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FDA Releases Final FSMA Rules for Produce and Imported Foods

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The U.S. Food and Drug Administration (FDA) on Nov. 13 released the agency's final rules mandated by the Food Safety Modernization Act (FSMA) for [produce safety](#), [foreign supplier verification programs \(FSVP\)](#), and [accreditation of third-party certification bodies/auditors](#).

FDA's final rules for FSVP and accreditation of third-party certification cover a wide variety of entities involved with importing food, including importers of raw agricultural commodities (e.g., grain and oilseeds), animal feed and feed ingredients, and human food and food ingredients. The final rules are expected to be published in the *Federal Register* on Nov. 27.

The three new rules will serve as components of the new prevention-orientated regulatory framework for food and feed being implemented by FDA under authority provided by FSMA. FDA published the first two "cornerstone" FSMA rules on Sept. 17 that established preventive controls requirements for human food and animal food. In addition to these five rules now released, FDA is under a court order to issue two other major FSMA-related rulemakings by March 31 and May 31 for sanitary transportation of food and intentional adulteration of food, respectively.

Overview of FSVP Rule

The final FSVP rule requires importers to verify that imported food has been produced in a manner that meets applicable U.S. safety standards. Within the rule, "importer" means the U.S. owner or consignee of an article of food that is being offered for import into the United States. Further, as defined by the rule, "U.S. owner or consignee" means the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food. If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. 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 as required under the rule.

Significantly, the rule covers importers regardless of whether they are required to register with FDA as a food facility under the regulations established by the Bioterrorism Preparedness and Response Act of 2002. As such, an entity that does not manufacture, process, pack or hold food is obligated to comply with the FSVP requirements if it is the importer of the food as defined by the final rule.

The requirements in the final rule apply to all food imported or offered for import into the United States and to the importers of such food except:

- Juice, fish, and fishery products that are imported from a foreign supplier that is required to comply with, and is in compliance with, the FDA’s juice and seafood hazard analysis and critical control point regulations.
- Food imported for research or evaluation.
- Food imported for personal consumption.
- Alcoholic beverages imported from a foreign supplier that would be subject to permitting requirements established by the Federal Alcohol Administration and is required to register with FDA as a food facility.
- Food that is transshipped or imported for processing and export.
- Food that is manufactured/processed, raised, or grown in the United States, exported, and returned to the United States without further manufacturing/processing in a foreign country.
- Meat, poultry, and egg products subject to USDA regulations

Covered importers are responsible for developing and implementing a written FSVP that includes analysis of hazards and implementation of risk-based controls. To do so, the rule requires a “qualified individual” to develop, implement and oversee the plan.

The rule defines a “qualified individual” to mean a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under the rule, and can read and understand the language of any records that the person must review in performing this activity. A qualified individual may be, but is not required to be, an employee of the importer. A government employee, including a foreign government employee, may be a qualified individual.

The importer’s FSVP is to include:

- **Foreign Supplier Approval:** The importer is required to establish and follow written procedures to ensure that foods are imported only from foreign suppliers that have been approved based on the evaluation conducted under the rule’s requirements (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods are subject to adequate verification activities before importing the food). The importer is required to document the use of the written procedures.

Significantly, “foreign supplier,” as defined by the rule, means the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature. Therefore, a foreign facility that simply holds food within the supply chain is not a foreign supplier for the purposes of the

rule because it does not manufacture, process or grow the food. As an example, an importer may import grain into the United States from a foreign grain elevator that holds the grain. In this case, the grain elevator is not the foreign supplier because it did not manufacture or grow the grain. Instead, the foreign supplier for purposes of the final rule is the producer(s) that grew the grain.

- **Hazard Analysis:** A written hazard analysis is to be conducted by the importer's "qualified individual" to identify and evaluate "known or reasonably foreseeable hazards" associated with the food and its foreign supplier. The hazard analysis is to include an evaluation of the hazards to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of controls.
- **Foreign Supplier Verification:** If an importer conducts a hazard analysis and appropriately determines that the foreign supplier and food have no hazards requiring a control, then the importer does not need to conduct supplier approval and verification activities. This exemption from further supplier approval and verification activities does not apply if the food is a raw agricultural commodity that is a fruit or vegetable that is "covered produce" as defined by FDA's produce safety rule.

An importer may rely on an entity other than the foreign supplier to determine and perform appropriate supplier verification activities so long as the importer reviews and assesses that entity's relevant documentation in accordance with the rule's requirements.

If the hazard analysis does establish that there is a hazard requiring a control, then the hazard must be controlled by either: 1) the foreign supplier; or 2) the importer (when the importer is subject to FDA's preventive controls rule); or 3) the importer's customer.

In the case when the importer controls the hazard, importers subject to and in compliance with FDA's final rules published on Sept. 17 that established preventive controls requirements for human and animal food are deemed to be in compliance with the FSVP requirements if the importer, in accordance with the preventive controls rules, has implemented preventive controls for the hazard in the food.

In the case when the importer relies on the foreign supplier to control the hazard in the food, the rule establishes that the importer is to conduct appropriate supplier verification activities that provide assurance the hazard requiring a control in the food has been significantly minimized or prevented. The rule specifies that such supplier verification activities may include:

- Annual on-site audits of the foreign supplier's facility. An annual on-site audit generally is required when there is a reasonable probability that exposure to a hazard controlled by the foreign supplier will result in serious adverse health consequences or death to humans or animals (called a SAHCODHA hazard). When conducted, audits are to be performed by a "qualified auditor" as defined by the rule. However, the importer can choose a means of verification other than an audit provided that the

importer documents that the alternate choice is appropriate and provides adequate assurances that the foreign supplier is producing the food in accordance with applicable U.S. safety standards.

- Sampling and testing.
- A review of the supplier's relevant food safety records.
- Other appropriate supplier verification activities, as provided by the rule.

In the case when the importer relies on its customer to control the hazard, the importer is not required to conduct supplier verification activities if they:

- Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and
 - Annually obtain from the customer written assurance that it is, as applicable, either significantly minimizing or preventing the identified hazard or manufacturing, processing, or preparing the food in accordance with applicable food safety requirements.
- **Reevaluation of a foreign supplier's performance and the risk posed by a food:** Under the final rule, the importer is required to reevaluate the risk associated with a food at least every three years, or sooner if new information becomes available about the factors associated with the food's hazard analysis.
 - **Corrective actions:** An importer is required to promptly take appropriate corrective actions if it determines that a foreign supplier of imported food does not produce the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under applicable U.S. safety standards. Under the rule, such a determination could be based on a review of consumer, customer, or other complaints related to food safety, the verification activities conducted, a reevaluation of the risks posed by the food and the foreign supplier's performance, or any other relevant information. The appropriate corrective actions to be taken will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance have been adequately addressed.
 - **Modified FSVP Requirements:** The final rule provides for modified requirements for very small importers and importers of food from certain small foreign suppliers. The rule's definition of very small importer is consistent with the definition of very small business in the preventive controls rules - average annual sales of \$1 million for human food and \$2.5 million for animal feed and pet food. Small foreign suppliers as specified by the rule include:
 - Facilities subject to modified requirements under the preventive controls rules because they are qualified facilities.

- Farms that are not covered farms under the produce safety rule because they average \$25,000 or less in annual produce sales or because they meet requirements for a qualified exemption.
- Shell egg producers with fewer than 3,000 laying hens

Under the modified requirements, the rule generally establishes that very small importers and importers of food from certain small foreign suppliers would not have to conduct hazard analyses and would be able to verify their foreign suppliers by obtaining written assurances from their supplier.

Compliance Dates: The date by which importers are to comply with the FSVP regulations is the latest of the following dates:

- 18 months after publication of the final rule (publication expected to occur on Nov. 27, 2015).
- For the importation of food from a supplier that is subject to the preventive controls or produce safety rules, six months after the foreign supplier is required to meet the relevant regulations.
- For an importer that is 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.

Overview of Accreditation of Third-Party Certification Bodies/Auditors Rule

FDA's final rule establishes a voluntary program for the accreditation of third-party certification bodies and auditors to conduct food safety audits and issue certifications of foreign facilities and foods produced for humans and animals.

Third-party certifications under FSMA may be used for two purposes:

- Certifications may be used by importers to establish eligibility for participation in the Voluntary Qualified Importer Program (VQIP), which offers expedited review and entry of food.
- FDA also may require in specific circumstances that a food offered for import be accompanied by a certification from an accredited third-party certification body.

The final rule establishes the framework, procedures and requirements for accreditation bodies seeking recognition by FDA, as well as requirements for third-party certification bodies seeking accreditation. These requirements cover legal authority, competency, capacity, conflict-of-interest safeguards, quality assurance and record procedures.

In limited circumstances, FDA may directly accredit third-party certification bodies. For example, FDA could directly accredit third-party certification bodies if it has not identified and recognized an accreditation body within two years after establishing this program.

To promote international consistency and utilize an existing framework that is familiar to industry, accreditation bodies and certification bodies will be allowed to use documentation of their conformance with International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) standards, supplemented as necessary, in meeting program requirements under FDA's rule.

FDA Related Actions on Accreditation of Third-Party Certification Bodies/Auditors:

- FDA's draft recommendations on certification body competency are contained in the [Model Accreditation Standards draft guidance](#) issued by the agency in July 2015. The draft guidance contains recommendations on the qualifications that third-party certification bodies and their agents should have in such areas as education and experience. FDA will finalize this guidance after public comments are considered.
- FDA published in June 2015 [a draft guidance for industry explaining how VQIP will work](#). In order to participate in VQIP, importers must import food from certified facilities. Importers with a robust system of supply-chain management may qualify for expedited review and entry for foods they seek to import.
- FDA published in July 2015 a [proposed rule establishing user fees for accreditation bodies and certification bodies](#). FSMA requires that a user-fee program be established to reimburse the agency for its work in establishing and administering the voluntary third-party certification program.

FDA intends to implement the third-party accreditation program as soon as possible after publication of the final Model Accreditation Standards guidance and the final user fee rule, both of which will be published separately.

FDA Webinars: FDA has scheduled a webinar on Nov. 23 to provide further information on its rules for FSVP and Accreditation of Third-Party Certification Bodies/Auditors. Information about the webinar may be accessed on [FDA's FSMA website](#).