

## **Food Safety Modernization Act Set To Bring Big Changes To Food And Feed Industry**

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Individuals and businesses engaged in processing, packing, or holding food for human consumption, manufacturing or processing animal feed, growing produce, or transporting food may soon need to comply with a myriad of new rules and regulations promulgated by the Food and Drug Administration (“FDA”) implementing the Food Safety Modernization Act (“FSMA”) (Public L. 111-353). The FDA is set to release many of these proposed regulations in late October or November 2011 for public review and comment.

On January 4, 2011, President Barack Obama signed FSMA into law which amended the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq. FSMA aims to ensure the safety of the U.S. food supply by shifting the focus from responding to contamination to preventing contamination. The new law, however, gives the FDA broad new authority and oversight over both human and animal feed facilities in the U.S. and abroad and places numerous new obligations on those engaged in the food and feed industry.

The law applies to most facilities registered with the FDA under the Bioterrorism Act of 2002 which includes “any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States” and requires those facilities to renew their registration with the FDA biennially. The first renewal registration period will be October 1, 2012 thru December 31, 2012.

FSMA requires most registered facilities to identify, evaluate, and develop a written analysis of known or reasonably foreseeable hazards (including physical, chemical, and/or biological hazards) that could affect food manufactured, processed, packed, or held by such facilities. Further, the law requires those facilities to implement comprehensive, preventative controls which are scientific, risk based practices that a facility can take to prevent or significantly minimize the likelihood of adulterated or misbranded food or feed. FSMA mandates that each facility prepare a written preventative control plan specific to the facility to describe the procedures used by the facility. In the plan, facilities area also to monitor the performance of those controls such as through product and environmental testing or supplier-verification activities, and to specify the corrective actions to be taken when the controls are found to be ineffective.

In conjunction with this portion of the law, the FDA is expected to promulgate regulations to require facilities to adopt and implement certain prerequisite current good manufacturing practices (“CGMPs”). These CGMPs are expected to cover such topics as personnel training, upkeep and sanitation of facilities, access to and maintenance of equipment, storage, and manufacturing operations.

FSMA provides certain exemptions and/or modification of these requirements for “very small” facilities and for facilities in compliance with the FDA’s Seafood Hazard Analysis Critical Control Points Program (“HACCP”) or the Juice Hazard Analysis Critical Control Points Program. The FDA, however, has yet to promulgate regulations defining “very small” facility.

FSMA also imposes new recordkeeping requirements. In addition to the written hazard analysis and control plans, facilities also must keep records of their routine monitoring of the adequacy and effectiveness of such controls, including records of test results, instances of nonconformance, and corrective actions taken. FSMA also grants the FDA authority to promulgate additional recordkeeping requirements related to the previous sources and subsequent recipients of food.

FSMA also mandates increased FDA inspections. Under FSMA, inspections are to be based on risk and the frequency of such inspections are to increase. The law calls for all high-risk domestic food facilities to be inspected within five years of January 4, 2011, and then at least once every three years thereafter. All other domestic food facilities are to be inspected within seven years of January 4, 2011, and then at least once every five years thereafter. The law also mandates increased inspections of foreign facilities.

FSMA provides for the collection of new fees. Specifically, the law authorizes the FDA to assess and collect fees related to facility reinspections and importer reinspections. A facility or importer reinspection is an inspection conducted by the FDA following a previous inspection that revealed a material violation. The FDA conducts reinspections to determine that compliance has been achieved. Under FSMA, the FDA will invoice a facility for the direct hours spent performing the reinspection multiplied by the FDA-established hourly rate. For October 1, 2011 through September 30, 2012, FDA set the hourly rate at \$224 per hour for domestic reinspections and \$325 per hour if foreign travel is required. Payment must be made within 30 days of the invoice date. There is no reduced fee rate for small businesses. However, the FDA has indicated that it may consider waiving in limited cases some or all of a fee based on “severe economic hardship”, the nature and extent of the violation, and other relevant factors. Currently, there is no fee for an initial FDA inspection.

FSMA brings changes to those importing food products. For the first time, importers of foods are now required to implement a program to verify that their foreign suppliers have adequate preventative controls in place that provide the same level of protection as those required under FSMA.

In addition to regulating certain food and animal feed facilities and importers, FSMA places additional requirements upon produce growers. Under FSMA, the FDA is required to establish science-based minimum standards for the safe production and harvesting of fruits and vegetables. These standards must consider naturally occurring hazards as well as those that may be introduced unintentionally or intentionally. The regulations will consider materials added to the soil, hygiene, packaging, temperature controls, water, and animals in the growing area. The law provides a modification of the requirements for small and very small businesses as well as a limited exemption for direct farm marketing.

FSMA also increases FDA's authority to enforce its rules and regulations through registration suspension, expanded administrative detention, and mandatory recalls.

Under FSMA, FDA now has the authority to suspend a facility's registration thereby preventing that facility from introducing any food into commerce in the United States and effectively shutting down the facility. The FDA may suspend a facility's registration if it determines that food "manufactured, processed, packed, received, or held by a facility . . . has a reasonable probability of causing serious adverse health consequences or death to humans or animals" and that facility either "created, caused or was otherwise responsible for such reasonable probability" or "knew of, or had reason to know of, such reasonable probability and . . . packed, received or held such food." 21 U.S.C. 350d(b). To be reinstated, the facility must submit a corrective action plan that demonstrates how the registrant plans to correct the conditions found by the FDA.

FSMA provides the FDA with expanded administrative detention authority by authorizing the FDA to administratively detain articles of food the FDA has "reason to believe" may be adulterated or misbranded. Under the prior law, to detain food, the FDA needed "credible evidence or information" that an article of food "present[ed] a threat of serious adverse health consequences or death to humans or animals".

Also, for the first time, FSMA grants the FDA mandatory recall authority for all food products. Before imposing a mandatory recall, the FDA is required to first give a responsible party the opportunity to cease distribution and conduct a voluntary recall. If the responsible party does not voluntarily recall the produce within the time frame and manner prescribed by the FDA, the FDA may proceed with a mandatory recall. The FDA is also authorized to assess and collect fees for food recall activities where a facility does not comply with a recall order. The same hourly rates applicable to reinspections apply to recalls.

FSMA sets a deadline of July 3, 2012, for the FDA to issue final regulations under the act. The FDA has indicated that it may provide a staggered phase-in period for certain regulations, based on the size of the facility (i.e., requiring compliance by the largest companies first and giving the smallest companies up to three years to comply).

**IMPORTANT:** The foregoing is intended as educational in nature and not legal advice. Competent legal counsel should be contacted with respect to questions about compliance with the FSMA and related issues. For questions about this article, contact: **Kristi Kress Wilhelmy** at BARRETT, EASTERDAY, CUNNINGHAM & ESELGROTH LLP; phone: 614-210-1840; E-Mail: [kkwilhelmy@farmlawyers.com](mailto:kkwilhelmy@farmlawyers.com)