Foreign Supplier Verification Programs: The Final Rule

http://www.fda.gov/fsma
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
VSIs 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
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