WELCOME!

FSPCA Special Focus Webinar
May 24, 2018
WELCOME AND INTRODUCTIONS

Hilary Thesmar
FSPCA Trainer of Trainers
Work Group Co-Chair
Agenda

- Welcome – Hilary Thesmar
- FSVP Module – Hilary Thesmar
- Q&A Session – Type question into the Q&A box and click send
Q&A

• Ask questions by typing into the Q&A box
  1. Click on the Q&A icon
  2. To pose a question, begin typing in the Q&A box that is provided on the screen and click “send”
  3. Your question will be sent to the host of the webinar and the host will read it aloud

  • We will do our best to answer as many questions as time allows but we may not be able to address every question
FSPCA 2018 Special Focus Webinars

- The next FSPCA Special Focus Webinar will be held on September 20 and will focus on Intentional Adulteration.
- Register on the FSPCA website
- Previously held webinar recordings and presentations are available on the FSPCA website: https://www.ifsh.iit.edu/fspca/fspca-webinars
FSVP MODULE

Hilary Thesmar
FSPCA Trainer of Trainers
Work Group Co-Chair
FSVP Module

• Optional slides (~35) and text (34 pages) for Lead Instructor to use in:
  • Preventive Controls for Human Food Participant Course
  • Preventive Controls for Animal Food Participant Course
• Intent is to familiarize foreign suppliers about what U.S. importers are required to do
• Foreign suppliers may be asked for information by their importers
• Optional FSVP Materials found in Instructor Portal
  • FSVP Module Slides for PCHF Participant Course
  • FSVP Module for PCHF Participant Course – Instructor Guide
  • FSVP Module for PCHF Participant Course - Participant Manual
Instructor Portal
FSVP Requirements Module: Ensuring the Safety of Foods Imported into the United States for Human and Animal Consumption

As you already know, the 2011 Food Safety Modernization Act (FSMA) set forth a new preventative paradigm for ensuring the safety of food consumed in the U.S. that gives everyone in the supply chain a role. Those who manufacture, process, package, or hold food have primary responsibility for food safety and must satisfy FDA food safety standards, including complying with the Preventive Controls rules. This is true whether they are inside or outside the U.S. FDA is responsible for overseeing compliance with these standards.

For domestic firms, FDA and the U.S. states and territories are establishing an integrated food safety regulatory system to oversee compliance with the Preventive Controls rules (Human Food and Food for Animals). FDA also conducts foreign inspections, but inspecting foreign firms is more difficult. That is why Congress provided FDA with a new tool to help ensure that foreign facilities are meeting their food safety obligations. The Foreign Supplier Verification Programs (FSVP) rule requires that U.S. food importers verify that their foreign suppliers are producing food using processes and procedures that meet the U.S. level of public health protection. So, whether you are a...

Instructor’s Notes:
This module is intended for insertion into the Food Safety Preventive Controls Alliance (FSPCA) courses on U.S. Food and Drug Administration’s (FDA) Risk-Based Preventive Controls for Human Food and Food for Animals rules. FDA’s Foreign Supplier Verification Programs (FSVP) rule also originates from the same 2011 Food Safety Modernization Act (FSMA) as the Preventive Controls rules. Under the FSVP rule, U.S. importers are required to take responsibility for the safety of the food they import into the U.S. and to ensure that the food and foreign supplier meet U.S. safety standards, including the requirements of the Preventive Controls rules. Because manufacturers/processors of food for humans and animals in countries other than the U.S. are considered “foreign suppliers” under the FSVP rule, they may need to know more about the FSVP rule.
FSVP Requirements Module:
Ensuring the Safety of Foods
Imported into the United States
for Human and Animal
Consumption

As you already know, the 2011 Food Safety Modernization Act (FSMA) set forth a new prevention paradigm for ensuring the safety of food consumed in the U.S. that gives everyone in the supply chain a role. Those who manufacture, process, package, or hold food have primary responsibility for food safety and must satisfy FDA food safety standards, including complying with the Preventive Controls rules. This is true whether they are inside or outside the U.S. FDA is responsible for overseeing compliance with these standards.

For domestic firms, FDA and the U.S. states and territories are establishing an integrated food safety regulatory system to oversee compliance with the Preventive Controls rules (‘Human Food and Food for Animals’). FDA also conducts foreign inspections, but inspecting foreign firms is more difficult. That is why Congress provided FDA with a new tool to help ensure that foreign facilities are meeting their food safety obligations. The Foreign Supplier Verification Programs (FSVP) rule requires that U.S. food importers verify that their foreign suppliers are producing food using processes and procedures that meet the U.S. level of public health protection. So, whether you are a

© 2017 IFISH
• High level overview of FSVP Rule Requirements
• Definitions
• Foods that are covered
• Overview of requirements for FSVP Importers
  ▪ Standard requirements
  ▪ Modified Requirements
  ▪ Exemptions
Foreign Supplier Verification Programs (FSVP) Requirements

ENSURING THE SAFETY OF FOODS IMPORTED INTO THE UNITED STATES FOR HUMAN AND ANIMAL CONSUMPTION
FSVP Module Description and Target Audience

• **Module Description:** This module 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 module is designed specifically for the foreign suppliers that manufacture, process, pack, or hold food intended for human or animal consumption in the U.S.

• The FSVP rule requirements are directed at importers, not foreign suppliers.
FSVP Module: Goal and Learning Objectives

Goal: Upon completing this module, participants will be able to:

- Recognize how to support U.S. importers in meeting their FSVP responsibilities.

Learning Objectives:

- Upon completing this module, participants will be able to:
  1. Explain the purpose of FSVP requirements.
  2. Define an FSVP importer.
  3. Define a foreign supplier.
  4. Describe the foods subject to and exempt from FSVP requirements.
  5. Describe the FSVP requirements (standard and modified) and to whom they apply.
  6. Discuss the importance of early communication between importers, foreign suppliers, and others in the supply chain in meeting FSVP requirements.
Purpose of the FSVP Rule

• The purpose of the FSVP rule is to ensure that foreign suppliers of human and animal food that will be consumed in the U.S. are:

  ▪ 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, unless specifically exempted, and

  ▪ Producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (regarding labeling of human food for the presence of major food allergens) of the FD&C Act.
FDA Definitions

• **Food**: “(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. (Section 201(f), FD&C Act)

• **Adulterated**: Adulterated food is food that violates Section 402 of the Food Drug and Cosmetic Act (FD&C Act) and is, therefore, subject to being refused entry into the U.S.

• **Allergen Labeling**: Allergen labeling refers to the labeling of human food for the presence of major food allergens that must be in compliance with Section 403(w) of the FD&C Act.
FDA Definitions (continued)

• **Foreign Supplier:** “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.” (21 CFR 1.500)
FDA Definitions (continued)

- **Importer** (for FSVP purposes): “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.” (21 CFR 1.500)
FDA Definitions (continued)

- **Qualified Individual** (for FSVP purposes): “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...” (21 CFR 1.500)
What Foods Are Covered By FSVP?

• FSVP applies to all human and animal food offered for import into the U.S. and intended for consumption in the U.S., unless exempted.

• Exemptions that apply to foods imported into the U.S. include foods that are:
  ▪ Imported for research or evaluation,
  ▪ Imported for personal consumption,
  ▪ Transshipped through the U.S. or imported for further processing and export (no distribution in the U.S.), and or
  ▪ Produced in the U.S., then exported and returned.

• Certain meat, poultry, and egg products are also exempt because they are regulated by the U.S. Department of Agriculture (USDA).
In addition to verifying that their foreign supplier is following the Preventive Controls rules, U.S. importers of food are required to develop, maintain, and follow an FSVP for each type of food they import including:

- Conducting a hazard analysis to identify known or reasonably foreseeable biological, chemical, and physical hazards,
- Evaluating and approving each foreign supplier,
- Determining what foreign supplier verification activities are necessary and appropriate as well as their frequency,
- Taking corrective actions based on verification activities, and
- Reevaluating their FSVP whenever they become aware of a food safety problem and at least every three years.
- Identifying the FSVP importer at entry.
- Documenting all of the above, keeping adequate records, and making those records available to FDA upon request.
Appropriate Verification Activities

FDA has stated that appropriate verification activities include:

• Audits,
  ▪ Audits are the default verification activity for a Serious Adverse Health Consequences or Death to Humans or Animals (SAHCODHA) hazard, but another verification activity may be chosen, if adequate,

• Sampling and testing,

• Review of foreign supplier records that demonstrate production of safe food, and

• Other appropriate verification activities for known or reasonably foreseeable hazards requiring a control.
Creating and Maintaining Records

- All documentation that is required by the FSVP rule must be complete, must be kept for at least two years, and must be made available to FDA upon request.
If Food Is from A Recognized System

- If a foreign supplier is under the regulatory oversight of a governmental authority whose food safety system FDA has officially recognized as comparable or equivalent to that of the U.S., the FSVP importer is not required to:
  - Perform a hazard analysis,
  - Conduct a foreign supplier evaluation for supplier approval, nor
  - Conduct the supplier verifications as described earlier.
If Food Is from A Recognized System (continued)

• However, **before** importing a food from the foreign supplier, the FSVP importer **must** determine and document that the foreign supplier is:
  - Under the oversight of the regulatory authority with whom FDA has the systems recognition agreement,
  - Within the scope of the systems recognition agreement, and
  - In good compliance standing with the recognized food safety authority.

• If any information indicates food safety hazards associated with the food are not being significantly minimized or prevented, the FSVP importer must take **prompt** corrective action.
The Importance of Communications Within Your Supplier/Importer Chain

• The new FDA regulations for Preventive Controls, Produce Safety and FSVP anticipate that those involved in the food supplier/importer chain will communicate with each other before the compliance dates for these rules.
  ▪ Foreign suppliers may be asked to provide additional documentation to the FSVP importer.

• Everyone in the foreign supplier/importer chain could benefit by initiating discussions as soon as possible about their individual roles in complying with the new U.S. food safety requirements.
FSVP Module for Preventive Controls: Summary

• FSVP importers are responsible for verifying that their foreign suppliers are supplying food that meets the U.S. level of public health protection and is not adulterated under Section 402 of the FD&C Act or in violation of the allergen labeling provisions of Section 403(w) (for human foods) of the FD&C Act.

• FDA will hold FSVP importers accountable for:
  - Conducting a hazard analysis to identify known or reasonably foreseeable hazards,
  - Evaluating and approving their foreign suppliers,
  - Determining what foreign supplier verification activities are necessary and appropriate as well as their frequency,
  - Taking corrective actions when necessary,
  - Reevaluating their FSVP for cause and at least every three years,
  - Assuring that they are properly identified as the FSVP importer on entry filing, and
  - Documenting all of the above, keeping adequate records, and making those records available to FDA upon request.

• FSVP importers may use modified requirements in some situations.
How to find the FSVP Module...
Coming Up Next

Q & A
Q&A

• **Reminder**: Ask questions by typing into the Q&A box

1. Click on the Q&A icon
2. To pose a question, begin typing in the Q&A box that is provided on the screen and click “send”
3. Your question will be sent to the host of the webinar and the host will read it aloud

• *We will do our best to answer as many questions as time allows but we may not be able to address every question*
Questions?

If you have any questions, please contact the FSPCA at fspca@iit.edu or visit the FSPCA website at fspca.net for resources on preventive controls, lead instructor application, and details of other FSPCA activities.
THANK YOU!