



Welcome

OnTrak with FSMA: A Webinar Series

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FSVP: What Should be Verified, Whether You're the Importer or Not

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FMI Antitrust Statement

FMI believes strongly in competition. Our antitrust laws are the rules under which our competitive system operates. It is FMI's policy to comply in all respects with the antitrust laws.

Association meetings or workshops by their very nature bring competitors together. It is expected that all member representatives involved in FMI activities, as well as FMI consultants and other participants, will be sensitive to the legal issues and act in compliance with applicable antitrust and competition laws both at FMI meetings and FMI-sponsored events.

Accordingly, it is necessary to avoid discussions of sensitive topics that can create antitrust concerns. Agreements to fix prices, allocate markets, engage in product boycotts and to refuse to deal with third parties are illegal under the antitrust laws. At any association meeting discussions of prices (including elements of prices such as allowances and credit terms), quality ratings of suppliers, and discussions that may cause a competitor to cease purchasing from a particular supplier, or selling to a particular customer, should be avoided. Also, there should be no discussion that might be interpreted as a dividing up of territories.

An antitrust violation does not require proof of a formal agreement. A discussion of a sensitive topic, such as price, followed by action by those involved or present at the discussion is enough to show a price fixing conspiracy. As a result, those attending an association-sponsored meeting should remember the importance of avoiding not only unlawful activities, but even the appearance of unlawful activity.

As a practical matter violations of these rules can have serious consequences for a company and its employees. Antitrust investigations and litigation are lengthy, complex and disruptive. The Sherman Act is a criminal statute, and may even result in penalties punishable by steep fines and imprisonment. The Justice Department, state attorneys general and any person or company injured by a violation of the antitrust laws may bring an action for three times the amount of the damages, plus attorney's fees.

About the FSVP Rule

- Final Rule published on November 27, 2015 in the *Federal Register*
- *Section 301 of FSMA*
- *FD&C Act Section 805*
- Requires importers to complete risk based verification activities to assure that foods have the same level of public health protection as foods produced in the US



The Rule Basics

- Flexible and risk based
- Considers known or reasonably foreseeable food safety hazards



To Be Considered

- Supplier approval program
- Hazard analysis
- Evaluation of supplier's performance and the risk posed by the food
- Verification Activities
- Corrective actions, as needed
- Reevaluate and reassess hazards periodically
- Recordkeeping



FSVP Importer



- The US owner or consignee of an article of food that is being offered for import into the US. If there is no US owner or consignee of an article of food at the time of US entry, the importer is the US agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart.

Are you the Importer?

- Importer Identification
- FSVP Importer must be identified at entry
 - Customs and Border Patrol Importer must identify the FSVP importer on the customs forms
 - FSVP Importers must have a Unique Facility Identifier (such as a DUNS number)



Communication among Supply Chain Partners

- If ownership is uncertain, communication is needed about FSVP responsibilities
- FDA will follow the information on the CBP forms to identify the FSVP importer and investigate the paper trail from there



What does the Importer Need to Do?

- CBP Importer – Designate a FSVP Importer
- FSVP Importer – Comply with FSVP

*If there is no US owner or consignee of an article of food at the time of US entry, **the importer is the US agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart.***

Records to be Kept by the Importer

1. Signed statement of consent from the US Agent or representative if there is no US owner or consignee of the product
2. Written procedures for the supplier approval program
3. Hazard analysis of the food or documentation of review of the HA
4. Documentation of the evaluation of the foreign supplier's performance (food safety procedures, compliance with regulations, food safety history)
5. Hazard disclosures and assurances
6. Verification activities
7. Reevaluations – when needed or every 3 years
8. Corrective actions



Who is responsible for the FSVP and Verification Activities?

- **Importer**
- **Qualified Individual**
 - Develop FSVP and perform each of the required activities
 - Must have the education, training or experience to perform assigned duties
- **Qualified auditor**
 - Responsible for audits as verification activities
 - Must have technical expertise obtained through education, training, or experience to perform the auditing function



What are the Foreign Supplier Verification Programs?

- The FSVP are the records that verify the programs were developed, implemented and followed.

FSVP = documentation + records



What if my Supplier has a GFSI Certification?

- Have strong food safety management programs in place
- Ongoing conversations between FDA and GFSI
- FSVP regulation requires compliance with FDA standards



For Foreign Suppliers

- Foreign suppliers exporting products to the US need to have risk based food safety **programs that meet** the same level of public health protection as **the preventive controls regulation for human and animal food and for produce safety**
- They need to work with a US owner or the consignee of their products who verifies their food safety programs



What is Not Covered?

- Juice covered under Juice HACCP
- Seafood covered under Seafood HACCP
- Meat, poultry and egg products covered under USDA jurisdiction
- Food imported for research or evaluation
- Food imported for personal consumption
- Alcoholic beverages
- Food transshipped or imported for processing and export



Covered under Modified Requirements

- Dietary Supplements
- Very small importer or importing certain food from certain small foreign suppliers
- Importing from a country with a recognized or equivalent food safety system



FDA Enforcement

- Education
- FSVP Importer listed on CBP Documentation
- Records review
- Onsite inspection
- Electronic submission of records





CHECKLISTS

Your Checklist – Retailers/Wholesalers

- Identify the FSVP importer
- If you are the FSVP importer - plan, develop and implement your Foreign Supplier Verification Programs
- Communicate with your foreign suppliers about the food safety program requirements
- Communicate with your importers



Your Checklist - Foreign Suppliers

- Understand the food safety requirements for export to the US
- Work with your CBP and FSVP importer in the US
- Work with your US owner or consignee to communicate and meet their requirements for the FSVP



Your Checklist - Importers

- Know your foreign suppliers
- Communicate with your customers about the food safety program requirements
- Communicate with your customers about your responsibilities, duties and expectations from them
- Communicate with CBP Importer
- Plan, develop and implement your Foreign Supplier Verification Programs



For Help

- **FDA Technical Assistance Network**
 - <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>
- **FDA FSMA Email updates**
 - https://public.govdelivery.com/accounts/USFDA/subscribe_r/new?topic_id=USFDA_206
- **FSPCA**
 - <https://www.ifsh.iit.edu/fspca/courses/foreign-supplier-verification-program-fsvp>
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