

FDA NEWS RELEASE

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FDA takes step to help ensure the safety of imported food

Agency releases new proposed rules under FSMA for verifying foreign suppliers and accrediting third-party auditors

In order to implement the bipartisan Food Safety Modernization Act (FSMA) signed by President Obama, the U.S. Food and Drug Administration today issued two proposed rules aimed at helping to ensure that imported food meets the same safety standards as food produced in the United States.

These proposals are part of the FSMA approach to modernizing the food safety system for the 21st century. FSMA focuses on preventing food safety problems, rather than relying primarily on responding to problems after the fact. The FDA encourages Americans to review and comment on these important proposed rules.

Under the proposed rules, importers would be accountable for verifying that their foreign suppliers are implementing modern, prevention-oriented food safety practices, and achieving the same level of food safety as domestic growers and processors. The FDA is also proposing rules to strengthen the quality, objectivity, and transparency of foreign food safety audits on which many food companies and importers currently rely to help manage the safety of their global food supply chains.

The new measures respond to the challenges of food safety in today's global food system. Imported food comes into the United States from about 150 different countries and accounts for about 15 percent of the U.S. food supply, including about 50 percent of the fresh fruits and 20 percent of the fresh vegetables consumed by Americans.

“We must work toward global solutions to food safety so that whether you serve your family food grown locally or imported you can be confident that it is safe,” said FDA Commissioner Margaret A. Hamburg, M.D. “Today’s announcement of these two new proposed rules will help to meet the challenges of our complex global food supply system. Our success will depend in large part on partnerships across nations, industries, and business sectors.”

Under the proposed regulations for Foreign Supplier Verification Programs (FSVP), U.S. importers would, for the first time, have a clearly defined responsibility to verify that their suppliers produce food to meet U.S. food safety requirements. In general, importers would be required to have a plan for imported food, including identifying hazards associated with each food that are reasonably likely to occur. Importers would be required to conduct activities that provide adequate assurances that these identified hazards are being adequately controlled.

“FSMA provides the FDA with a modern tool kit that shifts the paradigm for imports, as well as domestic foods, from a strategy of reaction to one of systematic prevention,” said Michael R. Taylor, deputy commissioner for foods and veterinary medicine. “Rather than relying primarily on FDA

investigators at the ports to detect and respond to food safety problems, importers would, for the first time, be held accountable for verifying, in a manner transparent to the FDA, that the food they import is safe.”

FSMA also directs the FDA to establish a program for the Accreditation of Third-Party Auditors for imported food. Under this proposed rule, the FDA would recognize accreditation bodies based on certain criteria such as competency and impartiality. The accreditation bodies, which could be foreign government agencies or private companies, would in turn accredit third-party auditors to audit and issue certifications for foreign food facilities and food, under certain circumstances.

Importers will not generally be required to obtain certifications, but certifications may be used by the FDA to determine whether to admit certain imported food that poses a safety risk into the United States.

The two proposed rules, which are available for public comment for the next 120 days at <http://go.usa.gov/j5xG>, will help the FDA create an integrated import oversight system that works efficiently to improve food safety and protect the public health.

These proposals work in concert with the proposed rules released in January 2013, for produce safety and preventive controls in facilities that produce human food. Those proposed rules are currently open for comment until September 16, 2013, but the FDA intends to grant a 60-day final extension of the comment period to allow commenters an opportunity to consider the interrelationships between the January proposals and the two proposals being announced today.

For more information:

- [FDA Food Safety Modernization Act \(FSMA\)](http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm)
(<http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>)
- [Fact Sheet: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals](http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM362557.pdf)
(<http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM362557.pdf>)
- [Fact Sheet: Proposed Rule on Accreditation of Third-Party Auditors](http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM362561.pdf)
(<http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM362561.pdf>)
- [Consumer Update](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm362462.htm) (<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm362462.htm>)

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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