

# **Overview of the Foreign Supplier Verification (FSVP) Regulation as it relates to Produce**

WEBINAR 7 IICA-FDA

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# Disclaimer

This presentation reflects the views of the author and should not be construed to represent FDA's views or policies.

# Key Principles of FSVP Rule

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

# Purpose of an FSVP

- 21 CFR Part 1 Subpart L - <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=1&showFR=1&subpartNode=21:1.0.1.1.1.11>
- To 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 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 – Control hazard after food imported**
- **1.508 – Corrective actions**
- **1.509 – Identification**
- **1.510 – Records**
- **1.511 – Dietary supplements**
- **1.512 – Very small importer; small foreign supplier**
- **1.513 – Officially recognized country**
- **1.514 – Authority**

# 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)



# Use of Qualified Individual

- Must use a *qualified individual* to perform required FSVP activities
  - 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

# Standard FSVP Requirement

- Develop FSVP
- Conduct Hazard Analysis
- Evaluate Risks Posed by a Food and Performance of the Foreign Supplier
- Approval of Foreign Supplier
- Foreign Supplier Verification Activities
- Corrective Actions
- Maintenance of Records

# Hazard Analysis: 1.504

- Known or reasonably foreseeable hazards requiring a control
  - Biological, chemical, radiological, and physical hazards
  - Naturally occurring, unintentionally introduced, or intentionally introduced for economic gain
- May review and assess another entity's hazard analysis
- Requirements vary depending on the type of food
  - Raw agricultural commodities (RAC) considered “covered” produce under the Produce Safety Rule – not required to evaluate biological hazards

# Evaluation for Approval and Verification

## Activities: 1.505

- Evaluation of risks posed by a food and the performance of foreign supplier
- Evaluation is basis for:
  - Approval of foreign suppliers
  - Determination of verification activities

# Considerations for Food and Supplier

- Considerations for risks posed by a food:
  - Hazard analysis, nature of hazard
  - Entity responsible for the control of hazards
- Considerations for performance of foreign supplier:
  - Procedures, processes, and practices
  - Food safety regulations and history
  - Any other relevant factors

# Foreign Supplier Verification Activities: 1.506

- Establish and document use of written procedures to ensure the:
  - Use of approved suppliers or unapproved foreign suppliers on a temporary basis
  - Appropriate verification activities are conducted with respect to the imported food

# Appropriate Verification Activities

- Must document determination, performance, conduct, review and assessment of results
- Verification activities include:
  - Onsite audits (qualified auditor), sampling and testing of the food, a review of foreign supplier relevant food safety records, other appropriate activities

# Onsite Audits & SAHCODHA

- Hazard controlled by foreign supplier
- **Serious Adverse Health Consequence Or Death to Humans or Animals (SAHCODHA)**
- Must conduct or obtain documentation of onsite audit
- Prior to importing food and annually thereafter
- Exception - written determination of other activities



# Reliance on Another Entity

- May rely on another entity to:
  - Conduct hazard analysis
  - Perform evaluation of food and supplier
  - Establish written procedures for the use of approved or unapproved foreign suppliers
  - Determine and conduct verification activities

# Modified Requirements

- Certain importers may choose to comply with the modified FSVP requirements
- Only certain verification activities must be conducted
- Applies to sections 1.507, 1.511, 1.512, and 1.513

# Hazards Controlled or Controlled After Importation: 1.507

- Foods intended for further manufacturing or processing and hazards will be controlled after importation
- Foods imported in the raw state; cannot be consumed raw (generally does not apply to food that is “covered produce”)
- Not required to conduct an evaluation of the food and supplier or verification activities if hazards requiring a control are identified and any of the circumstances apply

## Hazards Controlled After Importation (1.507) – Continued

- Modified requirements apply in circumstances where the importer:
  - Determines food cannot be consumed without a control
  - Relies on their customer (subject to PC) to control hazard
  - Relies on their customer (not subject to PC) to control hazard
  - Relies on an entity in the distribution chain subsequent to their customer
  - Establishes, documents, and implements a system to control the hazard

## Very Small Importers: 1.512

- Must meet definition as a very small importer
- Less than \$1 million/yr. in human food sales
- Less than \$2.5 million/yr. in animal food sales
- Annually documentation of eligibility

# FSMA Inflation Adjusted Cut Offs

## Foreign Supplier Verification Programs

*Very Small Importer*: Definition 1 for Human Food – an importer (including any subsidiaries and affiliates) averaging less than \$1 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year in sales of human food combined with the U.S. market value of human food imported, manufactured, processed, packed, or held without sale.

Baseline Value for Cut-offs (2011)	Value in 2019	Value in 2020	Value in 2021	Value in 2022	Value in 2023	Average 3 Year Value for 2021 - 2023
\$1,000,000	\$1,136,936	\$1,151,944	\$1,204,764	\$1,289,590	\$1,336,594	\$1,276,983

# Importers of Certain Foods from Certain Small Foreign Suppliers: 1.512

- Small foreign suppliers:
  - Qualified facility
  - Produce from certain small suppliers that are not covered farms
  - Shell egg producers with < 3,000 laying hens

# Countries with Comparable or Equivalent Food Safety Systems (1.513)

- Importers of certain food from a foreign supplier in a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent.
- Systems Recognition Countries (SRC)
- Applies to food that is not intended for further manufacturing or processing



## Requirements of Section 1.513

- Food not intended for further manufacturing or processing
- Foreign supplier located in and under the regulatory oversight of an officially recognized country
- The food is within the scope of the country's official recognition or equivalency determination
- Foreign supplier is in good compliance and standing with the food safety authority of the country

# Other FSVP Requirements

- Corrective Actions: 1.508 or applicable section
- Importer Identification at Entry: 1.509
- Maintenance of Records: 1.510 or applicable section

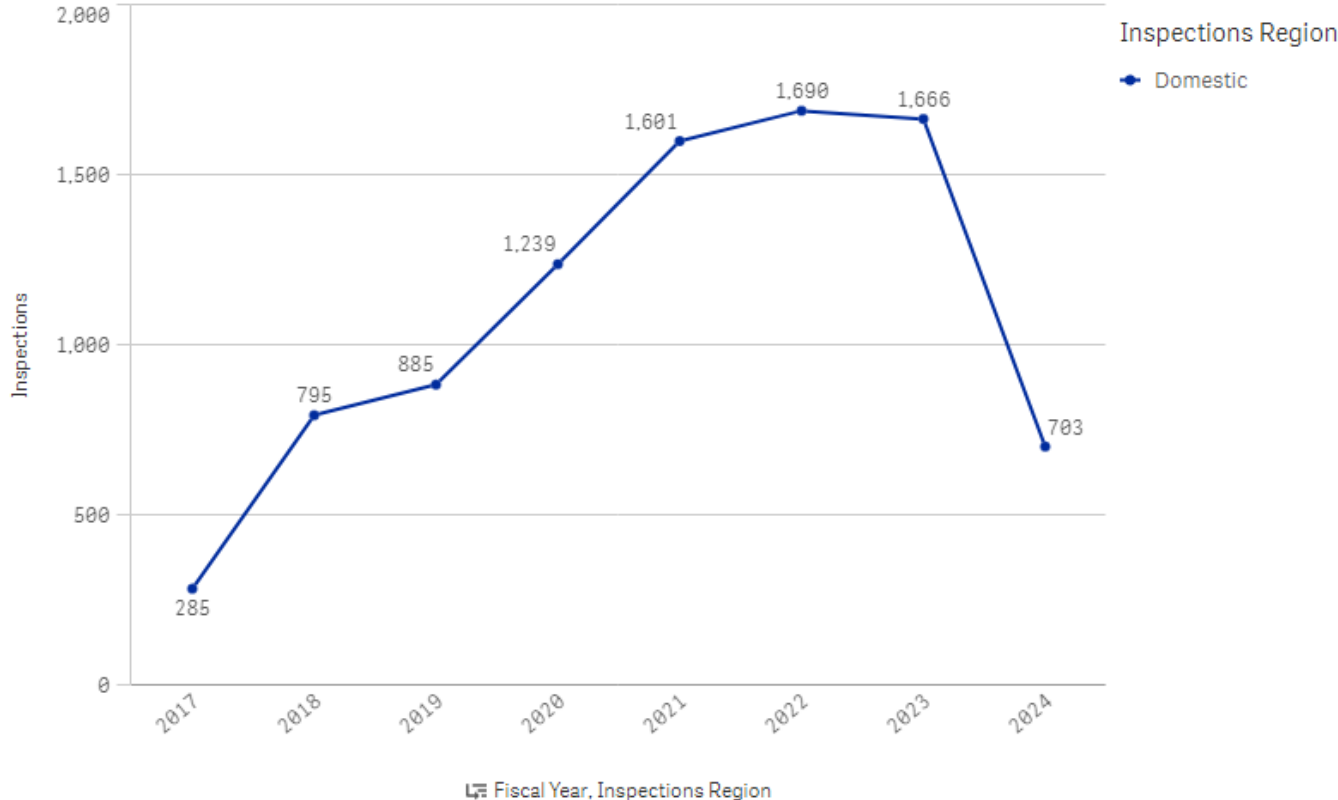
## **What are some consequences of failing to comply with the requirements of this subpart? (1.514)**

- An article of food is subject to refusal of admission
- The importation or offering for importation into the U.S. a food without having an FSVP is a prohibited act
- A person who commits a prohibited act is subject to imprisonment for not more than one year and fine of not more than \$1,00 or both (FD&C Act 301 (zz))
- Providing false information may be a criminal offense (18 U.S.C. 1001)

# FDA Data Dashboard – FSVP Inspections

## Foreign and Domestic Inspections

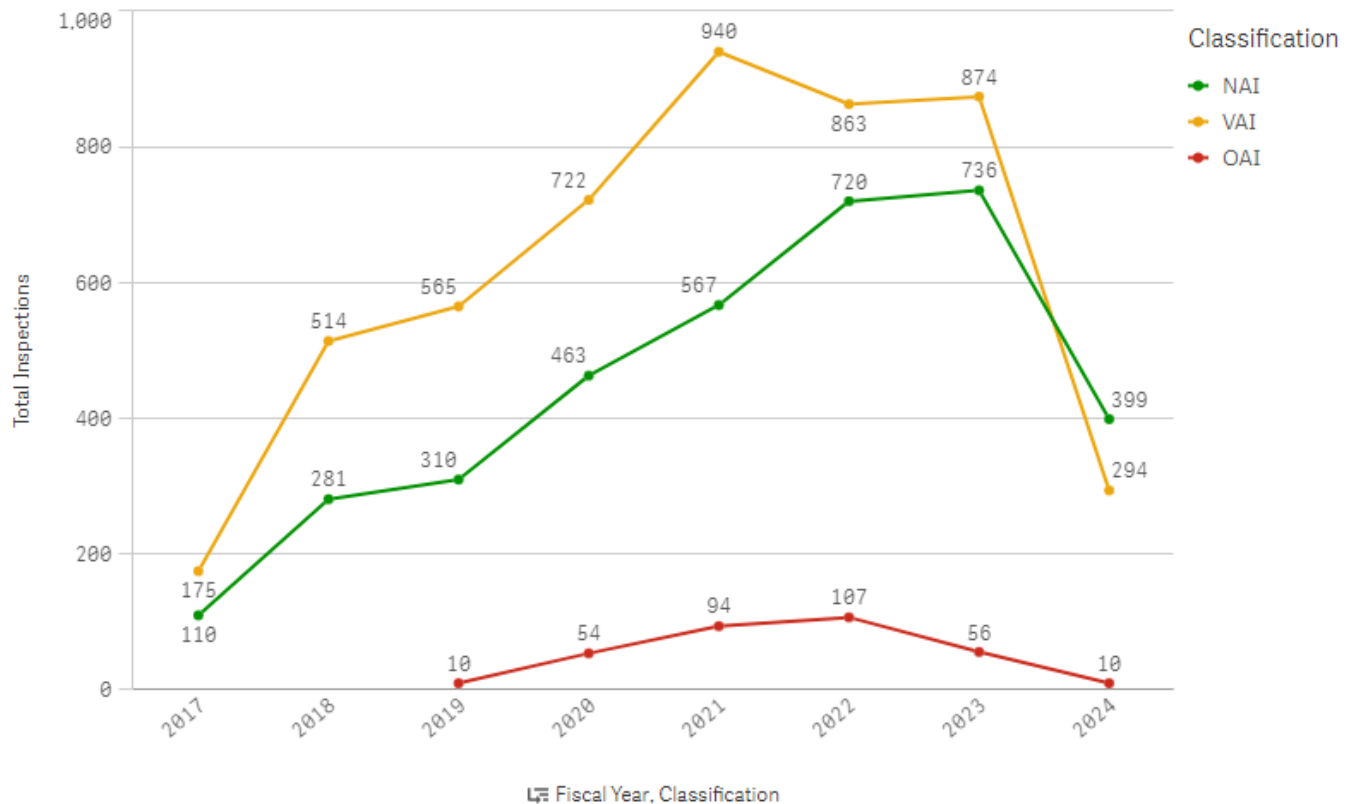
Fiscal Years: 2017 - 2024



# FDA Data Dashboard – Inspection Classification

## Inspections Classification by Fiscal Year

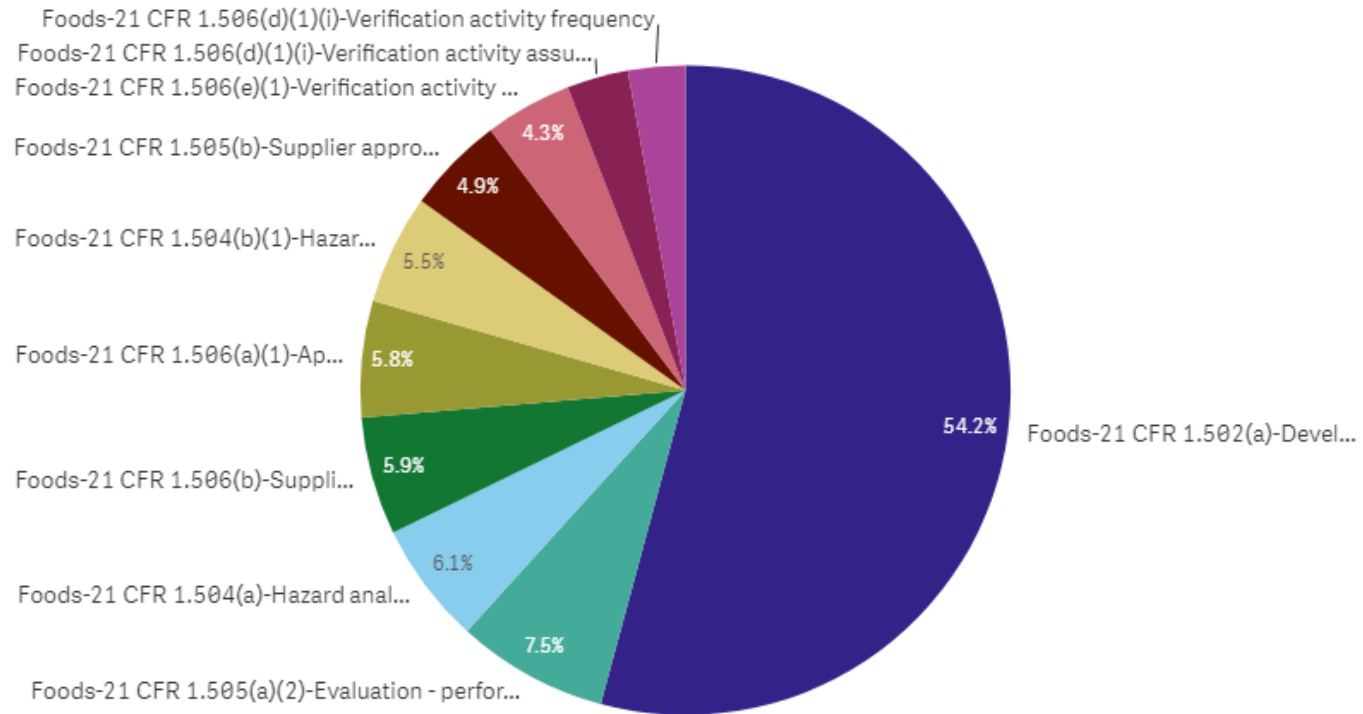
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# FDA Data Dashboard – Top 10 Citations

## Top 10 Citations

Fiscal Years: 2017 - 2024



# Questions?



