Final Rule on Foreign Supplier Verification Programs

http://www.fda.gov/fsma



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

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

- 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
- Subscription feature available
- To submit a question about FSMA, visit www.fda.gov/fsma and go to <u>Contact Us</u>

Implementation Activity	Materings, Hearings, and Worsshops Speeches and Statements	or U.S. Department of Health and Huma	an Services	
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Contact Us How to Contact FDA about FSMA		The Law, Rules & Guidance	f share V TWEET in LINKEON @ PNIT S EMAL	. 😝 PRMT
		How to Comment on FSMA	You may contact FDA about FSMA by submitting an	inquiry form.
Pope List Updated. 10/05/015 Note: If you need help accessing internation in different file formate, see instructions for Downloading Verwers and Players Accessibility Cartero TOA basics FOA. No FEAR Act	one Mato Transparency Website Policies	Fact Sheets & Presentations		that are specific to FSMA and its implementation. Your use of th work with the information needed to give accurate and timely
Pope List Update: 1000015 tote it you need help accessing internation in deterret ble formate, see instructions for University Accessibility Careets FDA Basics FOA No FEAR Act	Side Mado Hantonia Performante a Local Officials	Frequently Asked Questions	responses and to improve our customer service. We nature of your inquiry and we remain open to sugges	hope you find our online form useful in identifying the specific tions about improving the form to meet your needs.
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Contact FDA Regulatory Information	ance	Archive	Food and Drug Administration 5100 Paint Branch Pkwy	
HIRATING SAME			Wiley Building, HFS-009 Attn: FSMA Outreach	
			College Park, MD 20740	