



# THE COMMITTEE ON ENERGY AND COMMERCE

## MEMORANDUM

February 3, 2014

To: Health Subcommittee Members

From: Majority Committee Staff

Re: Hearing entitled "Examining the Implementation of the Food Safety Modernization Act"

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On Wednesday, February 5, 2013, the Subcommittee on Health will hold a hearing entitled "Examining the Implementation of the Food Safety Modernization Act." The Subcommittee will convene at 10:00 a.m. in 2322 Rayburn House Office Building. This hearing will focus on the Food and Drug Administration's (FDA) implementation of the Food Safety Modernization Act (FSMA). Below is background on the witness and FSMA.

### **I. Witness**

Michael R. Taylor, J.D.  
Deputy Commissioner for Foods and Veterinary Medicine  
Food and Drug Administration

### **II. Background**

The FSMA was signed into law by President Obama on January 4, 2011. Under FSMA, FDA is responsible for issuing numerous regulations and guidance documents that will affect the wide array of individuals and industries associated with our nation's food supply. Since January 2013, the agency has issued a number of proposed rules and received a significant amount of comments in response. The following is a brief description of some of the major FSMA rules along with relevant timelines:

*1. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventative Controls for Human Food*

FDA issued a proposed rule on preventative controls for human food on January 4, 2013. In general, the rule would require food facilities to evaluate hazards, implement controls to prevent or minimize them, and maintain related records. The comment period closed in November 2013, but FDA released a statement in December stating that based on particular concerns that were raised, the agency would revise and republish certain sections by "early summer 2014" for additional comment (along with an updated proposed rule on produce safety, discussed below).

*2. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*

FDA issued a proposed rule on produce safety on January 4, 2013, as well. The rule would establish standards and requirements related to the production, harvesting, handling, and packing of fruits and vegetables. Like the preventative controls rule, based on concerns raised by farmers and other stakeholders, FDA is revising and will be reissuing the proposed rule for comment. In general, the changes will address sections covering water quality standards and testing, standards for using raw manure and compost, certain provisions affecting mixed-use facilities (i.e., farms with processing facilities), and procedures used to withdraw a qualified exemption from such requirements for certain farms. FDA has stated that that the agency may decide to include other changes based on additional feedback.

*3. Food Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals*

In July 2013, FDA issued a proposed rule under which importers would be required to verify that their food and ingredient suppliers are meeting U.S. safety standards. The initial comment period was extended until January 27, 2014.

*4. Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certification*

Related to and issued in conjunction with the FSVP proposal, FDA issued a proposed rule that would establish a program for accreditation of third-party auditors to conduct food safety audits and issue certifications of foreign facilities and the foods they produce for both humans and animals. The extended comment period for this proposal also ended on January 27.

*5. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventative Controls for Food for Animals*

On October 29, 2013, FDA issued a proposed rule on preventative controls for animal feed and recently extended the comment period until March 31, 2014. Under the proposal, facilities that manufacture, process, pack, or hold food for animals would be required to adhere to current good manufacturing practices and to implement hazard analysis and risk-based preventative controls.

*6. Focused Mitigation Strategies to Protect Food Against Intentional Adulteration*

The intentional adulteration proposed rule was issued on December 24, 2013, and will remain open for comment until March 31, 2014. It would require large food businesses in the U.S. and abroad to take steps to prevent facilities from being the target of intentional attempts to contaminate the food supply.

*7. Sanitary Transportation of Human and Animal Food*

On January 31, 2014, FDA proposed the food transportation rule under FSMA. The comment period for the sanitary transportation proposal will remain open until May, 31, 2014. The rule would establish standards governing sanitary practices by shippers, carriers by motor

vehicle and rail, and receivers engaged in the transportation of food products for humans and animals.

**III. Staff Contacts**

Should you have any questions concerning this hearing, please contact Carly McWilliams or John Stone at (202) 225-2927.