CHAPTER 03: FOODBORNE MICROBIOLOGICAL HAZARDS

Subject:	Foreign Supplier Verification Programs Inspections
Implementation Date:	09/27/2023
Product Codes:	Use appropriate product codes
Product/Assignment Codes:	**03878** (FOREIGN SUPPLIER VERIFICATION PROGRAMS HUMAN FOOD INSPECTIONS) **03878D** (FOREIGN SUPPLIER VERIFICATION PROGRAMS DIETARY SUPPLEMENT INSPECTIONS) **03878P** (FOREIGN SUPPLIER VERIFICATION PROGRAMS PRODUCE INSPECTIONS) **71878** (FOREIGN SUPPLIER VERIFICATION PROGRAMS ANIMAL FOOD INSPECTIONS)

FIELD REPORTING REQUIREMENTS:

Investigators must use eNSpect to complete the Establishment Inspection Report (EIR) and Inspection Protocol (IP) for an FSVP inspection (OP12) or for an investigation (OP13). See Investigations Operations Manual (IOM) subchapter *5.11 - Reporting* and subchapter *8.1.9 - General Investigation Reporting* for additional reporting instructions. An exception for creating an EIR or a related document (e.g., Form FDA 483a) or an investigation memorandum in eNSpect must be endorsed by the investigator's supervisor. IOM subchapter *5.11.2.1 – Reporting Verified Corrective Actions* directs Office of Inspections and Investigations (OII) field staff to document corrective actions taken during an inspection in the Corrective Action Reporting (CAR) system within eNSpect.

Contents

Change History

Item	Change	Date
Initial Issuance		10/20/2021
Update	• Changed the title of CP 7303.878 to *Foreign Supplier Verification Programs Inspections* from *Import Food Operations* to more accurately reflect the content of this compliance program. Instead of adding general import operations content to this CP, CP 7303.819 *Import Foods General* is being updated. • Updated office names and program contacts throughout document. • Added program interactions in Part II for CP 7303.803A *Domestic Low-Acid and Acidified Foods* and the new CP 7303.080 *Produce Safety Inspections*. • Fixed hyperlinks throughout document. • Significant changes to part V to provide additional clarity concerning enforcement processes and consistency in terminology.	09/27/2023
Pen/Ink (updates in red)	• Updated broken link to FSPCA training courses. • Updated part V to clarify that direct reference authority was granted for certain FSVP cases. • Updated program points of contact in Part VI	08/20/2024
Corrections (In red)	• Post-reorganization POC and office name/acronym updates.	08/28/2025

PART I – BACKGROUND

Section 301 of the FDA Food Safety Modernization Act (FSMA) added section 805, Foreign Supplier Verification Programs, to the FD&C Act. Section 805 enhanced our authority to ensure the safety of imported food. In November 2015, FDA published the Foreign Supplier Verification Programs for Food Importers (FSVP) regulation (21 CFR part 1, subpart L or 21 CFR 1.500 - 1.514).

This Foreign Supplier Verification Programs (FSVP) Inspections compliance program provides instruction to field staff based on the Food and Drug Administration's (FDA) mission to protect and promote public health, in line with the FDA Strategy for the Safety of Imported Food. This compliance program details legal and regulatory requirements for FSVP importers as well as administrative, inspection, and enforcement activities relating to human and animal food imported to the United States (U.S.).

Food imported into the U.S. must meet applicable U.S. requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and implementing regulations. FDA's strategy for the safety of imported food is to ensure that the food was produced using processes and procedures that provide, at least, the same level of public health protection as food produced in the U.S. To operationalize the FDA's Food Safety Strategy, FDA applies risk-based approaches to mitigate food safety risk.

The FD&C Act gives FDA the authority to regulate foods, including imported foods. Section 801 of the FD&C Act gives FDA authority to refuse admission to products that do not meet certain U.S. requirements and includes additional requirements specific to imported products, importers, and the import process.

1. Summary of Requirements

Below is a summary of the FSVP requirements. For complete requirements, please review 21 CFR part 1, subpart L or 21 CFR 1.500 - 1.514. Under 21 CFR 1.500, 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 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 the FSVP regulation.

When discussing within the context of FSVP, the term "importer" hereinafter means "importer" as defined in 21 CFR 1.500 and may be abbreviated as "FSVPI."

21 CFR 1.502(a) requires that for each food imported that is subject to the FSVP regulation, the FSVPI to develop, maintain, and follow an FSVP that provides adequate assurances that the

FSVPI's foreign supplier is in compliance with processes and procedures that provide at least the same level of public health protection as those required under:

- Section 418 of the FD&C Act (regarding hazard analysis and risk-based preventive controls) and the implementing regulations, or Section 419 of the FD&C Act (regarding standards for produce safety) and the implementing regulations.

21 CFR 1.502(a) also requires the FSVPI to ensure that the foreign supplier is producing the food in compliance with sections 402 (regarding adulteration) and section 403(w) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens for human food) of the FD&C Act.

Section 1.509 of the FSVP regulation requires the FSVPI to ensure that, for each entry line of food they offer for importation into the U.S., their name, electronic mail address, and unique facility identifier (UFI) recognized as acceptable by the FDA, are provided electronically when filing entry with U.S. Customs and Border Protection (CBP). The importer's DUNS number is the UFI that is recognized as acceptable by FDA. See *Guidance to Industry: Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation* for more information.

The FSVP regulation establishes requirements for FSVPIs, definitions, exemptions from the FSVP regulation, and the consequences for failure to comply with the FSVP regulation. FDA has designated certain sections of the FSVP regulation as either standard requirements or modified requirements as described below. Note that FSVPIs who meet the criteria for modified requirements may choose to follow standard requirements.

A. FSVP Definitions, Exemptions, Consequences

- Section 1.500 What definitions apply to this subpart?
- Section 1.501 To what foods do the requirements in this subpart apply?
- Section 1.514 What are some consequences of failing to comply with the requirements of this subpart?

B. FSVP Standard Requirements

- Section 1.502 What foreign supplier verification program (FSVP) must I have?
- Section 1.503 Who must develop my FSVP and perform FSVP activities?
- Section 1.504 What hazard analysis must I conduct?
- Section 1.505 What evaluation for foreign supplier approval and verification must I conduct?
- Section 1.506 What foreign supplier verification and related activities must I conduct?
- Section 1.508 What corrective actions must I take under my FSVP?
- Section 1.509 How must the importer be identified at entry?

- Section 1.510 How must I maintain records of my FSVP?

C. FSVP Modified Requirements

- Section 1.507 What requirements apply when I import a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation?
- Section 1.511 What FSVP must I have if I am importing a food subject to certain requirements in the dietary supplement current good manufacturing practice regulation?
- Section 1.512 What FSVP may I have if I am a very small importer or I am importing certain food from certain small foreign suppliers?
- Section 1.513 What FSVP may I have if I am importing certain food from a country with an officially recognized or equivalent food safety system?

2. FSVP Exemptions (21 CFR 1.501)

FSVP regulation applies to all food imported or offered for import into the U.S. and to the FSVPIs of such food, except as follows:

- Juice and fish and fishery products provided the supplier is in compliance with 21 CFR part 120, or 123, respectively (1.501(b)(1)).
- Raw materials or other ingredients used to manufacture juice or fish and fishery products provided the FSVPI is in compliance with 21 CFR part 120, or 123, respectively (1.501(b)(2)).
- Food imported for research or evaluation (1.501(c)).
- Food imported for personal consumption (1.501(d)).
- Alcoholic beverages, raw materials and other ingredients that are imported and used by the FSVPI to manufacture/process, pack or hold an alcoholic beverage, and certain foods that are not alcoholic beverages (1.501(e)).
- Food that is transshipped through the U.S. (1.501(f)(1); or food that is imported for processing and further export and is not sold or distributed to the public in the U.S. (1.501(f)(2)).
- Food that is manufactured/processed, raised, or grown in the U.S., exported, and returned to the U.S. without further manufacturing/processing in a foreign country (1.501(g)).
- Certain meat, poultry, and egg products that at the time of importation are subject to the requirements of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), respectively (1.501(h)).

3. Enforcement Discretion

FSVP guidance documents relating to enforcement discretion may be found at the FDA.gov web page FSMA Rules & Guidance for Industry.

PART II – IMPLEMENTATION

1. Objectives

- Conduct FSVP inspections for importers subject to the *Foreign Supplier Verification Programs for Food Importers* regulation.
- Document FSVP inspections and observations.
- Enforce the FSVP regulation when appropriate to prevent importation of food by importers not in compliance with the FSVP regulation or food that appears to be in violation of the FD&C Act.

2. Program Management Instructions

OII Import Field Divisions ("Divisions") are responsible for ensuring that investigators verify, correct, and enter changes to the Official Establishment Inventory (OEI) (including Profile data) on the firm's maintenance screens in eNSpect during each inspection or investigation. Investigators should consult with their supervisor and OEI Coordinator to ensure data is accurately updated.

A. Inspection Priorities

The Human Foods Program (HFP), Center for Veterinary Medicine (CVM), and OII/Office of Import Operations (OIO) are responsible for developing prioritization criteria for selecting FSVPIs for FSVP inspections. OII/OIO will select FSVPIs for surveillance and compliance follow-up inspections from the FSVPI inventory. For-cause FSVP inspections may also be requested by the Divisions, Division of Import Operations (DIO), HFP, or CVM. See FSVP Implementation Work Instructions for additional information on the procedure for assigning inspections in eNSpect.

When selecting an FSVPI for an FSVP inspection, Divisions should review the current fiscal year's (FY) FSVP National Work Plan Inventory and Prioritization, found under the Work Planning subheading on the FSVP Resources Sharepoint Page. An importer of human foods from a country with a Systems Recognition Agreement (SRA), may still be eligible for an FSVP inspection. See FDA Oversight of Food Covered by Systems Recognition Arrangements: Guidance for Food and Drug Administration Staff for additional information.

Additionally, the following criteria should be considered:

- **Priority #1: Compliance History**

  FSVPIs with history of noncompliance with the FSVP regulation or who import from a foreign supplier with a history of noncompliance that presents a potential public health risk should be the first priority for FSVP inspection. History of noncompliance

includes: class 1 recalls, laboratory class 3 findings, official action indicated (OAI) inspection classifications, and foodborne illness outbreaks. History of noncompliance would also include situations where the importing country or region is associated with a trend of noncompliance for a specific food or industry (e.g., country-wide import alert, import bulletin, or emerging public health issues).

- **Priority #2: Prioritized Food**

  Food that should be prioritized for FSVP inspection coverage include:

  - Ready-to-eat food (RTE food) for which a significant hazard is identified. Ready-to-eat food (RTE food) is defined in 21 CFR 117.3 to mean any food for humans that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.
  - Raw agricultural commodities (RACs) that are "covered produce" under 21 CFR 112.3 (e.g., leafy greens, cucumbers, tomatoes, peppers, cantaloupes, honeydew, papayas).
  - Human food for which an undeclared major food allergen or a major food allergen presence due to cross-contact is a significant hazard. See CPG Sec 555.250, DRAFT: Major Food Allergen Labeling and Cross-Contact for additional information.
  - Food intended for use by special populations, such as infants (such as infant formula), young children, elderly, pregnant women, and persons who are immunocompromised.
  - Food for which a process control (e.g., cooking, pasteurization, refrigeration, acidification) is required.
  - Finished dietary supplements.
  - Pet food, pet treats, and chews.

- **Priority #3: Other Factors**

  After priorities #1 and 2, the Division should prioritize FSVP inspections based on other relevant factors, including higher:

  - numbers of different foods imported by the FSVPI,
  - numbers of foreign suppliers from which an FSVPI imports food, and
  - volume and value of the lines of food imported by the FSVPI.

  These factors will help maximize surveillance coverage for imported food.

B. Planning Instructions

The OII Import Program Workplan identifies the number of FSVP inspections that Divisions should complete each FY.

Only investigators who have successfully completed the following training may independently conduct FSVP inspections:

- Food Safety Preventive Controls Alliance (FSPCA) Preventive Controls for Human Food course
- FSPCA Foreign Supplier Verification Programs course
- FDA's Office of Training Education and Development (OTED) IM220 Foreign Supplier Verification Programs Regulator Course.

Additionally:

- Investigators conducting FSVP inspections of produce importers must have successfully completed the Produce Safety Alliance for Growers Training course.
- Investigators conducting FSVP inspections of animal food importers must have successfully completed the FSPCA Preventive Controls for Animal Food course.
- Investigators conducting FSVP inspections of dietary supplement importers that are subject to the requirements of section 1.511 of the FSVP regulation must be knowledgeable of the Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements (dietary supplements CGMP) regulation (21 CFR part 111) and have watched and reviewed the FSVP Dietary Supplement Training Videos.

Refer to the FSVP Implementation Work Instructions, found on the FSVP Resources Sharepoint Page under the Work Instruction subheading, for information on how to meet training requirements.

C. Resources and Reporting

All FSVP operations conducted under this compliance program will be created in eNSpect Assignment Management System (AMS). FDA staff should refer to the Assignment Management System (AMS) User Guide for any questions on the use of AMS in eNSpect to create operations. OIO will generate a new eNSpect Assignment ID each FY. FDA staff must not create an ad-hoc FSVP operation for this compliance program without concurrence from the DIO FSMA Team and the program coordinator identified in part VI of this compliance program. Divisions should coordinate resources to ensure that inspections conducted under this compliance program meet inspection obligations under other compliance programs that also apply. See Table 1 below for additional resources and reporting information.

Table 1 – Resources and Reporting

Activity	Work Types	Planning PAC	Reporting PAC
Foreign Supplier Verification Programs Inspections (Human Foods)	Op 12 Inspection Op 13 Investigation	03878	**03878** (FOREIGN SUPPLIER VERIFICATION PROGRAMS HUMAN FOOD INSPECTIONS) **03878D (**FOREIGN SUPPLIER VERIFICATION PROGRAMS DIETARY SUPPLEMENT INSPECTIONS) **03878P** (FOREIGN SUPPLIER VERIFICATION PROGRAMS PRODUCE INSPECTIONS)
Foreign Supplier Verification Programs Inspections (Animal Food)	Op 12 Inspection Op 13 Investigation	71878	**71878** (FOREIGN SUPPLIER VERIFICATION PROGRAMS ANIMAL FOOD INSPECTIONS)

3. Program Interactions

Programs that interact with this compliance program include the following:

A. Preventive Controls and Sanitary Human Food Operations (CP 7303.040) or Comprehensive Animal Foods Inspection (CP 7371.000)

In some cases, an FSVPI is also a receiving facility subject to section 418 of the FD&C Act. An FSVPI that is a manufacturer/processor subject to the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation (preventive controls for human food) (21 CFR part 117) or the Current Good Manufacturing

Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (preventive controls for animal food) regulation (21 CFR part 507) that imports a raw material or other ingredient they use in the food they manufacture/process may be subject to an inspection to determine compliance with the preventive controls for human food regulation or preventive controls for animal food regulation. If the manufacturer is deemed in compliance with supply chain requirements in 21 CFR part 117 or 21 CFR part 507, they are also deemed to be in compliance with the FSVP requirements for foods they import (except they must comply with section 1.509 of the FSVP regulation).

An importer that is not a receiving facility, defined in section 1.500, for a food they import must comply with the FSVP requirements for that food. For example, an FSVPI that is also a facility solely engaged in the storage of unexposed packaged food requiring time/temperature control for food safety and that is subject to inspection to determine compliance with modified requirements in Subpart D (section 117.206 for human food or section 507.51 for animal food) may be subject to an FSVP inspection. Similarly, an FSVPI that is a facility solely engaged in the storage of unexposed packaged food not requiring time/temperature control for food safety (i.e., ambient warehouse) and is subject only to the CGMP requirements found in subpart B of 117 or 507 may also be subject to an FSVP inspection.

B. Dietary Supplements – Foreign and Domestic Inspections, Sampling, and Imports (CP 7321.008)

An FSVPI that imports a dietary supplement or dietary supplement component for further manufacturing, processing, or packaging as a dietary supplement by the FSVPI or their customer and they or their customer are subject to inspection to determine compliance with certain requirements in the Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements (dietary supplements CGMP) regulation may also be subject to an FSVP inspection under modified FSVP requirements in 1.511.

C. Produce Safety Inspections (CP 7303.080)

An FSVPI that imports covered produce (see part III.1.A.i. for additional information on covered produce) is subject to inspection to determine compliance with the FSVP regulation. Additionally, FSVP inspections may be conducted on farms that import covered produce. More information can be found in the produce safety inspections compliance program covering the coordination of activities between DIO and OII PSN as well as in Part II.D. of this compliance program when an FSVP inspection is being planned at a farm.

D. Domestic Acidified and Low-Acid Canned Foods (CP 7303.803A)

According to § 1.502(a)-(b):

- An FSVPI of low-acid canned foods not subject to further manufacturing or processing, with respect to those microbiological hazards that are controlled by 21 CFR part 113, must verify and document that the food was produced in accordance

with part 113. With respect to all matters that are not controlled by 21 CFR part 113, an FSVPI must have an FSVP, and

- Certain FSVPIs of raw materials or other ingredients subject to 21 CFR part 113 of this chapter, with respect to microbiological hazards that are controlled by part 113, an FSVPI is not required to have a FSVP for raw materials or other ingredients that imported and use in the manufacturing or processing of low-acid canned food provided the FSVPI is in compliance with 21 CFR part 113 with respect to the imported low-acid canned food the FSVPI manufactures or processes from the imported raw materials or other ingredients. With respect to all hazards other than microbiological hazards that are controlled by 21 CFR part 113, an FSVPI must have an FSVP for the imported raw materials and other ingredients that the FSVPI uses in the manufacture or processing of low-acid canned foods.

4. Food Facility Registration

An FSVPI may also be a facility that is required to register under section 415 of the FD&C Act if it manufactures, processes, packs, or holds food for consumption in the United States and no exemptions apply. If Division staff determine that an FSVPI is also a facility that is required to register and the facility is operating with no registration, a suspended registration, an invalid registration, or a cancelled registration, or that the registration in the Food Facility Registration Module (FFRM) is not accurate, the Division staff should send an email to FoodFacilityRegistration@fda.hhs.gov in accordance with IOM subchapter 5.4.1.5.2, *Food Facility Registration Resources*. When food facility registration is discussed during an inspection of a facility that is required to register, the investigator should document the discussion in the EIR.

5. Interactions with Federal Agencies, State and Local Counterparts, and Foreign Authorities

A. Federal Agencies

Interaction with other Federal agencies is not expected for FSVP inspections.

B. State and Local Counterparts

Currently, FDA is not assigning FSVP inspections to State and Local counterparts.

C. Foreign Authorities

If a human food covered during an FSVP inspection is covered by a SRA, the FSVPI may be eligible for modified requirements per Section 1.513 of the FSVP Regulation. The existence of a SRA facilitates FDA's ability to consider information provided by the regulatory authorities, as appropriate, when FDA considers regulatory action. See Systems Recognition (Food) for more information.

The modified FSVP requirements in section 1.513 of the FSVP regulation apply only to human foods that are not intended for further manufacturing/processing and within the scope of the applicable SRA.

D. When to Contact Other Offices within FDA

Import Divisions should coordinate with the Office of Human Food Inspectorate (OHFI) Divisions to ensure that they are not inspecting a facility or farm more than once per year, except when a for-cause inspection is necessary. Import Divisions should share their FSVP inspection assignments with the appropriate OHFI Divisions at the beginning of the FY and exchange quarterly accomplishment updates thereafter. Additional situations that may require communication between Divisions and other FDA offices include the following.

- For FSVPIs for which there are overlapping inspection responsibilities for OIO and OHFI, the appropriate field Division will coordinate inspection activities to ensure consistent and timely inspections are conducted to fulfill OII's commitment to industry relating to inspection coverage and to ensure that qualified staff are conducting inspections. Refer to the work planning prioritization tool which flags FSVPIs as being subject to both OHFI and FSVP inspection.
- HFP, CVM, or DIO may issue a for-cause FSVP inspection assignment for one or more FSVPIs of a food that is subject to a recall, implicated in a foodborne outbreak, from a foreign supplier with an OAI inspection, or for which data indicates a food safety concern.
- Investigations Branch (IB) should consult with the appropriate Compliance Branch (CB) as soon as possible if an advisory, administrative, or judicial action is being considered. IB should also consult with CB if a recall activity is in progress or being considered (see FMD-86 Establishment Inspection Report Conclusions and Decisions).

For questions pertaining to the content of this compliance program or its implementation, please contact the appropriate individuals identified in part VI of this compliance program.

The Regulator Technical Assistance Network (rTAN) is a resource primarily for investigators to request assistance during inspections. It is not intended to replace the current enforcement communication mechanism between field inspection staff, supervisors, and compliance officers. The rTAN is an information assistance system designed to connect field inspection staff with Subject Matter Experts (SMEs) to get answers and clarification on interpretation of a FSMA regulation and for specific food-related questions, as needed.

i. Human Food rTAN

Investigators should send all human food rTAN inquiries relating to FSVP inspections conducted under this compliance program to FSVPrTAN@fda.hhs.gov. As necessary, FSVP rTAN members will reach out to SMEs on the rTAN list for FSMA rule policy interpretation or for clarification on commodity-specific hazards (e.g., produce, ready-to-eat foods, foods refrigerated for safety, dietary supplements).

Investigators may reach out to additional SMEs on the FSMA rTAN list found on the FSVP Resources Sharepoint Page as appropriate based on the food being covered and the nature of the question. However, ALL applicable SMEs must be included in all communications to ensure consistent information is provided and to prevent duplication of effort. The investigator may contact FSMA rTAN directly via e-mail prior to or during an inspection. If an inspection is in-progress, or potentially OAI, and an answer is required as soon as possible, indicate that in the e-mail subject heading.

ii. Animal Food rTAN

Investigators should email CVMAnimalFoodPrograms@fda.hhs.gov or call 301-796-0001 with questions before, during, or after an inspection of an FSVPI that imports animal food and copy their supervisor. Investigators should include "rTAN" or "Regulator TAN" in the subject line of their email. A CVM rTAN Coordinator will forward the question to the appropriate CVM SMEs, summarize the final answer, and respond to the investigator in the manner the question was received (i.e., email or telephone). If an inspection is in-progress, or potentially OAI, and an answer is required as soon as possible, indicate that in the e-mail subject heading.

PART III – INSPECTIONAL

1. Operations

A. Inspections

Investigators will conduct FSVP inspections (on-site or remote) under this compliance program to evaluate the FSVPI's compliance with the FSVP regulation. Additional information on Remote Regulatory Assessments (RRAs) is found at Draft Guidance for Industry: Conducting Remote Regulatory Assessments Questions and Answers. Divisions should determine if there are any pending administrative or regulatory actions or ongoing investigations relating to the food, foreign supplier, or FSVPI before conducting an FSVP inspection.

As appropriate to inform and enhance the FSVPI's understanding of the FSVP regulation, during discussion with the FSVPI, the investigator should reference and provide relevant FSVP resources, such as:

- *Final Rule on Foreign Supplier Verification Programs*
- *Key Requirements: Final Rule on Foreign Supplier Verification Program* (This at-a-glance document summarizes the key requirements of the FSVP regulation.)
- *Guidance for Industry: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (final guidance)* (This document provides guidance to industry on the requirements of the FSVP regulation.)
- *Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) Regulation Records Requirements* (This document helps the FSVPI determine the required records for the sections in the FSVP regulation that apply to the food they import.)
- *Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation* (This document helps the FSVPI understand the requirement in section 1.509 to provide their DUNS number as part of their importer identification for each line entry of food.)
- *FSMA Inflation Adjusted Cut Offs* (This information helps the FSVPI to make a determination of a very small importer status.)
- Food Safety Preventive Controls Alliance (FSPCA) (The FSPCA, established by FDA and the Illinois Institute of Technology's Institute for Food Safety and Health, has developed a training curriculum for importers and others who wish to obtain additional information on implementation of the FSVP regulation.)

The investigator will determine if the FSVPI developed FSVPs for the foods they imported and ask questions to determine whether the importer has the required FSVP records (e.g., hazard analysis, documentation of supplier verification activities). The investigator will encourage the FSVPI to take corrective actions for deviations observed

during the inspection. The investigator will document in the EIR all corrective actions taken by the FSVPI during the inspection and any corrective actions the importer indicated they plan to take, including the importer's timeframe for correction. In addition, the investigator will document in the corrective action reporting system (CAR) within eNSpect any corrective actions taken by the FSVPI during the inspection and any corrective actions received as a result of the inspection.

The investigator will discuss with the importer, significant observations listed on Form FDA 483a, FSVP Observations, and also discuss with the importer other observations that are not significant enough to impact public health (i.e., signing a record). The investigator will document the discussion in the EIR (see IOM 5.2.3).

i. FSVP Inspection of FSVPI of Covered Produce

An investigator conducting a FSVP inspection of a produce FSVPI must have successfully completed the Produce Safety Alliance for Growers Training course and must be knowledgeable of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (21 CFR part 112). See Part II.2.B for investigator training requirements. Investigators should review the information related to "covered produce" in the FSVP Implementation Work Instructions and under the "guidance" buttons in the Inspection Protocol (IP). To determine if the produce covered during an FSVP inspection is "covered produce" investigators should:

- Review the "covered produce" list 21 CFR 112.1
- Review the "not covered produce" list 21 CFR 112.2.

If the produce is not covered because it will be commercially processed to reduce the presence of microorganisms of public health significance, under 112.2(b), documents must accompany the produce disclosing that it is not processed to adequately reduce the presence of microorganisms of public health concern. If the FSVP importer indicates the produce was not covered by the PSR because of the commercial processing exemption, the investigator should request documentation to show the produce is accompanied by the disclosure statement.

ii. FSVP Inspections of Firms Subject to Modified Requirements

Investigators assigned inspections of FSVPIs that fall under modified requirements should clearly indicate in the EIR which requirements the FSVPI is subject to regardless of the actual documentation provided by the FSVPIs (i.e., even when they have "No FSVP" or provided no FSVP records). In addition to instructions below, investigators should review the information in the FSVP Implementation Work Instructions and under the "guidance" button in the Inspection Protocol (IP) related to specific modified requirements.

- FSVP Inspection of FSVPI importing a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation.

  The investigator should follow the IP and document the appropriate circumstances.

- FSVP Inspection of FSVPI of Dietary Supplements

  Investigators conducting FSVP inspections of importers of dietary supplements that are subject to the requirements of section 1.511 of the FSVP regulation must be knowledgeable of the Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements (dietary supplements CGMP) regulation (21 CFR part 111). See Part II.2.b. for further investigator training requirements.

  If you are assigned an inspection for an importer of dietary supplements, you should verify that 1.511(c) applies to the importer by asking if the product is further manufactured by the importer (1.511(a)) or the importer's customer 1.511(b)). If you find the importer is actually subject to 1.511(a) or (b) because they are the manufacturer or their customer is the manufacturer of the dietary supplement, you should work with your supervisor to determine whether your assignment should be converted to an Op 13.

  If determined 1.511(c) does apply, investigators should refer to the guidance tabs and recommended citations in the FSVP IP.

  Note that if the FSVPI imports a food that will be used as a component in a dietary supplement, but neither the importer nor the importer's customer will conduct the manufacturing/processing of the dietary supplement, the modified requirements in 21 CFR 1.511 do not apply.

- FSVP Inspection of FSVPI who is a very small importer (VSI)

  Investigators conducting FSVP inspections of VSIs should include a review of available FDA data related to the sales of human food or animal food and the US market value of imported human food or animal food, respectively, as part of the pre-inspection preparation and document that information in the EIR (e.g., ORADSS reports, OEI/FMS data, DUNS, etc.).

  Investigators conducting an inspection of a VSI should document in the EIR that they informed the FSVPI of the modified requirements even if they choose not to

comply with modified requirements. If VSI ***does not*** have documentation of any modified requirement, including eligibility, it is appropriate to cite that the importer had "No FSVP" records under 1.502(a). Further, if documentation of eligibility is provided but is not part of an effort or correction during the inspection to maintain FSVP records (e.g., the documents are maintained solely for other business reasons unrelated to FSVP) citing the importer for "No FSVP" may be appropriate. If necessary, investigators should explain in the EIR how and why the firm provided the documents to support the most appropriate charge for the situation.

Investigators assigned an inspection of a FSVPI that indicates they are a VSI and choose to comply with the modified requirements should conduct an inspection under modified requirements when records are provided for ***any*** modified requirement under section 1.512 and pre-inspection data indicates that the importer may be a VSI. For example, if the importer did not document that they met the definition of VSI and provides records documenting compliance with other requirements under section 1.512, the investigator should conduct the inspection under modified requirements and apply the appropriate citation for not having documentation of eligibility.

If a FSVPI indicates they may be a VSI but pre-inspection FDA data does not support that claim, investigators should document that they informed the importer of both the modified and standard requirements and ask the FSVPI if they have any records that document that they met the definition of VSI and any records that meet either the modified requirements for VSI or standard requirements. For additional instructions, investigators should refer to the guidance tabs and recommended citations in the FSVP IP.

- FSVP Inspection of FSVPI who is importing food from a small foreign supplier

  Investigators conducting an inspection of an FSVPI who indicates they are importing the subject food from a certain small foreign supplier (21 CFR 1.512(a)(2)) and choose to comply with the applicable modified requirements, should document they informed the FSVPI of the applicable modified requirements. This includes the additional requirements that apply if the FSVPI is importing food from certain small foreign suppliers and is not a VSI (21 CFR 1.512(c)).

  The investigator should conduct an inspection for the subject food under modified requirements when the FSVPI provides records documenting compliance with ***any*** applicable modified requirement under section 1.512. If the importer ***does not*** have documentation of any modified requirement, it is

appropriate to cite that the importer had "No FSVP" records under 1.502(a).

- FSVP Inspection of FSVPI that is importing certain human food from a country with an officially recognized or equivalent food safety system

  Investigators conducting an inspection of an FSVPI that covers a human food from a SRA not intended for further manufacturing/processing should verify the foreign supplier is located in, and under regulatory oversight of, a country whose human food safety system has officially been recognized by FDA as comparable or determined to be equivalent to that of the U.S. and that the human food is within the scope of that official recognition or equivalency determination. "Discuss with the FSVPI their determination and documentation that their foreign supplier is in good compliance standing with the food safety authority of the country in which the supplier is located. See Part II.C. for program interaction instructions.

iii. For-cause inspections

Investigators conducting for-cause inspections should follow instructions in any directed assignment provided and refer questions as needed to the appropriate contacts. Investigators should inform the FSVPI of the applicable foreign supplier evaluation and corrective action provisions, depending on the requirements that apply to the food and importer, (e.g., 1.505(c)(4), 1.508(a) and (b), 1.512(b)(4)), and document any actions the importer documented after they became aware of new information or made a relevant determination about a foreign supplier. As necessary, the investigator should review and document the FSVP in place prior to the event that resulted in the for-cause inspection, to determine whether the assurances provided were "adequate" as required under 1.502(a).

B. Investigations

FSVP Domestic Investigations (OP13) may be performed under this compliance program. See IOM subchapter 8.1.9, *General Investigation Reporting,* for guidance covering how to conduct and report an investigation.

C. Sample Collections

Samples will not be collected as part of an FSVP inspection.

D. Other

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2. Reporting

The EIR and IP for an FSVP inspection must be completed in eNSpect as instructed in IOM subchapter 5.11. FSVP Investigational Memorandums must be prepared according to IOM subchapter 8.1.9. Corrective actions taken during an FSVP inspection must be reported in the Corrective Action Reporting system (CAR). Use eNSpect to report corrective actions observed during the inspection and those received after the inspection but before the inspection report is finalized in eNSpect. Use CMS to report and assess any corrective actions received after the EIR has been finalized in eNSpect. Investigators and compliance officers should view the **OCAR Human & Animal Food Inspection Protocols & Tabular-EIR Webinar:** Full video before initially using CAR to enter corrective actions.

FDA staff should contact the OII Apps Desk via the Employee Resource and Information Center (ERIC) for questions or issues pertaining to the functionality of eNSpect, the FSVP IP, or CAR.

PART IV – ANALYTICAL

1. Analyzing Laboratories

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2. Analyses to be Conducted

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3. Methodology

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4. Reporting

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PART V - REGULATORY/ADMINISTRATIVE STRATEGY

1. Findings

The FSVP regulatory/administrative strategy is to obtain industry compliance with the FSVP regulation. Divisions will encourage the FSVPI to voluntarily correct observations identified during an FSVP inspection. However, an FSVPI who does not take appropriate corrective actions to comply with the FSVP regulation will be subject to appropriate regulatory and enforcement action.

Note: FDA does not view compliance with the disclosure requirement under 21 CFR 1.507 as a substitute for the information required under section 801(b) of the FD&C Act and 21 CFR 1.95 for reconditioning proposals to bring a product into compliance (e.g., by applying a "kill step" to a contaminated food). For a detailed explanation, see Q&A. G.8. in the Guidance for Industry Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (2023).

A. FSVP Inspection Observations

OII/OIO staff should refer to FSVP Implementation Work Instructions for information on determining the regulatory significance of inspection observations listed on Form FDA 483a.

The most significant FSVP inspection observations are those that may impact the FSVPI's development or implementation of an FSVP or that prevents or interferes with FDA's review of the FSVP records. These may include:

- The FSVPI did not develop, maintain, and follow an FSVP.
- The FSVPI did not conduct a written hazard analysis or document review of another entity's hazard analysis, including when the lack of a hazard analysis impacted development or implementation of their FSVP (e.g., the FSVPI did not conduct appropriate foreign supplier verification activities for a food having a Serious Adverse Health Consequences or Death to Humans or Animals (SAHCODHA) hazard).
- The FSVPI did not conduct and document an evaluation of their foreign supplier for approval or to determine appropriate verification activities.
- The FSVPI did not conduct and document foreign supplier verification activities.
- The FSVPI did not conduct and document an FSVP activity required for compliance with an FSVP modified requirement (e.g., for a food for which the hazards are controlled after importation, the FSVPI did not provide a disclosure statement as required; or the FSVPI did not obtain the appropriate written assurance from their foreign supplier).
- The importer did not provide FSVP records electronically, or through another means, promptly to FDA after a written request from FDA.

When the most significant observations above are not present, FSVP inspection observations that are significant, but may have less impact on the FSVPI's implementation of FSVP, may include:

- The importer did not document their approval of the foreign supplier.
- The importer did not establish written procedures for ensuring they import foods only from approved foreign suppliers or for ensuring that appropriate foreign supplier verification activities were conducted with respect to an imported food.
- The importer did not document changes made to their FSVP after determining that their foreign supplier was not in compliance with applicable FDA food safety standards.
- The importer did not ensure their name, electronic mail address, or the unique facility identifier recognized as acceptable by FDA (i.e., the DUNS number) were provided electronically when filing entry with the U.S. Customs and Border Protection.

Other FSVP inspection observations not included above may be considered less significant but may be discussed with the FSVPI during the inspection or included in combination with more significant observations in a recommendation for an enforcement action.

B. Corrective Actions

FSVPI's voluntary corrective actions are often the most effective and expedient means to obtain compliance. Divisions should take steps to encourage FSVPI voluntary corrective actions prior to initiating regulatory action. When voluntary corrective actions are not forthcoming, the OII/OIO Divisions should pursue routine regulatory procedures to address significant observations.

The Division should consider informal communication (e.g., email, telephone calls) with an FSVPI when there are questions relating to corrective actions submitted in their response to the Form FDA 483a for which clarification may impact the Division's decision to pursue regulatory actions or to determine if a follow-up inspection is necessary.

C. Factors to Consider

The following factors should be considered when evaluating deviations and when considering regulatory action.

- Do the FSVP violations involve an FSVPI or foreign supplier with a history of non-compliance?
- Do the FSVP violations involve RTE human food, pet food or treats, or covered produce associated with a known risk of SAHCODHA? The lack of food safety assurances for an imported food associated with an outbreak or recall, or found to be adulterated, or

misbranded related to major food allergens, presents the highest potential risk to US consumers and should be prioritized for regulatory action.

- Do the FSVP violations involve an FSVPI who imports a high volume of food and foreign supplier combinations?
- Are the deviations based on findings from an initial inspection? Initial FSVP violations should be prioritized for regulatory action only when there are known food safety risks associated with the food or foreign supplier.
- Do the findings represent limited or broad non-compliance? For example, a limited deviation from FSVP records requirements (e.g., deviation that impacts one verification activity record or one out of several foods/foreign suppliers reviewed) may be less significant than continued or expanding pattern of deviations (e.g., follow-up inspection finds the importer has no verification activity records for any new foods/foreign suppliers).
- Does the FSVPI demonstrate ongoing voluntary compliance? FSVPIs who demonstrate adequate voluntary compliance, including meaningful incremental improvement should be encouraged to continue to work towards compliance. FSVPIs who do not make adequate attempts to comply with FSVP should be prioritized for regulatory action.
- Does the FSVPI share ownership or a responsible party with another FSVPI who is subject to regulatory action? Do the findings indicate an FSVPI, who is subject to regulatory action, started importing under a new business name?

D. Classification

Inspection classifications are based on the significance of the observations to public health and the importer's response and include "No Action Indicated (NAI)," "Voluntary Action Indicated (VAI)," and "Official Action Indicated (OAI)." For inspections classified as OAI, the Division should submit any recommendation for enforcement follow-up via CMS. Refer to SOP-001642 OII Establishment Inspection Report Classification Procedure for further information and Part V(3) of this compliance program for additional information on Direct Reference authority.

2. Charges

An FSVPI that is not in compliance with the requirements of the FSVP regulation (21 CFR part 1, subpart L) is not in compliance with section 805 of the FD&C Act. FDA may refuse admission into the U.S. of a food offered for import if it appears that the FSVPI is not in compliance with the FSVP requirements with respect to that food (section 801(a)(3) of the FD&C Act; 21 CFR 1.514(a)). The charge for refusing entry of a food for which the importer is not in compliance with the requirements of section 805 of the FD&C Act is:

The food article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears that the importer (as defined in section 805 of the FD&C Act) is in violation of section 805 of the FD&C Act.

In addition, the importing or offering for importation of a food into the U.S. without the FSVPI having an FSVP that meets the requirements of section 805 of the FD&C Act, including the

requirements of the FSVP regulation, is a prohibited act under section 301(zz) of the FD&C Act (21 U.S.C. 331(zz)); 21 CFR 1.514(b).

Under section 302 of the FD&C Act (21 U.S.C. 332), the U.S. can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 303 of the FD&C Act (21 U.S.C. 333), the U.S. can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Under section 306 of the FD&C Act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the U.S. In addition, false representations to the U.S. government, including falsely identifying a U.S. agent or representative, may result in criminal prosecution of those involved.

3. Actions

All FSVP compliance cases will be routed to the Import Division Compliance Branch (CB) responsible for the geographical location where the inspection was conducted based on the FSVPI's place of business. A recommendation for regulatory action based on FSVP violations (i.e., warning or untitled letter or listing on Import Alert 99-41 recommendation) not covered by direct reference authority must be routed in CMS to HFP OCE OE Imports Enforcement Branch unless otherwise indicated or CVM Office of Surveillance and Compliance, Division of Food Compliance (CVM OSC DFC), as appropriate. See FSVP Implementation Work Instructions for additional information.

Direct reference authority for enforcement authority relating to FSVP (i.e., FSVP warning or untitled letter or listing on Import Alert 99-41) has only been provided to Divisions in limited circumstances as described in HFP Enforcement Bulletin #13. As a result, unless covered by direct reference authority, the Division must seek inspectional classification concurrence with the Centers for OAI classification, as well as any classification (OAI or VAI) associated with an advisory action such as an Untitled Letter or regulatory meeting. HFP OCE OE has developed an HFP Enforcement Bulletin to be used as a resource to support Division Compliance Officers when drafting deviations statements not covered by direct reference authority in regulatory letters for FSVP. See EB #6 FSVP Deviation Statements at HFP Enforcement Bulletins. HFP and CVM will consider the factors described in this compliance program when reviewing Division recommendations.

A. Regulatory Meeting

When the Division believes a discussion with the FSVPI of the violations and their significance may help clarify requirements and result in more effective voluntary corrective actions by the FSVPI, it may be appropriate for Divisions to consider conducting a regulatory meeting.

B. FSVP Warning Letter

Divisions should consider recommending to HFP or CVM issuance of a warning letter (WL) to an FSVPI who did not respond to a Form FDA 483a or otherwise take appropriate corrective actions for significant FSVP violations not covered by direct reference authority. Divisions should weigh the Factors to Consider (see Part V.1.C.), including repetition of the violations or voluntary corrective actions, that may indicate the effectiveness of obtaining compliance.

C. FSVP Import Alert

Import Alert 99-41 "Detention Without Physical Examination of Human and Animal Foods Imported from Foreign Suppliers by Importers Who Are Not in Compliance with the Requirements of the Foreign Supplier Verification Programs (FSVP) Regulation" provides instruction to the field for detention without physical examination of an article of human or animal food when offered for import by an FSVPI that is not in compliance with the FSVP regulation, per 801(a)(3) of the FD&C Act.

i. Addition of FSVPI, Food, and Foreign Supplier (Combination) on Import Alert 99-41

If an FSVPI does not take appropriate corrective actions after being advised of significant FSVP violations such as in a WL, including when no response is received or the Division finds the WL response is inadequate, the Division may consider a recommendation to place the FSVPI on the Red List of Import Alert 99-41 for each specific food and specific foreign supplier combination or for all food, as appropriate, for which the FSVPI is not in compliance with the FSVP regulation.

Divisions may determine a follow-up inspection is appropriate to verify corrective actions to the WL before determining appropriate regulatory action, as described in Regulatory Procedures Manual (RPM) 4-1-8,Warning Letter Follow-Up.

An FSVPI that is not listed on the Red List of FSVP Import Alert 99-41 may continue to import the same food and other food from a listed foreign supplier, provided the food or foreign supplier are not subject to other import alert(s) for the appearance of adulteration or misbranding. If FDA's review of the FSVP records indicates that there may be a food safety issue relating to an imported food, FDA can follow up to determine whether enforcement action against the food and/or the foreign supplier are warranted. See addition discussion in Q&A N.10 of the FSVP Guidance for Industry.

Circumstances may reveal that the same party is responsible for FSVP violations across multiple FSVPIs. When considering regulatory action based on evidence of FSVP violations by an FSVPI and the responsible party and violations are the same as for another FSVPI who has been subject to regulatory action, the Division may consider whether it is necessary to issue another WL to the same responsible party (see Regulatory Procedures Manual (RPM) 4-1-8, Warning Letter Follow-Up and Follow-Up

Enforcement). On a case-by-case basis in such circumstances as described above, Divisions may consider recommending an FSVPI to be added to Import Alert 99-41, based on evidence of significant FSVP violations found during an FSVP inspection.

ii. Removal of FSVPI, Food, and Foreign Supplier (Combination) from Import Alert 99-41

The FSVPI should follow the instructions stated in Import Alert 99-41 to submit information supporting their request for removal. The request should be sent to the Division that issued the regulatory letter notifying the FSVPI of their FSVP violations and placement on Import Alert 99-41. If the Division determines that the FSVPI provided sufficient evidence of appropriate corrective actions, the Division will submit a recommendation in CMS to OIO/DIO to remove the FSVPI for each specific food and foreign supplier combination, or for all food, as appropriate, from the Red List. OIO/DIO will consult with HFP OCE OE or CVM OSC DFC to determine whether to remove the FSVPI from the Red List, as appropriate.

The Division may review a petition for removal from Import Alert 99-41 that addresses removal of all or certain specific food. The submitted information should demonstrate that the FSVPI has resolved the conditions that gave rise to the appearance of FSVP violations,

After the Division has reviewed FSVPs or FSVP records to have assurance that the FSVPI is meeting the requirements of FSVP for future entries of all food, or for specific food from a foreign supplier, and it appears the conditions that gave rise to the addition of such to Import Alert 99-41 have been overcome, the Division may recommend removal of the FSVPI, food, and foreign supplier combination, or all food from the Red List of Import Alert 99-41, as appropriate. As appropriate, the division may conduct an FSVP inspection to determine whether the FSVPI have resolved the conditions that gave rise to the appearance of the FSVP violation.

Divisions should encourage FSVPIs to request removal from Import Alert 99-41 prior to attempting to import a specific food or all food from the specific foreign supplier listed on the Import Alert 99-41. If an entry, or multiple entries, are subject to refusal because the importer is listed on the Red List of Import Alert 99-41 for the specific food and foreign supplier combination, any testimony received in response to a Notice of FDA Action should be evaluated to consider compliance with the FSVP regulation and potential consideration for the removal from the Red List of Import Alert 99-41.

If a Division, other than the Division that inspected the FSVPI, receives testimony from an importer of record that appears to be a petition for removal from Import Alert 99-41, the receiving Division will refer the testimony to the Division responsible for the FSVP inspection.

If the Division receives a request to extend the time period for responding to the Notice of FDA Action, particularly when the requester is the FSVPI, in responding to the extension request the Division should consider that the FSVPI received a WL advising them of their FSVP violations, and the FSVPI was provided adequate opportunity to correct the violations prior to being placed on the Red List of Import Alert 99-41.

Removal of an FSVPI, food, and foreign supplier combination from Import Alert 99-41 does not preclude the FDA from taking future enforcement action, based on subsequent determination that the FSVPI is in violation of the FSVP regulation.

4. Regulatory Follow-Up

Divisions will determine whether the FSVPI provided adequate documentation of compliance with FSVP for the FSVP records reviewed during the previous inspection, or in response to a warning or untitled letter, or in a regulatory meeting. If a follow-up inspection is conducted, the investigator may need to review additional FSVP records to determine the FSVPI's compliance with FSVP if they no longer import the same food evaluated during the previous inspection. The investigator may review the same FSVPs, if still relevant, or may select one or more different FSVPs for review to verify adequate corrective actions were taken by the FSVPI.

5. Foreign Owner or Consignee Follow-Up

If the results of an FSVP Investigation (OP13) indicate there was no U.S. owner or consignee for the food at the time of entry and the foreign owner or consignee did not designate a U.S. agent or representative to serve as the FSVPI, as agreed in writing, the Division's Investigations Branch should submit their investigation package to their Division's CB. The CB should prepare a foreign owner or consignee letter (see FSVP Implementation Work Instructions) and submit in CMS using the "FSVP Informational Letter" work type, to HFP OCE OE or CVM OSC DFC. HFP or CVM will coordinate review of the letter with DIO and Office of the Chief Counsel (OCC), and, as appropriate, will send the cleared letter to the foreign owner or consignee. The DIO FSMA Team will subsequently monitor food entries from the foreign supplier to determine whether additional follow-up is needed to verify that the FSVPI is accurately identified at entry, as required in section 1.509 of the FSVP regulation.

6. Other

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PART VI - REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

1. References

A. Investigations Operations Manual
B. Regulatory Procedures Manual
C. 21 CFR Part 1 Subpart L *Foreign Supplier Verification Programs for Food Importers*
D. Draft Guidance for Industry: *Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA*
E. Establishment Inspection Report Classification Procedure
F. *Final Rule, Federal Register Notice September 17, 2015*
G. Draft Guidance for Industry: *Hazard Analysis and Risk-Based Preventive Controls for Human Foods*
H. Form FDA 483a, *FSVP Observations*
I. Form FDA 482d, *Request for FSVP Records*
J. Key Requirements: Final Rule on Foreign Supplier Verification Programs
K. Final Rule on Foreign Supplier Verification Programs
L. Guidance to Industry: Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Program
M. Food Safety Plan Builder
N. Reportable Food Registry (RFR) At A Glance fact sheet
O. SOP 51, OEI Development and Maintenance Procedure
P. Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Food for Animals
Q. Guidance for Industry: Application of the Foreign Supplier Verification Program Regulation to the Importation of Live Animals
R. Guidance for Industry: Foreign Supplier Verification Programs for Importers of Foods for Humans and Animals
S. Draft Guidance for Industry: Conducting Remote Regulatory Assessments Questions and Answers

2. Attachments

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3. Program Contacts

A. HFP

Purpose	Name	Organization	Contact
General Program Contact	Mark Farrell	HFP/OCE/OCOI/DCI/CPAB	Mark.farrell@fda.hhs.gov
Enforcement questions	Aleta Flores	HFP/OCE/OE	Aleta.flores@fda.hhs.gov
Compliance Policy Questions (Regulatory)	Kevin Kwon	HFP/OCE/OCOI/DCI/CPPB	Kevin.Kwon@fda.hhs.gov

Purpose	Name	Organization	Contact
Compliance Policy Questions (Operational)	Shannon Ingram	HFP/OCE/OCOI/DCI/CPPB	Shannon.Ingram@fda.hhs.gov

B. CVM

Purpose	Name	Organization	Contact
CVM Policy Questions	CVM Animal Food Programs	CVM/OSC/DFC	CVMAnimalFoodPrograms@fda.hhs.gov
CVM Import/FSVP Questions	Brandy Gillilan; CVM Import Requests	CVM/OSC/DFC	Brandy.Gillilan@fda.hhs.gov; CVMImportRequests@fda.hhs.gov

C. OII

Purpose	Name	Organization	Contact
General Imports/FSVP Questions	OII OIO DIO Inquiries	OII/OIO/DIO	FDAImportsInquiry@fda.hhs.gov
~~General Food Questions~~	~~Linda Stewart~~	~~ORA/OHAFO/DDHAFO~~	~~Linda.stewart@fda.hhs.gov~~

PART VII - CENTER RESPONSIBILITIES

HFP Office of Compliance and Enforcement and CVM's Office of Surveillance and Compliance are the lead offices for evaluating this compliance program. HFP and CVM will provide subject matter expertise for evaluating this compliance program and provide information relating to program priorities, relevant evaluation questions, and recommended program changes. HFP and CVM will evaluate this compliance program on a periodic basis. The evaluation will include a statement of the compliance program objectives, general and specific program evaluation questions, a list of recommendations for process improvement, and highlights of data patterns and trends for better targeting and resource allocation. HFP Office of Compliance and Enforcement will make the evaluations and tracking reports available annually or as frequently as needed to track accomplishments.