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# FDA Law Update

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## President Obama Signs New Expansive Food Safety Law

*By Deborah M. Shelton*

In the flurry of legislation passed by the 111th Congress in its final days, the Food Safety and Modernization Act (FSMA) cleared the Senate by unanimous voice vote on December 20, passed the House 215-144 the following day, and was signed into law by President Obama on January 4, 2011 ("date of enactment"), immediately upon returning from his holiday vacation in Hawaii.

The FSMA amends the Food, Drug, and Cosmetic Act ("FDCA") to confer FDA with significant additional authorities over food products, including the mandatory recalls and expanded inspection authority. The further strengthening of FDA's enforcement authorities over food products follows a spate of recent reports of tainted food products, including, for example, eggs, tomatoes, spinach, and peanuts.

With the enactment of this legislation, uncertainty now looms about how it will be funded. The CBO projects the cost of implementation of the FSMA to be approximately $1.4 billion over the next 5 years. The funding issue is further complicated by the fact that the legislation was passed in the final days of the 111th Congress, so it is the newly seated 112th Congress, with its shift in power in the House, that is charged with its funding. Concerns have been raised already by some members as to the cost of this legislation.

Although many of the new requirements imposed by the FSMA do not take effect immediately, there are a few significant requirements that do, including: (1) FDA's enhanced inspectional authority; (2) FDA's mandatory recall authority; (3) FDA's authority to require import certifications; (4) FDA's expanded authority to order an administrative detention; and (5) the protections provided to employees who provide information to the government about an employer's FDCA violations. These provisions are discussed below, followed by a brief summary of some of the other key provisions.

**Enhanced Inspectional Authority** – Section 101 of the FSMA expands FDA's authority to inspect records of any entity (excluding farms and restaurants) that manufactures, processes, packs, distributes, receives, holds, or imports food products. The trigger for FDA's enhanced inspectional authority is broad: "a reasonable belief that an article of food, and any other article of food that [FDA] reasonably believes is likely to be affected in a similar manner." The records for which FDA is given authority to access and copy is similarly broad, and includes any records for the foregoing that "are needed to assist [FDA] in determining whether there is a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals."

**Mandatory Recall Authority** – Section 206 of the FSMA amends the FDCA to add Section 423, which provides FDA with the authority to require a recall. FDA may invoke its mandatory recall authority based upon the Agency's determination that there is a "reasonable probability" that an article of food (other than infant formula) is adulterated or misbranded and the use of such food will cause "serious adverse health consequences or death to humans or animals." Prior to invoking its mandatory recall authority, FDA must first provide the

applicable entity an opportunity to voluntarily cease distribution and recall the food. If the company does not do so voluntarily, FDA may then order a recall.

In addition, to further increase transparency into FDA recalls, the Agency must, within 90 days after the date of enactment, update FDA's website to provide users with the capability to search for all recall information, including status.

**Authority to Require Import Certifications for Food** – Section 303 of the FSMA requires refusal of admission for any imported food that fails to meet the certification requirements or other assurance that the food meets all applicable FDCA requirements. Section 304 of the FSMA further directs that FDA require, prior to importation of a food product, notice of any country to which such article has been refused entry. Section 306 requires the refusal of admission into the U.S. any imported food from a foreign facility to which a U.S. inspector is refused entry for inspection. Finally, Section 308 requires FDA, within 2 years of the date of enactment, to establish a system to recognize entities that accredit third-party auditors to certify that eligible entities meet all applicable FDCA requirements for importation of food into the U.S.

**Administrative Detention of Food** – Section 207 of the FSMA strengthens FDA's authority to order an administrative detention of food product by broadening the standard from "credible evidence or information" to that of "reason to believe," and "presents a threat of serious health consequences or death to humans or animals" to "adulterated or misbranded."

**Employee Protections** – Section 402 of the FSMA provides whistleblower protections for employees of entities involved in the manufacturing, processing, packing, transporting, distributing, receiving, holding or importing food who provide information relating to any violation of the FDCA.

In addition to the above provisions which take effect immediately, the FSMA also includes several other provisions, including, for example, the following:

**Registration of Food Facilities** – Section 102 of the FSMA expands the food-facility registration requirement by (1) requiring biennial renewal by registrants; (2) giving FDA the authority to suspend a registration if the Agency deems a food associated with that facility to have "a reasonable probability of causing serious adverse health consequences or death to humans or animals; and (3) giving FDA the discretion to require a registration for "any other food categories" determined appropriate by FDA, whether by regulation or guidance.

The new registration requirements take effect on the earlier of the date of FDA's issuance of implementing regulations (which may include interim final regulations) or 180 days after the date of enactment.

**Hazard Analysis and Risk-Based Preventive Controls** – Section 103 of the FSMA requires food facilities to have in place numerous HACCP-like controls. Specifically, each owner, operator, or agent in charge of a food facility must (1) evaluate the hazards that could affect the applicable food products; (2) identify and implement preventive controls to "significantly minimize or prevent" those hazards and provide assurances that the food is not adulterated or misbranded; (3) monitor the performance of those preventive controls; and (4) maintain records of such routine monitoring.

These requirements take effect 18 months after the date of enactment.Notably, however, the FSMA provides additional time for compliance by a "small business" and a "very small business," both terms to be defined by FDA regulation. An entity meeting the definition of a "small business" has until 6 months after the effective date of FDA's final regulations to comply, and a "very small business" has until 18 months after that same effective date.

Seafood, juice, and low-acid canned food facilities subject to HACCP are exempt from the FSMA hazard

analysis and risk-based preventive controls. In addition, these controls do not apply to a facility's activities that are subject to the standards for produce safety codified at Section 419 of the FDCA. Finally, certain small business and other facilities with limited sales meeting the FSMA definition of a "qualified facility" are eligible for an exemption from full hazard analysis and risk-based preventive control requirements. Notably, however, such a "qualified facility" is still subject to specific documentation submission and labeling requirements as set forth in the FSMA.

Within 18 months of the date of enactment, FDA is required to issue regulations establishing minimum standards for compliance with the hazard analysis and risk-based preventive control requirements, and is also required to issue industry guidance related to those regulations.

**Produce Safety** – Section 105 of the FSMA requires FDA, to issue regulations establishing "science-based minimum standards for the safe production and harvesting" of the types of fruits and vegetables that are "raw agricultural commodities" for which FDA has determined that "such standards minimize the risk of serious adverse health consequences or death." FDA is required to promulgate these regulation in coordination with USDA, state departments of agriculture, and in consultation with Homeland Security.

The FSMA provides FDA with the discretion to exclude from such rulemaking, or otherwise modify as applicable, the production and harvesting of fruits and vegetables by small business and very small businesses that FDA has determined are "low risk and do not present a risk of serious adverse health consequences or death."

Direct farm marketing is also exempt from these requirements. Specifically, the FSMA provides that farms are exempt if during the previous 3-year period, the average annual monetary value of the food sold by such farm directly to "qualified end-users" during that period exceeded the average annual monetary value of the food sold by such farm to all other buyers; and the average annual monetary value of all food sold during such period was less than $500,000 adjusted for inflation. For purposes of this exemption, a "qualified end user" is defined as a non-commercial consumer or restaurant or retail food establishment) located either in the same state, or within 275 miles, of that farm. Foods exempt from these requirements pursuant to the exemption for direct farm marketing are subject to certain labeling requirements (if a packaging label is required for that food) or similar notification (if a food packaging label is not required for that food product).

In addition, these produce safety requirements are not applicable to activities of a facility subject to the HACCP-like controls set forth in Section 103 of the FSMA.

In terms of the timing of the notice-and-comment rulemaking process itself, FDA is required to publish a notice of proposed rulemaking within one year after the date of enactment, and then issue a final regulation not later than 1 year after the close of the comment period for the proposed rulemaking. Similar to other FSMA provisions, FDA is required to issue a small entity compliance guide on these requirements within 180 days after issuing the final regulations.

In addition to the regulations, the FSMA requires FDA, within one year after date of enactment, to issue guidance providing updated good agricultural practices and guidance for the safe production and harvesting of specific types of fresh product. FDA is also required to hold at least 3 public meetings in diverse geographical areas of the U.S. to conduct related education and outreach.

Notably, the FSMA explicitly states that none of the new federal produce safety requirements preempt state, local, country or other non-federal law regarding the safe production, harvesting, holding, transporting, and sale of fresh fruits and vegetables, and that compliance with the federal requirements shall not relieve one from either common law liability or liability under codified state law.

**Protection Against Intentional Adulteration** – Section 106 requires FDA, in coordination with the Department of Homeland Security and in consultation with the Department of Agriculture, to issue regulations to protect against the intentional adulteration of food. Specifically, these regulations are to specify how an assessment should be made as to whether one must implement mitigation strategies or measures intended to protect against the intentional adulteration of food, and, as appropriate, to specify science-based mitigation strategies or measures to prepare and protect the food supply chain at vulnerable points. FDA is required to issue such regulations within 18 months after date of enactment of the FSMA.

Section 106 further limits the applicability of these regulations, however, only to food for which there is a high risk of intentional contamination --as determined by FDA in consultation with the Department of Homeland Security -- that could cause serious adverse health consequences or death to humans or animals, including those foods for which there has been identified clear vulnerabilities (including short-self-life or susceptibility to intentional contamination at critical control points) prior to being packaged for the end user.

Farms (except for those that produce milk) are exempt from these regulations. For purposes of this exemption, a "farm" is a facility satisfying the definition set forth in 21 C.F.R. 1.227 (i.e., a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both.

In addition to the issuance of these regulations, Section 106 requires FDA to issue guidance documents further clarifying these requirements pertaining to the protection against the intentional adulteration of food. FDA is required to issue such guidance within a year after the date of enactment of the FSMA.

**Foreign Supplier Verification Program** – Section 301 of the FSMA requires U.S. importers to verify, via risk-based foreign supplier verification activities, that imported food is produced in compliance with all applicable requirements pertaining to hazard analysis and standards for product safety, and is not adulterated or misbranded.

Within one year of the date of enactment of the FSMA, FDA is required to issue regulations to provide for the content of this foreign supplier verification program. Also within 1 year after the date of enactment of the FSMA, FDA is required to issue guidance to assist importers in developing such programs.

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The foregoing is intended to provide a high-level overview of some of the key provisions of the Food Safety Modernization Act. As FDA's implementation efforts get underway, more detailed information will be provided.

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