Voluntary Qualified Importer Program (VQIP) and Foreign Supplier Verification Program (FSVP)

Association of Food Industries Webinar Series

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What is VQIP?

- FDA required to establish a program to provide for the expedited review of food imported by voluntary participants.
- Eligibility is limited to importers who demonstrate a high level of control over the safety and security of their supply chains.
- VQIP Importer is “the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States.”

Elements of the Guidance

- Benefits
- Eligibility Criteria
- Application (e.g., submission, timing, amendments, FDA review)
- User Fees
- Revocation Process
- Reinstatement Process

Benefits of VQIP

- Expedited entry into the U.S.
- Examination and/or sampling generally limited to “for cause” situations
- Any sampling or examination done at location chosen by the importer
- Expedited laboratory analysis if sampled
- VQIP Importers Help Desk
- FDA will post approved VQIP importers, if desired

Should you apply?

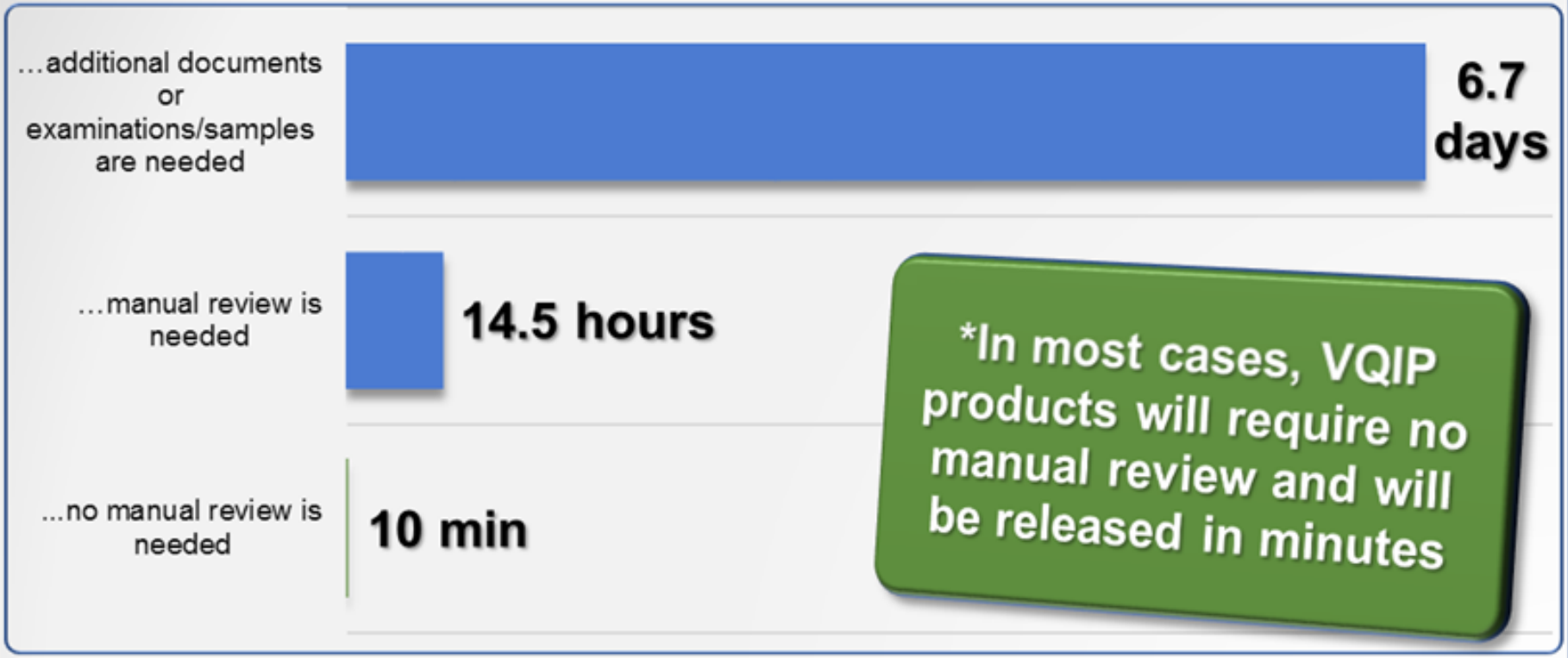
VQIP offers importers speed and predictability when bringing food into the United States. This will help importers meet customer demands, and will be particularly helpful for those importing:

- perishable products
- foods for “just in time” processing, in which ingredients must be at a food facility at a certain time in the manufacturing process

How long can your product wait?

Time for FDA to release a food shipment when...

Data is based on average for all human and animal food shipments submitted to FDA between 10/1/2017 - 05/31/2018



** In limited cases, FDA may need to exam a valid VQIP shipment "for cause", for VQIP auditing, or for statistically necessary risk-based microbiological samples.*

Eligibility Criteria

- 3-year history of importing food into the U.S.
- DUNS Number
- Paperless filers/brokers with acceptable FDA Filer Evaluation results
- Assurance of compliance with FSVP or HACCP regulations
- Current facility certification issued in accordance with FDA's third party accredited certification program for each foreign supplier of food
- Quality Assurance Program (QAP)
- Annual VQIP user fee

Eligibility Criteria, cont.

- No food subject to DWPE under an Import Alert or a Class 1 recall at the time of application
- No ongoing FDA administrative or judicial action, or history of significant non-compliances relating to food safety
- No CBP penalties, forfeitures, or sanctions that are related to the safety or security of any FDA regulated product within the last 3 years

Accredited Third-Party Certification Program

- FDA recognizes “Accreditation Bodies”
- Accreditation Bodies accredit third-party “Certification Bodies”
- Certification Bodies conduct food safety audits & issue certifications of foreign food facilities
- Public Registry, as of 05/26/2020
  - 4 Recognized Accreditation Bodies
  - 11 Accredited Third-Party Certification Bodies

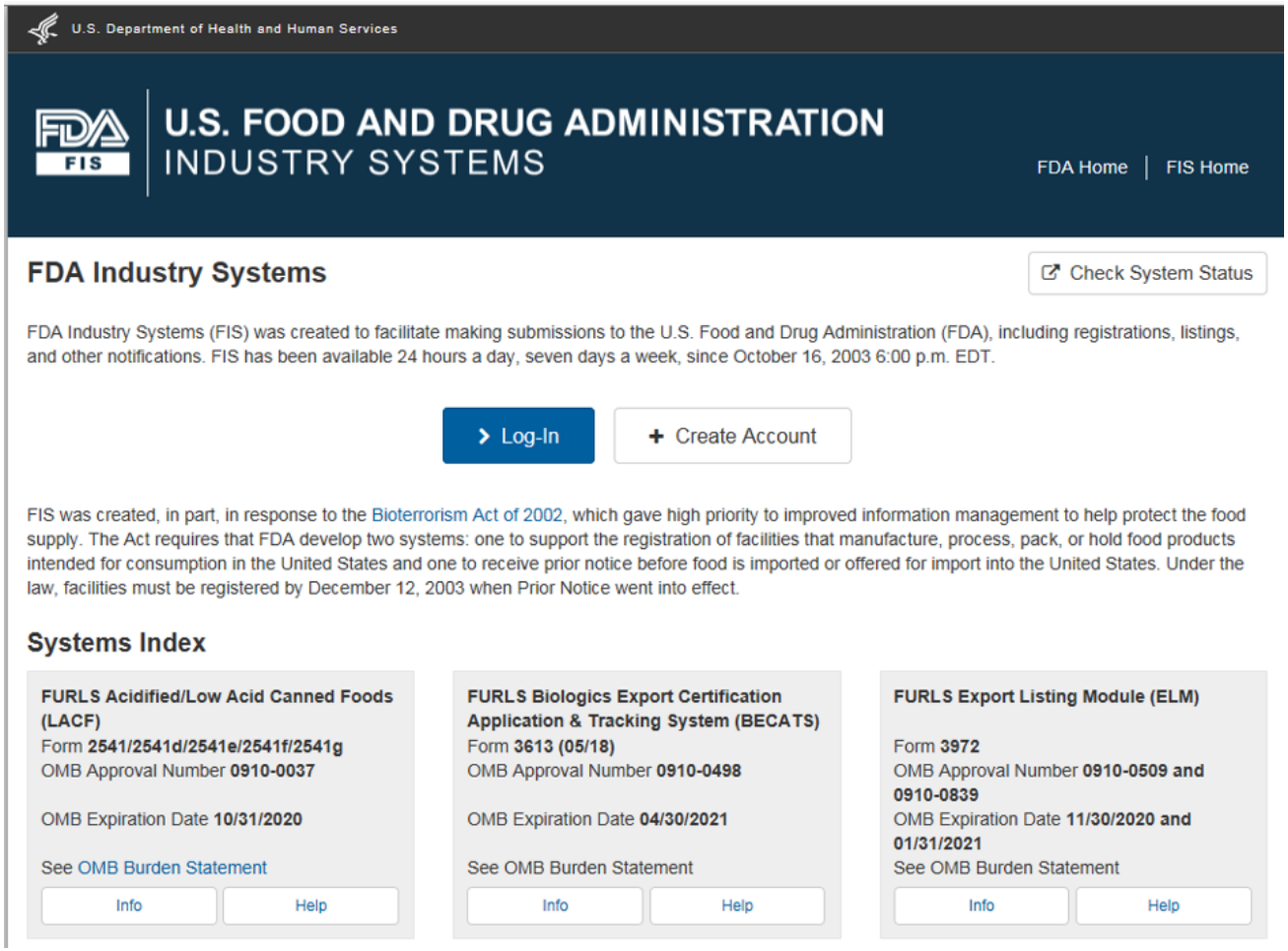
Application

- Notice of Intent to Participate
- Applicant & Firm Information
- FSVP and/or HACCP importer information
- Quality Assurance Program (QAP)
- Filer/Broker information
- Foreign Supplier information
- Summary
- E-Signature

How do importers apply for VQIP?

- Importers will be able to apply online at the FDA Industry Systems website January 1st, 2020.
- An account will need to be established and a **Notice of Intent to Participate** in VQIP must be submitted before submitting an application.
- The **VQIP Application User Guide** covers all of this.

How do *importers* apply for VQIP?



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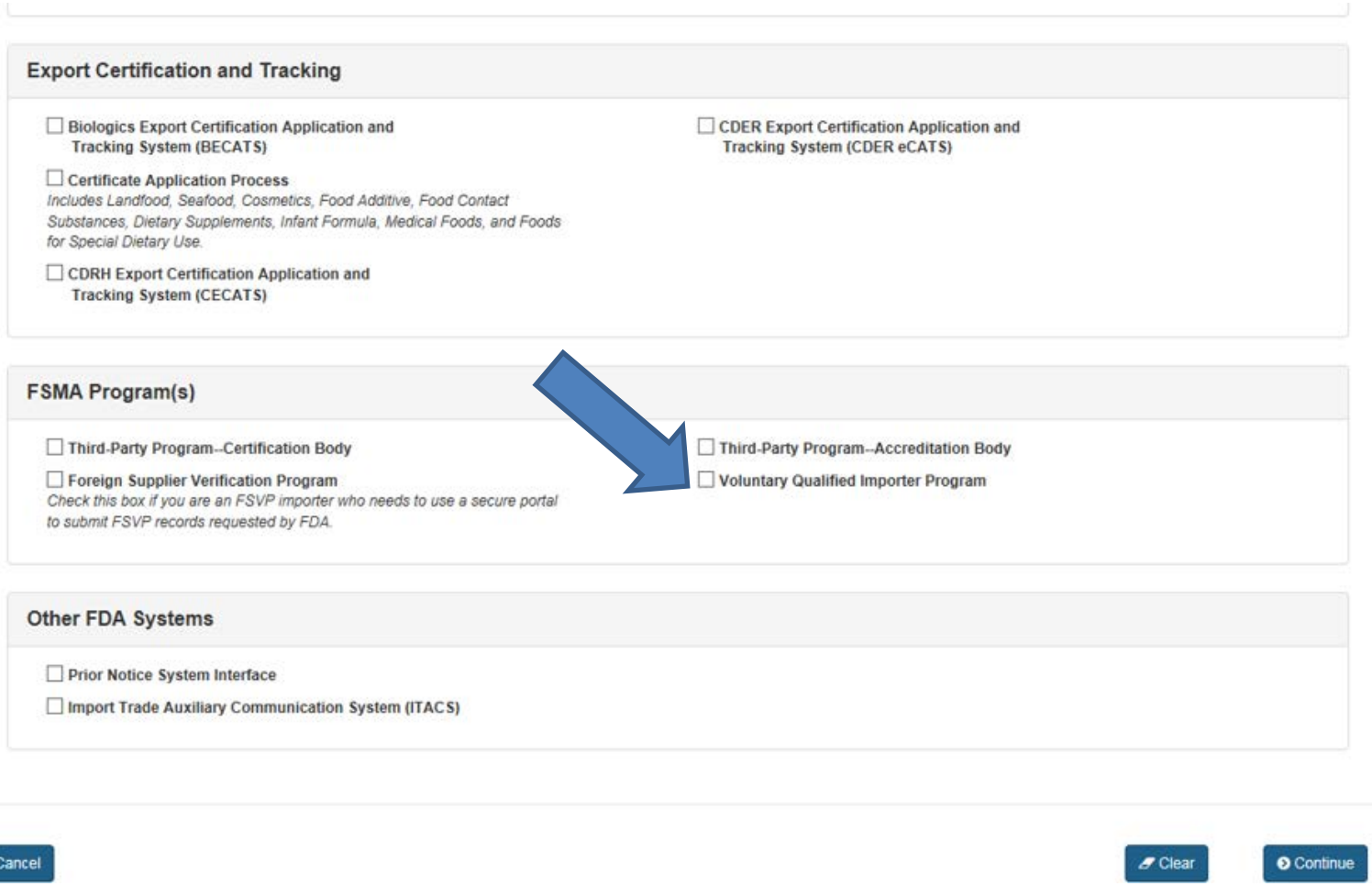

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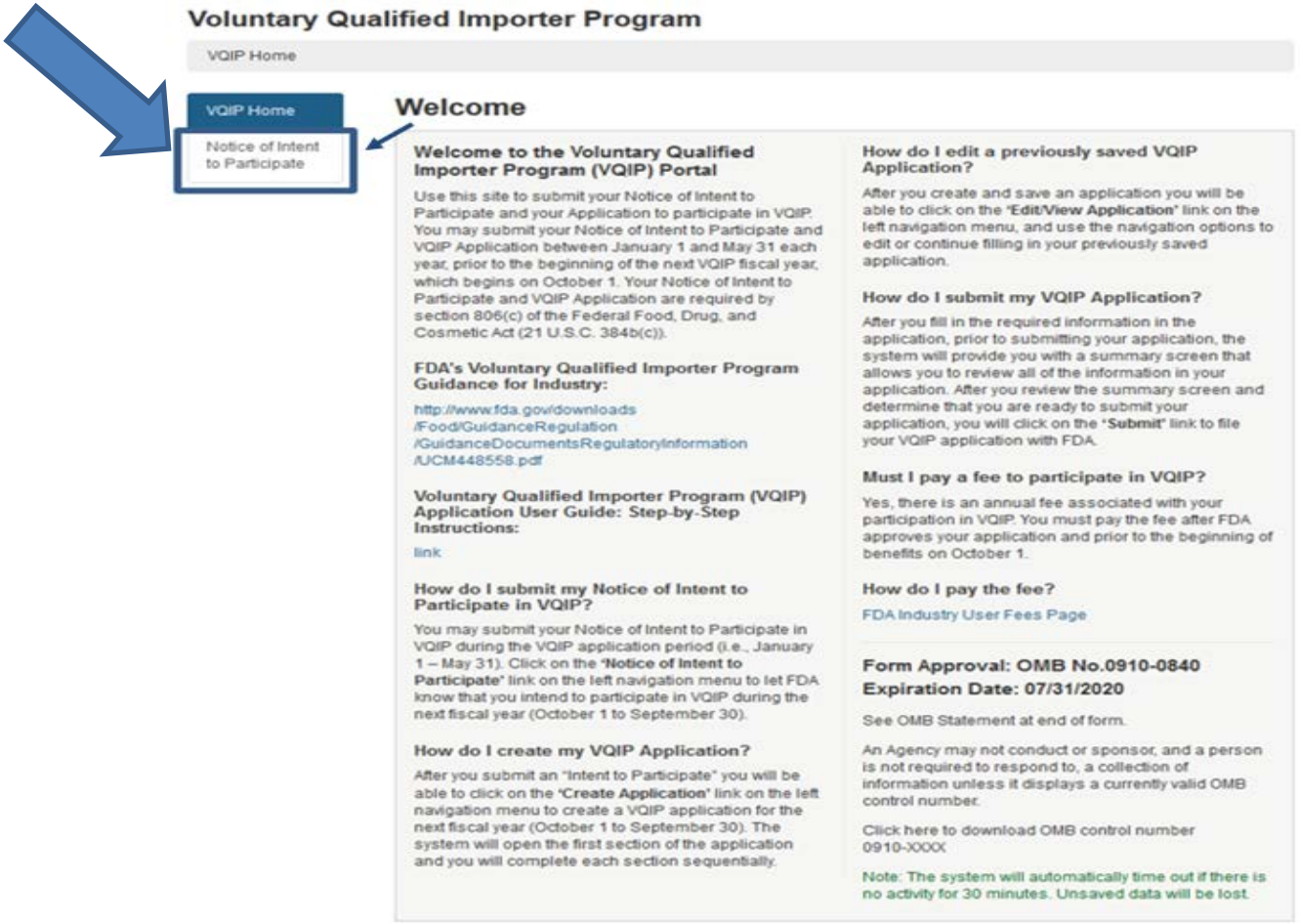


VQIP User Fee Status

- User fee rates announced July 24, 2019
- Annual fee finalized at $16,681 for FY20
  - User fee previously estimated to be ~$16,400
  - FY21 fees will be published around August 2020
- Fee assessed after application is approved
- Provides benefits for all foods covered under VQIP

Resources for VQIP

- **VQIP Website**: https://www.fda.gov/food/importing-food-products-united-states/voluntary-qualified-importer-program-vqip
- **VQIP Guidance for Industry** (translations available): https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-fdas-voluntary-qualified-importer-program
- **VQIP Fact Sheet** (translations available): https://www.fda.gov/food/food-safety-modernization-act-fsma/fact-sheet-final-guidance-industry-fdas-voluntary-qualified-importer-program
- **Accredited Third-Party Certification Program (TPP) Website:** https://www.fda.gov/food/guidanceregulation/importsexports/importing/ucm558461.htm
- **VQIP Application User Guide**: https://www.fda.gov/media/113346/download

Questions

- VQIP Importer's Help Desk
  - M-F 8am – 8pm EST
  - FSMAVQIP@fda.hhs.gov
  - 1-301-796-8745

21 CFR Part 1 Subpart L

Foreign Supplier Verification Program (FSVP)

- Federal Food, Drug, & Cosmetic Act (FD&C Act) 21 CFR part 1 subpart L

- Fifteen (15) Sections: 1.500 – 1.514

Purpose of FSVPs

- FSVP is the cornerstone of FSMA's new preventive, risk-based approach to imports.
- Importers must provide adequate assurances that:
  - Foreign suppliers produce food using processes and procedures providing same level of public health protection as FSMA preventive controls or produce safety provisions
  - Food is not adulterated or misbranded (as to allergen labeling)

Key Principles of FSVP Rule

- Requires importers to share responsibility for ensuring safety of imported food
- Risk-based (according to types of hazards, importers, and suppliers)
- Flexibility in meeting requirements (assessing activities conducted by others)
- Alignment with PC supply-chain provisions

Who Must Comply?

- "Importer" is U.S. owner or consignee of a food at time of U.S. entry.

- If no U.S. owner or consignee at entry, importer is U.S. agent or representative of the foreign owner or consignee, as confirmed in signed statement of consent.

FSVP Exemptions

- Firms subject to juice or seafood HACCP regulations
- Food for research or evaluation
- Food for personal consumption
- Alcoholic beverages and alcoholic beverage ingredients

FSVP Exemptions (cont.)

- Food transshipped through U.S.
- Food imported for processing and export
- “U.S. foods returned”
- Meat, poultry, and egg products subject to USDA regulation at time of importation
- Low acid canned food facilities (microbiological hazards only)

FSVP Requirements

- Hazard Analysis
- Evaluation of Food and Foreign Supplier
- Supplier Verification Activities
- Corrective actions
- Importer identification at entry
- Recordkeeping

Use of Qualified Individuals

- Must use a *qualified individual* to perform all required FSVP tasks
  - Must have education, training, or experience (or combination thereof) necessary to perform the activity
  - Must be able to read and understand the language of any records reviewed in performing an activity

FAQ FSVP Questions

- Who is the importer under FSVP?

For the purposes of FSVP, the definition of the term “importer” is:
The “U.S. owner or consignee” of an article of food offered for import into the U.S.

This is the person in the United States who, at the time of entry of an article of food into the United States, either owns the food, has purchased the food, or has agreed in writing to purchase the food.

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. (See 21 CFR 1.500.)

FAQ FSVP Questions

- Is the “importer” under the FSVP rule the same as the “importer of record” for U.S. Customs and Border Protection at the time of entry?

  The importer of record (as defined by CBP) ***may be*** the same as the importer under FSVP, but is not necessarily.

  The FSVP Importer performs certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards.

  In contrast, the CBP importer of record of a food might be an express consignment operator with little to no knowledge of the safety regulations applicable to the products for which they obtain clearance from CBP.

FAQ FSVP Questions

- I am a very small importer. Do I need to keep FSVP records, and send them to FDA? If so, what is the best way to notify FDA?

As a very small importer subject to the FSVP rule, you are required to keep FSVP records in accordance with 21 CFR 1.512(b)(5).

However, you are not required to send your records to FDA unless FDA requests, in writing, that you send your records (see 26 21 CFR 1.512(b)(5)(ii)(C)). (FDA may also request you to make your records available for inspection and copying at your place of business (see 21 CFR 1.512(b)(5)(ii)(A)).

FAQ FSVP Questions

- What do I need to do to verify my foreign supplier is following the FSVP rule?

Importers covered by FSVP must have a program in place to verify that their foreign suppliers are producing food in a manner that provides the same level of public health protection as the preventive controls requirements for human and animal food under section 418 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the produce safety requirements under section 419 of the FD&C Act , if applicable, and the implementing regulations, and to ensure that the food is not adulterated and is not misbranded with respect to allergen labeling.

Numbers/Metrics

Inspection Numbers:

- Completed **285** inspections in **FY17**
- Completed **795** in **FY18**
- Completed **858** in **FY19**
- Completed approx. **194** to-date in **FY20**

Imported Food Safety Measures

Outcome: More Effective Oversight of Foreign Suppliers by Importers (FSVP)

I. Number and Percent of FSVP inspections classified NAI, VAI, OAI

The inspection classification is based on the FSVP citations and rankings documented in the Establishment Inspection Report (EIR). FDA classifies inspections in terms of significance of observations and monitors trends at the firm and aggregate level. This information will allow FDA to identify areas of industry in need of outreach and education in coming into compliance with the Foreign Supplier Verification Programs (FSVP) provision.

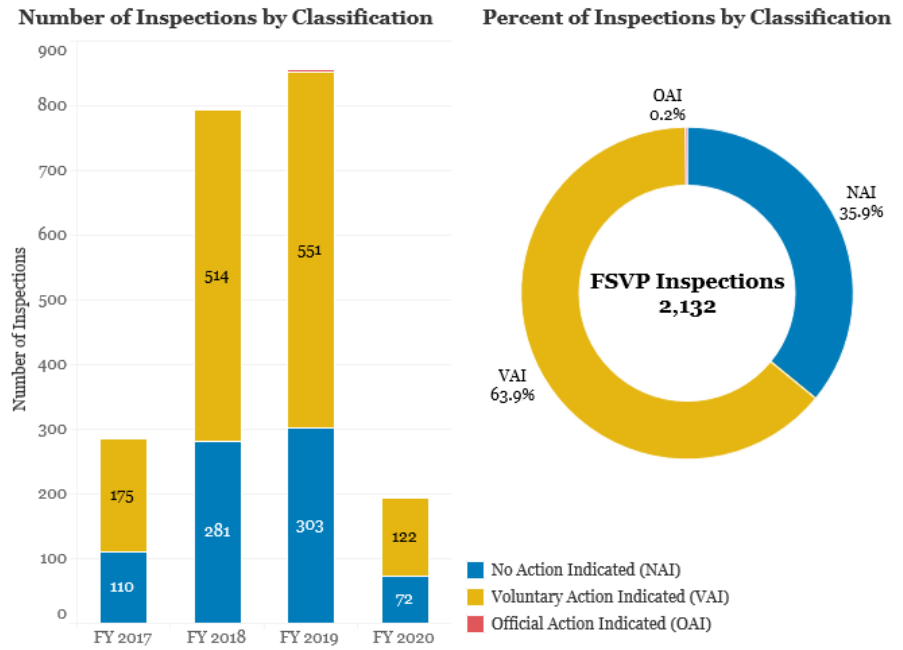
Glossary (click here)

Note: Current Fiscal Year represents performance year-to-date.

Commodity:
- (•) Human Food
- ( ) Animal Food

Fiscal Year: (All)

Inspection Classification: (All)



https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/imported-food-safety-measures#3

FSVP Inspections – Significant Observations

- Failure to:
  1. Develop an FSVP
  2. Have a written hazard analysis
  3. Document approval of foreign supplier
  4. Establish written procedures to ensure that foods are imported only from approved foreign suppliers
  5. Document the evaluation of foreign supplier performance and the risk posed by the food
  6. Establish written procedures for ensuring that appropriate foreign supplier verification activities are conducted

**Incorrect entry data

Trends in Compliance/Enforcement

Since implementation, the most commonly cited observation on Form 483a, FSVP Observations is:

21 CFR 1.502(a): You did not develop an FSVP

Trends in Compliance/Enforcement

Additional commonly used citations:

21 CFR 1.504(a): You did not have a written hazard analysis to identify and evaluate known or reasonably foreseeable hazards [to determine whether there are any hazards requiring a control].

21 CFR 1.505(b): You did not document your approval of your foreign supplier.

Issuance of Import Alert 99-41

"Detention Without Physical Examination (DWPE) of Human and Animal Foods Imported from Foreign Suppliers by Importers Who Are Not in Compliance with the Requirements of the Foreign Supplier Verification Program (FSVP) Regulation“

Published Date: 07/31/2019

Key Points of Import Alert 99-41

- An importer may be added to this import alert because their appears of non-compliance with FSVP requirements
- The specific food or foods from a specific foreign supplier are subject to DWPE when imported or offered for import by the identified importer.
- An importer may be subject to DWPE for all food they import if it appears that the importer is in violation of FSVP requirements for all such foods.

Key Points of Import Alert 99-41

- Even when an importer is not in compliance with FSVP the food and/or foreign supplier may be in compliance with applicable requirements.
- The only food that may be subject to DWPE under this import alert is the specified food when imported by the identified importer (but not when imported by other importers).

The Charge: "The article is subject to refusal of admission pursuant to section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act (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."

Moving Towards Enforcement "For Cause" and Reinspection

- 18 FSVP Warning Letters issued
- 5 FSVP importers on Import Alert 99-41

FSVP Remote Inspections

April 3, 2020 –
FDA announced the agency would start remote inspections of FSVP importers.

In rare situations, such as in response to an outbreak of foodborne illness, FDA may still choose to conduct an onsite FSVP inspection.

In these instances, an FDA investigator will make arrangements to conduct the inspection while practicing the social distancing recommendations provided by the Centers for Disease Control and Prevention.

Questions

- FDA Imports Inquiries

FDAImportsInquiry@fda.hhs.gov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