Legal and Practical Effects of the FDA Food Safety Modernization Act

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Food producers, suppliers and consumers have a shared interest in the safety of America's food supply. The U.S. Food and Drug Administration (FDA) reports that foodborne illnesses strike 48 million people each year, resulting in 128,000 hospitalizations and 3,000 deaths.[1] In recent years, the United States has experienced large scale outbreaks of salmonella contamination in eggs and peanut butter, as well as numerous other less publicized food contamination cases. By some estimates, the peanut butter recall cost peanut producers $1 billion in lost production and sales.[2] Not surprisingly, producers of these contaminated foods have faced numerous consumer lawsuits.

Partly in response to these recent outbreaks, Congress passed the FDA Food Safety Modernization Act (FSMA), which was signed into law on January 4, 2011. This article discusses the major provisions of the FSMA and some of its legal and practical effects on the food industry.

The FSMA refocuses FDA's authority towards preventative controls. For example, the FSMA requires food facilities to develop written hazard analysis and preventative control plans. It also mandates FDA to increase the number of facility inspections. The FSMA also increases FDA's authority to react to actual and potential food contamination outbreaks by giving FDA the authority to order mandatory recalls and expanding its authority for administrative detentions.

Hazard Analysis & Preventative Controls Plans. Section 103 of the FSMA (21 U.S.C. 350g) requires the owner, operator or agent in charge of a food facility to develop a written plan which: evaluates hazards that can affect food manufactured, processed, packaged or held by the facility; implements preventive controls to significantly minimize hazards and assure that its food is not adulterated; monitors the performance of those controls and maintains records of this monitoring; establishes procedures to ensure that if the preventive controls are not properly implemented or are not effective, action will be taken to prevent recurrence, and that all affected food is evaluated for safety and prevented from entering commerce if the facility cannot ensure that the food is not adulterated. The written plan must be reanalyzed every three years and whenever there is significant change in the facility's activities. The written plan and documentation of preventative controls must be "promptly" provided to FDA upon oral or written request. FDA must issue regulations establishing science-based minimum standards for hazard analysis and preventative controls by July 4, 2012.

A facility that is subject to HACCP regulations (*e.g.*, seafood and juice facilities) is exempt from Section 103. Also exempt are "Qualified Facilities" which meet the criteria for a "Very Small Business", a term which Congress directed FDA to define by regulation, and facilities with limited sales (*i.e.*, the average monetary value of all food sold by the business is less than $500,000 per year for the previous three-year period). This and other criteria mandated by Congress will ensure that the Qualified Facilities exemption is a very narrow one.

Qualified Facilities will be required to submit certain documentation to FDA demonstrating: (a) that the facility's management has identified potential hazards and has implemented and will monitor preventative controls; or (b) compliance with state and/or local food safety laws. FDA is required to issue guidelines for the documentation required of Qualified Facilities by January 4, 2012.

Some argue that Section 103 will have a disparate impact on non-exempt small businesses.[3] Small companies may lack personnel with the requisite expertise to develop the type of plan FDA will require and, thus, be forced to retain outside consultants and/or hire extra personnel to develop, implement or monitor the plan. FDA is required to consider companies of all sizes when it proposes and implements regulations on the minimum standards for hazard analysis plans. Section 103's impact on the food industry will be difficult to determine until FDA issues these rules.

Facility Inspections. While FDA has long had the authority to inspect a food facility, Section 201 of the FSMA (21 U.S.C. 350j) requires FDA to allocate the resources necessary to inspect all registered food facilities more frequently using a prioritization system that is based on safety risks. Domestic high risk facilities must be inspected at least once in the five-year period following January 4, 2011 and at least every three years after that. Domestic non-high risk facilities must be inspected at least once during the seven-year period following January 4, 2011, and at least every five years after that. FDA must inspect at least 600 foreign facilities by January 4, 2012 and must double the previous year's number of inspections each year through 2017. Factors for determining whether a facility is "high risk" include the known safety risks of the food(s) at the facility and the facility's history of compliance, violations and outbreaks.

Funding will play a critical role in FDA's implementation of the FSMA's inspection mandates. As FDA concedes, "Without additional funding, FDA will be challenged in implementing the legislation without compromising other key functions."[4] Regardless of funding, companies at all levels of the food supply chain should expect to be inspected by FDA more frequently than they have been in the past.

Inspection of Records. Under Section 101 of the FSMA (21 U.S.C. § 350c), FDA can now demand immediate access to company records relating to a food that it reasonably believes to be adulterated and which presents a serious risk of adverse health consequences or death to humans or animals. Prior to the FSMA, FDA was required to initiate a court action to obtain these records if the company did not voluntarily turn them over. Certain types of records are exempt from Section 101, such as recipes, financial, sales and pricing data, research data and personnel data. This provision became effective immediately upon being signed into law.

Mandatory Recalls. Section 206 of the FSMA (21 U.S.C. § 350l) gives FDA authority to order that all distribution of an adulterated or misbranded food be ceased and that the food be recalled, if FDA determines that there is a reasonable probability that food will cause serious adverse health consequences or death in humans or animals. FDA is also authorized to notify all necessary parties in the supply chain to cease distribution. However, FDA must first provide the responsible party with the opportunity to initiate its own recall voluntarily. The party against whom a recall order is issued is entitled to a hearing within two days of issuance of the order. FDA gained this mandatory recall authority immediately upon the FSMA's enactment.

Some commentators argue that FDA's new authority will actually discourage or slow down the recall process because the previous system placed the onus on the company to initiate a recall in order to avoid a possible seizure and public relations damage from FDA alerts and press releases.[5] FDA's mandatory recall authority could shift the pressure to FDA because the seller may now have some cover if it decides to wait for FDA to issue a recall order.[6] Others welcome FDA's new power, saying that FDA's previous lack of recall authority slowed responses to

serious outbreaks.[7] FDA's current position is that "mandatory recall authority will be used in rare instances."[8]

The language of Section 206's mandatory recall authority closely tracks FDA's criteria for Class I recalls, which addresses the most serious food contamination outbreaks that would expose companies to the greatest risk of liability to consumers. Nothing in the FSMA revokes FDA's ability to use consumer alerts and press releases to encourage companies to quickly initiate a recall. Nor does the FSMA limit FDA's power to pursue a seizure. Companies should, therefore, retain the same motivation (or lack thereof) to adhere to FDA requests for a "voluntary" recall. Less serious Level II and III outbreaks will likely be addressed by measures less drastic than mandatory recall, such as FDA's expanded authority for administrative detentions.

Administrative Detentions. Section 207 of the FSMA (21 U.S.C. § 334(h)) permits any FDA officer or qualified employee to order the detention of a food if he or she has a reason to believe that the food is adulterated or misbranded. FDA is authorized to detain the food for twenty days, with the possibility of obtaining a ten-day extension. Depending on findings made during the detention period, FDA may impose a corrective action plan or exercise its long-held authority to initiate a court proceeding to seize and condemn the food. Section 207 repealed the previous requirement of "credible evidence or information" that the food presents a risk of serious adverse health consequences. This provision became effective in June 2011.

FDA's expanded administrative detention authority has the potential to become a significant enforcement tool. At a June 2011 public meeting at FDA headquarters, food industry participants expressed concern that FDA could use this authority to detain a product that was adulterated or misbranded, but which did not present a health risk. FDA representatives acknowledged that the FSMA now gives FDA this authority, but emphasized that public health would be the primary concern driving decisions about whether to detain food.

FDA has not used its administrative detention powers since it was granted that authority in 2004 (under the more strict standard).[9] But under the new criteria, FDA is "more likely to use administrative detention against articles of food in situations … where … a volatile product may cause temporary or reversible adverse health consequences or where the probability of serious adverse health consequences is remote." This is essentially the criteria for Class II recalls.[10]

The food industry can expect the number of voluntary Class II recalls requested by FDA to decrease, as the number of administrative detentions increases significantly. Detention of foods for technical violations that do not impact consumer safety (*e.g.*, minor labeling violations) should not be an issue, absent other compliance problems for the company. Although an administrative detention will likely interrupt a company's operations to some degree and could become costly, it is probably less burdensome and costly than a Class II recall.

Food Facility Registration. Section 102 of the FSMA (21 U.S. C. § 350d) adds two major provisions regarding registration of food facilities. First, although it was previously mandatory for food facilities to register with FDA, now these facilities must renew their registration every odd-numbered year. Second, FDA can suspend a facility's registration if the agency determines that a food from the facility has a reasonable probability of causing serious adverse health consequences or death. A suspension prohibits any food from that facility from being introduced into commerce (*e.g.*, sales, distribution, imports and exports). The facility's registrant is entitled to a hearing on an order of suspension within two days of issuance of the order. These provisions became effective in June 2011.

Other Provisions. The FSMA also includes several other provisions, such as requirements for FDA to: propose regulations for the safe production and harvesting of certain vegetables and fruit; initiate pilot programs for enhancing the tracking and traceability of foods; exercise greater oversight over imported foods; and issue guidance as to what constitutes a New Dietary Ingredient for which pre-market notification must be given to FDA.[11]

Criticism of FSMA. In addition to concerns expressed above, some commentators are critical that the FSMA does not do anything to unify the federal food safety regulatory system.[12] Although FDA regulates approximately 80% of the country's food supply, the U.S. Department of Agriculture (USDA) regulates most meat and poultry, as well as egg products (but not eggs still in their shells, which fall under FDA jurisdiction).[13] USDA's Food Safety and Inspection Service oversees an extensive inspection program and has its own voluntary recall policies. Although USDA partners with FDA on many food safety programs, the FSMA does not apply to any USDA-regulated food.

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[1] FSMA, Frequently Asked Questions, http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm.

[2] Peanut Industry: Recall Price Tag $1 billion, http://www.msnbc.msn.com/id/29634279/ns/business-going_green/t/peanut-industry-recall-price-tag-billion/.

[3] *See* Josh Ozerky, *The Food Safety Bill: Flawed, and Needed*, TIME, http://www.time.com/time/nation/article/0,8599,2035806,00.html.

[4] FSMA, Frequently Asked Questions, *supra*.

[5] Kenneth Odza, *Unintended Consequences of FDA Mandatory Recall Authority*, Food Liability Law Blog (December 10, 2009).

[6] *Id.*

[7] Katie Stewart, JD, MPH and Lawrence O. Gostin, JD, *Food & Drug Administration Regulation of Food Safety*, Journal of the American Medical Association, Vol. 306, No. 1 (July 6, 2011).

[8] FSMA, Frequently Asked Questions, http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm.

[9] Criteria Used to Order Administrative Detention of Foods for Human or Animal Consumption, Interim Final Rule; Request for Comments., FED. REG. 25540, 25538, 25440 (May 5, 2011).

[10] *Id.*

[11] FDA issued a draft guidance document regarding NDI criteria on July 5, 2011 and is accepting public comments.

[12] Stewart and Gostin, *supra*.

[13] *Id.*