FSMA Facts

FDA FOOD SAFETY MODERNIZATION ACT

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

Summary
On July 26, 2013, FDA issued proposed regulations that would greatly strengthen the oversight of foods imported for U.S. consumers. Under the Foreign Supplier Verification Program (FSVP) regulations, importers would be required to perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that provides the same level of public health protection as that required of domestic food producers. The FSVP regulations would implement section 301 of the FDA Food Safety Modernization Act (FSMA).

The proposed regulations vary based on the type of food product (such as processed foods, produce, and dietary supplements), the category of importer, the nature of the hazard in the food, and who is to control the hazard.

Background
Food arrives in the United States from farms and producers around the world. About 15 percent of the U.S. food supply is imported, and for some commodities, such as produce, that percentage increases greatly. It is important that food imported into the United States meets the same level of public health protection as food produced domestically.

FSMA, signed into law on January 4, 2011, enables the FDA to better protect public health by helping to ensure the safety and security of the U.S. food supply. The vision of FSMA is prevention -- preventing food safety problems before they occur, rather than reacting to problems when they happen. One of the most significant changes that FSMA made to FDA's food safety authorities is in the area of imports. These new import authorities will help FDA transition from its historical focus on catching food safety problems at the border to one that builds safety in throughout the supply chain, from foreign producers to U.S. consumers.

Although FSMA directs the FDA to increase its inspections of foreign food facilities, Congress also provided FDA with the authority to develop regulations that would require industry to share responsibility and be accountable for preventing food safety problems.

Highlights of the Proposed Rule

FSVP Requirements
All importers must establish and follow an FSVP, unless otherwise exempted. An importer of food under the proposed FSVP regulations is the U.S. owner or consignee of the food at the time of entry, or, if there is no U.S. owner or consignee at the time of entry, the U.S. agent or representative of the foreign owner or consignee. Under the proposed FSVP regulations, an importer would be required to develop, maintain, and follow an FSVP for each food it imports, which, in general, would need to include the following:

- **Compliance Status Review:** Importers would be required to review the compliance status of the food and the potential foreign supplier before importing the food and periodically thereafter. Such review would need to include any FDA warning letters, import alerts, and requirements for certification issued by the FDA under section 801 (q) of the Food, Drug, and Cosmetic Act (FD&C Act).
- **Hazard Analysis:** Importers would be required to analyze the hazards associated with each food they import. The hazard analysis would identify the hazards that are reasonably likely to occur for each type of food imported, and evaluate the

severity of the illness or injury if such a hazard were to occur.

- **Verification Activities:** Importers would be required to conduct activities that provide adequate assurances that the hazards identified as reasonably likely to occur are adequately controlled. Verification activities could include: onsite auditing of foreign suppliers; periodic or lot-by-lot sampling and testing of food; and periodic review of foreign supplier food safety records; or other appropriate risk-based procedures. Verification activities applicable to all FSVPs, regardless of identified hazards, include maintaining a written list of foreign suppliers from which food is imported, and establishing and following adequate written procedures for conducting verification activities.
- **Corrective Actions:** Importers would be required to review complaints they receive concerning the foods they import, investigate the cause or causes of adulteration or misbranding in some circumstances, take appropriate corrective actions, and revise their FSVPs when they appear to be inadequate.
- **Periodic Reassessment of the FSVP:** Importers would be required to reassess their FSVPs within three years of establishing the FSVP or within three years of the last assessment. However, importers would have to reassess the effectiveness of their FSVP sooner if they become aware of new information about potential hazards associated with the food. Examples of such information might include information on changes to the source of raw materials or to product formulation.
- **Importer Identification:** Importers would be required to obtain a Dun and Bradstreet Data Universal Numbering System (DUNS) number for their company and to ensure that, for each food product offered for importation into the United States, their name and DUNS number are provided electronically when filing for entry with Customs and Border Protection.
- **Recordkeeping:** Importers would be required to keep certain records, including those that document compliance status reviews, hazard analyses, foreign supplier verification activities, investigations and corrective actions, and FSVP reassessments.

Control of Hazards

The FDA is proposing a flexible, risk-based approach to foreign supplier verification. The proposed regulation focuses on foreseeable food safety risks identified through a hazard assessment process, rather than all risks covered by the adulteration provisions in the FD&C Act. Because the principle of hazard assessment is well accepted and understood throughout the food industry, the FDA believes that it provides the most effective way to implement a risk-based framework in which importers can evaluate potential products and suppliers and conduct appropriate verification efforts.

The requirements for supplier verification in the proposed rule on FSVP are primarily based on who is to control the hazards that are reasonably likely to occur with a particular food and the nature of the hazard. In the proposed rule, the FDA is proposing two options for the supplier verification activities for hazards that the foreign supplier will control or that the foreign supplier verifies are being controlled by its raw material or ingredient supplier.

Option 1

Under Option 1 of the proposal, 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. Onsite auditing would also be required for microbiological hazards in certain raw agricultural commodities. For non-SAHCODHA hazards that the foreign supplier controls, the importer would be required to conduct one of more of the verification activities mentioned above (onsite auditing, sampling and testing, review of the supplier's food safety records, or some other

appropriate procedure) before using or distributing the food and periodically thereafter. In determining the appropriate verification activities, the importer must consider the risk presented by the hazard and the food and foreign supplier's compliance status.

Option 2

Under Option 2 of the proposal, 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, or some other appropriate procedure. In determining the appropriate verification activities and how frequently they should be conducted, the importer would need to consider the risk presented by the hazard, the probability that exposure to the hazard will result in serious harm, and the food and foreign supplier's compliance status.

If the importer, rather than the foreign supplier or its supplier, will be responsible for controlling a hazard that it has identified as reasonably likely to occur, the proposed rule would require the importer to document, at least annually, that it has established and is following procedures that adequately control the hazard. If the importer's *customer* will be controlling a hazard identified by the importer, the importer would need to obtain written assurance, at least annually, that its customer has established and is following procedures (identified in the written assurance) that adequately control the hazard.

The proposed rule also states the FDA's intent 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 human and animal food. This would avoid imposing duplicative requirements on entities that would be subject to both the FSVP and preventive controls regulations (because the entity is both a food importer and a registered food facility).

Modified Requirements and Exemptions

Under the proposed rule, modified FSVP requirements would apply in certain circumstances, including the following:

- Importation of a dietary supplement or dietary supplement component;
- Importation of food by a very small importer or importation of food from a very small foreign supplier; and
- Importation of food from a foreign supplier in good compliance standing with a food safety system that FDA has officially recognized as comparable or determined to be equivalent to that of the United States.

The proposed rule would exempt the importation of the following from the FSVP requirements:

- Juice and seafood from facilities that are in compliance with the Hazard Analysis & Critical Control Points (HACCP) regulations, which contain their own supplier verification provisions;
- Food imported for research or evaluation purposes;
- Food imported for personal consumption;
- Alcoholic beverages; and
- Food that is transshipped or imported for further processing and export.

Effective and Compliance Dates

The FDA is proposing that the FSVP regulations become effective 60 days after the final rule is published in the *Federal Register*, but FDA is proposing to provide additional time before importers would be required to come into compliance. The compliance dates would vary depending on the circumstances. In general, the compliance date would be 18 months after the publication date of the final FSVP regulations. However, recognizing that the FSVP proposed rule is closely tied to the proposed rules on preventive controls and produce safety, the compliance dates for importers in many cases would depend on the compliance dates for those rules. In general, the importer would be required to comply with the FSVP

regulations six months after the foreign supplier of the food is required to comply with the new FSMA preventive controls regulations.

Economic Impact of the Proposed Rule

The proposed rule is aimed at reducing the public health burden of foodborne illness by helping to ensure that imported food is produced in compliance with applicable food safety regulations. The annual cost of the illnesses associated with imported foods that would be subject to the FSVP regulations is approximately $1.18 billion, which is more than one-fifth of the entire estimated burden of illness related to foods consumed in the United States.

For option 1, the proposed rule has a first-year cost to industry of $492 million and an annualized cost of $473 million, using a 7 percent discount rate according to Office of Management and Budget guidelines.

For option 2, the proposed rule has a first-year cost to industry of $480 million and an annualized cost of $462 million, using a 7 percent discount rate according to Office of Management and Budget guidelines.

The Preliminary Regulatory Impact Analysis for the proposed rule is available at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

Rulemaking Process and How to Submit Comments

When the FDA issues a proposed rule on a matter, it publishes the proposed rule in the Federal Register so that the public can review it and submit comments. The FDA considers comments received during the comment period on a proposed rule and then considers revising the rule based on the Agency's review of the comments before issuing a final rule. In the preamble to the final rule, we discuss the significant comments received. The proposed and final rules and supporting documents are filed in the FDA's official docket on http://www.regulations.gov and can also be accessed at www.fda.gov/fsma. Comments on the proposed rule "Food Supplier Verification Programs for Importers of Food for Humans and Animals," which published in the July 29, 2013 Federal Register, are due 120 days after publication, on November 26, 2013.

The FDA has conducted extensive outreach to industry, the consumer community, other government agencies, and the international community to gain input and perspective on how to structure this and other proposed rules to implement FSMA. That input and perspective helped shape the proposed regulations in a way that will help to ensure that they are practical and flexible as well as effective. The FDA held a public meeting on FSMA provisions concerning imported food, including FSVPs, in March 2011, and we will be holding three additional public meetings during the comment period on the FSVP proposed rule.

Assistance to Industry

The FDA plans to publish, at the time of the final rule on FSVPs, draft guidance to assist importers in developing and following FSVPs as well as how to comply with the other requirements of the FSVP rule.

For additional information

- FR Notice
- Preliminary Regulatory Impact Analysis
- FDA Food Safety Modernization Act web site: www.fda.gov/fsma
- Fact Sheet: Accreditation of Third Party Auditors/Certification Bodies to Conduct Food Safety Audits and Issue Certifications
- Fact Sheet: Foreign Supplier Verification Programs diagrams
- Fact Sheet: Preventive Controls for Human Food
- Fact Sheet: Standards for Produce Safety
- The Food Safety Law and the Rulemaking Process: Putting FSMA to Work
- Video: The Rulemaking Process: A Primer by FDA
- Video: FDA Food Safety Modernization Act: A Primer