Food Safety Legislation Enacted, Expanding FDA's Authority

Congress passed the Food Safety and Modernization Act (the Food Safety Act or the Act)[1] on December 21, 2010, after resolving a procedural hitch that threatened to stall the legislation. President Obama signed the Act into law on January 4, 2011. The Act greatly expands the US Food and Drug Administration's (FDA) authority over regulated foods, in the hope of improving food safety and preventing the types of outbreaks of foodborne illness that occur every year, and often lead to large multi-state recalls.[2] The legislation is intended to reposition FDA as a proactive rather than primarily reactive food regulator, allowing FDA to focus on prevention rather than remediation of food-safety-related incidents. FDA Commissioner Margaret Hamburg has called the Act a "major step in the right direction."[3] For the food industry, the Act is expected to have profound effects on business practices and costs—if funds are appropriated to permit full FDA implementation of the legislation.

The Food Safety Act applies to all food facilities except meat, poultry, and certain egg producers regulated by the US Department of Agriculture (USDA). Large food manufacturers and processers are most affected by the Act. Small farms and small businesses are exempt to varying degrees or subject to modified requirements, if they sell the majority of their food within the same state (or within 275 miles), and have less than $500,000 in annual sales; however, these facilities remain subject to state and local food safety requirements. Some have lauded these exemptions and modifications as a victory for "family farmers" and the local food movement; others have criticized them as undermining the Food Safety Act's science-and risk-based safety paradigm.[4]

1 H.R. 2751, 111th Cong., 2nd Sess. (2010).

2 One example is the outbreak of *Salmonella* Typhimurium in late 2008 and early 2009, associated with a single firm's peanut butter and other peanut-based ingredients, which sickened more than 700 people in 46 states. *See* Congressional Research Service (CRS), "Food Safety in the 111th Congress: H.R. 2749 and S. 510" (Nov. 16, 2010), at p. 2.

3 *Id.,* at p. 6.

4 *See, for example,* J. Banville, "Senate Passes Food Safety Overhaul With Tester's Amendment Exempting Smaller Farmers," *New West Food & Agriculture* (Nov. 30, 2010), *available at* http://www.newwest.net/topic/article/senate_passes_food_safety_overhaul_with_testers_amendment_exempting_smaller/C619/L619/.

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This advisory summarizes major provisions of the enacted Food Safety Act (H.R. 2751). Key features of the Food Safety Act include: requirements for domestic and foreign food facilities to analyze food safety hazards and adopt risk-based controls; increased FDA inspections; mandatory FDA recalls; administrative detention of foods; heightened scrutiny of food imports; enhanced registration and recordkeeping requirements; and increased oversight over certain farms.

MAIN PROVISIONS OF FOOD SAFETY ACT (H.R. 2751)

TITLE I—FOOD SAFETY

Registration (§ 102). The Food Safety Act enhances the existing requirement in the Federal Food, Drug, and Cosmetic Act (FDCA) that food facilities register with FDA. Currently, domestic and foreign food facilities—except for farms, restaurants, retailers, and some other entities[5]—must register once with FDA, and notify FDA of relevant changes in status.[6] The Food Safety Act requires regular renewal of this registration every two years. The exemption for farms, restaurants, retailers, and some other entities remains in effect.

Further, the Act grants FDA a significant new registration-related authority: suspension. The FDA Commissioner can suspend registration based on a determination that "food manufactured, processed, packed, received, or held by a facility registered under this section has a reasonable probability of causing serious adverse health consequences or death to humans or animals."[7] Facilities subject to a suspension are entitled to notice and an opportunity for a hearing. Unless and until the suspension is lifted, suspended facilities cannot import food or introduce food into commerce. This prohibition also applies to facilities that have failed to meet the registration requirement, as before passage of the Food Safety Act.

Hazard Evaluation and Prevention Plans (§ 103). The Food Safety Act requires facilities to adopt a comprehensive hazard-management plan that parallels Hazard Analysis Critical Control Point (HACCP), which FDA currently requires of seafood and juice processors[8] and which the USDA requires of meat and poultry establishments.[9] Food processing, manufacturing, shipping, and other regulated facilities must evaluate and prepare written analyses of known or reasonably foreseeable food safety hazards that could affect food manufactured, processed, packed, transported, or held there (such as chemical hazards, pesticides, parasites, and allergens, whether unintentionally or intentionally introduced) at least every three years or sooner, as appropriate. They must then implement preventive controls to minimize or eliminate such hazards, monitor the effectiveness of such controls, take corrective action as needed, and maintain documentation of the controls. FDA must issue implementing regulations within 18 months of the Act's enactment, establishing science-based minimum standards. Excepted from this hazard evaluation and prevention requirement are facilities already in compliance with an applicable HACCP, facilities in compliance with FDA requirements for low-acid canned foods,[10] facilities manufacturing dietary supplements, and facilities subject to new produce safety requirements established by the Act.

Evidently concerned about the impact of this new requirement on small businesses, Congress directed FDA to "provide [in its regulations] sufficient flexibility to be practicable" for all sizes and types of facilities. Congress also established a later-effective date for small businesses and very small businesses (6 months and 18 months, respectively, after FDA regulations take effect) and directed FDA to issue a Small Entity Compliance Policy Guide to assist small business in achieving compliance. FDA is to define "small business" and "very small business" by regulation. FDA is also prohibited from requiring, through regulation, that businesses hire

5 Other entities excepted are fishing vessels not engaged in processing and certain types of nonprofit food establishments. Federal Food, Drug, and Cosmetic Act (FDCA) § 415, 21 U.S.C. § 350d (2002).

6 FDCA § 415, 21 U.S.C. § 350d.

7 H.R. 2751, § 102(b)(1).

8 *See* http://www.fda.gov/food/foodsafety/hazardanalysiscriticalcontrolpointshaccp/default.htm.

9 *See* 61 Fed. Reg. 38806 (July 25, 1996).

10 *See* http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/AcidifiedLow-AcidCannedFoods/default.htm.

third-party consultants or certifiers except as part of certain enforcement agreements.

Performance Standards (§ 104). Presently, FDA has performance standards in place for only a small number of hazards, such as pesticide tolerances and drug residues; more such standards are expected with passage of the Food Safety Act. The Food Safety Act requires FDA, in coordination with USDA, to review and evaluate health, epidemiological, toxicological, and other data at least every two years, to determine the most significant food contaminants. FDA must issue or revise contaminant-specific and science-based guidance documents, action levels, or regulations, where appropriate to reduce risk of serious illness or death, prevent adulteration of food, or prevent the spread by food of communicable disease. These standards must apply to products or product classes, not to individual facilities. They are intended to help control risk factors in food, ensure acceptable processing controls, and enable FDA to more quickly assess whether a food is safe and whether a facility should be inspected and corrected.

Produce Safety Standards (§ 105). This section of the Food Safety Act is likely to have the most direct effect on on-farm production. Historically, farms have been exempt from many FDA requirements or otherwise subject to less intensive regulation. For example, farms are exempt from FDA's Good Manufacturing Practice (GMP) requirements at 21 C.F.R. Part 110, from FDA registration requirements, and from various record-retention requirements. Instead, FDA mainly relies on voluntary guidance documents to encourage good agricultural practices, with the exception of FDA's final rule requiring eggshell producers to adopt on-farm measures to prevent *Salmonella* contamination.[11]

This practice will change with the Food Safety Act. The Act requires FDA to issue regulations establishing science-based minimum standards for safe production and harvesting of fruits and vegetables (raw agricultural commodities) for which FDA determines such standards minimize the risk of serious adverse health consequences or death. These standards must address growing, harvesting, sorting, storage, soil, hygiene, packaging, temperature controls, animal encroachment, and water. They would be enforced in the form of audit-based verification systems or inspections. Congress directs FDA to provide sufficient flexibility in its regulations to account for different scales and types of production, to coordinate with USDA and state agricultural agencies where appropriate, and to allow state or foreign governments to request a variance based on local growing conditions. As for hazard evaluation and prevention plans, for produce safety standards, FDA is to provide flexibility for small businesses and not require businesses to hire third-party consultants or certifiers (except as part of certain enforcement agreements).

Record-keeping (§ 101). The Food Safety Act moderately expands FDA's authority to inspect records at food facilities. Currently, FDA must provide written notice before accessing records and must have "a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals" (emphasis added).[12] Food safety advocates have argued that FDA needs greater record-related authority, to facilitate recalls and investigations and to ensure greater compliance with record-keeping requirements. The Food Safety Act removes the requirement that FDA must have a reasonable belief that the food is adulterated if FDA reasonably believes the food will cause serious adverse health consequences or death; FDA must still have a reasonable belief of adulteration where FDA reasonably believes the food presents a threat of serious adverse health consequences or death. Under each of these prior prongs, FDA's authority to inspect records now extends not only to the food in question but also to food likely to be affected in a similar manner, if there is at least a reasonable belief of a risk of harm. The requirement that FDA provide advance notice before accessing records remains in effect. Farms and restaurants remain exempt from these record-keeping requirements.

User Fees (§ 107). The Food Safety Act imposes a new range of user fees on food facilities. Fees will now be levied for: reinspection of domestic facilities, foreign facilities, and

11 74 Fed. Reg. 33030 (July 9, 2009) (codified at 21 C.F.R. Parts 16 and 118).

12 FDCA § 414, 21 U.S.C. § 350c(a).

importers, following findings of noncompliance related to food safety requirements; noncompliance with food recall orders that result in FDA performing part or all of the recall (e.g., technical assistance, follow-up effectiveness checks, and public notifications); and the voluntary qualified importer program, for those participating importers, to cover administrative costs.

TITLE II—IMPROVING CAPACITY TO DETECT AND RESPOND TO FOOD SAFETY PROBLEMS

Mandatory Recall Authority (§ 206). For the first time, the Food Safety Act grants FDA the authority to order mandatory recalls of food (other than infant formula, for which FDA previously had mandatory recall authority). The law grants FDA mandatory recall over food if (1) there is a reasonable probability that the food is adulterated or misbranded; (2) the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals; and (3) the responsible party has refused to voluntarily cease distribution and recall the products. For any mandatory recall, or for a voluntary recall of food that will cause serious adverse health consequences or death to humans or animals, FDA must set up an incident command operation within 24 hours after initiation of the recall. This operation will coordinate communications between federal agencies, as well as public communications.

Administrative Detention of Food (§ 207). Under prior law, FDA could order the detention of an article of food for up to 30 days if FDA "has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals."[13] The new law lowers the standards for administrative detention of food. Under the new law, FDA may impose administrative detention if it has "reason to believe" that an article of food is "adulterated or misbranded."

High-Risk Facilities (§ 201). The Food Safety Act will require FDA to identify and allocate resources to inspect "high-risk facilities." Such facilities will be identified based on a number of factors, including: known risks of the food, compliance history of the facility, rigor and effectiveness of the facility's hazard analysis and risk-based preventive controls, and other factors. FDA must further increase the frequency of inspection of all food facilities, domestic and foreign (whether or not high-risk), and consult with DHS to inspect food at ports of entry based on risk prioritization. In order to improve seafood safety, the Act authorizes FDA to enter into agreements with the US Department of Commerce, US Department of Homeland Security (DHS), the Federal Trade Commission, and "other appropriate agencies," for example, through: cooperative arrangements for examining and testing seafood imports; coordination of inspections of foreign facilities; standardization of data on seafood names, inspection records, and laboratory testing; joint training; and possible designation of National Oceanic and Atmospheric Administration personnel to carry out FDA seafood examinations and investigations.

Laboratory Accreditation (§ 202). Under the prior law, neither the FDCA nor its implementing regulations addressed accreditation of food laboratories. The new law requires FDA to establish, within two years, a program to recognize laboratory-accreditation bodies, and to develop model standards that laboratories must meet in order to be accredited for food sampling and analytical testing methodologies. Foreign labs must meet the same accreditation standards as domestic labs. FDA must establish a publicly available registry of accrediting bodies and accredited laboratories. Food testing in the following scenarios must be performed by an accredited laboratory: food testing by or on behalf of an owner or consignee in response to a specific testing requirement under the FDCA or implementing regulations, or otherwise required by the FDA, to address an identified or suspected food safety problem; and food testing on behalf of an owner or consignee to support food imports into the US or to meet testing requirements imposed as a result of an Import Alert.

Pilot Projects on Tracking and Tracing (§ 204). Traceability allows government and industry to locate both the source of food contamination (traceback) and entities that may have received contaminated food (trace forward). This information is very useful in product recalls. The Obama Administration's Food Safety Working Group has already taken some steps to improve traceability of food. The Food Safety Act furthers

13 FDCA § 304(h).

this effort. Under the Act, FDA must establish pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food, in order to prevent and mitigate outbreaks of foodborne illness and to address credible threats of serious adverse health consequences or death to human or animals related to adulterated or misbranded food. FDA also must coordinate with USDA and state governments to assess product-tracing technologies.

Foodborne Illness Surveillance and Public Education (§ 205). Traditionally, surveillance for foodborne illnesses has been conducted by the states, with assistance from the Centers for Disease Control and Prevention (CDC). Although FDA had some prior authority to conduct investigations and coordinate state activities, "foodborne-illness outbreak" was not specifically defined in the FDCA or implementing regulations. The Food Safety Act defines "foodborne-illness outbreak" as the occurrence of two or more cases of a similar illness resulting from the ingestion of a certain food. In addition, the Act sets up a new surveillance system for outbreaks of foodborne illness, which could include coordinating and integrating federal, state, and local surveillance systems; improved sharing of information; public access to aggregate surveillance data; and expanding system capacity.

Improving the Reportable Food Registry (§ 211). The Food and Drug Administration Amendments Act of 2007 (FDAAA) required FDA to establish a reportable food registry to facilitate product identification and tracing.[14] A "reportable food" is "an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals."[15] FDA published draft guidance on this requirement in September 2009 (revised in May 2010).[16] The Food Safety Act requires FDA to obtain consumer-oriented information about reportable foods, and to then prepare a one-page summary of the food that will be made available on the internet and provided to grocery stores. If a grocery that is part of a chain of 15 or more stores sells a reportable food, the store must prominently display the FDA one-page summary in a conspicuous location in the store for 14 days.

TITLE III—IMPORTED FOOD SAFETY ISSUES

Foreign Supplier Verification Program (§ 301). The Act establishes a Foreign Supplier Verification Program, effective two years after the Act's enactment. This program requires each importer to perform foreign supplier verification activities in accordance with FDA implementing regulations and guidance. Each importer's program would be required to ensure that each of its foreign suppliers produces imported food employing processes and procedures, "including reasonably appropriate risk-based preventative controls," that are documented in a written plan and designed to prevent adulteration and reduce hazards as required by other relevant provisions of the FDCA. Activities under this Verification Program may include monitoring records; lot-by-lot certification of compliance; annual on-site inspections; checking the hazard analysis and risk-based preventive control plan of the foreign supplier; or periodically testing and sampling shipments. Importers would maintain import-verification records for at least two years and make them available to FDA upon request. Importing food without a Foreign Supplier Verification Program is a prohibited act. Seafood, juice, and low-acid canned food facilities in compliance with required HACCP programs are exempt from this requirement.

Voluntary Qualified Importer Program (§ 302). The Act establishes a Voluntary Qualified Importer Program, which provides for expedited review and importation of food imported by qualified importers so participating. To be eligible for the program, an importer must be offering food from a facility certified by an accredited auditor. In considering requests for participation in the program, FDA must consider the risk of the imported food based on facts such as: the nature of the food imported; the compliance history and practices of the foreign supplier; the capability of the regulatory system of the originating country to ensure compliance with US food safety standards; the potential risk for intentional adulteration of the

14 FDAAA § 1005 (Pub. L.110-085) (codified at FDCA § 417).

15 FDCA § 417.

16 FDA Draft Guidance, "Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2)," *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodSafety/ucm212793.htm.

food; and any other factors that FDA deems appropriate.

Authority to Require Import Certifications for Food (§ 303). The Act contains a provision that authorizes FDA, based on public health considerations—including risks associated with the food or its place of origin—to require food imports to be accompanied by "certification or other such assurances as [FDA] deems appropriate" that the food complies with some or all requirements of the FDCA.[17] Certification can come from an agency, representative of the government of the originating country, or any auditor accredited under the Act. Based on a review of the regulatory authority of a foreign country, as well as on-site audits to verify implementation of such regulatory authority, FDA may determine whether that country can provide reasonable assurances that the food supply of the country meets or exceeds US food safety requirements.

Accreditation of Third Party Auditors (§ 307). The Food Safety Act lays out the process for accrediting third-party auditors to certify foreign entities in the food import supply chain. Evidence of certification provided by these accredited third-party auditors will be used to determine eligibility of an importer to receive certification under § 303 of the Food Safety Act or to participate in the voluntary qualified importer program described in § 302 of the Act. Third-party auditors may be foreign governments, foreign cooperatives, or other third parties deemed appropriate by FDA. FDA must either identify accrediting bodies from whom auditors can seek accreditation or accredit such auditors itself. FDA is to audit the performance of each accredited third-party auditor every four years and may conduct onsite audits of any entity certified by an accredited third-party auditor at any time, to ensure compliance with the requirements of this section.

Foreign Governments and Foreign Facilities (§§ 306 and 307). In addition to establishing verification and certification programs, the Food Safety Act contains provisions that encourage coordination with foreign countries to ensure imported food safety. The Act requires FDA, in consultation with other executive agencies and stakeholders, to develop a comprehensive plan to expand the technical, scientific, and regulatory capacity of foreign governments and their respective food industries, from which foods are exported to the US. The plan should include: recommendations for bilateral and multilateral agreements to ensure imported food safety; provisions for electronic data sharing; provisions for mutual recognition of inspection reports, laboratory methods, and detection techniques; training of foreign government and food producers on US requirements for safe food; and recommendations on whether and how to harmonize requirements under the Codex Alimentarius. The Act also allows FDA to enter into agreements with foreign governments to facilitate inspections of foreign facilities.

Other Provisions (§§ 306, 308, 309). The Food Safety Act gives FDA new authority to inspect foreign facilities and prevent smuggling of foods. FDA is required to establish satellite offices in foreign countries to provide assistance to the appropriate foreign government entities in ensuring safety of food and other products regulated by the FDA, including by directly conducting risk-based inspections of such articles and supporting inspections by foreign governmental entities (§ 308). Pursuant to the inspection agreements with foreign governments discussed above, FDA is required to direct resources to those foreign inspections (§ 306). If a foreign facility registered with FDA refuses such inspections, its food cannot be imported into the US (§ 306). FDA is also required to develop and implement a strategy to better identify smuggled food and prevent its entry into the US (§ 309). When smuggled food is identified as particularly dangerous, FDA must notify DHS and the public.

TITLE IV—MISCELLANEOUS

Employee Protections (§ 402). Among several miscellaneous provisions on FDA staffing, jurisdiction, and other matters, Title IV includes a provision on whistleblower protection. Section 402 establishes new whistleblower protections for food business employees who report FDCA violations, assist in the prosecution of such violations, or refuse to engage in activities that they reasonably believe violate the FDCA. This section prohibits such businesses from discharging or otherwise discriminating against such employees with respect to compensation or other terms of their employment. If an

17 H.R. 2751, § 303.

employee is discharged or discriminated against in violation of this section, the employee may file a complaint with the Secretary of Labor. This section details the government's investigation and hearing process to address complaints, and establishes the standards under which the Secretary of Labor may dismiss a complaint, determine whether a violation occurred, or order relief. Violators will be required to remedy the violation, reinstate and restore the complainant's employment, and pay compensatory damages. In addition, the Secretary of Labor may, at the complainant's request, require the employer to pay for the employee's incurred costs. The protections in this section will not apply to employees who, acting without direction from their employer, deliberately cause a violation

We will be closely monitoring FDA's implementation of the Food Safety Act, and will issue updates to this advisory as appropriate. If you have any questions, please contact your Arnold & Porter attorney or:

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