

Foreign Supplier Verification Programs: The Final Rule

<http://www.fda.gov/fsma>

**FDA FOOD SAFETY
MODERNIZATION ACT**

THE FUTURE IS NOW

Background

- FSMA Sec. 301 requires importers to have FSVPs and FDA to issue regulations.
- Proposed rule: July 29, 2013
- Supplemental proposal: Sept. 29, 2014
- Public comments: 300+ for proposed rule and 100+ for supplemental
- Final rule published: Nov. 27, 2015

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

Purpose of an FSVP

- 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)

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

- Juice and seafood from suppliers compliant with HACCP regulations
- Food for research or evaluation
- Food for personal consumption
- Alcoholic beverages and alcoholic beverage ingredients (when importer uses them to make an alcoholic beverage)

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 (microbiological hazards only)

Importers in Compliance with the Preventive Controls Rule

- Importers are deemed in compliance with most of FSVP when they:
 - Comply with PC supply-chain provisions
 - Implement preventive controls under PC regulation for hazards in food they import
 - Are not required to implement a preventive control under certain PC provisions

Use of Qualified Individuals

- Must use a *qualified individual* to perform all 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

Hazard Analysis

- Evaluate known or reasonably foreseeable hazards to determine if they require 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

Evaluation of Food and Foreign Supplier

- To approve suppliers and determine appropriate supplier verification activities
- Consider:
 - Risk posed by the food (hazard analysis)
 - Entities controlling hazards or verifying control
 - Supplier characteristics (procedures, processes, and practices; FDA compliance; food safety history)

Foreign Supplier Verification Activities

- Written procedures to ensure food is obtained from approved suppliers
- May use unapproved suppliers on temporary basis when subject food to verification
- Written procedures for appropriate verification activities

Verification Activities (cont.)

- Determine appropriate verification activities (and frequency) based on food and supplier evaluation
- Activities may include: onsite auditing; sampling and testing; review of supplier records; other appropriate measures
- Annual onsite auditing is default approach when a food has a SAHCODHA hazard

Reliance on Verification Activities Conducted by Others

- May rely on another entity's determination or performance of appropriate verification activities (e.g., farm audits conducted by produce distributor)
- Must review and assess results of verification activities (importer's own or others on which it relies)

Onsite Audits

- Must be conducted by “qualified auditor”; may be government employee
- Consider applicable FDA food safety regulations (or laws and regulations of country with comparable or equivalent food safety system)
- Substitute results of inspection by FDA or food safety authority in comparable or equivalent food safety system

Other FSVP Requirements

- Corrective actions
- Importer identification at entry
- Maintenance of records

Modified Requirements

- Food cannot be consumed without application of control; importer's customer or subsequent entity controls hazards
- Dietary supplements
- Very small importers and importers of food from certain small suppliers
- Food from countries with comparable or equivalent food safety systems

Supplier Verification Not Required

- Food cannot be consumed without application of control (e.g., coffee beans)
- Hazard controlled by importer's customer or subsequent entity in U.S. distribution
 - Disclosure statement
 - Written assurance
- Importer establishes other system to ensure control of hazard at subsequent distribution step

Dietary Supplements

- Most standard requirements do not apply when an imported dietary supplement component or packaging meets specifications established in accordance with dietary supplement CGMPs.
- Other dietary supplements (including finished supplements): hazard analysis not required; verification standard is compliance with CGMPs.

Very Small Importers and Food from Certain Small Suppliers

- Very small importer (VSI)
 - Less than \$1 million/yr. in human food sales
 - Less than \$2.5 million/yr. in animal food sales
- Food from certain small suppliers
 - Qualified facility
 - Produce from certain small suppliers that are not covered farms
 - Shell egg producers with < 3,000 laying hens

VSI and Importers of Food from Small Suppliers (cont.)

- Annually document eligibility
- Verification: Written assurances from suppliers
- Additional requirements for food from small suppliers:
 - Evaluate supplier compliance history
 - Approve suppliers
 - Ensure food is from approved suppliers

Countries with Comparable or Equivalent Safety Systems

- Most FSVP requirements would not apply when importing certain food from supplier in country whose food safety system FDA has officially recognized as comparable or determined to be equivalent.
 - Systems recognition initiative
- Applies to food that will not be processed further (packaged food; fresh produce)

Food from Countries with Comparable Systems (cont.)

- Importer must document that:
 - Foreign supplier is under oversight of comparable or equivalent food safety system.
 - Food is within scope of official recognition or determination.
 - Supplier is in good compliance standing with comparable or equivalent food safety authority.

Compliance Dates

- Importers will be required to comply with FSVP no earlier than 18 months after issuance of final rule (i.e., May 2017)
- If foreign supplier is subject to preventive controls or produce safety regulations, importer must comply with FSVP 6 months after supplier must meet the relevant regulations

Guidance and Outreach

- Developing FSVP draft guidance for industry
- Food Safety Preventive Controls Alliance will develop course materials for FSVP
- Webinars and meetings
- Developing the “FDA Data Dashboard” to assist importers

Inspections, Compliance, and Enforcement

- Developing a risk-based inspectional strategy for importers
- Considering both onsite and electronic records reviews
- Emphasis on assisting importers in achieving compliance

For More Information

- Web site: www.fda.gov/fsma
- Subscription feature available
- To submit a question about FSMA, visit www.fda.gov/fsma and go to [Contact Us](#)

