

# Final Rule on Foreign Supplier Verification Programs

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**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 FSVPs

- 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 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.

# Exemptions from FSVP

- Firms subject to juice or seafood HACCP regulations
- Food for research or evaluation
- Food for personal consumption
- Alcoholic beverages and 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. food returned”
- Meat, poultry, and egg products subject to USDA regulation at time of importation

# Importers in Compliance with Preventive Controls

- 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 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

# Hazard Analysis

- Evaluate known or reasonably foreseeable hazards to determine if they require a control
  - Biological, chemical (including radiological), and physical hazards
  - Naturally occurring, unintentionally introduced, or intentionally introduced for economic gain
- May assess another'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)

# Supplier Verification Activities

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

# Verification Activities (cont.)

- 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

# Requirements for Special Circumstances

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



# Other FSVP Requirements

- Corrective actions
- Importer identification at entry
- Recordkeeping

# 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 average in annual human food sales
  - Less than \$2.5 million average in annual animal food sales
- Food from certain small suppliers
  - Qualified facility
  - Produce from certain small farms 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

- Compliance is the latest of:
  - 18 months after final rule
  - If supplier is subject to the preventive controls or produce safety regulations, 6 months after the foreign supplier of the food is required to comply with the relevant regulations
  - For an importer that is itself a manufacturer or processor subject to the supply-chain program provisions in the preventive controls regulations, the date by which it has to comply with those provisions

# Guidance and Outreach

- Developing FSVP draft guidance for industry
- Food Safety Preventive Controls Alliance will develop course materials for FSVP.
- Webinars and meetings



# For More Information

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

