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FDA Food Safety Modernization Act Greatly Expands FDA Enforcement Powers

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Following final congressional passage on December 21, President Obama is expected to sign into law H.R. 2751, the Food and Drug Administration (FDA or the Agency) Food Safety Modernization Act (the Act). By amending the Federal Food, Drug, and Cosmetic Act (FFDCA), the Act creates a sweeping overhaul of the federal food safety regulatory system. The Act expands the FDA's authority to regulate food manufacturing, processing, and distribution facilities. Additionally, the Agency receives expanded inspection authority and is directed to establish a food registry of known or foreseeable hazards and to establish risk mitigation plans to prevent food contamination. Of perhaps the most importance is Section 206, which for the first time gives FDA authority to order recalls of food if the Agency determines that removal of the article from interstate commerce is necessary. The new Act thus has significant effects on food and food additive manufacturers, processors, and distributors.

Prior to the passage of the Act, the FDA did not have the authority to order a food recall. Food regulating agencies, such as the FDA and the U.S. Department of Agriculture (USDA), would negotiate with affected food facilities, which ultimately would conduct recalls voluntarily. Furthermore, the FDA rarely inspected food facilities and farms. The Act gives a boost to the FDA's inspection mandate and increases the number of inspections of food facilities. Furthermore, it allows the FDA to assess and collect fees, as determined by the Secretary of Health and Human Services (the Secretary) related to (1) food facility re-inspection, (2) food recalls, (3) the voluntary qualified importer program, and (4) importer re-inspection. (Section 107.) Up to $25,000,000 in annual fees may be collected for re-inspection-related costs, and up to $20,000,000 in annual fees may be collected for non-compliance with a recall order. (Section 107.)

The Act requires food producers, facilities, and distributors in the United States to, among other things, evaluate hazards more rigorously, undergo more inspections, implement preventive controls, and follow stricter standards to keep food from becoming adulterated or misbranded. (Sections 101, 103, 105, and 106.) The Act's new standards apply to foods regulated by the FDA. This includes all whole and processed foods, with the exception of meat, poultry, and some egg products, which are regulated by the USDA. (Section 403.) In addition, the Act does not change the definition of "facilities." Thus, if an entity did not need to register with FDA prior to the Act, it still will not need to register. Additionally, with some exceptions, farms and restaurants are exempt from certain portions of the Act.[1] (Sections 101 and 106.)

[1] Farms, except for those that produce milk, are excluded from regulations promulgated by the Secretary to protect against the intentional adulteration of food (Section 106). Farms and restaurants are exempt from the "inspection of records" requirements under Section 101.

Key Provisions

The Act provides FDA with the authority to inspect records related to an article of food when the FDA reasonably believes that the food in question is likely to be adulterated or cause serious adverse health consequences. (Section 101.) Inspection of records may also include any other article of food that FDA reasonably believes is likely to be affected in a similar manner. (Sec 101) Additionally, an administrative detention of food may be ordered if FDA has "reason to believe" that the food is adulterated or misbranded. (Section 207.) Furthermore, the Act requires FDA to complete inspections of "high-risk facilities," as determined by the Secretary, at least once every three years. (Section 201.) However, facilities not identified as "high-risk facilities" will only require FDA inspection once every five years. (Section 201.)

The Act creates a biennial registration renewal process for all food producers. (Section 102.) Additionally, FDA is given the authority to suspend the registration of a food facility if the food manufactured, processed, packed, or held by the facility has a reasonable probability of causing serious adverse health consequences to humans or animals. (Section 102.) Furthermore, all facilities will be required to have preventive plans in place that will enable them to perform a hazard analysis, implement preventive controls, and establish corrective actions. (Section 103.)

Flexibility for Small Businesses

The Act provides regulatory flexibility for small businesses. For example, under Sections 204, 103, and 105 of the Act, small and very small businesses, as defined by FDA, are given additional time to comply with new food safety practices and guidelines. Furthermore, two highly controversial provisions, Sections 103 and 105, exempt farms that sell directly to local consumers with average annual food sales below $500,000 from hazard-analysis and prevention-control requirements as well as from the new standards for produce safety. Under Sections 102, 103, and 105, the Secretary is required to publish several plain-language small-entity compliance guides to assist with the implementation of new practices.

Grants for Compliance Training

The Act makes competitive grants available, for up to three years, to enhance education, training, and technical assistance of food safety officials and small business operators to facilitate the implementation of new standards, examination procedures, inspections and investigations, and related food safety activities. (Section 209.) The Secretary is also authorized to award three-year grants for government entities to conduct examinations, inspections, and investigations; train inspectors; or build food safety program infrastructure for the purposes of determining whether entities are in compliance with the food safety provisions of the Act. (Section 210.)

Imported Food Verification Program

Section 301 requires U.S. importers to perform risk-based foreign supplier verification to ensure that imported food is produced in compliance with applicable hazard analysis requirements and standards for produce safety, and is not adulterated or misbranded. FDA may require certification for high-risk foods entering the United States or may deny admission of foods that lack certification or that are from a foreign facility that has refused U.S. inspectors. (Sections 303 and 306.)

For a more detailed look at the FDA Food Safety Modernization Act, please read our section-by-section summary, available online at http://www.morganlewis.com/pubs/FDA_FoodSafetyModernizationActSummary_jan2011.pdf.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact its authors, **Kathleen M. Sanzo** (202.739.5209; ksanzo@morganlewis.com) and **Stephen Paul Mahinka** (202.739.5205; smahinka@morganlewis.com).

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