Proposed Regulations for Foreign Supplier Verification Programs (FSVPs)

http://www.fda.gov/fsma

FDA FOOD SAFETY MODERNIZATION ACT

Key Principles

- Importers would be responsible for ensuring that the food they bring into the U.S. meets FDA safety standards
- The requirements provide flexibility based on the risk of the food
- Under FSMA section 404, requirements must be consistent with WTO, other agreements

Who Is Covered?

- All importers must establish and follow an FSVP, unless otherwise exempted.
- U.S. importer is the person who has purchased the food offered for import.
  - If there is no U.S. owner at the time of entry, the importer is the U.S. consignee
  - If no U.S. owner or consignee at time of entry, the importer is the U.S. agent/representative of the foreign owner/consignee.

Who Is Exempt?

- Importers of juice and seafood whose suppliers are in compliance with the HACCP program (part 120 or 123)
- Small quantities of food imported for research and evaluation purposes
- Food imported for personal consumption

Who Is Exempt (cont'd)

- Facilities subject to FDA's low acid canned food requirements (microbiological hazards only)
- Alcoholic beverages
- Food that is transshipped or that is imported for future export and not consumed or distributed in the U.S.

Overview of FSVP

- Importers' FSVPs must ensure that:
  - The supplier uses procedures that provide the same level of protection as those required under the preventive controls or produce safety regulations (if applicable)
  - The food is not adulterated or misbranded regarding allergen labeling

Overview of FSVP (cont'd)

The requirements vary based on:

– Type of food product

– Category of importer, such as very small

– Nature of the hazard identified in the food

– Who is to control the hazard

FSVP Requirements

- In general, importers would need to conduct the following activities:
  - Compliance status review of foods and suppliers
  - Hazard analysis
  - Supplier verification activities
  - Complaint reviews, investigations, and corrective actions (if necessary)
  - Periodic reassessment of the FSVP
  - Importer identification at entry
  - Recordkeeping

Requirements (cont'd)

- Compliance status review – the importer would need to determine whether the food or supplier is the subject of a warning letter, import alert, or certification requirement
- Hazard analysis – the importer would need to identify hazards reasonably likely to occur for each food imported

Requirements (cont'd)

- Verification activities – importers to conduct activities that provide adequate assurances hazards identified are adequately controlled
- Corrective actions – importers review complaints received concerning foods they import; investigate causes of adulteration; take appropriate corrective actions; revise FSVPs when they appear inadequate

Requirements (cont'd)

- Periodic reassessment of the FSVP – within 3 years of establishing the FSVP or within 3 years of the last assessment; sooner if new information surfaces about potential hazards associated with the food
- Importer identification at entry (name and DUNS number)
- Recordkeeping

Control of Hazards

- The requirements for supplier verification are primarily based on who is to control the hazards identified as reasonably likely to occur in a food
- FDA is proposing two options for when the foreign supplier controls the hazard or verifies control by its supplier; the options differ primarily according to the nature of the hazard

Option 1

- If the foreign supplier controls the hazard at its establishment and there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (SAHCODHA), the importer would be required to conduct or obtain documentation of onsite auditing of the foreign supplier

Option 1 (cont'd)

- For non-SAHCODHA hazards controlled by the foreign supplier, and all hazards that the foreign supplier verifies control by its supplier, the importer would need to conduct one or more of the following:
  - Onsite auditing
  - Sampling and testing
  - Review of supplier food safety records
  - Some other appropriate procedure

Option 1 (cont'd)

- Onsite auditing would also be required for microbiological hazards in certain raw agricultural commodities

Option 2

- For all hazards that the foreign supplier will either control or verify that its supplier is controlling, importers would need to choose a verification procedure from among:
  - Onsite auditing
  - Sampling and testing
  - Review of supplier food safety records
  - Some other appropriate procedure

Option 2 (cont'd)

- In determining which verification activities are needed and how often they should be conducted, the importer would need to consider:
  - Risk presented by the hazard
  - Probability that exposure to the hazard would result in serious harm
  - Food and foreign supplier's compliance status

Modified FSVP Requirements

- Importation of a dietary supplement or dietary supplement component
- Importation of food by very small importer or from very small foreign supplier
- Importation of food from a foreign supplier in good compliance standing with a food safety system FDA has officially recognized as comparable to U.S. system

FSVP and Preventive Controls

- FDA intends to align the supplier verification provisions in the FSVP regulations with any supplier verification provisions that are included in the final rules on preventive controls for both human and animal food

Compliance Dates

- FDA is proposing to provide adequate time before importers would be required to come into compliance (generally 18 months after publication of the final rule)

Input from FSMA Partners Is Vital

- Proposals are opportunity for government, industry, and the public to partner with FDA in putting FSMA regulations in place
- Your comments and feedback are important to us!
- Please provide your views, questions, and concerns to help FDA finalize the rules

How to Comment on the Proposed Rules

- Go to www.regulations.gov or www.fda.gov/fsma
- Published July 29, 2013; comments due January 27, 2014

How to Comment on the Regulatory Impact Analysis

- Comments also are being accepted on the Preliminary Regulatory Impact Analysis (PRIA)
- The PRIA is available at:
  - http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.