Angulo, F. J., Tauxe, R. V., & Hoekstra, R. M. (2011). Foodborne illness Acquired in the United States—Unspecified Agents. *Emerging Infectious Diseases*, 17(1), 16-22.
<https://dx.doi.org/10.3201/eid1701.P21101>



FSMA was needed because food was causing too many illnesses that could be prevented. The U.S. Centers for Disease Control and Prevention (CDC) estimates that 48 million Americans get sick, 128,000 are hospitalized, and 3,000 die each year from the food they eat. Foodborne diseases have been caused by both domestically produced foods and imported foods. Most foodborne illnesses are caused by things that can't be seen.

FDA believes that many illnesses caused by food could be prevented if everyone in the global food chain was held accountable for performing their responsibilities to control food hazards. FSMA provisions were designed to bring everyone in the food supply chain into partnership in preventing food hazards and foodborne illness.

Why Was FSMA Needed? (continued)

- Today, human and animal food produced in one location may be shipped long distances, often to other countries.
- While FDA has for decades overseen the safety of foods in the U.S., the tools available to ensure that food is safe needed to be updated.



Foods today are commonly produced in one location and then change hands several times as they are transported to another location (often from one country to another) where they change hands again before being sold to consumers. And the ingredients and finished food itself can be contaminated, temperature abused, or mishandled at any step in this food chain causing food safety problems.

While FDA has for decades overseen the safety of foods in the U.S., the tools available to ensure that food is safe were limited. FSMA was needed to provide FDA with the modern tools needed to be sure that everyone in the food chain is doing the things they need to do to ensure that food is safe to eat.

FDA Examples of Problems with Imported Food

FDA Examples of Problems with Imported Food

| Food/origin | Problem | Date | Action |
|-------------------------------|----------------------------|------------|-------------------------|
| Cilantro from Mexico | Cyclospora | 2013-2017 | Import Alert |
| Pet food from China | Melamine | 2007 | Recall/ Import Alert |
| Papaya from Mexico | Salmonella | 2011, 2017 | Recall/ Import Alert |
| Strawberries from Egypt | Hepatitis A | 2016 | Recall/ Import Alert |
| Various food items from Japan | Radionuclide Contamination | 2011 | Import Alert |

On the slide above we have some examples of problems (in the past and currently) that FDA identified with imported food. Actions taken by FDA included import alerts and recall in some instances.

What Are the Main FSMA Themes?

What Are the Main FSMA Themes?

- FSMA amended the FD&C Act to put more emphasis on preventing food hazards by requiring that:
 - Hazards be systematically identified, and
 - Controls be systematically implemented to prevent those hazards.
- FSMA addresses the safety of human and animal food (including fresh produce and processed food) throughout the supply chain.
- FSMA provides FDA with new tools to ensure that food for U.S. consumers is safe whether it is produced in the U.S. or elsewhere.



FSMA amended the FD&C Act to put more emphasis on preventing food hazards. For example, the approach under the PC rules is to require that hazards needing control be systematically identified by producers, and then to require that controls be systematically implemented to significantly minimize or prevent those hazards from occurring. Those controls need to be monitored, and if something goes wrong, corrective actions need to be taken.

Under the Produce Safety rule, FDA does not require hazard analysis because the agency has already concluded, based on scientific data and analysis on produce hazards, that microbiological hazards are the most prominent cause of foodborne illness from raw fruits and vegetables. Therefore, the Produce Safety rule defines and requires appropriate practices to prevent such biological hazards.

FSMA addresses the safety of human and animal food from farm to fork, including fresh produce and processed food. Importantly, the same food safety requirements apply whether the food originates in the U.S. or elsewhere. Although the primary focus is on preventing unintentional contamination, FSMA also has provisions intended to prevent intentional contamination of food.

In passing FSMA, Congress recognized that new tools were needed to ensure food safety and that FDA needed access to additional information and enforcement authorities.

FSMA: Regulations and Guidance

FSMA: Regulations and Guidance

- FSMA mandates that FDA develop regulations to implement FSMA's requirements, including the Foreign Supplier Verification Programs rule.
- FDA has also been providing outreach and information to those who are required to comply with FSMA.



U.S. Congress also mandated that FDA develop a number of regulations, including the FSVP rule, to implement FSMA's new food safety requirements. Along with the implementation of the new food safety requirements, FDA is providing outreach and information to those who are required to comply with FSMA.

Rulemaking Process

Key Point:

FDA proposes rules so it can receive comments from anyone affected by the rule and others, whether they be food importers, trade groups, brokers, the general public, foreign governments, or anyone else.

In the case of the FSVP rule, FDA also published a supplemental proposal in response to comments received on the initial proposal, giving a second opportunity for public comments on portions of the proposed FSVP rule.

Rulemaking Process

- FDA publishes a proposed rule that invites public comments
- FDA responds to the issues raised by the public comments in the preamble to the final rule
- The final rule is then published in the Federal Register



<https://www.federalregister.gov/>



U.S. laws in most cases do not take effect, nor do they provide sufficient detail to be applied, until implementing regulations are written. This is done by notice and comment rulemaking, which allows the public, domestic and international industry, foreign

governments, and essentially anyone to comment on proposed rules. Congress gave FDA the responsibility for writing the rules to implement FSMA. FDA is required by law to explain how it responds to the comments it receives and it does this in the preamble of the final rule when it is published. This process enables transparency of rulemaking decisions. Also, once the final rules are published, normally a reasonable amount of time is given before the rules go into effect. For the FSVP rule, that time period was six months. It should also be noted that all the FSMA proposed rules were notified to the World Trade Organization (WTO) so that its 164 Member governments would be aware of the regulations when proposed and could comment on them.

Where more detail is required for full understanding of how regulations are supposed to work in practice, FDA usually publishes guidance documents to help the food industry understand how to comply. Although FDA guidance statements are not requirements, they, like proposed regulations, are published with an invitation for public comments.

Important Rules from FSMA

Important Rules from FSMA

- 21 CFR Part 117 – *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food* (also known as the CGMP and PC rule for human food or just PC rule for human food); published September 17, 2015
- 21 CFR Part 507 – *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals* (also known as the CGMP and PC rule for animal food or PC rule for animal food); published November 27, 2015
- 21 CFR Part 112 – *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (also known as the Produce Safety rule [PS]); published November 27, 2015



Whether you import food for humans or animals, either raw or processed food, your foreign suppliers likely will need to adhere to one of these regulations described in this or the next two slides. The Preventive Controls (PC) rules, of which there are two, one applying to human food (Part 117) and the other to animal food (Part 507), require that **facilities that manufacture, process, pack or hold food must implement preventive risk-based controls to ensure food safety**. The PC rules for human and animal food **apply to both foreign and domestic manufacturers/processors and others**.

Resources:

Information on the PC rules and the Produce Safety rule:

Brief Overview:

A brief overview of the PC rules and the Produce Safety rule will be discussed later in the course in the PCPS Session.

Additional Information:

For additional information on the Preventive Controls (PC) rules for human and animal food, refer to Appendix 6a of this manual.

For additional information on the Produce Safety rule, refer to Appendix 6b of this manual.

Courses on PC and Produce Safety rules:

Separate, multi-day standardized courses on the PC rules and the Produce Safety rule are being offered for those who want a more detailed understanding of those rules. Information and links are available in Appendix 7 of this manual.

Resources:

A copy of the Federal Register FSVP rule without the preamble can be found in Appendix 1 of this manual.

Resources:

While FDA has not published their main guidance document, it is worth mentioning that FDA has published three FSVP related guidance documents as of this printing.

- Guidance for Industry: Recognition of Acceptable Unique Facility (UFI) for the Foreign Supplier Verification Programs Regulation
<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm549623.htm>
- Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the FSVP Regulation
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm55661.htm>
- Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA
<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm524553.htm>

The Produce Safety rule (Part 112) sets requirements for good agricultural practices that **apply to foreign and domestic growers of produce, and others**.

Important Rules from FSMA (continued)

Important Rules from FSMA (continued)

- On November 27, 2015, FDA published the final FSVP rule:
 - CFR 21 Parts 1, 11, and 111 – *Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals*
- The final FSVP rule was published in the Federal Register, along with its preamble explanations and responses to public comments
- We will talk more about the purpose of the FSVP rule in Chapter 2



FSPCA
FOOD SAFETY PRACTICE CONTROL ACT

On November 27, 2015, FDA also published the final rule on Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP rule) that **requires importers to verify that their foreign suppliers are doing what is needed to comply with U.S. food safety requirements**.

21 CFR Parts 1, 11, and 111 Subpart L – Foreign Supplier Verification Programs for Food Importers

In passing FSMA, the U.S. Congress required that U.S. food importers have Foreign Supplier Verification Programs and also required that FDA issue regulations spelling out the FSVP requirements.

The November 27, 2015, Federal Register publication (80 FR) contains both the final regulation and a lengthy preamble that addresses the issues raised by the comments. **The preamble is especially useful because it explains why FDA made the decisions it made in writing the proposals and the final rule. It also provides guidance for importers in explaining how they are expected to utilize the regulation's provisions in practice.** While FDA has not published their main guidance document, as of this printing, it is worth mentioning that FDA has published three FSVP related guidance documents (see the links to the right). The preamble and the guidance documents will be referred to frequently as we go through this course.

FSMA Affects the Food Supply Chain

FSMA Affects the Food Supply Chain

1. Foreign and domestic manufacturers or processors, packers, and holders of foods now must:
 - Assess hazards
 - Implement preventive controls
2. Foreign and domestic growers of fresh produce must:
 - Comply with Produce Safety requirements
3. U.S. food importers must:
 - Ensure that their foreign food suppliers are sending foods to the U.S. that meet the same level of U.S. food safety standards



Under the new rules, FSMA affects the food supply chain. Both foreign and domestic manufacturers/processors, packers, and holders of foods now must analyze whether "**known or reasonably foreseeable**" **hazards** require a preventive control; and if so, implement preventive controls to control those hazards.

Foreign and domestic growers of fresh produce also now need to comply with the new Produce Safety requirements. In addition, truck and rail transporters of food (generally those within the U.S.) will need to comply with FDA's new sanitary transportation requirements.

Most importantly for you as U.S. food importers, you need to develop and implement an FSVP to ensure that your foreign food suppliers are doing what they need to do to prevent hazardous foods from being exported to the U.S.

FSMA Creates New Role for Importers of Food

FSMA Creates New Role for Importers of Food

- You, as a U.S. importer of foods, play a key role in ensuring that your foreign suppliers are:
 - Providing the first line of defense in preventing food hazards.
- We will talk about the definition of an “FSVP Importer” in Chapter 2 and will be discussing the role in-depth throughout the rest of the course.



One of the major things FSMA does is define a new food safety role for food importers. In particular, you, as a U.S. importer of food, now need to verify that your foreign suppliers of human and animal food are meeting their obligation to produce food that meets the level of U.S. public health protection.

Resources:

FDA's Technical Assistance Network (TAN) is available to answer regulatory or rule interpretation questions.

TAN can be accessed at:

<http://www.fda.gov/fsma>

The FSPCA TAN is available to answer scientific/technical questions about the rule.

The FSPCA TAN can be accessed at:

<https://www.ifsh.iit.edu/fspca/fspca-technical-assistance-network>

More information about these and other resources are available in Appendix 7.

FSMA Implementation

FSMA Implementation

- In addition to publishing new regulations to implement FSMA, FDA will:
 - Help to educate those who must comply,
 - Provide technical assistance/rule interpretation by answering questions, and
 - Monitor food industry and importer compliance.
- Although the rules will be phased in, FDA will continue to take action to protect U.S. consumers from unsafe food.



As previously noted, FDA has already published the main FSMA rules. FDA has also published some guidance and plans to publish additional guidance to help those who need to comply with the new

requirements. FDA recognizes that it must do more, however, so FDA is also:

1. Helping to educate those who must comply with the rules,
2. Providing technical assistance/rule interpretation by answering questions, and
3. Monitoring food industry and importer compliance.

It needs to be emphasized, however, that, although the rule will be phased in, FDA will continue to take action to protect U.S. consumers from unsafe food.

Other FSMA Authorities

Other FSMA Authorities

- FDA authority to mandate a food recall
- FDA authority to access records
- Domestic and foreign food facilities required to renew FDA registration every two years
- FDA can suspend a facility's registration if reasonable probability that food presents serious health hazard
- FDA can require certification of food or a food facility when certain statutory criteria are met related to the risk of the food



Along with the new rules mentioned earlier and new role for importers, FSMA added other authorities to the FD&C Act that may be of interest to you. For instance, FSMA authorizes FDA to mandate the recall of hazardous foods from the U.S. marketplace. This is an authority that FDA did not previously have, although food companies usually cooperated with FDA in implementing a recall when either they or FDA discovered a food safety problem.

As will be discussed in later chapters, FDA now has authority to access records. Records are very important to the success of your FSVP program and will be the basis for FDA oversight of importer compliance.

FSMA now requires food facilities that are required to register with FDA renew their registrations every two years. This means that FDA will have current information about who is in the food business. Farms that do not process foods have never had to register with FDA and still do not. FSMA also authorizes FDA to suspend the registration

of either a foreign or domestic food facility if FDA determines the food presents a reasonable probability of causing serious adverse health consequences. If a facility's registration is suspended, they cannot ship food and you, as the importer, cannot import it.

Additionally, under FSMA, now FDA has authority to require certification of food or food facility when certain statutory criteria are met related to the risk of the food. **There is no general requirement for certification as a condition of entry into the U.S.** FDA expects to use this tool in limited circumstances when it is the most effective and efficient way to deal with a food safety problem. Moreover, FDA may refuse entry into the U.S. from a foreign facility if FDA is not permitted to inspect the facility.

Resources:

FDA's Technical Assistance Network (TAN) is available to answer regulatory or rule interpretation questions. TAN can be accessed at:

<http://www.fda.gov/fsma>

The FSPCA TAN is available to answer scientific/technical questions about the rule. The FSPCA TAN can be accessed at:
<https://www.ifsh.iit.edu/fspca/fspca-technical-assistance-network>

More information about these and other resources are available in Appendix 7.

Chapter 1: Summary

Chapter 1: Summary

- FSMA was enacted to:
 - Change regulatory focus to preventing hazards instead of detecting problems.
 - Add tools available to FDA to ensure safe food, no matter where it was produced.
- FDA has had authority since 1938 to take action against hazardous foods and the companies that violate the FD&C Act when a violation has been detected.
- The FSMA amendments to the FD&C Act require:
 - More emphasis on food safety from everyone in the food chain from farm to fork.
- FSVP importers have:
 - New responsibilities for ensuring the safety of imported food.



In this chapter, we have covered:

- FSMA's purpose to prevent food safety problems and improve the safety of human and animal food sold in the U.S., no matter where the food was produced.
- FDA's authority since 1938 to take action against hazardous foods and the companies that violate the FD&C Act.

We have also covered:

- FSMA's extensive amendments to the FD&C Act that require increased food safety accountability within the food supply chain.
- The new responsibilities for importers in ensuring the safety of imported food.

Chapter 1: Questions

Chapter 1: Questions

Thank you for your attention!

Questions?

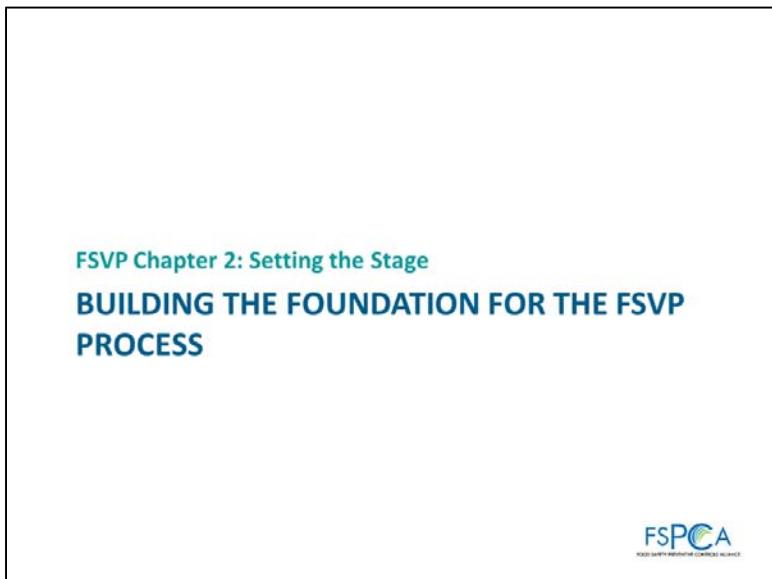


Notes:

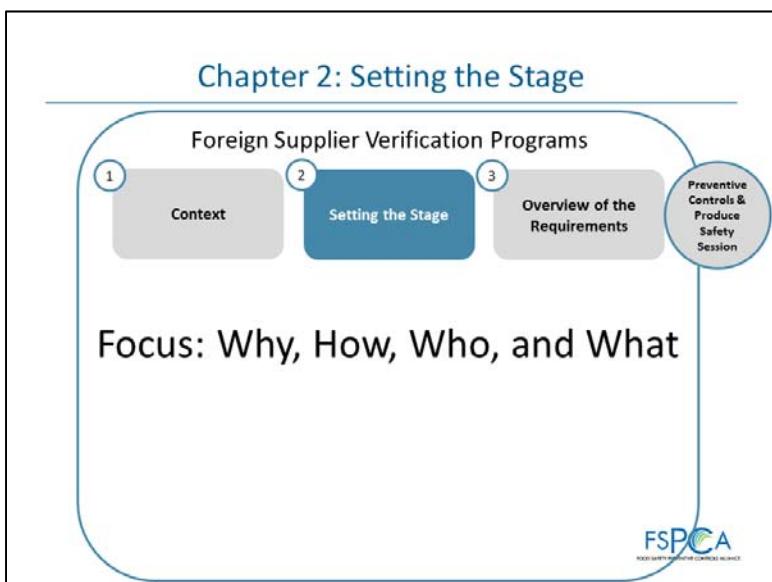
Blank Colored Insert-Front

Blank Colored Insert-Back

CHAPTER 2. Setting the Stage



Chapter 2 lays the foundation for the rest of the course by identifying the purpose of the FSVP rule and by defining key terms that are critical to proper implementation of the FSVP rule. The topics introduced in this chapter will be discussed in greater detail as the course progresses.



Chapter 2 focuses on the "WHO" of your FSVP. Most important is FDA's definition of "importer" as specifically defined in the FSVP rule. This definition differs from other definitions of "importer" in other regulations and needs to be understood. Each of the definitions in this

chapter are very important to understanding the rest of the FSVP course.

Chapter 2: Goal and Objectives

Chapter 2: Goal and Objectives

Goal: Participants will be able to explain the building blocks for creating an FSVP.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Articulate the key principles of the FSVP rule.
 2. Explain the purposes of FSVPs.
 3. Define FSVP importer.
 4. Determine which entity will be the FSVP importer.
 5. Differentiate between Importer of Record (IOR) and “FSVP importer.”
 6. Define FSVP foreign supplier.
 7. Define FSVP qualified individual.
 8. Discuss the scope of FDA’s definition of food.



This chapter outlines the key principles of the FSVP rule, identifies the purpose of FSVPs, and explains key definitions, and why they are important to you as you decide how to implement FSVP. For example, in defining the FSVP “importer”, this chapter also explains the difference between the FSVP “importer” and the “importer of record.” It also makes it clear that FDA will hold the FSVP “importer” accountable for complying with the FSVP rule.

This chapter will also define “foreign supplier” and your “qualified individual” under the FSVP rule. In addition, it will discuss the scope of the FD&C Act definition of “food.”

Each of these definitions will be important to remember as we discuss requirements in the rest of the course.

Finally, the chapter will help you in determining the appropriate FSVP importer in a variety of scenarios.

Purpose of the FSVP Rule

Purpose of the FSVP Rule

- To ensure that imported foods meet the same level of food safety standards that are required of food produced in the U.S.
- The U.S. importer now has a responsibility of verifying that its foreign suppliers are doing what they need to do to meet those requirements.



Key Point:

Americans consume a large amount of imported food. Imported food accounts for about 19 percent of the U.S. food supply, including about 52 percent of the fresh fruits and 22 percent of the fresh vegetables consumed by Americans (USDA Economic Research Service, 2013 statistics).

Before we discuss what an FSVP is and the purpose of FSVPs, it is important to stop for a moment to consider the overarching purpose and key principles of the FSVP rule. Recognizing that producers of food for the U.S. market and importers of that food were always expected to supply food that complies with U.S. food safety requirements, the FSVP rule sets forth requirements for importers to verify that U.S. food safety standards are being met. The rule gives importers a critical role in ensuring food safety and defines importers who must fulfill these obligations in a very specific way, including that they must reside in the U.S. But we will say more about this in the next few chapters.

Key Principles of FSVP Rule

Key Principles of FSVP Rule

- Importers share responsibility with foreign suppliers to ensure safety of food imported into the U.S.
- FSVP requirements are risk-based (according to types of food, types of hazards, and supplier performance).
- Importers have flexibility in how they meet requirements.



Whereas FDA has always recognized that all parties engaged in the production and handling of food have responsibility for ensuring/maintaining its safety, the FSVP rule now requires that importers covered by the rule must have in place a program to verify that their foreign suppliers are producing food in a manner that provides the same level of public health protection as the Preventive Controls (PC) or Produce Safety regulations, as appropriate. Importers also must ensure that the supplier's food is not adulterated under the FD&C Act, nor misbranded with respect to allergen labeling for human food. Allergen labeling is not required for animal food.

The number one principle of the FSVP rule is that food importers must now share responsibility for ensuring the safety of imported food. This means that U.S. importers of food must verify that their foreign suppliers are meeting the same food safety requirements that U.S. suppliers of food are required to meet.

What Is an FSVP?

What Is an FSVP?

Your FSVP = All records and documentation that demonstrate your compliance with applicable FSVP requirements for a particular imported food product/foreign supplier



A Foreign Supplier Verification Program does not have a set format. The FSVP rule sets forth requirements that must be met, but it may be the case that only a few or many requirements pertain to your particular food/foreign supplier circumstances. What you do in implementing the FSVP requirements constitutes your program. How you document what you do is what FDA will see in assessing your compliance with the FSVP rule. Therefore, records are very important. The cumulative records demonstrating implementation of FSVP requirements are your FSVP.

Purpose of FSVPs

Purpose of FSVPs

- FSVPs are intended to provide adequate assurances that:
 - Foreign suppliers produce food using processes and procedures that provide the same level of public health protection as the FSMA Preventive Controls or Produce Safety requirements.
 - Food is not adulterated under the FD&C Act or misbranded due to undeclared allergens (*allergens for human food only*).



This slide shows the main purpose of the FSVP requirements. Similar to all FSMA provisions, FSVP is about minimizing the risk of U.S. consumers contracting a serious foodborne illness or encountering other food safety problems from imported food.

Resources:

See the 21 CFR Part 1, Subpart L, 1.500 Definitions for FSVP “importer” and “U.S. owner or consignee.” Definitions are also in the Definitions and Acronyms in Appendix 10.

Who Is an “Importer” Under FSVP Rule?

Who Is an “Importer” Under FSVP Rule?

- **Definition:** “**Importer** means the U.S. owner or consignee of an article of food that is being offered for import into the United States...” [21 CFR Part 1, Subpart L, 1.500 Definitions]
 - Note that the term “**U.S. owner or consignee**” is also defined separately in the FSVP rule as “**the person in the United States who, at the time of the U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.**”



The definition of an “importer” is specific to the FSVP regulation (21 CFR 1.500). The first phrase of the definition says that the importer is the U.S. owner or consignee. Note that the terms “**U.S. owner or consignee**” are also defined in the rule as “**the person in the United States who, at the time of U.S. entry, either owns the food, has**

purchased the food, or has agreed in writing to purchase the food." The FSVP importer has to be identified at entry on the entry filing.

Who Is an "Importer" Under FSVP Rule? (continued)

- "...If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart." [21 CFR Part 1, Subpart L, 1.500 Definitions]



The definition also states that if there is no owner or consignee in the U.S., the foreign owner or consignee may designate a U.S. agent or representative to carry out the FSVP responsibilities. The rule requires that the U.S. agent or representative sign a statement of consent to serve as the FSVP importer. The rule does not require such a signed consent from the U.S. owner or consignee to serve as the FSVP importer. It is important, however, that **whoever is handling the U.S. Customs entry filing understands that the person identified as the FSVP "importer" is the person FDA will see as responsible for complying with the FSVP rule.**

Key Point:

Note that the definition of importer in the FSVP rule is different from other definitions that an importer may be used to, such as the "importer of record." The FSVP importer could be, but isn't necessarily, the "importer of record" for purposes of submitting entry with U.S. Customs and Border Protection (CBP). That person, who might be a customs broker or filer, might not always be a person with a financial interest in the food or have the knowledge and ability to conduct supplier verification.

Key Point:

Note that throughout the course, when the FSVP importer is referred to as a "person," it means an individual, a company, or other entity.

Key Points:

The Role of Communication

Communication about who should be identified as the U.S. importer for purposes of FSVP compliance among the parties involved in importing the food is very important. Adequate communications with the foreign suppliers of the food is also important.

Additional Responsibilities/Benefits:

Although you will have additional responsibilities as an FSVP importer, you will also receive many benefits, such as gaining insight into the supply chain and ensuring your standards are upheld.

Resources:

To help identify who should be the FSVP importer, we have provided Workaid A: "Determining the FSVP Importer" in Appendix 3. This workaid is intended to help a person/entity, who receives/sells imported food, ensure that an appropriate FSVP importer has been designated by parties involved in the importation of the food, AND that the U.S. Customs' filer enters that name, address, and DUNs number as the FSVP importer.

Determining Who Will Be the FSVP Importer

Determining Who Will Be the FSVP Importer

- Often, more than one entity will meet the FDA definition of "importer" for FSVP purposes.
 - The FSVP "importer" must be someone in the U.S. and meet the definition of FSVP importer.
- Entities that meet the definition of FSVP "importer" will need to decide among themselves:
 - Who will agree to be identified as the FSVP importer for a particular food/foreign supplier, and
 - Thus, be responsible for carrying out FSVP obligations.



Determining who will serve as the FSVP importer is a fundamental FSVP responsibility and a first step in the FSVP process. Persons/entities may wish to make arrangements to ensure that there will be no unknowns, mistakes, or fraudulent entry of an FSVP importer's identity on the CBP entry filing. This clarity is important for both fulfilling the entry requirements, as well as assuring that FSVP requirements have been implemented by the FSVP importer.

With regard to U.S. agents and representatives serving as FSVP importers on behalf of the foreign owners and consignees, FDA has stated that the parties they are representing need to ensure these agents "have or can obtain the information and capability needed to meet their obligations as importers subject to the FSVP regulation." It should be emphasized that the FSVP agent of a foreign owner or consignee is different from the agent for purposes of foreign food facility registration.

FSVP Importer vs. Importer of Record

FSVP Importer vs. Importer of Record

- A key difference between the FSVP “importer” as defined by FDA in the FSVP rule, and the “importer of record” (IOR) as defined by U.S. Customs and Border Protection (CBP) is that:
 - **The FSVP “importer” must be someone in the U.S.**
- If the IOR is located in the U.S., that importer can also be the FSVP importer (assuming that the IOR otherwise meets the FSVP importer definition).
- **The person/entity that is the FSVP importer is the person who FDA will hold accountable if FSVP requirements are not met.**



The FSVP “importer” definition from FDA is not the same as the definition of “importer of record” (IOR) under CBP rules. **The key difference is that the FSVP “importer” must be someone in the U.S. The FSVP importer can be, but doesn’t have to be the IOR.**

The preamble to the FSVP rule acknowledges that there are many different existing arrangements for importing food into the United States and that there may be more than one entity that could fall under the FSVP “importer” definition. Nevertheless, the rule expects that those entities, along with the foreign supplier of the food, and the other various parties engaged in the processes and transactions to import the food will sort out who should take responsibility for meeting the new FSVP requirements for that specific food and agree to identify that entity on the CBP entry filing. Further, the rule provides the flexibility for figuring this out.

The rule anticipates that discussions and negotiations among several parties may precede a decision on who will take on this new FSVP responsibility. Always remember that this party is the one that FDA will hold accountable for meeting the FSVP requirements. Also, remember that this decision-making/negotiation process must take place long **before** a food shipment is ready to be imported.

FSVP Importer Examples

FSVP Importer Examples

1. A U.S. company buys salsa products from various foreign suppliers, arranges for their shipment to the U.S., and then off-sells the salsa products to small retailers. Because this U.S. company is the owner or consignee of the salsa when it arrives in the U.S., it is the FSVP importer.
2. A U.S. salsa processor signs a contract and submits purchases orders to a foreign salsa ingredient supplier for the ingredients to be used in its salsa making facility, but relies on a foreign export company to make the arrangements for transportation and entry into the U.S. Also, this salsa processor doesn't pay for the salsa ingredients until they are delivered. Because the U.S. processor has agreed in writing to purchase the ingredients, it meets the FSVP definition of "importer."



1. A U.S. company buys salsa products from various foreign suppliers, arranges for their shipment to the U.S., and then off-sells the salsa products to small retailers. Because this U.S. company is the owner or consignee of the salsa when it arrives in the U.S., it is the FSVP importer.
2. A U.S. salsa processor signs a contract and submits purchase orders to a foreign salsa ingredient supplier for the ingredients to be used in its salsa making facility, but relies on a foreign export company to make the arrangements for transportation and entry into the U.S. Also, this salsa processor doesn't pay for the salsa ingredients until they are delivered. Because the U.S. processor has agreed in writing to purchase the ingredients, it meets the FSVP definition of "importer."

FSVP Importer Examples (continued)

3. A Canadian company ships a food product to a Montana warehouse in anticipation of possible orders from customers in the U.S. There is no person in the U.S. that owns or has agreed to purchase the food, as it is still owned by the Canadian firm. The FSVP “importer” would have to be a properly designated U.S. agent or representative of the Canadian company.
4. A U.S. retailer contracts with a foreign manufacturer to produce products that have the retailer’s name. The retailer actually purchases the products from a U.S. firm after the products have entered the U.S. If the other firm owns the product when offered for entry, they are the FSVP “importer.” If the retailer has agreed in writing to purchase the food at the time of entry, the retailer could also be the FSVP “importer.”



3. A Canadian company ships a food product to a Montana warehouse in anticipation of possible orders from customers in the U.S. There is no person in the U.S. that owns or has agreed to purchase the food, as it is still owned by the Canadian firm. The FSVP “importer” would have to be a properly designated U.S. agent or representative of the Canadian company.
4. A U.S. retailer contracts with a foreign manufacturer to produce products that have the retailer’s name. The retailer actually purchases the products from a U.S. firm after the products have entered the U.S. If the other firm owns the product when offered for entry, they are the FSVP “importer.” If the retailer has agreed in writing to purchase the food at the time of entry, the retailer could **also** be the FSVP “importer.”

Key Point:

You, as an FSVP importer, should have early discussions with your suppliers to ensure that the appropriate information is available to you throughout the entire supply chain.

Key Point:

"The term '*de minimis*' means insignificant. In this context, the term is referring to labeling or other activities that wouldn't cause the food to become hazardous or unsafe.

Who Is a "Foreign Supplier"?

Who Is a "Foreign Supplier"?

- **Definition:** "*Foreign Supplier* means, for an article of food, the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a *de minimis* nature."



Note that your foreign supplier may not be the person/business from whom you directly receive product. FDA defined the foreign supplier as the persons/businesses that have the most to do with the safety of the product that is produced or manufactured. The FSVP rule anticipates that there will be a connection between you and the "foreign supplier," whether direct or indirect, whereby the FSVP importer can assess the safety of the food and the foreign supplier and verify that the foreign supplier's practices are producing a food as safe as food produced by a U.S. supplier. The necessary connection between importers and their foreign suppliers will be discussed in detail later in the course.

The FSVP rule is written to incorporate sufficient flexibility to accommodate a variety of importing arrangements, but the basic concept is that the FSVP importer can effectively assess and verify the safety of each imported food.

In the preamble to the FSVP final rule, FDA states, "[w]hen foods are obtained from entities such as brokers, distributors, warehouses, and consolidators, rather than the entity that manufactured/processed, raised, or harvested the food, it could be difficult for the importer to know the identity of the producer (e.g., because the consolidator might refuse to reveal this information due to concern that the importer might decide to buy directly from the producer in the future)." FDA goes on to explain that for these reasons, the rule allows an importer to obtain information needed to meet certain FSVP requirements from other entities, such as the distributor of a processed food or the consolidator of produce. FDA then states, "This will reduce the need for importers to directly verify the compliance of producers from which the importers did not directly purchase the

imported food." A later chapter will discuss how to work with brokers/distributors to obtain information to fulfill your FSVP rule obligations, e.g., you can rely on work done by another entity if you review/assess and document that review.

Who Is a Qualified Individual?

Who Is a "Qualified Individual"?

- Food importers are required to do a number of things that can only be done by persons who meet the definition of "*qualified individual*."
- **Definition:** An FSVP "*qualified individual*" is "a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required" by the FSVP rule, "and can read and understand the language of any records that the person must review in performing this activity... ."



Because your FSVP is based on determining the known or reasonably foreseeable hazards in the foods you import and evaluating the risks posed by the food and your foreign supplier's performance, these activities, and others, must be conducted by someone who has the knowledge and expertise to perform them properly. Under the FSVP rule, you as an importer must use one or more "qualified individuals" to carry out all the FSVP requirements. For instance, you may use one person for conducting your hazard analysis and another person to perform your verification activities (each of these tasks is the subject of a dedicated chapter).

Under the FSVP rule, a qualified individual is a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required by the FSVP rule. A qualified individual must also be able to read and understand any records that must be reviewed in performing the activity (21 CFR 1.503(a)). The FSVP task to be accomplished determines what qualifications the qualified individual must have. Thus, the definition is simply stating that whoever is carrying out an FSVP activity should be someone qualified to do it.

Key Point:

The term "qualified individual" as used throughout the FSVP course is **ALWAYS** the FSVP definition, unless otherwise indicated (see Appendix 10: Definitions and Acronyms).

The qualified individual or QI definition in the FSVP rule states that a QI must have the education, training, or experience to carry out the tasks for which he/she is responsible. FSVP qualified individuals are not required to receive training under a standardized curriculum or equivalent training.

Additionally, the importer may use different qualified individuals to perform different tasks.

Required Tasks Must Be Done by a Qualified Individual

Required Tasks Must Be Done by a Qualified Individual

- Different FSVP tasks may require different qualified individuals.
- Some qualified individuals may be qualified for more than one task, e.g. hazard analysis, determining verification activities.
- Qualified individuals may be, but are not required to be, employees of the importer.
- Qualified auditors are qualified individuals for conducting audits (audits are an example of a verification activity).



The persons you use as qualified individuals can be employees of your company, but it is not necessary that they be employees.

Under the FSVP rule, a “qualified auditor” is also a qualified individual for that assigned activity and, thus, must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function (21 CFR 1.503(b)).

In the preamble to the FSVP rule, FDA states that “the importer of a food, not a foreign government or any other entity, is responsible for determining whether a person who is to conduct FSVP activities has the education, training, and/or experience necessary to conduct those activities in accordance [with] 1.503(a) of the final rule. The FSVP regulations do not require that a qualified auditor or qualified individual be accredited under any accreditation scheme or system,”

In the preamble, FDA also says that “...draft guidance on FSVPs will provide recommendations on the type of training that qualified individuals should have including, for persons who assess foreign suppliers’ preventive controls.... The draft guidance also will provide recommendations for training for individuals who will be conducting verification activities regarding suppliers of food that is subject to the produce safety regulations or other FDA food safety regulations.” FDA may also provide further guidance about the level of performance and responsibility of qualified individuals.

How Is “Food” Defined?

How Is “Food” Defined?

- **Definition:** “Food” is anything that is consumed as food or drink by humans or animals, including:
 - Ingredients in food and beverages,
 - Food additives and color additives put in food during processing,
 - Dietary supplements, and
 - Packaging and other food contact substances.



Resources:

The definition of food comes from the FD&C Act. Refer participants to Appendix 10 for more information.

Key Point:

Food contact substances include packaging, ceramicware, flatware, utensils, and plates.

FDA has provided a 2-year extension for importers of food contact substances to comply with the FSVP rule.

See FDA Guidance regarding the extension:

<https://www.fda.gov/food/guidanceregulation/fsma/ucm517545.htm>

The definition of food for the purposes of FSVP is the same as its definition in the FD&C Act. The term “food” means “(1) articles used for food or drink for humans or animals, (2) chewing gum, and (3) articles used for components of any such article” (Section 201(f), FD&C Act). The components of food include ingredients such as sugar, flour, and spices.

Food and color additives that are used in manufacturing food are also considered food. FDA regulations defining the safe conditions of use for food and color additives can be found in the U.S. Code of Federal Regulations (CFR).

The definition of food also includes food contact substances (see 80 *Federal Register*, 74233). Food contact substances, such as food packaging that contacts food, are regulated as a type of food additive because some of the materials used in making them migrate into food.

How Is “Food” Defined? (continued)

- Most food is regulated in the U.S. by FDA, except:
 - Most (not all) meat, poultry, certain processed egg products, or catfish (*Siluriformes* spp.), regulated by the U.S. Department of Agriculture (USDA).
- The requirements discussed in this course apply to human and animal food regulated by FDA.



Note that the U.S. Department of Agriculture (USDA) regulates most meat and poultry products, as defined in the U.S. Federal Meat Inspection Act (of 1906) and Poultry Products Inspection Act (of 1957), as well as certain egg products as regulated under the Egg Products Inspection Act (jointly administered by USDA and FDA (Department of Health and Human Services). USDA also regulates catfish (*Siluriformes* spp.) The food products regulated by USDA are not covered in this course and are NOT subject to FSVP or the other FSMA rules. If you import meat, poultry, or certain processed egg products, that do not fall under USDA's jurisdiction, you likely are already aware of the types of animal protein that are covered under the FD&C Act, e.g., venison or rabbit.

As we go through the course, you will learn that some FDA regulated foods are exempt from FSVP requirements. In addition, you will learn in Chapter 3 about modified requirements for very small importers or importers of food from certain small foreign suppliers.

Although dietary supplements are often regulated as drugs or as a special regulatory category in other countries, in the U.S., they are regulated as food and are covered by the FSVP rule. The FSVP requirements for dietary supplements differ, however, from the standard FSVP requirements. The modified FSVP requirements for dietary supplements are included in Appendix 4.

Chapter 2: Summary

Chapter 2: Summary

- Key definitions for FSVP “importer,” “foreign supplier,” “qualified individual,” and “food.”
- The **FSVP importer** must be determined by persons involved in importing the food and must carry out the requirements contained in the FSVP rule.
- FSVP tasks must be carried out by qualified individuals.



You have learned the key FSVP definitions, and know that the definition of FSVP “importer” differs from other definitions of “importer.” You have also learned that the definition of “food” basically includes anything consumed as food or drink by humans or animals.

You know that the FSVP importer is responsible for complying with all FSVP requirements. You also know that you need one or more qualified individuals to help you meet FSVP requirements.

The definitions for all these terms can be found in the Definitions and Acronyms in Appendix 10 of this manual.

Chapter 2 Exercise: “Who Is the FSVP Importer?”

Chapter 2 Exercise: “Who Is the FSVP Importer?”

- **Timing:** 45 minutes total
 - 10-15 minutes working in table groups
 - 30-35 minutes reporting out and discussing
- **Directions:** Read the scenarios and determine:
 - Scenarios #1-4: “Who Is the FSVP Importer?”
 - Scenarios #5a-5e: “Who Is the FSVP importer?” and “Who Is the Foreign Supplier?”

Note: All company names and products are fictitious for the purpose of this exercise.



This exercise provides some scenarios that allow participants to focus on the issue of who will be the FSVP importer. The exercise will provide clarity on this important point before moving further into the FSVP provisions. If desired, you can enter your answers to the questions in the Exercise Workbook (see Chapter 2, page 3).

Notes:

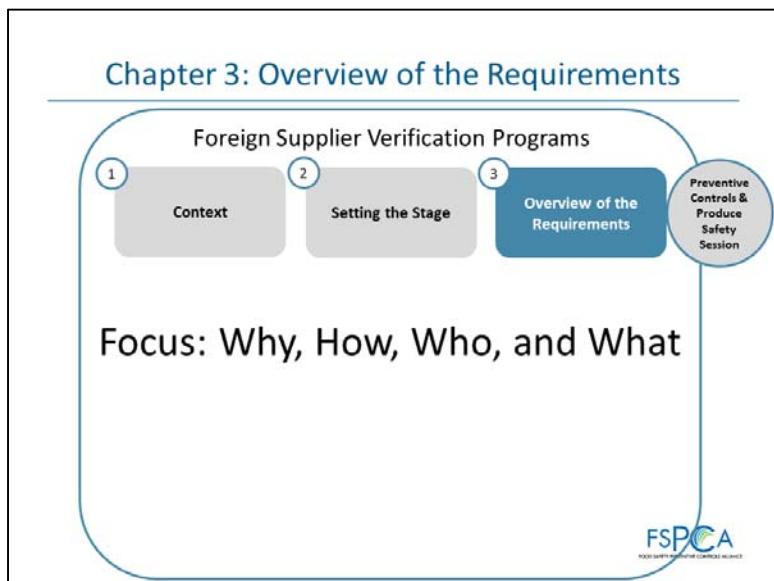
Blank Colored Insert-Front

Blank Colored Insert-Back

CHAPTER 3. Overview of the Requirements



First, it's important to understand that FDA wrote the FSVP rule in a way to be sufficiently general and flexible to apply to a variety of circumstances without being unduly burdensome or restrictive of trade. It was FDA's intention to allow flexibility to reflect modern food supply and distribution chains.



Chapter 3 is the last of the three introductory chapters that identify WHY, HOW, WHO, and WHAT of FSVP. Chapter 3 focuses on the

“WHAT,” i.e., identifying the standard and modified requirements of the FSVP rule.

This chapter begins by identifying the types of foods that come under the FSVP rule and the types that are exempt or partially exempt. Importers will see that they will need an FSVP for most foods.

Following foods subject to FSVP, this chapter provides an overview of the “standard” FSVP requirements. Later chapters will go into greater detail on some of the more critical FSVP requirements.

This chapter also contains a short overview on the “modified” requirements that apply to dietary supplements, food from “very small importers,” food from “certain small foreign suppliers,” or food from countries that FDA recognizes as having comparable food safety systems for certain foods, under Systems Recognition.

The chapter then presents an algorithm in the form of questions and answers that will reinforce your understanding of FSVP applicability and exemptions. It will also help you decide whether you need an FSVP for the food you import.

While not specifically covered in this course, note that importers of dietary supplements and dietary supplement components are NOT EXEMPT from FSVP requirements. The FSVP rule goes into some detail on how importers of dietary supplements should deal with their foreign suppliers, relative to dietary supplement ingredients, components, and finished products. **The differences in FSVP requirements for dietary supplements and dietary supplement components are explained in Appendix 4 of this manual.**

Chapter 3: Goal and Objectives

Chapter 3: Goal and Objectives

Goal: Participants will be able to demonstrate knowledge of FSVP requirements.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Determine if FSVP applies to their situation.
 2. Describe the FSVP exemptions.
 3. Identify the standard requirements.
 4. Determine if any modified requirements apply to them.
 5. Characterize the importance of communication within the supply chain.



Chapter 3 will help you understand what types of foods the FSVP rule applies to, and what types of foods are exempt. It will also describe:

1. If FSVP applies to a particular situation,
2. The exemptions to FSVP,
3. The “standard” FSVP requirements,
4. If any modified requirements apply to you, and
5. The importance of communication within the supply chain.

Chapter 2 has already covered the definition of the FSVP importer (contained in 21 CFR 1.500), that the importer is expected to implement the requirements of the FSVP rule, and that FDA will have the names of the FSVP importers from U.S. Customs and Border Protection (CBP) entry filing. FDA oversight of the FSVP rule will be directed at the FSVP importers. Note that unlike U.S. owners and consignees, the **U.S.-based agents and representatives** of foreign owners or consignees that serve as the FSVP importer are required to sign a statement of consent to serve in this role. FDA is expected to provide further guidance about the signed statement of consent to serve as the importer.

When multiple U.S. entities meet the definition of importer under the FSVP rule, it is advisable for those involved with importing the food to agree on who will perform the functions of the FSVP importer.

Before We Get Started...

Before We Get Started...

U.S. Level of Public Health Protection

- Your FSVP must ensure that your foreign supplier is:
 - Producing food using processes and procedures that provide at least the same level of public health protection as required under the risk-based preventive controls requirements in 21 CFR part 117 or part 507 or produce safety regulation, if applicable; **AND**
 - Producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (regarding labeling human food for the presence of major food allergens) of the FD&C Act.



Key Point:

The Preventive Controls (PC) rules (human and animal food) and the Produce Safety rule apply to both domestically produced and imported foods. Consequently, food importers need to have some understanding of those rules, which is why we are presenting background information on these rules in this FSVP course.

(Reference: Part 117 PC rule for human food, Part 507 PC rule for animal food, and Part 112 Produce Safety rule)

FSMA clearly states that the standard of public health protection for food imported into the U.S. is the same as the level of public health protection required under the preventive controls and produce safety requirements enforced by FDA. It is important, therefore, that you develop an FSVP that provides assurance that your foreign supplier is

Resources:

Both Sections 402 and 403(w) of the FD&C Act are included in Appendix 8 of your FSVP course manual.

Resources:

"Am I Subject to FSVP?" Flowchart is available in Appendix 7 of this manual. It can also be downloaded from FDA website at
<http://www.fda.gov/downloads/food/guidanceregulation/fsma/ucm472461.pdf>

producing food that provides at least the same level of public health protection as required under the risk-based preventive controls requirements of the Preventive Controls (PC) rules or the Produce Safety rule, if either is applicable (21 CFR 1.502(a)). Nevertheless, it is important to understand as an importer that—even if the food you import is exempted from FSVP—the food is still required to meet U.S. food safety standards.

Your foreign supplier also must produce the food in compliance with sections 402 (regarding adulteration) and 403(w) (regarding labeling human food for the presence of major food allergens) of the FD&C Act (21 CFR 1.502(a)). These refer to public health provisions that were in existence long before FSMA was passed.

As noted earlier, both sections 402 and 403(w) of the FD&C Act, in their entirety, are included in the appendix to your FSVP course manual. Chapter 4 will elaborate on why sections 402 and 403(w) of the FD&C Act are important.

Does FSVP Apply to My Situation?

Does FSVP Apply to My Situation?

- The FSVP regulation applies to **all** human and animal food offered for import into the U.S., unless exempted.
- In other words, whether or not the FSVP regulation applies to your situation is based on the human and/or animal food you import.
 - If the food(s) you import **IS(ARE) NOT EXEMPTED**, **FSVP DOES apply**.
 - If the food(s) you import **IS(ARE) EXEMPTED**, **FSVP DOES NOT apply**.
- **Most food(s) will require an FSVP.**



The FSVP regulations apply to all human and animal food offered for import into the U.S. unless the food has been exempted (21 CFR 1.501). In the upcoming slides, we will cover some of these exemptions. Importers should note that MOST foods will require an FSVP.

Exempted Foods (Foods Not Covered By FSVP)

Exempted Foods (Foods Not Covered By FSVP)

- Foods under FDA Hazard Analysis and Critical Control Points (HACCP) rules
- Alcoholic beverages (certain conditions)
- Foods not intended for sale or distribution in the U.S. and foods intended for personal use:
 - Food for research or evaluation (subject to certain requirements)
 - Food that is imported for processing and future export (no distribution in the U.S.)
 - Food for personal consumption
- Certain meat, poultry, processed egg products (products subject to Federal Meat Inspection, Poultry Products Inspection, and Egg Products Inspection Acts), and *Siluriformes* spp. fish, including catfish
- Food manufactured/processed, raised, or grown in U.S., then exported and returned without further manufacturing/processing in a foreign country



Several types of food are exempted as noted on the slide. We will cover each exemption in more detail in the following slides/text.

Foods Under FDA HACCP Rules

Foods Under FDA HACCP Rules

- Foods complying with **FDA HACCP** rules for **juice** and **seafood** are exempt from FSVP.
- Importers of **raw materials and ingredients for the manufacture of juice or seafood that are subject to HACCP** are exempt from FSVP.
- These importers will be addressing all the hazards associated with those ingredients under **FDA HACCP**.



Resources:

FDA has provided guidance and additional information about how the FSMA rules interact with requirements for Seafood and Juice HACCP and for LACF. The guidance can be accessed at:

<https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm569554.htm>

Several decades ago, FDA established regulations to require that a food safety controls system for juice and seafood called Hazard Analysis and Critical Control Points (HACCP). (See 21 CFR Part 120 for juice and 21 CFR Part 123 for seafood.) In addition to controls for processors, these rules imposed requirements on importers of these products. For this reason, Congress explicitly exempted these products from FSVP because importers of those products are subject

to supplier verification requirements under the HACCP regulations (21 CFR 1.501(b)).

Importers of raw materials and other ingredients for the manufacture of juice or seafood need not comply with the FSVP rule so long as they are in compliance with HACCP requirements under 21 CFR parts 120 or 123, with respect to the juice or seafood product they manufacture from those raw materials and ingredients, as these manufacturers will be addressing all the hazards associated with those ingredients under HACCP (21 CFR 1.501(b)).

Note: The above exemption from FSVP only applies to foods subject to U.S. HACCP regulations for juice and seafood, but not to other types of foods processed in the same facility. It is also true that many foreign suppliers may employ HACCP for the production/manufacture of other types of foods; it must be emphasized, however, that the FSVP rule requires that the U.S. importer consider the U.S. food safety regulations that apply to the foods it obtains from its foreign supplier, including, but not limited to, the preventive controls requirements. While HACCP is similar to the PC rule, it is not the same in all respects; a supplier may need to take additional safety measures to ensure compliance with the U.S. level of public health protection.

Alcoholic Beverages (Certain Conditions)

Alcoholic Beverages (Certain Conditions)

- FSMA exempted **alcoholic beverages** that meet certain conditions:
 - From a foreign facility that is required to register under Sec. 415
 - The foreign facility is the “same type of facility as those regulated by Department of Treasury in the U.S. under the Federal Alcohol Administration Act (FAAA) (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.)”
- Exemption applies to nonalcoholic, prepackaged food from such foreign suppliers, provided such foods constitute 5% or less of overall sales of the facility.
- Also applies to raw materials and ingredients imported by an importer who uses them to manufacture alcohol in the U.S.
- Similar exemption exists for domestically produced alcoholic beverages in the Preventive Controls (PC) for Human Food rule.



FSMA also exempted alcoholic beverages that meet certain conditions:

1. Products must come from foreign facilities required to register under Sec. 415.
2. The foreign facility is the “same type of facility as those regulated by Department of Treasury in the U.S. under the

Federal Alcohol Administration Act (FAAA) (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.)."

The exemption also applies to nonalcoholic, prepackaged foods from these foreign suppliers, provided such foods constitute 5 % or less of overall sales of the facility.

Additionally, the exemption applies to raw materials and other ingredients being imported for manufacturing/processing, packing, or holding into alcoholic beverages in certain circumstances.

This provision is basically the same exemption as for domestically produced alcoholic beverages under the PC rule for human food. This exemption also applies to raw materials and other ingredients being imported by an importer who uses them to manufacture alcoholic beverages in the U.S.

Foods Not Intended for Sale or Distribution in the U.S. and Foods Intended for Personal Use

Foods Not Intended for Sale or Distribution in the U.S. and Foods Intended for Personal Use

- Food imported for research or evaluation
(subject to certain requirements)
- Food that is transshipped through the U.S. or imported for further processing and export
(no distribution in the U.S.)
- Food imported for personal consumption



The FSVP rule provides for certain exemptions for certain types of food that are not for sale or distribution to the public in the U.S. and food intended for personal consumption. For example, small quantities of food that people might carry in their luggage for personal consumption and food that is shipped through the U.S. destined for another country would not be subject to FSVP requirements.

Certain Meat, Poultry, and Egg Products

Certain Meat, Poultry, and Egg Products

- Those food products and species subject to USDA requirements:
 - Federal Meat Inspection Act
 - Poultry Products Inspection Act
 - Egg Products Inspection Act
- USDA also is responsible for inspecting catfish (*Siluriformes* spp.)



Food that is subject to certain USDA requirements at the time of import, such as certain meats and poultry, processed egg products, and *Siluriformes* spp. fish (including catfish) are exempt from the FSVP rule.

U.S. Food Exports Returned

U.S. Food Exports Returned

- FSVP does not apply to food manufactured or processed, raised, or grown in U.S., then exported and returned to the U.S. without further manufacturing/processing in a foreign country
- Such products do not have a foreign supplier and are not regarded as being "imported," as they were produced in the U.S.
- Such products are still subject to U.S. food safety requirements



Foods that are produced in the U.S., then exported, and returned without further manufacturing or processing are not subject to the FSVP rule. This does not mean that such foods are not subject to the U.S. food safety regulations. If sold for consumption in the U.S., they will have to meet U.S. safety standards. These foods may be returned

for a variety of reasons, including not meeting a foreign buyer's specifications, which may include a food safety problem. Each product returned is handled individually according to the rationale for its return.

Low-Acid Canned Foods—Partial Exemption for Microbiological Hazards

Low-Acid Canned Foods—Partial Exemption for Microbiological Hazards

- Low-acid canned foods (LACFs) are NOT exempt from FSVP
- An importer of LACFs must:
 - Verify and document that the food was produced in accord with LACF regulations (21 CFR Part 113), which pertain to microbiological hazards.
 - For all hazards not controlled by part 113, the importer is required to have an FSVP.
- An importer who uses raw materials or other ingredients to manufacture/process an LACF in the U.S. is:
 - Required to be in compliance with Part 113, and
 - Must have an FSVP for all other hazards or comply with the PC rules.



Resources:

FDA has provided guidance and additional information about how the FSMA rules interact with requirements for Seafood and Juice HACCP and for LACF. The guidance can be accessed at:

<https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm569554.htm>

Low-acid canned foods (LACFs) are not exempt from FSVP. An importer of low-acid canned foods must verify and document that the food was produced in accordance with the LACF regulations (21 CFR Part 113) pertaining to microbiological hazards. For all hazards not controlled by Part 113, i.e., non-microbiological hazards, the importer must have an FSVP.

An importer of raw materials or other ingredients to be used in manufacturing/processing an LACF in the U.S. is not required to comply with FSVP requirements for microbiological hazards, if the importer itself is in compliance with part 113, but it must have an FSVP for all other hazards (21 CFR 1.502(c)). In other words, an importer of raw materials who is in compliance with the LACF rule in part 113 (which addresses microbiological hazards) must still have an FSVP for all other reasonably foreseeable hazards identified by the FSVP importer, as will be discussed later.

Foods Received and Processed by Importers Who Are Subject to PC Rules

Foods Received and Processed by Importers Who Are Subject to PC Rules

- If you are an importer who is also a processor/manufacturer **subject to and in compliance with the supply chain provisions of the PC rules:**
 - You are deemed to be in compliance with most of the FSVP requirements for the food you import, and
 - You do not have to carry out most of the FSVP requirements.
- **However, as the importer:**
 - You **must** be named on the Customs and Border Protection (CBP) entry filing as the importer in accord with the FSVP rule.



The PC rules require manufacturers/processors to have supply-chain preventive controls when they (or their customers) are not controlling the hazards. These provisions provide verifications that are similar to FSVP verifications. **Therefore, to avoid redundant requirements, FDA states, “if you are a manufacturer/processor who is subject to and in compliance with the supply chain provisions of the PC rules, you are deemed to be in compliance with most of the FSVP requirements for the food you import.”**

You as the importer must, however, be named on the CBP entry filing as the FSVP importer, in accordance with the FSVP rule, even if you are fulfilling the supply chain requirements through the PC rules.

FSVP Standard Requirements

Standard Requirements

- Conduct a **hazard analysis** of the food, including hazard identification and hazard risk evaluation.
- Conduct an **evaluation** of the foreign supplier's food safety performance and risk posed by the food.
- **Approve** the foreign supplier (based on above evaluations).
- Establish written procedures to ensure that food is imported only from approved foreign suppliers (with limited exceptions).
- Determine and apply appropriate **verification activities** and assess results.
- Implement **corrective action(s)**, if needed.
- **Reevaluate foreign supplier** (at least every three years or when there is a reason to do so).
- **Identify the FSVP importer** at entry.
- Keep required **records and documentation**.



Each of the FSVP standard requirements are covered in detail in Chapters 4 through 9. The concepts are just being introduced here.

If you go to Appendix 3, Workaid C, in your manual, you will see the "Summary of FSVP Requirements." This summary covers the steps we will be going over in Chapters 4-9, and can be used as a quick reference in the future.

When Do Modified Requirements Apply?

When Do Modified Requirements Apply?

- If you are a "Very Small Importer"
- If the imported food is from "Certain Small Foreign Supplier(s)"
- If the imported food is from foreign supplier(s) in countries with food safety systems recognized by FDA as "comparable" for certain foods under Systems Recognition
- If you import dietary supplements or dietary supplement components (see Appendix 4)
- More information on eligibility is introduced during the "Review: Questions About FSVP Requirements," later in this chapter, and is covered more fully in Appendix 5.



Generally, modified FSVP requirements are aimed at smaller entities or products falling under a discrete or distinctive

Key Point:

More details regarding modified requirements eligibility and the specific requirements are provided in Appendix 5, but in general, Importers who are eligible for the modified requirements do not have to perform the standard hazard analysis, evaluation of the supplier, or verification activities. However, they still must have a modified FSVP program that includes:

- Documentation of eligibility;
- Use of a qualified individual for each activity;
- Identification of the FSVP importer at entry; and
- Obtaining written assurance, before importing the food and at least every 2 years thereafter, that their foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under the section 418 or 419 of the FD&C Act (if applicable) and is producing the food in compliance with section 402 (adulteration) and 403(w) (allergen labeling, if applicable)

regulatory framework. Modified requirements may require less or different FSVP process steps than the “standard” requirements. Persons/companies that may be eligible for modified requirements may still choose to follow the “standard” FSVP requirements.

Modified FSVP requirements apply if you are a “very small importer”; if you are importing food from “certain small foreign suppliers” (21 CFR 1.512(a)); if the food you are importing is from foreign supplier(s) in countries with food safety systems recognized by FDA as “comparable” for certain foods under Systems Recognition; and finally, modified requirements apply if you import dietary supplements or dietary supplement components (**see Appendix 4**).

We will cover the eligibility criteria of the first three situations in more detail in the next few slides. For more information regarding “FSVP Modified Requirements,” see Appendix 5.

What Is a “Very Small Importer”?

What Is a “Very Small Importer”?

- You are a “very small importer” if, during the previous 3-year period, your annual average in sales of food, plus the U.S. market value of food imported, processed, packed, or held without sale is:
 - Less than \$1 million U.S. (importer of human food), or
 - Less than \$2.5 million U.S. (importer of animal food).
- These amounts are based on a 2011 U.S. dollar, and thus, subsequent years should be adjusted for inflation using 2011 as the base year.
- These figures also include sales of any subsidiaries and affiliates.



The FSVP rule says that you are a “very small importer” if, during the previous 3-year period, you average less than \$1 million U.S. (for importers of human food) or \$2.5 million U.S. (for importers of animal food) per year in sales of food combined with the U.S. market value of food imported, manufactured, processed, or held without sale (21 CFR 1.501).

FDA adjusted these calculations for inflation, with 2011 as the base year, and these figures include sales of any subsidiaries and affiliates of the importer. FDA has published charts to help with this:

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm554484.htm>

More information regarding modified requirements for the “Very Small Importer” is available in Appendix 5.

What Are “Certain Small Foreign Suppliers”?

What Are “Certain Small Foreign Suppliers”?

- Your supplier meets the criteria for “Certain Small Foreign Suppliers” if:
 1. The foreign supplier is a “qualified facility” as defined by the PC rules,
 2. You are importing produce from a foreign supplier that is a **farm that grows produce** and is not a “covered farm” under the **Produce Safety rule** (i.e., annual monetary value of produce sold is < U.S. \$25,000) or satisfies the **Produce Safety Rule** requirements for a “qualified exemption,” or
 3. You are **importing shell eggs** from a foreign supplier that is not subject to the FDA regulation for **Shell Eggs** in 21 CFR Part 118 because it has fewer than 3,000 laying hens .



Under 21 CFR 1.512(a)(2) your supplier meets the criteria for one of the three categories of “Certain Small Foreign Suppliers” if:

1. The foreign supplier is a “qualified facility” as defined by the PC rule for human food (21 CFR 117.3) or the PC rule for animal food (21 CFR 507.3), or
2. You are importing produce from a foreign supplier that is a farm that grows produce and is not a “covered farm” under the Produce Safety rule (21 CFR 112.4(a), less than \$25,000 U.S. average produce sales adjusted for inflation) or satisfies the PSR requirements for a “qualified exemption” (21 CFR 112.4(b) and 112.5), or
3. You are importing shell eggs from a foreign supplier that is not subject to the FDA regulation for Shell Eggs in 21 CFR Part 118 because it has fewer than 3,000 laying hens.

Each of the three categories and the modified requirements are explained in more detail in Appendix 5.

When Food Is Produced Under a Food Safety System Recognized by FDA

Key Point:

Currently, the food safety systems of New Zealand, Canada, and Australia have been recognized as having a comparable food safety system for certain foods under Systems Recognition.

When Food Is Produced Under a Food Safety System Recognized by FDA

- If you import foods from a foreign supplier in a country with food safety systems recognized by FDA as “comparable” for certain foods under Systems Recognition, your requirements can be reduced if:
 - The food is within the scope of the Systems Recognition arrangement;
 - Your supplier is under the regulatory oversight of that food safety authority; and
 - The supplier must be in good compliance standing.
- If these conditions are met, you are not required to, among other things:
 - Perform a hazard analysis, or
 - Conduct a foreign supplier evaluation for approval and verification.



Over time FDA is expected to evaluate whether other countries have food safety systems that effectively provide the same level of public health protection as that provided by the U.S. system. Currently, New Zealand's, Canada's, and Australia's systems have been recognized as comparable for certain foods under Systems Recognition. Information on the Australia's recognition with links to the evaluation process can be found on the FDA website at:

<https://www.fda.gov/food/newsevents/constituentupdates/ucm553382.htm>

If FDA officially recognizes that another country's food safety system is comparable for certain foods under Systems Recognition, and if your foreign supplier is providing food that is within the scope of that official recognition and under the jurisdiction of the government authority responsible for that food safety system—you, as the FSVP importer of food from the foreign supplier, are not required to:

1. Perform a hazard analysis, or
2. Conduct a foreign supplier evaluation for approval and verification.

When Food Is Produced Under a Food Safety System Recognized by FDA (Continued)

- You must, however:
 - Monitor whether the foreign supplier remains in good compliance standing with the foreign food safety authority,
 - Take prompt corrective action if any information indicates that the hazards associated with the food you import are not being significantly minimized or prevented,
 - Ensure that you as the FSVP importer maintains records relative to all FSVP activities, and
 - Identify yourself as the FSVP importer named on the CBP entry filing.
- Note: These provisions apply **ONLY** to food that is not intended for further manufacturing/processing before consumption.



You must, however, monitor whether the foreign supplier remains in good compliance standing with the foreign food safety authority, take prompt corrective action if any information indicates that the hazards associated with the food you import are not being significantly minimized or prevented, and ensure that you as the FSVP importer maintain records relative to all FSVP activities.

You must also ensure that you are identified as the FSVP importer on the CBP entry filing and maintain records relative to all FSVP activities. Remember, whoever is identified on the CBP entry filing as the FSVP importer is the person FDA will see as being responsible for all FSVP activities, including the maintenance of all FSVP records.

Note: This provision only applies to a food that is not intended for further manufacturing/processing before consumption, because if it is a food that is imported into the U.S. for further processing, the subsequent U.S. manufacturer/processor will likely need to comply with the PC rules (including regarding supply-chain programs) as well as other U.S. food safety requirements.

Before importing a food from the foreign supplier from a food safety system that has been officially recognized by FDA, you need to determine and document that the foreign supplier is in good compliance standing with the appropriate foreign food safety authority.

Thereafter, you must continue to monitor whether the foreign supplier is in good compliance standing with the foreign food safety authority. Also, if you become aware of any information indicating that the hazards associated with the food you import are not being significantly minimized or prevented, you must take prompt corrective action.

Determine the Food Safety Requirements that Apply to Your Supplier

Determine the Food Safety Requirements that Apply to Your Supplier

- Specific food safety requirements differ depending on the type of food:
 - You must determine which FDA requirements apply to the food you import.
- For example, if you are importing fresh produce that is “covered produce” under the Produce Safety rule:
 - You are not required to evaluate biological hazards, but
 - You must determine whether there are any other hazards requiring a control.



As noted in the previous discussions, the requirements in the FSVP rule vary depending on the type of food. You must, therefore, identify the requirements that apply to the food you import to develop the proper FSVP.

If, for example, you are importing fresh produce that is “covered produce” under the Produce Safety rule, you are not required to evaluate biological hazards in your hazard analysis, because FDA has dealt with biological hazards in the Produce Safety rule. You still must, however, determine whether there are any other chemical or physical hazards requiring a control for the produce you plan to import.

As was noted earlier, you are not required to conduct a hazard analysis under FSVP for microbiological hazards in low-acid canned foods, but 1) you must make sure your supplier is in compliance with LACF requirements under 21 CFR Part 113 and 2) you must conduct an FSVP, including a hazard analysis, for hazards other than microbiological ones.

Determine the Food Safety Requirements that Apply to Your Supplier (continued)

- Relevant FSMA regulations that may apply to your supplier include:
 - PC rules for human and animal food
 - Produce Safety rule
- Other FDA food safety regulations may pertain to the foods you import as well.

Resources:

We will be providing a short Preventive Controls and Produce Safety Session next, as part of this course. Additionally, more information can be found in Appendix 6a and 6b of this manual, which are overviews of the Preventive Controls and Produce Safety rules respectively.



Foods may be subject to PC rules for human and animal food or the Produce Safety rule that resulted from FSMA, but other FSMA and pre-FSMA food safety rules may also pertain to them.

Examples of Other Food Safety Requirements That May Apply to Food You Import

Examples of Other Food Safety Requirements That May Apply to Food You Import

- Examples of other food safety regulations include:
 - Low-acid canned foods (LACF) – 21 CFR part 113
 - Infant formula – 21 CFR part 107
 - Acidified foods – 21 CFR part 114
 - Shell eggs – 21 CFR part 118
 - Bottled drinking water – 21 CFR part 129



This slide identifies some of the other food safety rules that may pertain to the foods you import. You must make sure that you and your supplier are cognizant of the U.S. food safety rules that apply to their products and that those foods are meeting U.S. food safety standards.

The Importance of Communications with Your Supply Chain

The Importance of Communications with Your Supply Chain

- The construct of the FSVP rule presumes that:
 - Importers will communicate with their foreign suppliers and/or others engaged in the supply/import chain to determine how FSVP requirements will be met.
- Importers will benefit by **communicating as soon as possible** with:
 - All parties who need to understand and meet the FSVP requirements on how best to comply with FSVP and other FSMA requirements,
 - So there will be no disruptions in food trade.



It is clear that the FSVP requirements to ensure the safety of food imported into the U.S. anticipate that importers and their foreign suppliers, as well as others in the supply chain, will need to communicate among themselves if they are to be successful in meeting FSVP requirements. Because the FSMA PC, Produce Safety, and FSVP rules are interrelated, the communication channels should begin as soon as possible as it may take time to figure out how compliance with the rules can best be achieved. FSVP importers should start now to discuss FSVP requirements with their foreign suppliers.

Review: Questions About FSVP Requirements

Review: Questions About FSVP Requirements

- The questions relate to whether:
 - You are responsible for meeting FSVP requirements
 - The food imported is subject to the FSVP rule
 - You are subject to standard or modified FSVP requirements
- In approaching the following slides, think of a specific food that you import, before starting to go through the questions, and see how FSVP might apply to your specific situation.
- The questions are also located in the Exercise Workbook, Chapter 3, page 7.



The following slides are adapted from a tool developed by FDA (and available on the FDA website) to help importers understand if and how they are subject to FSVP for the foods they import. Going through the following slides should help crystallize some of the concepts you have learned so far.

In approaching the following slides, think of a specific food that you import, before starting through the questions, and see how FSVP might apply to your specific situation. If desired, you can enter your answers to the questions in the Exercise Workbook (see Chapter 3, page 7).

Note: If you have any confusion about the algorithm questions, now is the time to clear up that confusion before we go further. So, raise your hand. If your question pertains to a topic that requires a lengthy explanation and is covered in a later chapter, we might ask you to wait for the full answer.

Question 1

Question 1

- **Are you an importer for FSVP purposes?**
 - That is, are you the **U.S. owner or consignee** of an article of food that is being offered for import into the U.S.? **Or**
 - If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, are you the **U.S. agent or representative of the foreign owner or consignee** at the time of entry?

If your answer is:

- **NO:** FSVP does not apply to you for this food.
- **YES:** Continue to the next question.



Are you an importer for FSVP purposes? (See 21 CFR 1.500)

That is, are you the **U.S. owner or consignee** (assuming only one) of an article of food that is being offered for import into the United States?

Or, if there is no U.S. owner or consignee of an article of food at the time of U.S. entry, are you the U.S. agent or representative of the foreign owner or consignee at the time of entry?

If your answer is:

NO: FSVP does not apply to you for this food.

YES: Continue to the next question.

Question 2

Question 2

Are you importing the following foods?

1. Fish and Fishery Products (in compliance with part 123), or certain ingredients you use in fish and fishery products in compliance with part 123
2. Juice (in compliance with part 120), or certain ingredients you use in making juice products in compliance with part 120
3. Food for research or evaluation
4. Certain alcoholic beverages, or certain ingredients you use in making alcoholic beverages
5. Certain meat, poultry, and egg products regulated by USDA

(list continued on next slide)



Are you importing the following foods? (See 21 CFR 1.501)

1. Fish and Fishery Products (in compliance with part 123), or certain ingredients for use in fish and fishery products in compliance with part 123
2. Juice (in compliance with part 120), or certain ingredients for use in juice products in compliance with part 123
3. Food for research or evaluation
4. Certain alcoholic beverages, or certain ingredients for use in alcoholic beverages; also including prepackaged foods from same foreign supplier that do not constitute more than 5% of sales of that facility (determined by Secretary of Treasury)
5. Certain meat, poultry, and egg products regulated by USDA

Question 2 (continued)

Are you importing the following foods? (continued)

6. Food imported for personal consumption
7. Food that is transshipped through the U.S.
8. Food that is imported only to process and then export
9. Food that is produced in the U.S., then exported and returned without further manufacturing/processing in a foreign country

If your answer is:

- YES: FSVP does not apply to you for this food.
- NO: Continue to the next question.



6. Food imported for personal consumption
7. Food that is transshipped
8. Food that is imported for processing and export
9. Food that is produced in the U.S., then exported and returned without further manufacturing

If your answer is:

YES: FSVP does not apply to you for this food.

NO: Continue to the next question.

Question 3

Question 3

- Do you import low-acid canned food in compliance with 21 CFR Part 113?

If your answer is:

- YES: You do **not** need an FSVP with respect to **microbiological hazards** for that food. Instead, you must verify and document that the food was produced in accordance with 21 CFR Part 113. With respect to all matters that are not controlled by part 113, you must have an FSVP.
- NO: Continue to the next question.



Do you import low-acid canned food in compliance with 21 CFR Part 113? (see 21 CFR 1.502(b))

If your answer is:

Yes: You do not need an FSVP with respect to microbiological hazards for that food. Instead, you must verify and document that the food was produced in accordance with 21 CFR Part 113. With respect to all matters that are not controlled by part 113, you must have an FSVP.

NO: Continue to the next question.

Question 4

Question 4

- Are you an importer subject to the preventive controls regulation for human or animal food, a food processor/manufacturer receiving the imported food, and in compliance with one of the following requirements in 21 CFR parts 117 or 507?
 - **(1) You implement preventive controls for the hazards in the food in accordance with either of the Preventive Controls rules;**
 - **(2) You are not required to implement a preventive control under either of the preventive controls rules; or**
 - **(3) You have established and implemented a risk-based supply-chain program in compliance with either of the preventive controls rules.**

If your answer is:

- **YES:** You are deemed in compliance with most aspects of FSVP, except the requirement for importer identification at entry.
- **NO:** Continue to the next question.



Are you an importer subject to the preventive controls regulation for human or animal food, a food processor/manufacturer receiving the imported food, and in compliance with one of the following requirements in 21 CFR parts 117 or 507?

- (1) You implement preventive controls for the hazards in the food in accordance with either of the Preventive Controls rules;**
- (2) You are not required to implement a preventive control under either of the preventive controls rules; or**
- (3) You have established and implemented a risk-based supply-chain program in compliance with either of the preventive controls rules.**

If your answer is:

YES: You are deemed in compliance with most aspects of FSVP, except the requirement for importer identification at entry.

No: Continue to the next question.

Question 5

Resources:

For more information on dietary supplements, see Appendix 4: FSVP Requirements for Dietary Supplements: A Different Verification Focus.

Question 5

- Do you import dietary supplements subject to certain dietary supplement current good manufacturing practice requirements in 21 CFR part 111?

If your answer is:

- **YES:** You are subject to modified FSVP requirements for those dietary supplements subject to separate, pre-existing Current Good Manufacturing Practice (CGMP) requirements for dietary supplements.
- **NO:** Continue to the next question.



Do you import dietary supplements subject to certain dietary supplement current good manufacturing practice (DS CGMP) requirements in 21 CFR Part 111? (21 CFR 1.511)

If your answer is:

YES: You are subject to modified FSVP requirements for those dietary supplements subject to separate, pre-existing Current Good Manufacturing Practice (CGMP) requirements for dietary supplements.

NO: Continue to the next question.

Question 6

Question 6

Are You a “Very Small Importer”?

- For human food, an importer averaging less than \$1 million per year during the 3-year period preceding the applicable calendar year, in sales of human food combined with the U.S. market value of human food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee).

(question continued on next slide)



Key Point:

As an example of modified requirements, such importers might not have to conduct a hazard analysis. Instead, they could verify their foreign suppliers by obtaining written assurances of compliance.

Resources:

For more information on modified requirements eligibility and the specific requirements, see Appendix 5: Modified Requirements.

Are you a very small importer? (See 21 CFR 1.500 and 1.512)

For human food, this is an importer averaging less than \$1 million per year during the 3-year period preceding the applicable calendar year, in sales of human food combined with the U.S. market value of human food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee).

Question 6 (continued)

Are You a “Very Small Importer”? (continued)

- For animal food, an importer averaging less than \$2.5 million per year during the 3-year period preceding the applicable calendar year, in sales of animal food, combined with the U.S. market value of animal food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee).

If your answer is:

- YES:** You are subject to modified FSVP requirements.
- NO:** Continue to the next question.



For animal food, this is an importer averaging less than \$2.5 million per year during the 3-year period preceding the applicable calendar year, in sales of animal food, combined with the U.S. market value of animal food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee).

If your answer is:

YES: You are subject to modified FSVP requirements.

NO: Continue to the next question.

Question 7

Question 7

- Do you import food from certain small suppliers (i.e., qualified facilities under the PC rules, certain farms that are not “covered farms” under the Produce Safety regulation, and certain small shell egg producers)? (See 21 CFR 1.512)

If your answer is:

- **YES:** You are subject to modified FSVP requirements for food from those suppliers.
- **NO:** Continue to the next question.



Do you import food from certain small suppliers (i.e., qualified facilities under the PC rules, certain farms that are not covered farms under the produce safety regulation, and certain small egg producers)? (See 21 CFR 1.512)

Note that in this course, we will not go into all the details regarding modified requirements. We have primarily addressed the eligibility requirements and the concept of modified requirements in this overview chapter. Appendix 5 contains a section with more details on modified requirements. How many of you believe you may import from certain small foreign suppliers?

If your answer is:

YES: You are subject to modified FSVP requirements for food from those suppliers.

NO: Continue to the next question.

Question 8

Question 8

- Do you import a food that is not intended for further manufacturing/processing before consumption from a country that is officially recognized by FDA as having a food safety system that is comparable for certain foods under Systems Recognition?

If your answer is:

- **YES:** You may be subject to modified FSVP requirements for food from those countries if the food is under the regulatory oversight of the food safety authority, the food is within the scope of the recognition agreement, and the supplier is in good compliance standing with the relevant food safety authority in that country.
- **NO:** Continue to the next question.



Do you import a food that is not intended for further manufacturing/processing before consumption from a country that is officially recognized by FDA as having a food safety system that is comparable for certain foods under Systems Recognition?
(See 21 CFR 1.513)

We note that currently there are only three countries that have been officially recognized by FDA and those are New Zealand (2012), Canada (2016), and Australia (2017).

If your answer is:

YES: You may be subject to modified FSVP requirements for food from those countries if the food is under the regulatory oversight of the food safety authority, the food is within the scope of the recognition agreement, and the supplier is in good compliance standing with the relevant food safety authority(ies) in that country).

NO: Continue to the next question.

The Final Answer

The Final Answer

- If you answered “Yes” to question 1 and answered “No” to questions 2-8, then:

**YOU ARE SUBJECT TO THE STANDARD
FSVP REQUIREMENTS**



These questions and your individual answers to them for the import situation(s) you were envisioning in your minds may yield some clarity on your particular situation or provoke a host of questions. Either is possible and okay at this stage.

Chapter 3: Summary

Chapter 3: Summary

- This chapter covered:
 - Food imports that are exempt.
 - An introduction to the standard requirements.
 - Who is eligible for modified requirements.
 - The importance of communication within your supply chain.



You now have a basic understanding of the FSVP requirements, including:

1. The types of foods that are covered by the FSVP rule and the foods that are exempt,

2. An introduction to the standard requirements,
3. Whether you/and or your supplier are eligible for the "modified" requirements,
4. The importance of determining the food safety requirements that apply to their foreign suppliers, and
5. The importance of initiating communications with your foreign suppliers and others in your supply chain.

Chapter 3 Exercise: “Does FSVP Apply to These Food Products?”

Chapter 3 Exercise: “Does FSVP Apply to These Food Products?”

- **Timing:** 30 minutes total
 - 10 minutes working in table groups
 - 20 minutes reporting out and discussing
- **Directions:** In your group, read the example food products listed in the table (see Exercise Workbook, Chapter 3, page 10).
 - Discuss whether or not FSVP standard requirements or modified requirements apply or if the food is exempt.
 - The instructor will call upon each group to put your answers on the table displayed on the projector screen (next slide).



This exercise provides you with the opportunity to practice determining whether FSVP standard requirements or modified requirements apply to a specific food product or if the food product is exempt.

Directions: In your group, read the example food products listed in the Imported Food Product table in the Exercise Workbook (see Chapter 3, page 10). Identify whether FSVP standard requirements apply, modified requirements apply, or if the food is exempt for each food product.

The group will be called upon by the instructor to put a sticky note in the “correct” box projected on the slide screen in front of the class. The sticky note should have each group’s name or number.

Blank Colored Insert-Front

Blank Colored Insert-Back

Preventive Controls and Produce Safety Session

Preventive Controls and Produce Safety Session

A BRIEF SUMMARY OF THE PREVENTIVE CONTROLS RULES FOR HUMAN AND ANIMAL FOOD AND THE PRODUCE SAFETY RULE



This section is intended as a supplement to the FSVP instruction that will briefly focus on the rules that your foreign suppliers may be subject to. If the food they export is intended for sale and consumption in the U.S., the food must still meet the U.S. level of public health protection, and, therefore, your foreign supplier must comply with these rules as a condition for selling food that will be consumed in the U.S. You as the importer must pay attention to these rules as your job is to verify that your foreign supplier is providing you with food that meets U.S. food safety standards.

Resources:

This session is intended to provide a brief overview of the other major FSMA rules that are relevant to the verification responsibilities of importers. While we don't have time to answer the questions you are likely to have as we go through this session, Appendix 6a and 6b of your manual provide more detailed overviews. Also, remember that these other rules are the subject of separate courses that you can take, if desired.

PC for Human Food rule:
<https://www.fda.gov/food/guidanceregulation/fsma/cm334115.htm>

PC for Animal Food rule:
<https://www.fda.gov/food/guidanceregulation/fsma/cm366510.htm>

Produce Safety rule:
<https://www.fda.gov/food/guidanceregulation/fsma/cm334114.htm>



The Preventive Controls (PC) and Produce Safety Session is a summary of FDA's *Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food* regulation, 21 CFR part 117, (referred to as the CGMP & PC rule for human food or just PC rule for human food), *Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Food for Animals* regulation, 21 CFR Part 507, (referred to as the CGMP & PC rule for animal food or PC rule for animal food), and *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* rule, 21 CFR Part 112, (referred to as the Produce Safety rule).

Preventive Controls and Produce Safety Session: Goal and Objectives

Preventive Controls and Produce Safety Session: Goal and Objectives

Goal: Participants will be able to determine which of their foreign suppliers must comply with Preventive Controls (PC) and Produce Safety rules.

Learning Objectives:

- By the end of this session, participants will be able to:
 1. Determine which foreign suppliers must comply with the Current Good Manufacturing Practice (CGMP) & PC rules for human and animal food.
 2. Explain the key requirements of the CGMP & PC rules for human and animal food.
 3. Determine which foreign suppliers must comply with the Produce Safety Rule.
 4. Explain the key requirements of the Produce Safety rule.



Our goal in this brief session is to let you know which of your foreign suppliers is subject to the three FSMA rules that apply to food facilities (as well as packers and holders) and farms in the U.S. and other countries, if their food is intended for consumption in the U.S.

Who Must Comply with CGMP & PC Rules?

Who Must Comply with CGMP & PC Rules?

- **Facilities that manufacture, process, pack, or hold food intended for sale in the U.S.**
- In general, facilities required to register with FDA under section 415 of the FD&C Act
 - Not farms or retail food establishments
- **Applies to both U.S. facilities and foreign suppliers**
- Some exemptions and modified requirements apply



Facilities covered by the requirements in 21 CFR Part 117 are those that manufacture, process, pack, or hold human food intended for sale in the U.S. Facilities covered by the requirements in 21 CFR Part 507 are those that manufacture, process, pack, or hold animal food intended for sale in the U.S. In general, the provisions in both rules apply to facilities that are required to register with FDA under sec. 415 of the Food Drug and Cosmetic Act. Registration is not required for farms or for retail food establishments. The rules apply to both domestic and foreign food processors exporting food intended for consumption in the U.S. There are a number of exemptions and modified requirements that apply in both rules.

Resources:

For more information on the PC rules for human and animal food, refer to Appendix 6a of this manual.

PC for Human Food Rule Key Requirements

PC for Human Food Rule Key Requirements

- Two of the main requirements of the PC rule for human food are:
 - CGMP updated for human food production
 - Covered facilities **must establish and implement a food safety system** that includes an analysis of hazards and risk-based preventive controls. The rule sets requirements for a written food safety plan that includes:
 - Hazard analysis
 - Preventive controls
 - Oversight and management of preventive controls (monitoring, corrective actions and corrections, and verification)
 - Supply-chain program
 - Recall plan

Source: FDA Fact Sheet available at:
<http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM461834.pdf>



Facilities that manufacture, process, pack, or hold human food have been subject to CGMP for many years. The PC for human food rule updates the CGMP as basic prerequisite requirements for producing safe food. Preventive controls, however, are designed to significantly minimize or prevent hazards that have been identified and assessed through the food facility's hazard analysis of the food and its production. These preventive controls are placed into a facility's Food Safety Plan, which is intended to serve as an operational guide for both management and employees of the facility to follow to ensure food safety. Preventive controls can be of various types and include process controls, food allergen controls, and sanitation controls. These preventive controls must be written and include procedures for monitoring, corrective action, and verification. The food facility's hazard analysis also determines when a hazard requiring a supply-chain applied control exists. If a hazard does exist with an ingredient and that hazard is controlled before receipt by a manufacturer/processor, a written supply-chain program, as described by subpart G of the PC rule, will be required. Supply chain preventive controls are referenced frequently in this FSVP course. Facilities with food with a hazard requiring a preventive control must also have a recall plan to ensure that, if a food with a food safety problem leaves the facility's control, it can be recovered and contained as early as possible.

PC for Animal Food Rule Key Requirements

PC for Animal Food Rule Key Requirements

- Two of the main requirements of the PC rule for animal food are:
 - CGMP established for animal food production.
 - Covered facilities **must establish and implement a food safety system** that includes an analysis of hazards and risk-based preventive controls. The rule sets requirements for a written food safety plan that includes:
 - Hazard analysis
 - Preventive controls
 - Oversight and management of preventive controls (monitoring, corrective actions and corrections, and verification)
 - Supply-chain program
 - Recall plan

Source: FDA Fact Sheet Available at:
<http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM461884.pdf>



Key Point

Businesses have a staggered number of years after publication of the final PC for animal food rule to comply, based on business size. In addition, there will be staggered compliance between the CGMP requirements and the PC requirements.

First year is CGMP and second year is PC.

For more information on the compliance dates, review the FDA's PC for animal food fact sheet in Appendix 9 of this manual.

The PC rule for animal food follows the same structure as the PC rule for human food. There are differences, however. First and foremost is that application of CGMP for animal food is a new requirement. Also, it should be mentioned that allergen preventive controls do not apply to animal food.

Who Is Covered by the Produce Safety Rule?

Who Is Covered by the Produce Safety Rule?

- Covered Produce:
 - Certain produce that are fruits and vegetables (including sprouts, mushrooms, and certain nuts) that are:
 - "Raw Agricultural Commodities" (RACs) grown domestically or will be offered for import into any state or territory of the United States
- Covered Farms and Farm Definition:
 - Primary Production Farms
 - Secondary Activities Farms



The Produce Safety rule applies to covered produce, including certain fruits and vegetables (including sprouts, mushrooms, and certain nuts) that are Raw Agricultural Commodities (RACs). This includes a produce RAC that is grown domestically or will be imported or offered

for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. It does not apply to some types of produce, as explained below. Requirements for the growing and handling of fresh sprouts are also covered by the Produce Safety rule, in Subpart M. Those requirements are beyond the scope of this chapter and will not be mentioned further.

Beyond the type of food, the regulation only applies to operations that are “covered farms” that handle covered produce (i.e., does not apply to dairy or wheat farms that do not grow, harvest, or handle covered produce). FDA defines two types of operations as farms: A Primary Production Farm and a Secondary Activities Farm.

Who Is Covered by the Produce Safety Rule? (continued)

Primary Production Farms

- Devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities, including operations that just grow crops and operations that just harvest crops.
- In addition to these activities, a primary production farm can:
 - Pack or hold raw agricultural commodities (RACs), regardless of who grew or raised them
 - Manufacture/process, pack, or hold processed foods so long as:
 - all such food is consumed on that farm or another farm under the same management; OR
 - the manufacturing/processing falls into limited categories, such as dehydrating grapes to produce raisins, packaging, and labeling



A Primary Production Farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:

(A) Pack or hold raw agricultural commodities (RACs). Packing and holding also include activities performed as a practical necessity for the distribution of that food (such as blending of the same RAC and breaking down pallets), or the safe or effective packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing), but does not include activities that transform a RAC into a processed food.

(B) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or the manufacturing/processing falls into limited categories, such as dehydrating grapes to produce raisins,

and packaging and labeling these commodities. Treatment to manipulate the ripening of RACs (such as by treating produce with ethylene gas) and packaging and labeling them, and packaging and labeling RACs are also permitted, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation).

Who Is Covered by the Produce Safety Rule? (continued)

Secondary Activities Farms

- An operation **not** located on a primary production farm but performs the same activities as a primary production farm (i.e., packing and/or holding RACs)
- The primary production farm(s) that grow, harvest, and/or raise the majority of those RACs must own or jointly own a majority interest in the secondary activities farm
- Operations that pack and/or hold RACs but are **not** primary production or secondary activities farms may need to comply with the Preventive Controls (PC) rule (unless exempted)



A Secondary Activities Farm is an operation, not located on a Primary Production Farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of RACs, provided that the Primary Production Farm(s) that grows, harvests, and/or raises the majority of the RACs packed, and/or held by the Secondary Activities Farm owns, or jointly owns, a majority interest in the Secondary Activities Farm. A Secondary Activities Farm may also conduct those additional activities allowed on a Primary Production Farm. So, a packinghouse jointly owned by a co-op of farmers on a property not on one of their farms will still be covered by the Produce Safety rule provided that the packinghouse only does farming activities and most (>50%) of the RACs handled by the operation are grown by one or more of the owners (assuming that the operation is packing covered produce and is not subject to any other exemption). But, if more than 50% of the RACs handled by the operation are grown by non-owners then the operation is not a farm and most likely will need to comply with the PC for human food rule.

 * Key Point:

Produce that is rarely consumed raw, specifically the produce on the following exhaustive list, is not covered by the Produce Safety rule: asparagus, certain varieties of beans (black, great Northern, kidney, lima, navy and pinto beans), beets (garden beets, roots and tops, and sugar beets), cashews, sour cherries, chickpeas, cocoa beans, coffee beans, collards, sweet corn, cranberries, dates, dill (seeds and weed), eggplants, figs, ginger, hazelnuts, horseradish, lentils, okra, peanuts, pecans, peppermint, potatoes, pumpkins, winter squash, sweet potatoes, and water chestnuts.

Produce Exempt from Produce Safety or Subject to Modified Requirements

Produce Exempt from Produce Safety or Subject to Modified Requirements

- Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management
- Produce from a farm with less than or equal to \$25,000 average annual sales of produce
- Produce that is rarely consumed raw (see Key Point)
- Produce from a farm or farm mixed-type facility with less than \$500,000 average annual sales of food and a majority sold directly to qualified end-users



Some produce and farms are not covered by the Produce Safety rule or have modified requirements. Produce that is grown and harvested by an individual for personal consumption or produced for consumption on the farm or another farm under the same management is not covered by this rule. Likewise, produce from a farm with less than or equal to \$25,000 average annual sales of produce (over the previous 3-year period on a rolling basis and adjusted for inflation) is also not covered by the rule. Produce that is identified by FDA in the rule as rarely consumed raw is not covered by the rule regardless of the size of the farm.

A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if: (1) during the previous 3-year period, the average annual monetary value of the food the farm sold directly to qualified end-users during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and (2) the average annual monetary value of all food the farm sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation. The Produce Safety rule defines a qualified end-user as the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment that is located in the same State or the same Indian reservation as the farm that produced the food, or not more than 275 miles from the farm.

Produce Exempt from Produce Safety or
Subject to Modified Requirements (continued)

- Produce intended to receive commercial processing that adequately reduces the presence of microorganisms of public health significance
- Produce that is not a Raw Agricultural Commodity (RAC)
- RACs packed at a facility that is not a farm



Produce is eligible for exemption from the rule if the produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance as long as certain disclosures are made and appropriate documentation occurs. Some examples of such commercial processing include processing in accordance with part 113 (thermally processed low-acid foods packaged in hermetically sealed containers) or otherwise treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), or processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products. To be eligible for the exemption, the farm must disclose in documents accompanying the produce that the food is “not processed to adequately reduce the presence of microorganisms of public health significance” and must ensure appropriate documentation occurs.

The Produce Safety rule does not apply to produce that is not a RAC (e.g., has been fresh-cut or otherwise manufactured/processed into a product that is not a RAC) and does not apply to RACs packed at a facility that is not a covered farm. In those cases, produce that is not otherwise exempt or eligible for a qualified exemption is covered by other food safety regulations, such as the PC rules or Juice HACCP rule, as applicable.

Resources:

For more information on the Produce Safety rule, refer to Appendix 6b of this manual.

What Is Required by the Produce Safety Rule?

What Is Required by the Produce Safety Rule?

Potential Routes of Contamination

- Minimize hazards from:
 - Agricultural water
 - Domesticated and wild animals
 - Biological soil amendment of animal origin
 - Health and hygiene
 - Equipment, tools, buildings and sanitation
 - Growing, harvesting, packing, and holding activities



The Produce Safety rule, focuses on biological hazards and specifically defined hazard as any biological agent that has the potential to cause illness or injury in the absence of its control. FDA concluded that physical hazards that can cause injury and chemical hazards, such as from crop protection chemicals, rarely occur at levels that pose a risk of serious adverse health consequences or death for individuals that would consume the product, citing an analysis of scientific literature and recall data. Therefore, the rule focuses on potential microbiological hazards.

FDA identified major routes of contamination on farms and finalized requirements in certain areas, including agricultural water; domesticated and wild animals; biological soil amendments of animal origin and human waste; health and hygiene; equipment, tools, buildings, and sanitation; and growing, harvesting, packing, and holding activities. For more information on each of these you can review the Produce Safety Overview in Appendix 6.

How Does This Relate to FSVP?

How Does This Relate to FSVP?

- You will need to identify whether or not your foreign supplier is required to comply with:
 - PC for Human Food
 - PC for Animal Food
 - Produce Safety
- If your foreign supplier is required to comply, you must evaluate them and perform verification activities to assure that they are producing food that provides the same level of public health protection as these rules.
- Keep in mind that you also need to consider what other FDA food safety requirements apply to the foods that you import in determining and performing verification activities (e.g., low-acid canned foods (LACF), infant formula)



As stated earlier, this brief session is intended to let you know which of your suppliers must comply with the PC and Produce Safety rules. If you import food from these suppliers, you will have to verify that it is produced under the same level of public health protection as domestically produced food. You need to know something about these rules as you may be talking to your foreign supplier in order to satisfy FSVP requirements. Much of what your foreign supplier needs to do to satisfy the aims of the PC rules or Produce Safety rule will be useful to you in meeting your FSVP requirements. Keep in mind that you will also need to consider what other FDA food safety requirements apply to the foods you import when determining and conducting verification activities. For instance, FDA has additional requirements that must be considered beyond the PC rule for low-acid canned food or infant formula.

Preventive Controls and Produce Safety Session: Summary

Preventive Controls and Produce Safety Session: Summary

- In this session, we have covered:
 - Who must comply with the PC rules for human and animal food;
 - The key requirements of the PC rules for human and animal food;
 - Who must comply with the Produce Safety rule; and
 - The key requirements of the Produce Safety rule.



We hope this session has given you some familiarity with the main FSMA rules to which your foreign suppliers are subject. Familiarity with these rules will help you to not only have a conversation with your foreign suppliers on the subject of what you must do to comply with FSVP, but the steps and information they must carry out to meet their PC and Produce Safety goals should be helpful to you in implementing FSVP.

Preventive Controls and Produce Safety Session: Questions

Preventive Controls and Produce Safety Session: Questions

Thank you for your attention!

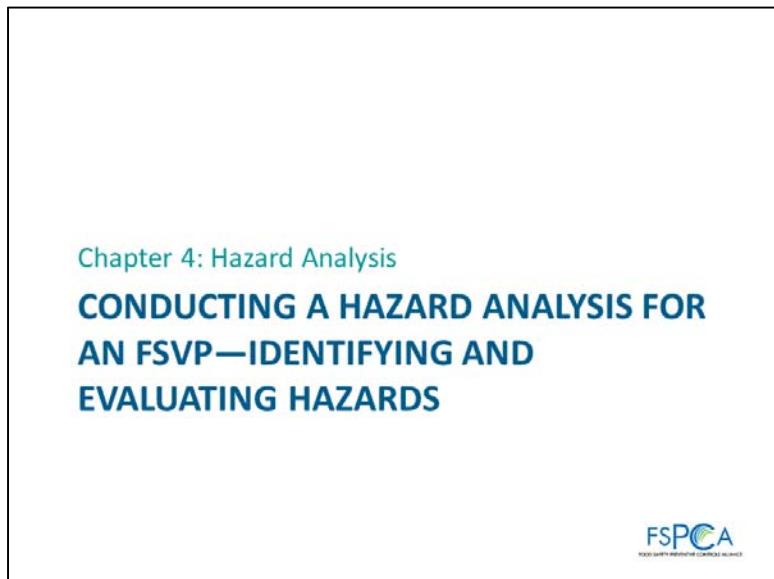
Questions?



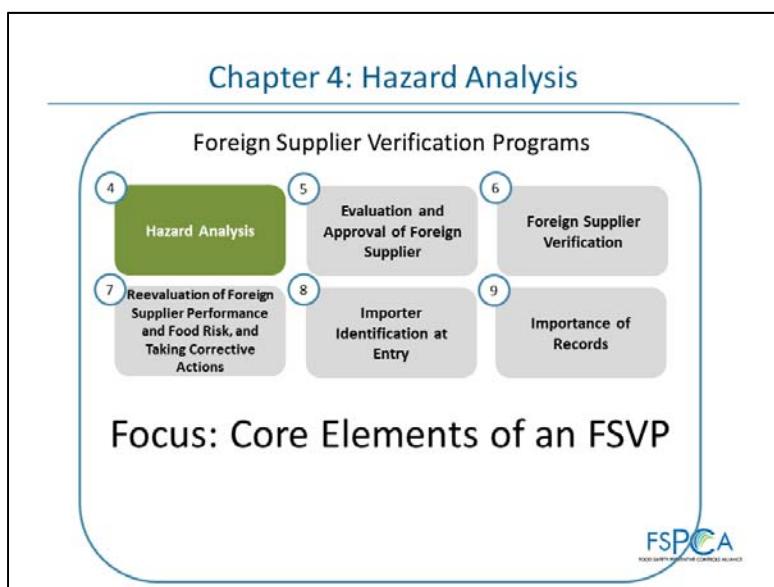
Blank Colored Insert-Front

Blank Colored Insert-Back

CHAPTER 4. Hazard Analysis



The first major task under the FSVP rule is to conduct a hazard analysis. Hazards identified and their risks considered through a hazard evaluation process are seen by FDA as the most effective way to implement a risk-based framework in which importers can evaluate potential products and suppliers and ensure that appropriate verification activities occur.



Chapter 4, Hazard Analysis, is the first chapter with a focus on the core elements (or standard requirements) of an FSVP and it is the first major task to be performed under the FSVP rule.

Chapter 4: Goal and Objectives

Chapter 4: Goal and Objectives

Goal: Participants will be able to evaluate “known or reasonably foreseeable” hazards in the food.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Define types of food hazards.
 2. Determine which hazards are associated with different types of food.
 3. Identify “known or reasonably foreseeable” hazards in each type of food you import.
 4. Describe what happens if no hazards requiring a control are identified.
 5. Document your hazard analysis.



Chapter 4 defines what a food hazard is and:

1. Defines the types of food hazards,
2. Explains that different types of foods are associated with different hazards,
3. Emphasizes the importance of identifying ‘known or reasonably foreseeable hazards’ requiring a control, and
4. Notes what happens if no hazards requiring a control are identified.

This chapter also points out the need to document your hazard analysis.

What Is a Hazard?

What Is a Hazard?

- A hazard in human or animal food is, “any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.”



It is important to be aware of the potential hazards that are associated with the food products you import. When hazards are understood, they can be controlled to significantly minimize or prevent illness or injury. This chapter introduces the definition of the term “hazard” and discusses types of hazards that are commonly of concern in producing and distributing food (see note to the right).

A hazard in human or animal food is, “any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in the absence of its control” (21 CFR part 1, Subpart L, Sec. 1.500).

Resources:

Much of the information in this chapter was adapted from the *Preventive Controls for Human Food Training Curriculum*, Chapter 8, Hazard Analysis.

What Is a Hazard? (continued)

- When hazards are not prevented or controlled:
 - They can cause illnesses and injuries to humans and animals.



When hazards are not significantly minimized, prevented, or controlled, they can cause illnesses and injuries to humans and animals.

How Do Food Hazards Occur?

How Do Food Hazards Occur?

- Hazards may be present in a food for any of the following reasons:
 - The hazard occurs naturally
 - The hazard is unintentionally introduced or incidentally present
 - The hazard may be intentionally introduced for purposes of economic gain



Hazards may be present in a food for any of the following reasons (21 CFR 1.504(b)(2)):

1. The hazard occurs naturally,
2. The hazard is unintentionally introduced, or
3. The hazard may be intentionally introduced for purposes of economic gain.

The fact that a hazard may be present naturally or occur by accident (unintentionally introduced) does not make the hazard any less hazardous. You will need to consider which hazards are most likely to occur naturally in the foods you import, as well as those that are most likely to be introduced unintentionally in those foods. More about this later.

Hazards that are intentionally introduced for purposes of economic gain—for example, a coloring agent to make a product appear fresher than it is—are not intended to cause illness or injury, but they sometimes do, and that's why they need to be identified. Note that hazards intentionally introduced to cause illnesses or injuries are the subject of a separate FDA final rule, “Mitigation Strategies to Protect Food Against Intentional Adulteration,” that was published in the Federal Register on May 27, 2016 (21 CFR Part 121).

Conducting a complete hazard analysis may be time consuming, but it is also very important. Systematic and thorough analysis of potential

hazards helps to ensure that all hazards requiring a control are identified.

“Known or Reasonably Foreseeable” Hazards

“Known or Reasonably Foreseeable” Hazards

- **Definition:** A biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with a food or the facility in which it is manufactured/processed.
(Food and Drug Administration (FDA), 21 CFR 1.500)

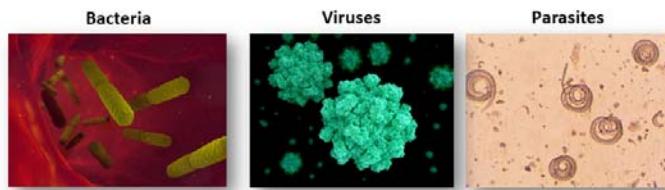


“Known or reasonably foreseeable” hazards are NOT hazards that are extremely rare or essentially unknown for the food being imported. There should be some history or known occurrence of the hazard occurring in the subject food or a similar food, or a good reason to believe the hazard could occur. Thus, you will likely need to research which food hazards have been associated with the foods you import.

What Types of Hazards Must I Consider?

What Types of Hazards Must I Consider?

- **Biological hazards**, including hazards such as bacteria, viruses, parasites, environmental pathogens, and other pathogens.



You are required to identify and consider all known or reasonably foreseeable hazards for the foods you import. The types of hazards that must be considered for each food include the following (21 CFR 1.504(b)(1)):

- Biological hazards, including hazards such as bacteria, viruses, parasites, environmental pathogens, and other pathogens,

What Types of Hazards Must I Consider? (continued)

- **Chemical hazards, including:**

- Radiological hazards,
- Pesticide and veterinary drug residues,
- Natural toxins,
- Products of decomposition,
- Unapproved food or color additives, and
- Food allergens in human food
- Nutrient deficiencies and toxicities (animal food) (1.504(b)(1)(ii))



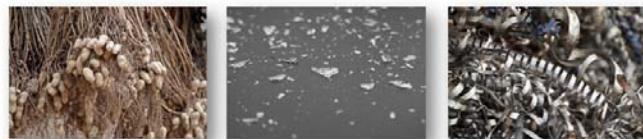
FSPCA
Food Safety Partnership Council

- Chemical hazards, including radiological hazards, pesticide and veterinary drug residues, natural toxins, products of decomposition, unapproved food or color additives, and food allergens, and

What Types of Hazards Must I Consider? (continued)

- **Physical hazards:**

- **Foreign objects** such as glass, metal, brittle plastic, wood and stones
- **Choking hazards** for young children



FSPCA
Food Safety Partnership Council

- Physical hazards, such as stones, glass, and metal fragments.

All these types of hazards that may reasonably or foreseeably occur in the food you are importing need to be identified as a first step in your hazard analysis.

Sources of Information About Food Hazards

Sources of Information About Food Hazards

- You will likely need to research which food hazards have been associated with the foods you import. A few good resources are:
 - FDA Reportable Food Registry
 - FDA Bad Bug Book
 - FDA Import Alerts



A useful source of information about the hazards that may be present in different foods is FDA's Reportable Food Registry available on at: [http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm](https://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm)

This registry collects information from the food industry and from public health authorities on foods that may cause serious adverse health consequences or death to humans or animals that consume them. Biological hazards are the primary category of food hazards that are reported, but undeclared food allergens are also a common food hazard.

FDA's Bad Bug Book is also a useful resource available at: [http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/](https://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/)

It provides technical information on foodborne pathogens in everyday language. In addition, FDA, the Centers for Disease Control and Prevention (CDC), the USDA, and food trade associations have other publicly available information that may be helpful to your situation.

And finally, FDA's Food Import Alerts page provides links to current import alerts at:

Resources:

Links to the FDA Reportable Food Registry, FDA Bad Bug Book, and FDA Import Alerts page are available below and in Appendix 7: Technical Assistance and Resources.

FDA Reportable Food Registry (RFR):

<https://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm>

FDA Bad Bug Book:

<https://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/>

FDA Import Alerts:

<https://www.fda.gov/industry/importprogram/actionsenforcement/importalerts/default.htm#list>

<https://www.fda.gov/forindustry/importprogram/actionsenforcement/importalerts/default.htm#list>

It provides information regarding products that appear to be in violation of FDA laws and regulations. The violations may be related to the product, manufacturer, shipper, and/or other information. You can browse by country/area, industry, the number assigned to each alert, or the last published date.

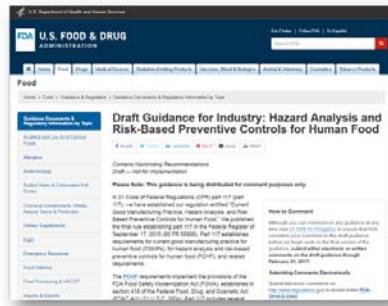
Resources:

Links to FDA Guidance Documents on Hazards are available in Appendix 7: Technical Assistance and Resources.

FDA Guidance Documents on Hazards

FDA Guidance Documents

- FDA's *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food* on FDA's website is another important resource.



Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food available at:
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517412.htm>



FDA has issued draft guidance on hazards and will continue to do so. Such guidance as illustrated in this slide provides extensive information on hazards and can be used as resources for performing hazard analyses.

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517412.htm>

An example of the first page of both biological and chemical hazards tables within the guidance are on the next page.

Preventive Controls Human Food Guidance— Appendix 1—Biological Hazards Tables

| Preventive Controls Human Food Guidance— Appendix 1—Biological Hazards Tables | | | | | | | | | | | | | | | |
|--|----|--|--------------------|-----------------|-----------------------|----------------|------------------|--------------------|-----------------|------------------|---------------------|-----------|------------------------|------------------------|--|
| Category | # | Subcategory | Storage Conditions | Bacillus cereus | Clostridium botulinum | C. perfringens | Escherichia coli | Campylobacter spp. | Salmonella spp. | L. monocytogenes | Staphylococcus spp. | S. aureus | Gram-negative bacteria | Histamine/scombrotoxin | Example Products |
| Unbaked Bakery Items - Ready-To-Bake (RTB) | 1a | Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust | Refrigerated | | | | X | X | X | | | | | | Buttermilk biscuits, Cinnamon rolls, Croissants, Pizza Crust, Chocolate Chip Cookie Dough, Puff Pastry, Phyllo |
| Unbaked Bakery Items - Ready-To-Bake (RTB) | 1b | Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust | Frozen | | | | X | X | X | | | | | | Buttermilk biscuits, Cinnamon rolls, Croissants, Pizza Crust, Chocolate Chip Cookie Dough, Puff Pastry, Phyllo |
| Unbaked Bakery Items - Ready-To-Bake (RTB) | 2a | Parbaked/ParBoiled Bread, Biscuits, Rolls, Pizza/Pie Crust | Refrigerated | | | | X | X | X | | | | | | Artisan breads, Bagels, Biscuits, Rolls, Croissant, Pizza Crust |
| Unbaked Bakery Items - Ready-To-Bake (RTB) | 2b | Parbaked/ParBoiled Bread, Biscuits, Rolls, Pizza/Pie Crust | Frozen | | | | X | X | X | | | | | | Artisan breads, Bagels, Biscuits, Rolls, Croissant, Pizza Crust |
| Unbaked Bakery Items - Ready-To-Bake (RTB) | 3 | Liquid Batter | Refrigerated | | | | X | X | X | | | | | | Pancake batter, Brownie batter, Waffle batter, and Doughnut batter |

The image on the slide above is taken from the first page of the biological hazards tables within the Preventive Controls Human Food Guidance document. It provides information as to what biological hazards may be found within a specific category of food product.

Preventive Controls Human Food Guidance— Appendix 1—Chemical Hazards Tables

| Preventive Controls Human Food Guidance— Appendix 1—Chemical Hazards Tables | | | | | | | | | | | | | |
|--|----|--|--------------------|----------------------|---------------|--------------|----------------------|-------------------------|------------|-------------------------------|------------|------------------|--|
| Category | # | Subcategory | Storage Conditions | Undeclared allergens | Drug residues | Heavy metals | Industrial chemicals | Nicotine/Natural toxins | Pesticides | Unapproved colors & additives | Biological | Example Products | |
| Unbaked Bakery Items - Ready-To-Bake (RTB) | 1a | Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust | Refrigerated | | | | | X | | | | | Buttermilk biscuits, Cinnamon rolls, Croissants, Pizza Crust, Chocolate Chip Cookie Dough, Puff Pastry, Phyllo |
| Unbaked Bakery Items - Ready-To-Bake (RTB) | 1b | Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust | Frozen | | | | | X | | | | | Buttermilk biscuits, Cinnamon rolls, Croissants, Pizza Crust, Chocolate Chip Cookie Dough, Puff Pastry, Phyllo |
| Unbaked Bakery Items - Ready-To-Bake (RTB) | 2a | Parbaked/ParBoiled Bread, Biscuits, Rolls, Pizza/Pie Crust | Refrigerated | | | | | X | | | | | Artisan breads, Bagels, Biscuits, Rolls, Croissant, Pizza Crust |
| Unbaked Bakery Items - Ready-To-Bake (RTB) | 2b | Parbaked/ParBoiled Bread, Biscuits, Rolls, Pizza/Pie Crust | Frozen | | | | | X | | | | | Artisan breads, Bagels, Biscuits, Rolls, Croissant, Pizza Crust |
| Unbaked Bakery Items - Ready-To-Bake (RTB) | 3 | Liquid Batter | Refrigerated | | | | | | | | | | Pancake batter, Brownie batter, Waffle batter, and Doughnut batter |

The image on the slide above is taken from the first page of the chemical hazards tables within the Preventive Controls Human Food

Guidance document. It provides information as to what chemical hazards may be found within a specific category of food product.

We will take a closer look at some of the potential biological, chemical, and physical hazards in the next few slides.

Potential Biological Hazards

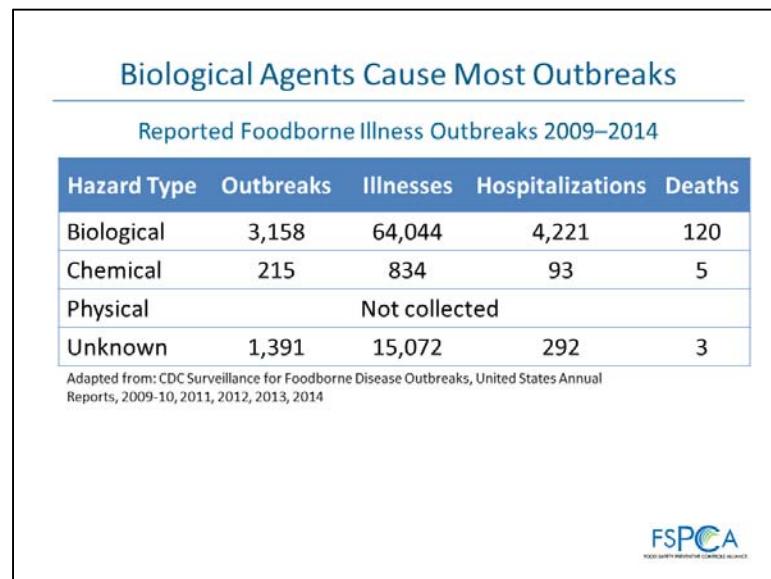
Potential Biological Hazards

- Microorganisms in foods may include:
 - Bacteria
 - Viruses
 - Protozoa
 - Yeasts
 - Molds
- Most microorganisms in food do not cause disease in humans or animals, but some do.



Most biological hazards belong to a group of living life forms that are too small to see with the naked eye, called *microorganisms*. Microorganisms are present in air, dirt, water, skin, hair, animal fur, plants, and numerous other sources like saliva and droplets expelled with coughs and sneezes. Microorganisms are classified into various groups including bacteria, viruses, protozoa, yeasts, and molds.

Biological Agents Cause Most Outbreaks



A compilation of data taken from multiple years of CDC surveillance data on foodborne disease outbreaks are illustrated here. The number of illnesses reported is just the “tip of the iceberg” because many foodborne illnesses are not reported to CDC; however, the data are useful to understand the types of hazards that are likely to cause illness.

Biological hazards, including bacteria, viruses, and some parasites, are the most frequently reported hazard group associated with foodborne illness in the U.S. Outbreaks caused by chemical agents are also reported, but as you can see, reported numbers are much lower than those for biological hazards. Food allergen reactions are not captured in these CDC data.

Allergic reactions are more sporadic, likely involving one person at a time, although mislabeled products containing allergens have been known to cause multiple cases of reactions before products are recalled. CDC surveillance systems do not report physical hazard outbreaks.

Resources:

To review U.S. residue limits (including action levels) for pesticides, heavy metals, animal drugs, or other contaminants in foods, review the information at the following links:

Chemical Contaminants, Metals, Natural Toxins, & Pesticides Guidance

Documents & Regulations:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ChemicalContaminantsMetalsNaturalToxinsPesticides/default.htm>

CPG Sec. 560.750

Radionuclides in Imported Foods - Levels ...

INSPECTIONS AND COMPLIANCE:

www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074576.htm

Action Levels for Poisonous or Deleterious Substances in Human and Animal Food:

<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm077969.htm>

Potential Chemical Hazards

Potential Chemical Hazards

- Naturally occurring
 - Food allergens, mycotoxins (mold toxins), decomposition by-products
- Used in food production
 - Food additives, color additives, pesticides, animal drug residues
 - Cleaning and sanitizing chemicals
- Others unintentionally present
 - Industrial chemicals, heavy metals, radionuclides



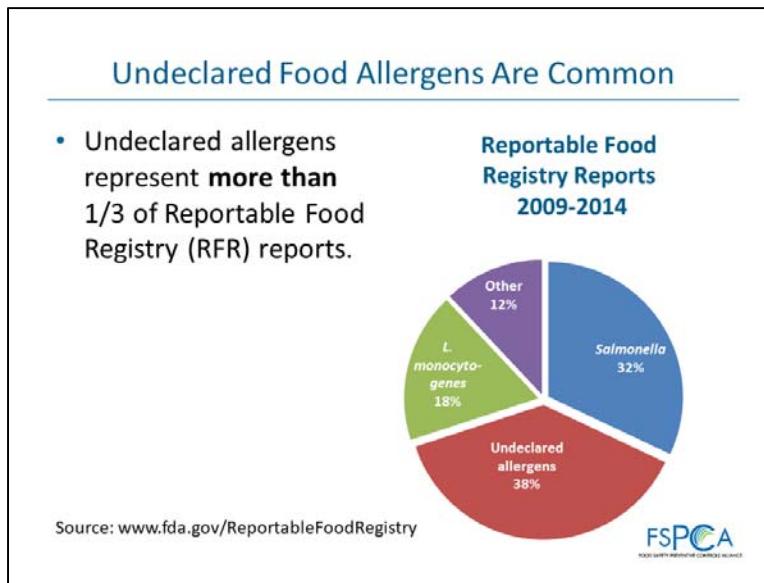
Contamination from chemical hazards can happen at any stage in food sourcing, production, processing, and distribution. Some “naturally occurring” chemical hazards are a natural component of a food, such as food allergens, or are produced in the natural environment generally unrelated to human activity, **such as mold toxins, called mycotoxins**. Other chemical substances may be hazardous due to errors in product formulation, such as sulfites or food additives. Still other chemical substances, such as pesticides and animal drugs used in the production of food, may not be used properly. While the residues of pesticides and animal drugs that are in current use in the U.S. are heavily regulated to assure safety, pesticides and animal drugs utilized in other countries on foods imported into the U.S. may not meet U.S. residue requirements.

It should be noted that pesticide and animal drug residues that violate U.S. residue requirements violate section 402 of the FD&C Act. In addition, food and color additives that violate the safe conditions of use (limits on amounts used and types of foods) specified in FDA food and color additive regulations also cause the food to be adulterated under section 402 of the FD&C Act.

Still other chemical hazards may be unintentionally present in the food, such as heavy metals from soil contamination, industrial chemical pollutants, or heavy metals such as arsenic, lead, and mercury may accumulate in plants if the growing environment has high concentrations of these chemical hazards. Examples include arsenic accumulation in rice, mercury accumulation in large fish, and lead accumulation in carrots grown in fields that previously were orchards treated with lead-based pesticides. Heavy metals may also leach from equipment if suitable materials are not used, especially for

food contact equipment. Levels of such chemicals that may cause the food to be injurious also cause the food to be adulterated under section 402 of the FD&C Act.

Undeclared Food Allergens Are Common



Food allergens are an example of a naturally occurring chemical hazard. Undeclared allergens in human foods represent about one third of the reports in FDA's Reportable Food Registry.

The RFR covers all human and animal food/feed (including pet food) regulated by FDA except infant formula and dietary supplements for which FDA has other mandatory reporting systems.

Many foods can cause an allergic reaction in people, but eight foods are responsible for over 90% of the allergic reactions in the U.S. These are milk, eggs, peanuts, tree nuts, fish, crustacean shellfish, wheat, and soy. Section 403(w) of the FD&C Act specifies the manner of identifying these major allergens on human food labels. Remember, the eight major allergens, if present in human food, are considered a hazard if they are not declared on food labels. For product groups like tree nuts, fish, and crustacean shellfish, the specific type of tree nut or fish must also be labeled.

Resources:

The RFR is an electronic reporting system, required by law, to enable persons to report promptly to FDA about a "reportable food." A reportable food is an article of food/feed that presents a reasonable probability that exposure to it will cause serious adverse health consequences or death to humans or animals. A report of all such instances is contained in the Reportable Food Registry Annual Report.

The link to the RFR is available in Appendix 7: Technical Assistance and Resources and below.

RER:

<https://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm>

Food Allergy

Food Allergy

- Food Allergy = adverse response by the body to foods containing allergenic proteins
- A minuscule amount of protein/allergen can trigger an allergic response
- Food allergy symptoms are unpredictable and vary from mild reactions to death
- Major allergens: milk, egg, peanut, tree nut, fish, crustacean shellfish, wheat, and soy require specific labeling



A food allergen reaction is a body's immunological response to proteins in the food that the body sees as foreign. Food allergens are naturally present in certain foods. These eight foods do not present a chemical hazard for most people. However, they can be life threatening for those with a food allergy. It is estimated that food allergies affect four to six percent of children and two to three percent of adults in the U.S. The presence of undeclared allergens in food is a major cause of product recalls. Therefore, it is important to label these allergenic foods or foods that contain these eight allergens appropriately.

Under the Preventive Controls (PC) for human food rule, the foreseeable inadvertent contamination of a food by a food allergen (food allergen cross-contact) is considered a hazard. It is even more important, therefore, to prevent the major food allergens from getting into foods where they are not intentionally being added, and thus, not labeled as present.

Potential Physical Hazards

Potential Physical Hazards

- Foreign objects – e.g., glass, brittle plastic, metal fragments, wood, stones
- May cause:
 - Choking hazards for young children
 - Cuts in mouth, internal organs
 - Broken teeth and other dental injury
- May require medical/dental attention and surgery



Key Point:

Note that physical adulterants such as hair, insects, and dirt may contaminate food but not be injurious to health. Thus, they may not constitute a hazard *per se*. Nevertheless, such physical adulterants may be indicators of insanitary conditions in the manufacture, handling, or storage of food and, therefore, indicate that chemical or biological hazards also could be present in the food. Of course, very high levels of physical contaminants like hair, insects, and dirt may by themselves be considered a hazard.

Physical hazards include any potentially harmful extraneous matter not normally found in food. Depending on the size and shape of the object, it may cause choking, injury in the mouth, or other adverse health effects. FDA's Health Hazard Evaluation Board has supported regulatory action against products with hard, sharp, and pointed fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length.

Glass fragments can cause injury to the consumer. Glass inclusion can occur whenever processing involves the use of glass containers, unprotected lighting, or process equipment with glass-front gauges and dials, for example. Normal handling and packaging methods, especially mechanized methods, can result in breakage.

Metal-to-metal contact in equipment can introduce metal fragments into products. Examples include mechanical cutting and blending operations and equipment that has parts that can break or fall off, such as wire-mesh belts or screens.

Certain ingredients, especially those of plant origin, may occasionally have stones or other hard objects present in the raw material. Depending on the size and shape of the hard object, they may present a hazard for dental injury or choking.

Economically Motivated Hazards

Economically Motivated Hazards

- Economically motivated adulteration of food is not intended to cause harm, but to increase profit margins.
- Still, such adulteration may introduce hazards to food.
- Focus should be on “known or reasonably foreseeable” hazards that may arise from economically motivated adulteration.



Hazards may be introduced into food for the purposes of economic gain. This type of adulteration, called Economically Motivated Adulteration, or EMA, may not be intended to cause harm, nor illness or injury, but sometimes it has happened that the economic adulterant produces a hazardous product. Such adulterants may increase the volume/weight of the food, e.g., peanut shells (a food allergen) in cumin; make the food more appealing, e.g., a coloring agent to make the food appear fresher; or improve the nutritional profile of the food, such as the first two examples below.

An example of a widespread incident of economically motivated adulteration occurred in China, where melamine, a nitrogen-rich industrial by-product, was added to diluted dairy products by some milk firms to increase the apparent protein content. This resulted in more than 290,000 ill infants and 6 deaths in that country.

Melamine was also added to pet foods exported from China to the U.S. and elsewhere, resulting in many pet deaths, until the cause of the deaths was determined to be the food. Melamine had been added to increase the nitrogen levels so protein levels appeared higher on chemical analysis.

Another example of economically motivated adulteration is the addition of dyes containing lead to ingredients such as spices or candy to enhance color. Lead can accumulate in the body over time and cause health problems such as impaired cognitive development in children. Lead chromate, a chemical with a vibrant yellow color, has been an adulterant in turmeric to change the color (FDA 2013). A number of years ago, lead oxide, a red chemical, was found as an adulterant in paprika, having been used to enhance its color. This

resulted in dozens of illnesses and several deaths in Hungary (Anon. 1995).

The FSVP preamble states “[A]s with other hazards, importers need only consider EMA hazards that are known or reasonably foreseeable. This means that importers are not required to consider purely speculative hazards. We expect that EMA hazards will be identified in rare circumstances, usually in cases where there has been a pattern of EMA in the past.” The rule also states that “information about incidents of EMA is widely available from public sources...” and provides several references in this regard.

Who Must Perform My Hazard Analysis?

Who Must Perform My Hazard Analysis?

- A qualified individual must develop your FSVP and perform each required FSVP activity, beginning with hazard analysis.
- Remember, a qualified individual must have the education, training, or experience (or a combination thereof) necessary to perform **assigned activities**, whatever that activity may be.
 - In this case, your qualified individual under the FSVP rule must be qualified to identify and evaluate the risks of hazards associated with the food you import.



Because your FSVP is based on determining the known or reasonably foreseeable hazards in the foods you import and evaluating the risks posed by the food and your foreign supplier's performance, these activities must be conducted by someone who has the knowledge and expertise to perform them properly. Under the FSVP rule, you as an importer must use a “qualified individual” to develop your hazard analysis and evaluate the risks.

It should be noted that the qualified individual you utilize to carry out the hazard analysis may also be able to carry out all the tasks required by the FSVP rule. The point is that a qualified individual must have the necessary capabilities to carry out FSVP activities that are in line with his/her education, training, or experience (or a combination thereof). For example, one QI might prepare the FSVP in consultation with other QIs who have microbiological or chemistry analytical expertise. Those QIs may then also need to review verification steps requiring their expertise, again in concert with the QI who is responsible for the overall FSVP. Also remember the person(s) you use as a qualified

individual(s) can be an employee of your company, but it is not necessary that the person be an employee.

What Hazard Analysis Must I Conduct?

What Hazard Analysis Must I Conduct?

- Your qualified individual under the FSVP rule must conduct a hazard analysis to identify and evaluate—based on experience, illness data, scientific reports, and other information:
 - Whether there are “known or reasonably foreseeable” hazards for each type of food you import.
 - Whether the identified hazards require a control.
- Your hazard analysis must be **written** regardless of its outcome:
 - For example, even if the hazard analysis results in no hazard requiring a control, this conclusion and the performance of the hazard analysis must be documented still.



To begin, the person you have chosen who is qualified to conduct a hazard analysis (a “qualified individual”) identifies known or reasonably foreseeable hazards for each type of food you import.

After identifying the known or reasonably foreseeable hazards, your qualified individual under the FSVP rule must evaluate them to determine whether there are any hazards requiring a control (21 CFR 1.504(a)). This evaluation must be based on experience, illness data, scientific reports, and other information.

FDA stated in preamble response 117 that, “any reliable source, not just FDA, would be relevant.... For example, importers might consider data on foodborne illnesses published by the Centers for Disease Control in determining whether hazards that cause such illnesses are hazards that require a control.” FDA also said, “For example, it might be appropriate to conduct a hazard analysis for multiple product sizes of a particular food, or to conduct one hazard analysis applicable to two or more related foods that are manufactured, processed, grown, or harvested under very similar conditions if all such food involves the same hazards.”

Whether evaluating transportation practices is necessary will depend on the supplier and the food being imported. If certain transportation practices could lead to hazards, an importer would need to verify that such hazards are significantly minimized or prevented.

Remember that your foreign supplier may have already performed a hazard analysis—and food manufacturers/processors are required to

do one under the PC rules for human and animal food—so your qualified individual under the FSVP rule may be able to review and assess your foreign supplier's hazard analysis.

Your hazard analysis must be written regardless of whether your qualified individual identifies a hazard needing a control.

Associating Hazards with Different Types of Food

Associating Hazards with Different Types of Food

- Past experience indicates that different types of foods are most commonly associated with certain hazards, and this can be a starting point for your hazard analysis.
- For instance, if you are importing a food that's packaged in glass jars, you should consider the potential for broken glass in that food.
- Additional examples of food and associated hazards:
 - *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food* (August 2016)



Key Point:

Manufacturers and processors of most foods will be conducting a hazard analysis for each of their foods. If you plan to import any of those foods into the U.S., you should ask your foreign suppliers for their hazard analysis.

Past experience with food safety problems indicates that different types of foods are most often associated with certain hazards, and this can be a starting point for your hazard analysis. For instance, if you are importing food that is packaged in glass jars, you should consider the potential for broken glass in that food.

FDA has issued draft guidance (for public comment) to help producers of food that are subject to the PC rule for human food to comply with the new requirements. Included are guidance and extensive resources on conducting a hazard analysis that could be helpful to FSVP importers in carrying out their hazard analyses. The *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food* (August 2016) is available at:

<http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM517394.pdf>

FDA may provide additional more resources for conducting hazard analyses in the future.

Identifying Hazards for Each Food

Identifying Hazards for Each Food

- Consider:
 - The type of food (fresh produce, processed food),
 - The source of the food (geographic region, country),
 - Who may be having an effect on the potential hazards (supplier, other handlers, transporters, customers, consumers),
 - The types of hazards that have arisen with similar foods in the past, and
 - Anything else that might introduce/suggest potential hazards with the food you import.



You need to identify the hazards for each food you import. You should consider:

- The type of food (e.g., fresh produce),
- Where the food originates,
- Who may be having an effect on the hazard (e.g., cause, prevent, or control),
- The types of hazards that may have arisen with similar foods in the past, and
- Anything else that might suggest potential hazards with the food you import.

Identified Hazards Must Be Evaluated

Identified Hazards Must Be Evaluated

- The hazard analysis must include an evaluation of the identified hazards to assess:
 - **The probability that the hazard will occur in the absence of controls, and**
 - **The severity of the illness or injury if the hazard were to occur.**
- The evaluation of the identified hazards helps you assess the consequences of not having a control for those hazards.



Your hazard analysis must include an evaluation of all the hazards you have identified to assess the probability that the hazard will occur in the absence of appropriate controls, **e.g., is a pathogen likely to contaminate a food without frequent and appropriate cleaning/sanitizing.**

Your hazard analysis also needs to assess the severity of the illness or injury if the hazard were to occur (21 CFR 1.504(c)(1)). The severity of a food safety hazard depends on a number of factors that may include the likelihood of a serious outcome (**e.g., choking hazard**), how long an individual is sick, whether disease symptoms are mild or severe (**e.g., whether hospitalization or death is common**), whether there are full recovery or health issues that persist for long periods of time, and whether the food's targeted consumer is a member of a vulnerable population such as infants, children, the elderly, or the immunocompromised. Again, information is available from government, scientific literature, and trade association resources, as well as the experience and knowledge of the qualified individual conducting the evaluation.

Resources:

Information resources for conducting the evaluation:

Centers for Disease Control and Prevention (CDC): Current Outbreaks List:

<http://www.cdc.gov/outbreaks/index.html>

Multistate Foodborne Outbreak Investigations:

<http://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html>

FDA Recalls, Market Withdrawals, & Safety Alerts:

- Import Alerts Industry

Group Foods:

http://www.accessdata.fda.gov/cms_ia/industrygroup_1.html

Identified Hazards Must Be Evaluated (continued)

- The hazard evaluation must include an evaluation of environmental pathogens whenever:
 - A ready-to-eat food is exposed to the environment before packaging, and
 - The packaged food does not receive a treatment or otherwise include a control or measure that would significantly minimize the pathogen.



Your hazard evaluation must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment before packaging and the packaged food does not receive a treatment or otherwise include a control or measure that would significantly minimize the pathogen (21 CFR 1.504(c)(2)). This evaluation is necessary to address the potential for a ready-to-eat food to become contaminated between the time it is prepared and the time it is consumed.

Information resources for conducting this evaluation include researching past outbreaks, which can be done on the CDC's website <http://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html>.

You will also want to research current and past recalls on FDA's website <http://www.fda.gov/Safety/Recalls/>, along with reviewing the scientific literature and establishment experience. FDA guidance, trade association information, and university extension documents also provide useful information on the likely occurrence of hazards in certain foods.

What Must Be Considered in a Hazard Evaluation?

What Must Be Considered in a Hazard Evaluation?

The hazard evaluation must consider the effect of the following factors on the safety of the finished food for the intended consumer:

1. The formulation of the food
2. The condition, function, and design of the establishment and equipment of a typical entity that manufactures/processes, grows, harvests, or raises this type of food
3. Raw materials and other ingredients
4. Transportation practices

(List continued on the next slide)



In the FSVP rule, FDA concluded that it is appropriate that importers evaluate certain factors related to a food and the foreign supplier in deciding what supplier verification activities (and the frequency of these activities) are needed to provide adequate assurance of the safety of the food. These are the same types of factors that manufacturers/processors are to consider under the PC rules.

The FSVP rule provides that your hazard evaluation for the foods you import must consider the effect of the following on the safety of the finished food (21 CFR 1.504(c)(3)):

1. The formulation of the food,
2. The condition, function, and design of the establishment and equipment of a **typical entity** that manufactures/processes, grows, harvests, or raises this type of food,
3. Raw materials and other ingredients,
4. Transportation practices, (list is continued on the next page)

Key Point:

When analyzing hazards, you must consider who is significantly minimizing, controlling, or preventing the hazards, even if it is not your foreign supplier. For example, some perishable food must be refrigerated properly for food safety after it leaves the foreign supplier.

This will be discussed in more detail in Chapter 5: Evaluating the Foreign Supplier's Performance and Food Risk.

What Must Be Considered in a Hazard Evaluation? (continued)

The hazard evaluation must consider the effect of the following factors on the safety of the finished food for the intended consumer (continued):

5. Harvesting, raising, manufacturing, processing, and packing procedures
6. Packaging and labeling activities
7. Storage and distribution
8. Intended or reasonably foreseeable use
9. Sanitation, including employee hygiene
10. Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of natural toxins).



5. Harvesting, raising, manufacturing, processing, and packing procedures,
6. Packaging and labeling activities,
7. Storage and distribution,
8. Intended or reasonably foreseeable use,
9. Sanitation, including employee hygiene, and
10. Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of natural toxins).

A number of these factors are facility or supplier-specific. So, the question becomes, how can you assess all these factors if you are not on site where the food is produced or grown?

How Will You Know About These Factors?

How Will You Know About These Factors?

- FDA recognized in the preamble to the FSVP rule that while the hazard analysis provisions for FSVP and Preventive Controls are similar, they are not the same.

"The former [FSVP] generally apply to importers who must analyze the hazards in the foods produced by their foreign suppliers, while the latter [Preventive Controls] primarily apply to food facilities that must determine the hazards for the food that they themselves manufacture, process, pack, or hold."



Clearly, a Preventive Controls qualified individual preparing a Food Safety Plan for a processing facility under the PC rules, will likely have a lot of information at their fingertips, as well as experience and knowledge, to carry out a hazard analysis for the hazards associated with the facility itself, its equipment, the ingredients, and finished foods it produces. A qualified individual performing an FSVP hazard evaluation is in a very different position in carrying out its evaluation of a food, be it an ingredient, fresh produce, or finished manufactured food. FDA acknowledged this in the FSVP rule. FDA noted in the preamble to the FSVP rule that while the hazard analysis provisions for FSVP and PC rules are similar, they are NOT the same.

"The former generally apply to importers who must analyze the hazards in the foods produced by their foreign suppliers, while the latter primarily apply to food facilities that must determine the hazards for the food that they themselves manufacture, process, pack, or hold." (FDA response to comment 115, 80 FR).

FDA will likely provide additional guidance to help importers better understand how they must evaluate hazards utilizing these factors that involve the operations of their foreign suppliers.

Key Point:

FDA also responded in the preamble to comments asking how importers, without an on-site audit, would know about the "condition, function, and design of the establishment and equipment..." saying:

"Importers can obtain information about the nature of establishments that produce a particular food and the equipment they use by consulting ...for example, trade journals and other publications, academic literature, and materials obtained directly from potential foreign suppliers."

The Importance of Site-Specific Information

The Importance of Site-Specific Information

- Foreign manufacturers/processors and growers who produce the food you import will likely have information for you to complete your hazard analysis:
 - Request information from them early.
 - Those subject to Preventive Controls (PC) rules may have conducted their own hazard analysis, as part of their Food Safety Plan.
 - Growers of produce may have also prepared a hazard analysis or have the information necessary for you to prepare yours.



If the food you are importing is the type of food that is covered by either of the PC rules, you can expect the manufacturer/processor to be knowledgeable about the food, and they likely know more about their facility than anyone else. If they have done a hazard analysis for the food produced in their facility, you may want to rely on their hazard analysis.

Likewise, it is possible that growers of produce will have the information for completion of your hazard analysis or may have conducted a hazard analysis themselves, which you can then review.

The overview of the PC rules and the Produce Safety rule in Appendix 6 can give you some ideas about the information that could be provided by your foreign suppliers.

Reviewing Another Entity's Hazard Analysis

Reviewing Another Entity's Hazard Analysis

- If **another entity** (including your foreign supplier) has analyzed the “known or reasonably foreseeable” hazards for the food to determine whether there are any hazards requiring a control:
 - You may meet your requirement to determine whether there are any hazards requiring a control in the food by **reviewing and assessing** the hazard analysis conducted by that entity.



If another entity (including your foreign supplier) has analyzed the known or reasonably foreseeable hazards for the food to determine whether there are any hazards requiring a control, you may meet your requirement to determine whether there are any hazards requiring a control in the food by reviewing and assessing the hazard analysis conducted by that entity (21 CFR 1.504(d)).

It is likely that many importers will choose to rely on a hazard analysis provided by their foreign suppliers.

Reviewing Another Entity's Hazard Analysis (continued)

- Your review and assessment of that hazard analysis must be documented by your qualified individual under the FSVP rule, and
- Must include documentation that:
 - The hazard analysis was conducted by a qualified individual, and
 - Your review was carried out by a qualified individual.



Your qualified individual under the FSVP rule must document that the hazard analysis was carried out by qualified individuals.

Hazards in Produce

Hazards in Produce

- If you are importing a raw fruit or vegetable that is “covered produce” (defined in Produce Safety rule):
 - You are not required to determine the biological hazards in such food, because
 - The Produce Safety rule requires the grower to control the biological hazards in such fruits or vegetables.
- But, you must determine whether there are any other hazards requiring a control.



The Produce Safety rule is focused on preventing biological hazards in fresh produce. Therefore, if you are importing a raw fruit or vegetable that is “covered produce” as defined in the Produce Safety rule (specifically, 21 CFR 112.3), you are not required to determine whether there are biological hazards in such food because the biological hazards in those foods require a control and compliance with the Produce Safety rule (21 CFR 112) significantly minimizes or prevents those hazards (21 CFR 1.504(e)).

You must, however, determine whether there are any other hazards requiring a control (21 CFR 1.504(e)). Knowing where and how the food is grown can help you make this determination. If you determine that there are other hazards requiring a control, you must evaluate those hazards as described above.

What If No Hazards Require a Control?

What If No Hazards Require a Control?

- If you evaluate the known or reasonably foreseeable hazards in a food and determine that there are no hazards requiring a control:
 - You are not required to conduct an evaluation for the purpose of foreign supplier approval and verification, and
 - You are not required to conduct foreign supplier verification activities.

Key Point:

If there are no hazards that require a control, you still must document that you performed the hazard analysis.



Under the FSVP rule, if you evaluate the known or reasonably foreseeable hazards in a food and determine that there are no hazards requiring a control:

1. You are not required to conduct an evaluation for the purpose of foreign supplier approval and verification, and
2. Also, you are not required to conduct foreign supplier verification activities—unless the food is a raw agricultural commodity (RAC) that is a fruit or vegetable and considered “covered produce” as defined under the Produce Safety rule in 21 CFR 112.3 (21 CFR 1.504(f)).

Note: Remember that importers of RACs covered by the produce rule will still need to conduct verification activities for biological hazards, even if they do not identify any chemical or physical hazards.

Hazard Analysis Process in Brief

Hazard Analysis Process in Brief

- Identify known or reasonably foreseeable food safety hazards, based on the food type and how food is grown/handled/processed
- Determine if the hazard requires a control
 - Severity and probability in the absence of a control
- Justify/document the decision



So, as the FSVP importer, you need to:

- Identify “known or reasonably foreseeable” hazards,
- Determine if the hazard requires a control based on the probability of illness or injury and the severity of the harm if the hazard is not controlled,
- Justify your decision in writing.

Example of a Preventive Controls Hazard Analysis Form

| Hazard Analysis | | PRODUCT: | | | PAGE X of Y |
|---|---|--|---|---|-------------|
| PLANT NAME | | | ISSUE DATE | | mm/dd/yy |
| ADDRESS | | | SUPERSEDES | | mm/dd/yy |
| (1) Ingredient/ Processing Step | (2) Identify potential food safety hazards introduced, controlled or enhanced at this step | (3) Do any potential food safety hazards require a preventive control? | (4) Justify your decision for column 3 | (5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i> | |
| | | | | Yes | No |
| B | | | | Yes | No |
| C | | | | | |
| PC Hazard Analysis Form Example – other formats may be used | | | | | |



The Preventive Controls (PC) hazard analysis form example on the slide relates to the hazard analysis process for products that are governed by the PC rule for human foods. It is included here to illustrate a systematic approach to conducting a hazard analysis and to provide a means of comparing some of the differences between the PC hazard analysis and an FSVP hazard analysis shown on the slide below.

Example of an FSVP Hazard Analysis Form

| Example of an FSVP Hazard Analysis Form | | | | | | |
|---|--|--|----|-------------------------|---|--|
| IMPORTER NAME | | DATE | | | | |
| ADDRESS | | QJ APPROVAL | | | | |
| FSVP Food Hazard Analysis (HA) Form Example* | | | | | | |
| (1) Food/Food Product | (2) Identify known and/or reasonably foreseeable food safety hazards <small>B=Biological C=Chemical P=Physical</small> | (3) Do any food safety hazards require a control? | | (4) If yes, by whom? | (5) Justify your decision for column 3 | (6) Describe the nature of the control(s) |
| | | Yes | No | | | |
| | B | | | | | |
| | C | | | | | |
| | P | | | | | |
| HA Performed by Another Entity (If yes, describe your assessment of HA and include Entity's name, address, email, and date of HA)** | | | | | | |
| <small>*All supporting documentation should be appended to this form **If another entity performs the HA, you may meet the requirement to determine whether there are any hazards requiring a control in the food by reviewing/assessing the HA performed by that entity. Your review/assessment of the HA must include documentation that the HA was</small> | | | | | | |
| FSVP Hazard Analysis Form Example – other formats may be used | | | | | | |

The FSVP hazard analysis form example on the slide relates to the hazard analysis process for food that is imported and is governed by the FSVP rule. The format is not mandatory under the rule, but it is an example of a format that importers might use when performing a hazard analysis as part of the FSVP. The form could be modified as needed to fit many of the situations that you may face.

Chapter 4: Summary

Chapter 4: Summary

- In this chapter, we have covered:
 - The types of food hazards.
 - How hazards may be associated with different foods.
 - How to identify known or reasonably foreseeable hazards.
 - If there are no known or foreseeable hazards requiring a control, you don't need to verify that hazards are being controlled.
 - That your qualified individual under the FSVP rule needs to perform and document your hazard analysis or document the assessment of another entity's hazard analysis.



This chapter has covered:

- The types of food hazards.
- How hazards may be associated with different foods.
- Identification of known or reasonably foreseeable hazards.
- That you don't need to verify that hazards are being controlled if there are no known or reasonably foreseeable hazards requiring a control.
- That your qualified individual under the FSVP rule needs to perform and document your hazard analysis or document the assessment of another entity's hazard analysis.

Chapter 4 Exercise: “Identify ‘Known or Reasonably Foreseeable’ Hazards”

Chapter 4 Exercise: “Identify ‘Known or Reasonably Foreseeable’ Hazards”

- **Timing:** 45 minutes total
 - 5-10 minutes to obtain examples (2-3 examples) and describe process for each example.
 - 35-40 minutes to identify any “known or reasonably foreseeable” hazards for each example.
- **Directions:**
 1. Review the example.
 2. Use two or three examples of food products imported by participants for the exercise.
 3. Describe the process each example food product goes through to be sure everyone has an understanding of the potential hazards.
 4. Walk-through identifying any “known or reasonably foreseeable” biological, chemical, and physical hazards.

Note: This exercise is NOT a hazard analysis; it is only one step within the hazard analysis. The goal of the exercise is to identify “known or reasonably foreseeable” hazards.



This exercise will provide you with the opportunity to practice identifying “known or reasonably foreseeable” food safety hazards for specific food products.

Directions: The instructor will review the example with the class and then will ask for two to three examples from the participants to use in the exercise. The participants or the instructor, as appropriate, will describe the process the food goes through. The class will walk-through identifying the “known or reasonably foreseeable” food safety hazards for each example.

“Identify ‘Known or Reasonably Foreseeable’ Hazards” Exercise Example

“Identify ‘Known or Reasonably Foreseeable’ Hazards” Exercise Example

| Example for Review | | | |
|---|--|--|--|
| Ingredient/ Food Product | Biological | Chemical | Physical |
| <i>Enter an imported ingredient/food product in this column; ask participants to describe the process the ingredient/food goes through, if applicable</i> | <i>Have participants identify any “known or reasonably foreseeable” biological hazards</i> | <i>Have participants identify any “known or reasonably foreseeable” chemical hazards</i> | <i>Have participants identify any “known or reasonably foreseeable” physical hazards</i> |
| Pumpkin seeds | <i>Salmonella spp.</i> | Mycotoxins/natural toxins Pesticides Illegal and/or undeclared colors Sulphites | Metal Glass |



FOOD SAFETY PATHWAY CONTROL AGENCY

This slide is an example of what the class will be doing during the exercise. During the whole group exercise, you may want to go to the Exercise Workbook, Chapter 4, starting on page 12, where there are tables for each example the class will be working through.

Notes:

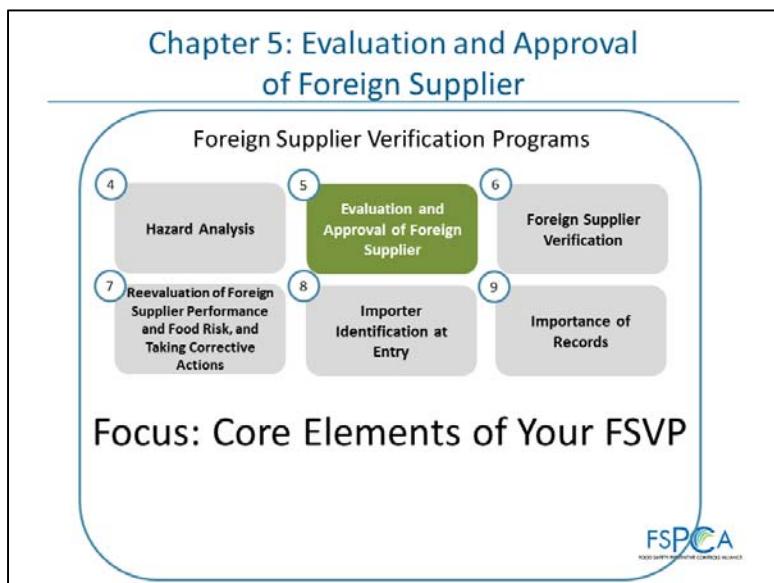
Blank Colored Insert-Front

Blank Colored Insert-Back

CHAPTER 5. Evaluation and Approval of Foreign Supplier



Chapter 5 deals with your evaluation and approval of your foreign suppliers.



Chapter 5 is the second chapter in the core elements (or standard requirements) of your FSVP. The FSVP rule requires that you approve your suppliers **before** importing food from them, so this part of your FSVP is very important.

Chapter 5: Goal and Objectives

Chapter 5: Goal and Objectives

Goal: Participants will be able to approve foreign suppliers.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Describe factors to consider when evaluating foreign supplier.
 2. Ascertain who is controlling hazards.
 3. Determine what food safety requirements apply to your foreign supplier/food.
 4. Research the history of the foreign supplier with FDA food safety requirements.



This chapter will focus on evaluating your foreign supplier's performance, both processes and procedures, as well as your supplier's food safety performance and history of compliance with FDA safety requirements. In addition to your food hazard evaluation, this evaluation can have some bearing on your determination of the actual food safety risk and, thus, whether you can approve your supplier for importing food. You must approve each of your foreign food suppliers for each food you import on the basis of these evaluations and **before** you start importing food from them.

The chapter also explains how knowing who will be controlling the hazard is not only important in performing your foreign supplier evaluation and approval, but also in determining which verification activities will be appropriate to ensure food safety requirements are met.

Remember that if you have evaluated the “known and reasonably foreseeable” hazards in the food you import and determine that there are no hazards requiring a control, you do not have to evaluate your foreign supplier’s performance, approve your supplier, nor conduct foreign supplier verification activities. (1.504(f))

Hazard Analysis vs. Evaluation of Foreign Supplier Performance

Hazard Analysis vs. Evaluation of Foreign Supplier Performance

- Your hazard analysis is primarily directed at determining whether there is a known or reasonably foreseeable hazard in the food that requires a control.
- Your evaluation of the foreign supplier is aimed at determining if the supplier can be approved for sourcing food for import.



Your hazard analysis is primarily aimed at determining if there are hazards in the food requiring controls. Your evaluation of the foreign supplier is directed at determining how those hazards are being controlled and whether your supplier should be approved. A qualified individual under the FSVP rule must evaluate your foreign supplier's performance (21 CFR 1.505(a)), taking into account the hazard analysis and who is controlling the hazards.

Food Hazard Analysis, Hazard Control, and Evaluation of Performance Are the Basis for Your Approval

Food Hazard Analysis, Hazard Control, and Evaluation of Performance Are the Basis for Your Approval



Key Point:

Although your approval of a foreign supplier must be documented, FDA does not require documentation of the evaluations of suppliers that importers do not approve.

Approval of your foreign supplier will be based on your food hazard analysis, who is controlling the hazard(s), and the evaluation of your foreign supplier's performance. We will discuss these in more detail in the upcoming slides and text.

Factors to Consider when Evaluating Your Foreign Supplier

Factors to Consider when Evaluating Your Foreign Supplier

- **Evaluation of a foreign supplier's performance and the risk posed by a food must consider:**
 1. The hazard analysis and nature of hazard requiring a control
 2. Who is controlling the hazard
 3. Foreign supplier performance, including:
 - The foreign supplier's food safety practices,
 - The foreign supplier's food safety history (e.g., testing, audits, responsiveness in correcting problems),
 - Whether the supplier's food and/or the supplier have been found by FDA to be in violation of U.S. requirements, and
 - Other factors (e.g., storage, transport), as appropriate.



In evaluating your supplier's performance and food risk, as it is called in the FSVP rule, you must also consider your hazard analysis, including the nature of the hazard requiring a control, as well as **who**, in fact, is the entity or entities that will be significantly minimizing or preventing the hazard(s). For example, your supplier may be utilizing a supply chain preventive control by requiring aflatoxin (a mycotoxin produced by a fungus often present in corn) testing results on every shipment of corn meal used to make a corn bread mix. In this case, the supplier's supplier is implementing the control, and your supplier is setting the specification and verifying that it is met.

In evaluating your foreign supplier, you are evaluating the supplier's food safety processes and procedures, as well as the supplier's history demonstrating food safety and history of food safety problems. You may wish to request a copy of your foreign supplier's Food Safety Plan (if your supplier is subject to a Preventive Controls rule) or a description from your foreign produce supplier on how the supplier is complying with the Produce Safety rule, to assist you in performing your evaluation of your suppliers' processes and practices.

Hazard Analysis and Who Controls the Hazard

Hazard Analysis and Who Controls the Hazard

- The hazard analysis and who is controlling the hazard must be considered when evaluating the foreign supplier's performance.
- Note that when the hazard is being controlled after importation, there is no need to do an evaluation of the supplier's performance.



You, as the FSVP importer, must consider the nature of the hazards requiring a control, recognizing that different types of hazards from different sources need to be dealt with in different ways. Your FSVP must focus on those hazards requiring a control, and who is responsible for their control (there may be more than one party responsible for the hazard's control)—whether they are being controlled by your foreign supplier, or, for example, your foreign supplier's supplier. As explained further in Chapter 6, there are modified requirements in 1.507 when the hazard is being controlled after importation into the U.S. In that case, there is no need to do an evaluation under 1.505.

How do you do this? Well, let's look at an example.

Example: A Hazard Requiring a Control

Example: A Hazard Requiring a Control

- You wish to import dried navy beans.
- Your supplier processes many types of beans such as pinto beans, great northern beans, soy beans, adzuki beans, and cannellini beans.
- You recognize that **soy** is an allergen and are concerned that your dried navy beans might be susceptible to cross-contact with this allergen.
- You need to verify that your supplier is effectively preventing allergen cross-contact, prior to approval of your foreign supplier.



Let's say that your foreign supplier regularly ships dried navy beans to you. The foreign supplier also processes other beans, including soy beans. **Your job is to verify** that the foreign supplier is implementing controls to significantly minimize or prevent allergen cross-contact from the soy beans throughout the process within the manufacturing facility. Your foreign supplier may apply a variety of controls, for example:

Allergen Control Procedures

- Scheduling protocols
- Clean-out procedures
- Change-out procedures
- Personnel practices
- Transportation practices
- Procedures for allergen testing in critical process area



Multiple preventive controls for the soy hazard can fall into various types of preventive controls, as illustrated in this slide. The need for allergen controls was determined through the hazard analysis process. The allergen control practices depend on who is implementing the control, the product, and manufacturing practices.

Foods That Cannot Be Consumed Without an Appropriate Control

Foods That Cannot Be Consumed Without an Appropriate Control

- When a food has a hazard, but it is the type of food that cannot be consumed without application of an appropriate control:
- **You are not required to:**
 - Conduct an evaluation of a foreign supplier performance, nor
 - Perform supplier verification activities for that hazard.
- **You must:**
 - Document your determination that the food falls into this category.
 - Perform a supplier verification for other hazards (see Chapter 6).
- For example, consumers aren't expected to eat raw coffee beans because beans are normally roasted before consumers consume them, which would address the reasonably foreseeable hazards.



Key Point:

Although an importer does not need to conduct an evaluation of nor approve the foreign supplier if the food does not present a hazard requiring a control, the importer must be identified as the FSVP importer at the time of entry.

As stated previously, you are not required to conduct an evaluation of a foreign supplier, approve the supplier, or perform supplier verification activities, if your hazard analysis does not demonstrate a hazard requiring a control. The same is true when you identify a hazard requiring a control and you determine that the type of food (e.g., a raw agricultural commodity such as coffee beans, as illustrated on the slide, or cocoa beans) could not be consumed without application of an appropriate control for that hazard, or if that hazard will be controlled by your customer or further down in the distribution chain in certain circumstances.

The point here is that coffee or cocoa beans, for example, are rarely consumed without significant processing that will control certain hazards associated with the raw beans while the beans are converted into something (hopefully tasty) for consumers to eat. Be careful, however, in making this determination for other foods as some toxins are known to persist through processing.

You must also document your determination that the food could not be consumed without application of an appropriate control.

Key Point:

Although produce that is rarely consumed raw is not covered by the Produce Safety regulation (see 21 CFR 112.2(a)(1)), importers of such produce will need to determine whether it has any chemical or physical hazards requiring a control. If produce rarely consumed raw has a chemical or physical hazard that is to be controlled before importation, the importer will need to conduct supplier evaluation, approve the supplier, and perform supplier verification activities under sec. 1.505 and sec. 1.506. If the importer relies on its customer or a subsequent entity in U.S. distribution to control the hazard, the importer will need to comply with sec. 1.507.

Group Exercise: Who Is Controlling the Biological Hazards?

Group Exercise: Who Is Controlling the Biological Hazards?

Note: For this exercise, we are only considering biological hazards, even though the hazard analysis must also include analyses for physical and chemical hazards. Also note that the purpose of this exercise is to consider who is controlling the hazards and not, specifically, who is the foreign supplier. Under the FSVP rule, there is only one foreign supplier but there may be several entities that control the hazards. While an importer must only verify one foreign supplier, they must still consider all entities that control the identified hazards (scenarios are on the next slide).



Group Exercise: Who Is Controlling the Biological Hazards? (continued)

Who is controlling the biological hazards? (continued)

- **Scenario 1:** You buy tomatoes for the fresh market from a foreign packer who packs tomatoes obtained from multiple farms.
- **Scenario 2:** You buy sliced tomatoes for a U.S. salad maker from a foreign facility that washes and slices the tomatoes.
- **Scenario 3:** Now the tomatoes in the above two exercises are going to a U.S. canner.



Let's have a short group exercise. If you would like to take notes during the exercise, go to Chapter 5, page 15, in the Exercise Workbook.

Evaluating Supplier Performance

Evaluating Supplier Performance

- When evaluating your foreign supplier performance, you need to consider:
 - The foreign supplier's procedures, processes, and practices related to the safety of the food, and
 - Applicable FDA FSMA and other food safety regulations.
- FDA regulations can be found in Title 21 of the U.S. Code of Federal Regulations (CFR).



In evaluating foreign supplier performance, you have considered the foreign supplier's procedures, processes, and practices related to the safety of the food. You also need to look at applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those regulations (21 CFR 1.505(a)).

In addition to the recently published regulations to implement FSMA, there are many older regulations relating to food safety. These include: requirements for infant formulas, specific food and color additive regulations, animal drug requirements, and shell egg requirements. All FDA regulations can be found in Title 21 of the U.S. Code of Federal Regulations (CFR). Title 21 of the CFR lists all of the topics that relate to human and animal food. For example—

Food Safety Requirements that Apply to Your Supplier

As part of your evaluation, you will need to determine what food safety requirements apply to your supplier. For example, if you are importing:

| Food Product | Food Safety Requirements that Apply |
|-------------------------|--|
| Vitamin C capsules | Dietary Supplement CGMP |
| Infant formula | Infant formula rule |
| Shell eggs | Shell egg requirements |
| Canned foods | LACF requirements |
| Cookies and baked goods | PC for Human Food rule, Allergen Labeling, food and color additive regulations |
| Jarred pickles | PC for Human Food rule, Acidified Food Regulations (if they are acidified) |



These examples are important to think about, as our next chapter will be focusing on supplier verification where you will want to make sure that your supplier is not only controlling the hazards, but also assuring yourself that the supplier is following other regulations that apply to the supplier and the food.

Key Point:

Currently, the food safety systems of New Zealand, Canada, and Australia have been recognized as having a comparable food safety system for certain foods under Systems Recognition.

Researching Foreign Supplier's Compliance with U.S. Regulations

Researching Foreign Supplier's Compliance with U.S. Regulations

- You need to research and evaluate FDA information (e.g., import alerts and warning letters) that is relevant to the foreign supplier's compliance with U.S. food safety requirements.
- When applicable, you need to determine:
 - That the foreign supplier is in compliance with the relevant food safety authority for countries whose food safety systems are recognized by the FDA as comparable for certain foods under "Systems Recognition."



When looking at your foreign supplier's history of complying with FDA requirements, you should check on whether the supplier has been the subject of an FDA warning letter or import alert related to food safety. If you learn that food from your foreign supplier has been refused entry or has been subject to a recall by FDA, you should find out why.

Researching Foreign Supplier's Compliance with U.S. Regulations

FDA Website Provides Many Resources for Importers

The screenshot shows the FDA website for the FSMA Final Rule on Foreign Supplier Verification Programs (FSVP). The main page features a search bar and navigation links for Home, Food, Drugs, Medical Devices, Radiation-Exempt Products, Importer, Import & Domestic, Animal & Veterinary, Cosmetics, and Tobacco Products. A sidebar on the left includes links for Food Safety Modernization Act of 2011, Food, Drugs & Biologics, FDA Actions & Initiatives, FDA Training, and FDA Technical Assistance Network (FDTAN). The central content area displays the "FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals". It includes sections for "About the Rule", "Implementation", "Key Requirements", "Compliance Dates", and "Importers". A red box highlights the "Supplier Evaluation Resources" link under "Additional Information". Other sections include "Import Alerts", "Recalls", "Import Refusals", "Inspection Classifications", and "Other Compliance Resources". A "Comment Period" section at the bottom indicates that input received during the comment period and during the public hearing will be considered.

There are many different resources available to the importer on FDA's "FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals" website available at: <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm>

On the website, there is information about the final rule, related guidance, supporting material, additional information, and contact information. Under the "Additional Information" section on the right-hand side of the website, there is a link to "Supplier Evaluation Resources," which is a website providing links to the resources you will need in evaluating your foreign supplier. We will review this resource more fully in the next slide.

Researching Foreign Supplier's Compliance with U.S. Regulations (continued)

"Supplier Evaluation Resources" Website

- Import alerts
- Recalls
- Import refusals
- Other

The screenshot shows the "Supplier Evaluation Resources" website, which is part of the FDA's FSMA Final Rule on Foreign Supplier Verification Programs (FSVP). The page title is "Supplier Evaluation Resources". It includes a sidebar with links for Home, Food, Drugs & Biologics, and Importer. The main content area contains a list of resources: Warning Letters, Import Alerts, Recalls, Import Refusals, Inspection Classifications, and Other Compliance Resources. A note at the bottom states: "These FDA FSVP rules, Foreign Supplier Verification Programs (FSVP), for importers of food for humans and animals, current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food, and current good manufacturing practice, hazard analysis, and risk-based preventive controls for animal food, are intended for importers that are subject to these rules. Importers must evaluate whether their suppliers are meeting applicable U.S. food safety standards. Under these rules, you must evaluate, among other things, the supplier's food safety systems, including any third-party audit results, to determine if any violations are present, including whether the supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation." Below this is a list of publicly available resources that can be used to meet the requirement set out in these regulations, as well as information on their use.

Supplier Evaluation Resources:
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm516330.htm>

Resources:

FDA has provided a "Supplier Evaluation Resources" website available on the "FSVP Final Rule" page at:

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm516330.htm>

On the slide, you will see a screenshot of FDA's "Supplier Evaluation Resources" website. From this one page, you will be able to access multiple resources, such as import alerts, recalls, import refusals, and other important resources. The link to the "Supplier Evaluation Resources" website is:

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm516330.htm>

Additional Considerations

Additional Considerations

- The foreign supplier's food safety history:
 - Any available information on food testing results,
 - Audit results relating to the safety of the food,
 - Responsiveness of the foreign supplier in correcting problems, and
 - History of meeting requirements.
- Other factors, e.g., storage and transportation.



In evaluating foreign supplier performance, you must also consider other aspects of the foreign supplier's food safety history, including: the available information about food testing results, audit results relating to the safety of the food, and responsiveness of the foreign supplier in correcting problems. You should also consider other appropriate factors, such as storage and transportation practices. You may have some of this information already in dealing with your foreign supplier over the course of time, but if you do not, ask your foreign supplier to provide the information you need to conduct your evaluation.

Using a Qualified Individual and Documenting Your Evaluation

Using a Qualified Individual and Documenting Your Evaluation

- Your evaluation must be conducted by a qualified individual under the FSVP rule.
- You must document your evaluation.



And finally, your evaluation must be conducted by a qualified individual under the FSVP rule and you must document everything you have considered/assessed in evaluating the foreign supplier's performance and the risk posed by a food.

May I Use Another Entity's Evaluation?

May I Use Another Entity's Evaluation?

- If an entity **other than the foreign supplier** has conducted a foreign supplier evaluation, you may meet your evaluation requirements by having your qualified individual:
 - Review and assess that entity's evaluation.
- You must document:
 - Your qualified individual's review and assessment, and
 - That the other entity's evaluation was conducted by a qualified individual.



If an entity **other than the foreign supplier** has conducted an evaluation of the foreign supplier, you may meet your evaluation

requirements by reviewing and assessing that entity's evaluation (21 CFR 1.505(d)).

You, that is, your qualified individual under the FSVP rule, must document your review and assessment and document that the other entity's evaluation was conducted by a qualified individual.

The following is an FDA example from the preamble to the FSVP rule of relying on another entity's evaluation of the foreign supplier:

"...an importer of oranges might rely on such an evaluation conducted by a firm that obtains oranges from many farms and exports them to the United States. In this case, the aggregator of the oranges would evaluate the risk posed by the food and the performance of the individual farms in deciding whether to accept oranges from particular farms and in determining what supplier verification activities should be conducted for each farm."

Note: The foreign suppliers are THE FARMS because they grow the produce. The aggregator is carrying out the duties of the FSVP importer, presumably the verification activities as well, but the actual U.S.-based FSVP importer is ultimately responsible for reviewing the hazard analysis and supplier performance evaluations, and making the decision on supplier approval.

Approving Foreign Suppliers

Approving Foreign Suppliers

Before you import food...

- You must approve each of your foreign food suppliers for each food you import on the basis of:
 - The hazard analysis,
 - Who is preventing or minimizing the hazard, and
 - The evaluation of the foreign supplier's performance.



You must approve each of your foreign food suppliers for each food you import on the basis of the evaluations you conduct or on the basis of evaluations conducted by another entity that you have reviewed and assessed (21 CFR 1.505(b)). Although another entity may conduct the foreign supplier performance evaluation, you as the FSVP importer **must approve the foreign supplier before importing food**. As mentioned, you must document your evaluation or your

review and assessment of the other entity's evaluation, whichever is appropriate. Remember, if your food presents no hazards requiring a control, the FSVP rule does not require you to perform an evaluation of your foreign supplier, nor do you have to approve your foreign supplier.

Approving Foreign Suppliers (continued)

Your suppliers must be approved before food is imported!

- Therefore, you must carry out the hazard analysis and evaluations of your foreign supplier well in advance of importing food.



FDA requires that you approve your foreign supplier for the particular food **before** you begin importing food from the supplier. Therefore, you must carry out the hazard analysis and evaluations of your foreign supplier well in advance of importing food.

Supplier Approval Summary

Supplier Approval Summary

Supplier Performance Evaluation and Risk Posed by Food Considerations:



- Evaluation of Foreign Supplier Performance:**
- Procedures and processes
 - Compliance with applicable U.S. food safety regulations (e.g., import alerts, warning letters)
 - Food safety history—results of audits, testing, responsiveness
 - Other factors—storage, transportation

This slide summarizes the three elements required in making a decision on whether to approve your foreign supplier.

FSVP Foreign Supplier Evaluation Form Example

| IMPORTER NAME | | DATE | | | | | |
|---|---------------|---|---|--|-------------------------------|---|--------------------------------|
| ADDRESS | | QJ APPROVAL | | | | | |
| FSVP Foreign Supplier Evaluation Form Example* | | | | | | | |
| Foreign Supplier Name | | Foreign Supplier Address (location) | | | | | |
| Food Product(s) Imported | | Food Product(s) Description(s), including Important Food Safety Characteristics | | | | | |
| Evaluation Considerations and Results | | | | | | | |
| Supplier's Procedures, Practices, and Processes [(1.505(a)(1)(iii)(A)] | Import Alerts | Recalls | Warning Letters [(1.505(a)(1)(iii)(B))] | Other Significant Compliance Action(s) [(1.505(a)(1)(iii)(C))] | Supplier's Corrective Actions | Information related to the safety of the food** | Rejection Date (if applicable) |
| | | | | | | | |
| Assessment of Results of Foreign Supplier Evaluation*** <small>[Note: if the evaluation was performed by another entity (other than the foreign supplier) include Entity's name, address, email, and date of evaluation.]</small> | | | | | | | |
| <small>*All supporting documentation should be appended to this form. **Includes previous and recent experience with the supplier (e.g., rejected shipments, lab results, audit results, or other food safety information you may have outside of the government oversight context). ***If another entity (other than the foreign supplier) performs the foreign supplier evaluation, you may meet your evaluation requirements by having your QJ review and assess the entity's evaluation. Your review/assessment of the evaluation must include documentation that the</small> | | | | | | | |
| FSVP Foreign Supplier Evaluation Form Example – other formats may be used | | | | | | | |

Note that there is a requirement to document the evaluation and approval process for your suppliers. The format on this slide is not mandatory under the rule, and may not fit every situation, but it serves as an example of a format that importers might use when performing a foreign supplier evaluation as part of the FSVP. The form could be modified as needed to fit many of the situations that you may face.

Chapter 5: Summary

Chapter 5: Summary

- In this chapter, we have covered the:
 - Factors to consider when evaluating your foreign suppliers' performance.
 - Importance of determining who is controlling hazards,
 - The relationship between your hazard analysis and evaluation of your foreign supplier performance and food risk.
 - Need to determine what food safety requirements apply to your foreign supplier/food,
 - Importance of researching the history of your foreign supplier's compliance history as part of the performance evaluation, and
 - The requirement to approve your foreign supplier **before** importing food.



This chapter has covered:

- Factors to consider when evaluating your foreign supplier's performance.
- The importance of considering who is controlling the hazards.
- The relationship between your hazard analysis and evaluation of your foreign supplier performance and food risk.
- Determining what food safety requirements apply to your foreign supplier/food.
- The need to research the history of your foreign supplier's compliance history as part of the performance evaluation.
- The requirement to approve your foreign supplier **before** importing food.

Chapter 5: Questions

Chapter 5: Questions

Thank you for your attention!

Questions?



Notes:

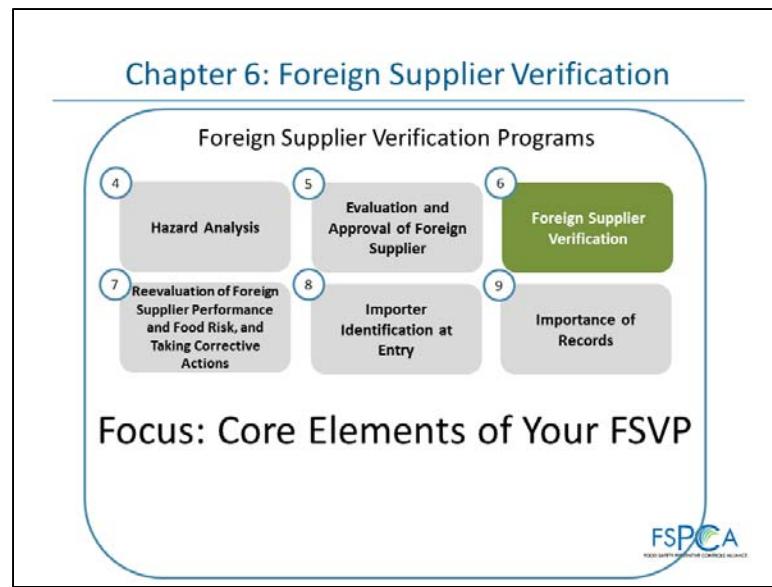
Blank Colored Insert-Front

Blank Colored Insert-Back

CHAPTER 6. Foreign Supplier Verification

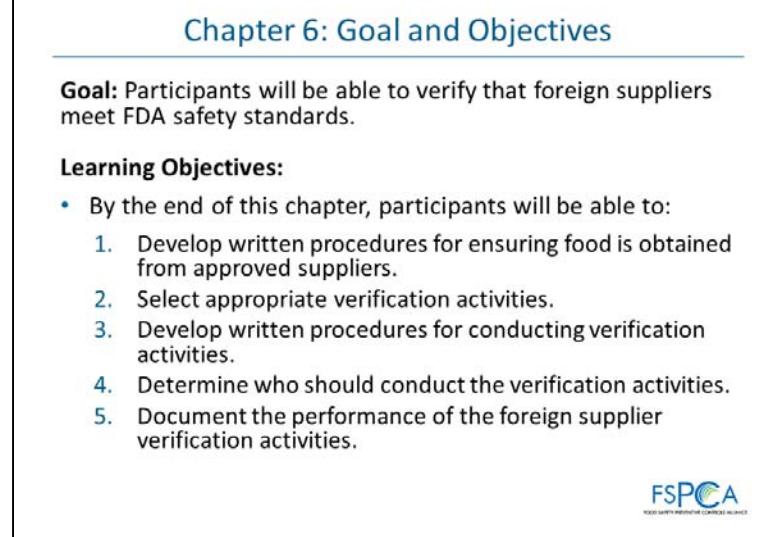


The purpose of the FSVP rule is to make sure that foreign suppliers of food to be consumed in the U.S. are producing food in accordance with U.S. food safety requirements. Although the FSVP rule specifically requires “verification” procedures when there are food safety hazards requiring a control, it is important to point out that **all** FSVP requirements are part of the overall verification that your foreign supplier is doing what is necessary to ensure that food exported to the U.S. meets the same safety standards as food produced in the U.S. Thus, your hazard analysis, your evaluation of your foreign supplier, the requirement to affirmatively approve your foreign supplier, and your verification activities can be viewed as the different parts of your Foreign Supplier Verification Program or FSVP.



Chapter 6 focuses on determining and applying foreign supplier verification activities, the third core element (or standard requirement) of your FSVP. This is what the hazard identification, hazard evaluation, and evaluation of supplier performance have been leading to. Now the focus is on selecting and performing one or more verification activities to ensure that the identified hazards needing controls are continuing to be controlled.

Chapter 6: Goal and Objectives



This chapter will address:

1. The development of written procedures for ensuring that food is obtained from approved suppliers,
2. The selection of appropriate verification activities.

3. The development of written procedures for conducting verification activities,
4. Determining who should conduct the selected verification activities, and
5. Documenting the performance of the foreign supplier verification activities.

Verifying the Food Is from Approved Suppliers

Verifying the Food Is from Approved Suppliers

- You must establish written procedures to ensure:
 - The food you import is only obtained from suppliers you approved (based on evaluations of food and foreign supplier).
- Unapproved suppliers may be used on a temporary basis, when necessary:
 - If subjected to **adequate verification activities before importation**.

→ Key Point:

Written procedures to ensure use of approved foreign suppliers could take the form of a Standard Operating Procedure (SOP) that explains the need for using approved suppliers and the process for identifying who they are.



At this point, you have already performed a hazard analysis, considered who would be controlling the hazard needing to be controlled, and reviewed your foreign supplier's performance (including the supplier's processes and procedures related to food safety, looked at the supplier's food safety history, and compliance history with U.S. regulations). As a result of those activities, you may have already directed that your supplier takes some corrective actions to address potential safety issues. If you have determined that the hazard requiring a control was a serious (SAHCODHA) hazard you may even have conducted an audit. All of this was done before you made the decision on whether to approve your foreign supplier. Hence, you may have already carried out activities to verify that the food you will be importing will be in accordance with U.S. food safety standards.

You must also use your evaluation of the food and supplier to determine what verification activities are appropriate to ensure that the hazards needing controls in the food you import have been and will continue to be controlled.

Once you approve your suppliers, the rule specifies that you must develop and follow written procedures to ensure you only import food from approved suppliers.

When necessary, you may import food from unapproved foreign suppliers on a temporary basis if you subject the food to adequate verification activities **before** you import the food. **FDA stated in the preamble to the FSVP rule that it intends to provide guidance on the temporary use of unapproved suppliers. You must document the use of your procedures.**

Key Point:

FDA does not explain in the FSVP rule how to verify temporary suppliers, but it did state in the preamble that it intended to provide guidance. See narrative on this page regarding when an unapproved supplier might be used on a temporary basis.

FDA also stated in the preamble that, "Examples of circumstances in which the use of an unapproved supplier on a temporary basis would be 'necessary and appropriate' include a problem with a long-standing supplier due to an equipment breakdown or an environmental or weather-related crisis (e.g., severe drought or flooding). Because the importer would be unable to immediately fully evaluate the potential supplier, the importer would need to take other steps to verify that the food obtained from the unapproved supplier is safe."

You should document your reason for using an unapproved supplier. Logically, FDA would not expect a "temporary" unapproved supplier to be utilized for a prolonged period of time.

Purpose of Verification Activities

Purpose of Verification Activities

- Foreign supplier verification activities provide adequate assurances that the hazards requiring control in the food you import are:
 - Significantly minimized, or
 - Prevented.
- You must determine which verification activities are appropriate, including their frequency, taking into account:
 - Who is controlling the hazard, and
 - Who is verifying that the hazards are controlled.
- **You must establish and follow written procedures** for ensuring that verification activities are conducted.



The purpose of foreign supplier verification activities is to provide assurance that the hazards requiring a control in the food you import are continuously being significantly minimized or prevented (21 CFR 1.506(c)).

Before importing a food from a foreign supplier, you need to establish and follow written procedures to ensure that appropriate foreign

supplier verification activities are conducted. Those procedures cover your determination of which verification activities are appropriate and the frequency with which they must be conducted, while considering who is actually controlling the hazard(s), as well as who will be carrying out the verifications (21 CFR 1.506(b)).

Determining Appropriate Verification Activities

Determining Appropriate Verification Activities

- Written verification procedures **must be established before** importing a food from a foreign supplier.
- Remember, the basis for determining which verification activities are appropriate is your previous evaluations of the:
 - Foreign supplier performance, and
 - The risk posed by the food.



Remember that you already evaluated your foreign supplier and the risk posed by the food in order to approve the supplier in the first place (21 CFR 1.505). Now you are establishing written procedures to verify that appropriate foreign supplier verification activities are conducted for the foods you import. These activities should demonstrate that the hazards requiring a control have been significantly minimized or prevented.

Knowledge of your foreign supplier's procedures, processes and practices related to food safety can influence your decisions on which hazards require a control, as well as your choice of verification procedures. For example, if your foreign supplier produces only peanuts, there would not be a concern with controlling allergen cross-contact of non-peanut products with peanut allergens. However, a supplier that makes a variety of single and multi-variety nut products with different kinds of nuts may require verification activities to ensure that allergen cross-contact does not occur. Understanding how your foreign supplier controls allergens may be very important to your FSVP.

Appropriate Verification Activities

Appropriate Verification Activities

- The FSVP rule identifies the following as appropriate verification activities:
 - Onsite audits
 - Sampling and testing of food
 - Review of the foreign supplier's relevant food safety records
 - Other appropriate supplier verification activities
- Your verification activities must be performed by a qualified individual under the FSVP rule.



The FSVP rule has identified the following as appropriate verification activities: (21 CFR 1.506(d)(1))

1. Onsite audits,
2. Sampling and testing of food,
3. Review of the foreign supplier's relevant food safety records, and
4. Other appropriate supplier verification activities.

By listing “other appropriate supplier verification activities,” FDA is expressing a willingness to accept other verification activities, as well as acknowledging that appropriate verification activities need to be decided based on the specific food, supplier, manufacturing details and other pertinent factors. One size does not fit all. You may also decide that **several** verification activities are appropriate to ensure the hazard is being properly controlled. Whatever verification activity(ies) you choose, you should document your justification for its suitability.

Verification Activities for Serious Hazards

Verification Activities for Serious Hazards

- If there is a reasonable probability that exposure to a hazard in food will result in:
 - Serious Adverse Health Consequences Or Death to Humans or Animals (a **SAHCODHA** hazard),
 - The default verification option is an **onsite audit** of the foreign supplier **before** initially importing the food and at least annually thereafter.
 - An alternative, but equally effective, verification method can be chosen, but justify and document your rationale.



If there is a reasonable probability that exposure to a hazard in food will result in **Serious Adverse Health Consequences Or Death to Humans or Animals**, FDA refers to that hazard as a **SAHCODHA** hazard.

When a SAHCODHA hazard in a food will be controlled by the foreign supplier, the default verification procedure is the performance of a properly conducted onsite audit of the foreign supplier before initially importing the food and at least annually thereafter (21 CFR 1.506(d)(2)).

An alternative procedure or set of procedures can be used instead of annual onsite auditing, but only if such procedures provide equal assurances that the hazard(s) is being adequately controlled. For example, in the case of a long-term supplier who has a good food safety track record, you may decide that annual audits are excessive and adjust the frequency to every 2 years instead, perhaps combined with some sampling and testing of the food. Be sure to justify and document your rationale for an alternative verification method, as FDA will have a high interest in verification procedures for hazards that can have serious health consequences.

Key Point:

SAHCODHA Hazards are those that would prompt a Class I* recall if they were to occur. The FSVP rule did not include a list of SAHCODHA hazards. However, because the Reportable Food Registry (RFR) requires reporting of these hazards, examples of SAHCODHA hazards may be found in the RFR (see Appendix 7 for RFR link).

*A **Class I recall** situation is one in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death to humans or animals.

 **Key Point:**

An example of testing as a verification activity:

Pesticides may be a “known or reasonably foreseeable” hazard if FDA (or you) have found in the past high residue levels of pesticides not approved in the U.S. for use in the particular commodity. While sampling and testing may be an appropriate verification activity in that case, an alternative verification activity could be requesting records of pesticide used (e.g., pesticide name, application rates, application dates, preharvest interval) for the food in question.

Group Exercise: What Could Be an Appropriate Verification Activity?

Group Exercise: What Could Be an Appropriate Verification Activity?

- **Scenario 1:** If your supplier is providing food from a region where high levels of heavy metals (e.g., lead or cadmium) have been found in similar foods, **what could be an appropriate activity** to verify that heavy metal levels are within U.S. limits (if any) or at normal background levels?

Answer:



So, let's work through a short group exercise. Raise your hand to answer the question. Discuss what could be an appropriate verification activity for the scenarios described in the scenario. After a brief discussion, the instructor will display the answer. **Note:** If desired, you can write down the answer to Scenario 1 (above) in the Exercise Workbook (see Chapter 6, page 16).

Group Exercise: What Could Be an Appropriate Verification Activity? (continued)

- **Scenario 2:** If your evaluation of the manufacturer, who is your foreign supplier, reveals that temperature controls for a processing step are critical for controlling pathogens, **what could be an appropriate activity** to verify that temperature controls for the processing step were appropriately maintained?

Answer:



Again, if desired, you can write down the answer to Scenario 2 (above) in the Exercise Workbook (see Chapter 6, page 16).

What If You Choose Onsite Audits?

What If You Choose Onsite Audits?

- Your audit must consider all FDA food safety standards that the food is subject to.
- The audit must be performed by a **qualified auditor**.
- The qualified auditor can be a government employee—U.S. or foreign—or a private entity.
- A review of the supplier's written food safety plan, if any, and its implementation **must be included**.



Key Point:

Audits to private standards/schemes may contribute to the safety of the food supply but may not meet the requirements of the FSVP rule. Under this rule, audits must consider the hazards requiring a control and all applicable FDA food safety standards, including the hazards you identified in your hazard analysis. Also, audits must be conducted by a qualified auditor, as defined in FSVP rule (sec. 1.500).

We have already mentioned that onsite audits are the appropriate default verification activity in the case of a SAHCODHA hazard, but they may be useful in other situations as well. It is up to you to decide what is suitable for your situation. For example, given your knowledge of your supplier and for less serious hazards, you may wish to perform an onsite audit on an alternate year schedule and ask for supplier records in the other years. **Nevertheless, whenever an audit is conducted, it must be conducted by a qualified auditor, who can understand the hazards identified in your hazard analysis, the effectiveness of controls for those hazards, and the relevant FDA regulations.**

The definition of a qualified auditor is included in the FSVP rule, and in the *Definitions and Acronyms* in Appendix 10. Note that a qualified auditor can be a government employee or a private entity. If FDA officially recognizes that another country's food safety system is comparable for certain foods under Systems Recognition, and if your foreign supplier is providing food that is within the scope of that official recognition and under the jurisdiction of the government authority responsible for that food safety system, the auditor may inspect to that country's applicable standards.

It is important to ensure that audits include both a records review and the observation of supplier practices for a complete picture. Comprehensive systems audits that include records reviews are more likely to reflect conditions throughout the year, as opposed to an audit that examines the state of the facility at a particular time. The audit must consider applicable FDA food safety regulations, including the CGMP and Preventive Controls (process, allergen, sanitation, and supply-chain) (for suppliers subject to those requirements),

Key Point:

FDA expressed the following in the preamble to the FSVP rule:

"We believe that as importers and foreign suppliers become more familiar with the FSVP requirements, more suppliers are likely to arrange to be audited and share the audit results with multiple U.S. importers."

This could be done "by a foreign government employee with appropriate technical expertise obtained through education, training, and/or experience, as long as the foreign official considers applicable FDA food safety standards."

compliance with the Produce Safety rule (for farms subject to that rule), and any other applicable FDA food safety regulation (e.g., LACF). In all cases, the audit must address the specific hazards identified in your hazard analysis. In theory, an importer's hazard analysis may not be identical to a supplier's hazard analysis, if one exists, but they should identify the same hazards and if not, they will need to be reconciled. It also must include a review of the supplier's written food safety plan, if any, and its implementation (21 CFR 1.506(e)(1)(i)). Other regulations that an auditor might consider in auditing a foreign supplier producing food for sale in the U.S. are the FSMA rules pertaining to "Sanitary Transportation of Human and Animal Food" and food defense ("Mitigation Strategies to Protect Food Against Intentional Adulteration").

How Do I Document My Onsite Audit?

How Do I Document My Onsite Audit?

- You must retain documentation of each onsite audit.
- Documentation must demonstrate that your supplier is using **processes and procedures that control the hazards requiring a control**.
- Include in documentation:
 - Audit procedures,
 - Qualification of the auditor,
 - Dates the audit was conducted,
 - The conclusions of the audit, and
 - Any corrective actions taken in response to noted deficiencies.



You must retain documentation of each onsite audit and the audit procedures. Your documentation of your audit, together with documentation of any other verification activities you conduct, must demonstrate that the hazards requiring a control have been significantly minimized or prevented. Your documentation should, at a minimum, include the following:

1. Audit procedures,
2. Qualification of the auditor,
3. Dates the audit was conducted,
4. The conclusions of the audit, and
5. Any corrective actions taken in response to noted deficiencies.

It should be noted that the FSVP rule also accepts food safety inspections, as substitutes for onsite audits, from appropriate officials

of a foreign government, but only if FDA has recognized the food safety system of the country as comparable for certain foods under Systems Recognition, and provided that the food that is the subject of the onsite audit is within the scope of that official recognition, and that the foreign supplier is under the regulatory oversight of the that country.

What If You Choose Sampling and Testing?

What If You Choose Sampling and Testing?

- You must retain documentation of each sampling and testing of a food, including:
 - Identification of the food tested and the number of samples,
 - The tests conducted (including the analytical methods(s) used) and the dates conducted, and
 - The results of the tests and any corrective actions taken.
- Retain documentation identifying:
 - The laboratory conducting the testing, and
 - That the testing was conducted by a qualified individual.



You can choose to perform the testing, require such testing from your foreign supplier, or rely on another entity's test results. It may be that the routine testing records of your foreign supplier are enough. Your foreign supplier may already test in-process materials, environmental samples, or raw ingredients, for example, which can provide meaningful information in verifying hazard controls.

You may wish to define sampling protocols to make sure representative samples are being tested, implement third-party sampling, or establish other criteria to assure sample integrity and test results adequately represent the food shipped. It is also important to use methods that are fit for purpose and to understand the limitations of testing methodologies. Your approach should depend on the potential hazards and the controls in place for the specific product. Testing requirements for a **new** foreign supplier approval are likely to be more extensive than for maintenance of approved supplier status.

You must retain documentation of each sampling and testing of a food, including: (21 CFR 1.506(e)(1)(ii))

1. Identification of the food tested and the number of samples,

2. The tests conducted (including the analytical methods used) and the dates, and
3. The results of the tests and any corrective actions taken.

You must also retain documentation identifying the laboratory conducting the testing, and documentation that the testing was conducted by a qualified individual (**someone qualified to do the testing**).

What If You Choose to Review Supplier Records?

What If You Choose to Review Supplier Records?

- You must retain documentation of each review of supplier records, including:
 - The dates of your review and the nature of the records reviewed, and
 - The conclusions of the review and any corrective actions taken in response to identified deficiencies.
- You must also retain documentation that your review was conducted by a qualified individual.



Reviewing the foreign supplier's food production or other records, especially those relating the implementation and monitoring of controls for the hazards identified, is another way of verifying that the supplier (and other entities in the supply chain) is doing what needs to be done to control safety hazards. Many believe that food safety records are essential to verifying that preventive controls are implemented as designed.

You must, of course, retain documentation of each review of supplier records, including: the dates of review, the nature of the records reviewed and the conclusions of the review. You must also document any corrective actions taken in response to identified deficiencies (21 CFR 1.506(e)(1)(iii)) and that your review was conducted by a qualified individual under the FSVP rule.

What If You Choose Another Appropriate Activity?

What If You Choose Another Appropriate Activity?

- You may conduct other supplier verification activities that are appropriate, but always based on your evaluation of:
 - Foreign supplier performance, and
 - The risk posed by the food.
- You must, of course, document performance of the verification activity and that it was performed by a qualified individual under the FSVP rule.



You may conduct other supplier verification activities that are appropriate based on foreign supplier performance and the risk posed by the food (21 CFR 1.506(e)(1)(iv)).

You must, of course, document the other supplier verification activity chosen and the details of its performance.

Key Point:

Appropriate verification activities are based on a combination of food and supplier risk.

Key Points About Verification Activities

- Remember, you can choose to perform a single or multiple verification activities.
- What is important is that they be suitable to verify that the hazard(s) is being controlled.



Remember, you can choose to perform a single or multiple verification activities. What is important is that they be suitable to verify that the hazard(s) is being controlled.

Who Is Controlling the Hazards?

Key Point:

You may have to verify more than one entity in your supply chain. For example, an importer of soft cheese may audit the cheese producer, but also review temperature records during transport after the cheese leaves the manufacturing facility.

Who Is Controlling the Hazards?

- Your written verification procedures must address:
 - The entity or entities that are significantly minimizing or preventing the hazards, and
 - The entity or entities verifying that the hazards have been significantly minimized or prevented.
 - e.g., when the foreign supplier's raw material supplier significantly minimizes or prevents a hazard,
 - e.g., a fresh salsa manufacturer who must verify Produce Safety rule compliance of its suppliers.



Your verification activities must address the entity or entities that are significantly minimizing or preventing the hazards and the entity or entities verifying that the hazards have been significantly minimized or prevented, including when the foreign supplier's raw material supplier significantly minimizes or prevents a hazard (21 CFR 1.506(d)(1)).

It is very important that **importers consider which entities are controlling the hazard**. FDA has noted in the preamble to the FSVP rule that, "Knowing the entity or entities that will be significantly minimizing or preventing the hazards in a food is directly relevant to the type of foreign supplier or other verification activity that the importer will need to conduct under 1.506 or 1.507."

There may be several entities, in some cases, engaged in such controls. Your job, nonetheless, is to verify that someone is responsible and accountable for adequately controlling each hazard associated with the food you are importing, if the hazard requires a control. This verification does not mean that you, yourself, must deal with multiple entities, but it does mean that your FSVP must verify that such hazards are being handled and appropriate assurances/documentation obtained.

Example from preamble: "When a foreign supplier's raw material supplier is controlling a hazard in a food that the importer obtains from the foreign supplier, the importer might conclude that reviewing the supplier's records of verification that its supplier produced the raw material in accordance with the Preventive Controls (PC) or Produce Safety regulations is more appropriate than auditing the foreign supplier with respect to this hazard."

Hazards Controlled by Customers

Hazards Controlled by Customers

- In situations where your customer is controlling the hazard you must:
 - Disclose in documents accompanying the food that the food is "not processed to control [insert identified hazard]."
- You must also:
 - **(If your customer is subject to PC rules requirements)** obtain annually-written assurance of your customer's procedure to significantly minimize or prevent the identified hazard.
 - **(If your customer is NOT subject to PC rules requirements)** obtain annually written assurance that your customer is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements.



If your customer is controlling an identified hazard needing a control, you may rely on your customer to control the hazard if you:

1. Disclose in documents accompanying the food that the food is "not processed to control [identified hazard]," and

Key Point:

FDA's Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA

This guidance is intended for any entity that is subject to certain provisions (in part 117, part 507, the produce safety regulation, or the FSVP regulation) that require a disclosure statement, in documents accompanying food, that certain hazards have not been controlled by that entity. This guidance is not intended to address other requirements of part 117, part 507, the produce safety regulation, or the FSVP regulation.

The guidance is available at:

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm524553.htm>

2. For customers who are subject to PC rules requirements, you must also annually obtain from your customer written assurance of the procedure being followed to significantly minimize or prevent the identified hazard, or
3. When your customer is not subject to PC rules requirements, you annually obtain from your customer written assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements. Such applicable requirements could be applicable federal or state food safety requirements.

Hazards Controlled Further Down the Line...

Key Point:

While the requirement to obtain written assurances is in the final rule, the compliance date for this provision has been extended for two additional years past the original compliance dates.

The earliest compliance date for the written assurance provision is May 28, 2019. This extension was granted in response to industry's concerns over the burden of obtaining the assurances in complex supply chains (80 FR (Aug. 24, 2016)). This extension did not pertain to the disclosure requirement.

<https://www.fda.gov/food/guidanceregulation/fsma/ucm517545.htm>

Hazards Controlled Further Down the Line...

- If your customer is NOT controlling the hazard but someone further down in the distribution chain is:
 - You must comply with the previously stated requirements (disclosure and assurance), **and**
 - Only sell the food to another entity that agrees, in writing, that it will either:
 - Control the identified hazard, **or**
 - Obtain written assurance* from its customer that the customer will make a similar disclosure and obtain assurances.

*FDA has granted a two-year extension (until May 2019 at the earliest) for the written assurance requirement.



If someone further down in the distribution chain is controlling the hazard, you must follow the same regimen down the line. So, if your customer's customer is controlling the hazard, you annually obtain written assurance from your customer that the food will be processed to control the identified hazard by your customer's customer. Plus, your customer must assure you that he/she will:

1. Disclose in documents accompanying the food that the food is "not processed to control [identified hazard]," and
2. Only sell the food to another entity that agrees, in writing, it will either control the identified hazard or obtain written assurance from its customer that the customer will make a similar disclosure.

And so, it goes down the line if it is your customer's, customer's customer, etc., who controls the hazard. But note that FDA has granted a two-year extension (until May 2019 at the earliest) for the written

assurance requirement while it considers concerns raised by industry.

Written Assurances Must Include

Written Assurances* Must Include

- The written assurances identified in the previous slides must contain the following information:
 - The effective date,
 - Printed names and signatures of authorized officials, and
 - The required assurances.

*FDA has granted a two-year extension (until May 2019 at the earliest) for the written assurance requirement.



When and if they go into effect, the written assurances identified in the previous slides must contain the following information:

1. The effective date,
2. Printed names and signatures of authorized officials, and
3. The required assurances.

Actions Must Be Consistent With Written Assurances*

- The customer or other entity in the distribution chain who provides a written assurance must:
 - Act consistently with the assurance, and
 - Document the actions it takes to satisfy the written assurance.

*FDA has granted a two-year extension (until May 2019 at the earliest) for the written assurance requirement.



When and if they go into effect, the customer or other entity in the distribution chain that provides a written assurance must act

consistently with the assurance and document the actions it takes to satisfy the written assurance.

Alternative System to Demonstrate that Hazards Controlled After Importation

Alternative System to Demonstrate that Hazards Controlled After Importation

- You are NOT required to conduct an evaluation of foreign supplier or perform supplier verification activities when you identify a hazard requiring a control if you:
 - Have established and implemented a system (other than disclosures and assurances) that ensures control of a hazard(s) in the food at a subsequent distribution step, and
 - Documented your implementation of that system.



It is important to note that the rule provides some flexibility for importers when hazards are being controlled after importation. FDA is allowing the importer to establish an alternative system (other than using disclosures and customer assurances) to demonstrate that hazards are being controlled at a subsequent distribution step. This may be appropriate if you have a history of importing a food with a hazard that requires a control and you always sell the food to a customer that you know is aware of the hazard and is controlling it. In such a situation, the importer may establish and document an alternative to the disclosures and written assurances that are specifically outlined in the rule. As with other requirements, you must document your implementation of that system.

For example, you, as the FSVP importer, import an ingredient, from a foreign supplier, that needs to be cooked to kill a potential pathogen. You supply that ingredient to a restaurant chain that has agreed in writing to incorporate the ingredient only into foods that will be fully cooked before being served to consumers. Therefore, you know the hazard is being controlled. You can document this arrangement rather than performing supplier verification for pathogen control in this ingredient.

Determination of Verification Activities by Another Entity

Determination of Verification Activities by Another Entity

- You may rely on another entity (other than your foreign supplier) to determine appropriate foreign supplier verification activities, if you review and assess whether the entity's determination is appropriate.
 - The determination of appropriate verification activities must have been made by a qualified individual.
 - Your qualified individual under the FSVP rule must assess the appropriateness of the verification activities and must document your review and assessment, and document that the original determination was performed by a qualified individual.



You may rely on a determination of appropriate foreign supplier verification activities made by another entity (must be someone other than the foreign supplier) if you review and assess that entity's determination as being appropriate and adequate (21 CFR 1.506(d)(3)). **You need to remember, however, that the FSVP importer in the U.S., is ultimately responsible for appropriate verification activities.**

Of course, you must document your qualified individual's review and assessment, including documenting that the entity's determination of appropriate verification activities was made by a qualified individual.

Group Discussion: What Supplier Verification Activity(ies) Would Be Appropriate in the Following Scenario?

Group Discussion: What Supplier Verification Activity(ies) Would Be Appropriate in the Following Scenario?

Scenario: Importing fresh sliced tomatoes.

- **Question 1:** What hazard(s) require a control?
- **Question 2:** What verification activity(ies) would be appropriate?



FSPCA
FOOD SAFETY PRACTICE CENTER ALLIANCE

Instructions: The instructor will lead participants in a group discussion with the intent to first identify what hazard(s) require a control and then what verification activity(ies) would be appropriate. If you would like to take notes during the discussion, refer to Chapter 6, page 16, in the Exercise Workbook.

Verification Activities Must Be Conducted Properly

Verification Activities Must Be Conducted Properly

- You must ensure that the verification activities determined to be appropriate are properly performed, **whether by you or another entity**.
 - The verification activities must be performed by one or more qualified individuals.
 - You must document the performance of the verification activities and that they were performed by qualified individuals.
 - Your foreign supplier should neither determine what the appropriate verification activities should be, nor perform the activities, except that they may test product or provide records (but not conduct the record review).

FSPCA
FOOD SAFETY PRACTICE CENTER ALLIANCE

It is important that the verification activities that you determined to be appropriate are properly performed, and also those they are performed by one or more qualified individuals under the FSVP rule.

You must document the performance of those verification activities and that they were performed by qualified individuals.

You may also rely on supplier verification activities conducted by another entity (other than the foreign supplier) if you review and assess the results of these activities (21 CFR 1.506(e)(2)). Make sure that this entity is someone trustworthy and appropriate to do this work, as your FSVP is dependent on this person's results. As stated, however, you may rely on your foreign supplier's records, including testing results, as a verification procedure, if your qualified individual under the FSVP rule deems that such records and results are valid.

Note that whenever performing an on-site audit is chosen as an appropriate verification activity, it must be performed by a qualified auditor as defined by FDA. Qualified auditors are qualified individuals that have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

Verification Activities Must Be Credible

Verification Activities Must Be Credible

- The qualified individuals who conduct foreign supplier verification activities must **not**:
 - Have financial conflicts of interests that could influence the results of verification activities.
 - Receive payment for their services that is in any way related to the results of the activity.



The qualified individuals who conduct foreign supplier verification activities must not have financial conflicts of interests that could influence the results of verification activities (21 CFR 1.506(e)(4)). Also, payment for their services must not be related to the results of the verification activity. It's best to avoid any suspicion of a conflict of interest.

Assessment of Verification Activities and Corrective Actions

Assessment of Verification Activities and Corrective Actions

- You must document:
 - Your assessment of verification activities, and,
 - If the results are **not** adequate to assure that the hazards requiring a control have been controlled, you **must** take appropriate corrective actions.
- The corrective actions you take may require discontinuing use of that foreign supplier or another suitable alternative.



It is especially important that you document your assessment of verification activities, because this is the way you (and FDA) will be able to determine if your FSVP is working. If the results are not adequate to demonstrate that the hazards requiring a control have been controlled, you must take appropriate action to correct the problem (21 CFR 1.506(e)(3)).

The corrective actions you take may include selecting a different verification activity. In some cases, you may also decide that you need to replace that foreign supplier with another supplier.

Verification Activities—Before and After Importing

Verification Activities—Before and After Importing

- Remember, if you identify hazards requiring a control(s), you must:
 - Conduct and document (or obtain documentation) of one or more supplier verification activities **before importing food and periodically thereafter;**
 - Have written verification procedures to ensure that you only obtain food from approved suppliers and to conduct verification activities; and
 - Ensure that the verification activities address the entity controlling the hazard(s) needing control.



Sec. 1.506(e)) requires that importers conduct a verification activity **before importing food, as well as periodically thereafter.** Although the initial verification conducted prior to importation is not linked in the rule to supplier approval, or as a condition for foreign supplier approval, it may be that the first verification could be conducted and be part of the hazard and/or supplier evaluations.

FSVP Foreign Supplier Verification Activity(ies) Worksheet Example

FSVP Foreign Supplier Verification Activity(ies) Worksheet Example

| IMPORTER NAME | VERIFICATION DATE | SUPPLIER EVALUATION DATE | | |
|--|--|---|---|---|
| ADDRESS | QI APPROVAL | APPROVAL DATE | | |
| FSVP Foreign Supplier Verification Activity(ies) Worksheet Example* | | | | |
| Foreign Supplier Name | Foreign Supplier Address (location) | | | |
| Food Product Imported | Food Product Description(s), including Important Food Safety Characteristics | | | |
| Process Description (Ingredients/Packaging Materials) | | | | |
| Food Safety Hazard(s) Controlled by Foreign Supplier** | Description of Foreign Supplier Control(s) | Verification Activity(ies) and Frequency*** | Justification for Verification Activity(ies) and Frequency† | Verification Records (i.e., audit summaries, test results)* |
| Assessment of Results of Verification Activity(ies)†† | | | | |
| Corrective Action(s), if needed | | Reevaluation Date | | |

*All supporting documentation should be appended to this form.
 **If someone other than the foreign supplier controls the hazard(s), document who is controlling the hazards and note if written assurances are required.
 ***When a Serious Adverse Health Consequences Or Death to Humans or Animals (SAHCODHA) hazard in a food will be controlled by the foreign supplier, the default verification procedure is the performance of a properly conducted onsite audit of the foreign supplier before initially importing the food and at least annually thereafter (21 CFR 1.506(d)(2)).
 †You may rely on another entity's (other than the foreign supplier) determination of appropriate verification activities if you review and assess their determination, including documenting that the determination was made by a QI.

FSVP Foreign Supplier Verification Activity(ies) Worksheet Example – other formats may be used

The FSVP Foreign Supplier Verification Activity(ies) worksheet example on the slide, relates to the supplier verification process for food that is imported and governed by the FSVP rule. The format is not mandatory under the rule, but it is an example of a format that importers might use when performing foreign supplier verification as part of the FSVP. The form could be modified as needed to fit many of the situations that you may face.

Chapter 6: Summary

Chapter 6: Summary

- In this chapter we have discussed:
 - The need for written procedures for 1) ensuring that you only obtain food from approved suppliers and 2) conducting verification activities.
 - Determination of appropriate verification activities must be based on the evaluation of a foreign supplier's performance and the risk of the food
 - Verification activities must be appropriate for the food, the hazard, and who controls the hazard.
 - **SAHCODHA** hazards require either annual onsite auditing or other activities providing adequate assurance.
 - The choice and performance of verification activities must be accomplished by qualified individuals under the FSVP rule.
 - Documentation is key.



This chapter has discussed:

- The need for written procedures for:
 - Ensuring that you only obtain food from approved suppliers, and
 - Conducting verification activities.
- Determination of appropriate verification activities must be based on the evaluation of a foreign supplier's performance and the risk of the food
- Verification activities must be appropriate for the food, the hazard, and who controls the hazard.
- **SAHCODHA** hazards require either annual onsite auditing or other activities providing adequate assurance.
- The choice and performance of verification activities must be accomplished by qualified individuals under the FSVP rule.
- Documentation is key.

Chapter 6: Questions

Chapter 6: Questions

Thank you for your attention!

Questions?



Notes:

Blank Colored Insert-Front

Blank Colored Insert-Back

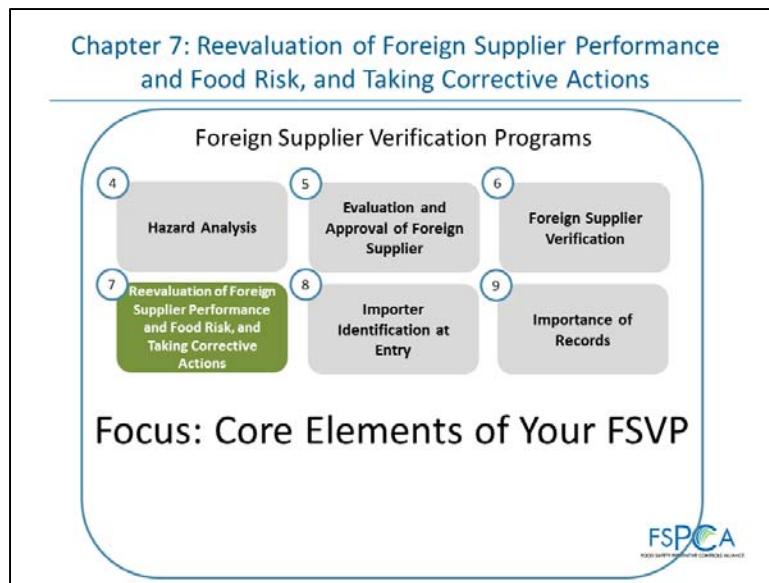
Chapter 7. Reevaluate Foreign Supplier Performance and Food Risk, and Taking Corrective Actions

Chapter 7: Reevaluate Foreign Supplier Performance and Food Risk, and Taking Corrective Actions

**REEVALUATING THE APPROPRIATENESS
OF FSVP ON A REGULAR BASIS AND
WHEN PROBLEMS OCCUR**



Chapter 7 is about reevaluating foreign supplier performance and food risk, and taking corrective actions. Reevaluations are necessary because the situation with your food or your foreign supplier may change over time. Corrective actions are necessary to ensure future shipments of food are in compliance with U.S. food safety requirements.



Chapter 7 is the fourth chapter in the core elements (or standard requirements) of your FSVP. The purpose of this chapter is to show you how your reevaluation determines if any changes to your FSVP are needed to ensure that your supplier is controlling the hazards and that the food you import meets U.S. safety standards.

Chapter 7: Goal and Objectives

Chapter 7: Goal and Objectives

Goal: Participants will be able to confirm continued compliance with FSVP requirements.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Determine when reevaluations are needed.
 2. Describe considerations for reevaluation.
 3. Document the reevaluation.
 4. Determine appropriate corrective actions to ensure compliance.
 5. Determine appropriate corrective actions to address deficiencies in your FSVP.
 6. Document corrective actions.

FSPCA
FOOD SAFETY PERFORMANCE CONTROL AUTHORITY

This chapter will focus on:

1. Determining when reevaluations are needed,
2. Factors to consider for reevaluation,
3. Documenting the reevaluation,

4. Determine appropriate corrective actions to ensure compliance,
5. Determine appropriate corrective actions to address deficiencies in your FSVP, and
6. Document corrective actions.

FSVP Reevaluations

FSVP Reevaluations

When are reevaluations necessary?

- At least **every 3 years** you must reevaluate the previously identified factors relating to the evaluations of your **foreign suppliers and the foods** you import and take appropriate actions, if necessary.
- At any time you become aware of new information that may affect your food and foreign supplier performance evaluations, you must promptly review the appropriateness of your FSVP.



At a minimum, your food risk and foreign supplier performance must be evaluated **every 3 years**. In performing your evaluations, you must reevaluate the previously identified factors relating to your foreign suppliers and the foods you import, and take appropriate corrective actions on the basis of the reevaluation, if necessary (21 CFR 1.505(c)). FSVP importers must promptly review their evaluations pertaining to the food and their foreign supplier's performance at any time you become aware of new information that may affect your prior evaluations.

FSVP Reevaluations (continued)

- When considering new information, you generally need to determine:
 - Whether the supplier verification activities need to be changed, or
 - Whether to continue importing food from your foreign supplier.
- All reevaluations and the corrective actions taken as a result of them must be documented.



When considering the new information, you need to determine whether it is appropriate to take corrective action, including whether to continue to import the food from the foreign supplier and/or whether the supplier verification activities need to be changed. We will talk more about corrective actions below.

All reevaluations must be documented.

What if Modified Requirements Apply?

What if Modified Requirements Apply?

- If you are a “very small importer,” operating under modified FSVP requirements that allow you to rely on written assurances from your supplier:
 - A supplier evaluation and reevaluation are not required.
- However, if you are an importer that imports foods from “certain small foreign suppliers” (sec. 1.512(a)(2)), or an importer who imports dietary supplements (sec. 1.511(c)), you must:
 - Conduct a supplier reevaluation as required under the applicable sections.
- You must also monitor whether the modified requirements continue to apply.



If you are operating under certain modified FSVP requirements that allow you to rely on written assurances from your foreign supplier because you are a very small importer under section 1.512(a)(1)), a supplier evaluation and reevaluation are not required.

However, if you are an importer that imports certain foods from certain small foreign suppliers under section 1.512(a)(2) or an importer of certain dietary supplements under section 1.511(c), you must conduct supplier reevaluation as required under the applicable sections. You must also monitor whether the modified requirements continue to apply.

Group Discussion: What Issues Could Trigger a Reevaluation and Why?

Group Discussion: What Issues Could Trigger a Reevaluation and Why?

Examples of Possible Triggers for Reevaluation:

- Importer learns of a prohibited pesticide on fresh produce.
- A recall and/or illness outbreak involving the same or related products.
- You change your hazard analysis.
- Your supplier takes corrective action on a hazard in your food.
- Customer complaints related to food safety.
- An import is refused by FDA due to food safety concerns.
- Audit revealing significant deviations that could cause a food safety violation.
- Other similar indications of a food safety failure.

Note: The list on this slide is NOT exhaustive.



Let's have a short group discussion. If you would like to take notes, go to Chapter 7, page 17, in the Exercise Workbook.

Considerations for Reevaluation

Considerations for Reevaluation

- When reevaluating foreign supplier performance and food risk your considerations should include:
 - Any changes in the supplier's procedures, processes, and practices related to the safety of the food;
 - New information about the supplier's compliance with food safety standards (e.g., FDA warning letters);
 - Responsiveness of the foreign supplier in correcting food safety problems;
 - Any new information on food testing results; and
 - Any new audit results relating to the safety of the food.



When reevaluating foreign supplier performance and food risk your considerations should include:

- Any changes in the supplier's procedures, processes, and practices related to the safety of the food,
- New information about the supplier's compliance with food safety standards (e.g., FDA warning letters),
- Responsiveness of the foreign supplier in correcting food safety problems,
- Any new information on food testing results, and
- Any new audit results relating to the safety of the food.

Reevaluate Foreign Supplier Performance and Food Risk, and Taking Corrective Actions

FSVP Foreign Supplier Reevaluation Form Example

| FSVP Foreign Supplier Reevaluation Form Example | | | | | | |
|---|--|---|---|--|---|--|
| IMPORTER NAME | Page 1 | REEVALUATION DATE | REAPPROVAL DATE (IF APPLICABLE) | | | |
| ADDRESS | | QJ APPROVAL | DISCONTINUANCE DATE (IF APPLICABLE) | | | |
| FSVP Foreign Supplier Reevaluation Form Example* | | | | | | |
| Foreign Supplier Name | | Foreign Supplier Address [location] | | | | |
| Food Product(s) Imported | | Imported Food Product(s) Description, including Important Food Safety Characteristics | | | | |
| Type of Reevaluation** (I.e., regularly scheduled, "for cause") | | If "For Cause," Describe*** | | | | |
| Reevaluation Considerations and Results | | | | | | |
| Changes to the Supplier's Procedures, Practices, and Processes [1.505(a)(1)(ii)(A)] | New Import Alerts | New Recalls | New Warning Letters | New Other Significant Compliance Action(s) [1.505(a)(1)(iii)(B)] | Supplier's Corrective Actions | Other new information related to the safety of the food† |
| Changes to Food Safety Hazard(s) Controlled by Foreign Supplier††, ††† | Changes to Description of Foreign Supplier Control(s)††† | | | | | |
| Current Verification Activity(ies) and Frequency††† | Changes to Verification Activity(ies) and Frequency††† | | Justification for Changed Verification Activity(ies) and Frequency††† | | New Verification Records (I.e., audit summaries, test results)* | |

FSVP Foreign Supplier Reevaluation Form Example
– other formats may be used

This slide shows page 1 of a type of form that may be used to document your supplier reevaluation for food that is imported and governed by the FSVP rule. The format is not mandatory under the rule, but it is an example of a format that importers might use when performing a foreign supplier reevaluation as part of the FSVP. The form could be modified as needed to fit many of the situations that you may face.

| FSVP Foreign Supplier Reevaluation Form Example (continued) | |
|--|--------|
| FSVP Foreign Supplier Reevaluation Form Example* (continued) | |
| Assessment of Results of Foreign Supplier Reevaluation‡ <small>[Note: If the reevaluation was performed by another entity (other than the foreign supplier) include entity's name, address, email, and date of reevaluation.]</small> | Page 2 |
| Corrective Action(s) Taken as a Result of the Reevaluation†† | |
| <small>*All supporting documentation should be appended to this form. **Foreign supplier performance and food risk must be evaluated at least every 3 years or "for cause." ***"For cause" may include any changes in the supplier's procedures, processes, and practices related to the safety of the food; new information about the supplier's compliance with food safety standards (e.g., import alerts, recalls, FDA warning letters); responsiveness of the foreign supplier in correcting food safety problems; new information on food testing results; new audit results relating to the safety of the food; or other food safety considerations. †Includes previous and recent experience with the supplier (e.g., rejected shipments, lab results, audit summaries, or other food safety information you may have outside of the government oversight context). ††If someone other than the foreign supplier controls the hazard(s), document who is controlling the hazards and note if written assurances are required. †††When a Serious Adverse Health Consequences Or Death to Humans or Animals (SAHCODHA) hazard in a food will be controlled by the foreign supplier, the default verification procedure is the performance of a properly conducted onsite audit of the foreign supplier before initially importing the food and at least annually thereafter [21 CFR 1.506(d)(2)]. ‡If another entity (other than the foreign supplier) performs the foreign supplier reevaluation, you may meet your reevaluation requirements by having your QJ review and assess the entity's reevaluation. Your review/assessment of the reevaluation must include documentation that the reevaluation was conducted by a QJ. ††You must document all reevaluations and corrective actions taken, if any are necessary.</small> | |

FSVP Foreign Supplier Reevaluation Form Example
– other formats may be used

This slide shows page 2 of a type of form that may be used to document your supplier reevaluation for food that is imported and governed by the FSVP rule.

Relying on Another Entity's Reevaluation

Relying on Another Entity's Reevaluation

- You may rely on another entity's reevaluation and meet your reevaluation requirements by:
 - Reviewing and assessing that entity's reevaluation.
- Requirements for relying on another entity's reevaluation are:
 - The other entity's reevaluation must be performed by a qualified individual.
 - Your qualified individual must review the other entity's reevaluation and determine what actions are appropriate.
 - You must document your review and assessment.



You may rely on another entity's reevaluation to meet your reevaluation requirements by reviewing and assessing that entity's reevaluation.

But remember:

- The other entity's reevaluation must be performed by a qualified individual,
- Your qualified individual must determine what actions are appropriate.
- You must document your review and assessment.

Corrective Actions to Ensure Compliance

Corrective Actions to Ensure Compliance

- Corrective actions are the steps necessary to ensure that **future shipments of that food** are in compliance with U.S. food safety requirements.
- If you find through a routine reevaluation, verification activities, or other means that your foreign food supplier is NOT producing food that meets applicable U.S. safety standards, you will need to take corrective action.
 - Your qualified individual must determine whether corrective actions are necessary.
 - Corrective actions must be taken promptly once you ascertain that a food safety problem exists and that corrective actions are necessary.
 - You must verify that appropriate corrective action has been taken.
 - You must also document your investigations, corrective actions, and changes to your FSVP (1.508(b)).



System failures that effect food safety can occur in your supplier's process or procedures from time to time. Under the Preventive Controls (PC) and Produce Safety rules, food producers/suppliers are expected to correct the failure or deficiencies in their systems that might cause food to be unsafe. You, too, are expected to take corrective actions when you learn about problems that could impact the safety of the foods you import.

Your job as the FSVP importer, however, is to develop and carry out foreign supplier approval and other verifications to ensure that your suppliers are producing the food you import in compliance with processes and procedures that provide the same level of public health protection as the preventive controls requirements and the produce safety rule, if applicable, and that the food is neither adulterated under section 402 of the FD&C Act nor misbranded with respect to the labeling of major food allergens.

You may discover that your foreign supplier's food safety processes and procedures have failed to produce food for export to the U.S. that complies with applicable U.S. food safety requirements. You may learn of this noncompliance through your reevaluation, the results of your verification activities, or through some other means, such as consumer complaints. Once you discover the noncompliance, corrective actions must be taken to protect public health and prevent a reoccurrence. Your qualified individual must be the person to determine whether corrective actions are necessary to ensure compliance.

If corrective actions are needed to ensure compliance, then you, as the importer, must verify that appropriate corrective actions are taken and, as discussed below, you must document them appropriately.

Appropriate Corrective Actions

Appropriate Corrective Actions

- The appropriate corrective actions will depend on your findings, but could include:
 - Notifying the supplier of the problem and requesting documentation that it has been adequately addressed, or if necessary,
 - Discontinuing use of the foreign supplier until the cause or causes of noncompliance have been adequately addressed.
- Corrective actions will vary depending on the deficiency, but the test is that they need to correct the deficiency for the long term.



When you learn of system failures or actual food safety issues from your foreign suppliers, through consumer/customer complaints, your verification procedures, or otherwise, you need to consider what corrective actions are appropriate for you to take. You will need to determine if unsafe product was actually produced, or if your foreign supplier took appropriate corrective actions to prevent any contaminated food from being produced or being exported. The action you take should be appropriate to the nature of the hazard, the situation, and your and your supplier's ability to prevent a recurrence of the problem. Nevertheless, some situations require substantial corrective action, including discontinuing use of the foreign supplier. You must be confident that the consuming public is not exposed to any food that could cause illness or injury.

When you identify a gap in supplier performance related to food safety you must take **appropriate** steps to correct the deficiency. As noted earlier, corrective actions will vary depending on the deficiency, but the test is that they need to correct the deficiency for the long term. Taking an ineffective action is not good science, good compliance, or good business.

Corrective Actions to Address Deficiencies in Your FSVP

Corrective Actions to Address Deficiencies in Your FSVP

- If you determine that your supplier's noncompliance is based on something other than your reevaluation or your verification activities, then, in addition to taking corrective actions to address the noncompliance:
 - You must investigate to determine if your FSVP is adequate; and
 - If you determine it is inadequate, you must change your FSVP.



While taking action to address your supplier's noncompliance is critical, you must also assess whether you need to take corrective action to address deficiencies in your own FSVP. This is most likely when you discover your supplier's deficiencies through means outside your FSVP, such as through consumer complaints. You need to ask yourself, "Why you didn't find the deficiencies yourself"? The rule requires that you investigate the matter and, if you discover deficiencies in your FSVP, make changes to address them.

Documenting Corrective Actions

Documenting Corrective Actions

- You **must** document any corrective actions you take, including:
 - All corrective actions involving the supplier/food, and
 - Any investigations and changes made to your FSVP.



Key Point:

Documenting your corrective actions is important, but remember that records requirements are flexible and the FDA accepts a wide variety of record forms and documents. Existing records are acceptable if they meet the regulation. Records for corrective actions should include investigations, actions taken and changes made to FSVP, i.e., results of evaluations and determinations.

Finally, you must document all corrective actions taken (1.508(a)). If you discover the noncompliance through means other than your reevaluation or your verification activities, you must also document your investigations and changes to your FSVP (1.508(b)), in addition to your corrective actions.

Chapter 7: Summary

Chapter 7: Summary

- In this chapter we have covered:
 - When you must reevaluate your FSVP.
 - What to consider when you conduct your reevaluation.
 - The need to take appropriate and effective corrective actions to address supplier/food noncompliance.
 - The need to investigate and take corrective actions to address deficiencies in your FSVP.
 - That reevaluations and corrective actions must be documented.



This chapter has covered the following:

- When you must reevaluate your FSVP.
- What to consider when you conduct your reevaluation.
- The need to take appropriate and effective corrective actions to address supplier/food noncompliance.
- The need to investigate and take corrective actions to address deficiencies in your FSVP.
- The need to document reevaluations and corrective actions.

Chapter 7: Questions

Chapter 7: Questions

Thank you for your attention!

Questions?

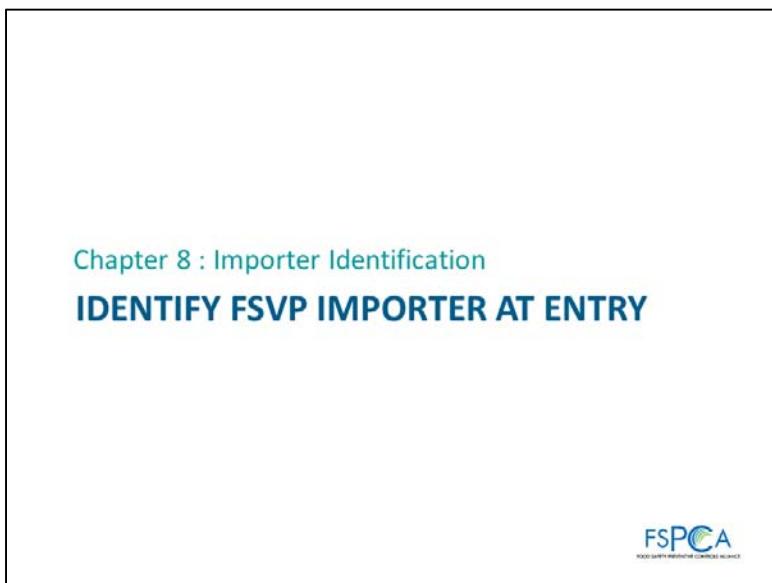


Notes:

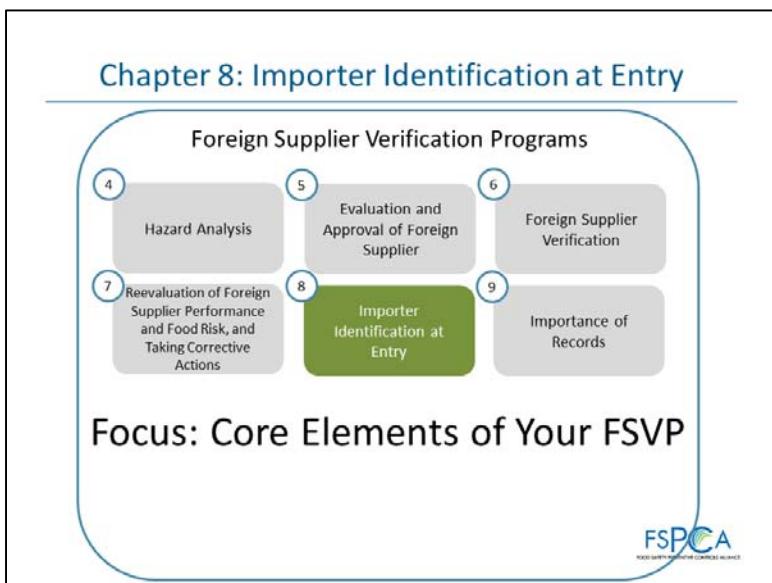
Blank Colored Insert-Front

Blank Colored Insert-Back

Chapter 8. Importer Identification at Entry



Under the FSVP rule, you must provide additional data to U.S. Customs when a food is offered for entry into the United States.



Chapter 8 is next to the last chapter in the core elements (or standard requirements) of your FSVP. This chapter provides more information on the importer at entry FSVP requirement.

Chapter 8: Goal and Objectives

Chapter 8: Goal and Objectives

Goal: Participants will be able to identify FSVP importer at entry.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Explain the change to import entry procedures.
 2. Recall which entity should be the FSVP importer.
 3. Ensure entry data identifying the FSVP importer is submitted.
 4. Show where to obtain a unique facility identifier (DUNS number).
 5. Recognize when written consent of a U.S. agent is needed.



This chapter will discuss the requirement, what information must be submitted, and how to obtain a DUNS number. It will discuss the need to ensure that the responsible FSVP importer is correctly identified by the entry filer and that, if the FSVP importer is the U.S. agents or representatives of the foreign supplier, written consent is required to be identified in an entry filing. This chapter also makes the linkage between FDA oversight/enforcement and the FSVP importer's identification information into the U.S. Customs entry system.

U.S. Entry Procedures

U.S. Entry Procedures

- The FSVP rule will not generally affect FDA's current entry process.
- The only change you will see at entry is the requirement to identify the FSVP importer at entry.
- Changes have been implemented to the Customs and Border Protection (CBP) entry system to accept this data.



In general, you will not see changes to the entry procedures as a result of the FSVP rule. The one exception is that you must identify the FSVP

importer at the time of entry. Identifying the FSVP importer at time of entry should be a simple task. Still, there are a number of aspects of this FSVP process that can be delineated and certain aspects that must be stressed to ensure it is done properly.

FSVP requires that the FSVP importer identification requirements be entered through the Customs entry system for each applicable line entry. The Customs entry system has been modified to accept this additional data.

It is important to understand that FDA will not assess FSVP compliance on a shipment by shipment basis during the admissibility process. Rather, FDA will assess the FSVP importer's compliance by reviewing FSVP records at the FSVP importer's place of business in the U.S., as identified through the new data requirements.

Importance of Identifying FSVP Importer

Importance of Identifying FSVP Importer

- Identifying the FSVP importer is a legal requirement for entering food into the U.S.
- Failure to provide such information will lead to a rejection of the entry filing.
- FDA will be building an inventory of FSVP importers off the Customs' data.



Once your compliance date has arrived for a particular line entry, you must provide the additional information properly identifying the FSVP importer when the entry is offered for import. If you do not, your filer will receive an error message from Customs. The information entered will allow FDA to build an inventory of FSVP importers for oversight purposes. You should be working with your filer prior to entry to ensure he/she has the appropriate information to be submitted to Customs.

What FSVP Information Must Be Provided at Entry?

What FSVP Information Must Be Provided at Entry?

- For each line entry of food product presented for entry into the U.S., FSVP requires the following information to be provided electronically to identify the FSVP importer of the food:
 - Name
 - Electronic mail address
 - Unique facility identifier (UFI) (more detail to follow)



The entity role code, FSV, mentioned earlier, is required to be input into the system for each line entry of food product offered for importation into the U.S. (21 CFR 1.509(a)). The FSV entity role code will trigger a request for additional information that will identify the FSVP importer:

- Firm Name
- Email address
- Unique Facility Identifier

If the line entry is exempt from the requirements of FSVP or the product being submitted for entry is not subject to the rule based on the compliance date applicability, the AofC codes FSX (FSVP Exempt or compliance date applicability) or RNE (Research and Evaluation) are to be used.

If line item is a food and one of these two codes are not transmitted as stated above, the entry will be rejected by the CBP's ACE system. The rejection will generate an error message so the filer can make the appropriate adjustments to the entry submission and retransmit the entry line.

FDA will be able to view transmitted data to ensure the accuracy of the information and determination if the correct coding was used at the time of submission.

For additional technical information some may want to reference FDA's *Supplemental Guidance for the CBP and Trade Automated Interface Requirements* at:

<https://www.cbp.gov/sites/default/files/assets/documents/2017-Jan/FDA%20Supplemental%20Guide%20Release%202.5%20FINAL%20DEC%202016%20.pdf>

You Must Have a Unique Facility Identifier

You Must Have a Unique Facility Identifier

- The FSVP rule requires that each FSVP importer have a unique facility identifier (UFI) that is acceptable to FDA to be placed in the Customs entry filing.
- FDA has recognized the DUNS number as acceptable.
- The FSVP importer must, therefore, obtain a DUNS number prior to your first compliance date.
 - **Anyone can obtain at no cost from Dun & Bradstreet**
 - The DUNS number provided must be associated with the person listed as the FSVP importer



The final FSVP rule requires the submission at entry of a unique facility identifier (UFI). In a guidance issued in March 2017, FDA recognized the DUNS number as acceptable. At this time, the DUNS number is the only UFI recognized by FDA.

DUNS numbers can be obtained online by anyone and at no cost from: <http://www.dnb.com/government/duns-request.html>

It should be mentioned that DUNS numbers are specific to physical locations; therefore, an importer with more than one physical location likely would have more than one DUNS number. Make sure the DUNS number provided is associated with the person/company location identified as the FSVP importer because this is the location FDA will inspect (typically the location at which FSVP records are maintained, although records may be kept offsite under the rule).

Key Point:

If you already have a DUNS number: You do not need to get a new one.

If you do NOT have a DUNS number, you should get one prior to your first compliance date. If you are unable to obtain a DUNS number, FDA will allow filers to transmit the value “UNK” (to represent “unknown”) in the UFI field.

FDA will contact FSVP importers for whom “UNK” was transmitted to ensure that they understand the UFI FSVP regulation requirement and take steps to obtain a UFI.

Chapter 8

Key Point:

Basically, all commercial CBP entries are now filed electronically via special software (offered by private vendors) that interfaces with CBP's ACE system. The ACE system is the primary system through which the trade community reports imports and exports and the government determines admissibility. ACE is already required for most entries.

CBP ACE Home page:
<https://www.cbp.gov/trade/automated>

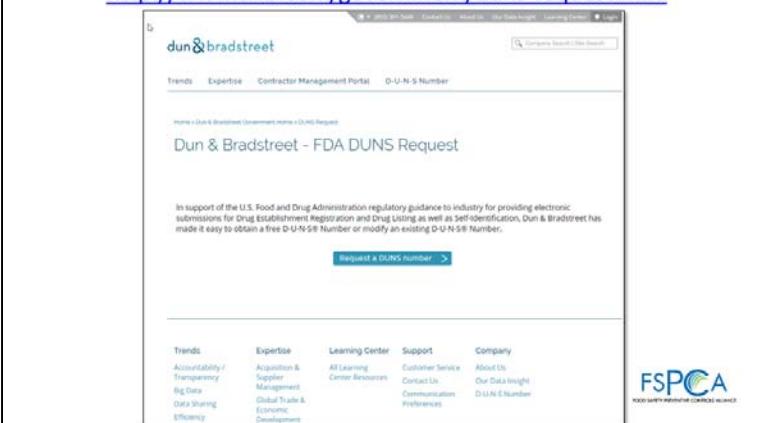
Key Point:

FDA Guidance on Complying with the UFI Requirement at Entry:

- Guidance for Industry: Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation:
<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocuments/RegulatoryInformation/UCM549647.pdf>
- Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation:
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm556661.htm>

Request a Free DUNS Number

To request a FREE DUNS number go to Dun & Bradstreet's Website
<http://www.dnb.com/government/duns-request.html>



Above on the slide is a screenshot of the Dun & Bradstreet "FDA DUNS Request" web page, along with the link information.

You will want to be sure you have all of the information identified earlier that you need before trying to fill out and submit the request.

Complying with the Unique Facility Identifier (UFI) Requirement

Complying with the Unique Facility Identifier (UFI) Requirement at Entry

- When a food product under FDA oversight is offered for entry into the U.S., the CBP Automated Commercial Environment (ACE) system will prompt the filer to transmit one of the following codes:
 - An entity role code "FSV" – signals to ACE system that entry line subject to FSVP rule;
 - ACE will request FSVP importer's name, email address, and DUNS number
 - An Affirmation of Compliance code "FSX" – entry line is exempt from or not yet subject to FSVP;
 - An Affirmation of Compliance code "RNE" – entry line is exempt from FSVP as food is being imported for research or evaluation.
- If one of these codes is not transmitted, the filer will receive an error message.
- The filer can make the appropriate adjustments to the entry submission and retransmit the entry line.



As of May 30, 2017, the data elements that relate to the FSVP rule are utilized and accepted by CBP.

The electronic filing is done by a licensed custom broker. As the entry information is input into CBP's Automated Commercial Environment (ACE) the system will be able to detect based on an agency program code **FOO** if the line entry is associated with a food (human or animal) commodity. Once this detection has been made the system will prompt the filer to enter one of two types of codes: An entity role code **FSV**, which will signal to the system that the line entry is under the jurisdiction of the FSVP regulation or; an Affirmations of Compliance (AofC) using either of the AofC codes **FSX** for "FSVP Exempt" or **RNE** for "Research and Evaluation."

Example of a Software Screen Where You Select Role Code FSV and Enter FSVP Importer Information

Entry of Code FSV for FSVP

Entry of DUNS #, Name, Address, and Email of the FSVP Importer

Note: Each Software Vendor May Handle the Entry(ies) Differently

Image: Courtesy of SmartBorder by SouthRanch, Inc.

The screenshot shows a software window titled 'Product Edition' with a sidebar for 'Entity Role Codes'. Under 'Selected Codes (FSV)', the 'FSV | FSVP IMPORTER' option is selected. The main panel contains fields for 'Entity ID Type' (DUNS #), 'Name' (ATLAS SFTL), and 'Address 1' (4112 MADISON ST, DALLAS, TX, 75202). Below this is a table for 'Individual Entries' with columns for 'IndividualQualifier', 'Name', 'Phone', and 'Email or Fax'. One row is shown: 'FSV' with 'FSV CONTACT NAME' and 'FSVCONTACT@ATLAS.COM'. At the bottom are 'OK' and 'Cancel' buttons.

The software used to provide this information is purchased by the filer from a software company, not FDA, and will vary. The screenshot on the slide is one example of a software screen where the role code FSV is to be selected and the FSVP importer information is to be entered. **Note: There are many different software vendors and the screens may be different for each one, but the required information will be the same no matter what software the licensed broker is using.**

At the top of the screenshot, you can see where the FSV code for FSVP is available to select. This is the role code we mentioned earlier. When the FSV code is selected, this software requires, among other things, the entry of the UFI (DUNS #) and the name and an email address. The filer's software may also request additional information, such as the physical address. If so prompted, the address entered should be that of the FSVP importer.

Example of a Software Screen When Entering Affirmation of Compliance (AofC) Code

Example of a Software Screen When Entering Affirmation of Compliance (AofC) Code

Note: Each Software Vendor May Handle the Entry(ies) Differently

SmartBox

Code Description

- FSX Food Safety and Research Exempt
- CAN Carrier Name
- CCC Orville Ceramic Ware Factory Code
- FAP Food Additive Permit Application Number
- ACE Food Canning Establishment Number
- PRN Food Processor/Establishment Registration Number
- RNE Research and Evaluation
- GRN Growers food facility registration number
- DBP Dealer/Bulk Pepper Certificate
- IEP Importer Exporter
- JRF Juice Handler Facility Registration Number
- OBN Owners food facility registration number
- MFN Manufacturers food facility/registration number
- REI Research and Evaluation, FSVP Exempt
- GRF Graders food facility registration number
- SID Schedule Identifier Number
- SHP Seafood HACCP Importer Firm
- SPN Supplier food facility/registration number
- TFN Transmitter food facility/registration number
- URN Ultimate consignee food facility/registration number
- VES Vessel Name
- VFT Voyage, Trip, Flight Number

Example of codes (e.g., FSX, RNE) to choose from for Affirmation of Compliance (AofC) Code

Cancel

Image: Courtesy of SmartBorder by South Ranch, Inc.

FSPCA
Food Safety Partnership Council

The screenshot in the slide above is showing the two AofC codes (FSX and RNE) mentioned earlier. Again, if the line entry is exempt from the requirements of FSVP or the product being submitted for entry is not subject to the rule based on the compliance date applicability, the AofC codes FSX (FSVP Exempt or compliance date applicability) or RNE (Research and Evaluation) are to be used.

Some Importer Identification Issues

Some Importer Identification Issues

Name in CBP entry = Person responsible for FSVP

- FDA will hold the FSVP importer identified on the CBP filing responsible for meeting the FSVP requirements and will inspect that entity for compliance.
- Be sure the person filling out the CBP entry filing for any food you import or any imported food you receive knows the proper party to enter as the FSVP importer.

FSPCA
Food Safety Partnership Council

Several points should be made relative to the FSVP importer named on the CBP entry filing. First, FDA will conduct oversight, that is, inspect the FSVP importer, based on an inventory, which will be

established through this identification requirement of the regulation. Per FSMA, FDA has a statutory requirement to develop and publicly post a list of FSVP importers. In fact, FDA states in the FSVP preamble that it will publish such a list. "In publishing the list of importers 'participating' in FSVP, we intend to develop a list that includes importers who are subject to the FSVP regulation (and not exempt from the requirements under 1.501 of the final rule)....Besides the name and location of importers, we are uncertain what other information, if any, we will include as part of our list of importers subject to the FSVP regulation."

Second, it is important that you ensure that the person filling out the CBP entry filing for any food you import or any imported food you receive knows the proper party to enter as the FSVP importer, as well as the electronic mail address and DUNS number. If you do not wish to be the FSVP importer, but you may meet the definition for FSVP importer in the FSVP rule, you need to be part of the decision about who the FSVP importer will be. Otherwise, someone might decide it should be you, which leads to the discussion on the next slide.

Some Importer Identification Issues (continued)

- **U.S. agent/representative consent:**

- In the event that there is no U.S. "owner or consignee," U.S. agents or representatives of foreign exporters are required to consent in writing before being designated as an FSVP importer.
- Consent will be verified through FDA's inspection of the FSVP importer.



Remember that when there is no U.S. "owner or consignee," U.S. agents and representatives of foreign owners and consignees can serve as the FSVP importer. In that case, the U.S. agent or consignee is required to consent to be the FSVP importer in writing. That consent is not checked at time of entry, but FDA will check this when enforcing the FSVP rule.

Persons who fall under the definition of U.S. owner or consignee do NOT have to consent in writing to be the FSVP importer, but may unknowingly have their names placed on the CBP entry filing as the FSVP importer, such as when more than one entity meets the definition of U.S. owner or consignee of a food. You may not learn that you were identified as the FSVP importer of a line entry of food until

FDA contacts you to review your FSVP records. If you are concerned, you may want to periodically check FDA's public list of FSVP importers to see if you are named. **It is important to understand who is the designated FSVP importer for all imported foods you receive. In cases in which you are one of multiple entities who meet the definition of U.S. owner or consignee of an imported food, you should seek to reach agreement on which these entities will serve as the U.S. importer of the food for FSVP purposes.**

Group Exercise: Importer Designation at Entry—Scenario 1

Group Exercise: Importer Designation at Entry—Scenario 1

A U.S. retailer regularly uses a multinational produce distributor (who has offices in the U.S.) to buy pineapples.

- The distributor generally sources the pineapples from Asian countries and occasionally Central America.
- The distributor takes care to ensure that the product, wherever it is sourced, will meet the U.S. retailer's specifications, including food safety requirements.
- The distributor handles all shipping arrangements and CBP entry filing.
- Generally, there are a number of individual retailers that have purchase orders for the pineapples in an individual line item shipment.
- Multiple retailers and the produce distributor may fall under the FSVP "importer" definition.

Questions:

1. How is a decision made on who should be the FSVP importer designated on the CBP entry filing?
2. Who is in the best position to be the FSVP importer?



Review Scenario 1 and participate in a group discussion to answer the questions below. If you would like to take notes during the discussion, go to Chapter 8, page 18, in the Exercise Workbook.

1. How is a decision made on who should be the FSVP importer designated on the CBP entry filing?
2. Who is in the best position to be the FSVP importer?

Group Exercise: Importer Designation at Entry—Scenario 2

Group Exercise: Importer Designation at Entry—Scenario 2

The distributor in Scenario 1, has heard about, but does not wish to deal with, the FSVP requirements for the pineapple shipments.

- The distributor looks up the DUNS number for one of the several retailers who purchases their pineapples and, now, regularly types in the retailer's name, email address, and DUNS number on the Customs entry filing as the FSVP "importer."
- The retailer, who purchases many imported foods and has not yet focused on its pineapple imports as purchase orders are continuing to be fulfilled without disruption, is surprised when an FDA inspector turns up at the door asking to see the company's FSVP records.

Question:

1. What options are available for avoiding this scenario?



Review Scenario 2 and participate in a group discussion to answer the question below. Again, if you would like to take notes during the discussion, go to Chapter 8, page 18, in the Exercise Workbook.

1. What options are available for avoiding this scenario?

Chapter 8: Summary

Chapter 8: Summary

- In this chapter, we have discussed:
 - It is important to identify the FSVP importer at entry.
 - The traditional CBP entry process is the same except that now you must also identify the FSVP importer by providing additional data elements to CBP upon entry.
 - You must know what information is required, how to obtain a DUNS number, and how to enter the required information at entry.
 - If more than one entity meets the FSVP definition of importer for a particular entry, it is important to decide ahead of time which one will serve as the FSVP importer and be identified at entry.
 - FDA will view that person as the responsible party for meeting all FSVP obligations under the regulation.



We have discussed the importance of properly identifying the FSVP importer at entry. You should now know what information has to be provided to Customs, how to obtain a DUNS number, and how to enter the information at entry. FDA will use this information to oversee the

FSVP importer. Ensuring that the appropriate party is entered on CBP entry filing is very important, from a standpoint of ensuring that FSVP obligations have been met, as well as making sure that persons NOT implementing the FSVP requirements are not unknowingly listed as the FSVP importer. Making stable arrangements to designate an appropriate FSVP importer and to confirm that the appropriate person is the ONLY one identified at entry cannot be overemphasized.

Chapter 8: Questions

Chapter 8: Questions

Thank you for Your Attention!

Questions?



Notes:

Blank Colored Insert-Front

Blank Colored Insert-Back

Chapter 9. Importance of Records

Chapter 9: Importance of Records

EXAMINING THE IMPORTANCE OF RECORDS AND A RECORDKEEPING SYSTEM, WHICH ARE THE BASIS FOR DETERMINING COMPLIANCE WITH FSVP REQUIREMENTS.

FSPCA
FOOD SAFETY PRACTICE CENTER ALIANCES

Making and maintaining adequate records is not only required, but also very important for demonstrating to FDA that you are in compliance with the FSVP rule. **Your performance of every aspect of developing and conducting your FSVP must be documented, and you must make your FSVP records available to FDA promptly upon request.**

Chapter 9: Importance of Records

Foreign Supplier Verification Programs

- 4 Hazard Analysis
- 5 Evaluation and Approval of Foreign Supplier
- 6 Foreign Supplier Verification
- 7 Reevaluation of Foreign Supplier Performance and Food Risk, and Taking Corrective Actions
- 8 Importer Identification at Entry
- 9 Importance of Records

Focus: Core Elements of Your FSVP

FSPCA
FOOD SAFETY PRACTICE CENTER ALIANCES

Chapter 9 is the last chapter in the core elements (or standard requirements) of your FSVP. This chapter presents the details of the FSVP record requirements.

Chapter 9: Goal and Objectives

Chapter 9: Goal and Objectives

Goal: Participants will be able to set up an FSVP recordkeeping system.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Recognize the importance of FSVP records.
 2. Identify the records that demonstrate FSVP compliance.
 3. Describe the requirements for FSVP record maintenance.



Chapter 9 will help you recognize why records are important for documenting everything you do to comply with the FSVP rule. It will also help you to:

1. Recognize the importance of FSVP records,
2. Identify the records that demonstrate FSVP compliance, and
3. Describe the requirements for FSVP record maintenance.

Your Records Are Important

Your Records Are Important

- Records provide evidence to the FDA that you are meeting your FSVP obligations.
- Records may be helpful in demonstrating that your foreign suppliers are producing safe food for U.S. consumers.
- Failure to comply with the FSVP record requirements may hinder your ability to import food.



FDA has stated that it will rely heavily on records inspections in determining your compliance with FSVP requirements, so it's in your best interest to make and maintain adequate records.

Failure to keep adequate records is a violation of the FSVP rule and the FD&C Act. FDA can take enforcement action against you if you violate FSVP requirements, including the records requirements. Additionally, FDA has authority to refuse future entry of your food into the U.S.

FDA is, however, providing importers with considerable flexibility with regard to records. In the preamble to the FSVP rule, FDA states "...the regulation generally does not specify a particular form or format for required documentation."

What Is an FSVP?

What Is an FSVP?

Your FSVP = All records and documentation that demonstrate your compliance with applicable FSVP requirements for a particular imported food product/foreign supplier



As previously noted in Chapter 2, a Foreign Supplier Verification Program does not have a set format. The FSVP rule sets forth requirements that must be met, but it may be the case that only a few or many requirements pertain to your particular food/foreign supplier circumstances. What you do in implementing the FSVP requirements constitutes your program. How you document what you do is what FDA will see in assessing your compliance with the FSVP rule. Therefore, records are very important. The cumulative records demonstrating implementation of FSVP requirements are your FSVP.

Illustration: FSVP Records

Illustration: FSVP Records

- If you are the FSVP importer subject to the standard requirements, **all of the following records** make up your FSVP:
 - Hazard analysis
 - Evaluation of foreign supplier performance and risk posed by food
 - Procedures for approving foreign suppliers
 - Documentation of foreign supplier approval
 - Procedures to ensure use of only approved foreign suppliers
 - Determination of verification activities and frequency
 - Performance of verification activities
 - Discussion of any needed corrective actions
 - Reevaluations of your FSVP, either routinely every 3 years or for cause



Key Point:

Many importers may want to develop a written program overview document, e.g., Standard Operating Procedures (SOP), that helps explain how all of these records fit together. This may be a useful tool during FDA inspections.

The following are records relevant to your foreign supplier that you should maintain, including:

- The hazard analysis,
- Evaluation of foreign supplier performance and risk posed by the food,
- Procedures for approving foreign suppliers,
- Documentation of foreign supplier approval,
- Procedures to ensure use of only approved foreign suppliers,
- Determination of verification activities and their frequency,
- Performance of verification activities,
- Discussion of any needed corrective actions, and
- Reevaluations of your FSVP, either for routinely every 3 years or for cause.

An Example: Hazard Analysis Records You Need for an FDA Inspection

An Example: Hazard Analysis Records You Need for an FDA Inspection

- You will need records that demonstrate that you performed a hazard analysis. This documentation should include, but not be limited to:
 - Determination of the hazards, if any, and whether they are known or reasonably foreseeable.
 - Assessment of the probability that the hazard will occur in the absence of controls.
 - Assessment of the illness or injury if the hazards are to occur.
 - Any review and assessment of a hazard analysis performed by another entity, including that it was done by a qualified individual.



An example of the hazard analysis records you need for an FDA inspection should include, but not be limited to:

- Determination of the hazards, if any, and whether they are known or reasonably foreseeable.
- Assessment of the probability that the hazard will occur in the absence of controls.
- Assessment of the illness or injury if the hazards are to occur.
- Any review and assessment of a hazard analysis performed by another entity, including that it was done by a qualified individual.

Maintaining FSVP Records

Maintaining FSVP Records

- You, as a food importer, must document and maintain records for every FSVP activity you are required to perform.
- The records may be:
 - Original records
 - True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche or other accurate reproductions of the original records)
 - Electronic records:
 - **Note:** Importers must maintain a system for their electronic records to ensure that the records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.
- Records may be maintained in a language other than English.



As noted earlier, the food importer must document and maintain records for every FSVP activity.

The records may be:

- Original records,
- True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche or other accurate reproductions of the original records), or
- Electronic records*, and
- Maintained in a language other than English.

**Note: Importers should maintain a system for their electronic records to ensure that the records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.*

Key Point:

If you rely on records prepared by another entity, you still need to retain, sign, and date the records of your qualified individual's assessment of the other entity's records. You should also recognize that, if FDA inspects your records, the agency will need to be able to evaluate whether the original activity (e.g., another entity's hazard analysis) was conducted in a manner that meets FSVP requirements. As an illustration of this, remember that the rule specifies in the case of audits that you are not required to maintain a copy of another entity's audit report, but you must retain documentation of 1) audit procedures, 2) dates of the audit, 3) conclusions of the audit, 4) any corrective actions taken to correct deficiencies, and 5) that the audit was done by a qualified auditor.

Key Point:

The FSVP importer is ultimately responsible for these activities. Each activity must be conducted by an importer's qualified individual (a person who is qualified to conduct the particular activity). The qualified individual is likely either an employee of the importer or acting on behalf of the importer so the qualified individual will sign the records for the importer (who, remember, is most likely a business entity). If the activity is done by someone who is not acting on behalf of the importer (e.g., hazard analysis of the supplier performed by another entity), then the importer, through its qualified individual, has to review and assess that activity and must sign the documentation that they reviewed or assessed it. That assessment would include that they have determined that whoever did that activity is a qualified individual.

Records Must Be Signed and Legible

Records Must Be Signed and Legible

- You, as a food importer, must sign and date records concerning your FSVP upon:
 - Initial completion, and
 - Any modification of the FSVP.
- All records must be legible and stored in a manner to prevent deterioration or loss.
- All records should be made at the time the activity is being performed—not two hours or two days later.
- All records should include enough detail to demonstrate your compliance with FSVP requirements.



You must sign and date records concerning your FSVP upon initial completion and upon any modification of the FSVP.

All record entries must be accurately recorded in a permanent and legible manner and stored to prevent deterioration or loss.

It is recommended that your records should be made at the time the activity is being performed—not two hours or two days later—so that you can ensure your documentation is accurate. Records also should include enough detail to demonstrate your compliance with FSVP requirements.

Records May Be Maintained in a Language Other Than English

Records May Be Maintained in a Language Other Than English

- If requested by FDA, you must provide an English translation of records maintained in a language other than English to FDA within a reasonable time.
- A qualified individual must be able to read and understand the language of any records that the person must review.



Records are not required to be maintained in English, but you must translate records to English upon FDA request. The qualified individual must be able to read and understand the language of any records that the person must review in performing an activity required under the rule.

FDA explained in the preamble to the final rule that, “Although existing FDA regulations (120.14(c) and 123.12(c)) require importers of juice and seafood to maintain records in English, we conclude that it is not necessary to include such a requirement in the FSVP regulation.” “First, because an importer would not be able to meet its FSVP requirements (e.g., hazard analysis, review of results of supplier verification activities) if it could not understand the documents that it was reviewing, we have added a requirement, in § 1.503(a) of the final rule, that a qualified individual must be able to read and understand the language of any records that the qualified individual must review in performing activities to meet FSVP requirements.”

Key Point:

FDA states in the preamble to the rule, "We believe that a 'reasonable' time in which to provide translated records would depend on the volume of the records requested, but should not be so long as to impair the Agency's ability to conduct record reviews and follow-up enforcement activities. Without the requirement to translate records in a reasonable time, we would not be able to efficiently enforce section 805 of the FD&C Act."

Resources:

To review the information regarding records maintained in a language other than English, see Appendix 1, pg. A1-24, sec. 1.510(b)(1).

Records Must Be Available to FDA

Records Must Be Available to FDA

- All records required by the FSVP rule must be made available promptly:
 - To an authorized FDA representative, upon request,
 - For inspection and copying.
- If requested in writing by FDA, you must:
 - Send records to FDA electronically, or
 - Through another means that delivers the records promptly.
- An English translation of records must be provided within a reasonable amount of time.



You must make all records required by the FSVP rule available promptly to an authorized FDA representative, upon request, for inspection and copying. Note that FDA may not always make a visit to your premises to request records but may request records be provided electronically or through another means that delivers the records promptly. FDA is required to make such requests in writing. Because all or some records may be recorded in a language other than English, FDA may request that records be provided in English and you must provide a translation of records within a reasonable amount of time, if requested to do so.

FDA has indicated that the inspection of U.S. food importer records will be an important agency activity after the compliance dates for the FSVP rule become effective.

Offsite Records

Offsite Records

- Offsite storage of records is permitted:
 - If the records can be **retrieved and provided onsite within 24 hours** of a request for FDA review.



Offsite storage of records is permitted if the records can be retrieved and provided onsite within 24 hours of request for FDA review.

Although FDA is being flexible about offsite records, you need to remember that failure to deliver the records promptly will be considered a violation. If you are unable to deliver your records to FDA within 24 hours, you should communicate with the FDA investigator making the request as soon as possible and discuss a reasonable alternative.

Retaining Records

Retaining Records

- You **must retain records** that relate to **your processes and procedures for any required activities, including the results of evaluations and verifications you conduct:**
 - For at least 2 years after their use is discontinued, e.g., after discontinuing use of a particular supplier.
- You must retain **all other records:**
 - For at least 2 years after you created or obtained the records.
 - Note: Documentation for “very small importer” eligibility must be retained for at least 3 years.



You must retain records that relate to your processes and procedures, including the results of evaluations and determinations you conduct, for at least 2 years after use of the processes and procedures is discontinued.

So, if you have stopped importing a particular food, or stopped using a particular foreign supplier, or changed your FSVP, these could be considered examples of records whose use is discontinued.

All other records should be retained for at least 2 years after you created or obtained the records. There is also a 3-year retention requirement for documentation of “very small importer” eligibility.

If FDA asks for records that have been lost or destroyed too soon, it will be as if the records never existed and FDA will have no evidence that you did what you were required to do.

Existing Records for FSVP Purposes

Existing Records for FSVP Purposes

- If existing records contain required information for FSVP purposes:
 - You can use them; you do not need to duplicate.
- If existing records contain only some of the required information you must:
 - Obtain any required new information, and
 - Maintain additional required new information either separately or combined with the existing records.



You do not need to duplicate existing food safety-related records if they contain information required for FSVP purposes. However, if your existing records contain only some of the required information, you may maintain any required additional records either separately or combined with the existing records. For example, many retailers utilize private international food safety management schemes. Records that foreign suppliers or importers maintain under such systems may be similar to those needed for FSVP purposes, but again, importers may need to supplement their existing records to make sure that all requirements under FSVP record requirements can be satisfied.

FSVP records obtained by FDA are subject to the information disclosure regulations in 21 CFR Part 20.

Some Records Provided to FDA May Be Subject to Public Disclosure

Some Records Provided to FDA May Be Subject to Public Disclosure

- Under § 1.510(f) of the final rule, FDA states, “records obtained by FDA in accordance with the FSVP regulation will be subject to the public disclosure provisions in part 20 (21 CFR part 20), including the protections against disclosure of trade secrets and commercial or financial information that is privileged or confidential.”
- Part 20 requires the disclosure, but also contains the **exemptions** that protect trade secrets and confidential commercial information from disclosure.



Resources:

See 21 CFR Part 20 regarding Public Information available on FDA website at:

<https://www.gpo.gov/fdsys/pkg/CFR-1999-title21-vol1/pdf/CFR-1999-title21-vol1-part20.pdf>

Many organizations and people submit “freedom of information” or FOI requests to FDA, and the agency is required to make many types of documents (but not all) available to the public. Records obtained by FDA in the process of enforcing FD&C Act requirements, including FSVP requirements, may be disclosed in response to an FOI request.

The FDA regulations that explain the rules for disclosing records to the public are contained in 21 CFR Part 20 (see link in the Resources textbox to the right of the slide). Part 20 requires the disclosure, but also contains the exemptions that protect trade secrets and confidential commercial information from disclosure.

Importance of Records

Importance of Records

- Records are important in demonstrating that:
 - You are carrying out FSVP requirements properly.
 - Your foreign supplier is meeting U.S. food safety standards.
- A good recordkeeping system facilitates FDA inspections and record requests.



Records are important in determining whether you are properly performing your FSVP responsibilities and your foreign suppliers are meeting their food safety responsibilities. If the records don't exist or are not available for an FDA inspection or records request, then FDA will conclude that you are not meeting the requirements of the FSVP rule. FDA will issue guidance that relates to recordkeeping.

Chapter 9: Summary

Chapter 9: Summary

- We have discussed:
 - The requirements for creating and maintaining adequate records.
 - The importance of records to you and to FDA.
 - Documenting the performance of every FSVP requirement.
 - Maintaining records for at least two years and making them available to FDA upon request.



This chapter has focused on the importance of records. It has explained:

- The requirements for creating and maintaining adequate FSVP records,
- The importance of those records to you and to FDA,
- The need to make them available to FDA immediately upon request, and
- The need to maintain your records for at least two years.

Chapter 9 Exercise: “What Records Are Required of FSVP Importers?”

Chapter 9 Exercise: “What Records Are Required of FSVP Importers?”

- **Timing:** 20 minutes total
 - 10 minutes to answer the True/False questions.
 - 10 minutes for instructor to go over the answers and respond to any questions.
- **Directions:** Identify what records are required of FSVP importers by selecting true or false at the end of each question (see Chapter 9, page 19, in the Exercise Workbook for the questions).
- The instructor will share and discuss the answers after everyone has finished.
- You will be given 10 minutes to answer the questions.



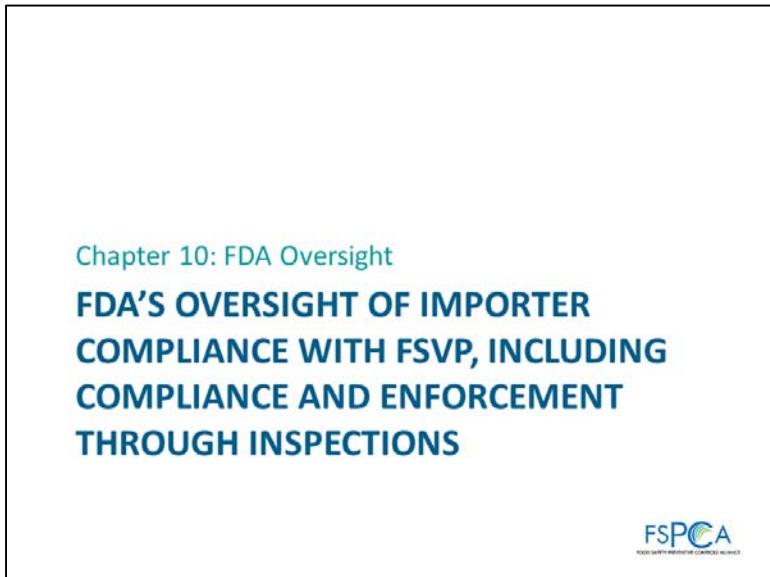
This exercise provides an opportunity not only to reinforce the FSVP records concepts, but also to review some of the other FSVP requirements for which records are required.

Directions: Identify what records are required of FSVP importers by selecting true or false at the end of each question (see Chapter 9, page 19, in the Exercise Workbook).

Blank Colored Insert-Front

Blank Colored Insert-Back

CHAPTER 10. FDA Oversight



FDA has stated that its primary goal is to work with the food industry to create a culture of food safety and compliance. They emphasize that they will be educating before and while they are regulating. In the preamble of the FSVP rule FDA stated, "We understand the need for both flexibility and accountability when conducting records reviews for compliance with the FSVP regulation.... However, the regulation requires importers to document their procedures, determinations, and activities to allow us to assess importers' compliance."



Chapter 10 is the last chapter in the FSVP curriculum and is focused on FDA oversight and what that means to you as an FSVP Importer.

Chapter 10: Goal and Objectives

Chapter 10: Goal and Objectives

Goal: Participants will be able to articulate FDA's oversight of importer compliance with FSVP.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Describe the FDA inspection process.
 2. Prepare for an FDA inspection.
 3. Explain consequences of non-compliance with FSVP rule.
 4. Describe FDA's enforcement tools.
 5. Recognize the phase-in of compliance dates.



Good recordkeeping to document compliance with the FSVP rule will be key to having a good result when FDA inspects an FSVP importer. In the FSVP final rule, FDA clarified, “Because the FSVP regulation requires documentation of an importer’s implementation of its FSVP, our inspections will be records-based.” This chapter will help in getting you ready for such an inspection in letting you know what to expect and how to be prepared. The more you know about how FDA operates and what authorities it has to enforce the law, the more comfortable you will be in dealing with FDA’s regulatory inspectors and the more helpful you can be to one another.

How Will FDA Oversee FSMA Rules?

How Will FDA Oversee FSMA Rules?

Initially, FDA will:

- Emphasize education and outreach on the new FSMA rules, including FSVP, both within and outside the U.S. to promote awareness of the new rules.
- Publish guidance to assist with compliance.
- Monitor the foreign supplier verification efforts of food importers to be sure that they are complying with FSVP requirements.



Generally, FDA will oversee the implementation of FSMA by providing outreach on PC and Produce Safety rules both within and outside the U.S., providing guidance on the final rules, and initially emphasizing education about the rules. Information will be available in multiple languages. This means that your foreign suppliers and others in the food import distribution chain should know something about the PC and Produce Safety rules before you as the FSVP importer contact them regarding FSVP requirements. Clearly, the FSVP implementation should follow the same course of outreach, education, and guidance. Because FDA has provided a significant period of time between the publication dates of the rules and the dates by which compliance with the new rules is expected, there is time for all parties to learn about the new requirements and make decisions about their food import operations.

The FSVP rule requires that many new records relating to food safety be kept, and those records must be made available to FDA upon request. FDA will rely heavily on those records as it determines whether those who need to comply with U.S. food safety requirements are in compliance. This is particularly true with implementation of the FSVP rule. Records will be key in FDA's monitoring of the foreign supplier verification efforts of food importers to be sure that U.S. food importers are complying with the foreign supplier verification requirements.

Will FDA Inspect FSVP Importers?

Will FDA Inspect FSVP Importers?

- FDA has always conducted inspections of food-related operations falling within its jurisdiction to protect public health.
- To enforce FSVP, FDA will certainly inspect FSVP importers.
- FDA is expected to rely heavily on its authority to access the records that must be kept by FSVP importers to demonstrate compliance with FSVP requirements.



Although FDA has always relied heavily on inspections of food manufacturing/processing facilities, as well as inspections of food on import and elsewhere, FSVP inspections will have a somewhat different focus.

FDA states in the rule preamble “[o]ur enforcement of FSVP therefore ordinarily will not hinge on the observation of manufacturing/processing, packing, and holding activities. Rather, it ordinarily will be based on whether importers have conducted adequate verification activities, documented those activities, and maintained appropriate records.”

FDA further states “[c]onsequently, our review of FSVP records will help us target our inspection resources towards those importers that present a greater risk to food safety because their records are inadequate and/or raise concerns about compliance with other FSVP requirements. Conversely, our review of records will help us determine which importers present a lower risk because they have adequate records, therefore, lessening the need for follow-up inspection. Importers we identify as lower risk will therefore be less likely to be burdened by an FDA inspection.”

FSVP Compliance Activity for FSVP

FDA Compliance Activity for FSVP

FDA may:

- Conduct an onsite inspection of records.
- Request electronic submission of your records:
 - May be delivered by other means, if done promptly.
 - FDA review of these records is the same as an onsite inspection.
- Request that records kept offsite be made available within 24 hours.
- Request that some records be translated into English within a reasonable time.



Key Point:

The FSVP rule requires that records be made available promptly. Under normal circumstance FDA expects the records to be made available within 24 hours of a request for official review.

Key Point:

You may need to translate records kept in a language other than English upon request by an FDA investigator.

FDA oversight of the FSVP rule may include onsite inspection of records at the FSVP importer's office, as indicated by the importer's DUNS number.

It is also possible that FDA may contact the FSVP importer and request all the records for a particular food and foreign supplier. With regard to electronic transmission of records, Section 1.510(b)(3) of the rule states that if requested in writing by FDA, an importer must send records to FDA "electronically or through another means that delivers the records promptly, rather than making the records available for review at the importer's place of business."

As mentioned in Chapter 9 on records, importers should be able to make any records that are kept offsite available within 24 hours and be able to translate any records that are maintained in a language other than English within a reasonable time period. What is reasonable will depend on the specific circumstances. Also, as FDA inspectors gain more experience with enforcing the FSVP rule, it is likely importers and FDA can reach some reasonable accommodation about when translations are needed, and the timeframes involved.

The main points to consider with this slide are that inspections do not always involve an onsite inspection, but that records will be key to FDA oversight of FSVP compliance, so they should be maintained in a way that makes them easily accessible and easily transmitted upon an official FDA request.

What to Expect During an Inspection

What to Expect During an Inspection

- Generally FDA does not give advanced notice that it is about to carry out an inspection.
- FDA will present a formal "Request for FSVP Records" (Form FDA 482d)
- You should expect that FDA will:
 - Review all of the different types of documentation that relate to your compliance with the FSVP rule.
 - Look at your records to determine whether you have maintained them in compliance with FSVP requirements.
 - Request copies of some of your records.
- FDA will provide you with "FSVP Observations" (Form FDA 483a) that will describe any deficiencies in compliance.



If FDA does do an onsite inspection, it is probable that you will have no advanced notice. No advanced notice would be the normal course for a facility inspection, and it is likely to be the same for an FSVP inspection. FDA may inspect FSVP records onsite or conduct an electronic review of the records. FDA considers each type of review as equivalent. In any case, the FDA investigators will focus on your FSVP implementation. They may also request that you provide copies of some records.

Resource:

Copies of the "Request for FSVP Records" (Form FDA 482d) and "FSVP Observations" (Form FDA 483a) are available in Appendix 7 and on the FDA's website at:

Form FDA 482d (9/16) available at:

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM493417.pdf>

Form FDA 483a (2/16) available at:

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM493415.pdf>

Form FDA 482d and Form FDA 483a

| Form FDA 482d and Form FDA 483a | |
|---|---|
| <p>Request for FSVP Records (482d)</p> <p>Form 482d available at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM493417.pdf</p> | <p>FSVP Observations (483a)</p> http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM493415.pdf'."/> <p>Form 483a available at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM493415.pdf</p> |

In the slide above are screenshots of the two FDA forms you can expect to see during an inspection. The first is the “Request for FSVP Records” (Form FDA 482d (9/16)); the second is the “FSVP Observations” (Form FDA 483a (2/16). Copies of the forms are in Appendix 7.

Electronic Submission of Records

Electronic Submission of Records

- If requested in writing by FDA, you must send your FSVP records to the Agency electronically, or by another means that delivers the records promptly, rather than making the records available for review at your place of business (21 CFR 1.510(b)(3)).
- If sending electronically, you may send an email with attached PDF files through the FDA Unified Registration and Listing System (FURLS) portal system available on FDA’s Web site (see screenshots of the system in Appendix 7).
- If sending paper copies of records, you may use the U.S. Postal Service or commercial delivery providers.



If requested in writing by FDA, you must send your FSVP records to the Agency electronically, or by another means that delivers the records promptly, rather than making the records available for review at your place of business (21 CFR 1.510(b)(3)). FDA might request that you submit some or all of your FSVP records. For example, FDA might request that you send all of your records for one or more FSVPs for particular foods and their foreign suppliers, or request records of significant portions of one or more FSVPs, such as records relating to hazard analysis, determination of appropriate supplier verification activities, or corrective actions.

If sending records electronically, you may send an email with attached PDF files through the FDA Unified Registration and Listing System (FURLS) portal system available on FDA’s Web site. To use this portal, you will need to have an active account and password in FURLS or create an account in the Online Account Administration (OAA) system. During the OAA account creation process, users can select which FURLS systems they will need to access. After you create your account and log onto OAA, you can view your account profile information and all the FURLS systems you have access to from the Account Management page.

You may already have a FURLS account (it is the same system used to create and maintain Food Firm Registrations). To use FURLS to

→ Key Point:

If you have previously filed a facility registration, you may already have a FURLS account.

submit FSVP records you will need to log into your account and activate FSVP by checking the FSVP box. For additional information and to create a FURLS account, go to the FDA industry Systems Main page at <http://www.access.fda.gov>. Online help instructions are available at:

<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm114181.htm>.

As an alternative to using of the FURLS portal, you may submit paper copies of records to the FDA using the U.S. Postal Service or commercial delivery providers.

Note: Screenshots of the “Login” Screen, “Create Account” Screens 1 and 2, and the “Main Menu” (after login) Screen are available in Appendix 7 of your manual.

What to Expect After an FDA Inspection

Key Point:

The importer should determine who interacts with the FDA and have a back-up person or two in case of vacations or extenuating circumstances. Reception or the employees at the entry location should also know what to do and who to contact when FDA arrives for an inspection. You may want to establish a protocol for greeting the FDA.

What to Expect After an FDA Inspection

- During the initial phase of FSVP implementation, the FDA emphasis will be on education, training, and technical assistance to help importers comply with the new requirements.
- FDA will inform you of all deviations from the FSVP rule immediately after an inspection (whether conducted onsite or electronically).
- You will have an opportunity to discuss violations with FDA and make corrections.
- Enforcement will focus on violations that may impact public health.



During the inspection, the emphasis will be on bringing importers into compliance with the FSVP rule. The FDA inspector will provide opportunity to discuss and correct violations. Although FDA can always take enforcement actions for violations of the rule, the agency has stated that it will focus initially on violations that may impact public health.

Now that you know what an FDA onsite inspection or records review consists of, let's talk about how to prepare for an FDA inspection.

How to Prepare for an FDA Inspection

How to Prepare for an FDA Inspection

- Make sure FSVP records are easily accessible and other records can be retrieved within a reasonable timeframe.
- Assure that FSVP records are complete, accurate, and up-to-date.
- Designate a person who will interact with FDA during an inspection.



So, to be ready for an FDA inspection, whether onsite or by a written request for records, unannounced or arranged for in advance, the advice in this slide and the next slide will ensure that you are prepared.

As noted earlier, you should designate who will interact with FDA during an inspection. Also, it would be advisable to have a backup person.

How to Prepare for an FDA Inspection (continued)

- Determine ahead of time how you would respond to an FDA onsite inspection or request for electronic records.
- Consider how you will translate into English any records in another language that FDA requests.



There have been some concerns that FDA will be doing FSVP enforcement at the time food is entered into the U.S., but FDA does not intend to oversee compliance with this rule on a shipment by shipment basis at the time of entry. Importation processes will occur

→ Key Point:

It is important to understand that FDA will not assess FSVP compliance on a shipment by shipment basis during the admissibility process. Rather, FDA will assess the FSVP importer's compliance by reviewing FSVP records at the FSVP importer's place of business in the U.S., as identified through the new data requirements.

The only change to entry procedures will be identifying the FSVP importer, as discussed in Chapter 8.

as usual, although the rule requires that the FSVP importer must be identified on import entry documents. FDA clarified this point in the FSVP preamble, “[w]e note, however, that FSVP inspections will not occur at entry. ...Entry decisions will only be affected if we find problems with an importer’s FSVP that remain uncorrected or pose a risk to public health.”

What to Do When FDA Notifies You of an Inspection

What to Do When FDA Notifies You of an Inspection

- Cooperate fully with the FDA investigator.
- Be prepared to discuss any deficiencies found by FDA.
- Be prepared to discuss any corrective actions necessary to correct any deficiencies, including establishing an acceptable timeframe for completing the corrective actions.
- Document any corrective actions taken.
- Communicate with FDA transparently before and after inspections, including explaining any delay in meeting acceptable timeframes for corrective actions.



Because inspections of importers to determine compliance with the FSVP rule is new, importers may wonder what they need to do during and after an FDA inspection. Keeping in mind that the FDA is focused on doing its job, you should:

- Cooperate fully with the FDA investigator.
- Be prepared to discuss any deficiencies found by FDA.
- Be prepared to discuss any corrective actions necessary to correct any deficiencies, including establishing an acceptable timeframe for completing the corrective actions.
- Document any corrective actions taken.
- Communicate with FDA transparently before and after inspections, including explaining any delay in meeting acceptable timeframes for corrective actions.

When FDA Finds a Deficiency or Non-Compliance

When FDA Finds a Deficiency or Non-Compliance

- You will have an opportunity to address the deficiencies cited before FDA takes further action.
- In most cases, FDA is expected to send warning letters to importers who aren't in full compliance with FSVP requirements.



When deficiencies are found you will have the opportunity to address and correct them prior to any enforcement action being taken. In most cases when there is not an imminent health threat, FDA is expected to send warning letters to importers who are not in compliance with FSVP requirements and have failed to take appropriate corrective action.

What Are FDA's Legal Enforcement Tools if I Don't Comply with FSVP?

What Are FDA's Legal Enforcement Tools if I Don't Comply with FSVP?

- FDA has authority to detain an imported food (possibly followed by a refusal of its entry into the U.S. under section 801(a)(3) of the FD&C Act):
 - If it appears to FDA that you, as the importer of the food, have failed to meet FSVP requirements;
 - **Note:** Your food may also be subject to refusal if it does not comply with other FD&C Act requirements.
- When a food is offered for importation into the U.S., U.S. Customs and Border Protection (CBP) will transmit the information to FDA. If a U.S. entity is not identified as the importer for purposes of FSVP, the import information will be rejected (Sec. 1.514).
 - The filer will receive an error message and will be able to offer adjustments and resubmit



The food you import is subject to detention (possibly followed by refusal of admission into the U.S.) under section 801(a)(3) of the FD&C Act, if it appears to FDA that you, as the importer of the food,

have failed to comply with the FSVP requirements (your food may also be subject to refusal if it does not comply with other FD&C Act requirements).

Section 1.514 of the FSVP rule focuses on what happens if the importer does not comply with the FSVP rule. When a food is offered for importation into the U.S., U.S. Customs and Border Protection (CBP) will transmit the information to FDA. If a U.S. entity is not identified as the importer for purposes of FSVP, the import information will be rejected, which will generate an error message, so the filer can make appropriate adjustments and resubmit the entry line.

As mentioned earlier, FDA initially wishes to focus on educating food importers and the entire food-importing sector about the FSVP requirements. Nevertheless, FDA will be inspecting U.S.-based FSVP importers and examining their records to assess their compliance efforts, and FDA has stated that the agency will act swiftly when appropriate. Note that FDA has stated that, “[a]s with all of our FSMA-related enforcement efforts, we intend to apply our FSVP enforcement resources in a risk-based manner, placing greater emphasis on violations of the regulation that are more likely to result in harm to public health.” If FDA finds violations that pose a risk to public health, the agency will use its enforcement authorities to protect consumers.

Additional FDA Enforcement Tools

Additional FDA Enforcement Tools

- FDA has the authority to place your violative food on **import alert** so that future shipments of the food would be Detained Without Physical Examination (DWPE).
- FDA also has the authority to take action against your food after it has entered the U.S., if it violates the adulteration or allergen labeling provisions of FD&C Act. FDA authority includes:
 - Requiring the recall of harmful food in U.S. commerce (along with warning consumers not to consume the food), and
 - Administratively detaining harmful food in domestic commerce while initiating an action to seize (and possibly destroy) the food.



In considering FDA's enforcement, it's important to keep in mind that there are differences between FDA's authorities over food and FDA's authority over producers of food and others in the food supply chain. It's also important to keep in mind that FDA has always given top

priority to protecting U.S. consumers from food that could injure them or make them ill. You should expect FDA to continue to take action against both domestically produced food and imported food that may be harmful to the public health.

FDA recognizes, however, that the new FSMA rules will require food producers and others in the food chain to make adjustments in the way they operate. FDA has, therefore, stated its intent to educate before and while it regulates.

Also, as FDA clarified in the rule preamble "...when we identify violations with respect to products, shippers, and/or importers, we may place the products, shippers, and/or importers on an **import alert**. Import alerts provide guidance to FDA field staff that future shipments appear violative within the meaning of applicable FD&C Act provisions. Based on information in an import alert, field staff might detain products in shipments without physical examination." When a product is detained without physical examination, the burden shifts to the importer to demonstrate that each shipment of the product is in compliance. "Our [FDA's] decisions to remove an importer from an import alert are based on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved and we have confidence that future entries will be in compliance with the relevant FD&C Act requirements."

Although FDA's oversight of FSVP compliance will not be focused at the time of entry of food into U.S. commerce, as mentioned earlier, FDA will be inspecting FSVP importers and examining their records. If FDA determines that FSVP requirements are not being met, there can be consequences, as noted above, that would impact that importer's ability to import foods.

Most of FDA enforcement tools are not specific to FSVP. They pertain to actions against the food and actions against a person/company. Several are set forth in the previous slide and here. For any action taken, FDA would cite the provision(s) of the regulation and FD&C Act that were violated. As always, opportunity to demonstrate compliance is provided.

Key Point:

While the requirement to obtain written assurances is in the final rule, the compliance date for this provision has been extended for two additional years past the original compliance dates. This extension applies to U.S. suppliers downstream only.

The earliest compliance date for the written assurance provision is May 28, 2019. This extension was granted in response to industry's concerns over the burden of obtaining the assurances in complex supply chains (Federal Register, August 24, 2016). This extension did not pertain to the disclosure requirement.

For more information on compliance dates, see Appendix 2 in this manual or review the compliance dates available on FDA's website at:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm>

For more information on Compliance Date Extensions and Clarifications for FSMA Final Rules, see Appendix 2 in this manual or review the extended compliance dates available on FDA's website at:

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm517545.htm>

FSVP Compliance Dates Are Being Phased In

FSVP Compliance Dates Are Being Phased In

- FDA has established different compliance dates for different importers subject to the FSVP rule because of several considerations, including:
 - The size of the foreign supplier,
 - The type of food being imported, and
 - Whether the foreign supplier must meet the requirements of the final Preventive Controls (PC) rule for human food, the PC rule for food for animals, or the Produce Safety rule.



The date by which importers must comply with the FSVP rule varies depending on their situation and that of their foreign suppliers. On August 24, 2016, FDA extended some compliance dates for both Preventive Controls (PC) rules, the Produce Safety rule, and the FSVP rule. Because of interrelationships among these FSMA rules and FDA's desire to provide adequate lead-time to those who must comply with the rules, there are several different compliance dates for each rule, including the FSVP rule.

Compliance Dates for FSVP Importers

Compliance Dates for FSVP Importers

- The first compliance date for FSVP importers was May 30, 2017.
 - This applied to importers of food from the largest processing facilities that are subject to the PC rule, as well as food that is not subject to either the PC or Produce Safety rule.
- The various compliance dates for the FSVP rule are listed in Appendix 2 of the Participant Manual.



The FDA website states that the compliance dates for FSVP vary

according to a number of different factors relating to the nature of the importer, the size of the foreign supplier and the type of food imported. **The FSVP website does not include dates for importers that are themselves a manufacturer or processor subject to the supply-chain program provisions in the PC rules.** Importers who choose to comply with the supply chain provisions of the PC rule, rather than most of the FSVP requirements, should consult those rules for their compliance dates. The compliance dates for the FSVP rule are listed in Appendix 2.

Chapter 10: Summary

Chapter 10: Summary

- In this chapter we have covered:
 - How FDA will carry out an inspection.
 - That a review of records may be conducted onsite during an inspection or that FDA may request records be sent electronically to determine compliance with FSVP.
 - How to prepare for an FDA inspection.
 - That non-compliance with FSVP requirements could result in serious adverse consequences for you and your food.
 - FDA's enforcement authorities pertaining to both you and your food.
 - That, depending on circumstances pertaining to you or your foreign supplier, the earliest FSVP compliance date was May 30, 2017.



This chapter has looked at how FDA may carry out its inspections to enforce the FSVP rule, the importance of records in documenting and demonstrating your compliance with the FSVP rule, and the various consequences of not complying with the FSVP requirements. The chapter, while indicating the seriousness of not complying with the rule, has tried to indicate that there will be a transitional period where FDA will be emphasizing education to bring importers, as well as others in the supply chain, into compliance. However, this transitional period will not continue forever so it is important that you understand the requirements and comply fully.

Chapter 10: Questions

Chapter 10: Questions

Thank you for your attention!

Questions?



Notes:

Blank Colored Insert-Front

Blank Colored Insert-Back

APPENDIX 1: FSVP Summary, Rule, and Guidance

| Title of Document | Page |
|---|-------------|
| FDA Fact Sheet or Summary from FDA Website | A1-3 |
| 21 CFR Parts 1, 11, and 111 | A1-11 |
| FSVP Rule | |
| • Subpart L—Foreign Supplier Verification Programs for Food Importers | |
| Related Guidance | A1-37 |
| • Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation | |
| • Guidance for Industry: Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation | A1-41 |
| • FDA Guidances Explain Certain Exemptions from FSMA | A1-45 |
| • Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA | A1-47 |

Retrieved from FDA website (page last updated 10/28/2016) at:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm>

FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals

[Imports under the FSMA Main Page](#)

View the Final Rule Contents in the [Federal Register Notice](#)

Below is a fact sheet provided by FDA.

In this fact sheet:

- [Introduction](#)
- [Key Requirements](#)
- [Compliance Dates](#)
- [Assistance to Industry](#)

Introduction

The FDA FSMA rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals is now final, and compliance dates for some businesses begin in 18 months.

The final rule requires that importers perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards. This rule is the product of a significant level of outreach by the FDA to industry, consumer groups, the agency's federal, state, local, tribal and international regulatory counterparts, academia and other stakeholders. The FDA first proposed this rule in July 2013.

After input received during the comment period and during numerous engagements that included public meetings, webinars, and listening sessions, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions included providing importers flexibility in determining appropriate verification measures based on food and supplier risks, while acknowledging the greater risk to public health posed by the most serious hazards in foods.

The final rule has elements of both the original and supplemental proposals, with the addition of greater flexibility in meeting certain requirements to better reflect modern supply and distribution chains. For example, importers can meet key FSVP obligations by relying on analyses, evaluations and activities performed by other entities in certain circumstances, as long as those importers review and assess the corresponding documentation.

The FDA is responsible for ensuring that importers meet the FSVP requirements, and will also provide guidance, outreach and training.

Key Requirements

1. Scope

Who is covered by the rule?

For the purposes of FSVP, an importer is the U.S. owner or consignee of a food offered for import into the United States. If there is no U.S. owner or consignee, the importer is the U.S. agency or representative of the foreign owner of consignee at the time of entry, as confirmed in a signed statement of consent. See Am I Subject to FSVP? (PDF: 69KB) for more information.

There are exemptions discussed below:

- What is an FSVP? It is a program that importers covered by the rule must have in place to verify that their foreign suppliers are producing food in a manner that provides the same level of public health protection as the preventive controls or produce safety regulations, as appropriate, and to ensure that the supplier's food is not adulterated and is not misbranded with respect to allergen labeling.
- Importers are responsible for actions that include (and are explained further below):
 - Determining known or reasonably foreseeable hazards with each food
 - Evaluating the risk posed by a food, based on the hazard analysis, and the foreign supplier's performance
 - Using that evaluation of the risk posed by an imported food and the supplier's performance to approve suppliers and determine appropriate supplier verification activities
 - Conducting supplier verification activities.
 - Conducting corrective actions Importers must establish and follow written procedures to ensure that they import foods only from foreign suppliers approved based on an evaluation of the risk posed by the imported food and the supplier's performance or, when necessary on a temporary basis, from unapproved suppliers whose foods are subjected to adequate verification activities before being imported.
- Importers are required to develop, maintain and follow an FSVP for each food brought into the United States and the foreign supplier of that food. If the importer obtains a certain food from a few different suppliers, a separate FSVP would be required for each of those suppliers.
- Certain importers that are also manufacturers/processors are deemed in compliance with most FSVP requirements if
 - they are in compliance with the supply-chain program requirements under the preventive controls rules;
 - they implement preventive controls for the hazards in the food in accordance with the requirements in the preventive controls rules; or
 - they are not required to implement preventive controls under those rules in certain specified circumstances. Examples of such circumstances include when the type of food (e.g., such as coffee beans) could not be consumed without application of a preventive control, or when the customer will be significantly minimizing or

preventing identified hazards) and they comply with requirements for disclosures and written assurances.

- The evaluation of the risk posed by the imported food and the supplier's performance must be reevaluated at least every three years, or when new information comes to light about a potential hazard or the foreign supplier's performance.
- Importers are not required to evaluate the food and supplier or conduct supplier verification activities if they receive adequate assurances that a subsequent entity in the distribution chain, such as the importer's customer, is processing the food for food safety in accordance with applicable requirements. Importers must also disclose in documents accompanying the food that the food is not processed to control the identified hazard.

2. Hazard Analysis

- What do we mean by 'hazard'? An importer is required to identify and evaluate—based on experience, illness data, scientific reports and other information—the known or reasonably foreseeable hazards for each type of food it imports to determine if there are any hazards requiring a control. These include:
 - Biological hazards, including parasites and disease-causing bacteria
 - Chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, food decomposition, unapproved food or color additives, and food allergens
 - Physical hazards, such as glass
- They may be hazards reasonably likely to cause illness or injury that occur naturally, are unintentionally introduced, or are intentionally introduced for purposes of economic gain, such as substituting a less costly ingredient.
- The analysis must assess the probability that these hazards will occur in the absence of controls and the severity of the illness or injury that could occur.
- The evaluation would have to consider factors that include the:
 - Formulation of the food
 - Condition, function and design of the establishment and equipment of a typical entity that produces the food
 - Raw materials and other ingredients
 - Transportation practices
 - Harvesting, raising, manufacturing, processing and packing procedures
 - Packaging and labeling activities
 - Storage and distribution
 - Intended or reasonably foreseeable use
 - Sanitation, including employee hygiene
 - An importer can rely on another entity to conduct the hazard analysis, so long as the importer reviews and assesses the relevant documentation.

3. Evaluation of Food Risk and Supplier Performance

- What evaluation must be done of the risk posed by an imported food and a supplier's performance? An importer must evaluate:
 - The hazard analysis
 - The entity that will be significantly minimizing or preventing the hazards, such as the foreign supplier or the supplier's raw material or ingredient supplier
 - A foreign supplier's procedures, processes and practices related to the safety of food,
 - Applicable FDA food safety regulations, and information regarding the foreign supplier's compliance
 - The foreign supplier's food safety history, including the responsiveness of the foreign supplier in correcting past problems
 - Other factors as necessary, including storage and transportation practices
 - The importer can rely on another entity (other than the foreign supplier) to perform the evaluation of risk, so long as the importer reviews and assesses the relevant documentation.

4. Supplier Verification

- What supplier verification activities must be conducted? Based upon the evaluation of risk conducted, the importer must establish and follow written procedures to ensure, in most instances, that it only imports from approved foreign suppliers and must conduct appropriate supplier verification activities.
- Importers have the flexibility to tailor supplier verification activities to unique food risks and supplier characteristics. The options include:
 - Annual on-site audits of the supplier's facility. This is generally required when there is a reasonable probability that exposure to a hazard controlled by the foreign supplier will result in serious adverse health consequences or death to humans or animals (called a SAHCODHA hazard). However, the importer can choose another means of verification provided that the importer documents that the alternate choice is appropriate and provides adequate assurances that the foreign supplier is producing the food in accordance with applicable U.S. safety standards.
 - Sampling and testing
 - A review of the supplier's relevant food safety records
- An importer can rely on another entity (other than the foreign supplier) to determine and perform appropriate supplier verification activities, so long as the importer reviews and assesses the relevant documentation.

5. Corrective Actions

- What if something goes wrong? Importers must promptly take appropriate corrective actions if they determine that a foreign supplier has not used processes and procedures that provide the same level of public health protection as required under the produce safety and preventive controls regulations, as applicable, or that the supplier produces food that is adulterated or misbranded with respect to allergen labeling.
 - The appropriate corrective measure will depend on the circumstances, but could include discontinuing use of the foreign supplier until the cause of noncompliance, adulteration or misbranding has been adequately addressed.

6. Exemptions and Modified Standards

- The requirements for dietary supplements vary according to a number of factors, including whether the import is a finished product or an ingredient/component.
 - Importers who establish and verify compliance with certain specifications (concerning dietary supplement components and packaging) required under the separate, pre-existing dietary supplement Current Good Manufacturing Practices (CGMP) regulation, will not be required to comply with most of the standard FSVP requirements.
 - The same would apply to importers whose customer is required to establish such specifications and verify that they are met, except that the importer would have to obtain written assurance that its customer is complying with those requirements.
 - Importers of other dietary supplements, including finished products, would be required to comply with most of the standard FSVP requirements (except the hazard analysis requirement), but their verification activities would focus on compliance with the dietary supplement CGMP regulations.
- Modified FSVP requirements are established for very small importers and importers of food from certain small suppliers. (An example of these modified requirements is that certain importers would not have to conduct hazard analyses and would be able to verify their foreign suppliers by obtaining written assurances from their supplier.)
 - The definition of very small importer is consistent with the definition of very small business in the preventive controls rules: a sales ceiling of \$1 million for human food and \$2.5 million for animal food.
 - Importers of certain small foreign suppliers are subject to modified FSVP requirements. Those small suppliers are:
 - Facilities subject to modified requirements under the preventive controls rules because they are qualified facilities
 - Farms that are not covered farms under the produce safety rule because they average \$25,000 or less in annual produce sales or because they meet requirements for a qualified exemption

- Shell egg producers with fewer than 3,000 laying hens
- Each of these types of producers is either exempt from their underlying FDA food safety regulations or subject to modified requirements, mostly, and in some cases entirely, because of the size of these firms.
- There are modified requirements for certain foods from a foreign supplier in a country whose food safety system has been recognized as comparable or determined to be the equivalent of the United States' system.
- Additionally, certain categories of imported food are not covered by FSVP. These include:
 - Juice, fish, and fishery products subject to and in compliance with FDA's Hazard Analysis and Critical Control Point (HACCP) regulations for those products, and certain ingredients for use in juice and fish and fishery products subject to the HACCP regulations.
 - Food for research or evaluation Food for personal consumption
 - Alcoholic beverages and certain ingredients for use in alcoholic beverages Food that is imported for processing and future export
 - Low-acid canned foods (LACF), such as canned vegetables, but only with respect to microbiological hazards covered by other regulations, as well as certain ingredients for use in LACF products (but only with respect to microbiological hazards).
 - Certain meat, poultry and egg products regulated by the U.S. Department of Agriculture at the time of importation

Compliance Dates

The date by which importers must comply with the FSVP regulations is the latest of the following dates:

- 18 months after publication of the final rule;
- For the importation of food from a supplier that is subject to the preventive controls or produce safety rules, six months after the foreign supplier is required to meet the relevant regulations;
- For an importer that is itself a manufacturer or processor subject to the supply-chain program provisions in the preventive controls regulations, the date by which it has to comply with those provisions. A range of compliance dates were established in the preventive controls rules for the supply-chain program provisions, which vary based on the size of the receiving facility and when the receiving facility's supplier is required to comply with the new FSMA regulations.

Read more on [Compliance Dates for the FSVP Final Rule](#) and [Compliance Date Extensions and Clarifications for FSMA Final Rules](#).

Assistance to Industry

The FDA is developing several guidance documents on subjects that include:

- General guidance on FSVP
- How to obtain the necessary expertise to be a qualified auditor

Plans for training and technical assistance are well under way. They include:

- Collaborating with the food industry, educational organizations, USDA, the United States Agency for International Development, and foreign governments to develop the tools and training programs needed to facilitate compliance by exporters, including those from developing countries.
- Establishing the FDA FSMA Food Safety Technical Assistance Network, which is now operational, to provide a central source of information to support industry understanding and implementation of FSMA.
- Collaborating with the Food Safety Preventive Controls Alliance (FSPCA) to establish training and technical assistance programs.
 - FSPCA's training curriculum includes a module on the FSVP rule for processors who import foods, and a full FSVP course for non-processor importers.

Retrieved from U.S. Office of the Federal Register website at:

<https://www.federalregister.gov/documents/2015/11/27/2015-28158/foreign-supplier-verification-programs-for-importers-of-food-for-humans-and-animals>

The codified portion of the final FSVP rule follows a lengthy preamble that responds to the issues raised in comments that were submitted to the proposed FSVP rule and the supplemental proposal. The preamble is not presented below, but can be found at the website above. The preamble explains what FDA did and why, so it is useful as guidance on many aspects of the final rule. Only the codified portion of the rule, i.e., the portion that is now incorporated in Title 21 of the Code of Federal Regulations, is presented below.

Summary from the Federal Register:

The Food and Drug Administration (FDA) is adopting a regulation on foreign supplier verification programs (FSVPs) for importers of food for humans and animals. The regulation requires importers to verify that food they import into the United States is produced in compliance with the hazard analysis and risk-based preventive controls and standards for produce safety provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), is not adulterated, and is not misbranded with respect to food allergen labeling. We are issuing this regulation in accordance with the FDA Food Safety Modernization Act (FSMA). The regulation will help ensure the safety of imported food.

List of Subjects:

21 CFR Part 1 Federal Register Pages 74340-74351

(Also available at the U.S. Government Publishing Office (GPO) Electronic Code of Federal Regulations:

<http://www.ecfr.gov/cgi-bin/text-idx?SID=c9592e313616864752dfc499b46604fd&mc=true&node=sp21.1.1.l&rgn=div6>

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 11 Federal Register Pages 74351-74352

(Also available at the U.S. Government Publishing Office (GPO) Electronic Code of Federal Regulations:

http://www.ecfr.gov/cgi-bin/text-idx?SID=c9592e313616864752dfc499b46604fd&mc=true&node=se21.1.11_11&rgn=div8

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

21 CFR Part 111 Federal Register Page 74352

(Also available at the U.S. Government Publishing Office (GPO) Electronic Code of Federal Regulations:

<http://www.ecfr.gov/cgi-bin/text-idx?SID=c9592e313616864752dfc499b46604fd&mc=true&node=pt21.2.111&rgn=div5#sp21.2.111.a>

Dietary foods, Drugs, Foods, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, **21 CFR parts 1, 11, and 111 are amended as follows:**

74340 Federal Register / Vol. 80, No. 228 / Friday, November 27, 2015 / Rules and Regulations

PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 350j, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 374, 381, 382, 384a, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271.

2. Add subpart L, consisting of

§§ 1.500 through 1.514, to read as follows:

Subpart L—Foreign Supplier Verification Programs for Food Importers

Sec. ^[L]
~~SEP~~

1.500 What definitions apply to this subpart? ^[L]
~~SEP~~

1.501 To what foods do the regulations in this subpart apply? ^[L]
~~SEP~~

1.502 What foreign supplier verification program (FSVP) must I have? ^[L]
~~SEP~~

1.503 Who must develop my FSVP and perform FSVP activities? ^[L]
~~SEP~~

1.504 What hazard analysis must I conduct?

Federal Register /Vol. 80, No. 228 / Friday, November 27, 2015 /Rules and Regulations 74341

1.505 What evaluation for foreign supplier approval and verification must I conduct?

1.506 What foreign supplier verification and related activities must I conduct?

1.507 What requirements apply when I import a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation?

1.508 What corrective actions must I take under my FSVP?

1.509 How must the importer be identified at entry?

1.510 How must I maintain records of my FSVP?

1.511 What FSVP must I have if I am importing a food subject to certain dietary supplement current good manufacturing practice regulations?

1.512 What FSVP may I have if I am a very small importer or if I am importing certain food from certain small foreign suppliers?

1.513 What FSVP may I have if I am importing certain food from a country with an officially recognized or equivalent food safety system?

1.514 What are some consequences of failing to comply with the requirements of this subpart?

Subpart L—Foreign Supplier Verification Programs for Food Importers

§ 1.500 What definitions apply to this subpart?

The following definitions apply to words and phrases as they are used in this subpart. Other definitions of these terms may apply when they are used in other subparts of this part.

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Audit means the systematic, independent, and documented examination (through observation, investigation, discussions with employees of the audited entity, records review, and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.

Dietary supplement has the meaning given in section 201(ff) of the Federal Food, Drug, and Cosmetic Act.

Dietary supplement component means any substance intended for use in the manufacture of a dietary supplement, including those that may not appear in the finished batch of the dietary supplement. Dietary supplement components include dietary ingredients (as described in section 201(ff) of the Federal Food, Drug, and Cosmetic Act) and other ingredients.

Environmental pathogen means a pathogen that is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize or prevent the environmental pathogen. Examples of environmental pathogens for the purposes of this subpart include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeformers.

Facility means a domestic facility or [T]a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of subpart H of this part.

Farm means farm as defined in § 1.227.

Appendix 1

Farm mixed-type facility means an establishment that is a farm but that also conducts activities outside the farm definition that require the establishment to be registered under section 415 of the Federal Food, Drug, and Cosmetic Act.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Foreign supplier means, for an article of food, the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature.

Good compliance standing with a foreign food safety authority means that the foreign supplier—

(1) Appears on the current version of a list, issued by the food safety authority of the country in which the foreign supplier is located and which has regulatory oversight of the supplier, of food producers that are in good compliance standing with the food safety authority; or

(2) Has otherwise been designated by such food safety authority as being in good compliance standing.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Hazard means any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury.

Hazard requiring a control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the probability that the hazard will occur in the absence of controls or measures and the severity of the illness or injury if the hazard were to occur), establish one or more controls or measures to significantly minimize or prevent the hazard in a food and components to manage those controls or measures (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the control or measure and its role in the facility's food safety system.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/ dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

74342 Federal Register / Vol. 80, No. 228 / Friday, November 27, 2015 / Rules and Regulations

Importer means the U.S. owner or consignee of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart.

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with a food or the facility in which it is manufactured/processed.

Lot means the food produced during a period of time and identified by an establishment's specific code.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/ dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extruding (of animal food), formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging, pasteurizing, peeling, pelleting (of animal food), rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (*e.g.*, activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public health significance.

Qualified auditor means a person who is a qualified individual as defined in this section and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by § 1.506(e)(1)(i) or § 1.511(c)(5)(i)(A). Examples of potential qualified auditors include:

- (1) A government employee, including a foreign government employee; and
- (2) An audit agent of a certification body that is accredited in accordance with subpart M of this part.

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under this subpart, and can read and understand the language of any records that the person must review in performing this activity. A qualified individual may be, but is not required to be, an employee of the importer. A government employee, including a foreign government employee, may be a qualified individual.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

Receiving facility means a facility that is subject to subparts C and G of part 117 of this chapter, or subparts C and ~~D~~E of part 507 of this chapter, and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

U.S. owner or consignee means the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.

Appendix 1

Very small importer means:

(1) With respect to the importation of human food, an importer (including any subsidiaries and affiliates) averaging less than \$1 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of human food combined with the U.S. market value of human food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee); and

(2) With respect to the importation of animal food, an importer (including any subsidiaries and affiliates) averaging less than \$2.5 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of animal food combined with the U.S. market value of animal food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee).

You means a person who is subject to some or all of the requirements in this subpart.

§ 1.501 To what foods do the regulations in this subpart apply?

(a) *General.* Except as specified otherwise in this section, the requirements in this subpart apply to all food imported or offered for import into the United States and to the importers of such food.

(b) *Exemptions for juice and seafood*—(1) *Importers of certain juice and seafood products.* This subpart does not apply with respect to juice, fish, and fishery products that are imported from a foreign supplier that is required to comply with, and is in compliance with, the requirements in part 120 or part 123 of this chapter. If you import juice or fish and fishery products that are subject to part 120 or part 123, respectively, you must comply with the requirements applicable to importers of those products under § 120.14 or ~~§ 123.12~~ of this chapter, respectively.

(2) *Certain importers of juice or seafood raw materials or other ingredients subject to part 120 or part 123 of this chapter.* This subpart does not apply with respect to any raw materials or other ingredients that you import and use in manufacturing or processing juice subject to part 120 or fish and fishery products subject to part 123, provided that you are in compliance with the requirements in part 120 or part 123 with respect to the juice or fish or fishery product that you manufacture or process from the imported raw materials or other ingredients.

(c) *Exemption for food imported for research or evaluation.* This subpart does not apply to food that is imported for research or evaluation use, provided that such food:

(1) Is not intended for retail sale and is not sold or distributed to the public;

(2) Is labeled with the statement “Food for research or evaluation use”;

(3) Is imported in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of; and

(4) Is accompanied, when filing entry with U.S. Customs and Border Protection, by an electronic declaration that the food will be used for research or evaluation purposes and will not be sold or distributed to the public.

(d) *Exemption for food imported for personal consumption.* This subpart does not apply to food that is imported for

Federal Register /Vol. 80, No. 228 / Friday, November 27, 2015 /Rules and Regulations 74343

personal consumption, provided that such food is not intended for retail sale and is not sold or distributed to the public. Food is imported for personal consumption only if it is purchased or otherwise acquired by a person in a small quantity that is consistent with a non-commercial purpose and is not sold or distributed to the public.

(e) *Exemption for alcoholic beverages.* (1) This subpart does not apply with respect to alcoholic beverages that are imported from a foreign supplier that is a facility that meets the following two conditions:

(i) Under the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 *et seq.*), the facility is a foreign facility of a type that, if it were a domestic facility, would require obtaining a permit from, registering with, or obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States; and

(ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act, the facility is required to register as a facility because it is engaged in manufacturing/processing one or more alcoholic beverages.

(2) This subpart does not apply with respect to food that is not an alcoholic beverage that is imported from a foreign supplier described in paragraph (e)(1) of this section, provided such food:

(i) Is in prepackaged form that prevents any direct human contact with such food; and

(ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(3) This subpart does not apply with respect to raw materials and other ingredients that are imported for use in alcoholic beverages provided that:

(i) The imported raw materials and other ingredients are used in the manufacturing/processing, packing, or holding of alcoholic beverages;

(ii) Such manufacturing/processing, packing, or holding is performed by the importer;

(iii) The importer is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act; and

(iv) The importer is exempt from the regulations in part 117 of this chapter in accordance with § 117.5(i) of this chapter.

(f) *Inapplicability to food that is transshipped or imported for processing and export.* This subpart does not apply to food:

(1) That is transshipped through the United States to another country and is

not sold or distributed to the public in the United States; or

(2) That is imported for processing and future export and that is not sold or distributed to the public in the United States.

(g) *Inapplicability to U.S. food returned.* This subpart does not apply to food that is manufactured/processed, raised, or grown in the United States, exported, and returned to the United States without further manufacturing/ processing in a foreign country.

(h) *Inapplicability to certain meat, poultry, and egg products.* This subpart does not apply with respect to:

(1) Meat food products that at the time of importation are subject to the requirements of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(2) Poultry products that at the time of importation are subject to the requirements of the USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and

Appendix 1

(3) Egg products that at the time of importation are subject to the requirements of the USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

§ 1.502 What foreign supplier verification program (FSVP) must I have?

(a) *General.* Except as specified in paragraph (b) of this section, for each food you import, you must develop, maintain, and follow an FSVP that provides adequate assurances that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the Federal Food, Drug, and Cosmetic Act.

(b) *Low-acid canned foods—*(1) *Importers of low-acid canned foods not subject to further manufacturing or processing.* With respect to those microbiological hazards that are controlled by part 113 of this chapter, if you import a thermally processed low-acid food packaged in a hermetically sealed container (low-acid canned food), you must verify and document that the food was produced in accordance with part 113. With respect to all matters that are not controlled by part 113, you must have an FSVP as specified in paragraph (a) of this section.

(2) *Certain importers of raw materials or other ingredients subject to part 113 of this chapter.* With respect to microbiological hazards that are controlled by part 113, you are not required to comply with the requirements of this subpart for raw materials or other ingredients that you import and use in the manufacturing or processing of low-acid canned food provided that you are in compliance with part 113 with respect to the low-acid canned food that you manufacture or process from the imported raw materials or other ingredients. With respect to all hazards other than microbiological hazards that are controlled by part 113, you must have an FSVP as specified in paragraph (a) of this section for the imported raw materials and other ingredients that you use in the manufacture or processing of low-acid canned foods.

(c) *Importers subject to section 418 of the Federal Food, Drug, and Cosmetic Act.* You are deemed to be in compliance with the requirements of this subpart for a food you import, except for the requirements in § 1.509, if you are a receiving facility as defined in § 117.3 or § 507.3 of this chapter and you are in compliance with the following requirements of part 117 or part 507 of this chapter, as applicable:

(1) You implement preventive controls for the hazards in the food in accordance with § 117.135 or § 507.34 of this chapter;

(2) You are not required to implement a preventive control under § 117.136 or § 507.36 of this chapter with respect to the food; or

(3) You have established and implemented a risk-based supply-chain program in compliance with subpart G of part 117 or subpart E of part 507 of this chapter with respect to the food.

§ 1.503 Who must develop my FSVP and perform FSVP activities?

(a) *Qualified individual.* A qualified individual must develop your FSVP and perform each of the activities required under this subpart. A qualified individual must have the education, training, or experience (or a combination thereof) necessary to perform their assigned activities and must be able to read and understand the language of any records that must be reviewed in performing an activity.

(b) *Qualified auditor.* A qualified auditor must conduct any audit conducted in accordance with § 1.506(e)(1)(i) or § 1.511(c)(5)(i)(A). A qualified auditor must have technical

74344 Federal Register / Vol. 80, No. 228 / Friday, November 27, 2015 / Rules and Regulations

expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

§ 1.504 What hazard analysis must I conduct?

(a) *Requirement for a hazard analysis.* Except as specified in paragraph (d) of this section, you must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food you import to determine whether there are any hazards requiring a control. Your hazard analysis must be written regardless of its outcome.

(b) *Hazard identification.* (1) Your analysis of the known or reasonably foreseeable hazards in each food must include the following types of hazards:

- (i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;
- (ii) Chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, food allergens, and (in animal food) nutrient deficiencies or toxicities; and
- (iii) Physical hazards (such as stones, glass, and metal fragments).

(2) Your analysis must include known or reasonably foreseeable hazards that may be present in a food for any of the following reasons:

- (i) The hazard occurs naturally;
- (ii) The hazard may be unintentionally introduced; or
- (iii) The hazard may be intentionally introduced for purposes of economic gain.

(c) *Hazard evaluation.* (1) Your hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the probability that the hazard will occur in the absence of controls and the severity of the illness or injury if the hazard were to occur.

(2) The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment before packaging and the packaged food does not receive a treatment or otherwise include a control or measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

(3) Your hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

- (i) The formulation of the food;
- (ii) The condition, function, and design of the establishment and equipment of a typical entity that manufactures/processes, grows, harvests, or raises this type of food;
- (iii) Raw materials and other ingredients;
- (iv) Transportation practices;
- (v) Harvesting, raising, manufacturing, processing, and packing procedures;
- (vi) Packaging and labeling activities; (vii) Storage and distribution; (viii) Intended or reasonably foreseeable use; (ix) Sanitation, including employee hygiene; and (x) Any other relevant factors, such as the temporal (e.g., weather-related)

Appendix 1

nature of some hazards (e.g., levels of natural toxins).

(d) *Review of another entity's hazard analysis.* If another entity (including your foreign supplier) has, using a qualified individual, analyzed the known or reasonably foreseeable hazards for the food to determine whether there are any hazards requiring a control, you may meet your requirement to determine whether there are any hazards requiring a control in a food by reviewing and assessing the hazard analysis conducted by that entity. You must document your review and assessment of that hazard analysis, including documenting that the hazard analysis was conducted by a qualified individual.

(e) *Hazards in raw agricultural commodities that are fruits or vegetables.* If you are importing a raw agricultural commodity that is a fruit or vegetable that is "covered produce" as defined in § 112.3 of this chapter, you are not required to determine whether there are any biological hazards requiring a control in such food because the biological hazards in such fruits or vegetables require a control and compliance with the requirements in part 112 of this chapter significantly minimizes or prevents the biological hazards. However, you must determine whether there are any other types of hazards requiring a control in such food.

(f) *No hazards requiring a control.* If you evaluate the known and reasonably foreseeable hazards in a food and determine that there are no hazards requiring a control, you are not required to conduct an evaluation for foreign supplier approval and verification under § 1.505 and you are not required to conduct foreign supplier verification activities under § 1.506. This paragraph (f) does not apply if the food is a raw agricultural commodity that is a fruit or vegetable that is "covered produce" as defined in § 112.3 of this chapter.

§ 1.505 What evaluation for foreign supplier approval and verification must I conduct?

(a) *Evaluation of a foreign supplier's performance and the risk posed by a food.* (1) Except as specified in paragraphs (d) and (e) of this section, in approving your foreign suppliers and determining the appropriate supplier verification activities that must be conducted for a foreign supplier of a type of food you import, you must consider the following:

(i) The hazard analysis of the food conducted in accordance with § 1.504, including the nature of the hazard requiring a control.

(ii) The entity or entities that will be significantly minimizing or preventing the hazards requiring a control or verifying that such hazards have been significantly minimized or prevented, such as the foreign supplier, the foreign supplier's raw material or other ingredient supplier, or another entity in your supply chain.

(iii) Foreign supplier performance, including:

(A) The foreign supplier's procedures, processes, and practices related to the safety of the food;

(B) Applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety (or, when applicable, the relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations); and

(C) The foreign supplier's food safety history, including available information about results from testing foods for hazards, audit results relating to the safety of the food, and responsiveness of the foreign supplier in correcting problems.

(iv) Any other factors as appropriate and necessary, such as storage and transportation practices.

(2) You must document the evaluation you conduct under paragraph (a)(1) of this section.

(b) *Approval of foreign suppliers.* You must approve your foreign suppliers on the basis of the evaluation that you conducted under paragraph (a) of this section or that you review and assess under paragraph (d) of this section, and document your approval.

(c) *Reevaluation of a foreign supplier's performance and the risk posed by a food.* (1) Except as specified

Federal Register /Vol. 80, No. 228 / Friday, November 27, 2015 /Rules and Regulations 74345

in paragraph (d) of this section, you must promptly reevaluate the concerns associated with the factors in paragraph (a)(1) of this section when you become aware of new information about these factors, and the reevaluation must be documented. If you determine that the concerns associated with importing a food from a foreign supplier have changed, you must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier and whether the supplier verification activities conducted under § 1.506 or ~~or §§~~ 1.511(c) need to be changed.

(2) If at the end of any 3-year period you have not reevaluated the concerns associated with the factors in paragraph (a)(1) of this section in accordance with paragraph (c)(1) of this section, you must reevaluate those concerns and take other appropriate actions, if necessary, in accordance with paragraph (c)(1). You must document your reevaluation and any subsequent actions you take in accordance with paragraph (c)(1).

(d) *Review of another entity's evaluation or reevaluation of a foreign supplier's performance and the risk posed by a food.* If an entity other than the foreign supplier has, using a qualified individual, performed the evaluation described in paragraph (a) of this section or the reevaluation described in paragraph (c) of this section, you may meet the requirements of the applicable paragraph by reviewing and assessing the evaluation or reevaluation conducted by that entity. You must document your review and assessment, including documenting that the evaluation or reevaluation was conducted by a qualified individual.

(e) *Inapplicability to certain circumstances.* You are not required to conduct an evaluation under this section or to conduct foreign supplier verification activities under § 1.506 if one of the circumstances described in § 1.507 applies to your importation of a food and you are in compliance with that section.

§ 1.506 What foreign supplier verification and related activities must I conduct?

(a) *Use of approved foreign suppliers.* (1) You must establish and follow written procedures to ensure that you import foods only from foreign suppliers you have approved based on the evaluation conducted under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before importing the food). You must document your use of these procedures.

(2) You may rely on an entity other than your foreign supplier to establish the procedures and perform and document the activities required under paragraph (a)(1) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

(b) *Foreign supplier verification procedures.* You must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to the foods you import.

(c) *Requirement of supplier verification.* The foreign supplier verification activities must provide assurance that the hazards requiring a control in the food you import have been significantly minimized or prevented.

(d) *Determination of appropriate foreign supplier verification activities—(1)(i) General.* Except as provided in paragraphs (d)(2) and (3) of this section, before importing a food from a foreign supplier, you must determine and document which verification activity or activities listed in paragraphs (d)(1)(ii)(A) through (D) of this section, as well as the frequency with which the activity or activities must be conducted, are needed to provide adequate assurances that the food you obtain from the foreign supplier is produced in accordance with paragraph (c) of this section. Verification activities must address the entity or entities that are significantly minimizing or preventing the hazards or verifying that the hazards have been significantly minimized or prevented (e.g., when an entity other than the grower of produce subject to part 112 of this chapter harvests or packs the produce and significantly minimizes or prevents the hazard or verifies that the hazard has been significantly minimized or prevented, or when the foreign supplier's raw material supplier significantly minimizes or prevents a hazard). The determination of appropriate supplier verification activities must be based on the evaluation of the food and foreign supplier conducted under § 1.505.

(ii) *Appropriate verification activities.* The following are appropriate supplier verification activities:

(A) Onsite audits as specified in paragraph (e)(1)(i) of this section;

Appendix 1

- (B) Sampling and testing of a food as specified in paragraph (e)(1)(ii) of this section;
- (C) Review of the foreign supplier's relevant food safety records as specified in paragraph (e)(1)(iii) of this section; and
- (D) Other appropriate supplier verification activities as specified in paragraph (e)(1)(iv) of this section.

(2) *Verification activities for certain serious hazards.* When a hazard in a food will be controlled by the foreign supplier and is one for which there is ~~is~~ a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, you must conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless you make an adequate written determination that, instead of such initial and annual onsite auditing, other supplier verification activities listed in paragraph (d)(1)(ii) of this section and/or less frequent onsite auditing are appropriate to provide adequate assurances that the foreign supplier is producing the food in accordance with paragraph (c) of this section, based on the determination made under § 1.505.

(3) *Reliance on a determination by another entity.* You may rely on a determination of appropriate foreign supplier verification activities in accordance with paragraph (d)(1) or (2) of this section made by an entity other than the foreign supplier if you review and assess whether the entity's determination regarding appropriate activities (including the frequency with which such activities must be conducted) is appropriate. You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual.

(e) *Performance of foreign supplier verification activities—(1) Verification activities.* Except as provided in paragraph (e)(2) of this section, based on the determination made in accordance with paragraph (d) of this section, you must conduct (and document) or obtain documentation of one or more of the supplier verification activities listed in paragraphs (e)(1)(i) through (iv) of this section for each foreign supplier before importing the food and periodically thereafter.

(i) *Onsite audit of the foreign supplier.* (A) An onsite audit of a foreign supplier must be performed by a qualified auditor.

(B) If the food is subject to one or more FDA food safety regulations, an onsite audit of the foreign supplier must consider such regulations and include a review of the supplier's written food safety plan, if any, and its implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws

74346 Federal Register / Vol. 80, No. 228 / Friday, November 27, 2015 / Rules and Regulations

and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(C) If the onsite audit is conducted solely to meet the requirements of paragraph (e) of this section by an audit agent of a certification body that is accredited in accordance with subpart M of this part, the audit is not subject to the requirements in that subpart.

(D) You must retain documentation of each onsite audit, including the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor.

(E) The following inspection results may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date by which the onsite audit would have been required to be conducted:

(1) The written results of an appropriate inspection of the foreign supplier for compliance with applicable FDA food safety regulations conducted by FDA, representatives of other Federal Agencies (such as the USDA), or representatives of State, local, tribal, or territorial agencies; or

(2) The written results of an inspection of the foreign supplier by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the food that is the subject of the onsite audit is within the scope of the official recognition or equivalence determination, and the foreign supplier is in, and under the regulatory oversight of, such country.

(ii) *Sampling and testing of the food.* You must retain documentation of each sampling and testing of a food, including identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical method(s) used), the date(s) on which the test(s) were conducted and the date of the report of the testing, the results of the testing, any corrective actions taken in response to detection of hazards, information identifying the laboratory conducting the testing, and documentation that the testing was conducted by a qualified individual.

(iii) *Review of the foreign supplier's relevant food safety records.* You must retain documentation of each record review, including the date(s) of review, the general nature of the records reviewed, the conclusions of the review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.

(iv) *Other appropriate activity.* (A) You may conduct (and document) or obtain documentation of other supplier verification activities that are appropriate based on foreign supplier performance and the risk associated with the food.

(B) You must retain documentation of each activity conducted in accordance with paragraph (e)(1)(iv) of this section, including a description of the activity, the date on which it was conducted, the findings or results of the activity, any corrective actions taken in response to significant deficiencies identified, and documentation that the activity was conducted by a qualified individual.

(2) *Reliance upon performance of activities by other entities.* (i) Except as specified in paragraph (e)(2)(ii) of this section, you may rely on supplier verification activities conducted in accordance with paragraph (e)(1) of this section by another entity provided that you review and assess the results of these activities in accordance with paragraph (e)(3) of this section.

(ii) You may not rely on the foreign supplier itself or employees of the foreign supplier to perform supplier verification activities, except with respect to sampling and testing of food in accordance with paragraph (e)(1)(ii) of this section.

(3) *Review of results of verification activities.* You must promptly review and assess the results of the verification activities that you conduct or obtain documentation of under paragraph (e)(1) of this section, or that are conducted by other entities in accordance with paragraph (e)(2) of this section. You must document your review and assessment of the results of verification activities. If the results do not provide adequate assurances that the hazards requiring a control in the food you obtain from the foreign supplier have been significantly minimized or prevented, you must take appropriate action in accordance with § 1.508(a). You are not required to retain documentation of supplier verification activities conducted by other entities, provided

Appendix 1

that you can obtain the documentation and make it available to FDA in accordance with § 1.510(b).

(4) *Independence of qualified individuals conducting verification activities.* There must not be any financial conflicts of interests that influence the results of the verification activities set forth in paragraph (e)(1) of this section, and payment must not be related to the results of the activity.

§ 1.507 What requirements apply when I import a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation?

(a) *Circumstances.* You are not required to conduct an evaluation of a food and foreign supplier under § 1.505 or supplier verification activities under § 1.506 when you identify a hazard requiring a control (identified hazard) in a food and any of the following circumstances apply:

(1) You determine and document that the type of food (*e.g.*, raw agricultural commodities such as cocoa beans and coffee beans) could not be consumed without application of an appropriate control;

(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507 of this chapter to ensure that the identified hazard will be significantly minimized or prevented and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of paragraph (c) of this section, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard;

(3) You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507 of this chapter to provide assurance it is manufacturing, processing, or preparing the food in accordance with the applicable food safety requirements and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements;

(4) You rely on your customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:

Federal Register /Vol. 80, No. 228 / Friday, November 27, 2015 /Rules and Regulations 74347

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]"; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of paragraph (c) of this section, that your customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]"; and

(B) Will only sell the food to another entity that agrees, in writing, it will:

(1) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507 of this chapter) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507); or

(2) Obtain a similar written assurance from the entity's customer, subject to the requirements of paragraph (c) of this section, as in paragraphs (a)(4)(ii)(A) and (B) of this section, as appropriate; or

(5) You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food you distribute and you document your implementation of that system.

(b) *Written assurances.* Any written assurances required under this section must contain the following:

(1) Effective date;

(2) Printed names and signatures of authorized officials; and

(3) The assurance specified in the applicable paragraph.

(c) *Provision of assurances.* The customer or other subsequent entity in the distribution chain for a food that provides a written assurance under paragraph (a)(2), (3), or (4) of this section must act consistently with the assurance and document its actions taken to satisfy the written assurance.

§ 1.508 What corrective actions must I take under my FSVP?

(a) You must promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the Federal Food, Drug, and Cosmetic Act. This determination could be based on a review of consumer, customer, or other complaints related to food safety, the verification activities conducted under § 1.506 or § 1.511(c), a reevaluation of the risks posed by the food and the foreign supplier's performance conducted under § 1.505(c) or (d), or any other relevant information you obtain. The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph.

(b) If you determine, by means other than the verification activities conducted under § 1.506 or § 1.511(c) or a reevaluation conducted under

§ 1.505(c) or (d), that a foreign supplier of food that you import does not produce food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the Federal Food, Drug, and Cosmetic

Appendix 1

Act, you must promptly investigate to determine whether your FSVP is adequate and, when appropriate, modify your FSVP. You must document any investigations, corrective actions, and changes to your FSVP that you undertake in accordance with this paragraph.

(c) This section does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls.

§ 1.509 How must the importer be identified at entry?

(a) You must ensure that, for each line entry of food product offered for importation into the United States, your name, electronic mail address, and unique facility identifier recognized as acceptable by FDA, identifying you as the importer of the food, are provided electronically when filing entry with U.S. Customs and Border Protection.

(b) Before an article of food is imported or offered for import into the United States, the foreign owner or consignee of the food (if there is no U.S. owner or consignee) must designate a U.S. agent or representative as the importer of the food for the purposes of the definition of "importer" in § 1.500.

§ 1.510 How must I maintain records of my FSVP?

(a) *General requirements for records.* (1) You must keep records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records.

(2) You must sign and date records concerning your FSVP upon initial completion and upon any modification of the FSVP.

(3) All records must be legible and stored to prevent deterioration or loss. (b) *Record availability.* (1) You must make all records required under this subpart available promptly to an authorized FDA representative, upon request, for inspection and copying. Upon FDA request, you must provide within a reasonable time an English translation of records maintained in a language other than English.

(2) Offsite storage of records, including records maintained by other entities in accordance with § 1.504^[1], § 1.505, or § 1.506, is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(3) If requested in writing by FDA, you must send records to the Agency electronically, or through another means that delivers the records promptly, rather than making the records available for review at your place of business.

(c) *Record retention.* (1) Except as specified in paragraph (c)(2) of this section, you must retain records referenced in this subpart until at least 2 years after you created or obtained the records.

(2) You must retain records that relate to your processes and procedures, including the results of evaluations and determinations you conduct, for at least 2 years after their use is discontinued (*e.g.*, because you no longer import a particular food, you no longer use a particular foreign supplier, you have reevaluated the risks associated with a food and the foreign supplier, or you have changed your supplier verification activities for a particular food and foreign supplier).

(d) *Electronic records.* Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic

74348 Federal Register / Vol. 80, No. 228 / Friday, November 27, 2015 / Rules and Regulations

records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.

(e) *Use of existing records.* (1) You do not need to duplicate existing records you have (*e.g.*, records that you maintain to comply with other Federal, State, or local regulations) if they contain all of the information required by this subpart. You may supplement any such existing records as necessary to include all of the information required by this subpart.

(2) You do not need to maintain the information required by this subpart in one set of records. If existing records you have contain some of the required information, you may maintain any new information required by this subpart either separately or combined with the existing records.

(f) *Public disclosure.* Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter.

§ 1.511 What FSVP must I have if I am importing a food subject to certain dietary supplement current good manufacturing practice regulations?

(a) *Importers subject to certain dietary supplement current good manufacturing regulations.* If you are required to establish specifications under § 111.70(b) or (d) of this chapter with respect to a food that is a dietary supplement or dietary supplement component you import for further manufacturing, processing, or packaging as a dietary supplement, and you are in compliance with the requirements in §§ 111.73 and 111.75 of this chapter applicable to determining whether the specifications you established are met for such food, then for that food you must comply with the requirements in §§ 1.503 and 1.509, but you are not required to comply with the requirements in § 1.502, §§ 1.504 through 1.508, or § 1.510. This requirement does not limit your obligations with respect to part 111 of this chapter or any other laws enforced by FDA.

(b) *Importers whose customer is subject to certain dietary supplement current good manufacturing practice regulations.* If your customer is required to establish specifications under § 111.70(b) or (d) of this chapter with respect to a food that is a dietary supplement or dietary supplement component you import for further manufacturing, processing, or packaging as a dietary supplement, your customer is in compliance with the requirements of §§ 111.73 and 111.75 of this chapter applicable to determining whether the specifications it established are met for such food, and you annually obtain from your customer written assurance that it is in compliance with those requirements, then for that food you must comply with the requirements in §§ 1.503, 1.509, and 1.510, but you are not required to comply with the requirements in § 1.502 or §§ 1.504 through 1.508.

(c) *Other importers of dietary supplements—(1) General.* If the food you import is a dietary supplement and neither paragraph (a) or (b) of this section is applicable, you must comply with paragraph (c) of this section and the requirements in §§ 1.503, 1.505(a)(1)(i) through (iv), (a)(2), and (b) through (d), and 1.508 through 1.510, but you are not required to comply with the requirements in §§ 1.504, 1.505(a)(1)(i), 1.506, and 1.507. This requirement does not limit your obligations with respect to part 111 of this chapter or any other laws enforced by FDA.

(2) *Use of approved foreign suppliers.* (i) You must establish and follow written procedures to ensure that you import foods only from foreign suppliers that you have approved based on the evaluation conducted under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before importing the food). You must document your use of these procedures.

(ii) You may rely on an entity other than the foreign supplier to establish the procedures and perform and document the activities required under paragraph (c)(2)(i) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

(3) *Foreign supplier verification procedures.* You must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to the foods you import.

(4) *Determination of appropriate foreign supplier verification activities—(i) General.* Except as provided in paragraph (c)(4)(iii) of this section, before importing a dietary supplement from a foreign supplier, you must determine and document which verification activity or activities listed in paragraphs (c)(4)(ii)(A) through (D) of this section, as well as the frequency with which the activity or activities must be conducted, are needed to provide adequate assurances that the foreign supplier

Appendix 1

is producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under part 111 of this chapter. This determination must be based on the evaluation conducted under § 1.505.

(ii) *Appropriate verification activities.* The following are appropriate supplier verification activities:

- (A) Onsite audits as specified in paragraph (c)(5)(i)(A) of this section;
- (B) Sampling and testing of a food as specified in paragraph (c)(5)(i)(B) of this section;
- (C) Review of the foreign supplier's relevant food safety records as specified in paragraph (c)(5)(i)(C) of this section; and
- (D) Other appropriate supplier verification activities as specified in paragraph (c)(5)(i)(D) of this section.

(iii) *Reliance upon determination by other entity.* You may rely on a determination of appropriate foreign supplier verification activities in accordance with paragraph (c)(4)(i) of this section made by an entity other than the foreign supplier if you review and assess whether the entity's determination regarding appropriate activities (including the frequency with which such activities must be conducted) is appropriate based on the evaluation conducted in accordance with § 1.505. You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual.

(5) *Performance of foreign supplier verification activities.* (i) Except as provided in paragraph (c)(5)(ii) of this section, for each dietary supplement you import under paragraph (c) of this section, you must conduct (and document) or obtain documentation of one or more of the verification activities listed in paragraphs (c)(5)(i)(A) through (D) of this section before importing the dietary supplement and periodically thereafter.

(A) *Onsite auditing.* You conduct (and document) or obtain documentation of a periodic onsite audit of your foreign supplier.

(1) An onsite audit of a foreign supplier must be performed by a qualified auditor.

(2) The onsite audit must consider the applicable requirements of part 111 of this chapter and include a review of the foreign supplier's written food safety plan, if any, and its implementation (or, when applicable, an onsite audit may

Federal Register /Vol. 80, No. 228 / Friday, November 27, 2015 /Rules and Regulations 74349

consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(3) If the onsite audit is conducted solely to meet the requirements of paragraph (c)(5) of this section by an audit agent of a certification body that^[15] is accredited in accordance with subpart M of this part, the audit is not subject to the requirements in that subpart^[16].

(4) You must retain documentation of each onsite audit, including the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor.

(5) The following inspection results may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date by which the onsite audit would have been required to be conducted:

(i) The written results of appropriate inspection of the foreign supplier for compliance with the applicable requirements in part 111 of this chapter conducted by FDA, representatives of other Federal Agencies (such as the USDA), or representatives of State, local, tribal, or territorial agencies; or

(ii) The written results of an inspection by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the food that is the subject of the onsite audit is within the scope of the official recognition or equivalence determination, and the foreign supplier is in, and under the regulatory oversight of, such country.

(B) *Sampling and testing of the food.* You must retain documentation of each sampling and testing of a dietary supplement, including identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical method(s) used), the date(s) on which the test(s) were conducted and the date of the report of the testing, the results of the testing, any corrective actions taken in response to detection of hazards, information identifying the laboratory conducting the testing, and documentation that the testing was conducted by a qualified individual.

(C) *Review of the foreign supplier's food safety records.* You must retain documentation of each record review, including the date(s) of review, the general nature of the records reviewed, the conclusions of the review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.

(D) *Other appropriate activity.* (1) You may conduct (and document) or obtain documentation of other supplier verification activities that are appropriate based on foreign supplier performance and the risk associated with the food.

(2) You must retain documentation of each activity conducted in accordance with paragraph (c)(5)(i)(D)(1) of this section, including a description of the activity, the date on which it was conducted, the findings or results of the activity, any corrective actions taken in response to significant deficiencies identified, and documentation that the activity was conducted by a qualified individual.

(ii) *Reliance upon performance of activities by other entities.* (A) Except as specified in paragraph (c)(5)(ii)(B) of this section, you may rely on supplier verification activities conducted in accordance with paragraph (c)(5)(i) by another entity provided that you review and assess the results of these activities in accordance with paragraph (c)(5)(iii) of this section.

(B) You may not rely on the foreign supplier or employees of the foreign supplier to perform supplier verification activities, except with respect to sampling and testing of food in accordance with paragraph (c)(5)(i)(B) of this section.

(iii) *Review of results of verification activities.* You must promptly review and assess the results of the verification activities that you conduct or obtain documentation of under paragraph (c)(5)(i) of this section, or that are conducted by other entities in accordance with paragraph (c)(5)(ii) of this section. You must document your review and assessment of the results of verification activities. If the results show that the foreign supplier is not producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under part 111 of this chapter, you must take appropriate action in accordance with § 1.508(a). You are not required to retain documentation of

Appendix 1

supplier verification activities conducted by other entities, provided that you can obtain the documentation and make it available to FDA in accordance with § 1.510(b).

(iv) *Independence of qualified individuals conducting verification activities.* There must not be any financial conflicts of interest that influence the results of the verification activities set forth in paragraph (c)(5)(i) of this section, and payment must not be related to the results of the activity.

§1.512 What FSVP may I have if I am a very small importer or I am importing certain food from certain small foreign suppliers?

(a) *Eligibility.* This section applies only if:

(1) You are a very small importer; or

(2) You are importing certain food from certain small foreign suppliers as follows:

(i) The foreign supplier is a qualified facility as defined by § 117.3 or § 507.3 of this chapter;

(ii) You are importing produce from a foreign supplier that is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a) of this chapter, or in accordance with §§ 112.4(b) and 112.5 of this chapter; or

(iii) You are importing shell eggs from a foreign supplier that is not subject to the requirements of part 118 of this chapter because it has fewer than 3,000 laying hens.

(b) *Applicable requirements—(1) Documentation of eligibility—(i) Very small importer status.* (A) If you are a very small importer and you choose to comply with the requirements in this section, you must document that you meet the definition of very small importer in § 1.500 with respect to human food and/or animal food before initially importing food as a very small importer and thereafter on an annual basis by December 31 of each calendar year.

(B) For the purpose of determining whether you satisfy the definition of very small importer with respect to human food and/or animal food for a given calendar year, the relevant 3-year period of sales (and U.S. market value of human or animal food, as appropriate) is the period ending 1 year before the calendar year for which you intend to import food as a very small importer. The baseline year for calculating the adjustment for inflation is 2011. If you conduct any food sales in currency other than U.S. dollars, you must use the relevant currency exchange rate in effect on December 31 of the year in which sales occurred to calculate the value of these sales.

(ii) *Small foreign supplier status.* If you are importing food from a small foreign supplier as specified in paragraph (a)(2) of this section and you choose to comply with the requirements in this section, you must obtain written assurance that your foreign supplier

74350 Federal Register / Vol. 80, No. 228 / Friday, November 27, 2015 / Rules and Regulations

meets the criteria in paragraph (a)(2)(i), (ii), or (iii) of this section before first approving the supplier for an applicable calendar year and thereafter on an annual basis by December 31 of each calendar year, for the following calendar year.

(2) *Additional requirements.* If this section applies and you choose to comply with the requirements in paragraph (b) of this section, you also are required to comply with the requirements in §§ 1.502, 1.503, and 1.509, but you are not required to comply with the requirements in §§ 1.504 through 1.508 or § 1.510.

(3) *Foreign supplier verification activities.* (i) If you are a very small importer, for each food you import, you must obtain written assurance, before importing the food and at least every 2 years thereafter, that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 and 403(w) (if applicable) of the Federal Food, Drug, and Cosmetic Act.

(ii) If your foreign supplier is a qualified facility as defined by § 117.3 or § 507.3 of this chapter and you choose to comply with the requirements in this section, you must obtain written assurance before importing the food and at least every 2 years thereafter that the foreign supplier is producing the food in compliance with applicable FDA food safety regulations (or, when applicable, the relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States). The written assurance must include either:

(A) A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food; or

(B) A statement that the supplier is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

(iii) If your foreign supplier is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a) of this chapter, or in accordance with §§ 112.4(b) and 112.5 of this chapter, and you choose to comply with the requirements in this section, you must obtain written assurance before importing the produce and at least every 2 years thereafter that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(iv) If your foreign supplier is a shell egg producer that is not subject to the requirements of part 118 of this chapter because it has fewer than 3,000 laying hens and you choose to comply with the requirements in this section, you must obtain written assurance before importing the shell eggs and at least every 2 years thereafter that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(4) *Corrective actions.* You must promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food consistent with the assurance provided in accordance with § 1.512(b)(3)(i) through (iv). The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph (b)(4). This paragraph (b)(4) does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls.

(5) *Records—(i) General requirements for records.* (A) You must keep records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records.

(B) You must sign and date records concerning your FSVP upon initial completion and upon any modification of the FSVP.

(C) All records must be legible and stored to prevent deterioration or loss.

Appendix 1

(ii) *Availability.* (A) You must make all records required under this subpart available promptly to an authorized FDA representative, upon request, for inspection and copying. Upon FDA request, you must provide within a reasonable time an English translation of records maintained in a language other than English.

(B) Offsite storage of records, including records retained by other entities in accordance with paragraph (c) of this section, is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(C) If requested in writing by FDA, you must send records to the Agency electronically or through another means that delivers the records promptly, rather than making the records available for review at your place of business.

(iii) *Record retention.* (A) Except as specified in paragraph (b)(5)(iii)(B) or (C) of this section, you must retain records required under this subpart for a period of at least 2 years after you created or obtained the records.

(B) If you are subject to paragraph (c) of this section, you must retain records that relate to your processes and procedures, including the results of evaluations of foreign suppliers and procedures to ensure the use of approved suppliers, for at least 2 years after their use is discontinued (*e.g.*, because you have reevaluated a foreign supplier's compliance history or changed your procedures to ensure the use of approved suppliers).

(C) You must retain for at least 3 years records that you rely on during the 3- year period preceding the applicable calendar year to support your status as a very small importer.^[1]

(iv) *Electronic records.* Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.

(v) *Use of existing records.* (A) You do not need to duplicate existing records you have (*e.g.*, records that you maintain to comply with other Federal, State, or local regulations) if they contain all of the information required by this subpart. You may supplement any such existing records as necessary to include all of the information required by this subpart.

(B) You do not need to maintain the information required by this subpart in one set of records. If existing records you have contain some of the required information, you may maintain any new information required by this subpart either separately or combined with the existing records.

Federal Register /Vol. 80, No. 228 / Friday, November 27, 2015 /Rules and Regulations 74351

(vi) *Public disclosure.* Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter.

(c) *Requirements for importers of food from certain small foreign suppliers.* The following additional requirements apply if you are importing food from certain small foreign suppliers as specified in paragraph (a)(2) of this section and you are not a very small importer:

(1) *Evaluation of foreign supplier compliance history—(i) Initial evaluation.* In approving your foreign suppliers, you must evaluate the applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation. You may also consider other factors relevant to a foreign supplier's performance, including those specified in § 1.505(a)(1)(iii)(A) and (C).

(ii) *Reevaluation of foreign supplier compliance history.* (A) Except as specified in paragraph (c)(1)(iii) of this section, you must promptly reevaluate the concerns associated with the foreign supplier's compliance history when you become aware of new information about the matters in paragraph (c)(1)(i) of this section, and the reevaluation must be documented. If you determine that the concerns associated with importing a food from a foreign supplier have changed, you must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier.

(B) If at the end of any 3-year period you have not reevaluated the concerns associated with the foreign supplier's compliance history in accordance with paragraph (c)(1)(ii)(A) of this section, you must reevaluate those concerns and take other appropriate actions, if necessary, in accordance with paragraph (c)(1)(ii)(A). You must document your reevaluation and any subsequent actions you take in accordance with paragraph (c)(1)(ii)(A).

(iii) *Review of another entity's evaluation or reevaluation of foreign supplier compliance history.* If an entity other than the foreign supplier has, using a qualified individual, performed the evaluation described in paragraph (c)(1)(i) of this section or the reevaluation described in paragraph (c)(1)(ii), you may meet the requirements of the applicable paragraph by reviewing and assessing the evaluation or reevaluation conducted by that entity. You must document your review and assessment, including documenting that the evaluation or reevaluation was conducted by a qualified individual.

(2) *Approval of foreign supplier.* You must approve your foreign suppliers on the basis of the evaluation you conducted under paragraph (c)(1)(i) of this section or that you review and assess under paragraph (c)(1)(iii) of this section, and document your approval.

(3) *Use of approved foreign suppliers.* (i) You must establish and follow written procedures to ensure that you import foods only from foreign suppliers you have approved based on the evaluation conducted under paragraph (c)(1)(i) of this section (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before importing the food). You must document your use of these procedures.

(ii) You may rely on an entity other than the foreign supplier to establish the procedures and perform and document the activities required under paragraph (c)(3)(i) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

§ 1.513 What FSVP may I have if I am importing certain food from a country with an officially recognized or equivalent food safety system?

(a) *General.* (1) If you meet the conditions and requirements of paragraph (b) of this section for a food of the type specified in paragraph (a)(2) of this section that you are importing, then you are not required to comply with the requirements in §§ 1.504 through 1.508. You would still be required to comply with the requirements in §§ 1.503, 1.509, and 1.510.

(2) This section applies to food that is not intended for further manufacturing/ processing, including packaged food products and raw agricultural commodities that will not be commercially processed further before consumption.

(b) *Conditions and requirements.* (1) Before importing a food from the foreign supplier and annually thereafter, you must document that the foreign supplier is in, and under the regulatory oversight of, a country whose food safety system FDA has

Appendix 1

officially recognized as comparable or determined to be equivalent to that of the United States, and that the food is within the scope of that official recognition or equivalency determination.

(2) Before importing a food from the foreign supplier, you must determine and document whether the foreign supplier of the food is in good compliance standing with the food safety authority of the country in which the foreign supplier is located. You must continue to monitor whether the foreign supplier is in good compliance standing and promptly review any information obtained. If the information indicates that food safety hazards associated with the food are not being significantly minimized or prevented, you must take prompt corrective action. The appropriate corrective action will depend on the circumstances but could include discontinuing use of the foreign supplier. You must document any corrective actions that you undertake in accordance with this paragraph (b)(2).

§ 1.514 What are some consequences of failing to comply with the requirements of this subpart?

(a) *Refusal of admission.* An article of food is subject to refusal of admission under section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act if it appears that the importer of that food fails to comply with this subpart with respect to that food. If there is no U.S. owner or consignee of an article of food at the time the food is offered for entry into the United States, the article of food may not be imported into the United States unless the foreign owner or consignee has appropriately designated a U.S. agent or representative as the importer in accordance with § 1.500.

(b) *Prohibited act.* The importation or offering for importation into the United States of an article of food without the importer having an FSVP that meets the requirements of section 805 of the Federal Food, Drug, and Cosmetic Act, including the requirements of this subpart, is prohibited under section 301(zz) of the Federal Food, Drug, and Cosmetic Act.

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

3. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

74352 Federal Register / Vol. 80, No. 228 / Friday, November 27, 2015 / Rules and Regulations

4. In § 11.1, add and reserve paragraph (h) and (k) and add paragraph (l) to read as follows:

§ 11.1 Scope.

* * * *

(l) This part does not apply to records required to be established or maintained by subpart L of part 1 of this chapter. Records that satisfy the requirements of subpart L of part 1 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

PART 111—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS

5. The authority citation for 21 CFR part 111 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 371, 374, 381, 393; 42 U.S.C. 264.

6. In § 111.5, add a sentence after the existing sentence to read as follows:

§ 111.5 Do other statutory provisions and regulations apply?

*** For importers of dietary supplements and dietary supplement components, the regulation on foreign supplier verification programs can be found in subpart L of part 1 of this chapter.

Dated: October 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-28158 Filed 11-13-15; 8:45 am]

BILLING CODE 4164-01-P

Retrieved from FDA website (page last updated 05/10/2017) at:

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm556661.htm>

Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation

In this guidance:

- [Introduction](#)
- [Background](#)
- [Discussion](#)

Introduction

This guidance provides information on how you may comply with FDA's requirement to identify yourself as the importer of a food at entry into the United States under the Foreign Supplier Verification Programs (FSVP) regulation, including the requirement to provide a unique facility identifier (UFI) recognized as acceptable by FDA. This guidance also provides information on what to do if you are unable to obtain a Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS) number in time for applicable FSVP compliance date. The first FSVP compliance date is May 30, 2017. The pronoun "you" is used in this guidance to refer to the importer as defined in the FSVP regulation.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Background

The FSVP regulation was established in Title 21 of the Code of Federal Regulations, Part 1, subpart L, as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353). FDA issued the final rule on FSVPs for importers of food for humans and animals on November 27, 2015 (80 FR 74225). The FSVP regulation, codified in 21 CFR 1.500 through 1.514, specifies the foods and importers to which the FSVP regulation applies and establishes various requirements. Among other requirements, section 1.509(a) of the FSVP regulation requires that, for each line entry of food product offered for importation into the United States, the importer provide its name, electronic mail address, and unique facility identifier recognized as acceptable by FDA electronically when filing entry with U.S. Customs and Border Protection.

On March 31, 2017, FDA issued guidance recognizing the DUNS number as an acceptable UFI for the FSVP regulation (see <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm549623.htm>).

This guidance provides additional information about how importers may provide and filers may transmit the required information at entry.

Discussion

When a food product under FDA oversight is offered for entry into the United States (U.S.), the U.S. Customs and Border Protection (CBP) Automated Commercial Environment (ACE) system will prompt the filer to transmit one of the following codes:

1. An entity role code “FSV,” which will send a signal to the ACE system indicating the entry line is subject to the FSVP regulation; or
2. (2) One of two Affirmation of Compliance codes indicating the article of food and importer are not subject to the FSVP regulation at the time of entry.

The transmission of entity role code “FSV” will trigger a request for the FSVP importer’s name, email address, and DUNS number as the UFI recognized as acceptable by FDA.

If the food entry line is exempt from the requirements of the FSVP regulation, or not yet subject to the regulation based on the applicable compliance date, the filer should transmit the applicable Affirmation of Compliance code, either “FSX” (designating that the food is exempt from the FSVP regulation or that compliance with the FSVP regulation is not yet required) or “RNE” (designating that the food is exempt from the FSVP regulation in accordance with 21 CFR 1.501(c) because it will be used for research or evaluation). Note that we are requiring a specific “RNE” Affirmation of Compliance code for foods that are imported for research or evaluation because the final FSVP regulation specifically requires that a food be accompanied, when filing entry with U.S. Customs and Border Protection, by an electronic declaration that the food will be used for research or evaluation purposes and will not be sold or distributed to the public in order to qualify for this exemption. (21 CFR 1.501(c)(4)). By selecting the “RNE” Affirmation of Compliance code, filers would be providing such a declaration.

If one of these codes is not transmitted for an imported food product under FDA oversight, the entry line will be rejected. Similar to all rejections in the ACE system, the rejection will generate an error message to the filer. Once an error message is received, the filer can make the appropriate adjustments to the entry submission and retransmit the entry line.

While FDA expects all FSVP importers to provide their UFI starting on the applicable compliance date, the Agency recognizes that this is a new requirement and there may be factors that prevent importers from doing so. Therefore, for FSVP importers temporarily unable to obtain a DUNS number, FDA intends to allow filers to transmit the value “UNK” (to represent “unknown”) in the UFI field for the FSVP importer. FDA will allow this beginning May 30, 2017. This temporary allowance will allow for articles of food offered for import into the United States to be processed through the ACE system even if an importer has not yet provided a DUNS number. We will update the guidance and communicate with importers at such time when we discontinue this use of the “UNK” value.

During the time that FDA and CBP allow the use of the “UNK” value for the UFI field, FDA intends to contact those FSVP importers for whom “UNK” was transmitted in place of the UFI. We will provide additional information to help ensure that FSVP importers understand this FSVP regulation requirement and take the appropriate steps to obtain a UFI.

Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation (for reference only)

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance listed on the title page.

Guidance for Industry: Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation (for reference only)

Retrieved from FDA website (page last updated 03/31/2017) at:

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm549623.htm>

Guidance for Industry: Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation¹

Additional copies are available from:

Office of Compliance

Center for Food Safety and Applied Nutrition

Food and Drug Administration

5001 Campus Drive College

Park, MD 20740

(tel) 240-701-5986

<http://www.fda.gov/FoodGuidances>

Division of Compliance (HFV-230)

Center for Veterinary Medicine

Food and Drug Administration

7519 Standish Place,

Rockville, MD 20855

(tel) 240-402-7002

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2011-N-0143.

**U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine**

March 2017

Table of Contents

- I. Introduction**
- II. Background**
- III. Recognition of Acceptable Unique Facility Identifier (UFI)**

Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation: Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

This guidance specifies FDA's current thinking on what unique facility identifier (UFI) FDA recognizes as acceptable for purposes of the Foreign Supplier Verification Programs (FSVP) regulation established in Title 21 of the Code of Federal Regulation, Part 1, subpart L as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353). The pronoun "you" is used in this guidance to refer to the importer.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

FDA issued the rule on FSVPs for importers of food for humans and animals on November 27, 2015 (80 FR 74225). The FSVP regulation, codified in 21 CFR 1.500 through 1.514, specifies the foods and importers to which the FSVP regulation applies and establishes various requirements, including the requirement for importer identification for food offered for entry into the United States (21 CFR 1.509(a)).

¹ This guidance has been jointly prepared by the Office of Compliance in the Center for Food Safety and Applied Nutrition, the Office of Surveillance and Compliance in the Center for Veterinary Medicine, and the Division of Import Operations in the Office of Regulatory Affairs at the U.S. Food and Drug Administration.

In the FSVP proposed rule, FDA initially proposed to require that for each line entry of food product offered for importation into the United States, the FSVP importer's name and Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS) number identifying the FSVP importer be provided (78 FR 45729 at 45762, July 29, 2013).

In response to comments, in the FSVP final rule we replaced this proposed provision with a requirement that for each line entry of food product offered for importation into the United States, the FSVP importer provide its UFI recognized as acceptable by FDA (21 CFR 1.509(a)). We stated in the final rule that we anticipated issuing guidance specifying which UFI(s) we recognized as acceptable and that we expected to recognize DUNS numbers as being acceptable (80 FR 74226 at 74301). In addition, the final rule requires that for each line entry of food product offered for importation into the United States, the FSVP importer must also provide the importer's name and electronic mail address (21 CFR 1.509(a)).

III. Recognition of Acceptable Unique Facility Identifier (UFI)

At this time, FDA recognizes the DUNS number, assigned and managed by D&B, as an acceptable UFI for the purpose of compliance with the FSVP regulation.

Currently, FDA finds the DUNS number appropriate to meet Agency needs to accurately identify FSVP importers so we can effectively implement, monitor compliance with, and enforce the FSVP requirements. The DUNS number is available free of charge to all importers, and can be obtained by contacting D&B by phone at 866-705-5711 or via email at govt@dnb.com, or by visiting D&B's Web sites at <http://www.dnb.com/duns-number.html> or <https://fdadunslookup.com>. Although a DUNS number may be obtained within a few business days, in some circumstances it could take up to 45 days or more.

If you anticipate being unable to provide a DUNS number to identify yourself as the FSVP importer of a food product at entry, you may contact FDA's Division of Import Operations at 1- 301-796-0356 or via email at FDImportsInquiry@fda.hhs.gov prior to offering your product for import into the United States.

Retrieved from FDA website (page last updated 08/07/2017) at:

<https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm569554.htm>

FDA Guidances Explain Certain Exemptions from FSMA

Constituent update

August 7, 2017

If you are a food producer covered by FDA's regulations for low-acid canned foods, juice HACCP, or seafood HACCP, how do the rules that implement the FDA Food Safety Modernization Act (FSMA) affect you?

To answer this question, the FDA has published three guidances to help producers of food commodities covered by these earlier regulations understand which parts of the FSMA rules apply to them and how the FSMA rules may affect their operations.

FDA's HACCP (Hazard Analysis and Critical Control Point) and Low-Acid Canned Foods (LACF) regulations were in place long before the FSMA rules became final. FDA's HACCP regulations for juice and seafood processors require processors to perform a hazard analysis and develop a HACCP plan to address biological, chemical, and physical hazards, monitor the conditions and practices, and make corrections as needed. FDA's Low-acid canned foods regulation addresses biological hazards such as Clostridium botulinum unique to such foods, which include canned vegetables.

FSMA recognizes that FDA has previously-established regulations that are specific to seafood, juice, and LACF and so some exemptions have been made in the FSMA rules for these products. However, there are still some requirements in the FSMA regulations that apply to processors of the seafood, juice, and LACF products.

The new guidances aim to help industry identify these exemptions and understand the juice, seafood, and LACF regulations in connection with some of the new FSMA requirements. The overarching goal of many of the new FSMA requirements is to reduce the number of foodborne illnesses attributed to the preventable contamination of FDA-regulated food products.

For More Information

[Low-Acid Canned Foods and FSMA](#)

[Juice HACCP and FSMA](#)

[Seafood HACCP and FSMA](#)

Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA (for reference only)

Retrieved from FDA website (page last updated 11/02/2016) at:

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm524553.htm>

Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA¹

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 180 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2016-D-2841 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document as it relates to our regulation entitled “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food,” contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2166.

For questions regarding this draft document as it relates to our regulation entitled “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals,” contact the Center for Veterinary Medicine (CVM) at 240-402-6246.

For questions regarding this draft document as it relates to our regulation entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1636.

For questions regarding this draft document as it relates to our regulation entitled “Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals,” contact the Office of Policy, Food and Drug Administration at 301-796-4576.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
Office of Policy
October, 2016**

Table of Contents

Table of Contents

- I. Introduction**
- II. Background on the Four Foundational Rules**
 - A. Part 117**
 - 1. Framework of part 117*
 - 2. "Disclosure statement" required in the "customer provisions" of part 117*
 - B. Part 507**
 - 1. Framework of part 507*
 - 2. "Disclosure statement" required in the "customer provisions" of part 507*
 - C. Produce Safety Regulation**
 - 1. Framework of the produce safety regulation*
 - 2. "Disclosure statement" required in the "commercial processing exemption" of the produce safety regulation*
 - D. Foreign Supplier Verification Regulation**
 - 1. Framework of the FSVP regulation*
 - 2. "Disclosure statement" required in the "customer provisions" of the FSVP regulation*
- III. Discussion**
 - A. FDA's Recommendations Regarding the Part 117 Disclosure Statement**
 - 1. How to describe the identified hazard*
 - 2. Documents of the trade*
 - B. FDA's Recommendations Regarding the Part 507 Disclosure Statement**
 - C. FDA's Recommendations Regarding the Produce Safety Regulation Disclosure Statement**
 - 1. How to describe the identified hazard*
 - 2. Documents of the trade*
 - D. FDA's Recommendations Regarding the FSVP Regulation Disclosure Statement**
 - 1. How to describe the identified hazard*
 - 2. Documents of the trade*

Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting the form available at:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>.

I. Introduction

This guidance concerns four of the seven foundational rules that we have established in Title 21 of the Code of Federal Regulations (21 CFR) as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353). Table 1 lists these four rules.

Table 1. Four Foundational Rules Providing the Framework for Implementing FSMA

| Title | Regulatory Codification | Abbreviation for the Purpose of This Guidance | Publication |
|---|--------------------------|---|---------------------------------|
| Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food | 21 CFR part 117 | Part 117 | 80 FR 55908, September 17, 2015 |
| Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals | 21 CFR part 507 | Part 507 | 80 FR 56170, September 17, 2015 |
| Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption | 21 CFR part 112 | Produce safety regulation | 80 FR 74354, November 27, 2015 |
| Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals | 21 CFR part 1, subpart L | FSVP regulation | 80 FR 74226, November 27, 2015 |

¹ This guidance has been jointly prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition, the Office of Surveillance and Compliance in the Center for Veterinary Medicine, and the Office of Policy in the Office of the Commissioner at the U.S. Food and Drug Administration.

This guidance is intended for any entity that is subject to certain provisions (in part 117, part 507, the produce safety regulation, or the FSVP regulation) that require a disclosure statement, in documents accompanying food, that certain hazards have not been controlled by that entity. This guidance is not intended to address other requirements of part 117, part 507, the produce safety regulation, or the FSVP regulation.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background on the Four Foundational Rules

A. Part 117

1. Framework of part 117

In part 117, we have established our regulation entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.” Among other things, the rulemaking to establish part 117 amended our current good manufacturing practice (CGMP) regulation for manufacturing, packing, or holding human food to modernize it and establish it in new part 117, subparts A, B, and F. Part 117 also includes new requirements for domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350d)² in subparts A, C, D, E, F, and G to establish and implement hazard analysis and risk-based preventive controls for human food (the human food preventive controls requirements). The human food preventive controls requirements in part 117 implement the provisions of FSMA, established in section 418 of the FD&C Act (21 U.S.C. 350g), for human food.

Part 117 includes some exemptions from the CGMP requirements and the human food preventive controls requirements. See 21 CFR 117.5 for those exemptions.

Among other requirements, subpart C of part 117 requires a facility that manufactures/processes human food to conduct a hazard analysis to determine whether there are any hazards that require a preventive control (21 CFR 117.130) and identifies several types of possible preventive controls, including process controls (21 CFR 117.135(c)(1)), food allergen controls (21 CFR 117.135(c)(2)), sanitation controls (21 CFR 117.135(c)(3)), and supply-chain controls (21 CFR 117.135(c)(4)).

² The requirements for domestic and foreign facilities to register under section 415 of the FD&C Act are established in 21 CFR part 1, subpart H. In this document, we refer to those requirements as “the section 415 registration regulation.”

2. “Disclosure statement” required in the “customer provisions” of part 117

Subpart C of part 117 includes several provisions (referred to collectively as “customer provisions”) that apply when a manufacturer/processor of human food identifies a hazard requiring a preventive control (“identified hazard”), does not control the identified hazard, and relies on an entity in its distribution chain to address the hazard (21 CFR 117.136(a)(2), (3), and (4)). A manufacturer/processor that complies with the customer provisions is not required to implement a preventive control for the identified hazard. (In these provisions, “customer” means a commercial customer, not a consumer.)

One aspect of the customer provisions is a requirement for the manufacturer/processor to disclose, in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]” ((21 CFR 117.136(a)(2)(i), (3)(i), and (4)(i))). In this guidance, we refer to this required disclosure as the “part 117 disclosure statement.”

B. Part 507

1. Framework of part 507

In part 507, we have established our regulation entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.” Among other things, the rulemaking to establish part 507 established new requirements for CGMPs in subparts A, B, and F (CGMP requirements) and also established requirements for hazard analysis and risk-based preventive controls for food for animals in subparts A, C, D, E, and F (the animal food preventive controls requirements). The part 507 requirements apply to domestic and foreign facilities that are required to register under the section 415 registration regulation. The animal food preventive controls requirements in part 507 implement the provisions of FSMA, established in section 418 of the FD&C Act (21 U.S.C. 350g), for animal food.

Part 507 includes some exemptions from the CGMP requirements and the animal food preventive controls requirements. See 21 CFR 507.5 for those exemptions.

Among other requirements, subpart C of part 507 requires a facility that manufactures/processes food for animals to conduct a hazard analysis to determine whether there are any hazards that require a preventive control (21 CFR 507.33) and identifies several types of possible preventive controls, including process controls (21 CFR 507.34(c)(1)), sanitation controls (21 CFR 507.34(c)(2)), and supply-chain controls (21 CFR 507.34(c)(3)).

2. “Disclosure statement” required in the “customer provisions” of part 507

As with part 117, subpart C of part 507 includes “customer provisions” that apply when a manufacturer/processor of food for animals identifies a hazard requiring a preventive control (“identified hazard”), does not control the identified hazard, and relies on an entity in its distribution chain to address the hazard (21 CFR 507.36(a)(2), (3), and (4)). A manufacturer/processor that complies with the customer provisions is not required to implement a preventive control for the identified hazard.

As with part 117, one aspect of the customer provisions applicable to manufacturing/processing

food for animals is a requirement for the manufacturer/processor to disclose, in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is “not processed to control [identified hazard]” ((21 CFR 507.36(a)(2)(i), (3)(i), and (4)(i)). In this guidance, we refer to this required disclosure as the “part 507 disclosure statement.”

C. Produce Safety Regulation

1. Framework of the produce safety regulation

In part 112 (21 CFR part 112), we have established our regulation entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption”. Among other things, the rulemaking to establish the produce safety regulation set forth in a new part 112 procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. The produce safety regulation applies to certain produce farms, and does not apply to activities of facilities that are subject to part 117 (as established in part 117). The produce safety regulation established in part 112 implements the provisions of FSMA established in section 419 of the FD&C Act (21 U.S.C. 350h).

2. “Disclosure statement” required in the “commercial processing exemption” of the produce safety regulation

The produce safety regulation applies to “covered produce” as set forth in 21 CFR 112.1 and 112.2. Produce that would otherwise be covered is eligible for an exemption from the requirements of the produce safety regulation if it receives commercial processing that adequately reduces the presence of microorganisms of public health significance and certain other conditions are met, including the disclosure statement that is the subject of this guidance document (21 CFR 112.2(b)). Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of 21 CFR part 113, 114, or 120; treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes); and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products. In this document, we refer to this exemption as the “commercial processing exemption” from the produce safety regulation.

For the commercial processing exemption to be satisfied, the farm that produces the produce must, among other things, disclose in documents accompanying the produce, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance.” In this guidance, we refer to this required disclosure as the “produce safety regulation disclosure statement.”

D. Foreign Supplier Verification Regulation

1. Framework of the FSVP regulation

In part 1, subpart L (21 CFR part 1, subpart L), we have established our regulation entitled “Foreign Supplier Verification Programs for Importers of Food for Humans and Animals”. The FSVP regulation requires importers to establish foreign supplier verification programs to verify that their foreign suppliers are using processes and procedures that provide the same level of public health protection as those required under the provisions on hazard analysis and risk-based preventive controls and standards for produce safety in the FD&C Act, that the imported food is not adulterated, and that food is not misbranded with respect to food allergen labeling. The FSVP regulation established in part 1, subpart L implements the provisions of FSMA established in section 805 of the FD&C Act (21 U.S.C. 384a.).

2. “Disclosure statement” required in the “customer provisions” of the FSVP regulation

The FSVP regulation includes “customer provisions” that apply when an importer imports a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation (21 CFR 1.507). One aspect of these provisions is a requirement for the importer to disclose to customers that the food is “not processed to control [identified hazard]” (21 CFR 1.507(a)(2)(i), (a)(3)(i), and (a)(4)(i)). In this guidance, we refer to this required disclosure as the “FSVP regulation disclosure statement.”

III. Discussion

A. FDA’s Recommendations Regarding the Part 117 Disclosure Statement

1. How to describe the identified hazard

We believe that, in practice, the part 117 disclosure statement will be required mostly for biological hazards, because the part 117 disclosure statement only applies when a manufacturing/ processing facility has identified a hazard requiring a preventive control, but has not applied that preventive control. In the case of most chemical and physical hazards, a chemical or physical hazard that a manufacturing/processing facility identifies as requiring a preventive control would most likely be controlled by the first manufacturing/processing facility in the supply/distribution chain. For example, a corn miller that is the first manufacturer/processor could identify the chemical hazard aflatoxin in corn that it receives from a supplier and use physical sorting techniques to remove aflatoxin-contaminated corn (or moldy, damaged corn that could potentially be contaminated) during processing. Therefore, the miller controls the aflatoxin hazard and would not pass the chemical hazard on to a subsequent manufacturer/processor for control. Likewise, a manufacturing/processing facility that receives produce RACs likely would establish and implement a control for physical hazards such as stones that get into the RACs as a result of harvesting.

For biological hazards, we will consider a manufacturing/processing facility that describes the “identified hazard” using a general term (e.g., “microbial pathogens,” “microorganisms of public

health significance") rather than a specific biological hazard (e.g., *Salmonella* or *Listeria monocytogenes*) to be in compliance with the requirements for the part 117 disclosure statement. Such a statement adequately communicates the key safety information. Regardless of whether the establishment that receives food accompanied by such a disclosure statement is subject to the CGMP requirements, the human food preventive controls requirements, or both the CGMP and human food preventive controls requirements in part 117, that establishment is responsible for taking appropriate steps to ensure that biological hazards applicable to that food are controlled before the food reaches the consumer.

For chemical and physical hazards, a manufacturing/processing facility that chooses to not control chemical and physical hazards and to rely on its customers to do so, would be subject to the requirements of the part 117 disclosure statement. We expect such a facility to describe the identified chemical or physical hazard using a specific term (e.g., "mycotoxins," "aflatoxin," "stones") that adequately communicates the key safety information regarding the chemical or physical hazard that needs to be controlled. Referring to physical or chemical hazards using a general term only does not provide a customer with sufficient information to address the hazard.

2. Documents of the trade

The requirements for the part 117 disclosure statement specify that the disclosure must be made in "documents accompanying the food, in accordance with the practice of the trade." See 21 CFR 117.136(a)(2)(i), (a)(3)(i), and (a)(4)(i). This allows for the disclosure statement to be provided using a wide variety of types of documents that accompany the food, such as labels, labeling, bill of lading, shipment-specific certificates of analysis, and other documents or papers associated with the shipment that a food safety manager for the customer is likely to read.

However, it is not sufficient to reference a website in a document of the trade without including the disclosure statement, itself, in the document of the trade. It is permissible, for the purposes of the requirements of the part 117 disclosure statement, to use labeling that includes a disclosure statement such as "not processed to control microbial pathogens" and then directs the recipient to a website for additional information about those microbial pathogens.

We do not recommend documents such as contractual agreements, letters of guarantee, specifications, or terms and conditions be used to communicate the information required in the part 117 disclosure statement. Such documents generally are not specific to a particular shipment, and some of these documents may not be available to the customer's food safety manager.

B. FDA's Recommendations Regarding the Part 507 Disclosure Statement

See the discussion in section III.A of our recommendations regarding the part 117 disclosure statement. The same discussion and recommendations apply to the part 507 disclosure statement.

C. FDA's Recommendations Regarding the Produce Safety Regulation Disclosure Statement

1. How to describe the identified hazard

Because both part 117 and part 507 define the term “pathogen” to mean “microorganism of public health significance,” and because some disclosure statements in accordance with the requirements of part 117 or the requirements of part 507 likely will use terms such as “microbial pathogens,” we will consider a farm that discloses “not processed to adequately reduce the presence of microbial pathogens,” or similar phrases, to be in compliance with the requirements for the produce safety regulation disclosure statement.

2. Documents of the trade

See the discussion in section III.A of our recommendations regarding the part 117 disclosure statement. The same discussion and recommendations apply to the produce safety regulation disclosure statement.

D. FDA's Recommendations Regarding the FSVP Regulation Disclosure Statement

1. How to describe the identified hazard

We believe that, in practice, the FSVP regulation disclosure statement will be required mostly for biological hazards, because the FSVP regulation disclosure statement only applies when an importer has identified a hazard requiring a control, but that control has not been applied prior to importation, or by the importer if the importer is a manufacturer or processor. In the case of most chemical and physical hazards, a chemical or physical hazard that an importer identifies as requiring a control would most likely be controlled by the first manufacturing/processing facility in the supply/distribution chain. For example, an animal food vitamin pre-mix manufacturer that is a foreign supplier could identify the chemical hazard “nutrient toxicity” in the vitamin ingredients it receives from its supplier. The pre-mix manufacturer would evaluate the potency of the individual vitamin ingredients prior to manufacturing the pre-mix, controlling the nutrient toxicity hazard by combining the vitamin ingredients at an appropriate ratio. In this scenario, the pre-mix manufacturer would not pass the chemical hazard on to a future customer for control. Likewise, an importer that is a manufacturing/processing facility that receives produce RACs from a foreign supplier likely would establish and implement a control for physical hazards such as stones that get into the RACs as a result of harvesting.

For biological hazards, we will consider an importer that describes the “identified hazard” using a general term (e.g., “microbial pathogens,” “microorganisms of public health significance”) rather than a specific biological hazard (e.g., *Salmonella* or *Listeria monocytogenes*) to be in compliance with the requirements for the FSVP regulation disclosure statement. Such a statement adequately communicates the key safety information. Regardless of whether the establishment that receives food from the importer accompanied by such a disclosure statement is subject to the CGMP requirements, the preventive controls requirements, or both the CGMP and preventive controls

requirements in part 117 or part 507, that establishment is responsible for taking appropriate steps to ensure that biological hazards applicable to that food are controlled before the food reaches the consumer.

For chemical and physical hazards, an importer that chooses to rely on its customers to control chemical and physical hazards (instead of controlling the hazards itself or verifying that the hazards have been controlled prior to importation) would be subject to the requirements of the FSVP regulation disclosure statement. We expect such an importer to describe the identified chemical or physical hazard using a specific term (e.g., “mycotoxins,” “aflatoxin,” “stones”) that adequately communicates the key safety information regarding the chemical or physical hazard that needs to be controlled. Referring to physical or chemical hazards using a general term only does not provide a customer with sufficient information to address the hazard.

2. Documents of the trade

See the discussion in section III.A of our recommendations regarding the part 117 disclosure statement. The same discussion and recommendations apply to the FSVP regulation disclosure statement.

Blank Colored Insert-Front

Blank Colored Insert-Back

APPENDIX 2: Compliance Dates for the Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals

| Title of Document | Page |
|---|-------------|
| Compliance Dates for the Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals | A2-3 |
| Compliance Date Extensions and Clarifications for FSMA Final Rules | A2-5 |

Retrieved January 2017 from FDA website (page last updated 12/13/2016) at:
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm>

Compliance Dates for the Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals

For more information on **Compliance Date Extensions and Clarifications for FSMA Final Rules** see FDA web page: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm517545.htm>

The compliance dates for importers subject to the [Foreign Supplier Verification Programs \(FSVP\) rule](#) differ according to a number of considerations, including:

- the size of the foreign supplier,
- the nature of the importer,
- and whether the foreign supplier must meet the requirements of the final rules for
- [Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food](#),
- [Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals \(collectively, "PC rules"\)](#), or
- [Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption \("produce safety rule"\)](#).

The following compliance dates are grouped according to the category of FSVP importer. **This list does not include importers that are themselves a manufacturer or processor subject to the supply-chain program provisions in the PC rules.** If importers are subject to the supply-chain program requirements in those rules, the compliance date for FSVP is the later of the applicable date in the below list or the date by which the importer is required to comply with the PC supply-chain program provisions.

1. **FSVP importer whose foreign supplier is not subject to the PC or produce safety rules:** **May 30, 2017**
2. **FSVP importer whose foreign supplier is required to comply with the PC rule for human food.** Compliance dates when foreign suppliers are in these categories:
 - Small businesses as defined in 21 CFR 117.3: **March 19, 2018**
 - Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 117.3: **March 18, 2019**
 - Suppliers subject to the Pasteurized Milk Ordinance: **March 18, 2019**
 - "All Other" Businesses Suppliers: **May 30, 2017**
3. **FSVP importer of animal food whose foreign supplier is subject to the current good manufacturing practices ("CGMP") requirements in subpart B of 21 CFR part 507 in the PC rule for animal food.** Compliance dates when foreign suppliers are in these categories:
 - Small Businesses as defined in 21 CFR 507.3: **March 19, 2018**
 - Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 507.3: **March 18, 2019**

- “All Other” Businesses: **May 30, 2017**
4. **FSVP importer whose foreign supplier is required to comply with the animal food preventive controls requirements in subpart C of part 507 of the PC rule for animal food, but that is not required to comply with the CGMP requirements in subpart B of 21 CFR part 507.** Compliance dates when foreign suppliers are in these categories:
- Small Businesses as defined in 21 CFR 507: **March 18, 2019**
 - Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 507.3: **March 17, 2020**
 - “All Other” Businesses: **March 19, 2018**
5. **FSVP importer whose foreign supplier is required to comply with the produce safety rule, except for the requirements applicable to sprouts in subpart M of 21 CFR part 112.** Compliance dates when foreign suppliers are in these categories:
- Small Businesses as defined in 21 CFR 112.3: **July 29, 2019**
 - Very Small Businesses as defined in 21 CFR 112.3: **July 27, 2020**
 - “All Other” Businesses: **July 26, 2018**
6. **FSVP importer whose foreign supplier is required to comply with the requirements in the produce safety rule applicable to sprouts in subpart M of 21 CFR part 112.** Compliance dates when foreign suppliers are in these categories:
- Small Businesses as defined in 21 CFR 112.3: **July 26, 2018**
 - Very Small Businesses as defined in 21 CFR 112.3: **July 29, 2019**
 - “All Other” Businesses: **July 26, 2017**
7. **FSVP importer whose foreign supplier is subject to the produce safety rule and eligible for a qualified exemption** (other than when the foreign supplier is a farm producing sprouts). Compliance dates when foreign suppliers are in these categories:
- Small Businesses as defined in 21 CFR 112.3: **July 29, 2019**
 - Very Small Businesses as defined in 21 CFR 112.3: **July 27, 2020**
8. **FSVP importer whose foreign supplier is a farm producing sprouts that is eligible for a qualified exemption under the produce safety rule.** Compliance dates when foreign suppliers are in these categories:
- Small Businesses as defined in 21 CFR 112.3: **July 26, 2018**
 - Very Small Businesses as defined in 21 CFR 112.3: **July 29, 2019**

Retrieved August 2017 from FDA website (page last updated 08/23/2016) at:
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm517545.htm>

Compliance Date Extensions and Clarifications for FSMA Final Rules

General information on compliance dates for FSMA final rules is available on each rule page. The following is a summary of changes announced in the Final Rule: Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules that impacts provisions in these four rules:

- [Preventive Controls for Human Food](#)
- [Preventive Controls for Food for Animals](#)
- [Produce Safety Final Rule](#)
- [Foreign Supplier Verification Programs \(FSVP\)](#)

Extending compliance dates for certain provisions concerning written customer assurances

- All four rules contain “customer provisions” for modified requirements (or, in the case of the Produce Safety rule, an exemption) when food safety controls are applied downstream and certain conditions are satisfied. For example, the customer provisions in some of the rules allow a manufacturer/processor that does not control a hazard requiring a preventive control to rely on its customer to control the hazard.
- The manufacturer/processor must disclose in documents accompanying the food that it is not processed to control the hazard and must obtain a written assurance from the customer that the customer will manufacture the food in accordance with applicable food safety requirements or sell only to someone that agrees to do so.
- This final rule provides entities with an additional two years to comply with the customer assurance requirements while FDA considers the best approach to address feasibility concerns. The compliance dates for these requirements are different for each rule, with the earliest date being September 19, 2018 for large human food facilities.

Extending compliance dates for facilities that only pack and/or hold raw agricultural commodities that are produce and/or nut hulls and shells

- Compliance dates for facilities that are covered by the two Preventive Controls rules for human and animal food, including CGMPs, and are solely engaged in packing and/or holding produce raw agricultural commodities (for example, some packing houses) are extended to align with the compliance dates for farms conducting similar activities under the Produce Safety rule.
- This extension includes facilities that hull, shell, pack and/or hold nuts.
- The earliest compliance date is January 26, 2018.

Extending compliance dates for certain facilities that would qualify as secondary activities farms except for the ownership of the facility

- The FDA is extending the compliance dates for operations that would be secondary activities farms except that they do not meet the ownership criterion in the definition of a secondary activities farm.
- For example, some operations that might otherwise qualify as secondary activities farms own the primary production farm, rather than being owned by the primary production farm as currently required. Or they are not owned by (and do not own) the primary production farm but are majority owned by the same entity as the primary production farm.
- The extension is applicable only to an operation satisfying all of the following requirements: (1) the operation is not located on a primary production farm; (2) the operation is devoted to harvesting, packing, and/or holding of raw agricultural commodities; and (3) the operation is under common ownership with the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested packed, and/or held by the operation.
- FDA is considering future rulemaking to modify the definition of a farm in order to address ownership issues.
- The earliest compliance date is January 26, 2018.

Extending compliance dates for facilities coloring raw agricultural commodities

- Compliance dates for facilities that color raw agricultural commodities are being extended for 16 months to align with the Produce Safety rule. Currently coloring is considered a manufacturing/processing activity that requires food facility registration and is subject to the CGMP and Preventive Controls for Human Food rule.
- FDA is considering future rulemaking to modify the definition of a farm in order to address “coloring” activities.
- The earliest compliance date is January 26, 2018.

Extending compliance dates for cotton ginning facilities under animal food rule

- Off-farm facilities solely engaged in cotton ginning that provide products (for example, cotton seed and lint) without further processing for use as animal food now have an additional 16 months to comply with applicable requirements in the CGMP and Preventive Controls for Animal Food rule.
- The earliest compliance date is January 28, 2019.

Extending compliance dates for food contact substances under FSVP rule

- Importers subject to the FSVP rule have an additional two years to meet the requirements of this rule for the importation of food contact substances. (A food contact substance is any substance intended for use as a component of materials used in manufacturing, packing,

Compliance Dates for the Final Rule on Foreign Supplier Verification Programs (FSVP) (for reference only)

transporting, or holding food if the substance is not intended to have any technical effect on the food.)

- The agency will consider how best to address feasibility concerns for the application of FSVP to these substances. In doing so, the FDA noted the relatively rare occurrence of significant safety concerns associated with the manufacture of food contact substances and the agency's existing, extensive premarket approval and review processes for these substances provide some assurances regarding safety during this time.
- The earliest compliance date is May 28, 2019.

Extending CGMP compliance date for Grade "A" milk products

- This final rule extends the compliance date for National Conference on Interstate Milk Shipments (NCIMS) facilities producing Grade "A" milk and milk products to comply with CGMPs under the CGMP and Preventive Controls for Human Food rule.
- Originally, these facilities had different compliance dates for the CGMPs and the preventive control requirements.
- This change will create a single compliance date, September 17, 2018, for facilities producing Grade "A" milk products to comply with all requirements.

Clarifying agricultural water testing compliance timeframe

- The FDA is clarifying that farms subject to the Produce Safety rule have discretion in how they sample agricultural water to develop a microbial quality profile. They are allowed discretion as to both the number of samples they take in their initial survey, provided that the total is 20 or more samples. And they are allowed discretion as to the time period over which such samples are taken, provided that it is at least two years and no more than four years.
- The rule provides examples of approaches that farms may consider when collecting water samples and how they relate to compliance dates for the water-related requirements of the Produce Safety rule.

Blank Colored Insert-Front

Blank Colored Insert-Back

APPENDIX 3: Workaids

| Title of Document | Page |
|--|-------------|
| Workaid A: Determining the FSVP Importer | A3-3 |
| Workaid B: FSVP Requirements Based on What You Import and Size of Your Operations or Certain Foreign Supplier Operations | A3-5 |
| Workaid C: Summary of FSVP Requirements | A3-9 |
| Workaid D: FSVP Hazard Analysis Form Example | A3-13 |
| Workaid E: FSVP Foreign Supplier Evaluation Form Example | A3-15 |
| Workaid F: FSVP Foreign Supplier Performance/Food Product Approval Worksheet Example | A3-17 |
| Workaid G: FSVP Foreign Supplier Reevaluation Form Example | A3-19 |

Determining the FSVP Importer

Instructions: This workaid is intended to help a person/entity who receives/sells imported food to ensure that an appropriate FSVP importer has been designated by parties involved in the importation of the food AND that the U.S. Customs and Border Protection (CBP) filer enters that name, email address, and DUNs number as the FSVP importer.

| Imported Food(s)/Food Product(s) Information | Supplier Information | Determining FSVP Importer | Designated FSVP Importer* | CBP Entry Filer |
|---|--|---|--|---|
| What food(s)/food product(s) do you import (receive)? [Note: List each food/food product. Be specific, e.g., can sizes; size packages; bulk weight] | From whom do you purchase the food (i.e., supplier's name, address, etc.)? | Describe the current buying arrangement (s) (i.e., name all parties involved in obtaining the food fit the FSVP definition of foreign supplier (i.e., grower, manufacturer)?) | At time of entry, do you own the food, or have you purchased or agreed to purchase the food (i.e., do you fit the definition of "U.S. owner or consignee" or consignee" and therefore, FSVP supplier, if known) "Importer" for this food)?** | If more than one person/entity fits the definition of importer, negotiate with others to determine who will carry out FSVP requirements. [Note: Place name below and formalize the understanding (i.e., create an agreement identifying FSVP importer/distributor?] |
| | | | | |
| | | | | |
| | | | | |

*The person identified as the FSVP "importer" in the CBP entry filing is the person FDA will see as responsible for complying with the FSVP rule.

**You would also meet the definition of FSVP importer if there is no U.S. owner or consignee at time of entry and you are the U.S. agent or representative of the foreign owner or consignee.

FSVP Requirements Based on What You Import, If You Are a Very Small Importer (VSI), or If You Import from Certain Foreign Suppliers

Foods Not Subject to FSVP:

- A. **Seafood** (fish and fishery products and products subject to and in compliance with the Seafood HACCP regulation, as verified under the importer provisions of the Seafood HACCP rule; raw materials and ingredients that you use for manufacturing or processing of fish and fishery products provided you are in compliance with requirements in the Seafood HACCP regulation)
- B. **Juices** (juices subject to and in compliance with Juice HACCP regulation, as verified under the importer provisions of the Juice HACCP rule; raw materials and ingredients that you use for manufacturing or processing of juice provided you are in compliance with requirements in the Juice HACCP regulation)
- C. **Alcoholic beverages and ingredients imported for manufacture of alcoholic beverages, also prepackaged food from such a facility, if constitutes no more than 5% of the facility's sales.** Alcoholic beverages must come from facilities required to register under Sec. 415; facilities must be of the type that, if they were in the U.S., would be required to obtain permit from, register with, or obtain approval of a notice or application from U.S. Treasury rules. Exemption also applies to food that is not an alcoholic beverage that is imported from such foreign suppliers, provided that food is in prepackaged form and only constitutes 5 percent or less of overall sales of the facility. In addition, exemption applies for imported raw materials and other ingredients you use in manufacturing/processing, packing, or holding alcoholic beverages in certain circumstances.
- D. **Food for Personal Consumption, Research, or Evaluation** (food should be imported in small quantities consistent with such uses and must not be sold or distributed to the public; if the food is for research or evaluation, it must also be labeled as such and have electronic declaration that the food will be used for research or evaluation)
- E. **Products Not Intended for Sale in U.S., i.e., transshipped or foods imported for processing for export**
- F. **U.S. Food Returned (i.e., food manufactured/processed, raised, or grown in U.S., exported, and returned without further manufacturing/processing)**
- G. **Meat, Poultry, and Egg Products regulated by USDA's Food Safety and Inspection Service at time of entry** (subject to USDA regulations).

Importers Subject to FSVP Modified Requirements:

- A. **Very Small Importer (VSI)** (importer must qualify (human food <\$1M/year for 3-year average; animal food <\$2.5M/year for 3-year average) for VSI status on annual basis and before initially importing; obtain from each foreign supplier biennial written assurance that product complies with U.S. food safety requirements)
- B. **Importer importing from certain small foreign suppliers** (foreign supplier must qualify for one of 3 categories (<3000 laying hens, "qualified facility" **or** not a "covered farm" under 21 CFR 112.4(a) or 112.4(b) and 112.5); confirm eligibility on an annual basis; biennially obtain written assurance that supplier is complying with U.S. food safety requirements (or, for non-

covered farms or small shell egg producers, acknowledgement that food must not be adulterated); also must evaluate, approve, and periodically reevaluate suppliers, and have procedures to ensure use of approved suppliers)

- C. **Importers of food from country officially recognized as having a food safety system that is comparable or equivalent to that of the U.S.** (importer must assure that the supplier is under the regulatory oversight of the food safety authority with whom FDA has the agreement, that the specific food imported falls under the scope of that agreement, and that the foreign supplier is in good compliance standing with the foreign food safety authority).

Additional Food Categories with Non-Standard Requirements:

- A. **Produce that is “covered produce” under the Produce Safety regulation** (FSVP applies, but hazard analysis (HA) not required for biological hazards; for other hazards, HA required; all other FSVP requirements apply; importer must verify that biological hazards are controlled by verifying that the supplier is using processes and procedures providing the same level of public health protection as required with Produce Safety rule)
- B. **Produce that is not “covered produce” under the Produce Safety regulation** (exempt from Produce Safety rule, but not exempt from FSVP; standard HA required)
- C. **Low-Acid Canned Foods and Ingredients Intended for LACFs** (for finished products: importer must verify that foreign supplier complies with LACF regulation (Part 113); for all hazards not controlled by Part 113, standard FSVP requirements apply; for ingredients, an importer who is an LACF facility and complies with Part 113 does not need FSVP for microbiological hazards controlled by Part 113, but for all other hazards FSVP required; importers of LACF ingredients who are not the manufacturer/processor of the LACF must comply with all FSVP requirements.)
- D. **Food ingredients going to U.S. manufacturing/processing facility subject to Preventive Controls regulations:** If importer implements preventive controls for the hazards in foods in compliance with applicable PC requirement (i.e., either § 117.135 or §507.34), then FDA deems importer in compliance with FSVP, but manufacturer/processor must be identified as FSVP importer at entry under § 1.509. Importer also deemed in compliance with most of FSVP if it: (1) is not required to implement a preventive control because its customer or a subsequent entity is controlling the hazard under § 117.136 or § 507.36; or (2) it has established a supply-chain program for the food under subpart G of part 117 or subpart E of part 507.
- E. **Food products not intended for further processing** (all “standard” FSVP requirements apply) (provided the importer is not a very small importer and is not obtaining food from certain small foreign suppliers)
- F. **Dietary Supplements** (specific requirements for dietary supplements keyed to DS CGMP rule; requirements depend on whether: (1) importer required to establish certain specifications for foods that are dietary supplements or dietary supplement components; (2) importer’s customer required to establish certain specifications; or (3) if the imported food is a dietary supplement, and the previous two scenarios do not apply. For finished products, importer will generally be required to establish FSVP program that ensures foreign supplier uses processes and procedures that provide the same level of public health protection as DS CGMPs)
- G. **Meat, Poultry, and Egg Products not covered by USDA Meat, Poultry, and Egg Products Inspection Acts at time of entry, such as game meats** (FSVP required)

- H. **Food with no hazards requiring a control** (not required to conduct verification activities or evaluation for foreign supplier approval; all other FSVP requirements apply)

Delayed Implementation:

- A. **Food Contact Substances**
- B. **Written assurances that your customer or a subsequent entity is controlling hazards downstream (although you still must disclose that the food has not been processed to control the hazard)**

Summary of FSVP Requirements

General:

1. **Qualified Individual:** All FSVP requirements must be carried out by a **qualified individual (QI)**, i.e., someone with the education, training, or experience (or combination thereof) to perform the particular task. The QI may be an employee of the importer or not. More than one QI may be involved in performing the FSVP activities. If the importer is depending on a third party's hazard evaluation, verification or other steps in FSVP activities (other than supplier approval, which must be performed directly by the importer), the importer must ensure that the third party used a QI to carry out that activity and the importer's QI must review and assess that information and find it acceptable. Also, note, for example, that the importer's QI who reviews a hazard analysis (HA) may have different experience, education, or training than a QI who conducts the HA. A QI must be able to read and understand the language of any records the person reviews to perform an activity.
2. **Records:** For each FSVP requirement that an importer is required to do, documentation is necessary to demonstrate that activity was carried out. The importer is required to keep adequate records for at least two years after an activity is completed or the record is no longer used. Even when the importer is relying on a third party's HA, foreign supplier evaluation, verification determination, or another activity, the importer must document its review and assessment of the other party's information. Records should be made promptly available to FDA for inspection and copying upon request. Records may be kept offsite as long as the importer can make them available to FDA within 24 hours. FDA may also ask an importer to send records to the Agency electronically or through other prompt means. FDA may require that records not in English be translated.
3. **Identification of FSVP Importer:** Unless a food is explicitly exempt from FSVP, the FSVP importer who is responsible for carrying out FSVP requirements for the line entry of food must be identified electronically on U.S. Customs entry forms or the filing will be rejected by CBP and FDA will never review the entry for admission into U.S. commerce.

Specific FSVP Steps (dependent on type of food imported, importer size, certain foreign supplier types/sizes, and comparability/equivalence standing of originating country):

1. Hazard Analysis:

Your hazard analysis must identify and evaluate the known or reasonably foreseeable hazards in each food you import to determine if there are any hazards requiring a control.

- a. **Hazard identification:** What are the biological, chemical (including radiological), and physical hazards that are known or reasonably foreseeable in the food being imported? The hazard may occur naturally, be unintentionally introduced, or intentionally introduced for purposes of economic gain. Potential sources of information on hazards include, but are not limited to, FDA Reportable Food Registry, Bad Bug Book, EPA pesticide approvals, information on major allergens associated with manufacturing/processing facility, FDA guidance documents for Preventive Control rules.

- b. **Hazard evaluation:** How likely is the hazard to occur and how serious are the potential health consequences; requires knowledge of food, producer/manufacturer, and hazard itself. Factors to be evaluated include:
 - i. food formulation;
 - ii. condition, function, and design of the establishment and equipment of a typical entity that manufacture/processes, grows, harvests, or raises this type of food;
 - iii. raw materials and other ingredients;
 - iv. transportation practices;
 - v. harvesting, raising, manufacturing, processing, and packing procedures;
 - vi. packaging and labeling activities;
 - vii. storage and distribution;
 - viii. intended or reasonably foreseeable use;
 - ix. sanitation, including employee hygiene; and
 - x. any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of natural toxins).
 - c. **Results of Hazard Analysis:** If an importer's evaluation determines that there are no known or reasonably foreseeable hazards requiring a control, then the importer does not have to conduct an evaluation for foreign supplier approval and verification (Sec. 1.505), nor verification activities (Sec. 1.506).
 - d. **Note:** Raw fruits and vegetables that are "covered produce" in the Produce Safety rule do not require a hazard analysis for biological hazards, but do for other hazards.
2. **Evaluation for foreign supplier approval and verification:** When approving foreign suppliers and choosing a verification activity, the importer must consider several factors, including the hazard analysis, the entity or entities that will be controlling the hazards, and the foreign supplier's performance. In order to evaluate the foreign supplier's performance, the importer must evaluate 1) the foreign supplier's procedures, processes, and practices related to food safety; 2) FDA food safety regulations applicable to the foreign supplier and the foreign supplier's compliance with those regulations; 3) the foreign supplier's food safety history (e.g., testing results, audit results), and any other factors relevant to evaluating the foreign supplier's food safety performance, e.g., storage and transportation practices. If food safety problems are found in conducting this evaluation, those issues should be corrected prior to approving the foreign supplier or the foreign supplier should not be approved. Potential sources of information about your supplier's compliance with FDA food safety requirements include, but are not limited to, FDA warning letters, import alerts, import refusals, and inspection classifications available on FDA website.
 3. **Foreign Supplier Approval:** FSVP importers must approve their foreign suppliers. Approval must be based on the results of the importer's evaluation of foreign supplier performance and the risk posed by the food. Thus, the approval must take into account the hazard analysis of the food (including the nature of the hazard(s) requiring a control), who will be controlling this hazard(s), and the foreign supplier's performance (including all activities in #2 above). Generally, an importer must determine that hazards requiring controls are being significantly minimized or prevented and that the foreign supplier is utilizing processes and procedures that provide the same level of public health protection as required in the U.S.
 4. **Verification Activities:** In approving your foreign supplier, you have already verified that the foreign supplier is producing food that adequately controls hazards needing controls and

should meet U.S. food safety requirements. Verification activities are intended to ensure that your foreign supplier maintains this level of food safety assurance.

- a. **Only use “approved” foreign suppliers:** Importers must have written procedures to ensure they only use approved foreign suppliers. If circumstances require use of an unapproved foreign supplier on temporary basis, importer must still subject that foreign supplier’s food to adequate verification **before** importing. While the importer must approve the supplier itself, it may rely on other entities to establish and follow procedures to ensure that the imported food only comes from the approved suppliers.
 - b. **Determination of appropriate verification activities:** For each hazard requiring a control, appropriate verification activities and their frequency must be determined, i.e., what must your foreign supplier do to demonstrate that he/she is **continuing** to control the hazard requiring a control and meet U.S. adulteration and allergen labeling requirements? Verification activities must be appropriate to the hazard and the entity controlling the hazard to ensure that it can be done properly. If there is a serious (SAHCODHA) hazard, the default verification method is an annual onsite audit, which initially should be done **before** importing the food. Verification activities explicitly mentioned in the rule are 1) audits, 2) sampling/testing, 3) review of records, and 4) other appropriate activities.
 - c. **Performance of verification activities** provides assurance that hazards requiring controls are significantly minimized or prevented.
 - d. **Review/evaluate results of verification activities**, including those performed by others.
5. **Corrective Actions:** If there is an indication from verification activities or other information that foreign supplier is no longer employing processes and procedures to ensure that food is meeting U.S. level of public health protection, corrective actions must be taken. Actions taken should be appropriate to circumstances to correct the problem, and may include discontinuing use of foreign supplier.
 6. **Reevaluation of FSVP:** Required when importer becomes aware of a food safety issue or change causing concern occurs, but at least every 3 years. Reevaluation results should be reviewed promptly to determine if FSVP is adequate and if any corrective actions should be taken.

Important Notations:

- a. **Comparability or Equivalence:** If food originates from a country that FDA has officially recognized as having a food safety system that is comparable or equivalent to that of the U.S., to import the food under certain modified FSVP requirements, the importer must ensure that the supplier is under the regulatory oversight of the food safety authority with whom FDA has the agreement, that the specific food imported falls under the scope of that agreement, and that the foreign supplier is in good compliance standing with the foreign food safety authority.
- b. **Evaluation for foreign supplier approval and verifications are NOT required** if: 1) a food cannot be consumed without the application of adequate hazard controls (e.g., coffee beans); 2) you rely on customer to control hazard (importer must provide disclosure to customer that the food was “not processed to control [hazard]” and must receive from customer an annual assurance in writing that customer is preparing food in accord with U.S. food safety

Appendix 3

requirements); or 3) customer's customer or another entity further down the line is controlling hazard (disclosures and assurances required for each level). Written assurances must have dates and the names/signatures of person responsible. Note that the **compliance date for the written assurance requirement was extended 2 years.**

| | | | | | |
|---|--|---|---------------|--|---|
| IMPORTER NAME | | DATE | | | |
| ADDRESS | | QI APPROVAL | | | |
| FSVP Food Hazard Analysis (HA) Form Example* | | | | | |
| (1) Food/Food Product | (2) Identify known and/or reasonably foreseeable food safety hazards B=Biological C=Chemical P=Physical | (3) Do any food safety hazards require a control? | | (5) Justify your decision for column 3 | (6) Describe the nature of the control(s) |
| | | Yes | No | | |
| | B | | | | |
| | C | | | | |
| | P | | | | |
| | B | | | | |
| | C | | | | |
| | P | | | | |
| <p>HA Performed by Another Entity (if yes, describe your assessment of HA and include Entity's name, address, email, and date of HA)?**</p> <p>*All supporting documentation should be appended to this form</p> <p>**If another entity performs the HA, you may meet the requirement to determine whether there are any hazards requiring a control in the food by reviewing/assessing the HA performed by that entity. Your review/assessment of the HA must include documentation that the HA was conducted by a QI.</p> | | | | | |
| IMPORTER APPROVAL | | | APPROVAL DATE | | |

| IMPORTER NAME | DATE | | | |
|---|---|---------|-----------------|--|
| ADDRESS | QI APPROVAL | | | |
| FSVP Foreign Supplier Evaluation Form Example * | | | | |
| Foreign Supplier Name | Foreign Supplier Address (location) | | | |
| Food Product(s) Imported | Food Product(s) Description(s), including Important Food Safety Characteristics | | | |
| Evaluation Considerations and Results | | | | |
| Supplier's Procedures, Practices, and Processes (1.505(a)(1)(iii)(A)) | Import Alerts | Recalls | Warning Letters | Other Significant Compliance Action(s) ((1.505)(a)(1)(iii)(B)) |
| | | | | Supplier's Corrective Actions |
| | | | | Information related to the Safety of the food** |
| | | | | Rejection Date (if applicable) |
| | | | | Approval Date (if applicable) |
| Assessment of Results of Foreign Supplier Evaluation *** | | | | |
| [Note: if the evaluation was performed by another entity (other than the foreign supplier) include Entity's name, address, email, and date of evaluation.] | | | | |
| <p>*All supporting documentation should be appended to this form.</p> <p>**Includes previous and recent experience with the supplier (e.g., rejected shipments, lab results, audit results, or other food safety information you may have outside of the government oversight context).</p> <p>***If another entity (other than the foreign supplier) performs the foreign supplier evaluation, you may meet your evaluation requirements by having your QI review and assess the entity's evaluation. Your review/assessment of the evaluation must include documentation that the evaluation was conducted by a QI.</p> | | | | |
| IMPORTER APPROVAL | | | | APPROVAL DATE |

| IMPORTER NAME | VERIFICATION DATE | SUPPLIER EVALUATION DATE |
|---|--|---|
| ADDRESS | QI APPROVAL | APPROVAL DATE |
| FSVP Foreign Supplier Verification Activity(ies) Worksheet Example* | | |
| Foreign Supplier Name | Foreign Supplier Address (location) | |
| Food Product Imported | Food Product Description(s), including Important Food Safety Characteristics | |
| Process Description (Ingredients/Packaging Materials) | | |
| Food Safety Hazard(s) Controlled by Foreign Supplier** | Description of Foreign Supplier Control(s) | Verification Activity(ies) and Frequency*** |
| | | Justification for Verification Activity(ies) and Frequency† |
| Assessment of Results of Verification Activity(ies)†† | | |
| Corrective Action(s), if needed | | Reevaluation Date |
| *All supporting documentation should be appended to this form. | | |
| **If someone other than the foreign supplier controls the hazard(s), document who is controlling the hazards and note if written assurances are required. | | |
| ***When a Serious Adverse Health Consequences Or Death to Humans or Animals (SAHCODHA) hazard in a food will be controlled by the foreign supplier, the default verification procedure is the performance of a properly conducted onsite audit of the foreign supplier before initially importing the food and at least annually thereafter (21 CFR 1.506(d)(2)). | | |
| †You may rely on another entity's (other than the foreign supplier) determination of appropriate verification activities if you review and assess their determination, including documenting that the determination was made by a QI. | | |
| ††You may rely on verification activities conducted by another entity (other than the foreign supplier—except for sampling and testing) if you review and assess the results of those activities. | | |
| IMPORTER APPROVAL | | APPROVAL DATE |

| | | |
|---|--|--|
| IMPORTER NAME | REEVALUATION DATE | REAPPROVAL DATE (IF APPLICABLE) |
| ADDRESS | QI APPROVAL | DISCONTINUED USE DATE (IF APPLICABLE) |
| FSVP Foreign Supplier Reevaluation Form Example* | | |
| Foreign Supplier Name | Foreign Supplier Address (location) | |
| Food Product(s) Imported | Imported Food Product(s) Description, including Important Food Safety Characteristics | |
| Type of Reevaluation** (i.e., regularly scheduled, "for cause") | If "For Cause," Describe*** | |
| Reevaluation Considerations and Results | | |
| Changes to the Supplier's Procedures, Practices, and Processes (1.505(a)(1)(iii)(A)) | New Import Alerts | New Recalls |
| | | New Warning Letters |
| | | |
| Changes to Food Safety Hazard(s) Controlled by Foreign Supplier††† | Changes to Description of Foreign Supplier Control(s)††† | |
| Current Verification Activity(ies) and Frequency††† | Changes to Verification Activity(ies) and Frequency††† | Justification for Changed Verification Activity(ies) and Frequency††† |
| | | New Verification Records (i.e., audit summaries, test results)* |
| | | |

| FSVP Foreign Supplier Reevaluation Form Example* (continued) | |
|---|---|
| Assessment of Results of Foreign Supplier Reevaluation† <i>[Note: If the reevaluation was performed by another entity (other than the foreign supplier) include entity's name, address, email, and date of reevaluation.]</i> | Corrective Action(s) Taken as a Result of the Reevaluation‡‡ |
| | <p>*All supporting documentation should be appended to this form.</p> <p>**Foreign supplier performance and food risk must be evaluated at least every 3 years or "for cause."</p> <p>***"For cause" may include any changes in the supplier's procedures, processes, and practices related to the safety of the food; new information about the supplier's compliance with food safety standards (e.g., import alerts, recalls, FDA warning letters); responsiveness of the foreign supplier in correcting food safety problems; new information on food testing results; new audit results relating to the safety of the food; or other food safety considerations.</p> <p>+Includes previous and recent experience with the supplier (e.g., rejected shipments, lab results, audit summaries, or other food safety information you may have outside of the government oversight context).</p> <p>+If someone other than the foreign supplier controls the hazard(s), document who is controlling the hazards and note if written assurances are required.</p> <p>++When a Serious Adverse Health Consequences Or Death to Humans or Animals (SAHCODHA) hazard in a food will be controlled by the foreign supplier, the default verification procedure is the performance of a properly conducted onsite audit of the foreign supplier before initially importing the food and at least annually thereafter (21 CFR 1.506(d)(2)).</p> <p>#If another entity (other than the foreign supplier) performs the foreign supplier reevaluation, you may meet your reevaluation requirements by having your QI review and assess the entity's reevaluation. Your review/assessment of the reevaluation must include documentation that the reevaluation was conducted by a QI.</p> <p>##You must document all reevaluations and corrective actions taken, if any are necessary.</p> |
| IMPORTER APPROVAL | APPROVAL DATE |

Blank Colored Insert-Front

Blank Colored Insert-Back

APPENDIX 4: FSVP Requirements for Dietary Supplements: A Different Verification Focus

| Title of Document | Page |
|---|------|
| Appendix 4: FSVP Requirements for Dietary Supplements: A Different Verification Focus | A4-3 |

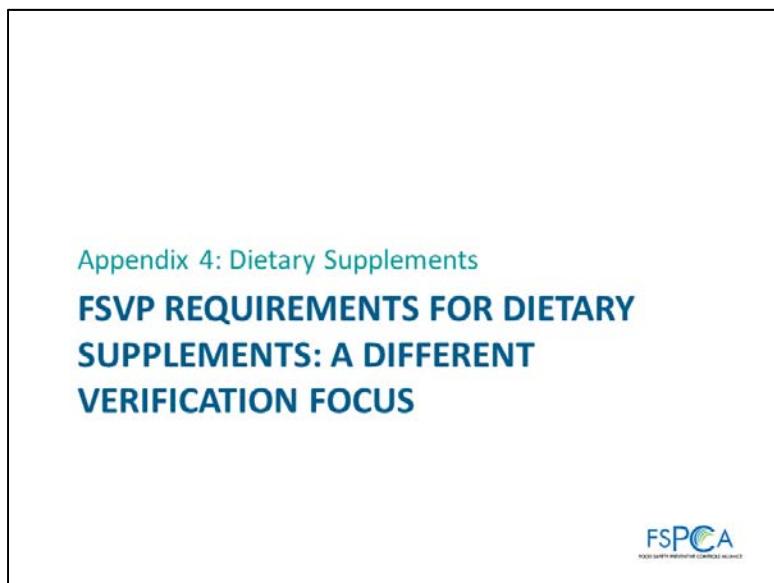
Goal: Participants will be able to evaluate their foreign suppliers, which must comply with the Dietary Supplement Current Good Manufacturing Practice (DS CGMP) requirements.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Define “dietary supplement.”
 2. Explain the importance of the CGMP for dietary supplements.
 3. Describe FSVP responsibilities whether you import dietary supplement components or finished dietary supplements.
 4. Describe how FSVP requirements for dietary supplements and dietary supplement components differ from other foods.

APPENDIX 4. FSVP

Requirements for Dietary Supplements: A Different Verification Focus



This Appendix focuses on FSVP as it relates to dietary supplements and dietary supplement components. In particular, it explains that compliance with the Dietary Supplement Current Good Manufacturing Practice (DS CGMP) requirements is what importers must be verifying when importing dietary supplements.

Appendix 4: Goal and Objectives

Appendix 4: Goal and Objectives

Goal: Participants will be able to evaluate their foreign suppliers, which must comply with the Dietary Supplement Current Good Manufacturing Practice (DS CGMP) requirements.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Define “dietary supplement.”
 2. Explain the importance of the CGMP for dietary supplements.
 3. Describe FSVP responsibilities whether you import dietary supplement components or finished dietary supplements.
 4. Describe how FSVP requirements for dietary supplements and dietary supplement components differ from other foods.



By the end of this chapter, you will be able to evaluate your foreign suppliers, which must comply with the DS CGMP requirements. More specifically, you will be able to:

1. Define “dietary supplement.”
2. Explain the importance of the CGMP for dietary supplements.
3. Describe FSVP responsibilities whether you import DS components or finished dietary supplements.
4. Describe how FSVP requirements for dietary supplements and dietary supplement components differ from other foods.

What Is a Dietary Supplement?

What Is a Dietary Supplement?

- The term “dietary supplement” is defined in the FD&C Act as a food intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
 - A vitamin
 - A mineral
 - An herb or other botanical
 - An amino acid
 - A dietary substance for use by man to supplement the diet by increasing the total dietary intake, or
 - A concentrate, metabolite, constituent, extract, or combination of the above.



Different countries regulate dietary supplements in different ways. Some regulate dietary supplements as drugs, but the U.S. regulates dietary supplements as foods. In the U.S. dietary supplements are only for human use and not animal use.

The FSVP rule definition of “dietary supplement” cross-references the statutory definition of “dietary supplement” that is found in section 201(ff) of the FD&C Act. The FSVP definitions (21 CFR 1.500) also define “dietary supplement component” as any substance intended for use in the manufacture of a dietary supplement, including “dietary ingredients” as described in section 201(ff) of the FD&C Act and other ingredients.

The statutory definition of “dietary supplement” provides that a dietary supplement is a food intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

- (A) a vitamin;
- (B) a mineral;
- (C) an herb or other botanical;
- (D) an amino acid;
- (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clauses (A) through (E).

What Is a Dietary Supplement? (continued)

What Is A Dietary Supplement? (continued)

- Dietary supplements:
 - Are intended for ingestion,
 - Are not represented for use as a conventional food or as a sole item of a meal, and
 - Must be labeled as dietary supplements.



Dietary supplements are intended for ingestion, are not represented for use as a conventional food or as a sole item of a meal, and must be labeled as dietary supplements.

It is also worth noting that:

- Dietary supplements don't need to be approved before being marketed, and
- Dietary supplements are subject to CGMP requirements that are similar, but not the same as, the CGMP that applies to conventional foods.
- Dietary supplements are exempt from the Preventive Controls (PC) for human food rule.

Manufacturers of Dietary Supplements and Their Components Are Subject to CGMP Requirements

Manufacturers of Dietary Supplements and Their Components Are Subject to CGMP Requirements

- Facilities that manufacture dietary supplements and dietary supplement components must be in compliance with the **Current Good Manufacturing Practice In Manufacturing, Packaging, Labeling, or Holding Operations For Dietary Supplements (DS CGMP)** in 21 CFR Part 111 and adverse event reporting.
 - Exempt from FSMA Preventive Controls requirements.
- The DS CGMP regulation contains "specification" requirements that **contain supplier verification provisions**, requiring:
 - Properly identified ingredients;
 - Ingredients of appropriate purity, strength, and composition; and
 - No contamination of ingredients that adulterate or could lead to adulteration.



In publishing the DS CGMP in 2007, FDA stated that **"consumers should have access to dietary supplements that meet quality standards and that are free from contamination and are accurately labeled."**

The CGMP applies to all domestic and foreign companies that manufacture, package, label, or hold dietary supplements, including those involved with the activities of testing, quality control, packaging, and labeling, and distributing them in the U.S. Because the CGMP address the hazards applicable to dietary supplements, these products are exempt from the PC rule.

The CGMP contains "specification" requirements that address supplier controls. Under these requirements, the dietary supplement manufacturer must ensure that all ingredients are properly identified; of appropriate purity, strength, and composition; and are not contaminated in a way that can adulterate the dietary supplement.

Importers of Dietary Supplements and Their Components Are Subject to Modified FSVP Requirements

Importers of Dietary Supplements and Their Components Are Subject to Modified FSVP Requirements

- FDA tied the FSVP requirements for importers of dietary supplements to the DS CGMP.
- Importers of dietary supplements and dietary supplement components that will undergo further processing (by importer or other customer) are subject to limited FSVP requirements because the "specification" requirements already contain supplier verification provisions.
- Importers of finished dietary supplements must follow FSVP requirements that are similar to the requirements for importers of other foods, except:
 - The importer must verify their suppliers' compliance with DS CGMP, and
 - No hazard analysis is required.



By way of background, FDA wanted to assure that the FSVP requirements for dietary supplements and their components reflected the manner in which such products are regulated. **Thus, the focus continues to be on the manufacturers' compliance with the Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements (DS CGMP) regulation (21 CFR Part 111), rather than on verifying hazards you identify, as with the standard FSVP provisions.** So, the basic task of FSVP importers is to verify that foreign suppliers are complying with the DS CGMP requirements. It is assumed that compliance with those regulations will ensure the safety of dietary supplements.

Therefore, while dietary supplements **are** subject to FSVP requirements, they are modified requirements. For example, because dietary supplements and dietary supplement components that require further processing after importation will be subject to the supplier verification provision in the CGMP regulations, there would be little added benefit to requiring a redundant supplier verification under FSVP.

FDA developed "modified" FSVP requirements that are tailored for dietary supplements. These modified requirements focus on manufacturers' compliance with the dietary supplement CGMP regulation, rather than on verification of hazard control (which is the focus of the "standard" FSVP requirements). In addition, there are FSVP requirements for two types of importers of dietary supplements:

- Importers who must (or whose customers must) establish certain specifications under the CGMP (e.g., for components or packaging) and ensure that the specifications are met (thereby performing a kind of “verification” of a dietary supplement or dietary supplement component). The only FSVP requirements for these importers are to use a qualified individual and ensure that the importer is identified as the importer at entry (and, if the importer’s customer is establishing and verifying conformance to a specification, obtain written assurance from the customer); and
- Importers of all other dietary supplements (e.g., “finished” dietary supplements), who are not required to conduct a hazard analysis and whose verification activities must provide assurances of the manufacturer’s compliance with dietary supplement CGMP.

Scenario 1: Dietary Supplement Manufacturer/Processor Importing Dietary Supplement Components

Scenario 1: Dietary Supplement Manufacturer/Processor Importing Dietary Supplement Components

- **If you are:**
 - An importer of dietary supplement components, and
 - A dietary supplements manufacturer or processor (**Note:** packaging and labeling is considered processing), and
 - You are complying with the DS CGMP (including the requirements relating to specifications) in 21 CFR 111.70(b) or (d),
- **Then you have met** your main FSVP obligations and only minimal documentation is required.



The DS CGMP requires that DS manufacturers establish specifications (21 CFR 111.70(b)) for each component used in the manufacture of a dietary supplement, including:

- Identification of each DS component (e.g., at least one test/examination to definitively identify the material)
- Other specifications for the DS component, sufficient to ensure the purity, strength, and composition of the final dietary supplement, and

- Limits on contamination that could adulterate the final dietary supplement..

Under 21 CFR 111.70(d), DS manufacturers are also required to establish specifications for labels and packaging that come in contact with the dietary supplement (or dietary supplement component) and could affect the safety of the finished dietary supplement.

The DS CGMP additionally requires (21 CFR 111.73 and 111.75) that the DS manufacturers determine that these requirements are met.

Therefore, if an importer of dietary supplement components is a dietary supplement manufacturer/processor (note that packaging and labeling is considered processing), and is complying with the DS CGMP (including these requirements relating to specifications) in 21 CFR 111.70(b) or (d), then that importer has met its main FSVP obligations.

Scenario 1: Dietary Supplement Manufacturer/Processor Importing Dietary Supplement Components (continued)

- **You must still, however:**

- Be identified as the FSVP importer on the U.S. Customs and Border Protection (CBP) entry filings,
- Use a qualified individual, and
- Maintain records.



This importer must still, however, be identified as the FSVP importer on the U.S. Customs and Border Protection (CBP) entry filings, use a qualified individual, and maintain records under FSVP.

Scenario 1: Dietary Supplement Manufacturer/Processor Importing Dietary Supplement Components (continued)

Other considerations:

- You are **not required** to comply with the other FSVP requirements.
- Your **finished dietary supplement components must** comply with all requirements in the DS CGMP rule and other FDA requirements.



To be clear, in this scenario you are not required to comply with the other FSVP requirements such as the hazard analysis, evaluation of foreign suppliers and verification activities. Your finished dietary supplements must, of course, comply with all requirements in the DS CGMP rule and other FDA requirements such as the nutrition labeling requirements for dietary supplements.

Scenario 2: What If My Customer Is the One Who Must Establish Specifications?

Scenario 2: What If My Customer Is the One Who Must Establish Specifications?

- If your customer is required to establish specifications for dietary supplement components under the DS CGMP and determine that specifications are met, you must:
 - Annually obtain from your customer written assurance that it is in compliance with those requirements,
 - Comply with the FSVP requirements for using qualified individuals,
 - Identify the importer at entry, and
 - Comply with the records requirements.
- But, you are not required to comply with the other FSVP requirements.



If your customer is required to establish specifications for dietary supplement components, and your customer is in compliance with the requirements applicable to determining whether specifications are met, you must:

- Annually obtain from your customer written assurance that it is in compliance with those requirements,
- Comply with the FSVP requirements for using qualified individuals and qualified auditors,
- Identify the importer at entry, and
- Comply with the records requirements of 21 CFR 1.510.
- But, you are not required to comply with the other FSVP requirements (21 CFR 1.511(b)).

Scenario 3: FSVP Requirements for Finished Dietary Supplements

Scenario 3: FSVP Requirements for Finished Dietary Supplements

- If you import a dietary supplement into the U.S., and
- Neither you nor your customer is required to establish specifications under 21 CFR 111.70(b) or (d):
- You do not need to conduct a hazard analysis, **but**
- You must comply with other standard FSVP requirements, **including:**
 - Using a qualified individual to develop your FSVP
 - Evaluating foreign supplier performance
 - Approving foreign suppliers
 - Determining and conducting appropriate supplier verification activities
 - Maintaining records



Importers of finished dietary supplements generally do not need to set specifications for dietary components nor packaging under (21 CFR 111.70(b) or (d)). If you are such an importer, you do not need to conduct a hazard analysis. You must, however, follow the FSVP requirements in 21 CFR 1.503, parts of 21 CFR 1.505, and 1.508 through 1.510, including:

- Using a qualified individual to develop your FSVP
- Evaluating foreign supplier performance
- Approving your foreign supplier
- Determining and conducting appropriate supplier verification activities
- Documenting and maintaining records
- Taking corrective actions
- Identifying the importer at entry.

Can Others Conduct Supplier Verification Activities?

Can Others Conduct Supplier Verification Activities?

- You may rely on supplier verification activities conducted by another competent entity:
 - If you review and assess the results of those activities
- You must document your review and assessment:
 - Including documenting that the activities were conducted by qualified individuals
- You may not, however, rely on the foreign supplier to perform supplier verification activities:
 - Except with respect to sampling and testing



As an importer of dietary supplements, you may rely on supplier verification activities conducted by another competent entity if you review and assess the results of those activities.

But, you must document your qualified individual's review and assessment of activities conducted by others, if you are relying on them.

Remember, however, that you may not rely on the foreign supplier to perform supplier verification activities, except with respect to the sampling and testing of dietary supplement components and the sampling and testing of the finished dietary supplement.

What Must I Verify?

What Must I Verify?

- Your foreign supplier verification activities for imported dietary supplements or dietary supplement components must:
 - Ensure that your foreign supplier is providing the same level of public health protection as required by the DS CGMP in 21 CFR Part 111
- Your choice of verification activities must be based on the evaluation of your supplier.



Your foreign supplier verification activities for imported dietary supplements or dietary supplement components must ensure that your foreign supplier is providing the same level of public health protection as required by the DS CGMP in 21 CFR Part 111. Your choice of verification activities must be based on your evaluation of the foreign supplier.

Appendix 4: Summary

Appendix 4: Summary

- What dietary supplements are and how they are affected by FSVP.
- If you import finished dietary supplements:
 - You must conduct most of the standard FSVP activities explained in other FSVP chapters, **and**
 - You must verify compliance with the DS CGMP requirements in 21 CFR Part 111, **but**
 - You are not required to conduct a hazard analysis.



You have learned:

- What dietary supplements are and how their importation is affected by FSVP.
- If you import finished dietary supplements or dietary supplement components, you are not required to conduct a hazard analysis and your foreign supplier verification activities are to determine compliance with is tied to the DS CGMP in 21 CFR Part 111.

Appendix 4: Summary (continued)

- If you are an importer that manufactures/processes dietary supplements, and:
 - You have established that your specifications for dietary supplement components/safe packaging and labeling have been met (21 CFR 111.70(b) or (d)),
 - You have met most of your FSVP requirements.
- If your customer is required to establish specifications for dietary supplement components under DS CGMP, and has established that specifications are met:
 - You must annually obtain from your customer written assurance that it is in compliance with those requirements.



- If you are an importer that manufactures/processes dietary supplements, and you have established that your specifications for dietary supplement components/safe packaging and labeling have been met (21 CFR 111.70(b) or (d)), you have met most of your FSVP requirements.
- If your customer is required to establish specifications for dietary supplement components under the DS CGMP and have established that specifications are met, you must annually obtain from your customer written assurance that it is in compliance with those requirements.

Appendix 4: Summary (continued)

- If you import finished dietary supplements or supplement components, you must
 - Be identified as the FSVP importer on the CBP entry filings,
 - Use qualified individuals to perform FSVP tasks, and
 - Maintain records in accordance with FSVP requirements.



- If you import finished dietary supplements or supplement components, you must
 - Use qualified individuals to perform FSVP tasks,
 - Maintain records in accordance with FSVP requirements, and
 - Be identified as the FSVP importer on the U.S. Customs and Border Protection (CBP) entry filings.

Appendix 4: Questions

Appendix 4: Questions

Thank you for Your Attention!

Questions?



Blank Colored Insert-Front

Blank Colored Insert-Back

APPENDIX 5: FSVP Modified Requirements

| Title of Document | Page |
|--|------|
| Appendix 5: FSVP Modified Requirements | A5-3 |

Goal: Participants will be able to demonstrate knowledge of FSVP modified requirements.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Describe the modified requirements.
 2. Identify if they are a “very small importer.”
 3. Identify if their supplier is a “certain small foreign supplier.”
 4. Describe requirements if they are not a “very small importer,” but are importing from a “certain small foreign supplier.”
 5. Describe requirements when importing from a recognized food safety system.

APPENDIX 5. FSVP Modified Requirements

Appendix 5: FSVP Modified Requirements

REVIEW OF THE MODIFIED REQUIREMENTS



As mentioned before, it's important to understand that FDA wrote the FSVP rule in a way to be sufficiently general and flexible to apply to a variety of circumstances without being unduly burdensome or restrictive of trade. It was FDA's intention to allow flexibility to reflect modern food supply and distribution chains.

Appendix 5 provides the details introduced in Chapter 3 regarding the "modified requirements" that are intended to be less burdensome on "very small importers." This discussion will also include the variations for importers who are not "very small importers," but who import from "certain small foreign suppliers."

It should be noted that while this course does not cover how FSVP applies to dietary supplements, the FSVP rule goes into some detail on how importers of dietary supplements should deal with their foreign suppliers, relative to dietary supplement ingredients, components, and finished product. More information on dietary supplements (or dietary supplement components) has been provided in Appendix 4.

Appendix 5: Goal and Objectives

Appendix 5: Goal and Objectives

Goal: Participants will be able to demonstrate knowledge of FSVP modified requirements.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Describe the modified requirements.
 2. Identify if they are a “very small importer.”
 3. Identify if their supplier is a “certain small foreign supplier.”
 4. Describe requirements if they are not a “very small importer,” but are importing from “certain small foreign suppliers.”
 5. Describe requirements when importing from a recognized food safety system.



Appendix 5 will describe the “modified” requirements in more detail for importers who have determined that modified requirements apply to them. This Appendix will identity:

1. What FDA means by a “very small importer” and “certain small foreign supplier,”
2. The requirements if they are not a “very small importer,” but are importing from “certain small foreign suppliers,” and
3. The requirements when importing from a recognized food safety system.

Modified Requirements

Modified Requirements

- Some importers and/or their foreign suppliers may meet criteria that allow for modified FSVP requirements.
- The importers and/or the foreign supplier must demonstrate/document that they meet the eligibility criteria
- Modified FSVP requirements apply:
 - If the importer is a “very small importer,”
 - If the imported food is from “certain small foreign suppliers,”
 - If the imported food is from foreign supplier(s) in countries with food safety systems recognized by FDA as “comparable” for certain foods under Systems Recognition, or
 - If the importer imports dietary supplements or dietary supplement components (see Appendix 4).

Up to this point we have focused on the standard requirements of the FSVP rule. There are instances, however, where an FSVP importer is able to follow modified requirements. Modified FSVP requirements apply if you are a “very small importer” and if you are importing foods from “certain small foreign suppliers” (21 CFR 1.512(a)).

Modified requirements also apply if the FSVP importer is importing food from foreign supplier(s) in countries with food safety systems recognized by FDA as “comparable” for certain foods under Systems Recognition. And finally, modified requirements apply if the FSVP importer is importing dietary supplements or dietary supplement components.

Importers or foreign suppliers must first meet the criteria to qualify for modified requirements and must continue to demonstrate their eligibility for these programs. Also, importers that do qualify can decide whether they wish to follow the standard requirements or the modified requirements.

We will cover the first three situations in more detail in the next few slides.

Key Point:

More details are provided within this appendix, but in general, Importers who are eligible for the modified requirement do not have to do the standard hazard analysis, evaluation of the supplier, or verification activities.

However, they still must have a modified FSVP program that includes:

- Documentation of eligibility;
- Use of a qualified individual for each activity;
- Identification of the FSVP importer at entry; and
- Obtaining written assurance, as described below in this appendix.

Resources:

For more information on the dietary supplement modified requirements, see Appendix 4 of this manual

“Very Small Importers” and “Certain Small Foreign Suppliers”

“Very Small Importers” and “Certain Small Foreign Suppliers”

- Modified FSVP requirements apply if you:
 - Are a “very small importer,” or
 - Are importing food from “certain small foreign suppliers”
- These categories are consistent with other FDA rules.



Modified FSVP requirements apply if you are a “very small importer.” Modified requirements also apply if you are importing foods from “certain small foreign suppliers” (21 CFR 1.512(a)).

Why did FDA set up these categories of “very small importers” and “certain small foreign suppliers”?

In the rules implementing the requirements of FSMA, FDA has tried, not only to be flexible, but also to be sensitive to the needs of small businesses. That is why the categories of very small importers and small foreign suppliers are analogous to the very small business categories in the FDA rules for Preventive Controls, for both human food and food for animals, and other FDA rules, and the modified requirements for supplier verifications in those rules. In addition to minimizing the burden on small businesses, FDA did not want to require importers to verify compliance with rules that the small supplier would not have to comply with because of its size. Moreover, FDA also concluded that modified FSVP requirements are appropriate for the importation of food from these small foreign suppliers because they provide a **relatively low volume of food imported into the United States, resulting in less consumer exposure and potential risk.**

FDA requires that you demonstrate your status as a “very small importer” or that you are importing from “certain small foreign suppliers.” Remember, “very small importers” do not have to conduct hazard analyses nor evaluations of the food and foreign supplier performance, but they still must comply with other FSVP provisions. **It is up to you as the FSVP importer to determine if you fall into**

these categories and wish to be subject to the modified requirements.

What Is a “Very Small Importer”?

What Is a “Very Small Importer”?

- You are a “very small importer” if, during the previous 3-year period, your **annual average in sales of food plus** the U.S. market value of food imported, processed, packed, or held without sale is:
 - Less than \$1 million U.S. (human food importers), or
 - Less than \$2.5 million U.S. (food for animals importers).
- These amounts are based on a 2011 U.S. dollar, and thus, subsequent years should be adjusted for inflation using 2011 as the base year.
- These figures include sales of any subsidiaries and affiliates.



The FSVP rule says that you are a “very small importer” if, during the previous 3-year period, you average less than \$1 million U.S. (for human food importers) or \$2.5 million U.S. (for animal food importers) **per year** in sales of food **combined with** the U.S. market value of food imported, processed, or held without sale (21 CFR 1.501).

FDA adjusted these calculations for inflation, with 2011 as the base year, and these figures include sales of any subsidiaries and affiliates of the importer. FDA has published charts to help with this: <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm554484.htm>

Do You Qualify as a “Very Small Importer”?

Do You Qualify as a “Very Small Importer”?

- You wish to qualify as a “very small importer” for 2017. You imported the following:
 - \$450,000 of asparagus in 2014 (\$427,576 U.S. in 2011 dollars)
 - \$1,100,000 boxed oat breakfast cereal in 2015 (\$1,043,946 U.S. in 2011 dollars)
 - \$8,000,000 canned pet food in 2015 (\$7,592,333 U.S. in 2011 dollars)
 - \$650,000 various French cheeses in 2016 (\$605,606 U.S. in 2011 dollars)
- **Do you qualify?**



You wish to qualify as a “very small importer” for 2017. You imported the following:

- \$450,000 of asparagus in 2014 (\$427,576 U.S. in 2011 dollars)
- \$1,100,000 boxed oat breakfast cereal in 2015 (\$1,043,946 U.S. in 2011 dollars)
- \$8,000,000 canned pet food in 2015 (\$7,592,333 U.S. in 2011 dollars)
- \$650,000 various French cheeses in 2016 (\$605,606 U.S. in 2011 dollars)

Do you qualify?

Instructions: Take a few minutes to do the arithmetic and then respond to the question when called upon by the instructor.

Documenting Your Status as a “Very Small Importer”

Documenting Your Status as a “Very Small Importer”

- You must document that you meet the definition of a “very small food importer”:
 - **Before** initially importing food as a “very small importer,” and
 - **Annually thereafter** by the end of each calendar year.
- The **relevant 3-year period of sales** is:
 - The period ending 1 year before the calendar year for which you intend to import food as a “very small importer.”
- If you plan to import food as a “very small importer” in March 2020, the relevant 3-year period is 2017 through 2019.



You must document that you meet the definition of a “very small food importer” **before** initially importing food as a “very small importer” and annually thereafter by the end of each calendar year. The relevant 3-year period of sales is the period ending one year before the calendar year for which you intend to import food as a “very small importer.”

So, if you intend to import food as a “very small importer” in March 2020, the relevant 3-year period is 2017 through 2019.

Modified Requirements for “Very Small Importers”

Modified Requirements for “Very Small Importers”

- If you are a “very small importer,” you must obtain from your foreign supplier:
 1. Written assurance that the food is being produced in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable, **and**
 2. Written assurance that the food is in compliance with FD&C Act adulteration provisions and for human food allergen labeling provisions.
- This should be done **before** importing the food and every 2 years thereafter.
- This must be done for every food you import.



As mentioned, qualifying as a very small food importer may be important to you because your FSVP compliance requirements are easier to meet in some regards, such as not having to perform a hazard analysis or evaluations. Nevertheless, you must qualify and you will still have verification requirements under FSVP, including that, you must obtain from your foreign supplier:

1. Written assurance that the food is being produced in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable, and
2. Written assurance that the food is in compliance with U.S. adulteration and allergen labeling provisions. Allergen labeling is NOT required animal food.

These assurances need to be obtained **before** importing the food and every 2 years thereafter, and they must be obtained for every food you import from the foreign supplier. We will say more about this later.

Modified Requirements for “Very Small Importers” (continued)

- Additionally, you must:
 - Identify the FSVP importer for each line entry of food product presented for entry into the U.S. (more details provided in Chapter 8)
 - Use a qualified individual for each activity
 - Promptly take corrective actions, if you determine that a foreign supplier of food you import does not produce the food consistent with the written assurances (more details are provided later in this chapter and in Chapter 7)
 - Maintain records and documentation that demonstrate your compliance with applicable FSVP requirements (more details are provided later in this chapter and in Chapter 9)



Along with obtaining written assurances, you must also identify as the FSVP importer for each line entry of food presented for entry into the U.S.; use a qualified individual for each activity; promptly take corrective actions, if you determine that a foreign supplier of food you import does not produce the food consistent with the written assurances; and maintain records and documentation that demonstrate your compliance with applicable FSVP requirements. More details will be provided later in this chapter and in Chapters 8, 9, and 10 respectively.

What Are “Certain Small Foreign Suppliers”?

What Are “Certain Small Foreign Suppliers”?

- Your supplier meets the criteria for “Certain Small Foreign Suppliers” if:
 1. The foreign supplier is a “qualified facility” as defined by the Preventive Controls (PC) rules;
 2. You are importing produce from a foreign supplier that is a farm that is not a “covered farm” under the Produce Safety Rule (PSR) (i.e., <\$25,000 U.S. average annual produce sales) or satisfies Produce Safety Rule requirements for a “qualified exemption”; or
 3. You are importing shell eggs from a foreign supplier that is not subject to the FDA regulation for Shell Eggs in 21 CFR Part 118 because it has fewer than 3,000 laying hens.



Under 21 CFR 1.512(a)(2) your supplier meets the criteria for one of the three categories of “Certain Small Foreign Suppliers” if:

1. The foreign supplier is a “qualified facility” as defined by the PC rule for human food (21 CFR 117.3) or the PC rule for animal food (21 CFR 507.3), or
2. You are importing produce from a foreign supplier that is a farm that grows produce and is not a “covered farm” under the Produce Safety rule (21 CFR 112.4(a), less than \$25,000 U.S. average produce sales adjusted for inflation) or satisfies the PSR requirements for a “qualified exemption” (21 CFR 112.4(b) and 112.5), or
3. You are importing shell eggs from a foreign supplier that is not subject to the FDA regulation for Shell Eggs in 21 CFR Part 118 because it has fewer than 3,000 laying hens.

We will cover each of these three categories in more detail in upcoming slides.

Documenting the Status of “Certain Small Foreign Suppliers”

Documenting the Status of Your “Certain Small Foreign Suppliers”

- If you are importing food from one of the three categories of “certain small foreign suppliers” and wish to be subject to the modified FSVP requirements, you must:
 - Obtain written assurance that your foreign supplier meets the specified criteria for one of the three categories **before approving the supplier and each applicable calendar year thereafter.**



If you are importing food from one of the three categories of small foreign suppliers and you wish to be subject to the modified (simpler) FSVP requirements, you must obtain written assurance that your foreign supplier meets the specified criteria for one of the three categories **before approving the supplier and annually thereafter by the end of each calendar year.**

What Are “Certain Small Foreign Suppliers”: “Qualified Facilities”?

What Are “Certain Small Foreign Suppliers”: “Qualified Facilities”?

- Your foreign supplier is a “qualified facility” under the PC rules if your foreign supplier is:
 - A “very small business” (which means that during the previous 3-year period, your annual average in sales of food plus the U.S. market value of food processed, packed, or held without sale is <\$1 million U.S. (human food), or <\$2.5 million U.S. (food for animals), **OR**
 - A facility to which both of the following apply:
 - During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
 - The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.



One of the three small supplier categories is a “qualified facility.” Your foreign supplier is a “qualified facility” under the PC rules if your foreign supplier is:

1. A “very small business” (which means that during the previous 3-year period, your annual average in sales of food plus the U.S. market value of food processed, packed, or held without sale is <\$1 million U.S. (human food), or <\$2.5 million U.S. (food for animals), OR
2. A facility to which both of the following apply:
 - a. During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
 - b. The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000 U.S., adjusted for inflation.

Modified Requirements for “Certain Small Foreign Suppliers”: “Qualified Facilities”

Modified Requirements for “Certain Small Foreign Suppliers”: “Qualified Facilities”

- If your foreign supplier is a “qualified facility,” you need to:
 - Obtain written assurance **before** importing the food and **at least every 2 years thereafter** that the foreign supplier is:
 - Producing the food in compliance with applicable FDA food safety regulations, if relevant, or
 - Producing the food in compliance with laws and regulations of a country that has been recognized by FDA as “comparable” for certain foods under Systems Recognition, and
 - That assurance must include a brief description of the supplier’s preventive controls, or a statement of compliance with relevant State or other non-Federal, including foreign, food safety laws and regulations.



If you are importing from a “qualified facility,” you need to obtain written assurance **before** importing the food and at least every 2 years thereafter that the foreign supplier is producing the food in compliance with:

1. Applicable FDA food safety regulations, if relevant, or
2. When applicable, the laws and regulations of a country that has a food safety system that FDA has officially determined to be comparable for certain foods under Systems Recognition.

If your foreign supplier is a “qualified facility,” your written assurance must also include a brief description of the supplier’s preventive controls, or a statement of compliance with relevant State or other non-Federal, including foreign, food safety laws and regulations.

What Are “Certain Small Foreign Suppliers”: Farms That Grows Produce

What Are “Certain Small Foreign Suppliers”: Farms That Grows Produce?

- If your foreign supplier is a farm that grows produce, but:
 - The average annual monetary value of produce sold is less than \$25,000 U.S., **or**
 - The monetary value of produce sold directly to consumers (or sold to restaurants or retailers within 275 miles) exceeds that sold to other purchasers and the average annual value of all food sold is less than U.S. \$500,000.



Your foreign supplier could be a farm that grows produce and is not a “covered farm” under the produce safety rule (21 CFR 112.4(a)) if the average annual monetary value of produce sold is less than \$25,000 U.S. (3-year average), adjusted for inflation with 2011 as the base year.

Under 112.4(b) and 112.5, your foreign supplier who is a farm that grows produce may not be a “covered farm” because it is eligible for a “qualified exemption based on the monetary value of produce sold directly to consumers (or sold to restaurants or retailers within 275 miles). This amount must exceed that sold to other purchasers **and** the average annual value of all food sold must be less than \$500,000 U.S. (average over previous 3-year period) to qualify for the modified requirements.

Modified Requirements for “Certain Small Foreign Suppliers”: Farms That Grows Produce

Modified Requirements for “Certain Small Foreign Suppliers”: Farms That Grows Produce

- Before importing the produce **and at least every 2 years** thereafter you need to obtain written assurance from your supplier:
 - That the farm acknowledges that its food is subject to the adulteration provisions (Section 402) of the FD&C Act, or
 - When applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as “comparable” for certain foods under Systems Recognition.



If so, and you want to take advantage of the modified requirements, you must obtain written assurance from your supplier **before** importing the produce and at least **every 2 years** thereafter that the farm acknowledges that its food is subject to the adulteration provisions (Section 402) of the FD&C Act, or when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable for certain foods under Systems Recognition.

For produce growers, examples of adulteration concerns would be contamination by pathogens, toxic chemicals, or unapproved pesticide residues.

Certain Small Foreign Suppliers: A Shell Egg Producer

"Certain Small Foreign Suppliers": Shell Egg Producers

- If your foreign supplier is a shell egg producer that is not subject to the requirements of 21 CFR 118 because it has fewer than 3,000 laying hens, **before** importing the shell eggs **and** at least **every 2 years** thereafter, you must obtain written assurance from the shell egg producer:
 - That the shell egg producer acknowledges that its food is subject to the adulteration provisions (Section 402) of the FD&C Act, or
 - When applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as "comparable" for certain foods under Systems Recognition.



If your foreign supplier is a shell egg producer that is not subject to the requirements of 21 CFR 118, because it has fewer than 3,000 laying hens and you want to take advantage of the modified requirements in the FSVP rule, you must obtain written assurance **before** importing the shell eggs and at least **every 2 years** thereafter that the shell egg producer acknowledges that its food is subject to the adulteration provisions (section 402) of the FD&C Act, or when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable for certain foods under Systems Recognition.

For shell egg producers, adulteration concerns might include contamination by *Salmonella enteritidis* or by an unapproved animal drug. FDA may provide further guidance on potential adulteration issues and the nature of the required acknowledgement from small shell egg suppliers.

What If the FSVP Importer Is Not a “Very Small Importer,” but Importing Food from “Certain Small Foreign Suppliers”?

What If the FSVP Importer Is Not a “Very Small Importer,” but Imports from “Certain Small Foreign Suppliers”?

- If the FSVP importer does NOT qualify as a “very small importer,” but does import from “certain small foreign suppliers,” the importer must:
 - Evaluate the foreign supplier’s compliance history with applicable food safety regulations (i.e., whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action) and you:
 - Must reevaluate your supplier when concerns arise or at least every 3 years.
 - May review and assess another’s evaluation or reevaluation.
 - Must document all evaluations and reevaluations.
 - Approve the foreign supplier, and
 - Establish and follow written procedures for ensuring that you only import foods from approved foreign suppliers.
 - You may rely on another to establish, follow, and document these procedures if you review and assess them.



If the FSVP importer is NOT a “very small importer,” but does import from “certain small foreign suppliers,” the importer must evaluate the foreign supplier’s compliance history, including whether the supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety. You must reevaluate the supplier when concerns arise or at least every 3 years. You can rely on another to evaluate or reevaluate the supplier, as long as you review and assess the evaluation or reevaluation. In addition, you must approve the foreign supplier on the basis of this evaluation. You must also establish and follow written procedures to ensure that you are only importing food only from approved foreign suppliers. You may rely on others to do this as long as you review and assess their procedures.

What If I Find Assurances Are Invalid?

What If I Find Assurances Are Invalid?

- As a “very small importer” or an importer importing from a “certain small foreign supplier,” you must:
 - **Promptly** take appropriate **corrective actions** if you determine that a foreign supplier of food you import does not produce the food consistent with the assurances the foreign supplier provided.



Even with modified requirements, however, you must pay attention to what the supplier is doing and the safety of the food. So, even as a “very small importer,” you must promptly take appropriate corrective actions if you determine, by whatever means, that a foreign supplier of food you import does not produce the food consistent with the assurances the foreign supplier provided.

What Are Appropriate Corrective Actions?

What Are Appropriate Corrective Actions?

- Appropriate corrective actions will depend on the circumstances, but **could include discontinuing use of the foreign supplier, until:**
 - The cause of the adulteration or misbranding has been adequately addressed.
- You must **document** any corrective actions you take.



The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause of the adulteration or misbranding has been adequately

addressed. Corrective actions should not just take care of the immediate problem but should ensure that it will not happen again in the long term. You must, of course, document any information, investigations, and corrective actions you take.

Record Keeping Requirements

Record Keeping Requirements

- A “very small importer” and importers who import from “certain small foreign suppliers” are subject to essentially the same recordkeeping provisions as discussed in Chapter 9.



Key Point:

An FSVP importer subject to modified requirements must still be identified on the U.S. Customs and Border Protection (CBP) entry filing as the FSVP importer, and is the person FDA will see as being responsible for all FSVP activities.

A very small food importer and importers importing from “certain small foreign suppliers” are subject to similar recordkeeping provisions as discussed in Chapter 9 of this manual. Remember you must sign and date records concerning your FSVP for every supplier and food you import upon completion and upon any modification of your FSVP.

When Food Is Produced Under a Food Safety System Recognized by FDA

Key Point:

Currently, the food safety systems of New Zealand, Canada, and Australia have been recognized as comparable to the U.S. food safety system.

When Food Is Produced Under a Food Safety System Recognized by FDA

- If you import foods from a foreign supplier in a country with food safety systems recognized by FDA as “comparable” for certain foods under Systems Recognition, your requirements can be reduced if:
 - The food is within the scope of the Systems Recognition arrangement;
 - Your supplier is under the regulatory oversight of that food safety authority; and
 - The supplier must be in good compliance standing.
- If these conditions are met, you are not required to, among other things:
 - Perform a hazard analysis, or
 - Conduct a foreign supplier evaluation for approval and verification.



Over time FDA is expected to evaluate whether other countries have food safety systems that effectively provide the same level of public health protection as that provided by the U.S. system. Countries currently recognized by FDA as having food safety systems comparable to the U.S. are New Zealand, Canada, and Australia. Information on the Australia’s recognition with links to the evaluation process can be found on the FDA website at:

<https://www.fda.gov/food/newevents/constituentupdates/ucm553382.htm>

If FDA officially determines that another country’s food safety system is comparable for certain foods under Systems Recognition, and if your foreign supplier is providing food that is within the scope of that official recognition and under the jurisdiction of the government authority responsible for that food safety system, you, as the FSVP importer of food from the foreign supplier, are not required to:

1. Perform a hazard analysis, or
2. Conduct a foreign supplier evaluation for approval and verification.

When Food Is Produced Under a Food Safety System Recognized by FDA (Continued)

- You must, however:
 - Monitor whether the foreign supplier remains in good compliance standing with the foreign food safety authority,
 - Take prompt corrective action if any information indicates that the hazards associated with the food you import are not being significantly minimized or prevented,
 - Ensure that you as the FSVP importer maintains records relative to all FSVP activities, and
 - Identify yourself as the FSVP importer named on the Customs & Border Protection (CBP) entry filing.
- Note: These provisions apply **ONLY** to food that is not intended for further manufacturing/processing before consumption.



You must, however, monitor whether the foreign supplier remains in good compliance standing with the foreign food safety authority, take prompt corrective action if any information indicates that the hazards associated with the food you import are not being significantly minimized or prevented, and ensure that you as the FSVP importer maintain records relative to all FSVP activities.

You must also ensure that you are identified as the FSVP importer on the CBP entry filing and maintain records relative to all FSVP activities. Remember, whoever is identified on the CBP entry filing as the FSVP importer is the person FDA will see as being responsible for all FSVP activities, including the maintenance of all FSVP records.

Note: This provision only applies to a food that is not intended for further manufacturing/processing before consumption, because if it is a food that is imported into the U.S. for further processing, the subsequent U.S. manufacturer/processor will likely need to comply with the PC rules (including regarding supply-chain programs) as well as other U.S. food safety requirements.

Before importing a food from the foreign supplier from a food safety system that has been officially recognized by FDA, you need to determine and document that the foreign supplier is in good compliance standing with the appropriate foreign food safety authority.

Thereafter, you must continue to monitor whether the foreign supplier is in good compliance standing with the foreign food safety authority. Also, if you become aware of any information indicating that the hazards associated with the food you import are not being significantly minimized or prevented, you must take prompt corrective action.

Appendix 5: Summary

Appendix 5: Summary

- Described the modified requirements.
- Described “very small importer” and “certain small foreign suppliers.”
- Discussed the requirements if you are not a “very small importer,” but are importing from “certain small foreign suppliers.”
- Described the requirements when importing from a recognized food safety system.



We have described the modified requirements, identified a “very small importer” and “certain small foreign supplier,” discussed requirements if you are not a “very small importer,” but are importing from a “certain small foreign supplier,” and the requirements when importing from a recognized food safety system.

Appendix 5: Questions

Appendix 5: Questions

Thank you for Your Attention!

Questions?



Blank Colored Insert-Front

Blank Colored Insert-Back

APPENDIX 6: Preventive Controls (PC) and Produce Safety Overview

| Title of Document | Page |
|--|-------------|
| Appendix 6a: Preventive Controls Overview | A6a-1 |

Goal: Participants will be able to explain key concepts/requirements of the PC rules.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Explain the key concepts/requirements of the CGMP and PC rule for human food.
 2. Explain the key concepts/requirements of the CGMP and PC rule for animal food.

| | |
|---|-------|
| Appendix 6b: Produce Safety Overview | A6b-1 |
|---|-------|

Goal: Participants will be able to explain key concepts/requirements of the Produce Safety rule.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Explain the key concepts that foreign fresh produce suppliers must follow.
 2. Explain the requirements that your foreign fresh produce suppliers must follow.
 3. Explain the requirements of produce operations not covered by the Produce Safety rule.

APPENDIX 6. Current Good Manufacturing Practice (CGMP) & Preventive Controls (PC) Rules Overview



FSVP CGMP & PC Rules

A slide titled "FSVP CGMP and PC Rules". It contains two sections: one for human food and one for animal food. The human food section features a photo of a worker in a lab coat and hairnet, and the animal food section features a photo of a large industrial silo facility. Both sections include the FSPCA logo at the bottom.

Appendix 6a

This Appendix chapter was developed to assist importers in understanding what a foreign supplier must have in place to comply with FDA's standards for the *Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food* regulation (referred to as the CGMP & PC rule for human food or PC rule for human food) and FDA's standards for the *Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Food for Animals* regulation (referred to as the CGMP & PC rule for animal food or PC rule for animal food). Also, when talking about both rules, we have referred to them as PC rules.

Resource:

FDA's Technical Assistance Network (TAN) is available to answer regulatory or rule interpretation questions. TAN can be accessed at:
<http://www.fda.gov/fsma>

The FSPCA TAN is available to answer scientific/technical questions about the rule. The FSPCA TAN can be accessed at:
<https://www.ifsh.iit.edu/fspca/fspca-technical-assistance-network>

More information about these and other resources are available in Appendix 7.

Appendix 6a: Goal and Objectives

Appendix 6a: Goal and Objectives

Goal: Participants will be able to explain key concepts/requirements of the PC rules.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Explain the key concepts/requirements of the CGMP & PC rule for human food.
 2. Explain the key concepts/requirements of the CGMP & PC rule for animal food.



By the end of this chapter, you will be able to:

1. Explain the key concepts/requirements of the CGMP & PC rule for human food.
2. Explain the key concepts/requirements of the CGMP & PC rule for animal food.

If you have specific questions on the interpretation of the rules, you can use FDA's FSMA Technical Assistance Network (TAN).

Where Can I Find CGMP & PC Requirements?

Where Can I Find CGMP & PC Requirements?

- CGMP & PC for human food regulation:
 - 21 CFR part 117
- CGMP and PC for animal food regulation:
 - 21 CFR part 507



On September 17, 2015, FDA's final regulations on CGMP & PC for human food and the CGMP & PC for animal food were published. The regulations focus on a preventive approach to food safety. The CGMP & PC for human food rule can be found in the Code of Federal Regulations (CFR) 21 CFR part 117 and the CGMP & PC for animal food rule can be found in 21 CFR part 507.

In the U.S., a regulation (a term we use interchangeably with "rule") is published 1) as a proposed rule for comment and 2) as a final rule that takes all the comments into account and describes how the various comments were addressed. The portion of the rule that addresses the comments is called the "preamble" and the rule itself, which is usually much shorter, is called the "codified text" of the rule, which is then placed permanently in the CFR.

What Does the CGMP & PC for Human Food Rule Do?

What Does the CGMP & PC for Human Food Rule Do?

- Modernizes longstanding current CGMP requirements
- Establishes new requirements for Hazard Analysis and Risk-based Preventive Controls for facilities that manufacture/process, pack, and hold human food intended for sale in the U.S.



The CGMP & PC for human food rule establishes new requirements for hazard analysis and risk-based preventive controls, as mandated by the 2011 FDA Food Safety Modernization Act (FSMA) and modernizes longstanding current good manufacturing practice—or CGMP—requirements (formerly in 21 CFR part 110).

Part 117 –CGMP for Human Food

Part 117–CGMP for Human Food

Updated CGMP for human food facilities:

- | | |
|------------------------------------|---|
| • Personnel | • Warehousing and distribution |
| • Plant and grounds | • Holding and distribution of human food by-products for use as animal food |
| • Sanitary operations | • Defect action levels |
| • Sanitary facilities and controls | |
| • Equipment and utensils | |
| • Processes and controls | |



The CGMP for human food are found in 21 CFR part 117, primarily in subpart B, and are shown in this slide. CGMP are the basis for determining whether human food products have been processed under sanitary conditions. They outline the minimum sanitary

standards that a human food processing facility must meet, including personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, warehousing, and distribution, and holding and distribution of human food by-products for use as animal food. They also provide for defect action levels for natural or unavoidable defects that, at low levels, are not hazardous to health. The CGMP can be considered a prerequisite program prior to implementation of preventive controls.

The previous CGMP found in 21 CFR 110 were updated to the new 21 CFR 117 (primarily in subpart B) to clarify that certain provisions requiring protection against contamination of food also includes protection against food allergen cross-contact. Further, language in the regulation was updated, such as using "must" instead of "shall." Certain provisions containing recommendations (provisions using "should" and "compliance may be achieved by") were deleted, but others were made mandatory, such as requiring cleaning of non-food contact surfaces as frequently as necessary to protect against allergen cross-contact and contamination of food, food-contact surfaces, and food packaging.

Additionally, new provisions were added for holding and distribution of human food by-products for use as animal food. Human food manufacturers that hold and distribute human food by-products without further manufacturing are not subject to the animal food rule if the human food facility is in compliance with CGMP and does not further manufacture or process the by-products intended for use as animal food, but the by-products must be held in a manner that protects against contamination.

Previously nonbinding provisions, such as education and training, are now binding—individuals must be trained in the principles of food hygiene and food safety as appropriate to the food, the facility, and the individual's assigned duties (subpart A).

What Does the CGMP & PC for Animal Food Rule Do?

What Does the CGMP & PC for Animal Food Rule Do?

- Establishes current CGMP requirements for animal food facilities
- Establishes new requirements for hazard analysis and risk-based preventive controls for facilities that manufacture/process, pack, and hold animal food intended for sale in the U.S.



There are two key areas addressed by the CGMP & PC for animal food rule. The first key area relates to establishing CGMP requirements. Prior to the publication of the final rule, CGMP were not required for all animal food facilities. The CGMP & PC for animal food rule established CGMP that are applicable to the animal food industry and are flexible enough to ensure that they are appropriate for a diverse array of animal food products, including food for livestock animals and pet animals.

The second key area is the 2011 FSMA-mandated requirement that facilities conduct a hazard analysis and implement risk-based preventive controls for identified hazards. Each facility is required to implement a written food safety plan that focuses on preventing hazards in food intended for sale in the U.S.

Part 507—CGMP for Animal Food

Part 507—CGMP for Animal Food

Established CGMP for animal food facilities:

- | | |
|-----------------------------|---|
| • Personnel | • Plant operations |
| • Plant and grounds | • Holding and distribution |
| • Sanitation | • Holding and distribution of human food by-products for use as animal food |
| • Water supply and plumbing | |
| • Equipment and utensils | |



The CGMP requirements for animal food are found in 21 CFR part 507, subpart B.

The CGMP were established to provide baseline requirements necessary to prevent animal food from contamination. Proper implementation of CGMP is necessary to produce safe animal food. The CGMP established in part 507 had to be flexible to address a variety of animal food facilities that make food for many different animal species. The CGMP can be considered a prerequisite program prior to implementation of preventive controls.

Food Safety Plan

Food Safety Plan

- Must be written and must include:
- Hazard analysis. If one or more hazards identified, then it must include:
 - Preventive controls
 - Procedures for monitoring
 - Corrective action/correction procedures
 - Verification procedures
- Supply-chain program
- Recall plan



Appendix 6a

Unless subject to an exemption or modified requirements, every human food and animal food facility is required to prepare, or have prepared, and implement a written Food Safety Plan that focuses on preventing hazards in foods. The Food Safety Plan is based on the hazard analysis. The requirements for the hazard analysis and risk-based preventive controls are found in Subpart C for both the CGMP & PC for human food and CGMP & PC for animal food rules. Unless noted, the requirements, primarily in subpart C, are the same for both the CGMP & PC for human food and CGMP & PC for animal food rules. For example, the CGMP & PC for animal food rule does not address “allergen preventive controls.”

There are several components to a food safety plan. First, a written hazard analysis is required regardless of its outcome. If one or more hazards are identified, then preventive controls must be identified and implemented for each hazard. Preventive controls must be written. A facility must have written procedures, including the frequency they are to be performed, for monitoring the preventive controls (as appropriate to the nature of the preventive control and its role in the food safety system) to ensure the effectiveness of the preventive controls. Monitoring must be documented in records subject to verification. A facility must have written corrective action procedures for steps to be taken when preventive controls are not properly implemented.

Written verification procedures must identify activities to be taken to determine that the food safety plan is being followed and that hazards are being controlled. Note, verification procedures may include validation (required for process controls); verification procedures including calibration, product testing and environmental monitoring, record review of monitoring and corrective action records and verification records (calibration, testing, supplier and supply-chain verification activities, and other verification activities); and reanalysis of the Food Safety Plan.

The hazard analysis process also determines when a hazard requiring a supply-chain-applied control exists. Some ingredients may not have hazards requiring a preventive control. If a hazard does exist, and that hazard is controlled before receipt by a supplier, a written supply-chain program, as described by subpart E of both rules, will be required. Note, the supply-chain provisions in the two rules are consistent with those in the Foreign Supplier Verification Programs (FSVP) regulation.

In addition, a written recall plan is required when a hazard requiring a preventive control is identified.

Food Safety Plan—Hazard Analysis

Food Safety Plan—Hazard Analysis

- Hazard **identification** must consider known or reasonably foreseeable biological, chemical (including radiological), and physical hazards
 - These could occur naturally, be unintentionally introduced, or be intentionally introduced for economic gain
- Hazard **evaluation** must consider severity of illness/injury and probability of occurrence in absence of preventive controls (May take into account effectiveness of CGMP on probability of occurrence)



The first component of a food safety plan is a hazard analysis. A facility is required to conduct a hazard analysis to **identify** and **evaluate** known or reasonably foreseeable hazards for foods being manufactured, processed, packed, or held by the facility. A known or reasonably foreseeable hazard is one that is known to be or has the potential to be associated with the facility or the food.

The hazard **identification** must consider biological (including environmental pathogens), chemical (including radiological) and physical hazards that could occur naturally, be unintentionally introduced, or be intentionally introduced for economic gain (where these would impact the safety of the food).

The hazard analysis must include an **evaluation** of the identified hazards to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

Food Safety Plan—Preventive Controls

Food Safety Plan—Preventive Controls

- If any known or reasonably foreseeable hazards are judged to require preventive controls:
 - The facility must identify measures to ensure that those hazards are significantly minimized or prevented.
- These measures can include:
 - Process controls
 - Food allergen controls (*for human food only*)
 - Sanitation controls
 - Supply-chain controls
 - Recall plan
 - Other controls, as needed



A facility is required to identify and implement preventive controls if one or more hazards are identified to ensure that hazards are significantly minimized or prevented. Preventive controls include process controls, food allergen controls (*for human food only*), sanitation controls, supply-chain controls, and a recall plan, as well as any other controls needed to significantly minimize or prevent hazards.

Note: While a recall plan is not used to manage hazards in a facility, it can reduce the number of illnesses if contaminated product is recalled quickly. The two regulations include a recall plan in the list of “preventive controls” to be consistent with the 2011 FDA FSMA language.

Food Safety Plan—Preventive Controls (continued)

- Preventive Controls will include controls currently identified as Critical Control Points (CCPs)
- Preventive Controls are not required when a hazard is controlled by another entity later in the distribution chain
 - Disclose that food is for further processing
 - Obtain assurances hazard will be controlled



Preventive controls may be controls at Critical Control Points (CCPs) or they may be controls other than those at CCPs that are appropriate for food safety. CCP means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

A facility is not required to implement preventive controls when a hazard is controlled by another entity later in the distribution chain, provided that the facility discloses to its customer in documents accompanying the food that the food is “not processed to control [identified hazard]” (with the hazard to be specified) and the facility obtains written assurance that hazard is being controlled, e.g., the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard.

The facility can also rely on its customer to provide assurance that the hazard will be adequately controlled by another entity in the distribution chain subsequent to the customer. The compliance date for written assurances was extended by two years for U.S. suppliers downstream to address feasibility concerns (see 81 Federal Register; August 24, 2016).

Food Safety Plan—Process Controls

Food Safety Plan—Process Controls

- Generally procedures, practices, and processes that control hazards during food processing, such as:
 - Heat processing,
 - Acidifying,
 - Irradiating, and
 - Refrigerating
- Process Controls require identification of maximum or minimum values or parameters that must be:
 - Monitored,
 - Have corrective actions applied, if violated,
 - Verified and recorded, and
 - Validated for effectiveness



Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system:

- (i) Parameters associated with the control of the hazard; and
- (ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

Food Safety Plan—Allergen Controls

Food Safety Plan—Allergen Controls

- Generally needed in human food facilities handling foods with food allergens
- Include procedures, practices, and processes that prevent cross-contact of allergens with foods not containing the allergen and mislabeling of product
- These can include enhanced sanitation after allergen-containing product, scheduling of allergen-containing products after non-allergen products, or review of labels for accuracy



Food allergen controls include procedures, practices, and processes to control food allergens in human food only. Food allergen controls must include those procedures, practices, and processes employed for:

- (i) Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and
- (ii) Labeling the finished food, including ensuring that the finished food is not misbranded

The objective is to prevent 'allergen cross-contact,' which FDA defines as, 'the unintentional incorporation of a food allergen into a food' (*human food only*).

Food Safety Plan—Sanitation Controls

Food Safety Plan—Sanitation Controls

- Used to prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards
- Generally include enhanced sanitation practices
- Environmental monitoring is used for verification of Sanitation Controls when used for environmental pathogens (e.g., *Listeria*, *Salmonella*)



Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the:

- (i) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;
- (ii) Prevention of allergen cross-contact (*for human food only*) and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.

Food Safety Plan—Supply-Chain Controls

Food Safety Plan—Supply-Chain Controls

- Only needed if identified hazards in raw materials and other ingredients have been controlled by supplier(s)
- Facility must approve suppliers for these raw materials and other ingredients before receipt
- Facility determines appropriate supplier verification activities, which may include:
 - Onsite audits*
 - Sampling and testing
 - Review of relevant food safety records
 - Other as appropriate

*An annual onsite audit is generally required when the hazard can cause Serious Adverse Health Consequences Or Death to Humans or Animals (SAHCODHA)



Manufacturing/processing facilities must have a risk-based supply-chain program to ensure control of hazards in raw materials and other ingredients when the control is applied before receipt.

A supply-chain program is not required for all raw materials and other ingredients used by a facility—it is only required when the control for a hazard is being applied by someone earlier in the food chain. It is not required when the preventive control for a hazard is being applied by the manufacturer/processor.

Facilities must ensure that these foods are received from approved suppliers by following written procedures and documenting they are being followed.

Facilities must determine the appropriate supplier verification activities and then conduct and document them. Supplier verification activities include onsite audits*, sampling and testing, review of relevant food safety records, and other procedures if applicable. In determining the appropriate supplier verification activity and its frequency, a facility would consider the nature of the hazard, the entity that applies the controls for the hazard, and supplier performance, including whether the supplier is subject to an FDA Warning Letter or Import Alert, and the supplier's history relevant to the raw material or other ingredient (e.g., results of testing, audit results, responsiveness to correcting problems, etc.).

***When a Serious Adverse Health Consequences Or Death to Humans or Animals (SAHCODHA) hazard in a food will be controlled by the foreign supplier, the default verification procedure is the performance of a properly conducted onsite**

audit of the foreign supplier before initially importing the food and at least annually thereafter (21 CFR 1.506(d)(2)).

Food Safety Plan–Recall Plan

Food Safety Plan–Recall Plan

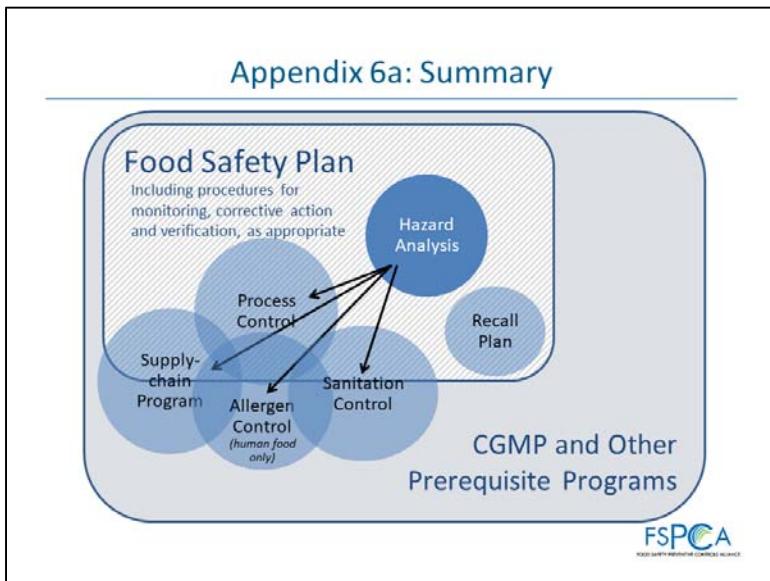
- A written plan is required if hazards requiring a preventive control are identified in the food safety plan
- Includes procedures that describe and assign responsibility for the steps to be taken, including:
 - Notify the direct consignees of the food being recalled
 - Notify the public
 - Conduct effectiveness checks
 - Appropriately dispose of recalled food



For food with a hazard requiring a preventive control, the facility must establish a written recall plan for the food. The written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:

- (1) Directly notify the direct consignees of the food being recalled, including how to return, or dispose of the affected food;
- (2) Notify the public about any hazard presented by the food when appropriate to protect public health;
- (3) Conduct effectiveness checks to verify that the recall is carried out; and
- (4) Appropriately dispose of recalled food—e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

Appendix 6a: Summary



In summary, the schematic above illustrates that the Food Safety Plan includes a number of elements. It starts with hazard analysis, which is used to identify required preventive controls for the process, for sanitation, for food allergens (*human food only*), and supply-chain programs, where these are needed to address the hazards requiring a preventive control. These elements, along with a recall plan make up the Food Safety Plan.

Many CGMP and other prerequisite programs are managed outside of the Food Safety Plan but serve as a foundation for the food safety system. Keep in mind that elements of CGMP that are not covered in the Food Safety Plan are still required by the two regulations.

Appendix 6a: Questions

Appendix 6a: Questions

Thank you for your attention!

Questions?



Notes:

APPENDIX 6. Produce Safety Overview



Produce Safety Rule



This Appendix chapter covers the *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* rule [21 CFR part 117], which we'll call by its shortened form, the Produce Safety rule.

Appendix 6b: Goal and Objectives

Appendix 6b: Goal and Objectives

Goal: Participants will be able to explain key concepts/requirements of the Produce Safety rule.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Explain the key concepts that foreign covered produce suppliers must follow.
 2. Explain the requirements that your foreign covered produce suppliers must follow.
 3. Explain the requirements of produce operations not covered by the Produce Safety rule.



By the end of this chapter, participants will be able to:

1. Explain the key concepts that foreign produce suppliers must follow.
2. Explain the requirements that your foreign produce suppliers must follow.
3. Explain the requirements of produce operations not covered by the Produce Safety rule.

What Is Required by the Produce Safety Rule?

What Is Required by the Produce Safety Rule?

Potential Routes of Contamination

- Minimize hazards from:
 - Agricultural water
 - Domesticated and wild animals
 - Biological soil amendment of animal origin
 - Health and hygiene of workers
 - Equipment, tools, buildings, and sanitation
 - Growing, harvesting, packing, and holding activities



The Produce Safety rule, focuses on biological hazards and specifically defined hazard as any biological agent that has the potential to cause illness or injury in the absence of its control. FDA concluded that physical hazards that can cause injury and chemical hazards, such as from crop protection chemicals, rarely occur at levels that pose a risk of serious adverse health consequences or death for individuals that would consume the product, citing an analysis of scientific literature and recall data. Therefore, the rule focuses on potential microbiological hazards.

FDA identified major routes of contamination on farms, and finalized requirements in certain areas, including agricultural water; domesticated and wild animals; biological soil amendments of animal origin; health and hygiene; equipment, tools, buildings, and sanitation; and growing, harvesting, packing, and holding activities. We'll cover these in more detail in the following slides.

Controlling Hazards from Agricultural Water

Controlling Hazards from Agricultural Water

- Inspection of water system under farm's control
- Water treatment, if a farm chooses to treat water
- Testing to demonstrate water used for certain purposes meets specific microbial criteria
- During growing activities:
 - Microbial water quality profile
 - GM of 126 CFU/100 mL or less generic *E. coli* and STV of 410 CFU/100 mL or less generic *E. coli*
- Certain activities (e.g., during and after harvest – washing, cooling):
 - No detectable generic *E. coli*/100 mL



Key Point:

Agricultural water means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces. If the water does not meet this definition, then the testing requirements and additional items in Subpart E of the Produce Safety rule do not apply. For example, if a grower irrigates their lettuce using overhead irrigation from a pond, this would be considered agricultural water because it directly contacts covered produce. But, if a grower uses pond water to irrigate their apple orchard with drip irrigation and the water is not likely to contact covered produce, this application of water may NOT represent agricultural water.

All agricultural water must be safe and of adequate sanitary quality for its intended use. At the beginning of a growing season or at least once annually, the farm must inspect all of its agricultural water systems, including water sources, water distribution systems, facilities, and equipment, to the extent that the systems are under the farm's control, and maintain them to ensure they are not sources of contamination.

If a farm chooses to treat the water, such as with a physical treatment or an antimicrobial pesticide product registered with the U.S. Environmental Protection Agency (EPA), the treatment method must be effective and consistently delivered and monitored in a manner to

Appendix 6b

make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria.

Unless the agricultural water is treated or is provided by a public water supply that furnishes water that meets certain microbial requirements (e.g., no detectable generic *E. coli* per 100 mL), testing is required to demonstrate agricultural water meets specific microbial criteria.

The farm must develop a microbial water quality profile of each water source used during growing activities. A microbial water quality profile consists of a geometric mean (GM) and a statistical threshold value (STV) of generic *Escherichia coli* (*E. coli*). For pre-harvest applications, each water source must have a GM of 126 CFU/100 mL or less and an STV of 410 CFU/100 mL or less generic *E. coli*. For during and after harvest activities, hand washing, or food contact surface applications, the water must have no detectable generic *E. coli*/100 mL.

Controlling Hazards from Domesticated and Wild Animals

Controlling Hazards from Domesticated and Wild Animals

- Assess, as needed, relevant areas during growing for potential contamination from animals
- If significant evidence of potential contamination is found (e.g., animal excreta, animal observation or destruction):
 - Evaluate whether covered produce can be harvested
 - Take steps throughout the growing season to ensure that covered produce that is reasonably likely to be contaminated will not be harvested



All domesticated and wild animals can be sources of human pathogens. When a reasonable probability that animals will contaminate covered produce in outdoor areas or partially enclosed buildings, farms are only required to assess, throughout the growing season, for potential contamination from animals. If significant evidence of potential contamination is found—such as animal excreta or crop destruction—the farm should evaluate whether the degree of animal contact makes it unwise to harvest some or all of the produce. Produce that is reasonably likely to be contaminated, such as with visible evidence of animal excreta, must not be harvested.

Controlling Hazards from Biological Soil Amendments of Animal Origin (BSAAO)

Controlling Hazards from Biological Soil Amendments of Animal Origin (BSAAO)

- Untreated human waste is not permitted
- Requirements for untreated and treated BSAAOs
 - Application requirements are in the rule
 - Standards for processes to adequately treat BSAAOs are in the rule
- No preharvest, application intervals for BSAAOs that are adequately treated (e.g., compost)—can apply at any time
- Preharvest, application intervals for certain untreated or incompletely treated BSAAOs are being researched, to be published later
- Untreated BSAAO may not be applied in a manner that contacts the harvestable portion of covered produce



Just as animal excreta can be a source of human pathogens, so can Biological Soil Amendments of Animal Origin (BSAAO) and human waste. FDA determined that BSAAOs that do not contain manure or other animal material are less likely to contain human pathogens. BSAAOs that have been composted or otherwise treated in a manner to meet certain microbial standards can be applied to the soil at any time. These standards for processes to treat BSAAOs adequately as well as application requirements are in the rule. Human waste that has been treated in compliance with U.S. Environmental Protection Agency (EPA) regulations are permitted, but untreated human waste is not permitted during production of any covered produce. FDA originally proposed a preharvest interval for raw or incompletely treated BSAAOs applied in a certain manner, but determined that there is currently insufficient science to set a particular interval. Research is ongoing and FDA intends to set a standard at a later date.

Controlling Hazards from Health and Hygiene

Controlling Hazards from Health and Hygiene

- Preventing contamination by ill or infected persons
- Certain hygienic practices are required
- Toilet and handwashing facilities must be adequate and readily accessible during covered activities
- Farms must make visitors aware of policies and give them access to toilet and handwashing facilities
- The rule specifies certain requirements for personnel qualifications, and
 - Harvesters and some supervisors receive additional training



Humans are a potential source of human pathogens, so health and hygiene practices, are important. Certain hygienic practices are required as well as certain measures to prevent those with applicable health conditions from contaminating covered produce and food contact surfaces (specified in Subpart D). Farms must have readily accessible toilet and handwashing facilities. These facilities should be adequately maintained and furnished whenever covered produce is being handled (Subpart L, Equipment, Tools, Buildings, and Sanitation). Not all carriers of pathogens will appear ill, so all workers who are reasonably likely to come in contact with produce or food contact surfaces must receive food safety training so that they know how they can avoid being a source of contamination. Harvesters and some supervisors must also receive additional training in recognizing and dealing with potential sources of contamination (Subpart C, Personnel Qualifications and Training). Farms must make visitors aware of policies and procedures to protect covered produce and food contact surfaces, and give them access to toilet and handwashing facilities.

Controlling Hazards from Equipment, Tools, Buildings, and Sanitation

Controlling Hazards from Equipment, Tools, Buildings, and Sanitation

- Equipment/tools: designed and constructed to allow adequate cleaning and maintenance
- Food contact surfaces of equipment and tools must be inspected, maintained, cleaned, and sanitized as necessary
- Buildings: Size, design, and construction must facilitate maintenance and sanitary operations
- Pest control



Equipment, tools, buildings, and other surfaces, can be harborage of human pathogens and potential sources of contamination. Equipment and tools must be designed and constructed to allow adequate cleaning and maintenance. Food contact surfaces of equipment and tools must be inspected, maintained, and cleaned, and sanitized when necessary and appropriate, to minimize the risk of contamination of covered produce. Buildings and other structures used in covered activities, such as to house food handling equipment or for produce handling or storage, must be of adequate size, design, and construction to facilitate maintenance and sanitary operations. Produce, food contact surfaces, and food-packing materials must be protected from contamination by pests in buildings. This means taking measures to exclude pests from fully-enclosed buildings, and taking measures to prevent pests from becoming established in partially-enclosed buildings (such as by use of screens or by monitoring for the presence of pests and removing them when present).

Controlling Hazards from Growing, Harvesting, Packing, and Holding Activities

Controlling Hazards from Growing, Harvesting, Packing, and Holding Activities

- Separate covered and excluded produce not grown in accordance with the rule
- Identify and not harvest covered produce that is reasonably likely to be contaminated
- Not distributing covered produce that drops to the ground before harvest (see rule for more details)
- Food-packing material appropriate for use



FDA identified several additional growing, harvesting, packing, and holding activities that farms should be aware of and control. If a farm handles both covered and non-covered produce, and the non-covered produce is not grown and handled in accordance with the Produce Safety rule, then the farm must take steps to keep them separate and not allow covered produce to come in contact with non-covered produce. This also applies to food contact surfaces used for non-covered produce until the surfaces have been adequately cleaned and sanitized.

As mentioned earlier, harvesters must be trained to recognize covered produce that must not be harvested. There is also a requirement to identify and not harvest covered produce that is reasonably likely to be contaminated. Dropped covered produce must not be distributed (i.e. covered produce that drops to the ground before harvest); this does not apply to root crops, crops that normally grow on ground (e.g., melons), or produce that is normally dropped to the ground during harvest (e.g., almonds).

Food-packing and packaging material must be appropriate for its intended use. For example, must be packaged in a manner to prevent toxin production by *Clostridium botulinum*. Also, if food-packing materials are reused, steps must be taken to ensure that they are cleanable, do not support bacteria, and food-contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.

Other Hazards to Be Controlled

Other Hazards to Be Controlled

- Physical and chemical hazards:
 - Not specifically required by the Produce Safety rule
 - Must be identified (in hazard analysis) and controlled by foreign supplier (or subsequent handler) if known or reasonably foreseeable at levels reasonably likely to cause illness or injury in the absence of control



While the Produce Safety rule is focused on potential biological hazards, importers must consider whether the produce they import may have known or reasonably foreseeable physical and chemical hazards at levels reasonably likely to cause illness or injury in the absence of control. If so, these must be identified in the importer's hazard analysis and the importer must identify how they will be controlled, either by the foreign supplier, a subsequent handler, or the importer.

Requirements for Produce Exempt from Produce Safety or Subject to Modified Requirements

Requirements for Produce Exempt from Produce Safety or Subject to Modified Requirements

- Produce from a farm or farm mixed-type facility with less than or equal to \$25,000 average annual sales of produce
 - No additional federal regulations; FD&C Act still applies and adulterated food cannot be offered for sale
- Farms that are eligible for a qualified exemption must:
 - Include prominently and conspicuously the name and the complete business address of the farm where the produce was grown on the food packaging label, on a poster, sign, or placard at the point of purchase, or on documents delivered with the produce;
 - Demonstrate that the farm satisfies the criteria for a qualified exemption, including a written record reflecting that the farm has performed an annual review and verification of the farm's continued eligibility for the qualified exemption;
 - Comply with the recordkeeping requirements (Subpart O) and Withdrawal of Qualified Exemption (Subpart R); and
 - Comply with the FD&C Act and ensure that the food offered for sale is not adulterated.



Appendix 6b

Produce from a farm or farm mixed-type facility with less than or equal to \$25,000 average annual sales of produce is not covered by the Produce Safety rule and is not subject to other federal regulations, except that it is still subject to the Federal Food, Drug, and Cosmetic (FD&C) Act, specifically that adulterated food cannot be offered for sale.

Farms that are eligible for a qualified exemption (i.e., a farm or farm mixed-type facility with less than \$500,000 average annual sales of produce food and a majority sold directly to qualified end-users) are subject to modified requirements. When a food packaging label is required on the produce, the food packaging label must include, prominently and conspicuously, the name and the complete business address of the farm where the produce was grown. When a food packaging label is not required (e.g., bulk produce), the name and complete business address of the farm where the produce was grown must be prominently and conspicuously displayed on a label, poster, sign, or placard at the point of purchase, or otherwise delivered contemporaneously with the produce in the normal course of business (e.g., in the case of Internet sales, in an electronic notice). The complete business address must include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms.

Initially and annually thereafter, the farm must demonstrate in a written record that it satisfies the criteria for a qualified exemption. Note: Keeping sales receipts is one way collect this information.

While exempt from most of the requirements in the Produce Safety rule, qualified farms must comply with the recordkeeping requirements described in Subpart O of the rule; e.g., records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption must be retained as long as necessary to support the farm's status during the applicable calendar year, other required records must be retained for at least 2 years past the date the record was created, and required records must be provided onsite within 24 hours of request for official review.

Qualified farms are subject to Withdrawal of Qualified Exemption, as described in Subpart R of the rule, under certain circumstances, such as an active investigation of a foodborne illness outbreak that is directly linked to the farm.

Produce from a farm with a qualified exemption is still subject to the requirements of the FD&C Act, so the importation of adulterated food for sale is a prohibited act.

Requirements for Produce Exempt from Produce Safety or Subject to Modified Requirements (continued)

- Produce that is not a Raw Agricultural Commodity (RAC) or packed at a facility that is not a farm
 - Produce that is processed is covered by Preventive Controls or, if processed into a juice or puree, the Juice HACCP rule (21 CFR 120)
- Produce that is rarely consumed raw
 - No additional federal regulations; FD&C Act still applies and adulterated food cannot be offered for sale
- RACs intended to receive commercial processing
 - Disclose in documents accompanying the food that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and written assurance from the customer that the food will be adequately processed



While packing of RACs at a Primary Production or Secondary Activities farm is covered by the Produce Safety rule, the packing of RACs at a facility that is not a farm is covered by the Preventive Controls rule. The processing of produce (for example, by cooking, cutting, freezing, modified atmosphere packaging, or peeling) so that it is no longer a RAC is also covered by the Preventive Controls rule, unless the produce is processed into a juice or puree, when it is subject to requirements in the Juice HACCP rule (21 CFR 120).

FDA exempted certain produce from the Produce Safety rule because it is rarely consumed raw, and so is not likely to pose a serious threat to public health if not produced according to the requirements of the rule. These specific fruits and vegetables are listed in the rule. For these fruits and vegetables, no additional federal regulations apply. However, produce that is rarely consumed raw is still subject to the FD&C Act, which prohibits adulterated food being offered for sale.

RACs that are imported specifically to be commercially processed in a manner sufficient to eliminate microorganisms of public health significance are also subject to modified requirements. Such produce must be accompanied by documents that disclose that the food is “not processed to adequately reduce the presence of microorganisms of public health significance.” Such produce can only be sold to customers who provide written assurance, at least annually, that the food will be adequately processed.

Appendix 6b: Summary

Appendix 6b: Summary

- We have described the primary routes of contamination covered by the Produce Safety regulation.
- We have explained the key concepts and requirements that your foreign covered produce suppliers must follow.
- We have explained the requirements of produce operations not covered by the Produce Safety rule.



In this Appendix, we have identified the primary routes of contamination covered by the Produce Safety regulation, explained the key concepts and requirements that your foreign covered produce suppliers must follow, and explained the requirements of produce operations not covered by the Produce Safety rule.

Appendix 6b: Questions

Appendix 6b: Questions

Thank you for Your Attention!

Questions?



Blank Colored Insert-Front

Blank Colored Insert-Back

APPENDIX 7: Technical Assistance and Resources

| Title of Document | Page |
|---|-------------|
| Technical Assistance and Resource Table | A7-3 |
| Request for FSVP Records (Form FDA 482d) | A7-9 |
| FSVP Observations (Form FDA 483a) | A7-11 |
| FDA Unified Registration and Listing System (FURLS) Screenshots of Login page, Create Account pages 1 and 2, and Main Menu (after login) page | A7-13 |
| FDA's "Am I Subject to FSVP?" Flowchart | A7-17 |

Technical Assistance and Resource Table

| Name of Resource | Location | Purpose |
|--|---|---|
| General Resources | | |
| FDA Technical Assistance Network (TAN) | http://www.fda.gov/fsma | Answers regulatory questions about FSMA rules and implementation of the rules |
| FDA Draft Guidance for FSMA Implementation | http://www.fda.gov/Food/GuidanceRegulation/FSMA/ | Answers compliance questions related to policy, compliance, and rule interpretation. Non-binding guidance that offers additional information and interpretation on FSMA rules |
| Food Safety and Preventive Controls Alliance (FSPCA) | http://www.iit.edu/iifsh/alliance/ | Answers compliance questions related to policy and compliance. Non-binding guidance that offers additional information on FSMA rules |
| FSPCA Technical Assistance Network | https://www.ifsh.iit.edu/fspca-technical-assistance-network | Answers scientific/technical questions related to Preventive Controls and FSVP |
| FSPCA Courses | http://www.iit.edu/iifsh/alliance/ | FSPCA offers courses on Preventive Controls for Human Food, Preventive Controls for Animal Food, FSVP, and Intentional Adulteration |
| Preventive Controls for Human Food Chapter Resources | https://www.ifsh.iit.edu/fspca/resources/resources-chapter-preventive-controls-human-food | FSPCA also has a chapter-by-chapter list of resources from the Preventive Controls for Human Food training |
| Produce Safety Alliance | http://www.producessafetyalliance.cornell.edu | Answers compliance questions related to policy and compliance. Non-binding guidance that offers additional information on FSMA rules |
| Produce Safety Alliance Training | https://producessafetyalliance.cornell.edu/resources | Produce Safety Alliance also is offering training on the Produce Safety Rule and has many resources pertaining to Good Agricultural Practices (GAP) |

| Name of Resource | Location | Purpose |
|---|---|--|
| Chapter-Specific Resources | | |
| Chapter 1: Context | | |
| <i>FSVP for Importers of Food for Humans and Animals</i> | https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm | Final rule for the Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals |
| Chapter 3: Overview of Requirements | | |
| <i>"Am I Subject to FSVP?" Flowchart</i> | http://www.fda.gov/downloads/food/guidanceregulation/fsma/ucm472461.pdf | To assist you in determining whether or not you are subject to the FSVP rule. |
| <i>Compliance Date Extensions and Clarifications for FSMA Final Rules</i> | https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm517545.htm | Summary of changes announced in the Final Rule *Also located in your manual in Appendix 2 |
| <i>Compliance Dates for the Final Rule on FSVP for Importers of Food for Human and Animals*</i> | https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm | The compliance dates for importers subject to the Foreign Supplier Verification Programs (FSVP) rule *Also located in your manual in Appendix 2 |
| <i>FSMA Inflation Adjusted Cut Offs</i> | https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm554484.htm | Several FSMA rules have provisions in which a value is adjusted for inflation and averaged over 3 years. We provide the values based on Price Deflators for Gross Domestic Product (GDP) and the average for the most recent 3 years starting with the base year 2011 |
| <i>Information on Australia's Recognition with Links to the Evaluation Process</i> | https://www.fda.gov/food/news/events/constituents/ates/ucm553382.htm | FDA signed an arrangement with the Australian Department of Agriculture and Water Resources recognizing each other's food safety systems as comparable to each other. This is the third time that the FDA has recognized a foreign food safety system as comparable, the first being New Zealand in 2012 and Canada in 2016. |

Technical Assistance and Resource Table

| Name of Resource | Location | Purpose |
|--|---|---|
| PCPS: Preventive Controls and Produce Safety Session | | |
| <i>PC for Animal Food Rule</i> | https://www.fda.gov/food/guidanceregulation/fsma/ucm366510.htm | Final rule for the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals |
| <i>PC for Human Food Rule</i> | https://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm | Final rule for the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food |
| <i>Produce Safety Rule</i> | https://www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm | Final rule for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption |
| Chapter 4: Hazard Analysis | | |
| <i>Action Levels for Poisonous or Deleterious Substances in Human and Animal Food</i> | http://www.fda.gov/food/guidanceregulation/guidance/documentsregulatoryinformation/ucm077969.htm | This booklet lists action levels established by the FDA for Action Levels for Poisonous or Deleterious Substances in Human and Animal Food. |
| <i>CPG Sec. 560.750 Radionuclides in Imported Foods - Levels ... INSPECTIONS AND COMPLIANCE</i> | www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074576.htm | This guidance provides information on CPG Sec. 560.750 Radionuclides in Imported Foods - Levels of Concern. |
| <i>Centers for Disease Control and Prevention (CDC): Current Outbreaks List</i> | http://www.cdc.gov/outbreaks/index.html | To obtain information regarding Infectious disease outbreaks currently being reported on by CDC. |
| <i>Chemical Contaminants, Metals, Natural Toxins & Pesticides Guidance Documents & Regulations</i> | http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ChemicalContaminantsMetalsNaturalToxinsPesticides/default.htm | This guidance provides information on Chemical Contaminants, Metals, Natural Toxins & Pesticides Guidance Documents & Regulations. |
| <i>Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food</i> | http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517412.htm | This guidance is intended to help required entities to comply with the following specific PCHF requirements established in subparts C and G of part 117 |

Appendix 7

| Name of Resource | Location | Purpose |
|---|---|--|
| <i>FDA Guidance Explain Certain Exemptions from FSMA*</i> | https://www.fda.gov/Food/NewsEvents/ConstituentUpdate/ucm569554.htm *Also located in your manual in Appendix 1 | FDA has published three Guidance documents to help producers of food commodities covered by these earlier regulations understand which parts of the FSMA rules apply to them and how the FSMA rules may affect their operations. |
| <i>FDA Recalls, Market Withdrawals, & Safety Alerts: Import Alerts Industry Group Foods</i> | http://www.accessdata.fda.gov/cms_ia/industrygroup_1.html | To obtain information regarding FDA Recalls, Market Withdrawals, & Safety Alerts by food groups. |
| <i>FDA's Bad Bug Book</i> | http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ | The Bad Bug Book 2nd Edition, released in 2012, provides current information about the major known agents that cause foodborne illness. |
| <i>FDA's Reportable Food Registry (RFR)</i> | http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm | The Reportable Food Registry (RFR or the Registry) is an electronic portal for Industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences |
| <i>Multistate Foodborne Outbreak Investigations</i> | http://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html | To obtain information regarding Multistate Foodborne Outbreak Investigations. |
| Chapter 5: Evaluation and Approval of Your Foreign Supplier | | |
| <i>FDA's Supplier Evaluation Resources</i> | http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm516330.htm | To research the history of your foreign supplier. |
| <i>Import Alerts</i> | http://www.accessdata.fda.gov/cms_ia/default.html | To research the history of your foreign supplier and identify any import alerts. |
| <i>Import Refusal Report</i> | http://www.accessdata.fda.gov/scripts/importrefusals/ | To research the history of your foreign supplier and identify any refused imports. |

Technical Assistance and Resource Table

| Name of Resource | Location | Purpose |
|--|--|---|
| Chapter 6: Foreign Supplier Verification | <i>Compliance Date Extensions and Clarifications for FSMA Final Rules</i> https://www.fda.gov/food/guidanceregulation/fsma/ucm517545.htm * Also located in your manual in Appendix 2 | This provides a summary of changes announced in the Final Rule: Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules that impacts provisions in these four rules: Preventive Controls for Human Food, Preventive Controls for Food for Animals, Produce Safety, and Foreign Supplier Verification Programs (FSVP) |
| <i>Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA</i> | <i>Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA</i> https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm524553.htm * Also located in your manual in Appendix 1 | This guidance is intended for any entity that is subject to certain provisions (in part 117, part 507, the produce safety regulation, or the FSVP regulation) that require a disclosure statement, in documents accompanying food, that certain hazards have not been controlled by that entity. |
| Chapter 8: Importer Identification | | |
| <i>Dun & Bradstreet – FDA DUNS Request web page</i> | http://www.dnb.com/government/duns-request.html | To apply for a free DUNS number |
| <i>FDA's Supplemental Guidance for the CBP and Trade Automated Interface Requirements</i> | https://www.cbp.gov/sites/default/files/assets/docum ents/2017-Jan/FDA%20Supplemental%20Guide%20Release%202015%20FINAL%20DEC%202016%20.pdf | To provide additional technical information on the CBP and trade automated interface requirements |
| <i>Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the FSVP Regulation*</i> | https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm556661.htm * Also located in your manual in Appendix 1 | Provides information on how you may comply with FDA's requirement to identify yourself as the importer of a food at entry into the United States under the Foreign Supplier Verification Programs (FSVP) regulation. Also provides information on what to do if you are unable to obtain a Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS) number in time for applicable FSVP compliance date. |

| Name of Resource | Location | Purpose |
|--|---|---|
| <i>Guidance for Industry: Recognition of Acceptable Unique Facility (UFI) for the Foreign Supplier Verification Programs Regulation*</i> | https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm549623.htm *Also located in your manual in Appendix 1 | Specifies FDA's current thinking on what unique facility identifier (UFI) FDA recognizes as acceptable for purposes of the Foreign Supplier Verification Programs (FSVP) regulation. |
| Chapter 9: Importance of Records | | |
| <i>21 CFR Part 20</i> | https://www.gpo.gov/fdsys/pkg/CFR-1999-title21-vol1-part20.pdf | Regulations that explain the rules for disclosing records to the public upon request. |
| Chapter 10: FDA Oversight | | |
| <i>FDA Unified Registration and Listing System (FURLS) FDA Unified Registration and Listing System (FURLS)*</i> | FDA Unified Registration and Listing System (FURLS) main page at: http://www.access.fda.gov Online help instructions are available at: http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm114181.htm *Screenshots of web pages located in your manual in Appendix 7 | If sending records electronically, you may send an email with attached PDF files through the FDA Unified Registration and Listing System (FURLS) portal system available on FDA's Web site. |
| <i>FSVP Observations (Form FDA 483a)*</i> | http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM493415.pdf *Also located in your manual in Appendix 7 | This form will be provided to you, if there are any deficiencies in compliance. |
| <i>Request for FSVP Records (Form FDA 482d)*</i> | http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM493417.pdf *Also located in your manual in Appendix 7 | This form will be presented by the FDA at the time of inspection |

Request for FSVP Records (Form FDA 482d) (for reference only)

Retrieved from FDA website at:
<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM493417.pdf>

| | | | |
|--|---|---|---|
| DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration | | 1. DISTRICT OFFICE ADDRESS AND PHONE NO. | |
| TO | 2. NAME AND TITLE OF INDIVIDUAL | | 6. DATE OF REQUEST |
| | 3. FIRM NAME | | 7. TIME OF REQUEST <input type="text"/> a.m. <input type="checkbox"/> p.m. |
| | 4. NUMBER AND STREET | | 8. EMAIL ADDRESS |
| | 5. CITY, STATE AND ZIP CODE | | |
| | Pursuant to Section 805 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 384a), 21 CFR 1.510(b)(1), 21 CFR 1.510(b)(3), 21 CFR 1.512(b)(5)(ii)(A), and/or 21 CFR 1.512(b)(5)(ii)(C) we are hereby requesting that you make all records described below promptly available. | | |
| 9. RECORDS NECESSARY <input type="checkbox"/> The records are to be made available for inspection and copying. <input type="checkbox"/> The records are to be sent to FDA electronically or through another means that delivers the records promptly. | | | |
| 10. SIGNATURE (Food and Drug Administration Employee(s)) | | 11. TITLE FDA EMPLOYEE | |
| FORM FDA 482d (9/16) | | REQUEST FOR FSVP RECORDS <small>FSC Publishing Services (301) 435-0740 EF</small> | |

Retrieved from FDA website at:
<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM493415.pdf>

| DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration | | | |
|---|-----------------------|--|--|
| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | | DATE(S) OF REVIEW OF YOUR FSVP RECORDS | |
| | | FEI NUMBER | |
| Industry Information: www.fda.gov/oc/industry | | | |
| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED | | | |
| FIRM NAME | | STREET ADDRESS | |
| CITY, STATE AND ZIP CODE | | E-MAIL ADDRESS | |
| <p>This document lists observations made by the FDA representative(s) during the review of your Foreign Supplier Verification Program (FSVP). They are observations, and do not represent a final agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s), including by submitting this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.</p> <p>During a review of your Foreign Supplier Verification Program I (we) observed:</p> <div style="background-color: #e0e0ff; height: 150px; width: 100%;"></div> | | | |
| ADD Continuation Page | | | |
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | EMPLOYEE(S) NAME AND TITLE (Print or Type) |
| | | | |
| FORM FDA 483a (2/16) | | FSVP OBSERVATIONS | |
| Page 1 of 2 FSC Publishing Service (201) 440-6740 EF | | | |

If sending records electronically, you may send an email with attached PDF files through the FDA Unified Registration and Listing System (FURLS) portal system available on FDA's Web site. Screenshots of the "Login Screen," "Create Account Screens 1 and 2, and the Main Menu (after login) are below and on subsequent pages.

FURLS Online Account Administration (OAA) "Login" Screen:

Appendix 7

FURLS OAA “Create Account” Screen 1:

The screenshot shows the 'Create New Account' page for the FDA Online Account Administration (OAA). The top navigation bar includes the U.S. Department of Health and Human Services logo, the FDA OAA logo, and the title 'ONLINE ACCOUNT ADMINISTRATION (OAA)'. Below the title, a sub-header reads 'Create New Account'. A message states: 'You must create a separate account to create your Medical Device Registration and Listing, Tobacco Registration and Product Listing or Food Facility.' A blue header bar indicates 'Step 1: Select Application(s) for Account Creation'. The main content area is divided into several sections:

- Registration and Listing Programs**:
 - Food**:
 - Acidified/Low Acid Canned Foods Registration and Process Filing
 - Dairy Listing Module
 - Food Facility Registration
 - New Dietary Ingredient Notification**:
 - Shell Egg Producer Registration
 - Structure/Function Claims Notification
- Medical Devices**:
 - Device Registration and Listing Module
- Tobacco Products**:
 - Tobacco Registration and Listing System
- Export Certification and Tracking**:
 - Biologics Export Certification Application and Tracking System (BECATS)
 - Certificate Application Process
 - Includes Landfood, Seafood, Cosmetics, Food Additive, Food Contact Substances, Dietary Supplements, Infant Formula, Medical Foods, and Foods for Special Dietary Use
 - CDRH Export Certification Application and Tracking System (CECATS)
 - Bulk Gelatin and Collagen Certificate Application Process
 - CDER Export Certification Application and Tracking System (CDEReCATS)
- FSMA Program(s)**:
 - Foreign Supplier Verification Program
- Other FDA Systems**:
 - Prior Notice System Interface

At the bottom are three buttons: 'Cancel', 'Clear', and 'Continue'.

FURLS OAA "Create Account" Screen 2:

Step 2: Enter Your Account Information

2A: Point of Contact Information

First Name: [Input Field]
Middle Initial (Optional): [Input Field]
Last Name / Surname: [Input Field]
Job Title: [Input Field]
Company Name: [Input Field]
Web Address (Optional): [Input Field]
Phone Number: [Input Field]
E-mail Address: [Input Field]
Confirm E-mail Address: [Input Field]

2B: Physical Address (Business) of Account Holder

Country / Area: [Select Box]
Address Line 1: [Input Field]
Address Line 2 (Optional): [Input Field]
City: [Input Field]
State / Province / Territory: [Select Box]
Zip Code (Postal Code): [Input Field]
Unique Facility Identifier (Optional): [Input Field]
Do you have preferred mailing address other than the physical address mentioned above?
 Yes No

2C: Account Information

Password: [Input Field]
Passwords must be at least 8 but not more than 32 characters, contain uppercase and lowercase letters, numbers and special characters (e.g., %\$). You will need to remember your password to login in the future.
Confirm Password: [Input Field]
Secret Question 1: [Select Box]
Secret Answer 1: [Input Field]
Secret Question 2: [Select Box]
Secret Answer 2: [Input Field]
Secret Question 3: [Select Box]
Secret Answer 3: [Input Field]

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.
 I understand.

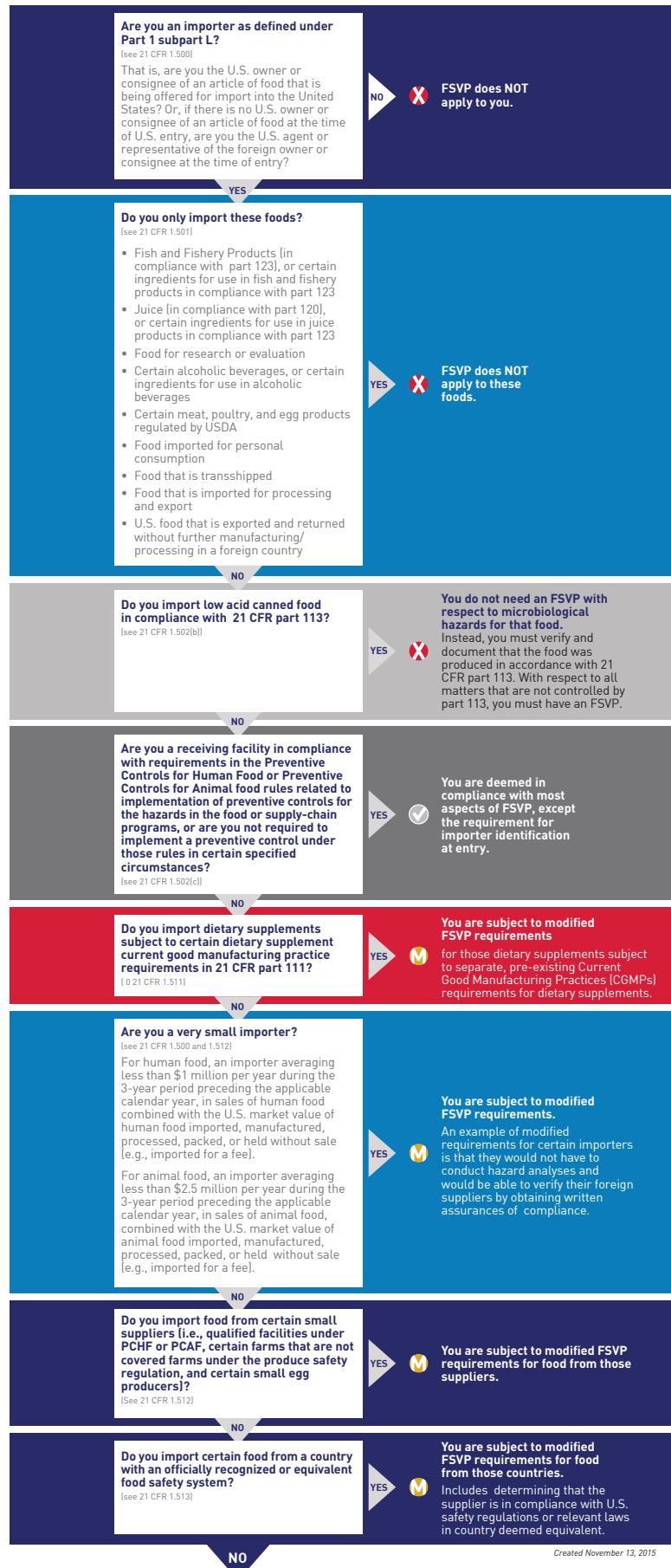
[Previous](#) [Clear](#) [Continue](#)

Appendix 7

FURLS OAA “Main Menu” (after login) Screen:

The screenshot shows the FDA Online Account Administration (OAA) main menu. At the top, there is a navigation bar with links for "Logout", "Help", and "Search". The main content area is titled "Account Management". On the left, a sidebar lists "Account Management" options: "Edit Account Profile", "Change My Password", "Update System Access", "Create a Subaccount", "Deactivate a Subaccount", and "Reactivate a Subaccount". The central area is divided into several sections: "Registration and Listing Programs" (Food, Medical Devices, Tobacco Products), "Export Certification and Tracking", "FSMA Program(s)" (Foreign Supplier Verification Program), and "Other FDA Systems" (Prior Notice System Interface, Systems Recognition Program). Each section contains a list of checkboxes for different modules or systems. At the bottom, there is a footer with links for "Accessibility", "Browser Requirements", "FAQ", "Help Desk", and "Privacy". The footer also includes the FDA logo, social media icons, and contact information: U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, 1-888-INFO-FDA (1-888-463-3332), and a "Contact FDA" button.

AM I SUBJECT TO FSVP?



Created November 13, 2015

Blank Colored Insert-Front

Blank Colored Insert-Back

APPENDIX 8: Sections 402 and 403 of the FD&C Act

| Title of Document | Page |
|--|-------------|
| Section 402 of the FD&C Act, or 21 USC 342: Adulterated Food | A8-3 |
| Section 403(w) of the FD&C Act, or 21 USC 343: Misbranded Food | A8-5 |

Retrieved from Section 402 of the FD&C Act or 21 USC 342: Adulterated Food

Section 402 of the FD&C Act, or 21 USC 342: Adulterated Food:

A food shall be deemed to be adulterated...

(a) Poisonous, insanitary, etc., ingredients

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.¹ (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 346 of this title; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a(a) of this title; or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 348 of this title; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 360b of this title; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

(b) Absence, substitution, or addition of constituents

(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) Color additives

If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of this title.

(d) Confectionery containing alcohol or nonnutritive substance

If it is confectionery, and-

(1) has partially or completely imbedded therein any nonnutritive object, except that this subparagraph shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health; (2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extracts, except that this clause shall not apply to confectionery which is introduced or delivered for introduction into, or received or held for sale in, interstate commerce if the sale of such confectionery is permitted under the laws of the State in which such confectionery is intended to be offered for sale; or (3) bears or contains any nonnutritive substance, except that this subparagraph shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this chapter, except that the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this subparagraph, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

(e) Oleomargarine containing filthy, putrid, etc., matter

If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

(f) Dietary supplement or ingredient: safety

(1) If it is a dietary supplement or contains a dietary ingredient that-
(A) presents a significant or unreasonable risk of illness or injury under-
(i) conditions of use recommended or suggested in labeling, or
(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

Appendix 8

(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;

(C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5 to affirm or withdraw the declaration; or

(D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a de novo basis.

(2) Before the Secretary may report to a United States attorney a violation of paragraph ² (1)(A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.

(g) Dietary supplement: manufacturing practices

(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

(2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5.

(h) Reoffer of food previously denied admission

If it is an article of food imported or offered for import into the United States and the article of food has previously been refused admission under section 381(a) of this title, unless the person reoffering the article affirmatively establishes, at the expense of the owner or consignee of the article, that the article complies with the applicable requirements of this chapter, as determined by the Secretary.

(i) Noncompliance with sanitary transportation practices

If it is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with regulations promulgated under section 350e of this title.

Retrieved from Section 403(w) of the FD&C Act, or 21 USC 343: Misbranded Food

Section 403(w) of the FD&C Act, or 21 USC 343: Misbranded Food:

A food shall be deemed to be misbranded...

(w) Major food allergen labeling requirements

(1) If it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either-

(A) the word "Contains", followed by the name of the food source from which the major food allergen is derived, is printed immediately after or is adjacent to the list of ingredients (in a type size no smaller than the type size used in the list of ingredients) required under subsections (g) and (i); or

(B) the common or usual name of the major food allergen in the list of ingredients required under subsections (g) and (i) is followed in parentheses by the name of the food source from which the major food allergen is derived, except that the name of the food source is not required when-

(i) the common or usual name of the ingredient uses the name of the food source from which the major food allergen is derived; or

(ii) the name of the food source from which the major food allergen is derived appears elsewhere in the ingredient list, unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of a food ingredient that is not a major food allergen under section 321(qq)(2)(A) or (B) of this title.

(2) As used in this subsection, the term "name of the food source from which the major food allergen is derived" means the name described in [section 321\(qq\)\(1\) of this title](#); provided that in the case of a tree nut, fish, or Crustacean shellfish, the term "name of the food source from which the major food allergen is derived" means the name of the specific type of nut or species of fish or Crustacean shellfish.

(3) The information required under this subsection may appear in labeling in lieu of appearing on the label only if the Secretary finds that such other labeling is sufficient to protect the public health. A finding by the Secretary under this paragraph (including any change in an earlier finding under this paragraph) is effective upon publication in the Federal Register as a notice.

(4) Notwithstanding subsection (g), (i), or (k), or any other law, a flavoring, coloring, or incidental additive that is, or that bears or contains, a major food allergen shall be subject to the labeling requirements of this subsection.

(5) The Secretary may by regulation modify the requirements of subparagraph (A) or (B) of paragraph (1), or eliminate either the requirement of subparagraph (A) or the requirements of subparagraph (B) of paragraph (1), if the Secretary determines that the modification or elimination of the requirement of subparagraph (A) or the requirements of subparagraph (B) is necessary to protect the public health.

(6)(A) Any person may petition the Secretary to exempt a food ingredient described in [section 321\(qq\)\(2\) of this title](#) from the allergen labeling requirements of this subsection.

(B) The Secretary shall approve or deny such petition within 180 days of receipt of the petition or the petition shall be deemed denied, unless an extension of time is mutually agreed upon by the Secretary and the petitioner.

(C) The burden shall be on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health.

(D) A determination regarding a petition under this paragraph shall constitute final agency action.

(E) The Secretary shall promptly post to a public site all petitions received under this paragraph within 14 days of receipt and the Secretary shall promptly post the Secretary's response to each.

(7)(A) A person need not file a petition under paragraph (6) to exempt a food ingredient described in [section 321\(qq\)\(2\) of this title](#) from the allergen labeling requirements of this subsection, if the person files with the Secretary a notification

Appendix 8

containing-

(i) scientific evidence (including the analytical method used) that demonstrates that the food ingredient (as derived by the method specified in the notification, where applicable) does not contain allergenic protein; or

(ii) a determination by the Secretary that the ingredient does not cause an allergic response that poses a risk to human health under a premarket approval or notification program under section 348 of this title.

(B) The food ingredient may be introduced or delivered for introduction into interstate commerce as a food ingredient that is not a major food allergen 90 days after the date of receipt of the notification by the Secretary, unless the Secretary determines within the 90-day period that the notification does not meet the requirements of this paragraph, or there is insufficient scientific evidence to determine that the food ingredient does not contain allergenic protein or does not cause an allergic response that poses a risk to human health.

(C) The Secretary shall promptly post to a public site all notifications received under this subparagraph within 14 days of receipt and promptly post any objections thereto by the Secretary.

Blank Colored Insert-Front

Blank Colored Insert-Back

APPENDIX 9: FDA FSMA Fact Sheets

| Title of Document | Page |
|---|-------------|
| Preventive Controls for Human Food Final Rule Summary from FDA Website | A9-3 |
| Preventive Controls for Animal Food Final Rule for Summary from FDA Website | A9-9 |
| Produce Safety Final Rule Summary from FDA Website | A9-15 |
| Accredited Third-Party Certification Final Rule Summary from FDA Website | A9-25 |
| Final Guidance for Industry for FDA's Voluntary Qualified Importer Program (VQIP) | A9-29 |

Retrieved from FDA website (page last updated 08/07/2017) at:

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

FSMA Final Rule for Preventive Controls for Human Food

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

Preventive Standards under the FSMA Main Page

View the Final Rule Contents in [Docket Folder FDA-2011-N-0920](#)

Below is a fact sheet provided by FDA.

In this fact sheet:

- [Key Requirements](#)
- [Compliance Dates](#)
- [Assistance to Industry](#)

The FDA Food Safety Modernization Act (FSMA) Preventive Controls for Human Food rule is now final, and compliance dates for some businesses begin in September 2016.

This final rule is the product of an unprecedented level of outreach by the FDA to industry, consumer groups, the agency's federal, state, local and tribal regulatory counterparts, academia, and other stakeholders. This outreach began before the rule was proposed in January 2013.

In response to input received during the comment period and during hundreds of engagements that included public meetings, webinars, listening sessions, and visits to farms and food facilities across the country, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions were designed to make the originally proposed rule more practical, flexible, and effective for industry, while still advancing the FDA's food safety goals.

The final rule has elements of both the original and supplemental proposals, in addition to new requirements that are the outgrowth of public input received during the comment period for both proposals. For example, flexibility has been built into key requirements, including control of the supply chain, and the definition of farms—which are exempt from these regulations—has significantly changed to reflect modern farming practices.

Key Requirements

1. Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. The rule sets requirements for a written food safety plan that includes:

- **Hazard analysis:** The first step is hazard identification, which must consider known or reasonably foreseeable biological, chemical, and physical hazards. These hazards could be present because they occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain (if they affect the safety of the food).
- **Preventive controls:** These measures are required to ensure that hazards requiring a preventive control will be minimized or prevented. They include process, food allergen, and sanitation controls, as well as supply-chain controls and a recall plan.
- **Oversight and management of preventive controls.** The final rule provides flexibility in the steps needed to ensure that preventive controls are effective and to correct problems that may arise.
 - **Monitoring:** These procedures are designed to provide assurance that preventive controls are consistently performed. Monitoring is conducted as appropriate to the preventive control. For example, monitoring of a heat process to kill pathogens would include actual temperature values and be more frequent than monitoring preventive maintenance activities used to minimize metal hazards, which could be a simple record of the date on which the activity took place.
 - **Corrective actions and corrections:** Corrections are steps taken to timely identify and correct a minor, isolated problem that occurs during food production. Corrective actions include actions to identify a problem with preventive control implementation, to reduce the likelihood the problem will recur, evaluate affected food for safety, and prevent it from entering commerce. Corrective actions must be documented with records.
 - **Verification:** These activities are required to ensure that preventive controls are consistently implemented and effective. They include validating with scientific evidence that a preventive control is capable of effectively controlling an identified hazard; calibration (or accuracy checks) of process monitoring and verification instruments such as thermometers, and reviewing records to verify that monitoring and corrective actions (if necessary) are being conducted.

Product testing and environmental monitoring are possible verification activities but are only required as appropriate to the food, facility, nature of the preventive control, and the role of that control in the facility's food safety system. Environmental monitoring generally would be required if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control.

2. The definition of a ‘farm’ is clarified to cover two types of farm operations. Operations defined as farms are not subject to the preventive controls rule.

- **Primary Production Farm:** This is an operation under one management in one general, but not necessarily contiguous, location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. This kind of farm can pack or hold raw agricultural commodities such as fresh produce and may conduct certain manufacturing/processing activities, such as dehydrating grapes to produce raisins and packaging and labeling raisins.

The supplemental rule proposed, and the final rule includes, a change to expand the definition of “farm” to include packing or holding raw agricultural commodities (such as fresh produce) that are grown on a farm under a different ownership. The final rule also includes within the “farm” definition companies that solely harvest crops from farms.

- **Secondary Activities Farm:** This is an operation not located on the Primary Production Farm that is devoted to harvesting, packing, and/or holding raw agricultural commodities. It must be majority owned by the Primary Production Farm that supplies the majority of the raw agricultural commodities harvested, packed, or held by the Secondary Activities Farm.

This definition for a Secondary Activities Farm was provided, in part, so that farmers involved in certain formerly off-farm packing now fit under the definition of “farm,” as the packing is still part of the farming operation. In addition to off-farm produce packing operations, another example of a Secondary Activities Farm could be an operation in which nuts are hulled and dehydrated by an operation not located at the orchard before going to a processing plant. If the farmer that owns the orchards and supplies the majority of the nuts is a majority owner of the hulling/dehydrating facility, that operation is a Secondary Activities Farm.

- Primary Production and Secondary Activities Farms conducting activities on produce covered by the Produce Safety Rule will be required to comply with that rule.

3. Supply-chain program is more flexible, with separate compliance dates established.

- The rule mandates that a manufacturing/processing facility have a risk-based supply chain program for those raw material and other ingredients for which it has identified a hazard requiring a supply-chain applied control. Manufacturing/processing facilities that control a hazard using preventive controls, or who follow requirements applicable when relying on a customer to control hazards, do not need to have a supply-chain program for that hazard.
- Covered food facilities are responsible for ensuring that these foods are received only from approved suppliers, or on a temporary basis from unapproved suppliers whose materials are subject to verification activities before being accepted for use. (Approved suppliers are those approved by the facility after a consideration of factors that include a hazard analysis of the food, the entity that will be controlling that hazard, and supplier performance.)
- A facility will not be required to implement a preventive control when an identified hazard will be controlled by a subsequent entity such as a customer or other processor. The facility will

have to disclose that the food is “not processed to control (identified hazard)” and obtain written assurance from its customer regarding certain actions the customer agrees to take.

- Another entity in the supply chain, such as a broker or distributor, can conduct supplier verification activities, but the receiving facility must review and assess that entity’s documentation of the verification of control of the hazard.
- Separate compliance dates have been established for the supply-chain program provisions so that a food facility will not be required to comply with the supply-chain program provisions before its supplier is required to comply with the preventive controls for human food rule or the produce safety rule.

4. Current Good Manufacturing Practices (CGMPs) are updated and clarified.

- The final rule does not include nonbinding provisions, which are more appropriate for guidance.
- Some of the previously nonbinding provisions, such as education and training, are now binding.
 - Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties.
 - Such employees must have the necessary combination of education, training, and/or experience necessary to manufacture, process, pack, or hold clean and safe food. Individuals must receive training in the principles of food hygiene and food safety, including the importance of employee health and hygiene.
 - Note that there are similar requirements related to preventive controls.
- The FDA’s longstanding position that CGMPs address allergen cross-contact is now explicit in the regulatory text.

Compliance Dates

Compliance dates for businesses are staggered over several years after publication of the final rule.

- **Very small businesses** (averaging less than \$1 million per year (adjusted for inflation) in both annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale): Three years, except for records to support its status as a very small business (January 1, 2016).
- **Businesses subject to the Pasteurized Milk Ordinance** (compliance dates extended to allow time for changes to the PMO safety standards that incorporate the requirements of this preventive controls rule): Three years
- **Small businesses** (a business with fewer than 500 full-time equivalent employees): Two years
- **All other businesses**: One year

Compliance dates after publication of the final rule for the requirements of the supply chain program:

- **Receiving facility is a small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule:** Two years
- **Receiving facility is a small business and its supplier will be subject to the human preventive controls rule or the produce safety rule:** Two years or six months after the supplier is required to comply with the applicable rule, whichever is later
- **Receiving facility is not a small or very small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule:** 18 months
- **Receiving facility is not a small or very small business and its supplier will be subject to the human preventive controls rule or the produce safety rule:** Six months after the supplier is required to comply with the applicable rule

For more information see, [Compliance Date Extensions and Clarifications for FSMA Final Rules.](#)

Assistance to Industry

The FDA is developing several guidance documents on subjects that include:

- Hazard analysis and preventive controls,
- Environmental monitoring,
- Food allergen controls,
- Validation of process controls,
- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule.
- Plans for training and technical assistance are well under way. They include:
 - Establishing a Food Safety Technical Assistance Network within the agency to provide a central source of information to support industry understanding and implementation of FSMA.
 - Collaborating with the Food Safety Preventive Controls Alliance to establish training and technical assistance programs.
 - Partnering with the National Institute of Food and Agriculture in the U.S. Department of Agriculture to administer a grant program to provide technical assistance to small and mid-size farms and small food processors.

Retrieved from FDA website (page last updated 05/31/2017) at:

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm>

FSMA Final Rule for Preventive Controls for Animal Food

Establish Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

Preventive Standards under the FSMA Main Page

View the Final Rule Contents in [Docket Folder FDA-2011-N-0922](#)

Below is a fact sheet provided by FDA.

In this fact sheet:

- [Key Requirements](#)
- [Compliance Dates](#)
- [Assistance to Industry](#)

The FDA Food Safety Modernization Act (FSMA) Preventive Controls for Animal Food rule is now final, and compliance dates for some businesses begin in September 2016.

This final rule is the product of an unprecedented level of outreach by the FDA to industry, consumer groups, the agency's federal, state, local and tribal regulatory counterparts, academia, and other stakeholders. This outreach began before the rule was proposed in October 2013.

In response to input received during the comment period and during hundreds of engagements that included public meetings, webinars, listening sessions, and visits to farms and food facilities across the country, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions were designed to make the originally proposed rule more practical, flexible, and effective for industry, while still advancing the FDA's food safety goals.

The final rule has elements of both the original and supplemental proposals, in addition to new requirements that are the outgrowth of public input received during the comment period for both preventive controls proposals.

Key Requirements

1. Current Good Manufacturing Practices (CGMPs) established for animal food production.

- The FDA has finalized baseline CGMP standards for producing safe animal food that take into consideration the unique aspects of the animal food industry and provide flexibility for the wide diversity in types of animal food facilities.
- Processors already implementing human food safety requirements, such as brewers, do not need to implement additional preventive controls or CGMP regulations when supplying a by-product (e.g., wet spent grains, fruit or vegetable peels, liquid whey) for animal food, except to prevent physical and chemical contamination when holding and distributing the by-product. Examples of physical and chemical contamination include placing trash or cleaning chemicals into the container holding the by-products. This regulation applies to human food facilities that donate or sell a by-product for use as animal food.

Further processing a by-product for use as animal food (e.g., drying, pelleting, heat-treatment) requires companies to process the by-product in compliance with CGMPs to ensure the animal food's safety and to make sure that the processing does not introduce hazards to the animal food. The company can choose to follow either the human food or animal food CGMPs when further processing the by-product. In addition, unless they are a qualified facility or otherwise exempt from subpart C (hazard analysis and preventive controls), the facility needs to assess its process and determine whether there are any hazards that would require a preventive control. A facility that appropriately determines through its hazard analysis that there are no hazards requiring a preventive control would document such a determination in its hazard analysis but would not need to establish preventive controls.

2. Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. The rule sets requirements for a written food safety plan that includes:

- **Hazard analysis:** The first step is hazard identification, which must consider known or reasonably foreseeable biological, chemical, and physical hazards. These hazards could be present because they occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain (if they affect the safety of the food).
- **Preventive controls:** These measures are required to ensure that hazards requiring a preventive control will be minimized or prevented.
- **Oversight and management of preventive controls:** The final rule provides flexibility in the steps needed to ensure that preventive controls are effective and to correct problems that may arise.
 - **Monitoring:** These procedures are designed to provide assurance that preventive controls are consistently performed. Monitoring is conducted as appropriate to the

preventive control. For example, proper refrigeration could be documented with either affirmative records demonstrating temperature is controlled or "exception records" demonstrating loss of temperature control.

- **Verification:** These activities are required to ensure that preventive controls are consistently implemented and effective. They include validating with scientific evidence that the control is capable of effectively controlling an identified hazard; confirming implementation and effectiveness; and verifying that monitoring and corrective actions (if necessary) are being conducted.

Product testing and environmental monitoring are possible verification activities but are only required as appropriate to the food, facility, nature of the preventive control, and the role of that control in the facility's food safety system.

- **Recall plan:** Every facility that produces animal food with a hazard requiring a preventive control must have a recall plan.

3. Supply-chain program is more flexible, with separate compliance dates established.

- The rule mandates that an animal food manufacturing/processing facility have a risk-based supply chain program for those raw materials and other ingredients for which it has identified a hazard requiring a supply-chain-applied control. Animal food facilities that control a hazard using preventive controls, or who follow requirements applicable when relying on a customer to control hazards, do not need to have a supply-chain program for that hazard.
- Animal food facilities are responsible for ensuring that raw materials and other ingredients with a supply-chain-applied control are received only from approved suppliers, or on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subject to verification activities before being accepted for use. (Approved suppliers are those approved by the facility after a consideration of factors that include a hazard analysis of the food, the entity that will be controlling that hazard, and supplier performance.)
- A facility will not be required to implement a preventive control when an identified hazard will be controlled by another entity in the distribution chain, such as a customer or other processor. The receiving facility will have to disclose that the food is "not processed to control (identified hazard)" and obtain written assurance from its customer regarding certain actions that customer agrees to take.
- Separate compliance dates have been established for the supply-chain program provisions so that a food facility will not be required to comply with the supply-chain program provisions before its supplier is required to comply with the preventive controls for animal food rule or the produce safety rule.

4. The definition of a ‘farm’ is clarified in the Preventive Controls for Human Food final rule to cover two types of farm operations. Operations meeting the definition of ‘farm’ are not subject to the preventive controls rule.

- **Primary Production Farm:** This is an operation under one management in one general, but not necessarily contiguous, location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities.

The supplemental rule proposed, and the final rule includes, a change to expand the definition of “farm” to allow farms to pack or hold raw agricultural commodities (food in its raw or natural state) that are grown on a farm under a different ownership. The final rule also includes within the “farm” definition companies that solely harvest crops from farms.

For example, a farm that raises beef cattle may own and operate a feed mill. The feed mill is considered part of the farm and is not subject to the preventive controls for animal food rule if the feed mill is managed by the farm or the same company as the farm, is in the same general physical location, and produces animal food that is fed only to the animals on that farm or another farm under the same management.

In another example, a poultry processor may own a feed mill but contract the raising of the poultry to a third-party farmer. The poultry processor and its feed mill are under different management than the farm raising the poultry. The feed mill owned by the poultry processor does not qualify as a farm and is subject to the preventive controls for animal food rule because it manufactures food for animals that are on a farm that is not under the same management as the feed mill.

- **Secondary Activities Farm:** This is an operation not located on the Primary Production Farm that is devoted to harvesting, packing, and/or holding raw agricultural commodities. It must be majority owned by the Primary Production Farm that supplies the majority of the raw agricultural commodities that are harvested, packed, or held by the Secondary Activities Farm. The secondary activities farm definition has very limited application to animal food beyond the packing and holding of grain.

5. Feed mills associated with farms (vertically integrated operations) not covered.

- Feed mills associated with fully vertically integrated farming operations (i.e., farms where the feed mill, animals, land, and establishment are all owned by the same entity) generally meet the definition of a farm and are therefore not subject to the Preventive Controls for Animal Food final rule.
- The FDA remains concerned that not having these operations subject to the Preventive Controls for Animal Food final rule leaves a gap in the protection of human and animal health because these feed mill operations manufacture significant amounts of animal food.
- The FDA intends to publish a proposed rule in the future that would require some feed mill operations that currently are part of a farm to implement the current good manufacturing practices established by the Preventive Controls for Animal Food rule.

Compliance Dates

Businesses have a staggered number of years after publication of the final rule to comply, based on business size. In addition, there will be staggered compliance between the CGMP requirements and the Preventive Control Requirements:

| Business Size | CGMP compliance date | PC compliance date |
|---|----------------------|--|
| Business other than small and very small | 1 year | 2 years |
| Small business (a business employing fewer than 500 full-time equivalent employees) | 2 years | 3 years |
| Very small business (a business averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale).) | 3 years | 4 years, except for records to support its status as a very small business (January 1, 2017) |

Compliance dates after publication of the final rule for the requirements of the supply chain program:

- **Receiving facility is a small business and its supplier will be subject to CGMPs but not to preventive controls:** six months after the receiving facility's supplier is required to comply with the CGMP requirements of this rule.
- **Receiving facility is not a small or very small business and its supplier will be subject to CGMPs but not to preventive controls:** six months after the receiving facility's supplier is required to comply with the CGMP requirements of this rule.
- **Receiving facility is a small business and its supplier is subject to the preventive controls for animal food final rule:** Three years after the rule's publication date or six months after the supplier is required to comply with the rule, whichever is later.
- **Receiving facility is not a small or very small business and its supplier will be subject to the preventive controls for animal food final rule:** Two years after the rule's publication date or six months after the supplier is required to comply with the rule, whichever is later.

For more information, see [Compliance Date Extensions and Clarifications for FSMA Final Rules](#).

Assistance to Industry

The FDA is committed to educating industry on the new rules while it regulates. The agency is developing several guidance documents that include:

- CGMP requirements
- Hazard analysis and preventive controls
- Human Food By-Products for Use as Animal Food
- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule

Plans for training and technical assistance are well under way. They include:

- Establishing a Food Safety Technical Assistance Network within the agency to provide a central source of information and a call center to support industry understanding and implementation of FSMA.
- Collaborating with the [Food Safety Preventive Controls Alliance](#) to establish training and technical assistance programs.

Retrieved from FDA website (page last updated 06/23/2017) at:

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

FSMA Final Rule on Produce Safety

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

[Produce Safety Standards under the FSMA Main Page](#)

View the Final Rule Contents in [Federal Register Notice](#)

Below is a fact sheet provided by FDA.

In this fact sheet:

- [Introduction](#)
- [Key Requirements](#)
- [Exemptions](#)
- [Variances](#)
- [Compliance Dates](#)
- [Environmental Impact Statement](#)
- [Assistance to Industry](#)

Introduction

The FDA Food Safety Modernization Act (FSMA) Produce Safety rule is now final, and the earliest compliance dates for some farms begin one year after the effective date of the final rule (see “Compliance Dates” below). The rule establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.

This rule was first proposed in January 2013. In response to input received during the comment period and during numerous public engagements that included public meetings, webinars, listening sessions, and visits to farms across the country, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions were designed to make the originally proposed rule more practical, flexible, and effective.

The final rule is a combination of the original proposal and revisions outlined in the supplemental proposal, with additional changes as appropriate. The definition of “farm” and related terms were revised in the final [Preventive Controls for Human Food rule](#), and the same definitions of those terms are used in this rule to establish produce safety standards. Operations whose only activities are within the farm definition are not required to register with FDA as food facilities and thus are not subject to the preventive controls regulations.

For operations that meet the farm definition, exemptions and modified requirements for the Produce Safety are explained in “[Exemptions and Variances](#)” and in the [Coverage and Exemptions/Exclusions flowchart \(PDF: 95KB\)](#).

Key Requirements

1. Agricultural Water

- **Water quality:** The final rule adopts the general approach to water quality proposed in the supplemental rule, with some changes. The final rule establishes two sets of criteria for microbial water quality, both of which are based on the presence of generic *E. coli*, which can indicate the presence of fecal contamination.
 - No detectable generic *E. coli* are allowed for certain uses of agricultural water in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact. Examples include water used for washing hands during and after harvest, water used on food-contact surfaces, water used to directly contact produce (including to make ice) during or after harvest, and water used for sprout irrigation. The rule establishes that such water use must be immediately discontinued and corrective actions taken before re-use for any of these purposes if generic *E. coli* is detected. The rule prohibits use of untreated surface water for any of these purposes.
 - The second set of numerical criteria is for agricultural water that is directly applied to growing produce (other than sprouts). The criteria are based on two values, the geometric mean (GM) and the statistical threshold (STV). The GM of samples is 126 or less CFU of generic *E. coli* per 100 mL of water and the STV of samples is 410 CFU or less of generic *E. coli* in 100 mL of water.
 - The GM is an average, and therefore represents what is called the central tendency of the water quality (essentially, the average amount of generic *E. coli* in a water source).
 - STV reflects the amount of variability in the water quality (indicating *E. coli* levels when adverse conditions come into play—like rainfall or a high river stage that can wash waste into rivers and canals). Although this is an over simplification, it can be described as the level at which 90 percent of the samples are below the value.
 - The FDA is exploring the development of an online tool that farms can use to input their water sample data and calculate these values.
 - These criteria account for variability in the data and allow for occasional high readings of generic *E. coli* in appropriate context, making it much less likely (as compared to the originally proposed criteria for this water use) that a farm will have to discontinue use of its water source due to small fluctuations in water quality.

- These criteria are intended as a water management tool for use in understanding the microbial quality of agricultural water over time and determining a long-term strategy for use of water sources during growing produce other than sprouts.
- If the water does not meet these criteria, corrective actions are required as soon as is practicable, but no later than the following year. Farmers with agricultural water that does not initially meet the microbial criteria have additional flexibility by which they can meet the criteria and then be able to use the water on their crops. These options include, for example:
 - Allowing time for potentially dangerous microbes to die off on the field by using a certain time interval between last irrigation and harvest, but no more than four consecutive days.
 - Allowing time for potentially dangerous microbes to die off between harvest and end of storage, or to be removed during commercial activities such as washing, within appropriate limits.
 - Treating the water.
- **Testing:** The final rule adopts the general approach to testing untreated water used for certain purposes proposed in the supplemental notice, with some changes. The rule still bases testing frequency on the type of water source (i.e. surface or ground water).
 - In testing, untreated surface water—considered the most vulnerable to external influences—that is directly applied to growing produce (other than sprouts), the FDA requires farms to do an initial survey, using a minimum of 20 samples, collected as close as is practicable to harvest over the course of two to four years. The initial survey findings are used to calculate the GM and STV (these two figures are referred to as the “microbial water quality profile”) and determine if the water meets the required microbial quality criteria.
 - After the initial survey has been conducted, an annual survey of a minimum of five samples per year is required to update the calculations of GM and STV.
 - The five new samples, plus the previous most recent 15 samples, create a rolling dataset of 20 samples for use in confirming that that the water is still used appropriately by recalculating the GM and STV.
 - For untreated ground water that is directly applied to growing produce (other than sprouts), the FDA requires farms to do an initial survey, using a minimum of four samples, collected as close as is practicable to harvest, during the growing season or over a period of one year. The initial survey findings are used to calculate the GM and STV and determine if the water meets the required microbial quality criteria.
 - After the initial survey has been conducted, an annual survey of a minimum of one sample per year is required to update the calculations of GM and STV.

- The new sample, plus the previous most recent three samples, create a rolling dataset of four samples for use in confirming that the water is still used appropriately by recalculating the GM and STV.
- For untreated ground water that is used for the purposes for which no detectable generic *E. coli* is allowed, the FDA requires farms to initially test the untreated ground water at least four times during the growing season or over a period of one year. Farms must determine whether the water can be used for that purpose based on these results.
 - If the four initial sample results meet the no detectable generic *E. coli* criterion, testing can be done once annually thereafter, using a minimum of one sample. Farms must resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criterion.
- There is no requirement to test agricultural water that is received from public water systems or supplies that meet requirements established in the rule (provided that the farm has Public Water System results or certificates of compliance demonstrating that the water meets relevant requirements), or if the water is treated in compliance with the rule's treatment requirements.

2. Biological Soil Amendments

- **Raw Manure:** The FDA is conducting a risk assessment and extensive research on the number of days needed between the applications of raw manure as a soil amendment and harvesting to minimize the risk of contamination. (A soil amendment is a material, including manure, that is intentionally added to the soil to improve its chemical or physical condition for growing plants or to improve its capacity to hold water.)
 - At this time, the FDA does not object to farmers complying with the USDA's National Organic Program standards, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil. The agency considers adherence to these standards a prudent step toward minimizing the likelihood of contamination while its risk assessment and research is ongoing.
 - The final rule requires that untreated biological soil amendments of animal origin, such as raw manure, must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application.
- **Stabilized Compost:** Microbial standards that set limits on detectable amounts of bacteria (including *Listeria monocytogenes*, *Salmonella* spp., fecal coliforms, and *E. coli* 0157:H7) have been established for processes used to treat biological soil amendments, including manure. The rule includes two examples of scientifically valid composting methods that meet those standards. Stabilized compost prepared using either of these methods must be applied in a manner that minimizes the potential for contact with produce during and after application.

3. Sprouts

- The final rule includes new requirements to help prevent the contamination of sprouts, which have been frequently associated with foodborne illness outbreaks. Sprouts are especially vulnerable to dangerous microbes because of the warm, moist, and nutrient-rich conditions needed to grow them.
 - Between 1996 and 2014, there were 43 outbreaks, 2,405 illnesses, and 171 hospitalizations, and 3 deaths associated with sprouts, including the first documented outbreak of *Listeria monocytogenes* associated with sprouts in the United States.
- Requirements specific to sprouts include, for example:
 - Taking measures to prevent the introduction of dangerous microbes into or onto seeds or beans used for sprouting, in addition to treating seeds or beans that will be used for sprouting (or relying on prior treatment by the seed/bean grower, distributor, or supplier with appropriate documentation).
 - Testing of spent sprout irrigation water from each production batch of sprouts, or in-process sprouts from each production batch, for certain pathogens. Sprouts cannot be allowed to enter commerce until it is ascertained that these required pathogen test results are negative.
 - Testing the growing, harvesting, packing, and holding environment for the presence of *Listeria* species or *Listeria monocytogenes*.
 - Taking corrective actions if spent sprout irrigation water, sprouts, and/or an environmental sample tests positive.
- Sprout operations will have less time to come into compliance with the rule than farms growing other produce. They will have one to three years to comply based on the size of their operation, with no additional time to meet the water requirements.

4. Domesticated and Wild Animals

- The rule addresses concerns about the feasibility of compliance for farms that rely on grazing animals (such as livestock) or working animals for various purposes. It establishes the same standards for these animals as it does for intrusion by wild animals (such as deer or feral swine). Farmers are required to take all measures reasonably necessary to identify and not harvest produce that is likely to be contaminated.
 - At a minimum, this requires all covered farms to visually examine the growing area and all covered produce to be harvested, regardless of the harvest method used.
 - In addition, under certain circumstances the rule requires farms to do additional assessment during the growing season, and if significant evidence of potential contamination by animals is found, to take measures reasonably necessary to assist

later during harvest. Such measures might include, for example, placing flags outlining the affected area.

- Although the final rule does not require establishing waiting periods between grazing and harvest, the FDA encourages farmers to voluntarily consider applying such intervals as appropriate for the farm's commodities and practices. The agency will consider providing guidance on this practice in the future, as needed.
- As was stated in the supplemental notice, farms are not required to exclude animals from outdoor growing areas, destroy animal habitat, or clear borders around growing or drainage areas. Nothing in the rule should be interpreted as requiring or encouraging such actions.

5. Worker Training and Health and Hygiene

- Requirements for health and hygiene include:
 - Taking measures to prevent contamination of produce and food-contact surfaces by ill or infected persons, for example, instructing personnel to notify their supervisors if they may have a health condition that may result in contamination of covered produce or food contact surfaces.
 - Using hygienic practices when handling (contacting) covered produce or food-contact surfaces, for example, washing and drying hands thoroughly at certain times such as after using the toilet.
 - Taking measures to prevent visitors from contaminating covered produce and/or food-contact surfaces, for example, by making toilet and hand-washing facilities accessible to visitors.
- Farm workers who handle covered produce and/or food-contact surfaces, and their supervisors, must be trained on certain topics, including the importance of health and hygiene.
- Farm workers who handle covered produce and/or food contact surfaces, and their supervisors, are also required to have a combination of training, education, and experience necessary to perform their assigned responsibilities. This could include training (such as training provided on the job), in combination with education, or experience (e.g., work experience related to current assigned duties).

6. Equipment, Tools, and Buildings

- The rule establishes standards related to equipment, tools, and buildings to prevent these sources, and inadequate sanitation, from contaminating produce. This section of the rule covers, for example, greenhouses, germination chambers, and other such structures, as well as toilet and hand-washing facilities.

- Required measures to prevent contamination of covered produce and food contact surfaces include, for example, appropriate storage, maintenance and cleaning of equipment and tools.

Exemptions

The rule does not apply to:

- Produce that is not a raw agricultural commodity. (A raw agricultural commodity is any food in its raw or natural state)
- The following produce commodities that FDA has identified as rarely consumed raw: asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts
- Food grains, including barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g. cotton seed, flax seed, rapeseed, soybean, and sunflower seed)
- Produce that is used for personal or on-farm consumption
- Farms that have an average annual value of produce sold during the previous three-year period of \$25,000 or less

The rule provides an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, under certain conditions.

The rule also provides a qualified exemption and modified requirements for certain farms.

- To be eligible for a qualified exemption, the farm must meet two requirements:
 - The farm must have food sales averaging less than \$500,000 per year during the previous three years; and
 - The farm's sales to qualified end-users must exceed sales to all others combined during the previous three years. A qualified end-user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same state or the same Indian reservation as the farm or not more than 275 miles away.
- A farm with the qualified exemption must still meet certain modified requirements, including disclosing the name and the complete business address of the farm where the produce was grown either on the label of the produce or at the point of purchase. These farms are also required to establish and keep certain documentation.
- A farm's qualified exemption may be withdrawn as follows:
 - If there is an active investigation of an outbreak of foodborne illness that is directly linked to the farm, or
 - If FDA determines it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions associated with the farm that are material to the safety of the farm's produce that would be covered by the rule.
- Before FDA issues an order to withdraw a qualified exemption, the agency:

- May consider one or more other actions to protect public health, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction.
- Must notify the owner, operator, or agent in charge of the farm, in writing, of the circumstances that may lead FDA to withdraw the exemption, provide an opportunity for response within 15 calendar days of receipt of the notification, and consider actions taken by the farm to address the issues raised by the agency.
- A withdrawn exemption may be reinstated if (as applicable):
 - The FDA determines that the outbreak was not directly linked to the farm, and/or
 - The FDA determines that the problems with conduct or conditions material to the safety of the food produced or harvested at the farm have been adequately resolved, and continued withdrawal of the exemption is not necessary to protect public health or prevent or mitigate an outbreak of foodborne illness.

Variances

The rule also permits states, tribes, or foreign countries from which food is imported into the U.S. to submit a petition, along with supporting information, to FDA requesting a variance(s) from one or more of the requirements of this rule.

- The rule enables a state, tribe, or country, if it concludes that meeting one or more of the rule's requirements would be problematic in light of local growing conditions, to request variances to those requirements. The state, tribe, or foreign country must demonstrate that the requested variance is reasonably likely to ensure that the produce is not adulterated and provides the same level of public health protection as the corresponding requirement(s) in the rule.
- The final rule makes it clear that federally recognized tribes may submit a variance petition.
- The request for a variance must be submitted by a competent authority, meaning a person or organization that is the regulatory authority for food safety for the state, tribe, or foreign country.
- A foreign government does not need to have a systems recognition arrangement or equivalence agreement with the FDA to obtain a variance.
- The variance request must include relevant and scientifically valid information specific to the produce or activity. Information could relate to crops, climate, soil, geography, or environment, as well as the practices of that particular region.
- Examples of types of variances that may be granted include a variance from the agricultural water microbial quality criteria for water used during growing covered produce (other than sprouts) using a direct water application method, a variance from the microbial die-off rate used to determine the time interval between the last irrigation and harvest and/or the accompanying maximum time interval; and a variance from the approach or frequency for water testing for water uses subject to the rule's microbial quality criteria.

Compliance Dates

Compliance dates for covered activities, except for those involving sprouts, after the effective date of the final rule are:

- Very small businesses, those with more than \$25,000 but no more than \$250,000 in average annual produce sales during the previous three-year period: four years
- Small businesses, those with more than \$250,000 but no more than \$500,000 in average annual produce sales during the previous three-year period: three years
- All other farms: two years
- The compliance dates for certain aspects of the water quality standards, and related testing and recordkeeping provisions, allow an additional two years beyond each of these compliance dates for the rest of the final rule

Compliance dates for modified requirements for farms eligible for a qualified exemption are:

- For labeling requirement (if applicable): January 1, 2020
- For retention of records supporting eligibility for a qualified exemption: Effective date of the final rule
- For all other modified requirements:
 - Very small businesses, four years after the effective date of the final rule
 - Small businesses, three years after the effective date of the final rule

Compliance dates for covered activities involving sprouts after the effective date of the final rule are:

- Very small businesses: three years
- Small businesses: two years
- All other farms: one year

For more information, see [Compliance Date Extensions and Clarifications for FSMA Final Rules](#).

Environmental Impact Statement

The FDA has also released the [Final Environmental Impact Statement \(EIS\)](#), which places the Produce Safety rule in the context of its likely impact on the environment, including human health and socioeconomic effects. The Draft EIS was published in January 2015. The FDA considered public comments submitted in the two months that followed in drafting the Final EIS. The FDA considered the findings of the Final EIS in finalizing the produce rule.

- The EIS evaluated actions that FDA proposed in the original and supplemental rules, as well as a number of alternative actions for each of the provisions identified as having the potential to result in significant environmental impacts. The provisions of the final rule represent FDA's preferred alternatives, which are detailed in a Record of Decision (ROD). The ROD addresses how the EIS findings were incorporated into decisions about the final rule. The agency's preferred alternatives are those that the FDA believes best fulfill the agency's statutory mission and responsibility, giving consideration to economic, environmental, technical, and other factors.

- A significant beneficial impact on public health is expected due to the anticipated decrease in the number of illnesses tied to produce contamination.
- As in the Draft EIS, the Final EIS notes that any produce regulation that causes a farmer to use ground water instead of surface water could exacerbate existing groundwater shortages, although added flexibility in the water provisions make such a management decision unlikely.
- The Final EIS also concludes that Native American farmers may be disproportionately affected by any increases in operating costs necessitated by the produce rule since their average income is 30 percent less than that of other farmers.

Assistance to Industry

The FDA is developing several guidance documents on subjects that include:

- General guidance on implementation and compliance.
- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule.
- Other documents, including guidance on sprouts, are being considered and prioritized.

Plans for training and technical assistance are well under way. They include:

- Establishing the FDA FSMA Food Safety Technical Assistance Network, already operational, to provide a central source of information to support industry understanding and implementation of FSMA.
- The FDA is developing a comprehensive training strategy that includes collaboration with:
 - The Produce Safety Alliance;
 - The Sprout Safety Alliance;
 - The National Institute of Food and Agriculture in the U.S. Department of Agriculture (to administer a grant program to provide food safety training, education and technical assistance to small and mid-size farms and small food processors, beginning farmers, socially disadvantaged farmers, and small produce merchant wholesalers); and
 - Cooperative agreement partners (to develop training programs for sustainable agriculture and tribal operations).
- The FDA also plans to work with cooperative extension units, land grant universities, trade associations, foreign partners, the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), and other stakeholders to develop a network of institutions that can provide technical assistance to the farming community, especially small and very small farms.
- FDA has entered into a cooperative agreement with National Association of State Departments of Agriculture (NASDA) to help with the implementation of the produce safety regulations.

Retrieved from FDA website (page last updated 06/21/2017) at:

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361903.htm>

FSMA Final Rule on Accredited Third-Party Certification

[Imports under the FSMA Main Page](#)

In this fact sheet:

- [Introduction](#)
- [Key Features](#)
- [Exemptions](#)
- [Implementation](#)

FDA's Accredited Third-Party Certification program is **now accepting applications**.

Introduction

The FDA Food Safety Modernization Act (FSMA) rule on Accredited Third-Party Certification was finalized in November 2015. The rule establishes a voluntary program for the accreditation of third-party certification bodies, also known as third-party auditors, to conduct food safety audits and issue certifications of foreign entities and the foods for humans and animals they produce. These requirements are intended to help ensure the competence and independence of the accreditation bodies and third-party certification bodies participating in the program.

FSMA specifies two uses for certifications under this program:

- Certifications may be used by importers to help establish eligibility for participation in the Voluntary Qualified Importer Program (VQIP), which offers expedited review entry of food.
- To prevent potentially harmful food from reaching U.S. consumers, the FDA can also require in specific circumstances that a food offered for import be accompanied by a certification from an accredited third-party certification body.

Key Features

1. Scope

- This rule establishes the framework, procedures and requirements for accreditation bodies seeking recognition by the FDA, as well as requirements for third-party certification bodies seeking accreditation.
 - These requirements cover legal authority, competency, capacity, conflict-of-interest safeguards, quality assurance and record procedures.
 - In limited circumstances, the FDA may directly accredit third-party certification bodies. For example, FDA can directly accredit third-party certification bodies if the agency does not identify and recognize an accreditation body to meet the requirements of the program within two years after establishing the program.
- To promote international consistency and utilize an existing framework that is familiar to industry, accreditation bodies and certification bodies can use documentation of their conformance with ISO/IEC standards, supplemented as necessary, in meeting program requirements under this rule. (ISO/IEC stands for the International Organization for Standardization and the International Electrotechnical Commission, which have issued voluntary international consensus standards.)
- The FDA will closely monitor participants in the program and may revoke an accreditation body's recognition or withdraw a certification body's accreditation under certain circumstances. The rule contains FDA procedures relating to monitoring and oversight of participating accreditation bodies and certification bodies.

2. Requirements for Recognized Accreditation Bodies

- An accreditation body recognized by FDA under this program could be a foreign government/agency or a private third party. The final rule requires recognized accreditation bodies to:
 - Assess third-party certification bodies for accreditation, including observing a representative sample of the prospective certification body's work
 - Monitor performance of the third-party certification bodies it accredits, including periodically conducting on-site observations, and notifying the FDA of any change in, or withdrawal of, accreditations it has granted
 - Assess and correct any problems in their own performance
 - Submit monitoring and self-assessment reports and other notifications to the FDA
 - Maintain and provide the FDA access to records required to be kept under the program

3. Requirements for Third-Party Certification Bodies

- Third-party certification bodies accredited under this program are required to perform unannounced facility audits and to notify the FDA upon discovering a condition that could cause or contribute to a serious risk to the public health. The final rule requires these accredited third-party certification bodies to:
 - Ensure their audit agents are competent and objective
 - Verify the effectiveness of corrective actions to address identified deficiencies in audited entities
 - Assess and correct any problems in their own performance
 - Maintain and provide the FDA access to records required to be kept under the program
- There are two kinds of audits that accredited third-party certification bodies can perform as part of the program: consultative and regulatory. In both kinds, auditors will examine compliance with applicable federal food safety requirements.
 - A consultative audit is conducted in preparation for a regulatory audit and is for internal use. In addition to compliance with federal standards, a consultative audit also considers how the facility meets industry standards and practices. Only a regulatory audit can be the basis for certification.
 - An accredited third-party certification body could be a foreign government or other third-party entity or individual.

4. Related FDA Actions

- FDA's final recommendations on third-party certification body standards are contained in the Model Accreditation Standards guidance issued in December 2016. They contain recommendations on the qualifications that third-party certification bodies and their agents should have in such areas as education and experience.
- In November 2016, the FDA published a final guidance for industry explaining how the Voluntary Qualified Importer Program (VQIP) will work. In order to participate in VQIP, importers must import food from certified facilities.
 - Importers with a robust system of supply-chain management may qualify for expedited review and entry for foods they seek to import.
 - Consumer protections are strengthened by enabling the FDA to focus its resources on food imports that are more likely to present a potential risk to public health.
- The FDA published in December 2016 a final rule to establish a user fee program for the voluntary Accredited Third-Party Certification Program. FSMA required a user-fee program be established to reimburse the agency for its work in establishing and administering this program.

Exemptions

The Third-Party Certification rule also provides that the mandatory import certification authority under FSMA does not apply to:

- Alcoholic beverages manufactured by foreign facilities under certain circumstances
- Certain meat, poultry and egg products that are subject to U.S. Department of Agriculture oversight at the time of importation.

Implementation

In June 2017 FDA launched a website where organizations can apply to be recognized as an Accreditation Body. The launch of this website will implement the Accredited Third-Party Certification Program

Third-party certification bodies can seek accreditation after one or more FDA-recognized accreditation bodies begin accepting applications.

Retrieved from FDA website (page last updated 11/14/2016) at:

<https://www.fda.gov/food/guidanceregulation/fsma/ucm448574.htm>

Final Guidance for Industry for FDA's Voluntary Qualified Importer Program

What is it?

A voluntary, fee-based program for the expedited review and importation of foods from importers who achieve and maintain a high level of control over the safety and security of their supply chains.

Who is eligible?

Importers (defined as the person who brings food, or causes food to be brought, from a foreign country into the United States) should meet several eligibility criteria to participate in the program. These criteria include:

- Developing and implementing a [Quality Assurance Program \(QAP\)](#) that demonstrates a high level of control over the safety and security of supply chains.
- Assurance of compliance with the supplier verification and other importer responsibilities under the applicable Foreign Supplier Verification Program (FSVP), juice HACCP (Hazard Analysis and Critical Control Points), or seafood HACCP regulations.
- A current facility certification issued under FDA's Accredited Third-Party Certification regulations for each foreign supplier of food intended for importation under VQIP. In the case of raw produce, there must be a certification for the farm.
- At least a three-year history of importing food to the United States. The import history may be based on the shared importation history of previous or parent companies, such as those that have been involved in a merger. If applicants have imported food for more than three years, the FDA may review additional years as necessary to adequately evaluate compliance history.
- No ongoing FDA administrative or judicial action (e.g., import alert, injunction, recall), or other history of significant non-compliance with food safety regulations by the importer, other entities in the supply chain (e.g., foreign suppliers, filers/brokers, and FSVP and HACCP importers), or food.
- Having a Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS) number. To obtain a DUNS number, contact D&B at 866-705-5711 or via e-mail to govt@dnb.com. All entities doing business with the U.S. government can receive a DUNS number free of charge.

What kinds of foods are allowed under VQIP?

- Foods from a facility (or farm) certified under FDA's Accredited Third-Party Certification regulations as following appropriate food safety practices.
- No food that an applicant imports, including those not intended for inclusion in VQIP, should be subject to an import alert or Class 1 recall.

Will FDA expedite entry of a VQIP food that is part of a mixed entry (i.e., the entry includes VQIP food and food that is not covered by my VQIP)?

- **FDA will only expedite the VQIP food.** A non-participating food will be subject to normal FDA review procedures, including routine examination and sampling, when applicable. Therefore, combining VQIP and non-VQIP foods into a single entry may slow the entry of the VQIP food.

Benefits of participating:

- The FDA will expedite entry into the U.S. for all foods included in an approved VQIP application.
- This means that the FDA will set up its import screening system to recognize shipments of food that are the subject of an approved VQIP application and, in most cases, immediately release the shipment after the receipt of entry information.
- The FDA will limit examination and/or sampling of VQIP food entries to “for cause” situations in which there is a potential threat to public health, to obtain statistically necessary risk-based microbiological samples, and to audit VQIP.
- In the event that FDA examines or samples a VQIP food, the location of such sampling or examination would, to the extent possible, be at the VQIP food’s destination or another location chosen by the importer.
- In the event that FDA samples a VQIP food, laboratory analysis of such samples would be expedited.
- The FDA will establish a VQIP Importers Help Desk dedicated to responding to questions and concerns from VQIP importers. The help desk will be available for assistance with completing the VQIP application, facilitating a review of VQIP food that does not receive an immediate release, and answering other questions from VQIP importers related to the program.
- The FDA will post on its VQIP web page a list of approved VQIP importers; however, VQIP importers may choose not to be listed.
- The FDA may suspend any or all of these benefits as necessary to protect public health or in the case of an unforeseen emergency.

What would necessitate a ‘For Cause’ examination of a VQIP food?

- A shipment from a VQIP-qualified importer may be subject to a “for cause” examination if the food is or may be associated with a risk to public health. For example, if there is an outbreak of foodborne illness that has been linked to the type of food or to a foreign supplier covered in the VQIP application, the FDA may examine and sample the food.

What is my VQIP Quality Assurance Program (QAP)?

A QAP is a compilation of the written policies and procedures you will use to ensure adequate control over the safety and security of the foods you import. Your QAP, submitted with your VQIP application, should include:

- A Corporate Quality Policy Statement related to food safety and security throughout the supply chain and an explanation of how this policy is communicated internally.
- A description of the organizational structure and individual responsibilities.

- Established policies and procedures that will be implemented to ensure food safety from source to entry (e.g., temperature and storage controls), including:
 - Compliance with supplier verification procedures in the FSVP or HACCP regulations, if applicable.
 - Written procedures for maintaining current foreign supplier certifications under FDA's Accredited Third-Party Certification Program,
 - Procedures for controlling the safety of each VQIP food throughout the transportation supply chain, including compliance with FDA's sanitary transport rule, if applicable.
 - Written procedures for communicating information about potential health hazards to FDA and others.
 - Written procedures for corrective actions to address food and foreign supplier non-compliances that pose a risk to public health.
 - A written description of your food defense system to protect against intentional adulteration, if applicable.
- Knowledge and qualification requirements for employees responsible for implementing the VQIP QAP.
- Written procedures for establishing and maintaining records relating to the structure, processes, procedures, and implementation of your VQIP QAP.

How soon will I receive benefits?

- **VQIP benefits will begin October 1 following your acceptance into the program and will last through September 30 of the following year (VQIP year).**

How do I apply?

- Visit the [FDA Industry Systems website](#) to establish an online account.
- From January 1 to May 31 each year, submit online a "Notice of Intent to Participate" in VQIP.
- **Your VQIP application must be renewed each year.**

Is there a user fee to participate in VQIP?

- **Yes.** Each importer participating in VQIP must pay a fee to cover FDA's costs of administering the program. The FDA will charge the VQIP user fee on an annual basis. You must pay the user fee by October 1, the start of the VQIP year, in order to receive benefits under the program.
- In the Federal Register of June 5, 2015 (80 FR 32136), FDA estimated that a flat annual fee of approximately \$16,400 will be paid by all VQIP participants. FDA has not yet finalized the fee for applications in January 2018, but will publish the fee amount in the Federal Register on or before August 1, 2017, and each year thereafter.

How will FDA evaluate my application?

- FDA will review the application, with all the relevant documents, to determine if you meet the VQIP eligibility criteria.

- If you are accepted into the program, FDA will conduct a VQIP inspection to verify that you meet the VQIP eligibility criteria and have fully implemented the food safety and any food defense systems established in your QAP.
- The inspection will typically include a review of the written procedures and records demonstrating compliance with VQIP. If you are both the VQIP and FSVP/Juice or Seafood HACCP importer for one or more foods you import under this program, FDA may also conduct an FSVP or HACCP importer inspection to assess your compliance with the applicable regulations.
- FDA may also request a copy of food labels for the foods you include in your application, to determine if there are labeling violations relating to the risk of the food (e.g., failure to disclose an allergen). You will be asked to address any label deficiencies. (Food labels do not have to be included in the VQIP application.)
- FDA ordinarily will conduct a VQIP inspection after your application is approved and prior to October 1 of the first year that you participate in VQIP.

How often will FDA evaluate me for VQIP eligibility?

- The first year that you submit a VQIP application, FDA will review all aspects of your application and conduct an inspection to verify your eligibility. Thereafter, we will reevaluate your eligibility at least once every three years that you participate in VQIP.
- An event such as an outbreak or recall linked to a food included in your VQIP application (or a similar food), a new hazard associated with a VQIP food, or intelligence data related to violations associated with one or more entities (e.g., foreign supplier, filer/broker) listed on your VQIP application may prompt FDA to reevaluate your eligibility, including conducting an inspection, more frequently than once every three years.

What amendments am I permitted to make to my VQIP application for business purposes during the VQIP fiscal year?

As necessary for your business purposes, you can amend your VQIP application to:

- Add a food from a foreign supplier already in your VQIP;
- Remove a food, the foreign supplier of a food, or the FSVP or Juice or Seafood HACCP importer for a food;
- Replace a foreign supplier or FSVP or Juice or Seafood HACCP importer for a food that is already listed in your VQIP application as long as the foreign supplier has a current facility certification; and
- Add or remove a filer/broker.

Can the FDA revoke my participation in VQIP and how will I be notified?

- Yes. The FDA may:
 - Revoke your participation in VQIP based on evidence that you do not meet one or more of the VQIP eligibility requirements or

- Immediately revoke your participation in VQIP based on evidence that you participated in smuggling or other fraudulent activities.
- Revocation of your participation in VQIP will apply to all foods you import under VQIP.
- If the FDA has credible evidence that you do not meet one or more of the VQIP eligibility requirements, FDA will send a "Notice of Intent to Revoke" your participation in VQIP by email to the contact person identified in your VQIP application.
- The notice will explain the basis for the proposed revocation and indicate that, within 30 days, you would need to make corrections and provide the FDA with evidence of the corrections to avoid revocation.
- Benefits will continue for those 30 days unless the FDA believes there is a risk to public health.

Can I obtain reinstatement of my participation in VQIP after a revocation?

- When revocation is based upon evidence that you do not meet one or more of the VQIP eligibility requirements, you may ask the FDA to reinstate your VQIP participation and benefits at any time after you have corrected the issues associated with your revocation. Your request should include documentation of actions you have taken to correct or resolve all of the identified issues.

Blank Colored Insert-Front

Blank Colored Insert-Back

APPENDIX 10: FSVP Definitions and Acronyms

| Title of Document | Page |
|-------------------------------|-------------|
| FSVP Definitions and Acronyms | A10-3 |

Note: All definitions are found in the FSVP final rule unless otherwise stated.

FSVP Definitions and Acronyms:

Note: All are found in FSVP Final Rule unless otherwise stated.

Adequate¹: That which is needed to accomplish the intended purpose in keeping with good public health practice.

Adequately reduce microorganisms of public health significance²: Means reduce the presence of such microorganisms to an extent sufficient to prevent illness.

Allergen cross-contact³: The unintentional incorporation of a food allergen into a food.

Audit¹: The systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess an entity's food safety processes and procedures.

Biological soil amendment²: Any soil amendment containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination.

Covered activity²: Growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of "farm" as defined in 21 CFR §112.3. Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in 21 CFR §112.2(b) are also covered activities. This part does not apply to activities of a facility that are subject to 21 CFR part 110.

Covered produce²: Produce that is subject to the requirements of this part in accordance with §§112.1 and 112.2. The term "covered produce" refers to the harvestable or harvested part of the crop.

Dietary supplement⁴:

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

- (A) a vitamin;
- (B) a mineral;
- (C) an herb or other botanical;
- (D) an amino acid;
- (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that-

- (A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or (ii) complies with section 411(c)(1)(B)(ii);
- (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and
- (C) is labeled as a dietary supplement; and

(3) does-

(A) include an article that is approved as a new drug under section 505 or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f); and

(B) not include-

(i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262)

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under the Act.

Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of the Act.

Dietary supplement component¹: Any substance intended for use in the manufacture of a dietary supplement, including those that may not appear in the finished batch of the dietary supplement. Dietary supplement components include dietary ingredients (as described in section 201(ff) of the Federal Food, Drug, and Cosmetic Act) and other ingredients.

Environmental pathogen¹: means a pathogen that is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize or prevent the environmental pathogen. Examples of environmental pathogens for the purposes of this subpart include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeformers.

Facility¹: Means a domestic facility or foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR part 1, subpart H.

Farm⁵: Means:

(i) Primary production farm. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term "farm" includes operations that, in addition to these activities:

(A) Pack or hold raw agricultural commodities;

(B) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and

(C) Manufacture/process food, provided that:

(1) All food used in such activities is consumed on that farm or another farm under the same management; or

(2) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(i) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(ii) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(iii) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(ii) Secondary activities farm. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

Farm mixed-type facility¹: Means an establishment that is a farm but that also conducts activities outside the farm definition that require the establishment to be registered under section 415 of the Federal Food, Drug, and Cosmetic Act.

Food⁶: (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

Food contact surfaces²: Means those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food contact surfaces” includes food contact surfaces of equipment and tools used during harvest, packing and holding.

Foreign supplier¹: Means, for an article of food, the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a *de minimis* nature.

Good compliance standing with a foreign food safety authority¹: means that the foreign supplier—

(1) Appears on the current version of a list, issued by the food safety authority of the country in which the foreign supplier is located and which has regulatory oversight of the supplier, of food producers that are in good compliance standing with the food safety authority; or

(2) Has otherwise been designated by such food safety authority as being in good compliance standing.

GMPs (Good Manufacturing Practice) and Current Good Manufacturing Practice (CGMPs)⁷: The regulation (117 Subpart B) that outlines the conditions and practices the regulated food industry must follow for processing safe food under sanitary conditions, including personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, warehousing and distribution, and defect action levels considerations.

HACCP (Hazard Analysis and Critical Control Point)⁸: A system which identifies, evaluates, and controls hazards which are significant for food safety.

Harvesting¹: applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Hazard¹: means any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury.

Hazard analysis¹³: The process of gathering information on potential hazards in the food you plan to import and assessing the probability of their occurrence in the subject food and the severity of harm were the hazard to occur.

Hazard requiring a control¹: means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the probability that the hazard will occur in the absence of controls or measures and the severity of the illness or injury if the hazard were to occur), establish one or more controls or measures to significantly minimize or prevent the hazard in a food and components to manage those controls or measures (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the control or measure and its role in the facility's food safety system.

Holding¹: Means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Importer as defined in FSVP rule: The U.S. owner or consignee of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under 21 CFR §1.500 Subpart L.

Known or reasonably foreseeable hazard¹: A biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with a food or the facility in which it is manufactured/processed.

Lot¹: The food produced during a period of time and identified by an establishment's specific code.

Major Food Allergen¹⁴: The term "major food allergen" means any of the following:

(1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

(2) A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:

(A) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.

(B) A food ingredient that is exempt under paragraph (6) or (7) of section 343(w) of this title.

Manufacturing/processing¹: Means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extruding (of animal food), formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging, pasteurizing, peeling, pelleting (of animal food), rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms¹: Yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens.

Monitor²: To conduct a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and, when required, to produce an accurate record of the observation or measurement.

Packing¹: Placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen¹: A microorganism of public health significance.

Potable water⁹: Water that meets the standards for drinking purposes of the State or local authority having jurisdiction, or water that meets the standards prescribed by the U.S. Environmental Protection Agency's National Primary Drinking Water Regulations (40 CFR 141).

Preventive controls³: Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive controls qualified individual³: A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

 **Key Point:**

Each of the Preventive Controls rules contains two definitions pertaining to “qualified individuals.” One definition, i.e., the “preventive controls qualified individual (PCQI),” focuses on the requirement that a PCQI must successfully complete training under a standardized curriculum or have equivalent training to be considered a PCQI. The second definition in the PC rules, i.e., “qualified individual,” is similar to the QI definition in the FSVP rule, in that a QI must have the education, training, or experience to carry out the tasks for which he/she is responsible. **FSVP qualified individuals are not required to receive training under a standardized curriculum or equivalent training.**

Produce²: Any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

Qualified auditor¹: A person who is a qualified individual as defined in this section and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by §1.506(e)(1)(i) or §1.511(c)(5)(i)(A). Examples of potential qualified auditors include:

- (1) A government employee, including a foreign government employee; and
- (2) An audit agent of a certification body that is accredited in accordance with subpart M of this part.

Qualified individual:

- 1) **Definition from FSVP¹:** A person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under this subpart, and can read and understand the language of any records that the person must review in performing this activity. A qualified individual may be, but is not required to be, an employee of the importer. A government employee, including a foreign government employee, may be a qualified individual.
- 2) **Definition from PCHF Rule³:** A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

Qualified facility¹⁰: Means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

- (1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
- (2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

Raw agricultural commodity¹¹: Any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

Ready-to-eat food (RTE food)¹: Any food that is normally eaten in its raw state or any food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

Receiving facility¹: A facility that is subject to subpart C [Hazard Analysis and Risk-based Preventive Controls] and subpart G [Supply-Chain Program] of 21 CFR part 117, or subparts C [Hazard Analysis and Risk-Based Preventive Controls] and E [Supply-Chain Program] of 21 CFR part 507, and that manufactures/processes a raw material or ingredient that it receives from a supplier.

Risk¹²: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

U.S. owner or consignee¹: The person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.

Very small importer¹:

- (1) With respect to the importation of human food, an importer (including any subsidiaries and affiliates) averaging less than \$1 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of human food combined with the U.S. market value of human food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee); and
- (2) With respect to the importation of animal food, an importer (including any subsidiaries and affiliates) averaging less than \$2.5 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of animal food combined with the U.S. market value of animal food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee).

You¹: A person who is subject to some or all of the requirements in 21 CFR 1.500 Subpart L.

Source of Definition:

¹ Food and Drug Administration (FDA). 21 CFR 1.500

² FDA. Derived from 21 CFR 112.3 (c)

³ FDA. Derived from 21 CFR 117.3 Definitions

⁴ FDA. Section 201(ff) of the Federal Food, Drug and Cosmetic Act (FD&C Act)

⁵ FDA. Derived from 21 CFR 1.227

Appendix 10

⁶ FDA. Section 201 (f) of the FD&C Act

⁷ FDA. Derived from 21 CFR 117 Subpart B Current Good Manufacturing Practice

⁸ Food and Agriculture Organization/World Health Organization (FAO/WHO). 2003. General Principles on Food Hygiene. CAC/RCP 1-1969, Rev. 4-2003

⁹ National Primary Drinking Water Regulations (40 CFR 141)

¹⁰ FDA. Derived from 21 CFR 507.3 Definitions

¹¹ FDA. Section 201(r) of the FD&C Act

¹² FAO/WHO. 2014. Section IV. Risk Analysis, Codex Alimentarius Procedural Manual, 22nd Edition.

¹³ This is an FSVP definition developed by the FSVP Working Group.

¹⁴ FD&C Act, 201 qq.

