

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

foreign supplier exporting to the U.S., or whether you are a U.S. processor who imports ingredients, you need to understand this rule and if/how it impacts you. This module will explain the requirements of the FSVP rule and how it will function in practice.

FSVP Module Description and Target Audience

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- **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.



This module will explain the requirements of the FSVP rule. The module is specifically designed for the foreign suppliers that manufacture, process, pack, or hold food intended for human or animal consumption in the U.S. The FSVP rule itself imposes requirements on importers, not foreign suppliers. Nevertheless, importers may make requests of foreign suppliers to assist in meeting the importers obligations.

FSVP Module: Goal and Objectives

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.




The goal of this module is for participants to be able to recognize how to support U.S. importers in meeting their FSVP responsibilities. More specifically, they 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

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.


FOOD SAFETY PREVENTIVE CONTROLS AGENCY


The purpose of the FSVP rule is 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 Risk-Based Preventive Controls or Produce Safety requirements—that is, the same level of protection required of U.S. producers and that the food is not otherwise adulterated or misbranded with respect to allergens.

U.S.-based FSVP importers must keep very clear records for meeting every requirement of the FSVP rule, and FDA will be checking their records to make sure they are performing their responsibilities appropriately. They may be asking you, as the foreign supplier, to provide additional information that helps demonstrate that they have met their responsibilities under the FSVP rule and we will talk more about that later. **It is important to note, however, that FDA has allowed importers a large amount of flexibility in implementing the FSVP rule, in acknowledging the variability in importing arrangements. Thus, while FDA is setting forth requirements for importers to assess and verify that their suppliers are meeting U.S. food safety requirements, FDA is, in most cases, enabling importers to figure out the best way to meet those requirements given their specific situations.**

FDA Definitions

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.


FOOD SAFETY AND INSPECTION SERVICE

The definition of food for the purposes of FSVP is the same as its definition in the U.S. Food, Drug and Cosmetic Act (FD&C Act). The term “food” means “(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).

An FSVP is required to help ensure that imported food, like U.S. produced food, is not adulterated under Section 402 of the FD&C Act or misbranded as to allergen labeling under Section 403(w) of the FD&C Act (*human food only*). Adulteration is a term that has been used in U.S. food law since the early part of the last century. Section 402, describes what is meant by adulteration and is too lengthy and complex to cover here, but is generally considered in the hazard analysis portion of this course. We are giving an abbreviated definition for the term in this slide. In its essence, as stated previously, an adulterated food is one that is potentially injurious to health either from a single exposure or chronic exposure to the adulterated food.

FDA Definitions (continued)

Definition:

“The term ‘*de minimis*’ means insignificant. In this context, the term is referring to activities, such as labeling, that wouldn’t cause the food to become hazardous or unsafe.

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)



Note that the FSVP importer may or may not be the foreign supplier’s direct customer. A foreign supplier may sell to an intermediary or someone who packs and labels the product. Nevertheless, under the FSVP rule, the foreign supplier will be the person/business outside the U.S. that usually has 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 the importer and the “foreign supplier,” whether direct or indirect, whereby the FSVP importer can evaluate 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 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.

FDA Definitions (continued)

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)



The definition of an “importer” is specific to the FSVP regulation (21 CFR 1.500) and must be fully understood before getting into the FSVP requirements. **The importer is the “U.S. owner or consignee”, also separately 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.”** It is important to the FSVP rule that the FSVP importer be located in the U.S. because FDA will be inspecting these importers and/or their records for compliance with the rule. It is the person in the U.S. who is taking responsibility for meeting the obligations under the FSVP rule.

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 and that person must consent in writing to do so. This requirement was put in so that U.S. agents or representatives (such as U.S. agents for food facility registration purposes) would not be identified as the FSVP importer without their knowledge.

The FSVP regulation does not change the general procedures for importing food; however, it does require the FSVP importer be identified for each line entry of food offered for import into the U.S., once the compliance date pertaining to that food arrives. Thus, it is important that whoever is filling out the U.S. Customs entry filing understand who is the appropriate party to designate as the FSVP “importer” as that person will be seen by FDA as the person responsible for complying with the requirements of the FSVP rule.

The FSVP “importer” definition is not the same as the definition of importer of record under U.S. Customs and Border Protection (CBP) rules. However, it is possible that the importer of record may appropriately serve as the FSVP importer, if the importer of record also meets the FSVP definition of importer. It should also be noted that more than one person might fall under the FSVP “importer” definition for a particular food and foreign supplier. It is also possible that under a particular importing arrangement, there may be no one who clearly falls under the definition.

Nevertheless, as you will see, the FSVP rule requires that someone be designated as the FSVP “importer” at entry or the Customs filing will be rejected. Whoever is identified should have already done the work necessary to fulfill the requirements of the FSVP rule far in advance of shipping the food.

We are spending time in describing who will be an FSVP importer because this importer is perhaps not the person/company who you might currently identify as your customer, even if your customer is in the U.S., if that customer does not meet the definition of FSVP importer. Nevertheless, the FSVP importer will be responsible for complying with the obligations set forth in the FSVP rule. Thus, the importer may contact you directly or through other means in order to fulfill the importer’s obligations under the FSVP rule; and FDA, in turn, will be checking to make sure that the FSVP importer is complying appropriately with the FSVP rule. We will cover what the importer’s obligations are in upcoming slides.

FDA Definitions (continued)

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)

The FSVP rule specifies that all required FSVP activities be performed by a “qualified individual”, recognizing that different tasks require different qualifications.


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 a qualified individual must have. **Thus, the definition is simply stating that whoever is carrying out a particular FSVP activity should be someone qualified to do it.** The persons used as qualified individuals can be an employee of the importer’s company, but it is not necessary that they be employees.

Remember, complying with FSVP requirements is the responsibility of the FSVP importer, not the foreign supplier. As noted before, the FSVP rule itself does not set forth **any** requirements for foreign suppliers. The rule is only directed at importers, specifically those importers who will implement the FSVP requirements for a specific food and foreign supplier. Nevertheless, these FSVP importers will be responsible for verifying that their foreign suppliers are complying with U.S. food safety rules. And, in some cases, the importer may be able to use work done by the supplier in support of meeting these requirements. We will talk more about that later.

What Foods Are Covered By FSVP?

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).


FOOD SAFETY AND INSPECTION SERVICE

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


Generally, the FSVP rule exempts foods that are not sold nor intended for U.S. consumption, or foods for which the importers are already regulated under other U.S. regulations, e.g., importers of seafood and juices are regulated under Hazard Analysis Critical Control Point (HACCP) regulations. Therefore, food that is transshipped through the U.S.; food imported for processing and future export; food imported into the U.S. solely for research; food imported for personal consumption, and in amounts considered consistent with personal consumption; or food produced in the U.S., then exported and returned, are all exempted from the FSVP rule requirements.

The FSVP rule also exempts meat, poultry and egg products that are regulated by the U.S. Department of Agriculture (USDA). Nevertheless, some imported (and domestic) meat, poultry and egg products are not covered by USDA laws and regulations and, thus, are subject to FDA jurisdiction. These products may include, for example, venison, rabbit, game meats, duck, and shell eggs.

What About Low-Acid Canned Foods?

What About 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 focus on microbiological hazards.
 - For all matters not controlled by the LACF requirements, i.e., non-microbiological hazards, the importer is required to 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 is in compliance with Part 113, but
 - Must have an FSVP for all other known or reasonably foreseeable hazards.


FOOD SAFETY AND INSPECTION SERVICE

Importers of low acid canned foods are not exempt from FSVP, but importers must verify and document that manufacturers are following U.S. LACF requirements under 21 CFR Part 113, which focus on microbiological hazards. For all matters not controlled by the LACF requirements, i.e., non-microbiological hazards, the importer is required to have an FSVP.

An importer who imports and uses raw materials or other ingredients in manufacturing/processing an LACF in the U.S. is not required to comply with FSVP requirements for microbiological hazards, if the FSVP importer 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.

What About Foods Under FDA HACCP Rules?

What About Foods Under FDA HACCP Rules?

- Foods complying with FDA HACCP rules for juice (21 CFR Part 120) and seafood (21 CFR Part 123) are exempt from FSVP because the HACCP rules contain their own supply-chain requirements for importers of those foods.
- Importers of raw materials and ingredients for the manufacture of juice or seafood need not comply with FSVP so long as the U.S. facility is in compliance with FDA HACCP requirements under parts 120 and 123, respectively, as these importers will be addressing all the hazards associated with those ingredients under FDA HACCP.



As mentioned earlier, importers of foods complying with FDA HACCP rules for juice and seafood are exempt from FSVP because they are already subject to supply chain requirements under these existing regulations. This exemption is aligned with the exemption in the Preventive Controls for human food rule for such foods.

Similarly, importers who import and use raw materials and ingredients for the manufacture/processing of juice and seafood products subject to FDA HACCP rules also do not have to comply with FSVP, as long as the importer is in compliance with FDA HACCP requirements.

Exemption for Alcoholic Beverages

Exemption for Alcoholic Beverages

- FSMA and FDA exempted alcoholic beverages that meet certain conditions:
 - The foreign facility is same type of facility as those regulated by the U.S. Department of Treasury.
 - The foreign facility is required to register under Sec. 415.
- This provision is basically the same exemption as for domestically produced alcoholic beverages under the Preventive Controls for Human Food rule.



FSMA also exempted alcoholic beverages that meet certain conditions, including that the foreign facility is the same type of facility as those regulated by the Department of the Treasury in the U.S. and the facility is required to register under Section 415. Again, this exemption is aligned with the exemption in the Preventive Controls for human food rule and also includes the exemption for packaged foods shipped with alcoholic beverages as described in the Preventive Controls for human food rule.

Importers of raw materials or other ingredients are also exempt if they manufacture, process, pack, or hold the alcoholic beverage, they are the type of facility that is required to register as a food facility under section 415 of the act, and they are exempt from the preventive controls for human food regulation.

What if the U.S. Importer is a Processor Who Imports Ingredients?

What if the U.S. Importer is a Processor Who Imports Ingredients?

- The Preventive Controls rules contain supply-chain provisions similar to those in the FSVP rule.
- If a U.S. importer is subject to and in compliance with the supply-chain provisions of the Preventive Controls rules, the importer is deemed to be in compliance with most of the FSVP requirements for the food being imported.
- However, a facility must still identify itself as the FSVP importer, in the Customs and Border Protection (CBP) entry filing in accordance with the FSVP rule.



As you know, the PC rules require manufacturers/processors to have supply-chain preventive controls. So, if the FSVP importer is a manufacturer/processor, and the importer does not control all the hazards in the foods received from a foreign supplier, the importer must implement appropriate supply-chain preventive controls, which provide verifications that are similar to FSVP verifications. Hence, if the FSVP importer is a U.S. manufacturer/processor who imports ingredients, and is in compliance with the relevant supply-chain provisions in the Preventive Controls rule, the importer is deemed by FDA to be in compliance with most of the FSVP requirements for the food imported. Conversely, if the importer is a manufacturer/processor who imports ingredients, the importer may choose to comply with the FSVP requirements rather than the supply-chain requirements in the Preventive Controls rule. FDA allowed this flexibility to avoid imposing redundant requirements on manufacturers to comply with both PC and FSVP rules.


However, regardless of which rule is followed for supplier verification, the FSVP importer must still be identified upon entry on the U.S. Customs entry filing as the FSVP importer for the food ingredients/raw materials imported.

Standard FSVP Requirements

Standard FSVP Requirements

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.



What are the basic or standard FSVP requirements? The standard requirements apply to the majority of foods imported into the U.S. (**Note:** We will cover some of the “modified” FSVP requirements at a later point in this module, such as those that pertain to “very small importers” or importers importing from “certain small foreign suppliers.”)

FSVP importers are generally tasked with 1) carefully considering the hazards of the foods they import and the risks such hazards could pose to U.S. consumers and 2) working with their foreign suppliers to help ensure that such hazards are significantly minimized or prevented. Importers are also expected to evaluate the performance of their foreign suppliers – their processes and practices, as well as their food safety compliance history.

Based upon this evaluation, the importer will choose an appropriate verification activity or activities that will help ensure that the foreign supplier is producing food using processes and procedures that provide the same the level of public health protection as used by domestic manufacturers/processors. The importer can then approve the supplier and determine and conduct verification activities that will help ensure that level of protection is maintained.

Additionally, the FSVP importer must be identified at entry and the importer must document and retain records of all the steps of the FSVP process. The importer may be asking their foreign suppliers for additional information and records to help them meet their responsibilities. These records make up the importer’s FSVP that FDA will review for compliance with the regulation. An importer’s FSVP must be reevaluated every three years or when the importer has


reason to believe that the supplier may not be producing product consistent with U.S. food safety requirements.

Note: An FSVP is not one specific thing. It is essentially everything that the FSVP importer has done to comply with the FSVP requirements to help ensure that the imported food will meet the U.S. level of public health protection, as well as the records documenting that these activities were, and are continuing to be, carried out.

Hazard Analysis

Hazard Analysis

- FSVP importers must identify and evaluate known or reasonably foreseeable hazards to determine if they require a control, including:
 - Biological, chemical (including radiological), and physical hazards, and
 - Hazards that are naturally occurring, unintentionally introduced, or intentionally introduced for economic gain.
- This hazard analysis must be documented by the FSVP importer.



The hazard analysis is primarily directed at the food. The importer is required to perform a hazard analysis for biological, chemical, and physical hazards—whether the hazards are naturally occurring, unintentionally or intentionally introduced. Once hazards have been identified, they must be evaluated for the probability of occurrence and the severity of the illness if consumers are exposed.

This is essentially the same as hazard analysis as the manufacturer/processor is required to do under the Preventive Controls rule, except that the importer is not inside the manufacturing/processing facility where all the factors can be assessed. Importers can rely on the hazard analysis done by their foreign suppliers as long as they review and assess it. So, importers may ask their foreign suppliers for their hazard analyses, so they will not have to repeat what their supplier has already accomplished. Nevertheless, it is left up to the importer to determine the best way to perform the hazard analysis.

Evaluation and Approval of the Foreign Supplier

Evaluation and Approval of the Foreign Supplier

- FSVP importers must evaluate each foreign supplier's performance, including:
 - Processes and procedures for ensuring food safety, and
 - Its history of compliance with food safety requirements.
- FSVP importers must approve each foreign supplier and have written procedures to ensure use of approved foreign suppliers only.
 - May use an unapproved supplier on a temporary basis if necessary.



The FSVP importer must also evaluate the foreign supplier—such as the supplier's general food safety procedures and practices, and history of compliance with U.S. food safety requirements, including compliance with the Preventive Controls rules. The importer should also consider whether the supplier has been subject to any FDA enforcement activities, and may wish to look at several years of data in FDA databases to see if the foreign supplier has received warning letters, had shipments refused entry for food safety violations, or is under an import alert. The importer may ask the foreign supplier for additional information regarding the supplier's compliance history. The importer should consider whether the supplier has resolved any previous problem.

Once the importer's qualified individual is satisfied with the evaluations of the food hazards and foreign supplier's performance, the importer can approve the foreign supplier. The importer can only import from "approved foreign suppliers." However, the rule does allow for use of a temporary supplier under certain circumstances—for instance, when the previously approved supplier is not able to export the product. FDA will likely provide more guidance on when this is acceptable and the conditions surrounding use of a temporary supplier, but FDA states in the rule that food imported from a temporary supplier must be verified as safe.

Verification Activities

Verification Activities

- **Before** importing, FSVP importers must:
 - Select and conduct one or more appropriate verification activities to verify that the hazards required to be controlled by their suppliers have been significantly minimized or prevented.
- Verification activities are required for all hazards requiring a control.
- FSVP Importers must determine, not only appropriate verification activities, but also the frequency of those activities based on food risk and supplier evaluations.


FOOD SAFETY AND INSPECTION SERVICE

Once the importer's compliance date arrives, all these steps must be carried out **before** the FSVP importer imports the first shipment of product into the U.S., so it is imperative that FSVP importers, foreign suppliers and others engaged in the importation of food understand the FSVP requirements in advance of the first shipment. Verification activities are required to be established and conducted prior to importing the food and periodically thereafter.

It is important to note that it is the importer, not the foreign supplier, who decides what verification activities are adequate, the frequency of those activities based on food risk and supplier evaluations, and who will carry them out. There should be no concerns regarding a conflict of interest.

Appropriate Verification Activities

Definition:

Audit: “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.” (21 CFR 1.500)

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.



FDA has stated that appropriate verification activities include audits, sampling and testing, and supplier records reviews, as well as other methods that will help ensure that the hazards requiring control are being significantly minimized or prevented.

For hazards that may result in serious illnesses or death (a SAHCODHA hazard), the default verification activity is an annual onsite audit, although the importer may determine that another activity or activities would provide the appropriate verification. If there is a potential for or a past history of a serious biological hazard associated with the food, the importer may wish to verify for a period of time that the practices or corrective actions taken by the foreign supplier have taken care of the problem. Therefore, an annual or even more frequent audit may be appropriate, perhaps coupled with periodic testing of the product or reviewing records of other testing. The point is that the verification method(s) must be appropriate to the hazard being controlled.

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 evaluation of risk of the supplier and food, as described above. Several verification activities may be appropriate to ensure the hazard is being properly controlled. Whatever verification activities are chosen, they should be suitable for the circumstances.

The importer may rely on a foreign supplier's food safety records or testing as long as the importer reviews and assesses the appropriateness of the records or testing results. While an importer may not rely on a foreign supplier's self-audit, the foreign supplier may supply the results of a third-party audit that is done by a qualified

auditor who is free from any conflict of interest. Such an audit may be supplied to several different customers for use as a verification activity.

Verification Findings and Corrective Actions

Verification of Findings and Corrective Actions

- The FSVP importer must:
 - Ensure that verification activities are performed properly.
- If an importer determines that its foreign supplier is not producing food in a manner that provides at least the same level of public health protection as U.S. safety standards, such as the Preventive Controls rules, the importer **must document and correct any deficiencies.**
 - Corrective actions may include using a different foreign supplier.



When a verification activity is carried out, it must be properly conducted and the importer must review the results to determine whether any corrective actions are necessary, on the part of the foreign supplier, the importer or another party in the supply chain. The corrective actions may necessitate a change in the foreign supplier's procedures, but it also may indicate that a different verification activity is needed. The importer may also decide to replace that foreign supplier with another supplier. Any findings and corrective actions must be documented.

Regular and “For Cause” Reevaluation of FSVPs

Regular and “For Cause” Reevaluation of FSVPs

- FSVP importers must regularly reevaluate their hazard analysis (food risk) and foreign supplier performance every three years to see if their FSVP is still valid.
- Importers must also promptly reevaluate their FSVP if they become aware of a food safety problem with the food they import, including a food safety problem they discover as the result of a verification activity.



The FSVP rule requires that an FSVP importer **must** reevaluate the FSVP at least every three years. In addition, an importer **must promptly** reevaluate its FSVP when it becomes aware of a food safety problem associated with the food it imports. In other words, an importer must reevaluate its FSVP whenever the importer has cause to do so, such as a deficiency found during a verification activity or a change in a foreign supplier’s practices that might give rise to a food safety concern.

Nevertheless, even if an FSVP importer has no known cause to reevaluate the FSVP, the importer still **must regularly** reevaluate the hazard analysis (food risk) and foreign supplier performance **at least every three years** to see if the FSVP is still valid. Of course, the importer **must document** the performance of the reevaluation.

Creating and Maintaining Records

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.



FSVP importers must keep very clear records for meeting every requirement of the FSVP rule, and FDA will be checking their records to make sure they are performing their responsibilities appropriately. It is important to note, that FDA has allowed a large amount of flexibility in implementing the FSVP rule, acknowledging the variability in importing arrangements. Thus, while FDA set forth requirements for importers to verify that their suppliers are meeting U.S. food safety requirements, FDA is letting importers determine the best way to meet and document FSVP requirements given their specific situations. Records generally must be kept for at least two years.

Public Version

Key Point:

In the preamble to the FSVP final rule, FDA stated “[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). It would be impractical and burdensome to have to conduct supplier verification of each original producer of the food and could result in multiple audits. For these reasons, for hazard analysis, evaluation for foreign supplier approval and verifications, the rule allows an importer to obtain information needed to meet certain FSVP requirements from other entities, such as a distributor or consolidator of the food. 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.”

FSVP Importer Is Accountable—Reliance on Others

**FSVP Importer is Accountable—
Reliance on Others**

- FDA will hold the FSVP importer accountable for meeting all of the requirements of the FSVP rule.
- The FSVP rule permits, however, the FSVP importer to rely on others, including its foreign suppliers, to perform many FSVP functions so long as each of those functions are performed by a **qualified individual** and each is reviewed by the FSVP importer’s **qualified individual**.
 - EXCEPT: The importer cannot rely on an audit conducted by the foreign supplier.



The FSVP importer is responsible for assuring that all FSVP requirements are met. FDA recognized, however, that there is great variability in food importation arrangements and, for that reason, built flexibility into the FSVP rule (see Key Point). Virtually all steps of the FSVP requirements can be carried out by entities other than the U.S.-based FSVP importer.

Still, the FSVP importer must make sure that the FSVP requirements have been carried out by qualified individuals AND the FSVP importer’s qualified individual must review what was done, as the FSVP importer will be held accountable for the FSVP program. FDA will review the FSVP importer’s records to determine compliance with the FSVP rule and take appropriate regulatory action if the importer has not followed the rule’s requirements.

Modified Requirements

Modified Requirements

- Some importers and/or their foreign suppliers may meet criteria that allow for modified FSVP requirements.
- The importers and/or the foreign supplier must demonstrate/document that they meet the eligibility criteria.
- Modified FSVP requirements apply:
 - If the importer is a “very small importer,”
 - If the imported food is from “certain small foreign suppliers,”
 - If the imported food is from foreign supplier(s) in countries with food safety systems recognized by FDA as “comparable” or “equivalent,” or
 - If the importer imports dietary supplements or dietary supplement components.



Up to this point we have focused on the standard requirements of the FSVP rule. There are instances, however, where an FSVP importer is able to follow modified requirements. Modified FSVP requirements apply if you are a “very small importer” and if you are importing foods from “certain small foreign suppliers” (21 CFR 1.512(a)).

Modified requirements also apply if the FSVP importer is importing food from foreign supplier(s) in countries with food safety systems recognized by FDA as “comparable” or “equivalent.” And finally, modified requirements apply if the FSVP importer is importing dietary supplements or dietary supplement components.

As mentioned earlier and here on this slide, dietary supplements for humans or animals are NOT EXEMPT from FSVP requirements. Importers must assure that manufacturers of these substances—finished products, ingredients, and components—are following CGMPs. FSVP requirements for dietary supplements and dietary supplement components need more time to explain than can be covered in this module. More detail is provided in the FSPCA FSVP course.

Importers or foreign suppliers must first meet the criteria to qualify for modified requirements and must continue to demonstrate their eligibility for these programs. Also, importers that do qualify can decide whether they wish to follow the standard requirements or the modified requirements.

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

“Certain Small Foreign Suppliers”

“Certain Small Foreign Suppliers”

- A foreign supplier meets the criteria for “Certain Small Foreign Suppliers” if the foreign supplier is:
 - A “qualified facility” as defined by the Preventive Controls rules,
 - A farm that grows produce and is not a “covered farm” under the Produce Safety rule (i.e., < U.S. \$25,000 average produce sales) or satisfies Produce Safety rule requirements for a “qualified exemption,” or
 - A foreign supplier of shell eggs 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.




Let’s begin with defining “certain small foreign suppliers.” As you can see from the slide, there are three categories. Because this course focuses on the PC rule, we will elaborate on the modified FSVP requirements that apply to very small suppliers subject to the PC rules.

Modified Requirements When Importing from “Certain Small Foreign Suppliers”

Modified Requirements When Importing from “Certain Small Foreign Suppliers”

- If an FSVP importer is importing food from one of these three categories of “certain small foreign suppliers” and wants to be subject to the modified FSVP requirements:
 - The importer must obtain **written assurance** from the foreign supplier that it meets the specified criteria for one of the three categories **before** approving the supplier for **each applicable calendar year**.



If the FSVP importer is importing food from one of the three categories of “certain small foreign suppliers” and wants to be subject

to the modified FSVP requirements, the importer must obtain written assurance from the foreign supplier that it meets the specified criteria for one of the categories **before** approving the supplier for **each applicable calendar year**.

Modified Requirements When Importing from “Certain Small Foreign Suppliers”: “Qualified Facilities”

Modified Requirements When Importing from “Qualified Facilities”

- If a foreign supplier is a “qualified facility,” the FSVP importer needs 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, or laws and regulations of a country whose food safety system has been recognized by FDA to be comparable or equivalent, and
 - That assurance must include a brief description of the supplier’s preventive controls, or a statement of compliance with relevant State or other non-Federal, including foreign, food safety laws and regulations.



If the foreign supplier is a “qualified facility,” the importer does not have to meet most of the FSVP rule requirements, but the importer must:

1. 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 laws and regulations of a comparable or equivalent country, and
2. That assurance must include a brief description of the supplier’s preventive controls, or a statement of compliance with relevant State or other non-Federal, including foreign, food safety laws and regulations.

In other words, a foreign supplier “qualified facility” would, in most cases, need to supply its FSVP importer with a statement that it is complying with U.S. food safety requirements and provide information on how it is doing that. For qualified facilities located in countries that FDA has found to be equivalent or comparable to the U.S. food safety system, the facility would need to provide assurance that it is meeting that country’s food safety requirements.


Note that the modified requirements that the FSVP importer must follow are those of a “very small importer,” but if the FSVP importer is

not “very small” there are additional requirements, we’ll cover in a few moments.

“Very Small Importers”

“Very Small Importers”

- A “very small importer” is an importer that during the previous 3-year period averages less than U.S. \$1 million (human food importers), or less than U.S. \$2.5 million (animal food importers) per year in sales of food; plus market value of food imported, processed, or held without sale.
- These calculations are adjusted for inflation with 2011 as the base year.
- These figures include sales of any subsidiaries and affiliates.



If the FSVP importer is a very small importer—that is, less than U.S. \$1 million average per year in sales over the last three years (adjusted for inflation) for human food or U.S \$2.5 million average for animal food, including the value of food imported and held without sale—the importer can also be subject to modified FSVP requirements.

The above calculations are adjusted for inflation with 2011 as the base year. FDA has published charts to help with this: <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm554484.htm>

Note that these figures include sales of any subsidiaries and affiliates.

Modified Requirements for “Very Small Importers”

**Modified Requirements for
“Very Small Importers”**

- “Very small importers” must obtain from their foreign supplier:
 - **Written assurance** that the food is being produced in compliance with processes and procedures that provide at least the U.S. level of public health protection, and
 - **Written assurance** that food is in compliance with U.S. adulteration and allergen labeling provisions (*for human food*).
- This must be done for every imported food, and needs to be done **before** first importing the food and **every 2 years thereafter**.


FOOD SAFETY AND INSPECTION SERVICE

If the FSVP importer is a “very small importer,” and importing from **any** foreign supplier (regardless of size), the importer must obtain 1) written assurance that the supplier’s food is being produced in compliance with processes and procedures that provide the U.S. level of public health protection, **AND** 2) written assurance that food is in compliance with U.S. adulteration provisions and allergen labeling (*for human food*) provisions.

This must be done for every imported food, and it needs to be done **before** importing the food and **every two years** thereafter.

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What If the FSVP Importer Is Not a “Very Small Importer,” but Imports from “Certain Small Foreign Suppliers”?

What If the FSVP Importer Is Not a “Very Small Importer,” but Imports from “Certain Small Foreign Suppliers”?

- If the FSVP importer does NOT qualify as a “very small importer,” but does import from “certain small foreign suppliers,” the importer must:
 - Evaluate the foreign supplier’s compliance history,
 - Approve the foreign supplier, and
 - Use only approved foreign suppliers.
- Importers must obtain written assurance from the foreign supplier that acknowledges that its food is produced 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 U.S.



If the FSVP importer is NOT a “very small importer,” but does import from “certain small foreign suppliers,” the importer must evaluate the foreign supplier’s compliance history, approve the foreign supplier, and use only approved foreign suppliers. And, as noted earlier, importers must obtain written assurance from the foreign supplier **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 brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food or a statement that supplier is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including the relevant laws and regulations of foreign countries.) The importer does not have to conduct further verification activities.

What If Assurances Are Invalid?

What If Assurances Are Invalid?

- If a “very small importer” or an importer importing from a “certain small foreign supplier” determines that a foreign supplier of food does not produce the food consistent with the **written assurances** the foreign supplier provided, the importer **must promptly** take appropriate **corrective actions**.



If the importer (“very small” or one importing from “certain small foreign suppliers”) determines that the foreign supplier is not producing food consistent with the assurances provided or finds a safety problem related to the food, the FSVP importer **must promptly** take appropriate corrective actions.

What Are Appropriate Corrective Actions?

What Are Appropriate Corrective Actions?

- The appropriate corrective actions will depend on the circumstances, but could include discontinuing use of the foreign supplier or another suitable alternative.
- FSVP importers **must document** any corrective actions they take.



As with standard FSVP requirements, corrective actions under modified requirements depend on the circumstances, but they must be intended to correct the problem for the long term. For example, the importer can discontinue use of the foreign supplier or decide to

impose a strict shipment-by-shipment verification requirement. In any case, the corrective actions should be appropriate for the situation at hand and the importer **must** document the corrective actions they take.

Key Point:

FDA has determined that New Zealand's, Canada's, and Australia's food safety systems are comparable to that of the U.S. food safety system in providing a very similar level of public health protection.

More information is available on FDA's website at:

<https://www.fda.gov/Food/InternationalInteragencyCoordination/InternationalCooperation/default.htm>

If Food Is from a Recognized System

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 US, 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.



The evaluations of another country's system are quite detailed and deliberative. Thus, they are labor-intensive and take a great deal of time for the country seeking a comparability or equivalence determination, as well as the U.S. FDA, to carry out the entire process. We can expect that more countries with mature food safety systems will be requesting such determinations from FDA.

If an FSVP importer is importing food from a foreign supplier in a country that has been found equivalent or comparable, 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)

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 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.



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, that the food in question falls under the scope of the official recognition of the country, AND that the foreign supplier is in good compliance standing with the foreign food authority. The FSVP importer must document each of these and check periodically that they are still valid.

As with any imported food, 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 and identify the FSVP importer at entry.

The Importance of Communications Within Your Supplier/Importer Chain

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.




It should have become clear in this module that communications among the FSVP importer, the foreign supplier and others in the importation chain are highly important. What is even more important is that these discussions must take place **early**—long **before** food shipments begin—on who is the FSVP importer, how are the FSVP requirements going to be met, what information does the importer need from the foreign supplier, and so forth. **Anyone in the supply chain can initiate the discussions**, but it is the FSVP importer who ultimately will be responsible for complying with the FSVP requirements and will be held accountable by FDA. Cooperation will be key. Foreign suppliers may be asked to provide additional documentation to the FSVP importer in order to facilitate compliance with this rule.

FSVP Module for Preventive Controls: Summary

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.



So, to review our main points—Foreign suppliers will be expected to work with U.S.-based FSVP importers and others in the supply/importation chain to provide information that FSVP requirements are being met—in particular, that foreign suppliers are supplying food that meets the U.S. level of public health protection, 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 as necessary,
- Reevaluating their FSVP for cause and 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.

Also, FSVP importers may use modified requirements if they qualify as “very small importers” or import food from “certain small foreign suppliers.”

