

FDA NEWS RELEASE

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FDA issues first new rules under Food Safety Modernization Act
Rules to prevent potentially unsafe food from reaching consumers

The U.S. Food and Drug Administration today announced two new regulations that will help ensure the safety and security of foods in the United States. The rules are the first to be issued by the FDA under the new authorities granted the agency by the FDA Food Safety Modernization Act (FSMA), signed into law by President Obama in January. Both rules will take effect July 3, 2011.

The first rule strengthens FDA's ability to prevent potentially unsafe food from entering commerce. It allows the FDA to administratively detain food the agency believes has been produced under insanitary or unsafe conditions. Previously, the FDA's ability to detain food products applied only when the agency had credible evidence that a food product presented was contaminated or mislabeled in a way that presented a threat of serious adverse health consequences or death to humans or animals.

Beginning in July, the FDA will be able to detain food products that it has reason to believe are adulterated or misbranded for up to 30 days, if needed, to ensure they are kept out of the marketplace. The products will be kept out of the marketplace while the agency determines whether an enforcement action such as seizure or federal injunction against distribution of the product in commerce is necessary.

Before this new rule, the FDA would often work with state agencies to embargo a food product under the state's legal authority until federal enforcement action could be initiated in federal court. In keeping with other provisions in the FSMA, FDA will continue to work with state agencies on food safety and build stronger ties with those agencies.

"This authority strengthens significantly the FDA's ability to keep potentially harmful food from reaching U.S. consumers," said FDA Deputy Commissioner for Foods Mike Taylor. "It is a prime example of how the new food safety law allows FDA to build prevention into our food safety system."

The second rule requires anyone importing food into the United States to inform the FDA if any country has refused entry to the same product, including food for animals.

This new requirement will provide the agency with more information about foods that are being imported, which improves the FDA's ability to target foods that may pose a significant risk to public health.

This new reporting requirement will be administered through the FDA's prior notice system for incoming shipments of imported food established under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

With prior notice, in the event of a credible threat for a specific product or a specific manufacturer or processor, the FDA is able to mobilize and assist in the detention and removal of products that may pose a serious health threat to humans or animals.

"The new information on imports can help the FDA make better informed decisions in managing the potential risks of imported food entering the United States," Taylor said. "These rules will be followed later this year and next year by a series of proposed rules for both domestic and imported food that will help the FDA continue building the new food safety system called for by Congress."

The issuance of these rules is the latest accomplishment of FDA in implementing the new food safety law. In April, the FDA launched a consumer-friendly web search engine for recall information and issued the first annual report to Congress describing FDA's activities in protecting the U.S. food supply. FDA also released a guidance document to the seafood industry on ways to reduce or eliminate food safety hazards.

In addition, since the law was signed, the FDA has held two large public meetings with industry and consumer groups on the import and preventive control provisions of the law, and reached out extensively to partners in other federal, state, and foreign governments.

For more information:

- FDA Web Page: Food Safety Modernization Act (<http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>)
- Federal Register Notice for Interim Final Rule on Criteria Used to Order Administrative Detention of Food for Human or Animal Consumption http://www.ofr.gov/OFRUpload/OFRData/2011-10953_PI.pdf
- Federal Register Notice for Interim Final Rule on Information Required in Prior Notice of Imported Food http://www.ofr.gov/OFRUpload/OFRData/2011-10955_PI.pdf

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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