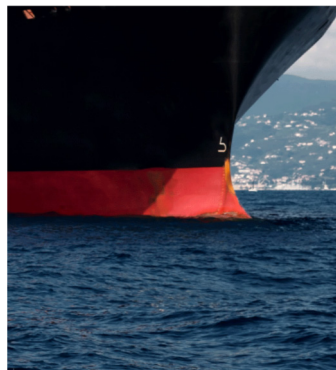
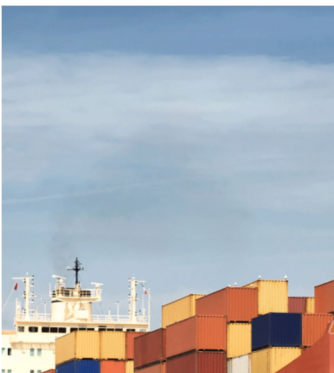


FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Foreign Supplier Verification Programs

First Edition – 2017



Participant Manual

FSPCA FOREIGN SUPPLIER VERIFICATION PROGRAMS *TRAINING CURRICULUM*

First Edition – 2017
(Version 1.0, January 2017)

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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.

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Developed by the



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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/>



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PREFACE. Introduction to the FSVP Course

Welcome and Introductions



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 foods, 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

- Introduce yourself to the group by providing your:
 - Name
 - Employer
 - 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 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.

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;
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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.

Food Safety Preventive Controls Alliance

- The FSPCA *Foreign Supplier Verification Programs (FSVP)* course was developed in consultation with FDA.
- 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 in consultation with FDA as part of the Food Safety Preventive Controls Alliance. 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.

In contrast to the Preventive Controls (PC) rules, the FSVP rule does not require you to attend a training program following “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. Because this course was developed in consultation with FDA, you can be assured that the content is consistent with the FSVP regulation. Note: The FSVP rule does require a “qualified individual” to perform required activities under the rule and specifies that a “qualified individual” as a person who has the education, training, or experience (or combination thereof) necessary to perform 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 the knowledge to implement 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 guidances 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 of 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 will be able to comply with the FSVP requirements.

Learning Objectives:

- By the end of this course, participants will be able to:
 1. Explain the underlying purpose(s) of FSVP rule.
 2. Develop an FSVP.
 3. Implement an FSVP.
 4. 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:
 - Preventive Controls (FSPCA courses, human and animal food, are available)
 - Produce Safety (PSA 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's Technical Assistance Network (TAN) is available to answer regulatory or rule interpretation questions. TAN can be accessed at: <http://www.fda.gov/fspa>

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.

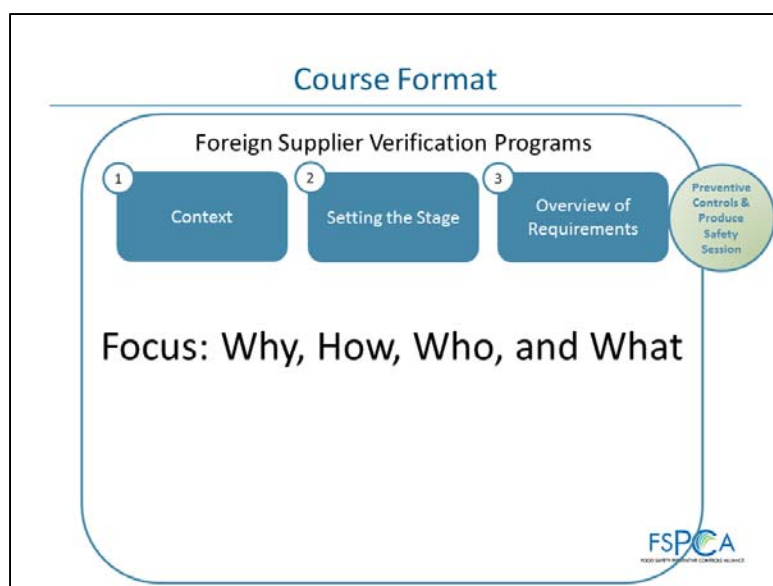
This course will not provide you with enough information to comply with the PC rules for either human food or animal food. If you must implement either or both of those two rules, you will need to take courses that teach those rules, as appropriate for your purposes. The same applies to the Produce Safety 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.

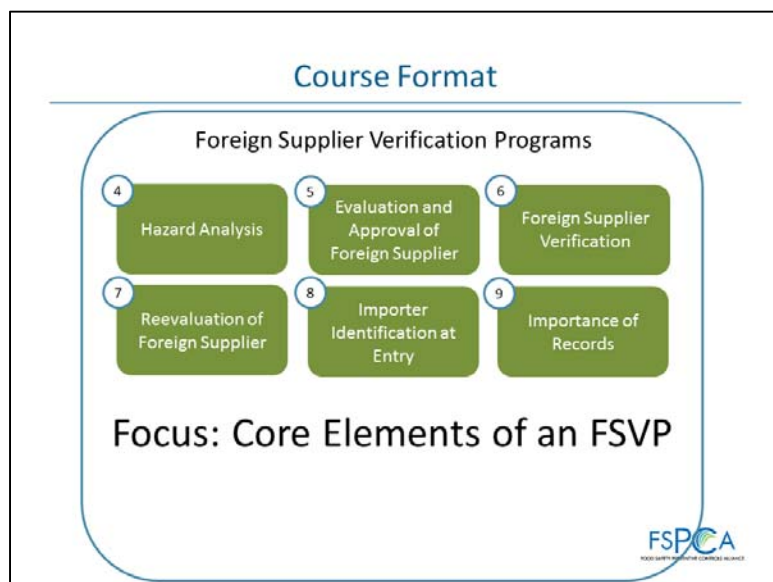
Course Format



The course is divided into 10 chapters, not including the Preface, Wrap-Up, 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.

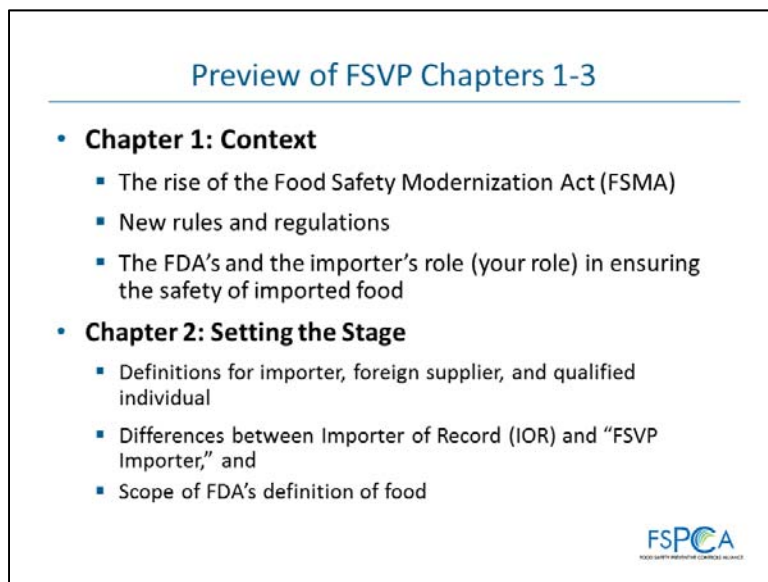


Chapters 4 through 9 focus on explaining the core elements of an FSVP, i.e., hazard analysis, evaluation and approval of foreign supplier, verification and corrective actions, reevaluation, importer identification at entry, and records and documentation.



And finally, Chapter 10 focuses on explaining FDA's oversight.

Preview of Chapters and FSVP Core Elements



Because many importers may not be very familiar with FDA's food regulatory role, U.S. food safety requirements and how they are enforced, or with the overarching goals of the FSMA law, chapter 1 will focus on helping you to understand some of the background and context for the FSVP rule.

From there, in Chapter 2, the course will begin building a foundation for the FSVP process by explaining the building blocks for creating an FSVP and will help you identify and define the role of each of the

players involved in developing your FSVP, i.e., FSVP importer, qualified individual, and your foreign supplier,

If you are contemplating whether or not you should be an FSVP importer or how you might be equipped to handle FSVP responsibilities, this course should help you to understand the basic concepts and how to carry out the steps of the FSVP process. You may use others to perform many FSVP activities on your behalf so long as you review and assess their activities, and document your review and assessment. Remember, however, that FDA will hold you, as the FSVP importer, accountable.

Grasping the concept of the FSVP importer as someone in the U.S. who has taken on the responsibilities of complying with the FSVP rule is the first step. The second concept is that you must have an FSVP for every food from every foreign supplier from whom you import. And a third important concept is that your FSVP is, in the majority of cases, founded upon the hazard analysis of the food.

Preview of FSVP Chapters 1-3 (continued)

Chapter 3: Overview of the Requirements

- General requirements
 - Make sure all FSVP steps are carried out by a **qualified individual**
- Standard requirements (hazard analysis, evaluation and approval of foreign supplier, verification activities and corrective actions, reevaluation, identification of importer at entry, recordkeeping)
- Exemptions from FSVP and modified requirements



Chapter 3 addresses the standard FSVP requirements that apply to most foods. There are also exemptions from FSVP, as well as some modified requirements that apply in certain circumstances.

Preview of the Preventive Controls (PC) and Produce Safety Session

- The PC and Produce Safety Session is intended as a timeout from FSVP instruction to briefly focus on the PC rules for human and animal food and the Produce Safety rules that your foreign suppliers may be subject to.



The PC and Produce Safety rules may apply to your foreign suppliers. This brief session is intended to be a supplement to the FSVP instruction that will focus on these other important FSMA rules, in particular, who must comply, and what are the requirements for compliance.

Preview of Chapters 4-9: FSVP Core Elements

- All of these requirements are FSVP core elements and will be presented in detail as we proceed through the course.
- A preview of the core elements are covered in the next few slides.



The requirements identified are important because the importer's process of addressing the FSVP required tasks, the records demonstrating how the requirements were addressed and the records of the importer's determinations make up the importer's FSVP. We will preview each of these core elements in the following slides.

Preview of Chapters 4-9: FSVP Core Elements (continued)

- **Chapter 4: Hazard Analysis:**
 1. Define hazards,
 2. Identify known or reasonably foreseeable hazards in the food being imported,
 3. Evaluate the food risk (probability and severity), and
 4. Determine if any hazards require controls.
- **Chapter 5: Evaluate and Approve Foreign Supplier(s)**
 - **Evaluate foreign supplier performance** – procedures, processes, compliance history.
 - **Approve foreign suppliers** before importing from them.



Chapters 4 through 9 focus on the FSVP standard requirements, or core elements, of an FSVP. Chapter 4, “Hazard Analysis” and Chapter 5, “Evaluate and Approve Foreign Supplier(s)” are the foundations for your FSVP. These steps, in fact, constitute your first verification of your foreign supplier to ensure that you are importing foods meeting U.S. standards for food safety.

Preview of Chapters 4-9: FSVP Core Elements (continued)

- **Chapter 6: Foreign Supplier Verification**
 - **Choose appropriate verification activities** and frequency, if needed.
 - **Apply verification activities.**
 - **Evaluate results of verification.**
 - **Take corrective actions**, if needed.
- **Chapter 7: Reevaluation of Food Risk and Foreign Supplier**
 - **Reevaluate FSVP**, at any time if changes or for cause, but at least every 3 years.



Chapters 6 and 7 focus on foreign supplier verification, corrective actions, if needed, and reevaluation of the foreign supplier.

Before you begin importing the food, you need an FSVP that includes:

1. The selection of one or more verification activities to ensure that the hazards are being controlled (discussed later);

2. A determination of how frequently the verification activities need to be conducted;
3. Taking corrective actions if the controls aren't working as they should; and
4. A reevaluation of your hazard analysis, your foreign supplier, and the other elements of your FSVP any time you have reason to believe a reevaluation is needed, and at least every three years.

Preview of Chapters 4-9: FSVP Core Elements (continued)

- **Chapter 8: Importer Identification at Entry**
 - The importance of identifying the importer at entry
 - Determining which entity will be the FSVP importer
 - Ensuring entry data identifies the designated FSVP importer
- **Chapter 9: Importance of Records:**
 - Recognizing the importance of records
 - Creating records to document your FSVP
 - Describing the requirements for record maintenance



Chapter 8 focuses on the importance of identifying the importer at entry. It will also explain the importance of determining which entity will be the FSVP importer, along with ensuring that entry data identifies the appropriate and designated FSVP importer.

Our next chapter, Chapter 9, focuses on the importance of records, creating records to document your FSVP, and describing the requirements for record maintenance.

Preview of Chapter 10: FSVP Oversight By FDA

- **Chapter 10: FDA Oversight:**
 - FDA inspection process, enforcement tools, consequences, and compliance dates



The final chapter in this course focuses on FDA oversight of FSVP importers and their implementation of the FSVP requirements. Chapter 10 describes the FDA inspection process, including how to prepare for an inspection, FDA's enforcement tools, consequences of not meeting requirements, and FSVP compliance dates.

Participation and Engagement

Participation and Engagement

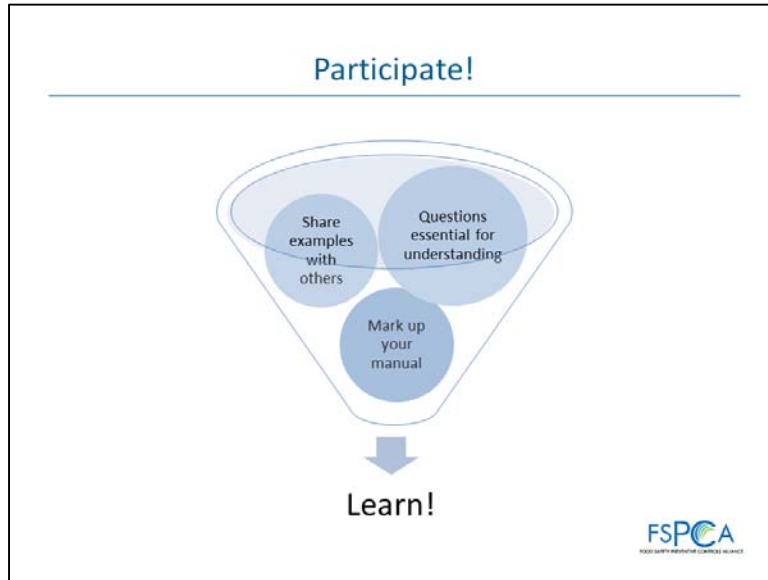
- We plan to keep you engaged by asking questions, presenting scenarios, and giving you exercises to supplement the course content.
- There will be time for questions at the end of every chapter. Raise your hand at anytime if you are lost or something does not make sense.
- Resources are listed in the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

How to Use This Training Manual


This manual is yours. Become familiar with it and use it as a reference. It 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.


As you learn more about developing an FSVP, there are many definitions that you need to understand. To assist you, the definitions of many commonly used terms are listed at the end of chapter 1. Refer to these pages as needed. You may also want to add other terms that you may need in developing and implementing your own FSVP.

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>



 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.

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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.

Key Point:

The FSVP rule is about ensuring that imported foods meet the same 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.

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.



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

- Establishing regulations and guidance to ensure that 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 establishing regulations and guidance to ensure that food is safe to eat, inspecting the food industry and food itself to ensure compliance with 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. standards. Traditionally, FDA has enforced these standards through inspection of facilities and collecting samples of human and animal foods, 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 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 cause:
 - 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.



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 foods 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.

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 foods from farm to fork:
 - Including fresh produce and processed food, and
 - Originating 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 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 foods 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.

What Are the Main FSMA Themes? (continued)

- The objective of FSMA is to ensure that U.S. consumers are not exposed to hazardous foods.
- FSMA gives FDA new tools to ensure parity between domestic and imported food with respect to food safety.



The objective of FSMA is to ensure that U.S. consumers are not exposed to avoidable food hazards, no matter where the foods are produced. 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

Rulemaking Process

- FDA publishes a proposed rule that invites public comments.
- In response to those comments, FDA sometimes publishes a supplemental proposal and invites additional public comments (as it did with the FSVP rule).
- FDA responds to the issues raised by the public comments in the preamble to the final rule(s).
 - **Final rule is then published in the Federal Register.**



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


Preventive Controls for Human Food Rule

- On September 17, 2015, FDA published the Preventive Controls rule (PC rule) for human food:
 - Part 117 – *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food*

Some of your foreign suppliers may be subject to this rule.





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

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 foods and the other for animal foods, 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**.

21 CFR Part 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

Preventive Controls for Animal Food Rule


- On September 17, 2015, FDA also published the Preventive Controls rule (PC rule) for animal food:
 - Part 507 – *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals*

Some of your foreign suppliers may be subject to this rule.



The PC rule for animal food is:



21 CFR Part 507 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

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

Produce Safety Rule

- On November 27, 2015, FDA published the final Produce Safety rule (PS rule):
 - Part 112 – *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*

Some of your foreign suppliers may be subject to this rule.



On November 27, 2015, FDA published the final Produce Safety rule setting requirements for good agricultural practices that **apply to foreign and domestic growers of produce, and others.**

21 CFR Part 112 – Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Foreign Supplier Verification Programs Rule

- On November 27, 2015 FDA, also published the final FSVP rule:
 - Part 1 – *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



FSPCA
FOOD SAFETY PROMOTION CENTER ALLIANCE

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 Part 1, 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 74226) 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. Until FDA issues further guidance on the FSVP rule, the Preamble to the final rule is the best guidance you have at this time. It will be referenced frequently as we go through this course. A copy of the Federal Register FSVP rule can be found in Appendix 1 of this manual.

Because complying with FSVP requirements requires some understanding of the PC rules and the Produce Safety rule, this course provides brief information about these other rules. Separate, multi-day standardized courses on each of those other rules are also being offered for those who want a more detailed understanding of those rules.

As required, FDA published the FSVP proposed rule on July 29, 2013, and published a supplemental notice of proposed rulemaking on September 29, 2014. 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. With FSVP, there were two opportunities for comment.

 A copy of the Federal Register FSVP rule can be found in Appendix 1 of this manual.

 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.

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 U.S. safety standards.



As stated in the previous slide, FSMA affects the food supply chain. Both foreign and domestic manufacturers/processors, packers, and holders of foods now must analyze whether **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.

FDA FSMA Authorities

FDA 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 food facility when certain statutory criteria are met related to the risk of the food



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 can 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.

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 rule will be phased in, FDA will continue to take action to protect U.S. consumers from unsafe food.


FOOD SAFETY PROGRAMS COORDINATED BY FDA

As 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

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.

FSMA Creates New Role for Food Importers

FSMA Creates New Role for Food Importers

- U.S. importers of foods play a vital role in ensuring that their 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, U.S. importers of food now need to verify that their foreign suppliers of human and animal foods are meeting their obligation to produce food that meets the level of U.S. public health protection.

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.



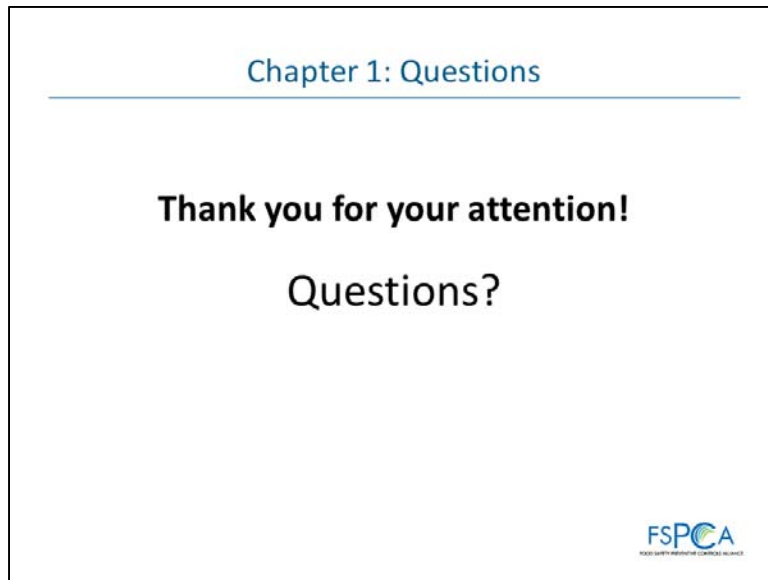
In this chapter, we have covered:

- 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

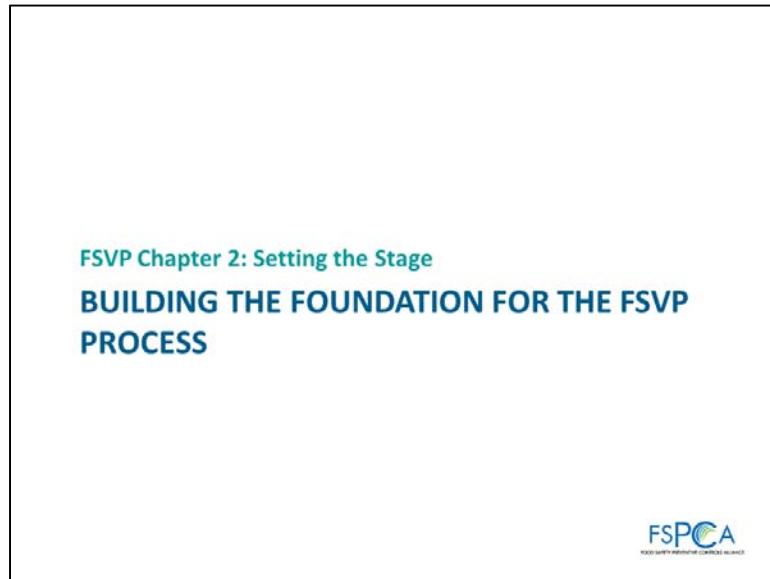


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CHAPTER 2. Setting the Stage



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 an FSVP “qualified individual.” 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.

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.

Americans consume a large amount of imported food. According to FDA, 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 (2013 statistics USDA, Economic Research Service).

Purposes of FSVPs

Purposes 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 (*as to allergen labeling, human food only*).



This slide shows the main purposes 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 safety problems from imported food.

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...”



See the 21 CFR Part 1, Subpart L, 1.500 Definitions for FSVP “importer”

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, once the FSVP rule is in effect 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.**

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.

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.
- 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 may wish to make arrangements to ensure that there will be no unknowns, mistakes, or fraudulent entry of an FSVP importer’s identity on U.S. Customs entry documentation. 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.

Importer of Record vs. FSVP Importer

Importer of Record vs. FSVP Importer

- A key difference between the FSVP “*importer*” as defined by FDA in the FSVP rule and the “importer of record” (IOR) as defined by 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).
- Whoever is the FSVP importer, that person is 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” under U.S. Customs and Border Protection (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 importer of record.**

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 U.S. Customs entry forms. Further, the rule provides the flexibility for figuring this out.

In other words, the rule does not necessarily foresee only one “correct” party as the FSVP importer. Instead, it 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:

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."
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. The retailer is not the FSVP importer if the other firm owns the product when offered for entry. If the retailer has agreed in writing to purchase the food at the time of entry, the retailer could **also** be the FSVP "importer."

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.

"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. Nevertheless, 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?

See the 21 CFR Part 1, Subpart L, 1.500 Definitions for FSVP “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**.”
 - 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.

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 aren't 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.


FOOD SAFETY PRACTICES AND CERTIFICATION ASSOCIATION

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 and conveyer belts that contact food in food processing facilities, 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 or certain processed egg products, regulated by the U.S. Department of Agriculture (USDA).
- The requirements discussed in this course apply to human and animal foods 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)). 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: Questions

Chapter 2: Questions

Thank you for Your Attention!

Questions?



Notes:

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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 countries that FDA recognizes as having equivalent or comparable food safety systems or food from certain small foreign suppliers.

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.

It should be noted that while this course does not include specifics on 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 has been provided in Appendix 4.


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. Describe 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 entry documents. 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 FDA rules for risk-based preventive controls or produce safety, if either is 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.



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 of foods produced in the U.S. It is important, therefore, that you develop an FSVP that provides assurance that your foreign supplier is producing food that provides at least the same level of public health protection as required under the risk-based Preventive Controls (PC) rules or the Produce Safety rule, if either is applicable, (21 CFR 1.502(a)). It is important to understand as an

The Preventive Controls (PC) rules (human and animal) 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)

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

“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>

importer that—even if the food you import is exempted from FSVP and you may not need to declare an FSVP importer on the Customs entry filing—the food is still required to meet U.S. food safety standards.

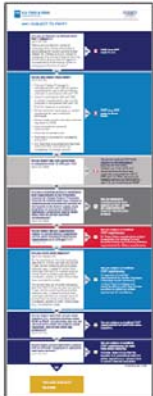
Your foreign supplier also must produce the food in compliance with sections 402 (regarding adulteration) and 403(w) (regarding labeling human food for the presence of major food allergens) of the FD&C Act (21 CFR 1.502(a)). These refer to public health provisions that were in existence long before FSMA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

- FDA has provided a flowchart that helps you determine whether or not you are subject to the FSVP rule.
- We will be going through this flowchart at the end of this chapter as an exercise.
- The small version of the flowchart is available in Appendix 7 of this manual.
- The full version is available on FDA's website at:
<http://www.fda.gov/downloads/food/guidanceregulation/fsma/ucm472461.pdf>



FDA has provided a flowchart on their website that helps you determine whether or not you are subject to FSVP. We will be going through this flowchart step-by-step near the end of this chapter. We have also provided a small version of the flowchart in Appendix 7 of this manual. The full version can be downloaded from FDA's website at:

<http://www.fda.gov/downloads/food/guidanceregulation/fsma/ucm472461.pdf>

Does FSVP Apply to My Situation? (continued)

- 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 foods 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.

Foods that Are Exempted?

The Question Is...


What foods are exempted?



Exempted Foods

Exempted Foods

- Foods under FDA Hazard Analysis Critical Control Points (HACCP) rules
- Alcoholic beverages (certain conditions)
- Foods not intended for sale or distribution in the U.S.
- Certain meat, poultry, and processed egg products (products subject to Federal Meat Inspection, Poultry Products Inspection, and Egg Products Inspection Acts)
- 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**.



A food safety control system focused on preventing foodborne illness was developed several decades ago, and called Hazard Analysis Critical Control Points (HACCP). This system was originally developed to ensure that food consumed by astronauts in space was as safe as it could be. For a number of reasons, FDA established regulations to require that this system be applied to certain foods where it was considered necessary. These regulations apply to juice and seafood.

Foods complying with the FDA HACCP rules for juice (21 CFR Part 120) and seafood (21 CFR Part 123) are exempt from FSVP because they are already subject to preventive controls in the form of the HACCP requirements (21 CFR 1.501(b)).


Importers of raw materials and 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 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 is required to register under Sec. 415
 - Foreign facility is same type of facility as those regulated by Department of Treasury in the U.S.
- 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 being imported for manufacture into alcoholic beverages.
- Same exemption exists for domestically produced alcoholic beverages in the Preventive Controls (PC) 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.,
3. 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.
4. Additionally, the exemption applies to raw materials and 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 ingredients being imported for manufacture into alcoholic beverages.

While not specifically covered in this course, note that importers of dietary supplements and dietary supplement components are NOT EXEMPT from FSVP requirements. It is significant, however, that importers of these substances are not required to perform a hazard analysis (see Appendix 4). The differences in FSVP requirements for dietary supplements and dietary supplement components are explained in Appendix 4 of this course.

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

**Foods Not Intended for Sale
or Distribution in the U.S.**

- The following foods are **exempted because they aren't intended for sale or distribution in the U.S.:**
 - Food imported for research or evaluation (subject to certain requirements)
 - Food imported for personal consumption
 - Food that is transshipped through the U.S. or imported for further processing and export (no distribution in the U.S.)


Food Safety and Inspection Service

The FSVP rule applies to food that is sold for sale or distribution to the public in the U.S. 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 falling under USDA jurisdiction:
 - 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 USDA jurisdiction, such as certain meats and poultry and processed egg products are exempt from the FSVP rule. These account for about 20% of the foods consumed in the U.S.

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 are not being imported by intention
- 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. 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

Low-Acid Canned Foods

- An importer of low-acid canned foods (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 other hazards, 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.



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 microbiological provisions of the LACF rule must still have an FSVP for all other hazards.

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 a processor/manufacturer subject to **and** in compliance with the PC rules,
 - You are required to employ supply chain preventive controls, as appropriate.
 - You do not also have to carry out FSVP requirements.
- **However, as the importer:**
 - You must be named on the 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 that, if you are a manufacturer/processor who is in compliance with the supply chain provisions of the PC rules, you are deemed to be in compliance with FSVP requirements for the food you import.

You as the importer must, however, be named on the Customs and Border Protection (CBP) entry form 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 reason to).
- **Identify the FSVP importer** at entry.
- Keep required **records and documentation**.



FOOD SAFETY PREVENTION CONTROL ALLIANCE

The FSVP standard requirements are the same as outlined in Chapters 4 through 9. We will briefly talk about them in the next few slides, but will go into more detail in Chapters 4 through 9.

Hazard Analysis

Hazard Analysis

- You must identify and evaluate known or reasonably foreseeable hazards to determine if they require a control, including:
 - Biological, chemical (including radiological), and physical hazards
 - Naturally occurring, unintentionally introduced, or intentionally introduced for economic gain
- You may rely on another's hazard analysis, **but it must be reviewed by a qualified individual you employ or have retained.**


FOOD SAFETY PREVENTION CONTROL ALLIANCE

A food hazard is something in the food that could cause illness or injury to humans or animals that eat the food. The first step in the FSVP process is to evaluate known or reasonably foreseeable hazards for the food being imported to determine if each of the potential hazards require a control(s). Importers are required to identify and evaluate (based on experience, illness data, scientific reports, and

other information) the hazards for each type of food they import to determine if there are any hazards requiring a control. It is important to note that **the hazards identified should be “known or reasonably foreseeable hazards,” not something that would be highly unusual.**

Hazards can be biological, chemical (including radiological), and physical, such as broken glass. Chemical hazards in human food include major food allergens that are not declared on food labels. Also, hazards reasonably likely to cause illness or injury can be naturally occurring (e.g., fungal toxins), unintentionally introduced, or intentionally introduced for economic gain (economic fraud).

The U.S. importer must use a qualified individual to evaluate the hazards. That qualified individual may or may not be an employee of the importer. As an alternative, the importer can rely on someone else’s hazard analysis of the foreign supplier’s food, including an analysis performed by the foreign supplier’s qualified individual, so long as the importer’s qualified individual has also assessed the hazard analysis and finds it adequate.

Foreign Supplier Performance Evaluation

Foreign Supplier Performance Evaluation

- The evaluation of your foreign supplier’s performance must include:
 - Procedures, processes, and practices related to food safety.
 - FDA food safety regulations and supplier compliance.
 - Supplier’s food safety history.
 - Other relevant factors such as storage and transportation practices.



The hazard analysis has identified known or reasonably foreseeable hazards, assessing both a) the probability that any of these hazards will occur in the absence of controls and b) the severity of the illness or injury that could occur if the hazards are not controlled. Thus, the first emphasis is on considering the risk posed by the food itself and whether any hazard requires a control.

In addition, the importer must evaluate supplier performance. Evaluating foreign supplier performance means examining their procedures, processes, and practices related to food safety, looking

into their compliance history with FDA food safety regulations, their food safety history and any other relevant factors such as storage or transportation practices. We will cover how to do this in later chapters.

In performing these evaluations of the food and foreign supplier, the importer must also consider the entity that will be significantly minimizing or preventing the hazards identified by the hazard analysis, such as the foreign supplier or the supplier's raw material or ingredient supplier, or perhaps a customer further down the line and located in the U.S. These are the entities that are controlling the identified hazards and actually verifying their control.

Approval of Foreign Suppliers

Approval of Foreign Suppliers

- You must approve foreign suppliers **before** importing food from them.
- Supplier approval is based on:
 - Evaluation of the risk posed by the food (hazard analyses findings)
 - Who is controlling the hazards
 - Evaluation of foreign supplier performance
 - Other relevant factors
- Unapproved suppliers may be used on a temporary basis, when necessary, if the food is subjected to adequate verification activities before importation.



Importers must approve their foreign suppliers. This must be done **before** importing food from them. The approval should be based on an evaluation of the risk posed by the food, i.e., the hazard analyses findings, who is controlling the hazards, and evaluation of foreign supplier performance, and other relevant factors. Importers also must have written procedures to ensure that only approved foreign suppliers are used to import food.

Unapproved suppliers may be used on a temporary basis, when necessary, but only if the food is subjected to adequate verification activities before importation. More will be said on this later in the course.

Determine Appropriate Verification Activities

Determine Appropriate Verification Activities

- If a known or reasonably foreseeable hazard needing a control is identified through the hazard analysis and foreign supplier performance evaluation, then
 - **Appropriate verification activities must be determined.**
- Food importers need to establish written procedures for conducting verification activities.
- FDA specifies what it considers to be acceptable verification activities in the FSVP rule.



It should be stressed that an importer must conduct an evaluation of the foreign supplier's performance and risk posed by a food to both **approve** the foreign supplier and **determine appropriate foreign supplier verification activities**. You must determine the appropriate verification activities and the frequency of those activities, based on your food and supplier evaluations. Food importers need to have **written procedures** for conducting their verification activities.


The FSVP rule provides importers with the flexibility to tailor supplier verification activities to their particular food risks and supplier characteristics. FDA has identified several acceptable types of verification activities, but FDA allows you the flexibility to use one or more of these acceptable types or to design your own based on your evaluations.

Importantly, importers can rely on another entity (other than the foreign supplier) to determine appropriate supplier verification activities, so long as the importer uses a qualified individual to review and assess the relevant documentation prepared by that entity's qualified individual.

Types of Verification Activities

Types of Verification Activities

- Acceptable verification activities may be one or more of the following:
 - Annual onsite auditing
 - Sampling and testing
 - Review of supplier records
 - Other appropriate measures
- Annual onsite auditing is the default approach when a food has a **SAH**azard **C**onsequences **O**r **D**eath to **H**umans or **A**nimals hazard (Serious Adverse Health Consequences Or Death to Humans or Animals).



FDA has identified four types of supplier verification activities that are acceptable. They are:

1. Onsite auditing,
2. Sampling and testing,
3. Review of supplier records, and
4. Other appropriate measures.

Annual on-site audits of the supplier's facility are the default option when there is a reasonable probability that exposure to a food hazard controlled by the foreign supplier will result in **Serious Adverse Health Consequences Or Death to Humans or Animals** (identified by FDA as a **SAH**azard **C**onsequences **O**r **D**eath to **H**umans or **A**nimals hazard). The importer may, however, choose another means of verification or frequency of audits if 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.

Conducting Verification Activities

Conducting Verification Activities

- Verification activities you have determined to be appropriate must be:
 - Properly conducted and documented.
- Whether you, as the importer, or someone else carries out the verification procedures, they must be:
 - Conducted by a **qualified individual (QI)**.



Conducting your chosen verification activities properly is essential to ensure that the food you import is made using processes and procedures that provide the same level of public health protection that is required of foods that are sold in the U.S. Furthermore, it is important for you to document the performance of the verification activities.

FDA does allow you the flexibility to perform the verification activities yourself, or to rely on someone else to perform the verification activities. It is critical, however, that the persons conducting verification activities be qualified to conduct those activities.

Conducting Verification Activities (continued)

- Whoever conducts the verification activities, your **qualified individual** must review and assess the results:
 - For adequacy, and
 - To determine if any corrective actions are needed.
- Remember to document your review and assessment.




If you are relying on someone else, your qualified individual must review the results of the verification activities to be sure they are adequate. This review also needs to be documented.

Corrective Actions and Reevaluations

Corrective Actions and Reevaluations

- If your verification review indicates that the food is being produced, grown, stored, transported or otherwise in a manner that jeopardizes food safety,
 - You must take appropriate corrective actions.
 - You will need to reevaluate your entire FSVP for that food and foreign supplier, unless your corrective action is to discontinue using that supplier.
- Your FSVP must be reevaluated whenever you:
 - Become aware of a problem or change with the imported food and/or foreign supplier, **but**
 - At least every 3 years.
- Corrective actions and FSVP reevaluations **must be documented.**



As a result of your verification activities you may discover that your foreign supplier is not properly controlling the hazards that have been identified. If this happens, you are required to correct the deficiency. You may also have to take steps to protect consumers, such as preventing distribution of or recalling the food.

Sometimes a simple corrective action may be sufficient. Depending on the situation, however, it may be necessary for you to reevaluate your entire FSVP for that food and foreign supplier. You may find that you need to discontinue importing food from the particular foreign supplier.

Even if everything is going well, you will need to reevaluate your FSVP at least every three years. If you discover a major change in the way your supplier is operating, or if you discover a food safety problem, you need to reevaluate your FSVP **promptly** when you make your discovery.

Creating and Maintaining Records

Creating and Maintaining Records

- All documentation required by the FSVP rule must be:
 - Complete,
 - Kept for at least two years, and
 - Made available to FDA upon request.
- Later chapters will get into greater detail about topics introduced in this chapter.



As with other FSVP requirements, the corrective actions you take and your reevaluations of your FSVP must be documented at the time of your actions or reevaluations. As will be further discussed later in this course, all your records must be kept for at least two years, and they must be made available to FDA for inspection and copying upon request. FDA may also ask you to send records to the Agency electronically or through other prompt means.

Reliance on Others

Reliance on Others

- You, as the importer, are responsible for meeting all FSVP requirements.
- FDA does allow you the flexibility of relying on others to perform FSVP functions (e.g., hazard analysis and supplier verification) if your **qualified individual** reviews and assesses the performance of those functions.
- You must, however, document that those functions were carried out by **qualified individuals**, and that the work was assessed by your **qualified individual**.



Although FDA allows you flexibility to rely on others to conduct FSVP functions (including your hazard analysis and your supplier

verification activities), your qualified individual must review and assess the performance of those functions and document that review. Remember, however, that FDA will hold you, as the importer, responsible for meeting all FSVP requirements.

You must document that those you relied upon are qualified individuals to perform the required functions. You must also document that the work was reviewed and evaluated by your qualified individual.


Although the FSVP importer can rely on other entities to carry out many FSVP tasks, the FSVP importer must “approve” its own foreign suppliers, and have written procedures to ensure that you import foods only from approved suppliers. More will be said on supplier approval in a later chapter.

If you go to Appendix 3, Workaid C in your manual, you will see the “Summary of FSVP Process Requirements.” This summary covers the steps we just went over in this presentation 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” or “equivalent”
- If you import dietary supplements or dietary supplement components (see Appendix 4)



Generally, modified FSVP requirements are aimed at smaller entities or products falling under a discrete or distinctive 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. Modified requirements also apply if you are importing certain foods from certain small foreign suppliers (21 CFR 1.512(a)). Modified

requirements also apply if the food you are importing is from foreign supplier(s) in countries with food safety systems recognized by FDA as “comparable” or “equivalent.” And finally, modified requirements apply if you import dietary supplements or dietary supplement components (*see Appendix 4 for more information on dietary supplements and Appendix 5 for more information on Modified Requirements overall*).

We will cover the first three situations in more detail in the next few slides.

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. (animal food 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 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 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. More information regarding “Very Small Importers” is available in Appendix 5.

“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., < \$25,000 U.S. average produce sales) or satisfies the **Produce Safety Rule** requirements for a “qualified exemption.”
 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, less than \$25,000 U.S. average produce sales adjusted for inflation) or satisfies the PSR requirements for a “qualified exemption” (21 CFR 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 are explained in more detail in Appendix 5.

When Food is Produced Under a Safety System Recognized by FDA

When Food is Produced Under a Safety System Recognized by FDA

- If you import certain foods from a foreign supplier in a country whose food safety system FDA has a systems recognition arrangement or equivalency agreement, your requirements can be reduced if:
 - Your supplier is under the regulatory oversight of that food safety authority;
 - The food is within the scope of the systems recognition arrangement or equivalency agreement; and
 - The supplier must be in good standing.
- If these conditions are met, you are not required to:
 - 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. We have already mentioned that currently New Zealand and Canada's systems have been found equivalent, and other systems recognitions are in process. Information on the 2016 Canada recognition with links to the evaluation process can be found on the FDA website at: <http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm498611.htm>.

If FDA officially determines that another country's food safety system is comparable or equivalent to the U.S. food safety system, 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 a small 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 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 on U.S. Customs documents at entry.
- Note: This provision **ONLY** applies 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 maintains records relative to all FSVP activities.

You must also identify yourself as the FSVP importer on U.S. Customs documents at entry and maintain records relative to all FSVP activities. Remember, whoever is identified on the Customs forms 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 need to comply with the PC rules 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.

More information on “Food from a Recognized System” is available in Appendix 5.

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 in order 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, 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 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.



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:
 - 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. anticipates 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
- We have covered the basic information needed for proceeding through the FDA-developed questions and answers about the FSVP rule.



This following review was developed by FDA 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.

Review: Questions About FSVP Requirements (continued)

- We will go through each question together.
- Follow along in your manual to:
 - Determine how each question applies to you as an importer of a particular food product from a particular foreign supplier.



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 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.
- **YES:** Continue to the next slide.



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.

YES: Continue to the next slide.


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. U.S. food that had been **exported and returned** without further manufacturing/processing in a foreign country

If your answer is:

- **YES:** FSVP does not apply to you.
- **NO:** Continue to the next slide.



6. Food imported for personal consumption
7. Food that is transshipped
8. Food that is imported for processing and export
9. U.S. food that is exported and returned without further manufacturing

If your answer is:

YES: FSVP does not apply to you.

NO: Continue to the next slide.

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 slide.



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: You continue to the next slide.


Question 4

Question 4

- Are you a receiving facility (i.e., you are both the FSVP importer and 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 [§ 117.135 or § 507.34](#);
 - (2) You are not required to implement a preventive controls under [§ 117.136 or § 507.36 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 with respect to the food](#).

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 slide.


FOOD SAFETY PROMOTION COUNCIL OF AMERICA

Are you a receiving facility (i.e., you are both the FSVP importer and 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 [§ 117.135 or § 507.34](#):

(2) You are not required to implement a preventive controls under [§ 117.136 or § 507.36 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 with respect to the food](#).

If your answer is:

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

No: You continue to the next slide.

Question 5

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 slide.



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

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 slide.

Question 6

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.

For more information on modified requirements see Appendix 5: Modified Requirements.

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)

(Continued on next slide)



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 slide.



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 slide.


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)?

If your answer is:

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


Food Safety Partnership Center

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 small suppliers?

If your answer is:

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

NO: Continue to the next slide.

Question 8

Question 8

- Do you import food from a country that is officially recognized by FDA as having a food safety system that is comparable or equivalent to the U.S. food safety system?

If your answer is:

- **YES:** You are subject to modified FSVP requirements for food from those countries. (Includes determining that the food is covered under the official recognition and that the supplier is in good standing with the relevant food safety authority(ies) in that country).
- **NO:** Continue to the next slide.



Do you import food from a country that is officially recognized by FDA as having a food safety system that is comparable or equivalent to the U.S. food safety system? (See 21 CFR 1.513)

We note that currently there are only two countries that have been officially recognized by FDA and those are New Zealand and Canada, in 2012 and 2016, respectively. A system recognition process is currently underway between FDA and Australia and the European Commission.

If your answer is:

YES: You are subject to modified FSVP requirements for food from those countries. (Includes determining that the supplier is in good standing with the food safety authorities in that country).


NO: Continue to the next slide.

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 provoke some clarity on your particular situation or a host of questions. Either is possible and okay at this stage.

Chapter 3: Summary

Chapter 3: Summary

- This chapter covered:
 - Which food imports are exempt.
 - An overview of the standard requirements.
 - Who is eligible for modified requirements.
 - The importance of communication within your supply chain.

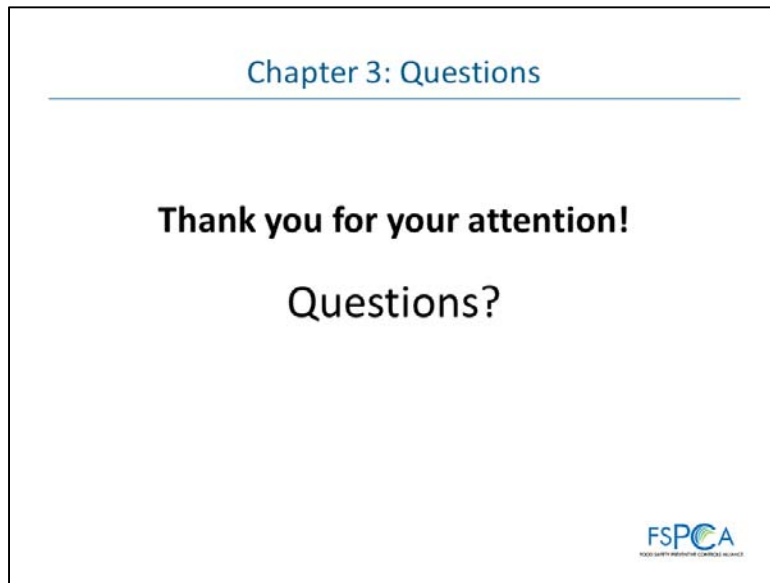


You now have a basic understanding of the FSVP requirements, including:

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

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

Chapter 3: Questions



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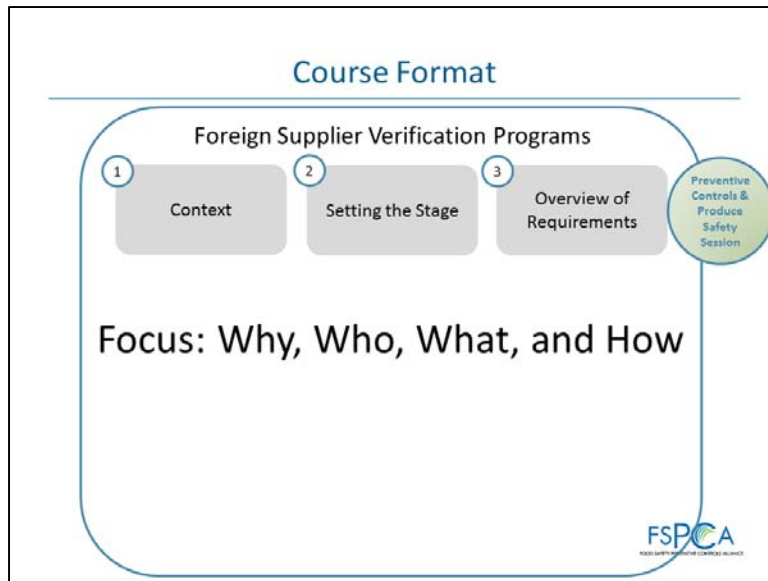
Preventive Controls and Produce Safety Session

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.



The Preventive Controls (PC) and Produce Safety Session is a summary of 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 and PC rule for human food or just PC rule for human food), FDA's standards for the *Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Animal Food* regulation (referred to as the CGMP and PC rule for animal food or PC rule for animal food), and FDA's standard for the *Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* rule (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 (CGMPs) and PC rules for human and animal food.
 2. Explain the key requirements of the CGMPs and 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 sale and consumption in the U.S.

Who Must Comply with CGMP and PC Rules?


Who Must Comply with CGMP and 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.

PC for Human Food Rule Key Requirements

 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

- The main focus of the PC rule for human food is that 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 CGMPs for many years. These practices are included in the PC rule for human food as basic prerequisite requirements for producing safe food. Preventive controls, however, are designed to prevent or substantially minimize 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 procedures. 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, a written supply-chain program, as required by subpart G of the PC rule, will be required. Supply chain preventive controls are referenced frequently in this FSVP course. Facilities with preventive controls must also have a recall plan to ensure that, if 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:
 - Current Good Manufacturing Practice (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>



📖 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 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.

PC rule for animal food follows the same structure as PC rule for human food. There are differences, however. First and foremost is that application of CGMPs 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?

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.

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.

The term “farm” includes operations that, in addition to these activities:

(A) Pack or hold raw agricultural commodities (RAC). 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 an 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, packaging and labeling. Treatment to manipulate the ripening of RACs (such as by treating produce with ethylene gas) 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).

If an operation performs manufacturing or processing beyond these limited examples, it may still be considered a farm if 1) it is a very small operation (<US\$250,000 average annual produce sales) AND 2) if the manufacturing/processing is limited to activities listed in the rule from which very small farms are exempted.

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. 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 rule.

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 very small farm or farm mixed-type facility with less than \$25,000 average annual sales of produce
- Produce that is rarely consumed raw (exhaustive list)
- 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 very small farm or farm mixed-type facility with less than \$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 defined 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. FSMA defined 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, such as by thermal processing sufficient to make the product shelf-stable 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.” The farm must also annually obtain written assurance from the customer that either the customer has established and is following procedures (identified in the written assurance) that adequately reduce the presence of microorganisms of public health significance; or that an entity in the distribution chain subsequent to the customer will perform the commercial processing. If the latter, the customer must also disclose in documents accompanying the food to their customer that the food is “not processed to adequately reduce the presence of microorganisms of public health significance” and will only sell to another entity that agrees, in writing, it will either perform the necessary commercial processing, or continue to disclose, with each shipment, that the food has not been processed and annually obtain

written assurance, as described above. This chain of disclosure and written assurance must continue until the produce reaches the entity that performs the commercial processing.

The Produce Safety rule does not apply to produce that is not an RAC (e.g., has been fresh-cut or otherwise manufactured/processed into a product that is not an RAC) and does not apply to RACs packed at a facility that is not a 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.


Produce Safety Rule Key Requirements

What Is Required by the Produce Safety Rule?

Hazards to be Controlled

- Microbiological hazards from:
 - **Agricultural water** that contacts produce (irrigation, crop chemicals, washing) or food contact surfaces (including hands)
 - **Domesticated and wild animals** and their excreta that may come into contact with produce
 - **Biological soil amendment of animal origin (manure)** that may reasonably come into contact with produce
 - **Health and hygiene of workers** that contact produce (harvesters, sorters, packers)
 - **Equipment, tools, buildings and sanitation** (tools, utensils, containers, equipment)
 - **Growing, harvesting, packing, and holding activities** that may reasonably be a source of contamination



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

For the Produce Safety rule, FDA specifically defined hazard as any biological agent that has the potential to cause illness or injury in the absence of its control. They concluded that physical hazards that can cause injury and chemical hazards, such as from crop protection chemicals, are not reasonably likely to occur in RACs grown and harvested in the U.S., citing an analysis of scientific literature and recall data that led them to conclude that non-biological hazards associated with produce rarely pose a risk of serious adverse health consequences or death for individuals that would consume the product. Therefore, the rule focuses on potential microbiological hazards.


FDA identified the 6 most likely sources of microbiological hazards on farms as agricultural water; domesticated and wild animals; biological soil amendments of animal origin; health and hygiene of workers; equipment, tools, buildings and sanitation; and growing, harvesting, packing, and holding activities that may reasonably be a

source of contamination. 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 any of these rules:
 - PC for Human Food
 - PC for Animal Food
 - Produce Safety
 - Other
- If your foreign supplier is required to comply, you must evaluate them and perform verification activities to assure that they are in compliance with FDA requirements.



As stated earlier, this brief session is intended to let you know something about the rules that your foreign suppliers are supposed to follow to ensure the food intended for U.S. consumers 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.

PC and Produce 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.

PC and Produce Session: Questions

Preventive Controls and Produce Safety Session: Questions

Thank you for your attention!

Questions?



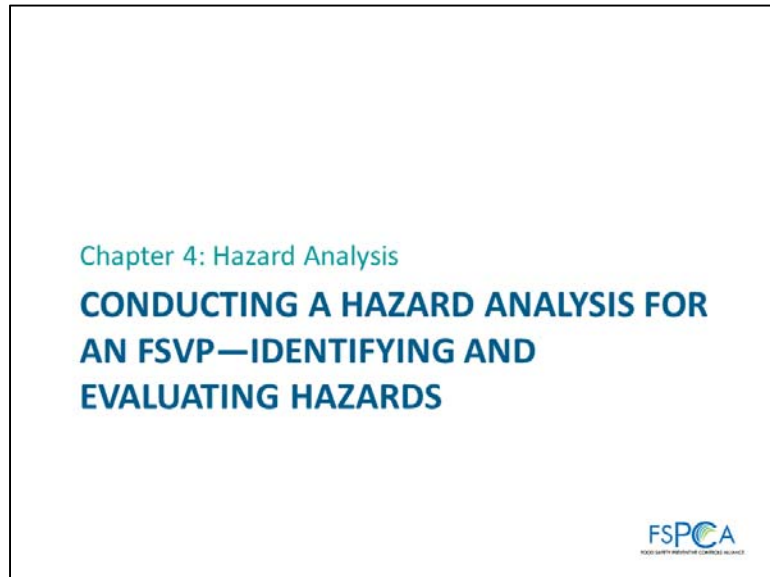
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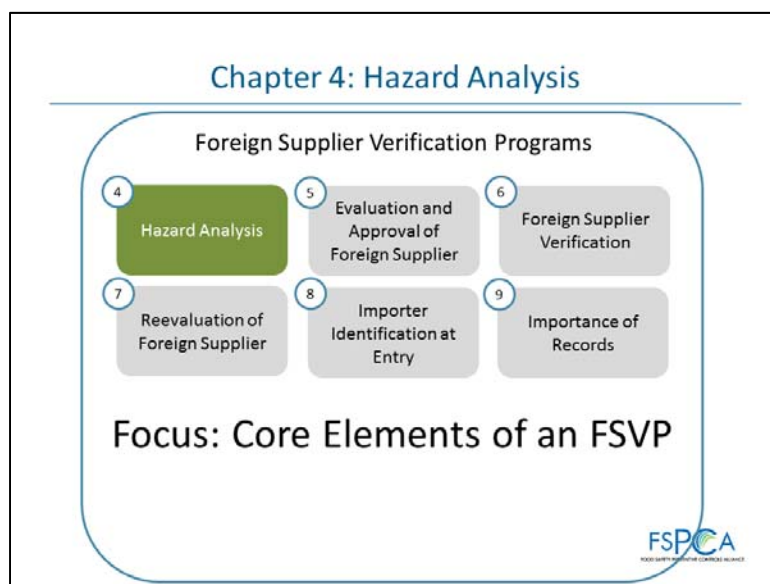
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CHAPTER 4. Hazard Analysis



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 of an FSVP and it is the first major task to be performed under the FSVP rule.


Chapter 4: Goals 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.”



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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 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.*

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.” (21 CFR 117.3)

*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.



Note: Dangerously high or low amounts of required nutrients in human or animal foods intended as a sole source of nutrition may also constitute “hazards,” e.g., animal food and infant formula.


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When hazards are not 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, “Focused Mitigation Strategies to Protect Food Against Intentional Adulteration” that was published in the Federal Register of May 27, 2016 (81 FR 34166).

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 Hazard

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)

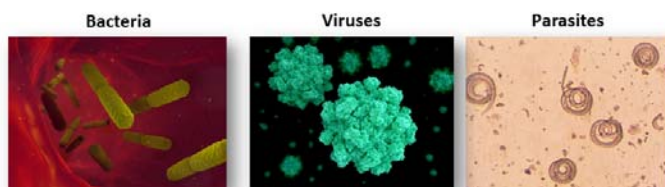


“Known or reasonably foreseeable hazards” are NOT hazards that are extremely rare or essentially unknown for the food being imported. There should be some history or known occurrence of the hazard occurring in the subject food or a similar food, or a good reason to believe the hazard could occur. Thus, 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)):

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,
- Food allergens in human food, and
- Deficient levels of nutrients (for animal, medical, or infant foods)

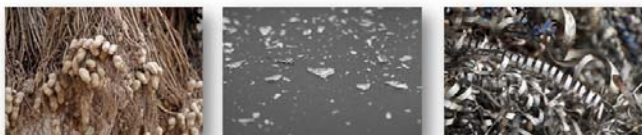


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2. Chemical hazards, including radiological hazards, pesticide and veterinary drug residues, natural toxins, products of decomposition, unapproved food or color additives, food allergens, and (for animal, medical, or infant foods) toxic or deficient levels of nutrients, 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



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3. 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 couple of good resources are:
 - FDA Reportable Food Registry
 - FDA Bad Bug Book



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The FDA Reportable Food Registry available on the FDA website at: <http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm>

is a useful source of information about the hazards that may be present in different foods. 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 <http://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.


FDA Guidance Documents

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>.

Biological Agents Cause Most Outbreaks

Biological Agents Cause Most Outbreaks				
Reported Foodborne Illness Outbreaks 2009–2014				
Hazard Type	Outbreaks	Illnesses	Hospitalizations	Deaths
Biological	3,158	64,044	4,221	120
Chemical	215	834	93	5
Physical	Not collected			
Unknown	1,391	15,072	292	3

Adapted from: CDC Surveillance for Foodborne Disease Outbreaks, United States Annual Reports, 2009-10, 2011, 2012, 2013, 2014

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A compilation of data taken from multiple years of the Centers for Disease Control and Prevention (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 is useful to understand the types of hazards that are likely to cause illness.


Biological hazards, including bacteria, viruses and 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 this CDC data.

Allergenic 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 can be recalled. CDC surveillance systems do not report physical hazard outbreaks.

Potential Biological Hazards

Potential Biological Hazards

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




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, some parasites, yeasts, and molds.

Potential Chemical Hazards

Potential Chemical Hazards

- Naturally occurring
 - Food allergens, mycotoxins, decomposition by-products
- Used in food production
 - Food additives, color additives, pesticides, animal drug residues
- Others incidentally present
 - Cleaning and sanitizing chemicals, 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.


 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>

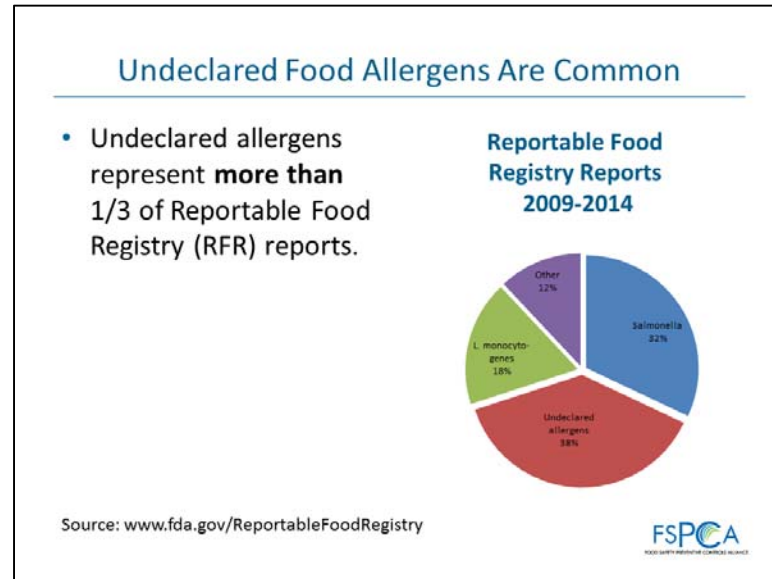
CPG Sec. 560.750
 Radionuclides in Imported Foods - Levels ...
 INSPECTIONS AND COMPLIANCE:
www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074576.htm

Action Levels for Poisonous or Deleterious Substances in Human and Animal Food:
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm077969.htm>

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 are contained in the Reportable Food Registry Annual Report.

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

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.

Food Allergy

Food Allergy

- Food Allergy = adverse response by the body to foods containing allergenic proteins
- A miniscule 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 to be 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



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 only on economically motivated adulteration circumstances that introduce hazards into the food.



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 extend 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** 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 capabilities. 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 FSVP **qualified individual** 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, you must still document performance of the hazard analysis.**



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 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 particular supplier and the particular 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 (human and animal)—so your qualified individual 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

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.

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)



Past experience with food safety problems indicates that different types of foods are most often associated with particular 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) available at:

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

Additional guidance on human and animal foods will provide more resources for conducting hazard analyses.

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:

1. The type of food (fresh produce),
2. Where the food originates,
3. Who may be having an effect on the hazard (e.g., cause, prevent or control),
4. The types of hazards that may have arisen with similar foods in the past, and
5. 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.


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 Centers for Disease Control and Prevention's (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 the 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 particular foods.

 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: Add import alerts to the text box. Import Alerts by food group:
http://www.accessdata.fda.gov/cms_ia/industrygroup_1.html

FDA Import Alerts by food group:
http://www.accessdata.fda.gov/cms_ia/industrygroup_1.html


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, (continued on the next page)

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).



When analyzing hazards, you must consider who is controlling or preventing the hazards, even if it is not your foreign supplier. For example, a perishable food must be transported and refrigerated properly after it leaves the foreign supplier.

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?

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.” (*response to comment 136*)

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.”*

(FDA response to comment 115, 80 FR 74267)



Clearly, a 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 74267).

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.

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.



Because the foreign growers of your produce are likely to be very knowledgeable about their produce, you could benefit from discussing the food and potential hazards with them.

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, and**
- **Must include documentation** that:
 - The hazard analysis was conducted by a **qualified individual, and**
 - **Your review was carried out by a qualified individual.**




You must, however, review that hazard analysis and document your review. You must also document that the hazard analysis was performed by a qualified individual and that your review and

assessment of the foreign supplier's hazard analysis was also conducted by your **own qualified individual**.

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
 - To significantly minimize or prevent the biological hazards.
- **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 identify and evaluate the biological hazards in such food because the Produce Safety rule (21 CFR 112) already requires that the produce grower significantly minimize or prevent those hazards (21 CFR 1.504(e)) by complying with the Produce Safety rule.

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?

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

What If No Hazards Require 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 the purpose of foreign supplier approval and verification, and
 - You are not required to conduct foreign supplier verification activities.



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

1. You are not required to conduct a hazard evaluation for foreign supplier approval and verification.
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)).

FDA identified two reasons in the preamble to the FSVP final rule for requiring supplier verification for RACs. First, importers must still conduct supplier verification to ensure that all hazards in RACs, including microbiological hazards, are significantly minimized or prevented. Second, FDA was concerned that while domestic produce is subject to continuous U.S. state, federal, and industry monitoring for chemical residues (e.g., pesticides) and natural toxins, such controls may not be operating in other countries. Thus, FSVP requires that importers of produce must verify that produce is produced not only in compliance with the Produce Safety regulation but also in accordance with section 402, i.e., that it is not adulterated with pesticide residues that violate U.S. pesticide requirements established by the Environmental Protection Agency.

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:

1. Identify known or reasonably foreseeable hazards,
2. 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,
3. Justify your decision in writing.

Hazard Analysis Format Examples

Preventive Controls Hazard Analysis Form Example							
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>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
B							
C							

Hazard Analysis Form Example -
other formats may be used


The example in the slide above 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.

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** needs to perform and document your hazard analysis or document the assessment of another entity's hazard analysis.



This chapter has covered:

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

Chapter 4: Questions

Chapter 4: Questions

Thank you for your attention!

Questions?



Notes:

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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 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

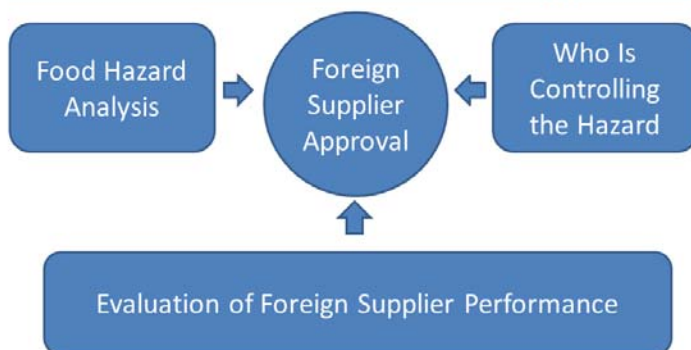
- Your hazard analysis is primarily directed at determining whether there is a known or reasonably foreseeable hazard in the food that requires a control.
- Your evaluation of the foreign supplier is aimed at determining if the supplier can be approved for sourcing food for import.



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 must evaluate your foreign supplier's performance (21 CFR 1.505(a)), taking into account the hazard analysis and who is actually 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




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

Whether or not you approve 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.

The Factors to Consider when Evaluating Your Foreign Supplier

**The 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

- Note that the hazard analysis and who is controlling the hazard must be considered when evaluating the foreign 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. The process focuses 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, your foreign supplier's supplier, a customer, or elsewhere in the supply chain.

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

Illustration: A Hazard Requiring a Control

- You wish to import a chocolate/peppermint candy.
- Your supplier also manufactures candies containing almonds and hazelnuts (known allergens).
- You are concerned that your candy might be susceptible to cross-contamination with these allergens.
- 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 a chocolate and peppermint candy to you. The foreign supplier also makes chocolate

bars containing almond pieces and another type of candy made from hazelnuts. **Your** job is to **verify** that the foreign supplier is implementing controls to prevent allergen cross-contact by either of those tree nuts within the manufacturing facility. Your foreign supplier may apply a variety of controls, for example:

Allergen Cross-Contact Prevention Considerations

- Equipment cleaning and sanitary design
- Scheduling
- Manufacturing and engineering controls
- Allergenic ingredient control
- Rework Management
- Personnel practices
- Employee training relevant to the above

Source: FSPCA Preventive Controls for Human Food Training Manual, Chapter 10



Multiple preventive controls for these two hazards 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.

Note: Tree nuts are known allergens, so 403(w) of the FD&C Act pertains to the labeling of candy bars containing tree nuts and could, as well, pertain to the labeling of your bars if there is any opportunity for allergen cross contact.

Foods That Cannot Be Consumed Without an Appropriate Control

Foods That Cannot Be Consumed Without an Appropriate Control

- When a food has a hazard that generally would not be consumed prior to the hazard being effectively controlled:
- **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.
- For example, consumers aren't expected to eat raw coffee beans because beans are normally roasted (and usually ground and brewed) before consumers consume, which would address most hazards.
- Supplier verification might still be needed for other hazards.



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.

The point here is that coffee or cocoa beans, for example, are rarely consumed without significant processing that will control most 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 as some toxins are known to persist through processing.

You must also document your determination that yours is such a product.

Group Discussion: Who Is Controlling the Hazards?

Group Exercise: Who Is Controlling the Hazards?

Who is controlling the hazard?

- **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 discussion. If you would like to take notes during the discussion, go to Chapter 5 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 foods. 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 CGMPs
Infant formula	Infant formula rule
Shell eggs	Shell egg requirements
Canned pet foods	LACF requirements, PC for Animal Food rule
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.

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

Currently, the food safety systems of New Zealand and Canada have been recognized as comparable to the U.S. food safety system.

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 good standing with the relevant food safety authority for countries whose food safety systems are recognized by the FDA.



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.

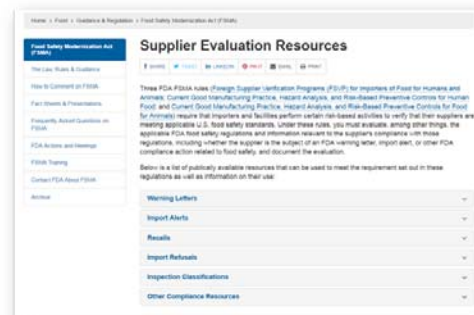
📖 FDA has provided Supplier Evaluation Resources on their website at:

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

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

FDA Provides Supplier Evaluation Resources on their Website

- Import alerts
- Recalls
- Import refusals
- Other



Supplier Evaluation Resources:

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



FDA website link for researching your supplier performance is:

<http://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.
- You must document your evaluation.



And finally, your evaluation must be conducted by a qualified individual 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 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, must document your review and assessment, and also document that the other entity's evaluation was conducted by a qualified individual.

The following is an FDA example 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 actually 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, you do not need to perform an evaluation of your foreign supplier, nor do you have to approve your foreign supplier.

Approving Foreign Suppliers (continued)

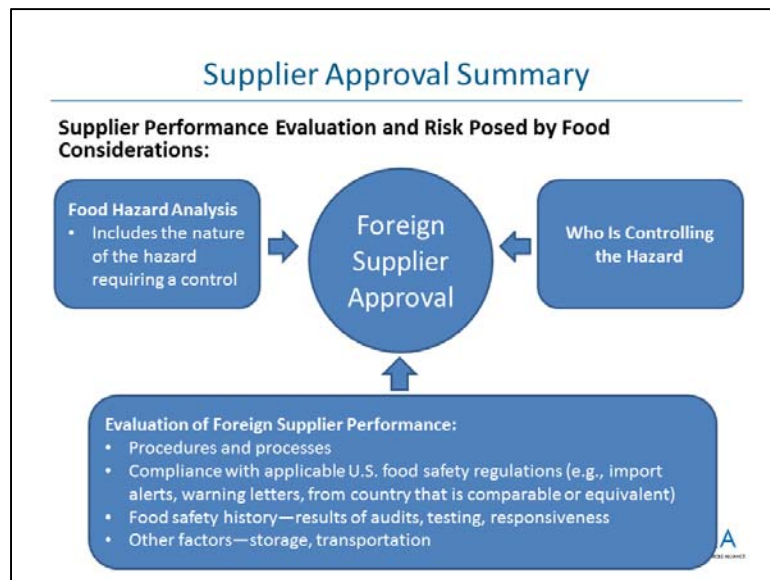
Your suppliers must be approved before food is imported!

- Therefore, you should begin your discussions:
 - **With** suppliers and/or others engaged in your importing arrangement **as soon as possible, and**
 - **Before** the compliance dates for the rule are in effect.


FOOD SAFETY PROMOTIONAL CAPACITY PROJECT

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



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

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:

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

Chapter 5: Questions

Chapter 5: Questions

Thank you for your attention!

Questions?



Notes:

This image shows a single sheet of white paper with horizontal blue ruling lines. The lines are evenly spaced and run across the width of the page. There are approximately 20 lines visible. The paper has a slightly aged or off-white appearance.

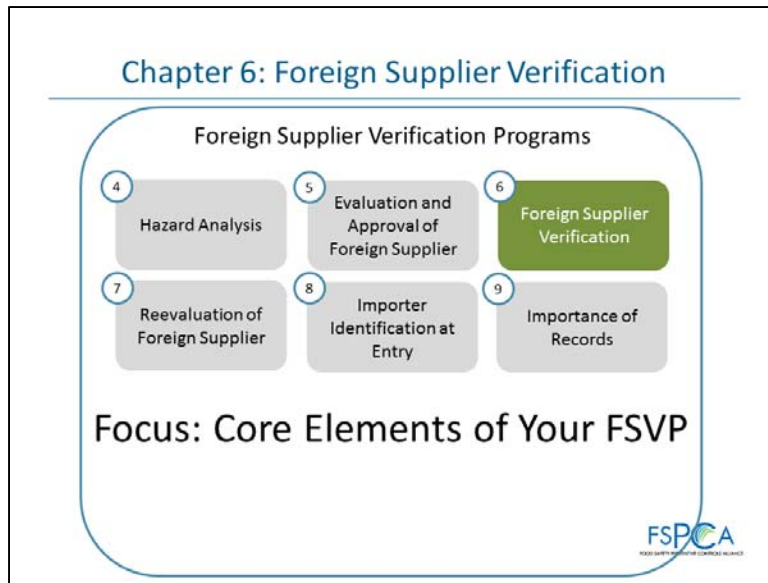
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CHAPTER 6. Foreign Supplier Verification



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 as safe as the food produced in the U.S., or, in other words, that all food consumed in the U.S. meets the same level of public health protection as foods produced in the U.S. 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. is safe to eat. 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. 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

Chapter 6: Goal and Objectives

Goal: Participants will be able to verify that foreign suppliers meet FDA safety standards.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Develop written procedures for ensuring food is obtained from approved suppliers.
 2. Select appropriate verification activities.
 3. Develop written procedures for conducting verification activities.
 4. Determine who should conduct the verification activities.
 5. Document the performance of the foreign supplier verification activities.

FSPCA
FOOD SAFETY PROMOTION CENTER ASSOCIATES

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

- Your first verification activity is establishing 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.



You may have already performed a hazard analysis, considered who would be controlling the hazard needing to be controlled, reviewed your foreign supplier's processes and procedures, looked at the supplier's food safety history and compliance with U.S. regulations. You also may have specified that your supplier take some corrective actions on the basis of these evaluations prior to approving your supplier. If the hazard requiring a control was a serious (SAHCOHHA hazard) you may even have conducted an audit as a result of the hazard analysis. All of this was done before you made the decision on whether to approve your foreign supplier. So, in essence, you have already verified that your supplier, along with others in the supply chain are carrying out their food safety responsibilities for the food in question.

The FSVP provisions on **verification activities** focus on ensuring that the hazards needing controls in the food you import **continue** to be controlled.

The rule specifies as an initial verification activity that you must develop written procedures to ensure you only utilize approved foreign suppliers to import food.

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.

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.


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.”

Because there needs to be a reason for using an unapproved supplier, that should also be documented. Logically, FDA will expect a “temporary” unapproved supplier to be converted to an approved supplier after a reasonable time.

Purpose of Written Verification Procedures

Purpose of Verification Procedures

- Foreign supplier verification must provide assurance that the hazards requiring a control in the food you import are continually being:
 - Significantly minimized, or
 - Prevented.
- You must have **written procedures** for determining which verification activities are appropriate, including their frequency, while considering:
 1. Who is controlling the hazard, and
 2. Who will be conducting the appropriate foreign supplier verification activities.



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 Verification Activities

Determining 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 are your previous evaluations of:
 - The food, and
 - The foreign supplier.



Remember that you verified that your foreign supplier was producing safe food in order to approve him/her in the first place based on the evaluations of the food and foreign supplier you previously conducted (21 CFR 1.506(d)). Now you are establishing written procedures to verify that the food will continue to meet the U.S. level of public health protection.

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 cannot occur. Understanding how such a company controls allergens may be very important to your FSVP.

SAHCODHA Hazards are those that would prompt a **Class I*** recall if they were to occur.

*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.

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.



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 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 an onsite audit, but only if such procedures provide equal assurances that the hazard(s) is being adequately controlled. Similarly, 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. 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.

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**.



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, however, you should document your justification for its suitability.

Illustrations

Illustrations

- If your evaluation of the manufacturer, who is your foreign supplier, reveals that temperature controls for a processing step are critical for controlling pathogens:
 - The review of the supplier's records of temperature recordings could be an **appropriate verification activity**.



So, let's look at a couple of illustrations.

If your evaluation of a foreign supplier indicates that temperature controls for a processing step are critical for controlling microbiological growth, then a review of the supplier's records of temperature recordings and equipment calibration could be appropriate verifications.

Another example of testing as a verification activity:

Testing could also be requested for raw foods that are from a region where FDA has found high residue levels of pesticides not approved in the U.S. for use in the particular commodity. In this case, an alternative verification activity could be requesting records of pesticide use (e.g., pesticide name, application rates, application dates, preharvest interval) for the food in question.

Illustrations (continued)

- 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:
 - Periodic sampling and testing by the supplier or a reputable laboratory could be an **appropriate activity to verify** that heavy metal levels are within U.S. limits (if any) or at normal background levels.



If the food is imported from a region that has a previous history of supplying similar foods containing significantly high levels of heavy metals, such as lead or cadmium, the importer might request that the supplier conduct periodic testing of the product and/or soil samples to assure that such high concentrations are not occurring in the

imported food. The testing could be done by the supplier or a reputable laboratory.

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**.



We have already mentioned that onsite audits are the appropriate default verification activity in the case of a SAHOCODHA 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 has recognized the food safety system of the foreign supplier's country as either comparable or equivalent to the U.S. system, the auditor may inspect to that country's 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 address CGMP and applicable preventive controls (process, allergen, sanitation, and supply-chain), or compliance with the Produce Safety rule. The audit must address the specific hazards identified in your hazard analysis.

Audits to private standards/schemes may contribute to the safety of the food supply but may not necessarily meet the requirements of the FSVP rule. Under this rule, audits must not only be conducted by a qualified auditor, but the auditor must consider applicable FDA food safety requirements.

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.”

FDA has stated that it “will not require that audits” carried out “to meet FSVP requirements” be conducted “by third-party auditors accredited under FDA’s 3rd party certification regulation...” “The only audits that must meet the requirements of the third-party certification regulation are regulatory audits performed for the purposes of the issuance of (1) certifications required for participation in the Voluntary Qualified Importer Program (VQIP) under section 806 of the FD&C Act and (2) mandatory import certifications under section 801(q) of the FD&C Act, as well as consultative audits conducted in preparation for a regulatory audit.”

If the food is subject to one or a number of FDA food safety regulations, an onsite audit of the foreign supplier must consider such regulations. 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”, food defense (“Mitigation Strategies to Protect Food Against Intentional Adulteration”), and the biennial renewal requirement for food facility registration.

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 SAHCODHA hazards**.
- Include in documentation:
 - Audit procedures,
 - Qualifications 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 must demonstrate that your supplier is using processes and procedures that control **SAHCODHA** hazards. Your documentation should 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 opposed to audits, from appropriate officials of a foreign government, but only if FDA has recognized the food safety system of the country as comparable or equivalent to the U.S. system and the inspector is acting within the scope of his/her responsibilities.

Also, it should also be made clear that FDA is not requiring certification of food imported into the U.S. under the Voluntary

Qualified Importer Program (VQIP). Instead, certifications issued under this voluntary program are used for **two purposes**.


First, importers will use facility certifications from foreign suppliers in helping to establish their eligibility to participate in the VQIP if they wish to participate. Once the importer has been accepted into VQIP, he or she will gain expedited review and entry of food covered by the facility certification.

The second use for certifications is related to a new import tool provided by FSMA that allows FDA to require certifications as a condition of admission into the U.S. **when certain statutory criteria are met**. Those criteria include the risk associated with the product, the risk associated with the country or region of origin, and the capability of the regulatory system of the exporting nation to ensure compliance with FDA safety standards.

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 (analytical method) 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 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.

What If You Choose Other 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 associated with the food.
- You must, of course, document performance of the verification activity and that it was performed by a qualified individual.



You may conduct other supplier verification activities that are appropriate based on foreign supplier performance and the risk associated with 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 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.**



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

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.

FDA may provide guidance about alternative supplier verification activities.

Who is Controlling the Hazards?

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 verifies 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
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...

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.



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.

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.




Compliance with the written assurances provisions of the FSVP rule has been delayed by two years on August 24, 2016 (80 FR 57784.)

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.



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.

Hazards Controlled by a System You Established

Hazards Controlled By a System You Established

- 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 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** 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 you, the U.S. importer, are ultimately responsible for appropriate verification activities.**

Of course, you must document your review and assessment, including documenting that both the entity's and your determination of appropriate verification activities were made by qualified individuals.

Group Discussion: What Supplier Verification Activity(ies) Would Be Appropriate in the Following Scenarios?

What Supplier Verification Activity(ies) Would Be Appropriate in the Following Scenarios?

- Scenario 1: Importing whole fresh tomatoes?
- Scenario 2: Importing fresh sliced tomatoes?




Discuss as a group. Your instructor will provide you with the answers after the group discussion. If you would like to take notes during the discussion, go to Chapter 6 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.



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**.

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 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. You may also decide that you need to replace that foreign supplier with another supplier.

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.
 - **SAHCODHA** hazards require an onsite audit or equivalent.
 - Verification activities must be appropriate for the food, the hazard, and who controls the hazard.
 - The choice and performance of verification activities must be accomplished by **qualified individuals**.



This chapter has discussed:

1. The need for written procedures for
 - a. Ensuring that you only obtain food from approved suppliers and
 - b. Conducting verification activities.
2. **SAHCODHA** hazards require either an onsite audit or something equivalent.
3. Verification activities must be appropriate for the food, the hazard, and who controls the hazard.
4. The choice and performance of verification activities must be accomplished by **qualified individuals**.

Chapter 6: Questions

Chapter 6: Questions

Thank you for your attention!

Questions?



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Chapter 7. Reevaluate Foreign Supplier Performance and Food Risk

Chapter 7: Reevaluate Foreign Supplier Performance and Food Risk

REEVALUATING THE APPROPRIATENESS OF FSVP ON A REGULAR BASIS AND WHEN PROBLEMS OCCUR



Chapter 7 is about reevaluating foreign supplier performance and food risk. Reevaluations are necessary because the situation with your food or your foreign supplier may change over time.

Chapter 7: Reevaluation of Foreign Supplier

Foreign Supplier Verification Programs



Focus: Core Elements of Your FSVP



Chapter 7 is the fourth chapter in the core elements 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 the U.S. level of public health protection.


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.
 5. Document corrective actions.



This chapter will focus on:

1. Determining when reevaluations are needed,
2. Factors to consider for reevaluation,
3. Documenting the reevaluation,
4. Determining appropriate corrective actions, and
5. Documenting corrective actions.

FSVP Reevaluations

FSVP Reevaluations

When are reevaluations 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.
- Generally 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.



For standard FSVP requirements, 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. 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 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 continue to import the food from the

foreign supplier and/or whether the supplier verification activities need to be changed.

All reevaluations and the corrective actions taken as a result of them **must be documented**.

What if Modified Requirements Apply?

What if Modified Requirements Apply?

- When operating under modified FSVP requirements where there isn't a reevaluation requirement *per se*, you must still:
 - Promptly take appropriate corrective actions for a particular foreign supplier/food, if you are aware of a potential food safety issue.
- You should also monitor whether the modified requirements continue to apply.



If you are operating under modified FSVP requirements that allow you to rely on written assurances from your supplier (e.g. you are a very small importer), there is not a reevaluation requirement *per se*. Nevertheless, you must promptly take appropriate corrective actions if you determine that your foreign suppliers are not producing food consistent with the assurances you receive from them.

FSVP Reevaluations When Relying Upon Entities Other than Your Foreign Supplier to Control Hazards

FSVP Reevaluations When Relying Upon Entities Other than Your Foreign Supplier to Control Hazards

- Remember, an FSVP that relies on entities **other than your foreign supplier** to control hazards must also be reevaluated:
 - At least every 3 years, or
 - When you become aware of any information that could potentially affect food safety.
- For instance, if you are relying on your customer to control a particular hazard, you must **still reevaluate every 3 years or when you become aware that the hazard has not been controlled.**



An FSVP that relies on entities other than your foreign supplier to control hazards must also be reevaluated at least every three years or when you become aware of information that could affect the safety of your food.

It is especially important to reevaluate your FSVP in the following situations because you are relying on another entity to control identified hazards:

1. You are relying on your customer to control the hazard and are disclosing to your customer that the hazard isn't controlled, or
2. You are relying on your customer to obtain written assurance that its customer will either control the hazard or disclose that the hazard hasn't been controlled.

Group Discussion: What Kinds of Issues Could Trigger a Reevaluation?

What Kinds of Issues Could Trigger a 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.




Consider why each of these issues identified on the slide above would be a trigger for a reevaluation. Share in the group discussion. If you would like to take notes during the discussion, go to Chapter 7 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:

1. Any changes in the supplier's procedures, processes, and practices related to the safety of the food,
2. New information about the supplier's compliance with food safety standards (e.g., FDA warning letters),
3. Responsiveness of the foreign supplier in correcting food safety problems,
4. Any new information on food testing results, and
5. Any new audit results relating to the safety of the food.

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:

1. The other entity's reevaluation must be performed by a qualified individual,
2. Your qualified individual must determine what actions are appropriate.
3. You must document your review and assessment.

Corrective Actions and Reevaluations:

The need for corrective actions to address deficiencies in your foreign supplier's food safety processes and procedures will also trigger the need to reevaluate the performance of your supplier and the risk posed by the food you are importing from that foreign supplier. A reevaluation is especially important if your foreign supplier provided you with a food for import into the U.S. that was refused entry by FDA, or if the food actually caused harm to consumers. It's also important to remember that a routine reevaluation of your foreign supplier could reveal the need for a corrective action.

What Are Corrective Actions?

What Are Corrective Actions?

- 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 the U.S. level of public health protection, you must take corrective actions.
- If you learn that the food is adulterated under section 402 or violates the allergen labeling provisions of section 403(w) of the FD&C Act, corrective action is needed.
- Corrective actions must be taken promptly once you ascertain that a food safety problem exists.
- Your **qualified individual** must determine whether corrective actions are necessary.



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, are 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 meet the U.S. level of public health protection, 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.

If you have reason to believe that your foreign supplier's food safety processes and procedures have failed to produce food for export to the U.S. that complies with U.S. food safety requirements, corrective actions must be taken to prevent a reoccurrence. Your qualified individual must be the person to determine whether corrective actions are necessary.

If corrective actions are needed then you, as the importer, must insist that your foreign supplier take immediate action to prevent further food safety failures. You also need to verify that appropriate corrective actions are taken.


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. It is possible that unsafe product may have been produced, or your foreign supplier may have taken appropriate corrections or corrective actions to prevent any contaminated food from being produced or exported. The action you take should be appropriate to the nature of the hazard, the situation, and yours 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.

Appropriate Corrective Actions

Appropriate Corrective Actions

- The appropriate corrective actions will depend on your findings, but could include:
 - 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.



You always need to be on the alert for food safety problems, both those that are foreseeable and those that are unexpected. This means that you should take consumer, customer, or other complaints about safety seriously. You also need to take care in conducting verification activities, and also when you reevaluate the risks posed by the food you obtain from foreign suppliers and their performance.

When you do encounter problems, you must:

1. Promptly investigate to determine whether your FSVP is adequate, and modify it, if necessary, and
2. Document your investigations, corrective actions, and changes to your FSVP (1.508(b)).

When you identify a gap in supplier performance related to food safety you must take **appropriate** steps to correct the deficiency. 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.

Documenting Corrective Actions

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.

Documenting Corrective Actions

- You **must** document your:
 - Investigations into the food safety issue,
 - Corrective actions you take involving the supplier/food, and
 - Changes to your FSVP.



The appropriate corrective actions will depend on your findings, but include changing the type or frequency of your verification activities. Your corrective action options also include discontinuing use of the foreign supplier until the cause or causes of noncompliance have been adequately addressed. You don't want to be importing questionable food.

You must document all reevaluations and corrective actions taken as a result of the reevaluations. If you are relying on another entity's reevaluation, you must document your review and assessment of the evaluation. When addressing corrective actions, you must document your investigations, corrective actions involving the supplier and food, and any changes to your FSVP.

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 when something goes wrong.
 - That reevaluations and corrective actions must be documented.



This chapter has covered the following:

1. When you must reevaluate your FSVP.
2. What to consider when you conduct your reevaluation.
3. The need to take appropriate and effective corrective actions when something goes wrong.
4. The need to document reevaluations and corrective actions.

Chapter 7: Questions

Thank you for Your Attention!

Questions?



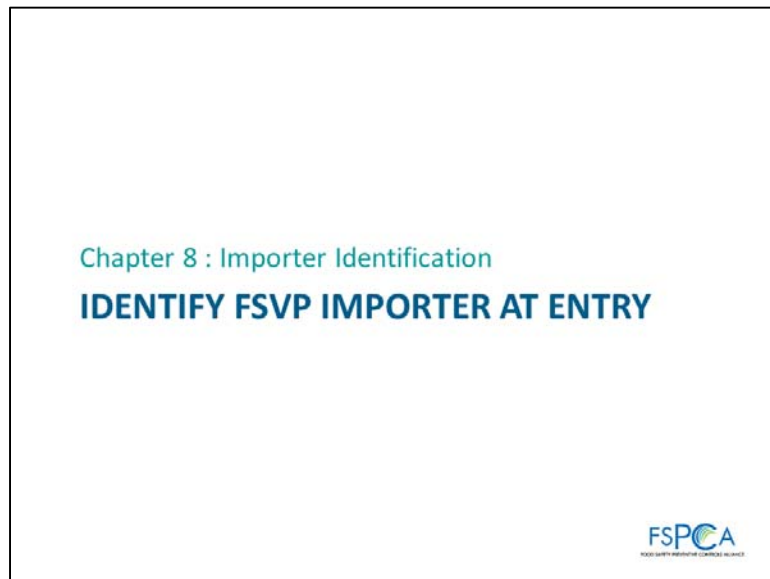
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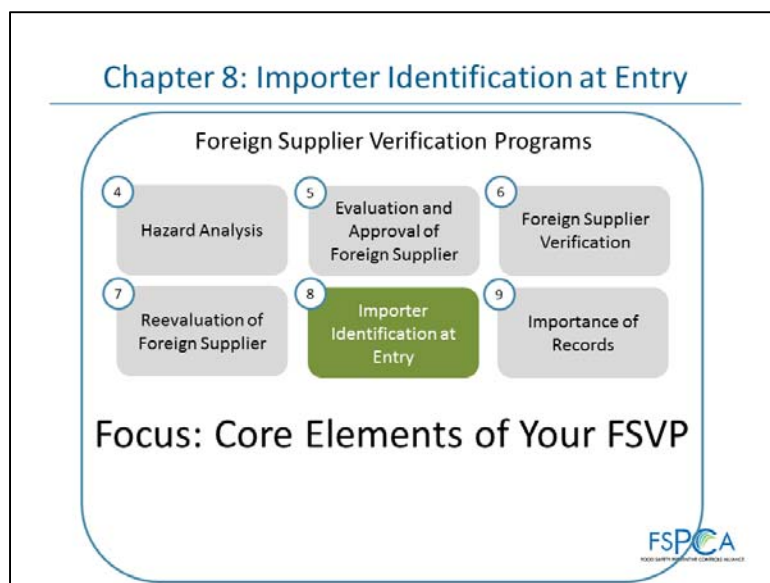
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Chapter 8. Importer Identification



What could be called the last step in carrying out the FSVP process is entering the properly designated FSVP importer's name and other particulars on filing with 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 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.



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.

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 U.S. agents or representatives of the foreign importer are required to consent to serve as the FSVP importer if they are 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 has required changes to be implemented to the Customs and Border Protection (CBP) entry system.
- FSMA and FDA (through the FSVP rule) have added the following requirement:
 - The U.S. food importer who is responsible for complying with FSVP requirements must be identified at entry.
- These new entry requirements will not affect the current FDA admissibility process.



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 so this required information will be able to be transmitted once the rule goes into effect. As stated in the preamble to the final rule, FDA has established data elements that identify both shipments that need to comply and those that are exempt from the FSVP regulation.

It is important to understand with the implementation of FSVP, there will not be any changes to FDA's current import admissibility process. Individual line entries will not be assessed against the FSVP requirements, but rather the FSVP importer's compliance will be determined through a domestic inspection program.

When Importing Food, What FSVP Information Must Be Provided at Entry?

When Importing Food, What FSVP Information Must Be Provided at Entry?

- For each line entry of food product presented for entry into the U.S., the following must be provided electronically when filing entry with CBP:
 - Name
 - Electronic mail address
 - Unique facility identifier (UFI) identifying the FSVP importer of the food



For each line entry of food product offered for importation into the U.S., your name (as the FSVP importer), electronic mail address, and a unique facility identifier (recognized as acceptable by FDA) identifying you as the importer of the food, must be provided electronically when filing entry with U.S. Customs and Border Protection (CBP) (21 CFR 1.509(a)).

FDA has identified DUNS numbers as being an acceptable facility identifier, which we talk about later in this chapter. FDA may name other acceptable facility identifiers in the future.

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 the FSVP rule is in effect, applicable shipments of food without transmission of an FSVP importer identified will be returned to the filer with an error message by Customs and could affect entries entering commerce. Nevertheless, it should be clear from the earlier chapters of this course that the work in learning and complying with FSVP obligations begins months, often many months, before a food is offered for entry into U.S. commerce.

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.
 - The FSVP importer must, therefore, obtain an acceptable UFI.
 - The only UFI that FDA has recognized as acceptable at this time is a DUNS number that anyone can obtain at no cost from Dun and Bradstreet.
 - The DUNS number provided should be associated with the person listed as the FSVP importer.



In the preamble to the FSVP final rule, FDA mentions that “...the final rule does not require the submission of DUNS numbers for importers of food offered for importation into the United States. Instead, it requires the submission of a unique facility identifier recognized as acceptable by FDA.” Nevertheless, at present no other UFIs have been identified as acceptable to FDA. Again, DUNS numbers can be obtained on-line by anyone and involve no cost.

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. DUNS numbers can be obtained from <http://www.dnb.com/duns-number.html>.

📖 Obtaining a DUNS number may take a while, so anyone interested in having a DUNS number should apply sooner rather than later.

The link below takes you to the site that explains what a DUNS number is and how to apply for one.

Dun & Bradstreet main website:

<http://www.dnb.com/duns-number.html>

To go directly to the “Get Started” web page:

<https://www.dandb.com/free-duns-number/>

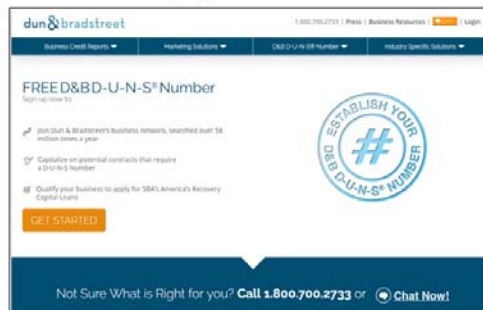
OR

Fill out the request at the fedgov.dnb.com web page

<https://fedgov.dnb.com/webform/newReq.do>

Obtaining a Free DUNS Number

- You can go directly to the Dun & Bradstreet website “Get Started” web page



FREE D&B D-U-N-S® Number: <https://www.dandb.com/free-duns-number/>



Above is a screenshot of the Dun & Bradstreet “Get Started” web page. The next page provides a screenshot and link to Dun & Bradstreet’s fedgov.dnb.com web page where you can start to fill out the application to request a new DUNS number.

Obtaining a Free DUNS Number (continued)

- Or, you can request a new DUNS number via Dun & Bradstreet’s fedgov.dnb.com web page

 A screenshot of the Dun & Bradstreet "Request for New D-U-N-S Number" web form. The form is titled "Request for New D-U-N-S Number" and includes a sub-header "Any affiliated companies at the same address, will not be affected. If there are affiliated companies at the same address, please specify in the Notes section." Below this, there is a section for "Company Name" with fields for "Legal Name", "Legal Structure" (a dropdown menu), "Trade Name 1 (optional)", "Trade Name 2", and "Trade Name 3". There is also a field for "Phone Number of Business (at the location listed below)". The next section is "Physical Address (Postbox, PO Box and APO/FPO address not accepted)" with fields for "Street", "City", "State", "Zip Code + 4 Postal Code", and "Country". The final section is "Mailing Address (optional)" with a checkbox "Same as Physical Address" and fields for "Street P.O. Box", "City", "State", and "Zip Code + 4 Postal Code".

Request for New D-U-N-S Number
<https://fedgov.dnb.com/webform/newReq.do>




You will want to be sure you have all of the information you need before trying to fill out and submit the request.

Some Importer Identification Issues

Some Importer Identification Issues

- **Name on CBP entry = Person responsible for FSVP**
 - FDA will use the entry identification of the FSVP importer as the responsible party for follow-up to assure compliance with FSVP requirements.
 - FDA does have the ability to determine if FSVP information is transmitted correctly.
 - Make sure the person responsible for the Customs entry filing understands who is the appropriate FSVP importer.



Several points should be made relative to the FSVP importer named on the CBP entry filing. First, the FDA will conduct oversight, that is, enforce the FSVP rule 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.”

A second point is that 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. 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.



U.S. agents and representatives of foreign owners and consignees are required to consent to being FSVP importers 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 owner or consignee do NOT have to consent to being the FSVP importer, but may unknowingly have their names placed on Customs entry filing as the FSVP importer, as a consequence of the FSVP importer definition. You may not learn that you were identified as the FSVP importer until FDA contacts you to review your FSVP records. **So, make sure to understand who is the designated FSVP importer for all imported foods you receive.**

Group Discussion: Importer Designation and Identification—Scenario 1

Importer Designation and Identification— 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 U.S. Customs paperwork.
- 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.



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 in the Exercise Workbook.

1. How is a decision made on who should be the FSVP importer designated on the CBP entry documents?
2. Who is in the best position to be the FSVP importer?

Group Discussion: Importer Designation and Identification—Scenario 2

Importer Designation and Identification— 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.




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 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:
 - That the traditional CBP entry process is the same except that now you must also identify the FSVP importer to CBP upon entry.
 - If more than one entity meets the FSVP definition of importer, only the entity who has implemented the FSVP obligations for the food/foreign supplier in question should be entered as the FSVP importer.
 - FDA will view that person as the responsible party for meeting all FSVP obligations under the law.
 - That it is important to determine who will be designated as the FSVP importer well in advance of shipping food so the FSVP requirements can be met and no difficulties will occur when the food is imported.
 - Where to obtain a DUNS number.



Assuring 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 that party is the ONLY one written into the CBP entry documents cannot be overemphasized.

Chapter 8: Questions

Chapter 8: Questions

Thank you for Your Attention!

Questions?



Notes:

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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.



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



Focus: Core Elements of Your FSVP



Chapter 9 is the last chapter in the core elements of your FSVP. This chapter presents the details of the FSVP record requirements.


Chapter 9: Goals 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 records.
 2. Identify records to document for FSVP compliance.
 3. Describe the requirements for 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. Identify the records that demonstrate FSVP compliance,
2. Understand the requirements for maintaining your FSVP records, and

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 will result in trouble for your imported food and you.



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 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



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
 - Foreign supplier performance evaluation
 - Procedures for approving foreign suppliers
 - Foreign supplier approval
 - Procedures to assure use of only approved foreign suppliers
 - Determination of verification methods and frequency
 - Performance of verification activities
 - Any necessary corrective actions
 - Reevaluations of your FSVP either for cause or routinely every 3 years



The following are records relevant to your foreign supplier that you should maintain, including:

1. The hazard analysis,
2. Foreign supplier performance evaluation,
3. Procedures for approving foreign suppliers,
4. Foreign supplier approval,
5. Procedures to assure use of only approved foreign suppliers,
6. Determination of verification activities and their frequency,
7. Performance of verification activities,
8. Discuss any needed corrective actions, and
9. Reevaluations of your FSVP either for cause or routinely every 3 years.

Examples of Hazard Analysis Records You Need for an FDA Inspection

Examples of 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**.



Even if no hazard needing a control is identified, importers need to document the hazard analysis. If performed by another entity, the importer needs to document the **qualified individual's** review and assessment of the hazard analysis.

Your records must demonstrate that you performed a hazard analysis and should include, but not be limited to:

1. Determination of the hazards, if any, and whether they are known or reasonably foreseeable.
2. Assessment of the probability that the hazard will occur in the absence of controls.
3. Assessment of the illness or injury if the hazards are to occur.
4. Any review and assessment of a hazard analysis performed by another entity, including that it was done by a **qualified individual**.

You, as the FSVP importer must sign and date the records pertaining to meeting **FSVP requirements**. If you rely on records prepared by another entity, you need to retain, sign, and date records of your **qualified individual's** review and assessment of the other entity's records. However, a signed statement will not be sufficient by itself to demonstrate compliance with the FSVP rule. FDA must be able to evaluate whether the original activity (e.g., hazard analysis, verification activity) was conducted in a way that meets regulatory standards. For example, if you are relying on your foreign supplier's hazard analysis, you may want to have your **qualified individual** sign and date that document. In addition, while you are not required to maintain a copy of the entire audit report done by another entity, you should retain documentation of each audit, including the audit procedures, the dates of the audit, the conclusions of the audit, and any corrective actions taken to correct deficiencies that were found, as well as documentation that the audit was done by a qualified auditor."

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
- 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:

1. Original records,
2. True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche or other accurate reproductions of the original records), or
3. Electronic records.

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.

Also note that FDA felt 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.”

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.


FOOD SAFETY PROMOTION CENTER ALLIANCE


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.

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.


FOOD SAFETY PROMOTION CENTER ALLIANCE

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.

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 some of the information required for FSVP purposes. If your existing records contain 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 provisions of 21 CFR Part 20.

Records Provided to FDA May Be Subject to Public Disclosure

**Records Provided to FDA
May Be Subject to Public Disclosure**

- Records obtained by FDA in the process of enforcing the FSVP requirements:
 - Can be subject to public disclosure in response to a “freedom of information” request.
- Regulations that explain the rules for disclosing records to the public upon request are contained in 21 CFR Part 20 (see link for 21 CFR Part 20 in manual).
- Note that FDA redacts trade secret and confidential business information prior to public disclosure.


Food Safety and Inspection Service

See the 21 CFR Part 20 Public Information is 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 textbox to the right of slide above). Importantly, FDA redacts information that it is forbidden by law from disclosing when responding to freedom of information requests. This includes trade secrets and confidential business information.

Importance of Records

Importance of Records

- Records are important in demonstrating that:
 - You are carrying out FSVP requirements properly.
 - That your foreign supplier is meeting U.S. 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. When FDA issues its guidance on FSVP requirements, it will include guidance that relates to recordkeeping.

Chapter 9: Summary

Chapter 9: Summary

- We have discussed:
 - The requirements for creating and keeping 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:


1. The requirements for making and maintaining adequate FSVP records,
2. The importance of those records to you and to FDA,
3. The need to maintain your records for at least two years,
4. The need to make them available to FDA immediately upon request, and
5. Where to obtain information about setting up a recordkeeping system.

Chapter 9: Questions

Chapter 9: Questions

Thank you for your attention!

Questions?

 FSPCA
FORD COUNTY SPCA

Notes:

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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 related to how food producers, manufacturers, importers and others may comply with the rules.
- 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.
 - 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.



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.

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. FDA will elaborate on this in guidance. 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 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 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.

It should be noted that records provided to FDA may be subject to public disclosure (although confidential commercial information and certain other non-public information is exempt from disclosure). In this regard, FDA states "[a]lthough we understand concerns about the security of data submitted electronically to the Agency, as well as concerns about confidential commercial information and terrorism, we will take appropriate steps to secure communications with importers and to protect any data we receive, whether submitted electronically or otherwise."

Form 482d and 483a

Form 482d and 483a

Request for FSVP Records (482d)

FSVP Observations (483a)

In the slide above are screenshots of the two forms you can expect to see during an inspection. The first is the “Request for FSVP Records” (Form 482d); the second is the “FSVP Observations” (Form 483a). Copies of the forms are in Appendix 7.

Copies of the “Request for FSVP Records” (Form 482d) and “FSVP Observations” (Form 483a) are available in Appendix 7 and on the FDA’s website at:

Form 482d available at:

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM493417.pdf>

Form 483a available at:

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM493415.pdf>

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 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

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.

How to Prepare for an FDA Inspection

How to Prepare for an FDA Inspection

- Make sure most critical 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.



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.

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.

FDA does not intend to delay shipments at the time of entry until the importer's compliance with the FSVP rule is verified. The only change to entry procedures will be identifying the FSVP importer, as discussed in Chapter 8.

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 delay shipments at the time of entry until the importer's compliance with the FSVP rule is verified. Importation processes will occur 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.
- 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:

1. Cooperate fully with the FDA investigator.
2. Be prepared to discuss any deficiencies found by FDA.
3. Be prepared to discuss any corrective actions necessary to correct any deficiencies, including establishing an acceptable timeframe.
4. Document any corrective actions taken.
5. 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.
- 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. 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?

- Failure to comply with FSVP requirements may result in the FSVP importer's food being placed on an Import Alert.
 - Future shipments would be detained without Physical Examination (DWPE), and possible refusal of admission into the U.S. under section 801(a)(3) of the FD&C Act.
- The offering for importation into the U.S. of a food without the importer having an FSVP that meets the requirements of section 805 of the FD&C Act and the FSVP rule is:
 - A **prohibited act** under section 301(zz) of the FD&C Act.
 - Those committing criminal acts can be subject to civil and criminal penalties.



Specific to FSVP, however, Section 1.514 of the FSVP rule focuses on what happens if someone chooses not to comply with the FSVP rule. When a food is offered for importation into the U.S. Customs and Border Protection 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.

Also, the food you import is subject to refusal of admission 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 for the food.

As mentioned earlier, FDA initially wishes to focus on educating food importers and the entire food-importing sector about the FSVP requirements. Nevertheless, will be inspecting importers to assess their compliance efforts. 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 the public health.” If FDA finds violations that pose a risk to public health, the agency will use its enforcement authorities to protect consumers.

FDA also 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 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 importer needs to demonstrate that each shipment of the product is in compliance. When products, shippers, and/or importers are included on an import alert, this prompts the FDA district offices to “flag” relevant shipments involving these products and entities. Flagging such shipments makes “port shopping” less likely to be successful.” “Our 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.”

As always, importers will be able to use existing procedures to challenge FDA findings regarding non-compliance with the FSVP regulation.

Additional Enforcement Tools

Additional Enforcement Tools

- FDA also has authority to take action against your food, including authority to:
 - Detain a food that appears to violate the FD&C Act (followed by the refusal of its entry into the U.S.),
 - Require the recall of harmful food in U.S. commerce (along with warning consumers not to consume the food), or
 - Administratively detain 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.

Although FDA's oversight of FSVP compliance will not be directed at the time of entry of food into U.S. commerce, as mentioned in and earlier slide, FDA will be inspecting importers and examining their records. If FDA determines that FSVP requirements are not being met, there can be consequences that could impact imported foods.

The array of FDA enforcement tools are not specific to FSVP. They pertain to actions against the food and actions against a person/company and 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 for an appeal or contrary evidence is provided.

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 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 animal food, 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 compliance date for those FSVP importers whose foreign supplier is not subject to either of the PC rules or the Produce Safety rule is May 30, 2017.
- The various compliance dates for the importation of food from a foreign supplier that is subject to **the PC rules or Produce Safety rule**, are listed in Appendix 2 of the Participant Manual.



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 (Federal Register, August 24, 2016, 57784-57796). 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>


The FDA website states that the compliance dates are grouped

according to the category of FSVP importer. **The 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 FDA list of compliance dates for the FSVP rule or the date by which the importer is required to comply with the PC rules supply-chain program provisions. The compliance dates for the FSVP rule are listed in Appendix 2.

Chapter 10: Summary

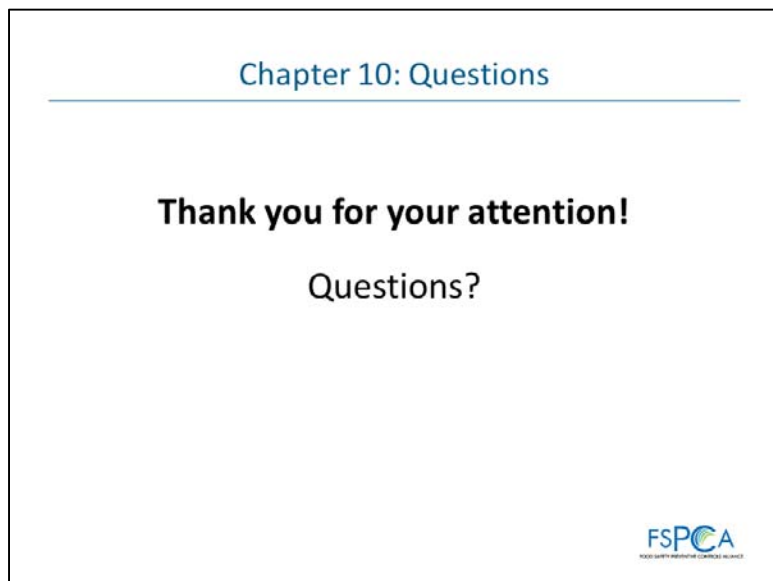
Chapter 10: Summary

- 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 could be 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 of time whereby both importers and others within the food importing industry, as well as FDA itself, will be getting used to working with and adjusting to this new rule. So, you can expect that the first year of FDA oversight after the rule goes into effect (respecting its phased in compliance dates) will be different in character from a few years hence.

Chapter 10: Questions



Notes:

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APPENDIX 1: FDA Regulation on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals

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	

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 or 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.

1.500 What definitions apply to this subpart?

1.501 To what foods do the regulations in this subpart apply?

1.502 What foreign supplier verification program (FSVP) must I have?

1.503 Who must develop my FSVP and perform FSVP activities?

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?

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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 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.

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.

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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 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.

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

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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

(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

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) 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

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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 § 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;

(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 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

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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 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:

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(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 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, § 1.505, 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

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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)(ii) 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 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

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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 is accredited in accordance with subpart M of this part, the audit is not subject to the requirements in that subpart.

(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 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

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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.

(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.

(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.

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(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 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:

Appendix 1

§ 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]

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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

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 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**

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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 Process Requirements	A3-9

Determining the FSVP Importer								
Instructions: This workaid is intended to help a person/entity who receives/sells imported food to assure that an appropriate FSVP importer has been designated by parties involved in the importation of the food AND that the Customs filer enters that name, address, and DUNS number as the FSVP importer.								
List foreign foods you receive (be specific, e.g., can sizes; size packages; bulk weight)	For each food, will the food or a product made from the imported food be offered for sale in the U.S.?	From whom do you purchase the food (Name, address)? Is this party a U.S. company or foreign company?	Does the person/ company from whom you directly purchase the food fall under the FSVP definition of foreign supplier (i.e., grower, manufacturer)? (Yes/No)	Describe current buying arrangements (name all parties involved in obtaining the food product, including foreign supplier, if known)	Do you potentially fall under the FSVP definition of "importer" for this food?	Who else might fall under the FSVP Importer (be specific, e.g., are there multiple purchasers for the same line item of food, do you purchase food from a U.S. importer/ distributor)?	If more than one possible "Importer," negotiate with others to determine who will carry out FSVP requirements (place name below) and formalize this understanding (state how)	Who fills out U.S. Customs' entry documents for this food (name, address)? Provide copy of agreement/ understanding that they will give name, email, and DUNS number of importer agreed upon FSVP importer.

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 for importers 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 for importers 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** (products 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 used 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 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. **Meat, Poultry, and Egg Products regulated by USDA's Food Safety and Inspection Service** (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 biannual 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/more 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. Specific requirements depend on category)

- 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 standing with the foreign food safety authority).

Additional Food Categories with Non-Standard Requirements:

- A. **Produce that is “covered produce” under the Produce Safety rule** (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 rule** (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 must comply with all FSVP requirements.)
- D. **Food ingredients going to U.S. manufacturing/processing facility subject to Preventive Controls rule** (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)
- E. **Food products not intended for further processing** (all FSVP requirements apply)
- 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, 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 Process 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 carrying out the FSVP activities. If the importer is depending on a third party's hazard evaluation, verification or other steps in the FSVP process (other than supplier approval, which must be carried out 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 no longer used. Even when the importer is relying on a third party's HA, foreign supplier evaluation, verification determination, or another requirement, 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 Process 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, 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 hazards 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 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 rule are 1) audits, 2) sampling/testing, 3) review of records, and 4) other appropriate activities.
 - c. **Performance of verification activities** ensures 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., 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 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

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.**

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APPENDIX 4: FSVP Requirements for Dietary Supplements: A Different Verification Focus

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Appendix 4: FSVP Requirements for Dietary Supplements: A Different Verification Focus

A4-3

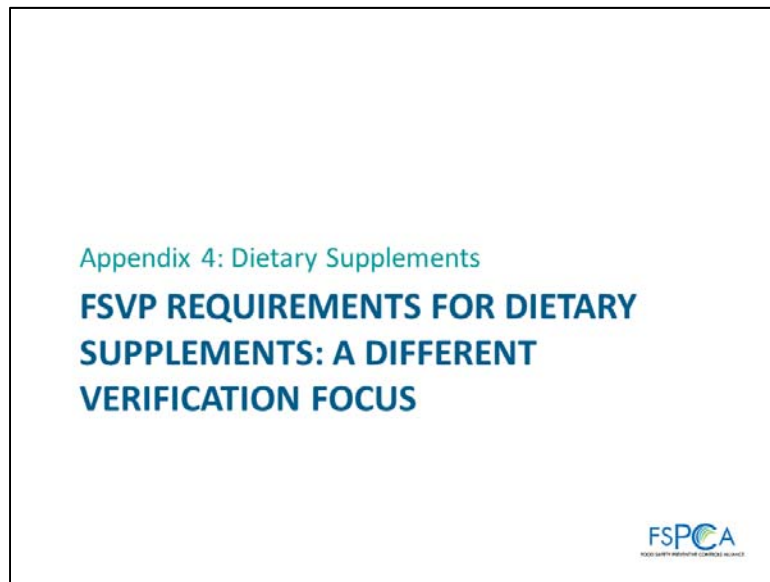
Goal: Participants will be able to evaluate their foreign suppliers, which must comply with the Dietary Supplement Current Good Manufacturing Practice (DS CGMP) requirements.

Learning Objectives:

- By the end of this chapter, participants will be able to:
 1. Define “dietary supplement.”
 2. Explain the importance of the CGMPs for dietary supplements.
 3. Describe FSVP responsibilities whether you import DS components or finished DS products.
 4. Describe how FSVP requirements for DS components and products 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 Practices (DS CGMPs) requirements is what importers must be verifying when importing dietary supplements.


Appendix 4: Goal and Objectives

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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 CGMPs for dietary supplements.
 3. Describe FSVP responsibilities whether you import DS components or finished DS products.
 4. Describe how FSVP requirements for DS components and products differ from other foods.




By the end of this chapter, you will be able to evaluate your foreign suppliers, which must comply with the Dietary Supplement Current Good Manufacturing Practice (DS CGMP) requirements. More specifically, you will be able to:

1. Define “dietary supplement.”
2. Explain the importance of the CGMPs for dietary supplements.
3. Describe FSVP responsibilities whether you import DS components or finished DS products.
4. Describe how FSVP requirements for DS components and products 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.

The FSVP rule definitions 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.”


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 supplement products are intended for ingestion, are not represented for use as a conventional food or as a sole item of a meal, and they must be labeled as dietary supplements.

It is also worth noting that:

1. Dietary supplements don't need to be approved before being marketed, and
2. Dietary supplements are subject to CGMP requirements that are similar, but not the same as the CGMPs that apply to conventional foods.
3. Dietary supplements are exempt from the Preventive Controls (PC) for human food rule.

Importance of DS CGMPs

Importance of DS CGMPs

- FDA tied the FSVP requirements for importers of dietary supplements to the regulation on Current Good Manufacturing Practice In Manufacturing, Packaging, Labeling, or Holding Operations For Dietary Supplements (DS CGMP) in 21 CFR 111.
- **For dietary supplements:**
 - **FSVP importers must verify that foreign suppliers are complying with the DS CGMP requirements.**



Dietary supplements are regulated under the DS CGMP (*Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements regulation*, 21 CFR 111). The CGMPs apply 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. The basic task of FSVP importers is to verify that foreign suppliers are complying with the DS CGMP requirements.

In publishing the DS CGMPs 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.”

FSVP Requirements for Dietary Supplements

FSVP Requirements for Dietary Supplements

- **Generally**, FSVP requirements for U.S. importers of dietary supplements are similar to the requirements for importers of other foods.
- The primary differences are that:
 - No hazard analysis is required, and
 - The importer must verify that the foreign supplier is complying with DS CGMPs.



Generally, FSVP requirements for U.S. importers of dietary supplements are similar to the requirements for importers of other foods (21 CFR 1.511). That is, importers must approve foreign suppliers, have a verification program for each product/foreign supplier, use qualified individuals, and identify the importer at entry, among the other requirements.


The primary differences are that:

1. No hazard analysis is required. That is because FDA believes that the DS CGMPs will address all the hazards that these products may pose.
2. Therefore, the importer must verify that the foreign supplier is complying with DS CGMPs.

Dietary Supplement Manufacturer/Processor Importing DS Components

**Dietary Supplement Manufacturer/Processor
Importing DS Components**

- **If you are:**
 - An importer of dietary supplement components, and
 - A DS manufacturer or processor (**Note:** Packaging and labeling is considered processing), and
 - You are complying with the DS CGMPs (including the requirements relating to specifications),
- **Then you have met your main FSVP obligations.**



The DS CGMPs require 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 component (e.g., at least one test/examination to definitively identify the material)
- Other specifications for the component, sufficient to ensure the purity, strength, and composition of the final DS product, and
- Limits on contamination that could adulterate the final DS product.

Under 21 CFR 170(d), DS manufacturers are also required to establish specifications for labels and packaging that come in contact with the dietary supplement (or DS component) and could affect the safety of the product.

The DS CGMPs additionally require (21 CFR 111.73 and 111.75) that the DS manufacturers determine that these requirements are met.

Therefore, if an importer of DS components is a DS manufacturer/processor (note that packaging and labeling is considered processing), and is complying with the DS CGMPs (including the requirements relating to specifications), then that importer has already met its main FSVP obligations.

Dietary Supplement Manufacturer/Processor
Importing DS Components (continued)

- **You must still, however:**
 - Be identified as the FSVP importer on the U.S. Customs entry forms,
 - Use a qualified individual, and
 - Maintain records.



This importer must still, however, be identified as the FSVP importer on the U.S. Customs entry forms, utilize a qualified individual, and maintain records under FSVP.

**Dietary Supplement Manufacturer/Processor Importing
DS Components (continued)**

Dietary Supplement Manufacturer/Processor
Importing DS Components (continued)

Other considerations:

- **You are not** required to comply with the other FSVP requirements.
- **Your finished DS products must** comply with all requirements in the DS CGMP rule and other FDA requirements.



You are not, however, required to comply with the other FSVP requirements. Your finished dietary supplement products 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.

What If My Customer Is the One Who Must Establish Specifications?

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 CGMPs 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:

1. Annually obtain from your customer written assurance that it is in compliance with those requirements,
2. Comply with the FSVP requirements for using qualified individuals and qualified auditors,
3. Identify the importer at entry, and
4. Comply with the records requirements of 21 CFR 1.510.
5. But, you are not required to comply with the other FSVP requirements (21 CFR 1.511(b)).

FSVP Requirements for Other DS Products

FSVP Requirements for Other DS Products

- 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 standard FSVP requirements, **including:**
 - Using a **qualified individual** to develop your FSVP
 - Evaluating foreign supplier performance
 - Approving foreign suppliers
 - Maintaining records



Importers of finished dietary supplement products 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 still 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:

1. Using a qualified individual to develop your FSVP
2. Evaluating the DS and foreign supplier performance
3. Approving your foreign supplier
4. Documenting and maintaining records
5. Implementing your FSVP
6. Taking corrective actions
7. Identifying the importer at entry.

What About Performance by Others?

What About Performance by Others?

- 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 evaluation was 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 supplement products, 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 review and assessment of activities conducted by others, if you are relying on them, including documenting that the evaluation was conducted by **qualified individuals**.

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 product.

What Safety Assurance Is Needed

What Safety Assurance Is Needed?

- Your foreign supplier verification activities for imported DS products must:
 - Ensure that your foreign supplier is providing the same level of public health protection as required by the dietary supplement CGMPs in 21 CFR Part 111
- This determination must be based on the evaluation of your supplier.



Your foreign supplier verification activities for imported dietary supplement products must ensure that your foreign supplier is providing the same level of public health protection as required by the dietary supplement CGMPs in 21 CFR Part 111.

You must make this determination based on your evaluation of your foreign supplier.

Appendix 4: Summary

Appendix 4: Summary

- What dietary supplements are and how they are affected by FSVP.
- If you import DS components or finished DS products, you are not required to conduct a hazard analysis and your foreign supplier verification is tied to the DS CGMPs in 21 CFR 111.



You have learned:

1. What dietary supplements are and how they are affected by FSVP.
2. If you import DS components or finished DS products, you are not required to conduct a hazard analysis and your foreign supplier verification is compliant with the DS CGMPs in 21 CFR 111.

Appendix 4: Summary (continued)

- If you are an importer and manufacturer/processor of DS products, and you have established that your specifications for DS components/safe packaging and labeling have been met, you have met most of your FSVP requirements.
- If you import finished DS products, you must carry out all of the standard FSVP activities explained in other FSVP Chapters.



3. If you are an importer and manufacturer/processor of DS products, and you have established that your specifications for DS components/safe packaging and labeling have been met, you have met most of your FSVP requirements.
4. If you import finished DS products, you must carry out all of the other standard FSVP activities explained in other FSVP Chapters.

Appendix 4: Questions



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APPENDIX 5: FSVP Modified Requirements

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Appendix 5: FSVP Modified Requirements

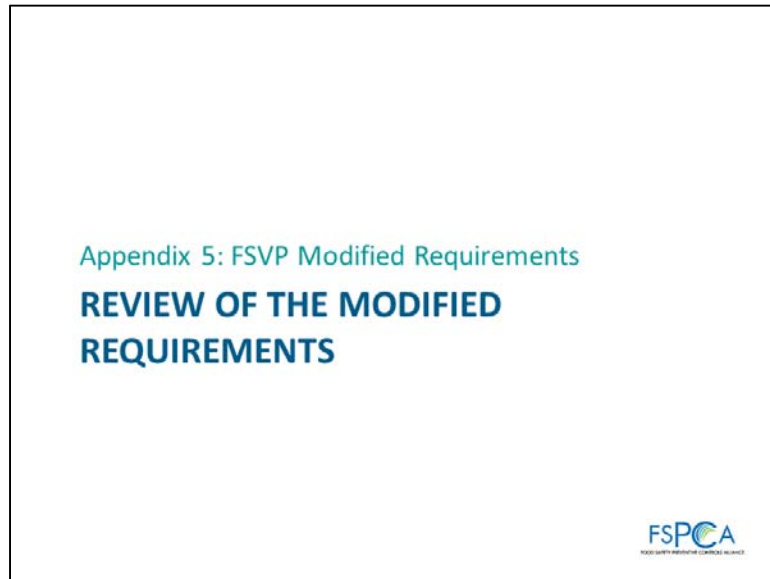
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Goal: Participants will be able to demonstrate knowledge of FSVP modified requirements.

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 you are not a “very small importer,” but are importing from a “certain small foreign supplier.”
 5. Describe requirements when importing from a recognized system.

APPENDIX 5. FSVP 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 continues the discussion from 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 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 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 you are not a “very small importer,” but are importing from a “certain small foreign supplier.”
 5. Describe requirements when importing from a recognized system.


FOOD SAFETY PROGRAMS AND CERTIFICATION ASSOCIATION


Appendix 5 will describe the “modified” requirements in more detail for importers who have determined that modified requirements apply to them. This Appendix will identify:

1. What FDA means by a “very small importer” and “certain small foreign supplier,”
2. The requirements if you are not a “very small importer,” but are importing from a “certain small foreign supplier,” and
3. The requirements when importing from a recognized system.

Modified Requirements

Modified Requirements

- Food imported by a “Very Small Importer”
- Food imported from “Certain Small Foreign Supplier(s)”
- Food imported from foreign supplier(s) in countries with food safety systems recognized by FDA as “comparable” or “equivalent”
- Dietary supplements or dietary supplement components (see Appendix 4)


FOOD SAFETY PROGRAMS AND CERTIFICATION ASSOCIATION


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

We will cover the first three situations in more detail in the following slides.

“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”
 - Are importing certain 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 certain 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 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 and animal foods, 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. (animal food 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.

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.

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 **PSR** requirements for a “qualified exemption.”
 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 (PSR) (21 CFR 112.4, less than \$25,000 U.S. average produce sales) or satisfies the PSR requirements for a “qualified exemption” (21 CFR 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 will be explained further in a moment.

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 Food Importers”

Modified Requirements for “Very Small
Food 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 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 food is in compliance with U.S. adulteration and allergen labeling provisions. Allergen labeling is NOT required for 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.

Importing from “Certain Small Foreign Suppliers”

Importing from “Certain Small Foreign Suppliers”

- If you are importing food from one of the three categories of “certain small foreign suppliers” further delineated in the following slides 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.



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 for each applicable calendar year thereafter.

“Certain Small Foreign Suppliers”: “Qualified Facilities”

**“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. (animal food), **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. (animal food), **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.

“Certain Small Foreign Suppliers”:
“Qualified Facilities” (continued)

- 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 laws and regulations of a comparable or equivalent country.
 - 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 or equivalent to the U.S. food safety system.

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.

“Certain Small Foreign Suppliers”: A Farm That Grows Produce

“Certain Small Foreign Suppliers”:
A Farm 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 \$500,000 U.S., **then**



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.

**“Certain Small Foreign Suppliers”:
A Farm That Grows Produce (continued)**

- **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 or determined to be equivalent to the U.S.



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 or determined to be equivalent to the U.S. 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”:
A Shell Egg Producer**

- 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 or determined to be equivalent to the U.S.



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 or determined to be equivalent to the U.S. 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 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.

If You Are Not a “Very Small Importer,” but Import from “Certain Small Foreign Suppliers”

If You Are Not a “Very Small Importer,” but Import from “Certain Small Foreign Suppliers”

- If you do NOT qualify as a “very small importer,” but do import from “certain small foreign suppliers,” you have additional requirements beyond those of a “very small importer.”
- **These pertain to:**
 1. Evaluating the foreign suppliers compliance history,
 2. Approval of the foreign supplier, and
 3. Use of approved foreign suppliers.



If you do NOT qualify as a very small importer but do import from “certain small foreign suppliers,” you have additional requirements beyond the written assurance described above.

These pertain to:

1. Evaluating the foreign supplier’s compliance history,
2. Approval of the foreign supplier, and
3. Having written procedures to ensure that food is only imported from approved foreign suppliers.

The details of these additional requirements are explained in the following slides.

If You Are Not a “Very Small Importer,” but Import from
“Certain Small Foreign Suppliers” (continued)

- Similar to approval of any foreign supplier:
 - You must approve small foreign suppliers on the basis of your evaluations.
- You must establish and follow written procedures to ensure that:
 - You import foods only from those “certain small foreign suppliers” that you have approved based on the evaluations that you or another entity have conducted.



Similar to approval of any foreign supplier, you must approve small foreign suppliers on the basis of the above evaluations. One of FDA’s objectives in the FSVP rule is to be sure that food importers become knowledgeable about their foreign suppliers. The process of approving foreign suppliers helps to achieve this objective.

You must also establish and follow written procedures to ensure that you import foods only from those “certain small foreign suppliers” that you have approved based on the evaluations that you have conducted. If you rely on another entity to conduct the evaluations, you must review that entity’s evaluation.

If You Are Not a “Very Small Importer,” but Import
from “Certain Small Foreign Suppliers” (continued)

- You must document:
 - The approval of your foreign food suppliers, **and**
 - Your use of written procedures to ensure use of approved suppliers.



You must document the approval of your foreign food suppliers and your use of written procedures to ensure use of approved suppliers.

If You Are Not a “Very Small Importer,” but Import from “Certain Small Foreign Suppliers” (continued)

- For your initial evaluation **in approving** your small foreign supplier, you must:
 - Evaluate applicable FDA food safety regulations and information relevant to your supplier’s compliance with those regulations,
 - **For example:** Is the foreign supplier the subject of an FDA warning letter, import alert, or other compliance action?



In your initial evaluation, when you approve your foreign supplier, you must evaluate the applicable FDA food safety regulations and the supplier’s compliance with those regulations. In particular, you must determine whether the foreign supplier is the subject of an FDA warning letter, import alert, or other compliance action.

If You Are Not a “Very Small Importer,” but Import from “Certain Small Foreign Suppliers” (continued)

- You must:
 - Promptly reevaluate the foreign supplier’s compliance history every 3 years, **or**
 - When you become aware of new information.
- If concerns about the foreign supplier prompt a reevaluation and those concerns are not resolved:
 - **You must take appropriate actions.**



If concerns about the foreign supplier prompt a reevaluation and those concerns are not resolved, you must take appropriate actions and document those actions, which may require considering if it is appropriate to continue importing from that small supplier.

If You Are Not a “Very Small Importer,” but Import from “Certain Small Foreign Suppliers” (continued)

- You may **utilize another entity’s evaluation** or reevaluation of your foreign supplier:
 - As long as it was done by a **qualified individual** and your **qualified individual** reviews and assesses it.
- All evaluations of your supplier’s performance must be **documented**.



You may utilize another entity’s evaluation or reevaluation (by a qualified individual) of your foreign supplier, so long as your qualified individual reviews and assesses it. All evaluations of your supplier’s performance must be documented.

Record Keeping Requirements

Record Keeping Requirements

- A very small food importer and importers importing from small foreign suppliers are subject to essentially the same recordkeeping provisions as discussed in Chapter 9.



An FSVP importer subject to modified requirements must still be identified on the Customs 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 very 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.

FSVP When Food Is from a Recognized System

When Food is Produced Under a Safety System Recognized by FDA

- If you import certain foods from a foreign supplier in a country whose food safety system FDA has a systems recognition arrangement or equivalency agreement, your requirements can be reduced if:
 - Your supplier is under the regulatory oversight of that food safety authority;
 - The food is within the scope of the systems recognition arrangement or equivalency agreement; and
 - The supplier must be in good standing.
- If these conditions are met, you are not required to:
 - 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. We have already mentioned that currently New Zealand and Canada's systems have been found equivalent, and other systems recognitions are in process. Information on the 2016 Canada recognition with links to the evaluation process can be found on the FDA website at: <http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm498611.htm>.

If FDA officially determines that another country's food safety system is comparable or equivalent to the U.S. food safety system, 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 a small 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 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 on U.S. Customs documents at entry.
- Note: This provision **ONLY** applies to food that is not intended for further manufacturing/processing before consumption.



You must, however, identify yourself as the FSVP importer on U.S. Customs documents at entry and maintain records relative to all FSVP activities. Remember, whoever is identified on the Customs 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, however, that this section 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 need to comply with the PC rules and/or other U.S. food safety requirements.

Foreign Supplier Must Be in “Good Standing”

Foreign Supplier from a Recognized System Must Be in “Good Standing”

- **Before** importing a food from the foreign supplier of a system that has been officially recognized by FDA:
 - Determine and document that the foreign supplier is in good compliance standing with the appropriate food safety authority of the country in which the foreign supplier is located.



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

Foreign Supplier Must Be in “Good Standing” (continued)

- You must continue to monitor the foreign supplier to:
 - Ensure the foreign supplier remains in good compliance standing with the foreign food safety authority.
- You must take prompt corrective action:
 - If any information indicates food safety hazards associated with the food are not being significantly minimized or prevented.



Also, you must continue to monitor whether the foreign supplier is in good compliance standing with the foreign food safety authority.

If any information indicates that the food safety 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 supplier.”
- Discussed the requirements if you are not a “very small importer,” but are importing from a “certain small foreign supplier.”
- Described the requirements when importing from a recognized 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 system.

Appendix 5: Questions

Appendix 5: Questions

Thank you for Your Attention!

Questions?



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APPENDIX 6: Preventive Controls (PC) and Produce Safety Overview

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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. FSVP Current Good Manufacturing Practice (CGMP) and Preventive Controls (PC) Rules Overview

Appendix 6a: Preventive Controls Overview

CURRENT GOOD MANUFACTURING PRACTICE (CGMP) AND PREVENTIVE CONTROLS (PC) RULES OVERVIEW



FSVP CGMP and PC Rules

FSVP CGMP and PC Rules




"Current Good Manufacturing Practice,
Hazard Analysis, and Risk-Based
Preventive Controls for Food for Animals"
(CGMP and PC for Animal Food rule)

"Current Good Manufacturing Practice,
Hazard Analysis, and Risk-Based
Preventive Controls for Human Food"
(CGMP and PC for Human Food rule)



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 and 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 Animal Food* regulation (referred to as the CGMP and 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.

Appendix 6a: Goal and Objectives

 FDA's Technical Assistance Network (TAN) is available to answer regulatory or rule interpretation questions. TAN can be accessed at: <http://www.fda.gov/fsm>

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

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.



By the end of this chapter, you 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

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 and PC requirements?

Where Can I find CGMP and PC requirements?

- CGMP and 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 and PC for human food and the CGMP and PC for animal food were published. The regulations focus on a preventive approach to food safety. The CGMP and PC for human food rule can be found in the Code of Federal Regulations (CFR)–21 CFR part 117 and the CGMP and 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 CGMP and PC for Human Food Rule Do?

What does CGMP and PC for Human Food Rule Do?

- Modernizes longstanding current Good Manufacturing Practice (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 and PC for human food rule establishes new requirements for hazard analysis and risk-based preventive controls, as mandated by the 2011 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 CGMPs for human food are found in 21 CFR part 117, subpart B and are shown in this slide. CGMPs 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 CGMPs can be considered a pre-requisite program prior to implementation of preventive controls.

The previous CGMPs found in 21 CFR 110 were updated to the new 21 CFR 117 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 is produced in compliance with CGMPs and is not further processed, 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.

What Does CGMP and PC for Animal Food Rule Do?

What does CGMP and PC for Animal Food Rule Do?

- Establishes current Good Manufacturing Practice (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 and PC for animal food rule. The first key area relates to establishing CGMP requirements. Prior to the publication of the final rule, CGMPs were not required for all animal food facilities. The CGMP and PC for animal food rule established CGMPs 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–CGMPs for Animal Food

Part 507–CGMPs 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	


FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE


The CGMP requirements for animal food are found in 21 CFR part 507, subpart B.

The CGMPs were established to provide baseline requirements necessary to prevent animal food from contamination. Proper implementation of CGMPs is necessary to produce safe animal food. The CGMPs 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 CGMPs can be considered a pre-requisite 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


FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Unless subject to an exemption or modified requirements, every human 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 and PC for human food and CGMP and PC for animal food rules. Unless noted, the requirements in subpart C are the same for both the CGMP and PC for human food and CGMP and PC for animal food rules. For example, the CGMP and 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, a written supply-chain program, as required by subpart G of both rules, will be required. Note, the supply-chain provisions in the two rules are consistent with those in the Foreign Supplier Verification Program 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 CGMPs 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 Food Safety Modernization Act 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.

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


FOOD SAFETY PROCESSING CONTROL ASSOCIATION

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

- Only needed if allergen hazard requires control beyond facility CGMP (*for human food only*)
- Generally 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

- Only needed if environmental, allergen (*human food only*) or other hazard requires facility or equipment sanitation controls beyond normal CGMP
- 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 are best 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



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.).

Food Safety Plan–Recall Plan

Food Safety Plan–Recall Plan

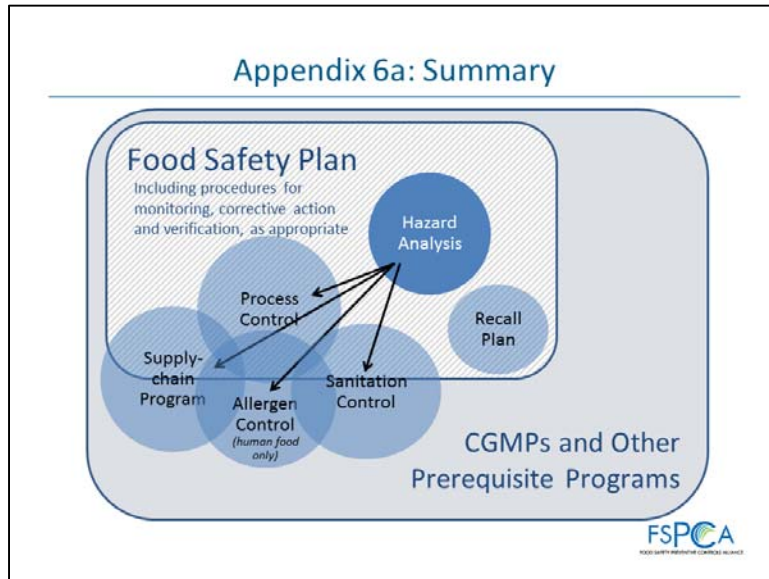
- A written plan is required if hazards requiring a preventive control are identified in the food safety plan
- Includes procedures that describe and assign responsibility for the steps to be taken, including:
 - Notify the direct consignees of the food being recalled
 - Notify the public
 - Conduct 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.

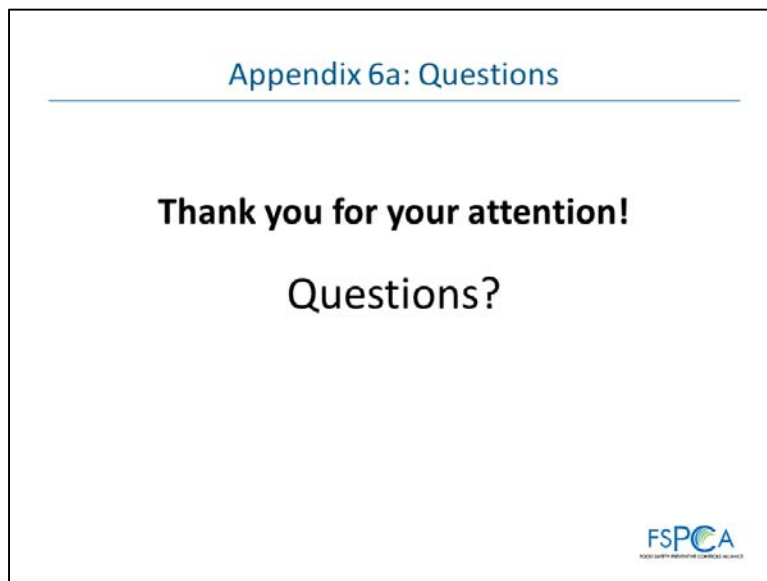
Appendix 6a: Summary



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 CGMPs 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 CGMPs that are not covered in the Food Safety Plan are still required by the two regulations.

Appendix 6a: Questions



Notes:

This image shows a blank sheet of white paper with horizontal ruling lines. The lines are evenly spaced and extend across the width of the page. There are no margins, text, or other markings on the paper.

APPENDIX 6. Produce Safety Overview

Appendix 6b: Produce Safety Overview

STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION



Produce Safety Rule

Produce Safety Rule



**“Standards for the Growing, Harvesting, Packing, and
Holding of Produce for Human Consumption”**



This Appendix chapter covers FDA’s Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 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 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.



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.

What Is Required by the Produce Safety Rule?

What Is Required by the Produce Safety Rule?

Hazards to be Controlled

- Microbiological hazards from:
 - **Agricultural water** that contacts produce (irrigation, crop chemicals, washing) or food contact surfaces (including hands)
 - **Domesticated and wild animals** and their excreta that may come into contact with produce
 - **Biological soil amendment of animal origin (manure)** that may reasonably come into contact with produce
 - **Health and hygiene of workers** that contact produce (harvesters, sorters, packers)
 - **Equipment, tools, buildings, and sanitation** (tools, utensils, containers, equipment)
 - **Growing, harvesting, packing, and holding activities** that may reasonably be a source of contamination




For the Produce Safety rule, FDA specifically defined hazard as any biological agent that has the potential to cause illness or injury in the absence of its control. They concluded that physical hazards that can cause injury and chemical hazards, such as from crop protection chemicals, are not reasonably likely to occur in RACs grown and harvested in the U.S., citing an analysis of scientific literature and recall data that led them to conclude that non-biological hazards associated with produce rarely pose a risk of serious adverse health consequences or death for individuals that would consume the product. Therefore, the rule focuses on potential microbiological hazards.

FDA identified the 6 most likely sources of microbiological hazards on farms as agricultural water; domesticated and wild animals; biological soil amendments of animal origin; health and hygiene of workers; equipment, tools, buildings and sanitation; and growing, harvesting, packing and holding activities that may reasonably be a source of contamination. 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
- Microbial water quality profile: testing to demonstrate water used for certain purposes meets specific microbial criteria
- For pre-harvest activities:
 - GM of 126 CFU/100 mL or less generic *E. coli* and STV of 410 CFU/100 mL or less generic *E. coli*
- For harvest, post-harvest activities (e.g., washing, cooling):
 - No detectable generic *E. coli*/100 mL



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 to meet microbiological criteria, 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 make the water safe and of adequate sanitary quality for its intended use.

Unless the water is treated or is provided by a public water supply that furnishes water that meets the microbial quality requirement, testing is required to demonstrate water meets specific microbial criteria. The farm must develop a microbial water quality profile of each water source. 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 harvest, hand, or food contact surface washing and any post-harvest applications, the water source 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 animal contamination
- 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. Domesticated animals, whether pets or work animals, should either be excluded from field operations or steps should be taken to minimize the likelihood that they or their excreta can come into contact with fresh produce. FDA recognizes that wild animals are less controllable. Therefore, farms are only required to assess, throughout the growing season and at harvest, growing and produce handling areas 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 has visible evidence of animal excreta or that is

otherwise reasonably likely to be contaminated should not be harvested or should be discarded.

Controlling Hazards from Biological Soil Amendments (BSAs) of Animal Origin

Controlling Hazards from Biological Soil Amendments (BSAs) of Animal Origin

- No preharvest intervals for BSAs that are adequately treated (compost)—can apply at any time
 - Criteria for processes to adequately treat BSAs are in the rule
- Untreated human waste is not permitted
- Preharvest intervals for raw or incompletely treated BSAs are being researched, to be published later




Just as animal excreta can be a source of human pathogens, so can Biological Soil Amendments (BSAs) of animal origin that are reasonably likely to come in contact with the harvestable crop. FDA determined that BSAs that do not contain manure or other animal material are less likely to contain human pathogens. Non-animal BSAs and BSAs that have been composted or otherwise treated in a manner adequate to destroy human pathogens can be applied to the soil at any time. Criteria for processes to treat BSAs adequately 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 BSAs of animal origin, 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 of Workers

Controlling Hazards from
Health and Hygiene of Workers

- Preventing contamination by ill persons
- Hygienic practices:
 - Toilet and hand-washing facilities must be adequate and readily accessible during covered activities
 - Farms must make visitors aware of policies and give them access to toilet and hand washing facilities
- All workers must receive food safety training
 - Harvesters and supervisors receive additional training

 Food Safety and Inspection Service

Humans, of course, are a potential source of human pathogens, so the health and hygiene of workers, particularly ill workers, is an important consideration. Farms must have toilet and hand-washing facilities in adequate number and adequately maintained and readily accessible whenever covered produce is being handled. Farms must make visitors aware of hygiene policies and give them access to toilet and hand-washing facilities. Not all carriers of pathogens will appear ill, so all workers 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 supervisors must receive additional training in recognizing and dealing with potential sources of contamination.

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



Equipment, tools, buildings, and other surfaces, during growing, harvesting, and in post-harvest handling, 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, cleaned, and sanitized as often as necessary to minimize the risk of becoming sources of contamination. Buildings and other structures used 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.

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
- 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 identify and not harvest covered produce that is reasonably likely to be contaminated. They must also be trained either to not harvest or not distribute covered produce that drops to the ground before harvest; this does not apply to root crops, crops that normally grow in contact with the ground (e.g., melons), or produce that is normally harvested on the ground (e.g., almonds).

Food-packing material must be appropriate for its intended use. For example, produce that is vulnerable to growth and toxin production by *Clostridium botulinum* must not be packaged in materials that will increase that risk.

Other Hazards to Be Controlled

Other Hazards to Be Controlled

- Physical and chemical hazards:
 - **Not specifically required by the 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 \$25,000 average annual sales of produce
 - No additional federal regulations; FD&C still applies and adulterated food cannot be offered for sale
- Farms that have a qualified exemption
 - On the food packaging label, on a poster, sign, or placard at the point of purchase, or on documents delivered with the produce, include prominently and conspicuously the name and the complete business address of the farm where the produce was grown
 - 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
 - Still subject to recordkeeping requirements (Subpart O) and Withdrawal of Qualified Exemption (Subpart R)
 - FD&C still applies and adulterated food cannot be offered for sale



Produce from a farm or farm mixed-type facility with less than \$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 Food Drug and Cosmetic Act (FD&C), specifically that adulterated food cannot be offered for sale.

Farms that have 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.

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 qualified farm is still subject to the requirements of the FD&C, 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 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 a Raw Agricultural Commodity (RAC) 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 an 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, 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 (e.g., cooking) 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 sources of microbiological hazards covered by the Produce Safety regulation.
- We have explained the key concepts and requirements that your foreign fresh 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 sources of hazards covered by the Produce Safety regulation, explained the key concepts and requirements that your foreign fresh 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?



Notes:

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APPENDIX 7: Technical Assistance and Resources

Title of Document	Page
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Am I Subject to FSVP Flowchart	A7-15
Standards for Produce Safety Flowchart	A7-17

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/ifsh/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/fspca-technical-assistance-network	Answers scientific/technical questions related to Preventive Controls and FSVP	
FSPCA Courses	http://www.iit.edu/ifsh/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.producesafetyalliance.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://producesafetyalliance.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 3: Overview of Requirements			
Am I Subject to FSVP Flowchart	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.
Chapter 4: Hazard Analysis			
FDA Reportable Food Registry (RFR)	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	
FDA's Bad Bug Book	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.	
Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food	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	
Chemical Contaminants, Metals, Natural Toxins & Pesticides Guidance Documents & Regulations	http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ChemicalContaminantsMetalsNaturalToxinsPesticides/default.htm	This guidance provides information on Chemical Contaminants, Metals, Natural Toxins & Pesticides Guidance Documents & Regulations.	
CPG Sec. 560.750 Radionuclides in Imported Foods - Levels ... INSPECTIONS AND COMPLIANCE	www.fda.gov/oc/oc/compliancemanuals/compliancepolicyguidancemanual/ucm074576.htm	This guidance provides information on CPG Sec. 560.750 Radionuclides in Imported Foods - Levels of Concern.	

Name of Resource		Location	Purpose
Action Levels for Poisonous or Deleterious Substances in Human and Animal Food		http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm077969.htm	This booklet lists action levels established by the FDA for Action Levels for Poisonous or Deleterious Substances in Human and Animal Food.
Centers for Disease Control and Prevention (CDC): Current Outbreaks List		http://www.cdc.gov/outbreaks/index.html	To obtain information regarding Infectious disease outbreaks currently being reported on by CDC.
Multistate Foodborne Outbreak Investigations		http://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html	To obtain information regarding Multistate Foodborne Outbreak Investigations.
FDA Recalls, Market Withdrawals, & Safety Alerts		http://www.accessdata.fda.gov/cms_ia/industrygroup1.html	To obtain information regarding FDA Recalls, Market Withdrawals, & Safety Alerts.
Chapter 5: Evaluation and Approval of Your Foreign Supplier			
FDA's Supplier Evaluation Resources		http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm516330.htm	To research the history of your foreign supplier.
Import Alerts		http://www.accessdata.fda.gov/cms_ia/default.html	To research the history of your foreign supplier and identify any import alerts.
Import Refusal Report		http://www.accessdata.fda.gov/scripts/importrefusals/	To research the history of your foreign supplier and identify any refused imports.
Chapter 8: Importer Identification			
Dun & Bradstreet's Get Started Web page		https://www.dandb.com/free-duns-number/	To apply for a free DUNS number
Chapter 9: Importance of Records			
21 CFR Part 20		https://www.gpo.gov/fdsys/pkg/CFR-1999-title21-vol1/pdf/CFR-1999-title21-vol1-part20.pdf	Regulations that explain the rules for disclosing records to the public upon request.

Name of Resource		Location	Purpose
Chapter 10: FDA Oversight			
Request for FSVP Records (Form 482d)*		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.
FSVP Observations (Form 483a)*		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.
FDA Unified Registration and Listing System (FURLS)*		<p>For additional information and to create a FURLS account, go to the FDA industry Systems Main page at: http://www.access.fda.gov</p> <p>Online help instructions are available at: http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm114181.htm</p> <p>*Screenshots of “Login” screen, “Create Account” screens 1 and 2, and “Main Menu” (after login) are located in your manual in Appendix 7</p>	<p>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.</p>

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
	4. NUMBER AND STREET		<input type="checkbox"/> a.m. <input type="checkbox"/> p.m.
	5. CITY, STATE AND ZIP CODE		8. EMAIL ADDRESS
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. <div style="background-color: #e0e0ff; height: 200px; width: 100%; margin-top: 10px;"></div>			
10. SIGNATURE (Food and Drug Administration Employee(s))		11. TITLE FDA EMPLOYEE	

FORM FDA 482d (9/16) REQUEST FOR FSVP RECORDS

PSC Publishing Services (301) 443-0740 EF

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	
Industry Information: www.fda.gov/oc/industry		FEI NUMBER	
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="height: 250px; border: 1px solid black; margin-top: 10px;"></div>			
ADD Continuation Page			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (<i>Print or Type</i>)	DATE ISSUED

FORM FDA 483a (2/16)
FSVP OBSERVATIONS
Page 1 of 2
FSC Publishing Services (301) 403-6740 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:

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FDA | **ONLINE ACCOUNT ADMINISTRATION (OAA)**

FDA Industry Systems [System Status](#)

Login

Existing account holders, enter your account ID & password.

Account ID

Password

Under 18 U.S.C. 1001, anyone who makes a knowingly false, fraudulent, or fraudulent statement to the U.S. Government is subject to criminal penalties.

☐ I understand.

[Login](#) [Forgot your password](#)

New User

[Create New Account](#)

[See Instructions](#) [See Tutorial](#) [Help Desk](#)

Getting Started

To make submissions to FDA (e.g., Food Facility Registration, Prior Notice, etc.) you must first create an account. Select "Create New Account" towards the bottom left side of this page.

If you already have an account, enter your account ID and password.

WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

Is your computer secure? Before using FDA Industry Systems (FIS), FDA strongly encourages all users to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

If you have Tobacco Registration and Product Use (TRPM) specific questions, please contact **AskCTP** at 1-877-087-1575 or **AskCTP** at AskCTP@fda.hhs.gov and the AskCTP staff can assist with answering your questions about TRPM.

FDA retains contractors to assist the agency in maintaining its databases. If you get a call from someone asking about your facility and you are concerned about whether the call is legitimate, get the name and company of the caller, as well as a phone number, and contact **FDA FURLS Help Desk** at 1-800-216-7321 to confirm that the caller is acting on behalf of FDA.

FDA Accessibility Browser Requirements FAQ Help Desk Privacy

U.S. Food and Drug Administration 10905 New Hampshire Avenue Silver Spring, MD 20910 1-800-FDA-1088	Academy of Nutrition and Dietetics Food and Nutrition Assistance Programs	Biologics Export Certification Application and Tracking System	Certificate Application Program
Contact Us	CDER Export Certification Application and Tracking System	CDER Export Certification Application and Tracking System	Dairy Listing Module
Twitter Facebook LinkedIn YouTube	Device Registration and Listing Module	Food Facility Registration	Humanitarian Importation
Prior Notice System Interface	Shell Egg Producer Registration	Shell Egg Producer Registration	Structural/Functional Control Verification
Tobacco Registration and Listing System			

FURLS OAA “Create Account” Screen 1:

U.S. Department of Health and Human Services

FDA OAA | **ONLINE ACCOUNT ADMINISTRATION (OAA)**

Create New Account

Create New Account

You must create a separate account to create your Medical Device Registration and Listing, Tobacco Registration and Product Listing or Food Facility.

Step 1: Select Application(s) for Account Creation

Registration and Listing Programs

Eggs

☐ Acidified/Low Acid Canned Foods Registration and Process Flow

☐ Infant Formula

☐ Food Facility Registration

☐ New Dietary Ingredient Notification

☐ Shell Egg Producer Registration

☐ Structured Infant Formula Notification

Veterinary 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)

☐ Cosmetic Approval Process

☐ Food Additive, Food Contact Substances, Dietary Supplements, Infant Formula, Medical Foods, and Foods for Special Dietary Use

☐ Veterinary Export Certification Application and Tracking System (VETCATS)

☐ Bulk Gelatin and Collagen Certificate Application Process

☐ (384) Export Certification Application and Tracking System (ECERCATS)

FSMA Program(s)

☐ Foreign Supplier Verification Program

Other FDA Systems

☐ Prior Notice System Interface

[Cancel](#) [Close](#) [Continue](#)

FURLS OAA "Create Account" Screen 2:

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FDA **ONLINE ACCOUNT ADMINISTRATION (OAA)**

Create New Account

Create New Account

Step 2: Enter Your Account Information

2A: Point of Contact Information

First Name

Mobile Initial (Optional)

Last Name / Surname

Job Title

Company Name

Web Address (Optional)

(e.g. <http://www.fda.gov> or <mailto:info@fda.gov>)

Phone Number

Country Area Extension

Country Area Phone Number Extension

Phone/FAX numbers have only numbers with no special dashes, periods or other letters. Country code is not required for US phone numbers.

FAX Number (Optional)

Country Area Fax Number

Country Area Fax Number

Email Address

Confirm Email Address

2B: Physical Address (Business) of Account Holder

Country / Area

Address Line 1

Address Line 2 (Optional)

City

State / Province / Territory

Zip Code (Postal Code)

Unique Facility Identifier (Optional)

(Do you have preferred mailing address other than the physical address mentioned above?)

☐ Yes ☐ No

2C: Account Information

Password

Confirm Password

Secret Question 1

Secret Answer 1

Secret Question 2

Secret Answer 2

Secret Question 3

Secret Answer 3

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](#) [Close](#) [Continue](#)

FURLS OAA “Main Menu” (after login) Screen:

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FDA ONLINE ACCOUNT ADMINISTRATION (OAA)

Account Management

Account Management

Edit Account Profile
Change My Password
Update System Access
Create a Subaccount
Deactivate a Subaccount
Reactivate a Subaccount

Welcome to the FDA Industry Systems. You are logged in as **tr125666** for **FDA**.

You may choose an option on the left to manage your account or sign on FDA system below. To obtain access to available FDA systems, choose the **Update System Access** option to add the FDA system to your account.

Registration and Listing Programs

Food

☐ Food Facility Registration

☐ Dairy Listing Module

☐ Institutional and Clinical Food Registration and Listing

☐ Structural/Packaging Claims Notification

☒ New Dietary Ingredient 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)

☐ Bulk Growth and Carapen Certificate Application Process

☐ CDER Export Certification Application and Tracking System (CDER-ETTS)

☐ CDER Export Certification Application and Tracking System (CDER-ETTS)

FSMA Programs

☒ Foreign Supplier Verification Program

Other FDA Systems

☐ Prior Notice System Interface

☐ Student Registration Program

Fri Dec 16 11:38:39 EST 2016

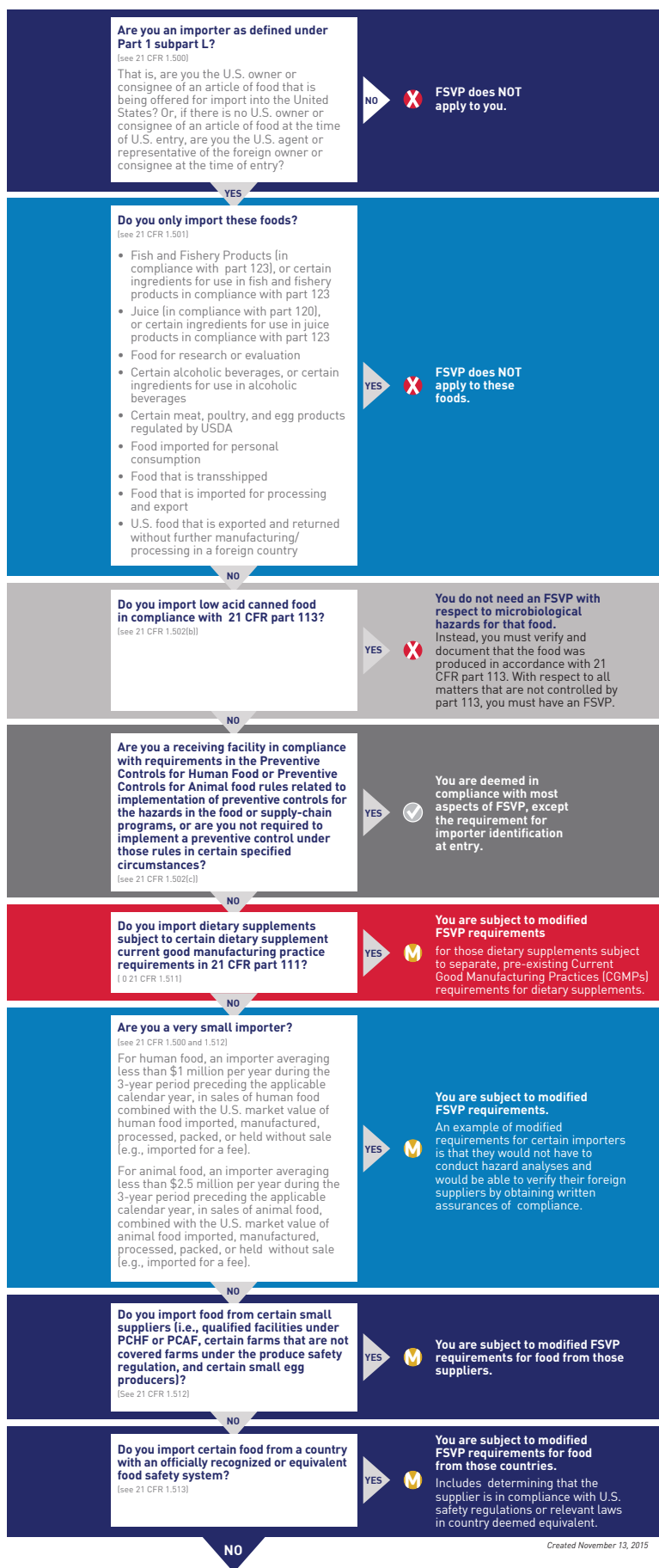
FDA Accessibility Browser Requirements FAQ Help Desk Privacy

U.S. Food and Drug Administration
10855 Sunrise Avenue
Silver Spring, MD 20993
4-888-NOT-FDA (1-888-463-4332)
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Food Facility Registration and Listing	Biologics Export Certification Application and Tracking System	Certificate Application Program
CDER Export Certification Application and Tracking System	CDER Export Certification Application and Tracking System	Dairy Listing Module
Device Registration and Listing Module	Food Facility Registration	New Dietary Ingredient Notification
Foreign Supplier Verification Program	New Dietary Ingredient Notification	Institutional and Clinical Food Registration and Listing

AM I SUBJECT TO FSVP?

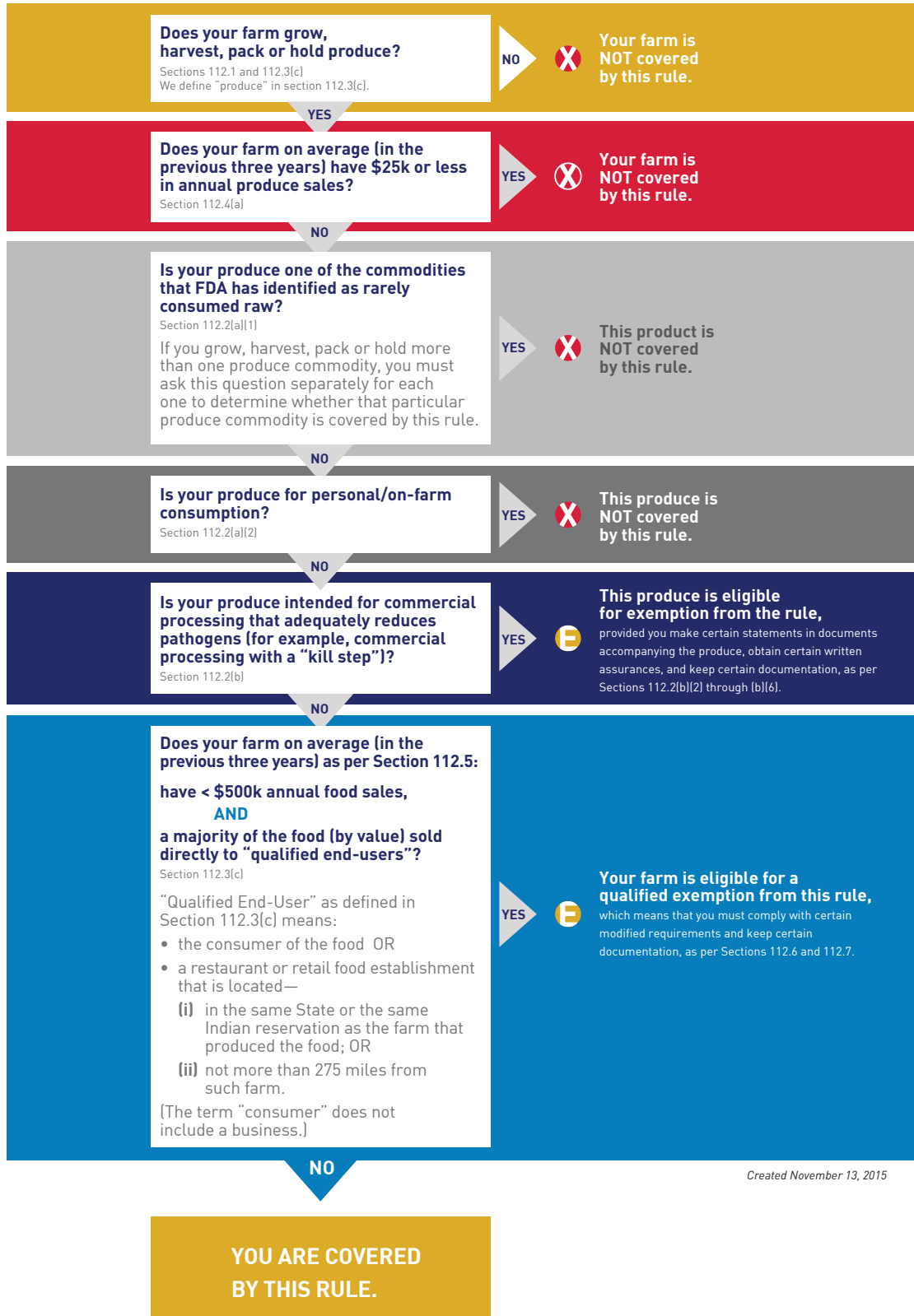


Created November 13, 2015

STANDARDS FOR PRODUCE SAFETY

Coverage and Exemptions/Exclusions for 21 PART 112

The Preventive Controls for Human Food rule clarified the definition of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same definition is used in the Produce Safety rule (section 112.3(c)). Below are basic criteria that determine whether an operation that meets the definition of “farm” is subject to the produce rule.



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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;

(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

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 allergenic 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.

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APPENDIX 9: Fact Sheets on FSVP Rule, PC Rules, Produce Safety Rule, Accredited Third-Party Certification, and VQIP

Title of Document	Page
FSMA Final Rule on Foreign Supplier Verification Programs Fact Sheet	A9-3
FSMA Final Rule on Preventive Controls for Human Food Fact Sheet	A9-9
FSMA Final Rule on Preventive Controls for Animal Food Fact Sheet	A9-13
FSMA Final Rule on Produce Safety Fact Sheet	A9-17
FSMA Final Rule on Accredited Third-Party Certification Fact Sheet	A9-25
FSMA Voluntary Qualified Importer Program (VQIP) Fact Sheet	A9-27

KEY REQUIREMENTS:

Final Rule on Foreign Supplier Verification Programs



The FDA Food Safety Modernization Act (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.

Below are the key requirements and compliance dates.

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.
- 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

FDA AT A GLANCE

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.

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.

MORE INFORMATION

Visit <http://www.regulations.gov/>

FDA's Food Safety Modernization Act page at www.fda.gov/FSMA

KEY REQUIREMENTS:

Final Rule on Preventive Controls for Human Food

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.

Below are the key requirements and compliance dates.

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

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.

MORE INFORMATION

Federal Register
www.regulations.gov

Frequently Asked Questions
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#PC_Rules

FDA Food Safety Modernization Act
www.fda.gov/fsma

FDA's FSMA Technical Assistance Network
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>

KEY REQUIREMENTS:

Final Rule on Preventive Controls for Animal Food

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.

Below are the key requirements and compliance dates.

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.

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■ 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.
- **Corrective actions and corrections:** Corrections are steps taken to timely identify and correct a minor, isolated problem that occurs during animal food production. Corrective actions include actions to identify a problem with preventive control implementation, to reduce the likelihood the problem will recur, evaluate affected animal food for safety, and prevent it from entering commerce. Corrective actions must be documented with records.

- **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 controls 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”

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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.

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.

MORE INFORMATION

Federal Register
www.regulations.gov

Frequently Asked Questions
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#PC_Rules

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<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>

KEY REQUIREMENTS: Final Rule on Produce Safety



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.

Below are summaries of some key requirements, compliance dates, and other information.

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 oversimplification, 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 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

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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.

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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

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(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

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.

FDA AT A GLANCE

- 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.
- 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.

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:

- 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.

MORE INFORMATION

Visit <http://www.regulations.gov/>

FDA's Food Safety Modernization Act page at www.fda.gov/FSMA

KEY REQUIREMENTS:

Final Rule on Accredited Third-Party Certification

The FDA Food Safety Modernization Act (FSMA) rule on the Accredited Third-Party Certification is now final.

This rule, proposed in July 2013, establishes a voluntary program for the accreditation of third-party certification bodies, also known as auditors, to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce. These requirements will help ensure the competence and independence of the accreditation bodies and third-party certification bodies participating in the program.

Foreign entities may use certifications for two purposes:

- Certifications may be used by importers to establish eligibility for participation in the Voluntary Qualified Importer Program (VQIP), which offers expedited review and 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.

Below are the key features of the rule.

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 could directly accredit third-party certification bodies if it has not identified and recognized an accreditation body within two years after establishing this program.

- To promote international consistency and utilize an existing framework that is familiar to industry, accreditation bodies and certification bodies will be allowed to 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 be closely monitoring participants in the program and may revoke an accreditation body's recognition and withdraw a certification body's accreditation if there is cause. 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. In addition to the requirements listed above, the final rule will require 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 public health. In addition to other requirements listed above, the final rule will require 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 facilities
 - 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 draft recommendations on certification body competency are contained in the Model Accreditation Standards draft guidance issued in July 2015. They contain draft recommendations on the qualifications that third-party certification bodies and their agents should have in such areas as education and experience. The guidance will be finalized after public comments are considered.

- In June 2015, the FDA published a draft guidance for industry explaining how 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 July 2015 a proposed rule establishing user fees for accreditation bodies and certification bodies. FSMA requires that a user-fee program be established to reimburse the agency for its work in establishing and administering the third-party certification program, which is voluntary.

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
- Meat, poultry and egg products that are subject to U.S. Department of Agriculture oversight at the time of importation.

IMPLEMENTATION

FDA intends to implement this program as soon as possible after publication of the final Model Accreditation Standards guidance, and the final user fee rule, both of which will be published separately.

Accreditation bodies could begin to apply for recognition when the program goes into effect, and third-party certification bodies could seek accreditation after one or more FDA-recognized accreditation bodies begin accepting applications.

MORE INFORMATION

Visit <http://www.regulations.gov/>
FDA's Food Safety Modernization Act page at
www.fda.gov/FSMA

Fact Sheet on the 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 if so 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.

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APPENDIX 10: FSVP Definitions and Acronyms

Title of Document	Page
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FSVP Definitions and Acronyms	A10-3
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Note: All are found in 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/processing 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.

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).

Key Point:

Note that the definition for the Preventive Controls (PC) Qualified Individual (QI) is different from the definition for a qualified individual under the FSVP rule. FSVP qualified individuals are not required to receive training under a standardized curriculum or an equivalent training.

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

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.

