



# FSPCA FOREIGN SUPPLIER VERIFICATION PROGRAMS (FSVP)

## Exercise Workbook

Developed by the



## **FSPCA FOREIGN SUPPLIER VERIFICATION PROGRAMS TRAINING CURRICULUM**

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### **Copyright Notice**

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

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## Chapter 1: Context

### Chapter Notes:

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## Chapter 2: Setting the Stage

### Exercise: "Who is the FSVP Importer?"

**Directions:** In your group, read the scenarios and determine "Who is the FSVP importer?" (Scenarios #1-4) and both "Who is the FSVP importer?" and "Who is the foreign supplier?" (Scenarios #5a-5e). Report out to the instructor and class when called upon.

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

#### Scenario #1:

BananaCo, a Guatemalan Company, sends a shipment of bananas to a retailer in the U.S. There is no written purchase agreement between BananaCo and the retailer at the time the shipment is entered into the U.S. and no payments have been made for the shipment. BananaCo owns the product at the time of entry.

**Who is the FSVP importer in this scenario?** \_\_\_\_\_

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#### Scenario #2:

BreadCo is incorporated in the United States; Paris Bakery is a French company. BreadCo orders bread from the Paris Bakery. Paris Bakery ships the bread to fulfill the order. Paris Bakery actually owns the bread at the time of entry and is the importer of record; however, BreadCo has a written purchase agreement with Paris Bakery at the time of entry.

**Who is the FSVP importer in this scenario?** \_\_\_\_\_

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## Chapter 2: Setting the Stage (continued)

### Exercise: "Who is the FSVP Importer?" (continued)

#### Scenario #3:

Retailer ABC, a U.S. company has a purchase order in place at the time of entry with Importer XYZ, a U.S. company, who has purchased candy from CandyCo, a British company, on behalf of Retailer ABC. Importer XYZ owns the product at the time of entry and is the importer of record.

**Who is the FSVP importer in this scenario?** \_\_\_\_\_

\_\_\_\_\_

#### Scenario #4:

A U.S. retailer works through an international importing firm who handles the procurement, shipment, and importation of foreign goods, including food, for its retail stores. The importing firm's office is in New York City and never sees the food it is importing. The importing firm does not own the food, nor has it agreed in writing to purchase the food at the time of entry. Unbeknownst to the U.S. retailer, their company's name and warehouse address is identified on the import documents as the FSVP importer.

**Who is the FSVP importer in this scenario?** \_\_\_\_\_

\_\_\_\_\_

#### Scenarios #5a through #5e: Who is the FSVP Importer and who is the Foreign Supplier?

Review the following scenarios. Identify the correct answer for each.

5a. A U.S. entity purchases fresh, whole tomatoes directly from a farm in Mexico.

- Who is the FSVP importer?

- **Answer:** \_\_\_\_\_

\_\_\_\_\_

- Who is the foreign supplier?

- **Answer:** \_\_\_\_\_

\_\_\_\_\_

## Chapter 2: Setting the Stage (continued)

### Exercise: "Who is the FSVP Importer?" (continued)

#### Scenarios #5a through #5e: Who is the FSVP Importer and who is the Foreign Supplier? (continued)

5b. A U.S. entity purchases fresh, whole tomatoes from a Mexican consolidator.

- Who is the FSVP importer?

○ **Answer:** \_\_\_\_\_

\_\_\_\_\_

- Who is the foreign supplier?

○ **Answer:** \_\_\_\_\_

\_\_\_\_\_

5c. A U.S. entity has agreed to purchase fresh, whole tomatoes imported by a U.S. consolidator who does not own the tomatoes at the time of entry.

- Who is the FSVP importer?

○ **Answer:** \_\_\_\_\_

\_\_\_\_\_

- Who is the foreign supplier?

○ **Answer:** \_\_\_\_\_

\_\_\_\_\_

5d. A U.S. entity has agreed to purchase tomatoes processed in Mexico.

- Who is the FSVP importer?

○ **Answer:** \_\_\_\_\_

\_\_\_\_\_

- Who is the foreign supplier?

○ **Answer:** \_\_\_\_\_

\_\_\_\_\_

## Chapter 2: Setting the Stage (continued)

### Exercise: “Who is the FSVP Importer?” (continued)

#### Scenarios #5a through #5e: Who is the FSVP Importer and who is the Foreign Supplier? (continued)

5e. A U.S. entity has agreed to purchase fresh, whole tomatoes imported by a U.S. consolidator who sources the tomatoes from Mexico and owns them at time of entry.

- Who is the FSVP importer?

○ **Answer:** \_\_\_\_\_  
\_\_\_\_\_

- Who is the foreign supplier?

○ **Answer:** \_\_\_\_\_  
\_\_\_\_\_

#### Additional Chapter Notes:

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## Chapter 3: Overview of the Requirements

### Review: Questions About FSVP Requirements:

Think of a specific food that you import, before starting through the questions, and see how FSVP might apply to your specific situation.

#### Question 1: Are you an importer for FSVP purposes?

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

**If your answer is:**

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

#### Question 2: Are you importing the following foods? (See 21 CFR 1.501)

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

**If your answer is:**

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

## Chapter 3: Overview of the Requirements (continued)

### Review: Questions About FSVP Requirements (continued):

**Question 3: Do you import low-acid canned food in compliance with 21 CFR Part 113?** (see 21 CFR 1.502(b))

**If your answer is:**

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

**Question 4: Are you an importer subject to the preventive controls regulation for human or animal food, a food processor/manufacturer receiving the imported food, and in compliance with one of the following requirements in 21 CFR parts 117 or 507?:**

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

**If your answer is:**

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

**Question 5: Do you import dietary supplements subject to certain dietary supplement current good manufacturing practice requirements in 21 CFR part 111?** (See 21 CFR 1.511)

**If your answer is:**

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

## Chapter 3: Overview of the Requirements (continued)

### Review: Questions About FSVP Requirements (continued):

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

**If your answer is:**

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

#### Question 7: Do you import food from certain small suppliers (i.e., qualified facilities under the PC rules, certain farms that are not “covered farms” under the Produce Safety regulation, and certain small shell egg producers)? (See 21 CFR 1.512)

**If your answer is:**

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

#### Question 8: Do you import a food that is not intended for further manufacturing/processing before consumption from a country that is officially recognized by FDA as having a food safety system that is comparable for certain foods under Systems Recognition?

**If your answer is:**

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

### Chapter 3: Overview of the Requirements (continued)

#### Review: Questions About FSVP Requirements (continued):

##### The Final Answer is:

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

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

#### Exercise: Does FSVP Apply to These Food Products?

**Directions:** In your group, read the example food products listed in the table. Discuss whether the FSVP standard requirements apply, the modified requirements apply, or if the food is exempt. The instructor will call upon each group to put their answers on the projector screen using post-it notes. Be sure to identify your group as suggested by the instructor.

Imported Food Product	Standard	Modified	Exempt
Frozen venison steaks, product of Uruguay			
Fresh salmon fillet, product of China			
Fresh beef tenderloins, product of Brazil			
Bottled maple syrup ready for retail sale, product of Canada			
Dietary supplements			
Tomatoes from Mexico sold to a U.S. canner			
Frozen chicken dinner, product of Egypt			
Squash from a farm with annual produce sales of \$24,000, product of Chile			
Butter cookies, product of France			
Tortillas from a qualified facility, product of Mexico			

## PCPS: Preventive Controls and Produce Safety Session

### Session 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 no margins, text, or other markings on the paper.

## Chapter 4: Hazard Analysis

## Exercise: Identify “Known or Reasonably Foreseeable” Hazards

## Directions:

1. Review the example (on page 34 in the Participant Manual and below).
2. The instructor will use two or three examples of food products imported by participants for the exercise (or the instructor will provide an example).
3. The instructor or the person(s) who provided the examples, will describe the process each example food product goes through to be sure everyone has an understanding of the potential hazards.
4. The instructor will walk the participants through the activity of identifying any “known or reasonably foreseeable” biological, chemical, and physical hazards for each example food product.

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

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

## Chapter 4: Hazard Analysis (continued)

## Exercise: Identify “Known or Reasonably Foreseeable” Hazards (continued)

Example Ingredient/Food Product 1 (to be completed in class)			
Ingredient/ Food Product	Biological	Chemical	Physical
<i>Enter an imported ingredient/food product in this column; ask participants to describe the process the ingredient/food goes through, if applicable</i>	<i>Have participants identify any “known or reasonably foreseeable” biological hazards</i>	<i>Have participants identify any “known or reasonably foreseeable” chemical hazards”</i>	<i>Have participants identify any “known or reasonably foreseeable” physical hazards</i>

Example Ingredient/Food Product 2 (to be completed in class, if time allows)			
Ingredient/ Food Product	Biological	Chemical	Physical
<i>Enter an imported ingredient/food product in this column; ask participants to describe the process the ingredient/food goes through, if applicable</i>	<i>Have participants identify any “known or reasonably foreseeable” biological hazards</i>	<i>Have participants identify any “known or reasonably foreseeable” chemical hazards”</i>	<i>Have participants identify any “known or reasonably foreseeable” physical hazards</i>

## Chapter 4: Hazard Analysis (continued)

## Exercise: Identify “Known or Reasonably Foreseeable” Hazards (continued)

Example Ingredient/Food Product 3 (to be completed in class, if time allows)			
Ingredient/ Food Product	Biological	Chemical	Physical
<i>Enter an imported ingredient/food product in this column; ask participants to describe the process the ingredient/food goes through, if applicable</i>	<i>Have participants identify any “known or reasonably foreseeable” biological hazards</i>	<i>Have participants identify any “known or reasonably foreseeable” chemical hazards”</i>	<i>Have participants identify any “known or reasonably foreseeable” physical hazards</i>

## Additional Chapter Notes:

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## Chapter 5: Evaluation and Approval of Foreign Supplier

### Group Exercise: Who Is Controlling the Biological Hazards?

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

**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: \_\_\_\_\_

\_\_\_\_\_

### Additional Chapter Notes:

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## Chapter 6: Foreign Supplier Verification

### Group Exercise: What Could Be an Appropriate Verification Activity in the Following Scenarios?

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

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

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

**Scenario:** Importing fresh sliced tomatoes.

**Question 1:** What hazard(s) require a control? \_\_\_\_\_  
\_\_\_\_\_

**Question 2:** What verification activity(ies) would be appropriate? \_\_\_\_\_  
\_\_\_\_\_

**Additional discussion notes:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## Chapter 7: Reevaluation of Foreign Supplier Performance and Food Risk, and Taking Corrective Actions

### Group Exercise: What Issues Could Trigger a Reevaluation?

**Directions:** The Instructor will review a few of the examples and ask if anyone can think of any other issues that could trigger a reevaluation. Be prepared to offer an example. Also, be prepared to identify why each of these examples issues would trigger a reevaluation. Discuss as a group.

- **Possible Trigger:** Importer learns of a prohibited pesticide on fresh produce.
  - **Why would this be a trigger?** \_\_\_\_\_  
\_\_\_\_\_
- **Possible Trigger:** A recall and/or illness outbreak involving the same or related products.
  - **Why would this be a trigger?** \_\_\_\_\_  
\_\_\_\_\_
- **Possible Trigger:** You change your hazard analysis.
  - **Why would this be a trigger?** \_\_\_\_\_  
\_\_\_\_\_
- **Possible Trigger:** Your supplier takes corrective action on a hazard in your food.
  - **Why would this be a trigger?** \_\_\_\_\_  
\_\_\_\_\_
- **Possible Trigger:** Customer complaints related to food safety.
  - **Why would this be a trigger?** \_\_\_\_\_  
\_\_\_\_\_
- **Possible Trigger:** An import is refused by FDA due to food safety concerns.
  - **Why would this be a trigger?** \_\_\_\_\_  
\_\_\_\_\_
- **Possible Trigger:** Audit revealing significant deviations that could cause a food safety violation.
  - **Why would this be a trigger?** \_\_\_\_\_  
\_\_\_\_\_
- **Possible Trigger:** Other similar indications of a food safety failure. \_\_\_\_\_  
\_\_\_\_\_

## Chapter 8: Importer Identification at Entry

### Group Exercise: Importer Designation at Entry

**Scenario 1: A U.S. retailer regularly uses a multinational produce distributor (who has offices in the U.S.) to buy pineapples.**

- The distributor generally sources the pineapples from Asian countries and occasionally Central America.
- The distributor takes care to ensure that the product, wherever it is sourced, will meet the U.S. retailer's specifications, including food safety requirements.
- The distributor handles all shipping arrangements and 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.

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? \_\_\_\_\_  
\_\_\_\_\_

**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.

1. What options are available for avoiding this scenario? \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## Chapter 9: Importance of Records

### Exercise: What records are required of FSVP importers?

**Directions:** Identify what records are required of FSVP importers by selecting true or false at the end of each question. The instructor will share and discuss the answers after everyone has finished. You will be given 10 minutes to answer the questions.

Record Requirement Questions	True	False
1. Importers must maintain records of their hazard analysis, including hazards identified and the evaluation of the risk posed by those hazards.	_____	_____
2. If an importer relies on the hazard analysis of another entity, the importer must keep records of its review and assessment of the hazard analysis.	_____	_____
3. If an importer reviews and assesses the foreign supplier's hazard analysis, the importer must keep a record that the supplier's hazard analysis was conducted by a qualified individual.	_____	_____
4. FSVP importers must have written procedures for 1) ensuring that foods are imported only from approved foreign suppliers, and 2) ensuring that appropriate foreign supplier verification activities are conducted for the foods you import.	_____	_____
5. Importers must reevaluate their FSVP (i.e., specifically their foreign supplier's food safety performance and risk posed by the food) promptly, if a problem or change occurs that could impact food safety, but at least every year.	_____	_____
6. Foreign supplier verification activities and the evaluation of those activities can be carried out by an entity other than the FSVP importer, including the foreign supplier, as long as the FSVP importer assesses the results of the activities and keeps a record of that assessment.	_____	_____
7. An FSVP importer who uses audits to verify their supplier's compliance with FDA food safety standards must retain copies of the full audit reports in their records.	_____	_____
8. Importers are required to maintain records for two years of corrective actions taken as a result of the importer's routine 3-year reevaluation of an FSVP, even if use of the particular foreign supplier is discontinued.	_____	_____
9. Importers' FSVP records must be signed and dated upon initial completion and any subsequent modification.	_____	_____

## Chapter 9: Importance of Records

### Exercise: What records are required of FSVP importers?

Record Requirement Questions	True	False
10. Offsite storage of records is permitted if they can be retrieved and provided onsite within 72 hours of FDA's request.	_____	_____
11. Importers must provide, within a reasonable period of time, an English translation of records maintained in a language other than English. This period of time is not specifically defined in the FSVP rule.	_____	_____

### Additional Chapter Notes:

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## Chapter 10: FDA Oversight

### Chapter notes:

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