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
  - Substitute results of inspection by FDA or other entities

Other Circumstances

- 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

Other FSVP Requirements

- Corrective actions

- Importer identification at entry

- Recordkeeping

Modified FSVP Requirements

- Dietary supplements
- Very small importers and importers of food from certain small foreign suppliers
- Certain food from suppliers in countries with comparable or equivalent food safety systems

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 comply with 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

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