

Dear Interested Stakeholder:

As you may know, the U.S. Food Safety Modernization Act (FSMA), signed into law in 2011, enables the U.S. Food & Drug Administration (FDA) to focus its food safety efforts on preventing problems rather than relying primarily on reacting to problems after they occur. Since January 2013, the FDA has proposed seven risk-based, foundational rules to implement FSMA.

The FDA conducted extensive outreach to industry, academia, consumer groups, tribal governments, trading partners, international stakeholders, and the agency's counterparts at the federal, state and local levels and received thousands of comments in response to the proposed rules published in the Federal Register. In October 2014, FDA re-proposed four of the seven rules based on feedback from the public comments. The agency has crafted the rules in a way that is flexible and practical, and seeks voluntary compliance before enforcement.

Once all seven foundational FSMA rules are finalized in 2016, they will work together in a risk-based way to systematically prevent food contamination throughout the food production process, strengthening the food safety system, and better protecting the public. The earliest compliance dates for certain firms begin in late 2016.

These final rules rely on strong partnerships with industry and foreign governments to ensure the safety of their human and animal food products. They are the result of extensive outreach by the FDA with domestic and international stakeholders. These final rules, including the amendments FDA made to the original proposed rules, illustrate the importance of stakeholder input, including the public comment process. The FDA will continue to make every effort to engage with all stakeholders -- including international stakeholders - throughout implementation of the final regulations.

CONTENT OF THE FINAL RULES

-The Preventive Controls for Human Food final rule will update current good manufacturing practices to require companies to evaluate potential hazards and institute preventive controls to mitigate those hazards.

-The Preventive Controls for Animal Food rule requires preventive controls and establishes, for the first time, current good manufacturing practices for animal food.

-The rules are risk-based. Facilities that produce either human food or animal food are not required to implement new controls for foods that do not pose a hazard to health. Additionally, facilities have flexibility with respect to the types of measures that they can take to control for any particular hazard. They will be able to continue to use the same techniques that they are using today as long as they deem them to be adequate.

-The final rules apply to both domestic and foreign facilities for the portion of the U.S. food supply under FDA jurisdiction. The rules do not apply to meat, poultry, and egg products, which remain under the jurisdiction of the U.S. Department of Agriculture (USDA).

- The FDA encourages foreign industry, government, and other international stakeholders to contact FDA for additional information. <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

FOR MORE INFORMATION:

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM414867.htm>

FSMA FAQ:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm>

FSMA page:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

Preventive controls for human food:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

Preventive controls for animal food:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm>

Foreign supplier verification program:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm>

Produce safety:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>