

Food and Drug Law Alert

July 26, 2013

U.S. Food and Drug Administration Issues Proposed Rules to Increase Oversight of Imported Foods

This morning, the U.S. Food and Drug Administration (FDA) released two proposed rules that will increase oversight of foods and dietary supplements that are imported into the United States. The proposed rules on the [Foreign Supplier Verification Program \(FSVP\)](#) and [Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications](#) continue FDA's implementation of the historic Food Safety Modernization Act (FSMA), signed into law in January 2011.

Foreign Supplier Verification Program

Earlier this year, FDA issued the first two major proposed rules stemming from FSMA. The proposed rules on *Preventive Controls for Human Food* and on *Standards for Produce Safety* seek to improve food safety by requiring food companies to adopt proactive approaches to food safety. These proposed rules, however, will only directly apply to U.S. companies. FDA touts that the FSVP rule will ensure the same level of public health protection for imported foods that the first two major FSMA rules provide for domestic foods.

The proposed rule will require all importers to establish and follow an FSVP for each food it imports, unless otherwise exempted. An importer's FSVP may vary according to several factors, including the type of food being imported and the hazards associated with that food, as well as the category of the importer, but an FSVP will generally include (1) a compliance status review, (2) hazard analysis, (3) verification activities, (4) corrective actions, (5) periodic reassessment of the FSVP, (5) importer identification through the DUNS system and (6) recordkeeping.

The requirements for supplier verification will depend on whether the foreign supplier is controlling hazards or whether the foreign supplier is certifying that hazards are being controlled by a raw material or ingredient supplier. Additionally, modified requirements would be available to certain imports, including dietary supplements, small importers, small foreign suppliers and foreign suppliers in compliance with an FDA-recognized, comparable food safety system. The proposed rule would exempt from FSVP requirements foods that are imported for research, personal consumption and further processing or export. Alcoholic beverages and juices subject to Hazard Analysis and Critical Control Points (HACCP) would also be exempt.

Accreditation of Third-Party Auditors

The proposed rule on Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications establishes the structure and requirements of the program, required by FSMA, under which third-party auditors are accredited to certify that food being imported into the United States meets FDA's food safety standards. FDA will separately issue model accreditation standards.

In accordance with FDA's proposed requirements under the proposed rules, third-party auditors will be authorized by accreditation bodies to conduct food safety audits and issue certifications of foreign facilities. FDA will not generally require importers to obtain certifications, but may require a certification as a condition of entry for certain foods that FDA believes are high-risk.

Additionally, the certifications issued by third-party auditors can be used by importers who choose to participate in the Voluntary Qualified Importer Program (VQIP), which is still being developed and which will provide importers with expedited review and entry of food.

Comment Period

Comments on FSVP and Accreditation of Third-Party Auditors are due 120 days after publication in the *Federal Register*, which is planned for July 29, 2013. Based on this, we anticipate comments will be due on November 26, 2013.

There is also still time to submit comments on the proposed rules on Preventive Controls for Human Food and on Standards for Produce Safety. Although comments were initially due in May, FDA extended the comment period for both. Interested parties now have until September 16, 2013 to submit comments to FDA.

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