FSVP: What Exporters to the U.S. Should Expect

Prepared for the Embassy of France

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U.S. Food Imports

About Us

Erik R. Lieberman

Principal Lieberman PLLC law firm, President U.S. Food Imports LLC

- JD, University of Pennsylvania
- Licensed customs broker
- Member FDA Food Safety Preventive Controls Alliance
- Formerly FMI VP and Chief Regulatory Counsel
- U.S. House Small Business Committee Regulatory Counsel
- National Grocers Assn
- U.S. Sen. Bob Graham

U.S. Food Imports LLC

Compliance Review

- ✓ Ingredients
- ✓ Food safety practices
- ✓ Food contact substances
- ✓ All label elements
- ✓ Facility/canning registration

Supplier Verification

- ✓ FSVP
- ✓ Risk evaluation
- ✓ Hazard analysis
- ✓ Sampling and testing
- ✓ Recordkeeping

U.S. Food Imports LLC

Supplier Assistance

- ✓ Arrange audits
- ✓ Labeling help
- ✓ Food facility registration and agent
- ✓ FSMA
- ✓ FSIS
- ✓ APHIS

Importing and Logistics

- ✓ Importer of record
- ✓ Prior notice
- ✓ ISF
- ✓ Customs brokerage
- ✓ Bonds and insurance
- ✓ EDI
- ✓ Sourcing help

Lieberman PLLC

- Focus on food law: USDA and FDA matters
- Food Safety Modernization Act (FSMA)
- Food trade law matters

Overview

- Who has the responsibility to verify facilities and farms?
- What documents are importers required to keep?
- What information will importers request of their foreign suppliers?

RESPONSIBILITY TO VERIFY

Who has responsibility to verify?

- Under the regulation it is the FSVP importer
- The FSVP importer will be stated to FDA at the time of entry
- The FSVP importer is different than the importer of record

Who has the responsibility to verify? (contd)

- The FSVP importer is the U.S. owner or consignee, if there is no U.S. owner or consignee at the time of entry then the foreign owner or consignee must appoint a U.S. agent or representative to serve as the FSVP importer

Who has responsibility to verify? (contd)

- You may see your U.S. customers structuring terms of sale and specifying in contacts that your company is responsible for appointing an agent in the U.S. to serve as the FSVP importer
- Many U.S. businesses do not want this responsibility

Violating FSVP Punishable as a Crime

FSMA creates new violations of the Food Drug and Cosmetic Act punishable with criminal penalties including:

- Noncompliance with Foreign Supplier Verification Program Rule

Criminal Penalties

- Under Supreme Court ruling in U.S. v. Park, CEO and other corporate officers can be held criminally liable for misdemeanor violations without engaging in or having actual knowledge of violation

Criminal Penalties (contd)

- Criminal penalties:
  - Prohibited act under 21 U.S.C. 331(hh)

§333. Penalties

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title **shall be imprisoned** for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section,1 if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person **shall be imprisoned** for not more than three years or fined not more than $10,000, or both.

- Fines can be up to $250k per violation for individual or $500k for organization under 18 U.S.C. 3571

Who is the foreign supplier?

- The last establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the U.S. without further manufacturing or processing by another establishment, with the exception of further manufacturing/processing that consists only of labeling or another similar activity of a de minimis nature
- Same establishment as reported in prior notice

RECORDS FSVP IMPORTERS MUST KEEP

Recordkeeping

Must maintain documentation of:

- Hazard analysis
- Review of another entity's hazard analysis
- Evaluation for foreign supplier approval and verification
- Approval of foreign suppliers
- Reevaluation of foreign supplier performance and risk posed by food

Recordkeeping (contd)

- Written foreign supplier approval procedures
- Written foreign supplier verification procedure
- Determination of appropriate foreign supplier verification activities
- Decision not to conduct annual onsite audit
- Performance of foreign supplier verification activities
  - Documentation of onsite audits
  - Sampling and testing
  - Review of foreign supplier's relevant food safety records
- Corrective actions

Sampling and Testing

- Must retain documentation of each sampling and testing of food including
  - Identification of the food tested (including the lot number as appropriate)
  - The number of samples tested
  - Test(s) conducted including analytical methods used
  - Date(s) on which the tests were conducted
  - Date of the report of the testing
  - Results of the testing
  - Corrective actions taken in response to detection of hazards
  - Information on laboratory
  - Documentation that testing was conducted by a qualified individual

Food Safety Record Review

Must retain documentation of each record review including:

- Dates of review
- General nature of records reviewed
- Conclusions of the review
- Corrective actions taken in response to significant deficiencies identified during the review
- Documentation that review was conducted by a qualified individual

Recordkeeping (contd)

- Signing and dating: records must be signed and dated concerning the FSVP upon initial completion and any subsequent modification
- All records required under the FSVP Rule must be made available promptly to an FDA representative for inspection and copying
- Offsite storage of records is permitted if they can be retrieved and provided onsite within 24 hours of request

Recordkeeping (contd)

- Records must be maintained for two years after they have been created or obtained
- Records relating to processes and procedures must be maintained for at least two years after their use is discontinued
- FDA's Part 11 relating to maintenance of electronic records and signatures does not apply to the FSVP Rule.

Outsourcing

- Importers can use other parties to satisfy compliance requirements of FSVP Rule
- An entity other than importer can most of the foreign supplier verification activities

Outsourcing (contd)

- An entity other than importer can conduct hazard analysis (including the foreign supplier)
  - Importer must review and document review
- An entity other than the importer can evaluate the risk posed by a food, using results of the hazard analysis, and evaluate the foreign supplier's performance
  - This evaluation informs the approval of foreign suppliers and determination of appropriate foreign supplier verification activities
  - If another entity is used the importer must review and assess the determination
  - An importer must approve its own foreign suppliers

Outsourcing (contd)

- An entity other than the importer may establish written procedures to ensure that foods are imported only from approved suppliers
- An entity other than the importer may determine appropriate foreign supplier verification activities
- An entity other than the importer may conduct foreign supplier verification activities

Records in English

- Records must be provided to FDA in English upon the Agency's request
- Importers may request that records be in English

INFORMATION REQUESTED OF FOREIGN SUPPLIERS

Hazard Analysis

- Importers will ask to see your hazard analysis (if you have conducted one)
- If you have not conducted a hazard analysis you can conduct one that the importer can rely on
  - The importer may conduct one instead; or
  - You can use a third party to conduct one

Hazard Analysis (contd)

- Hazard analysis must identify and evaluate known or reasonably foreseeable hazards for each type of food imported
- Importer is not required to establish separate FSVPs for different versions of the same food when the differences in the products will not impact the safety of the food
  - Package sizes, different varieties of the same fruit or vegetable

Hazard Analysis (contd)

- Must consider:
  - Biological hazards
  - Chemical hazards
  - Physical hazards
  - Unintentionally introduced hazards
  - Intentionally introduced hazards (EMA)
- An entity other than the importer may perform the hazard analysis, including the foreign suppler

Hazard Evaluation

- The hazard analysis must include an evaluation of the hazards you identify to assess the probability that the hazard will occur in the absence of controls and the severity of the illness or injury if the hazard were to occur

Hazard Evaluation (contd)

Must consider:

- Environmental pathogens (whenever a ready-to-eat food is exposed to the environment before packaging and the packaged food does not receive a treatment/control that would significantly minimize the pathogen)
- Formulation of food (effect of formulation of food on the safety of the finished food for the consumer)

Hazard Evaluation (contd)

- Condition, function and design of the establishment and equipment
- Raw materials and ingredients
- Transportation practices
- Harvesting, raising, manufacturing, processing, and packing procedures
- Packaging and labeling activities
- Storage and distribution
- Intended or reasonably foreseeable use
- Sanitation, including employee hygiene

Records for Approved Foreign Supplier Program

- Importers must have a formal written foreign supplier approval program
- Program must consider
  - Hazard analysis
  - Entities conducting controls
  - Foreign supplier's procedures, practices and processes related to the safety of the food
  - Applicable FDA food safety regulations and information relevant to the compliance with those regulations

Records for Approved Foreign Supplier Program (contd)

- Importers may ask to see documentation of food safety practices and procedures
- You should be prepared to provide:
  - Results of government inspections (whether FDA or from local authorities)
  - Records indicating good regulatory standing with local authorities
  - Food safety sampling and testing
  - Environmental testing results (where appropriate)
  - Audit results
  - HACCP records
- Importers may require records to be in English

Audits

- You should expect that importers will require you to have an annual audit
  - Annual onsite audits required for Class I recall hazards (serious adverse health consequences or death to humans or animals) unless importer can determine (and document) that other activities are adequate
  - Many large U.S. retailers are requiring GFSI certification for all suppliers

Onsite Audit Requirements

- Must be performed by a qualified auditor
- If food is subject to one or more FDA food safety regulations, the onsite audit must consider such regulations and include a review of the supplier's written food safety plan (if any)

Are GFSI Audits Sufficient?

- FDA has refused to endorse GFSI
- Right now audits are generally not sufficient as the GFSI standards do not completely reflect FSMA requirements
- FDA has stated they expect some GFSI schemes to change to meet FSMA requirements

FDA Accredited Audits

- FDA has established a new food safety auditing program
  - FDA conducts oversight on auditors that are part of this program
  - For Voluntary Qualified Importer Program, but also works for FSVP
  - Audit reports (regulatory) are submitted to FDA in English
  - Auditors must notify FDA immediately if they discover during an audit a condition that could cause or contribute to a serious risk to public health

FDA Accredited Audits

- Program is not operating yet
- Some importers may require these audits as it lowers their risk

What if EU is Recognized by FDA?

- If the EU or France is recognized by FDA as having a comparable or equivalent food safety system then most FSVP requirements do not apply
  - No hazard analysis
  - No hazard evaluation
  - No foreign supplier verification
  - No corrective actions
- Recognition only applies to foods that are not further manufactured or processed in U.S.

Questions?

Thank you!

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