FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

Foreign Supplier Verification Programs (FSVP)

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Food Safety Modernization Act

- President Obama signed the Food Safety Modernization Act on January 4, 2011.

Main Goal

The FDA Food Safety Modernization Act of 2011 mandates the creation of a food safety system in which the focus is on preventing contamination rather than primarily reacting to problems after they occur.

Latin America in Figures

40% of produce consumed in the U.S. comes from Latin America

- 80% of that produce is imported from Mexico
- 8 of the ten main exporters of produce to the U.S., by volume, are Latin American countries

81% increase in import entry of FDA-regulated products from 2015-2019

Basic Rules

- Preventive Controls for Human Food
- Preventive Controls for Animal Food
- Produce Safety
- **Foreign Supplier Verification Programs**
- Accredited Third-Party Certification
- Sanitary Transportation
- Intentional Adulteration

Purpose of the Foreign Supplier Verification Programs

- To provide adequate assurances that:

  –Foreign suppliers produce food using processes and procedures providing the same level of public health protection as FSMA preventive controls or standards for the safe production of raw agricultural commodities.

  – Food is not adulterated or misbranded (as it relates to allergen labeling).

21 CFR Part 1 Subpart L

- 1.500 – Definitions
- 1.501 – Exemptions
- 1.502 – FSVP, LACF, PC
- 1.503 – Qualified individual/auditor
- 1.504 – Hazard analysis
- 1.505 – Evaluation for approval
- 1.506 – Verification
- 1.507 – Hazard control after importation
- 1.508 – Corrective actions
- 1.509 – Identification
- 1.510 – Records
- 1.511 – Dietary supplements
- 1.512 – Very small importers; small foreign suppliers
- 1.513 – Country with an officially recognized system
- 1.514 - Consequences

FSVP Importer

An FSVP importer is defined as:

- The U.S. owner or consignee of an article of food that is being offered for import into the U.S.

- If there is no U.S. owner or consignee, 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

FSVP Importer

The key is that there be a FSVP importer in the United States who takes responsibility for meeting the FSVP requirements.

FSVP: Foreign Supplier

A foreign supplier is defined as:

- Establishment that manufactures/processes the food, raises the animal, or harvests the food that is exported to the U.S. 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

What Will I Have to Do Under the FSVP rule?

Unless exempt, or subject to modified requirements, an FSVP importer may need to perform the following activities:

- Use a qualified individual to develop an FSVP and to perform FSVP activities.

- Perform a hazard analysis that includes identifying known or reasonably foreseeable hazards associated for each type of food and determining whether they require a control. Potential hazards include:
  - o biological hazards, including parasites and disease-causing bacteria;
  - o chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, food decomposition, unapproved additives, food allergens, and (in animal food) nutrient deficiencies or toxicities; and o physical hazards, such as glass.

What Will I Have to Do Under the FSVP rule?

- Evaluate risks posed by the food and the performance of the foreign supplier, considering:

  - o the hazard analysis for the food;
  - o the entity that will be applying hazard controls, such as the foreign supplier or the foreign supplier's ingredient supplier;
  - o the foreign supplier's food safety practices and procedures;
  - o applicable U.S. food safety regulations and information regarding the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter or import alert; and
  - o the foreign supplier's food safety performance history, including results from testing, audit results, and the supplier's record of correcting problems.

What Will I Have to Do Under the FSVP rule?

- Conduct appropriate supplier verification activities to provide assurance that the hazards requiring a control in the food you import have been significantly minimized or prevented. These activities may include:
  - o annual onsite audits (must be performed by a qualified auditor); o sampling and testing of a food;
  - o a review of the supplier's relevant food safety records; and/or
  - o other appropriate activities.

- Take corrective actions (if necessary) and investigate the adequacy of the FSVP (when appropriate).

What Will I Have to Do Under the FSVP rule?

- Reevaluate the food and foreign supplier every three years or sooner if the FSVP importer becomes aware of new information about the hazards in the food or the foreign supplier's performance.

- Identify the FSVP importer when filing for entry with U.S. Customs and Border Protection using the FSVP importer's name, electronic mailing address, and unique facility identifier (UFI) recognized as acceptable to FDA.
    - o The FDA has recognized the Data Universal Numbering System (DUNS) number as an acceptable UFI for FSVP. A DUNS number can be obtained by visiting fdadunslookup.com.
    - o The FDA has also issued guidance stating that for FSVP importers temporarily unable to obtain a DUNS number, FDA intends to temporarily allow filers to transmit the value "UNK" (to represent "unknown") in the UFI field. This option will be available beginning May 30, 2017 so that food offered for import can be processed through the Customs and Border Patrol (CBP) Automated Commercial Environment (ACE) system, even if the importer has not yet provided a DUNS number.

Raw Agricultural Commodities (RACs)

- In the case of a raw agricultural commodity (RAC) that is a fruit or vegetable that is "covered produce" as defined in the Produce Safety Rule (21 CFR 112.3), the importer is not required to determine whether there are any biological hazards requiring a control.

- However, the importer must:
  - Determine whether there are any other types of chemical and physical hazards requiring a control
  - Conduct an evaluation for approval and carry out verification activities

What Will I Have to Do Under the FSVP rule?

FSVP importers can meet key FSVP obligations by relying on analyses, evaluations, and activities performed by other entities in certain circumstances, as long as the FSVP importer reviews and assesses corresponding documentation.

Voluntary Pilot Program

The Food and Drug Administration (FDA) has concluded the voluntary pilot program to evaluate alignment of private third-party food safety audit standards with applicable FDA regulations, taking into account that three FSMA regulations - the PC Human Food rule, Preventive Controls for Animal Food (PC Animal Food) rule, and Foreign Supplier Verification Programs (FSVP) rule – allow for third-party audits to be used as supplier verification activities.

This pilot program was launched to help both FDA and industry gain a better understanding of whether these standards align with FDA regulations.

Voluntary Pilot Program

This goal is consistent with the New Era of Smarter Food Safety Blueprint. The Blueprint, published on July 13, 2020, explains that the Agency is looking to explore how reliable third-party audits can help ensure food safety, including the use of audit data in risk prioritization for FDA regulatory activities.

The FDA understands that findings of alignment could create efficiencies for industry and help give importers and receiving facilities confidence that, in general, the third-party standards used to audit their suppliers adequately address applicable FDA food safety requirements. This information, along with results of a firm's audits also could help inform the FDA in determining risk prioritization and resource allocation.

Voluntary Pilot Program

While the FDA sees value in the use of third-party food safety audit standards in facilitating industry's implementation of FSMA, and the potential of these audits to inform risk prioritization, the Agency does not currently have adequate resources to continue to review and evaluate the alignment of third-party food safety standards beyond this pilot. The FDA will continue to assess future opportunities to leverage third party audit standards to help meet the agency’s public health mission.

https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/summary-foreign-supplier-verification-program-final-rule

Foreign Supplier Verification Programs Inspection

Inspections are an important tool the U.S. Food and Drug Administration (FDA) uses in ensuring human and animal foods are safe for U.S. consumers. The Foreign Supplier Verification Programs (FSVP) rule, which is one of the seven rules that make up the Food Safety Modernization Act (FSMA), requires that importers perform certain risk-based activities to verify that the human and animal food they import into the United States has been produced in a manner that meets applicable U.S. safety standards. This fact sheet provides an overview of steps FDA investigators will take when conducting routine inspections to determine compliance with the FSVP Rule.

An inspection of an FSVP importer to review FSVP records can occur if:

- The importer is subject to routine surveillance and follow-up;
- The importer has an inspectional history that includes a violative inspection and a compliance follow-up inspection is needed to observe voluntary corrections; or
- Products imported by the FSVP importer are associated with a recall, foodborne outbreak investigation, or complaint.

Foreign Supplier Verification Programs Inspection

Pre-Inspection Contact

For initial inspections, an FDA investigator will email and/or call the person or entity identified at the time of entry as the FSVP importer.

The investigator will confirm the entity as the FSVP importer for the specific product(s)/foreign supplier(s) assigned to be reviewed, including clarification of the importer's location and contact information. The investigator will also determine if the FSVP records are in English and available onsite, if they can be retrieved within 24 hours of written request; and if documents are not maintained in English, how soon an English translation can be provided.

Foreign Supplier Verification Programs Inspection

How to Prepare for the Inspection

Once contacted regarding an FSVP inspection, the importer should retrieve any records that may be stored offsite so that the documents are ready for the investigator at the start of the inspection. If records are not in English, the FSVP importer should have the records translated into English, prior to the inspection date.

The FSVP Regulation Records Requirements provide a list of FSVP records the investigator may request to review during the inspection. The list may be used to help the FSVP importer prepare for and facilitate the inspection.

Foreign Supplier Verification Programs Inspection

During the Inspection

FSVP inspections are generally conducted at the FSVP importer's location during normal business hours.

When the investigator arrives, they will ask to speak to the most responsible individual onsite. The investigator will introduce themselves (name, title, agency), provide the reason for the inspection, and show identification. The investigator will also request FSVP records in writing (Form FDA 482d).

If the firm is a warehouse, or other type of facility that stores or holds food, the investigator will also issue a Notice of Inspection (FDA Form 482) if a warehouse inspection is scheduled to take place as well. Inspections of warehouses are covered under a different section of the Food Drug and Cosmetic Act.

Foreign Supplier Verification Programs Inspection

The owner or the individual responsible for creating and maintaining the FSVP (e.g., a qualified individual) should be present for the inspection. If at the time of the inspection, the owner or the person responsible for creating or maintaining the FSVP is not available in person, he or she should be accessible by telephone. If another qualified entity performed FSVP activities on behalf of the importer, the importer may obtain records from their qualified individual during the inspection.

During the inspection, the investigator will review FSVP records for the product(s)/supplier(s) identified during the pre-inspection contact. They will ask questions and take notes to determine the adequacy of the FSVP records and may ask for copies of the records. They may also ask for labeling, if available, and take pictures.

Foreign Supplier Verification Programs Inspection

The amount of time an inspection takes depends on the basis on which the inspection is being conducted, and what is observed during the inspection. The investigator will report their observations to the most responsible individual present during the inspection. The FDA encourages open dialogue among all parties throughout the inspection.

Foreign Supplier Verification Programs Inspection

Please note: FSVP inspections may also take place remotely. Under section 1.510(b)(3), if requested in writing by FDA, the importer must send records to the Agency electronically, or through another means that delivers records promptly. This section provides the regulatory basis for conducting remote inspections. For a remote inspection, the FSVP records are reviewed by the investigator at a site other than the importer's premises.

Foreign Supplier Verification Programs Inspection

Close of the Inspection

The inspection concludes with an exit interview with the most responsible individual onsite. If the investigator made significant observations during the inspection, they will provide those observations in writing (Form FDA 483a, FSVP Observations), and discuss corrective actions.

Less significant observations found during the inspection will also be discussed during the exit interview. For more information about written inspectional observations, please see the FDA Form 483 Frequently Asked Questions webpage.

Foreign Supplier Verification Programs Inspection

If the importer responds during the inspection by making corrections to issues pointed out by the investigator, the investigator will take note and collect evidence, if possible.

If the deficiency is something that cannot be corrected during the inspection, the investigator should ask the importer about the corrective actions they plan to take.

The FDA highly encourages the importer to provide a written response to the FDA within 15 business days following the inspection. The response should include newly created and updated records and evidence of corrections.

Foreign Supplier Verification Programs Inspection

During the exit interview, the investigator will also answer any additional questions regarding the inspection and next steps.

More information about FSVP can be found on www.FDA.gov/FSMA .

Accredited Third-Party Certification Program

- Can audits conducted by accredited certification bodies be used to meet the supplier verification requirements of the Foreign Supplier Verification Program?

  – Yes, in circumstances where an onsite audit is an appropriate supplier verification activity, receiving facilities and importers are not required to use onsite audits conducted by a certification body accredited under TPP, but they may choose to do so.

Consequences of Failing to Comply (1.514)

- Food offered for importation is subject to refusal of admission if:
  - –The importer does not meet with the FSVP for that food
  - –The foreign owner or consignee has not designated a U.S. agent or representative
- The importation or offering for importation into the U.S. of an article of food without the importer having an FSVP is prohibited under section 301(zz)

Industry Training

- Food Safety Preventive Controls Alliance (FSPCA) FSVP
- Food Safety Preventive Controls Alliance (FSPCA) Preventive Controls for Human Foods
- Food Safety Preventive Controls Alliance (FSPCA) Preventive Controls for Animal Foods
- Produce Safety Alliance (PSA)
- Sprout Safety Alliance (SSA)

Guidance and Outreach

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-foreign-supplier-verification-programs-importers-food-humans-and-animals

Guidance for Industry: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

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Guidance and Outreach

- Webinars and meetings
- FSVP fact sheets
- FSVP At-a-Glance
- FSVP Guidance for Industry
- FDA Data Dashboard: Supplier Evaluation Resources
- Technical Assistance Network (TAN)
- Am I subject to FSVP?


THANK YOU

Any questions?

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