

The FDA Food Safety Modernization Act

The FDA Food Safety Modernization Act modernizes our food safety system to better prevent foodborne illness and respond to outbreaks. Below is a section-by-section description of the bill.

Title I – Improving Capacity to Prevent Food Safety Problems

Sec. 101. Inspections of Records –Enables the Food and Drug Administration (FDA) to access relevant records of a food processor if there is a reasonable probability food manufactured there will cause serious adverse health consequences or death to humans or animals.

Sec. 102. Registration of Food Facilities –Requires foreign and domestic food facilities to renew their registration with FDA biennially. A facility’s registration may be suspended if there is a reasonable probability that food it handled will cause serious adverse health consequences or death to humans or animals. Includes due process protections and allows the Secretary to reinstate suspended firms in appropriate situations. Establishments that sell the majority of their food directly to consumers at roadside stands, farmers markets, and through community supported agriculture are exempt from registration.

Sec. 103. Hazard Analysis and Risk-Based Preventive Controls –All registered facilities must identify known or reasonably foreseeable hazards and implement preventive controls to significantly minimize or prevent those identified hazards. Those subject to these requirements must have a written plan describing their hazard analysis and preventive controls, which must be made available to FDA upon request. The provision provides flexible compliance timeframes for small and very small businesses, and deems facilities already in compliance with existing seafood, juice, and low-acid canned foods regulations to be exempt from this section. Standards must be science-based, and the regulations are required to be flexible and minimize the burden for small businesses. FDA is also required to publish a small entity compliance guide on the new standards. For agricultural producers that also operate processing facilities, FDA can exempt small, low risk, on-farm facilities from the requirements of this section or modify those requirements as appropriate. The Secretary must clarify under what circumstances on-farm processing activities meet the existing definition of “facility.” An alternative means of compliance is established for small businesses that either (1) meet FDA’s definition of “very small business” or (2) have food sales with an average annual monetary value of less than \$500,000, and sell the majority of that food directly to consumers, and restaurants or “retail food establishments” within the same state or less than 275 miles from the facility.

Sec. 104. Performance Standards –Requires FDA, not less than every 2 years, to determine the most significant food-borne contaminants and, when appropriate to reduce the risk of serious illness or death, prevent adulteration, or prevent the spread of communicable disease, to issue science-based guidance documents, action levels, and/or regulations to prevent adulteration.

Sec. 105. Standards for Produce Safety –Gives FDA the authority to set commodity-specific standards for the safety of fresh produce. The standards must take into consideration sustainable agriculture and conservation practices; accommodate concerns about the scale of the operations; prevent adverse impact on organic agriculture; and provide flexibility for direct-to-consumer operations. The FDA must prioritize implementation of these regulations based on known risk of the fresh produce and can modify or exempt low risk commodities from the new standards. States may apply for variances from the standards due to local growing conditions. FDA is required to publish a

small entity compliance guide on the new standards. Exempts farms from the requirements of this section if they (1) sell the majority of their food directly to consumers, and restaurants or “retail food establishments” that are in the same state or less than 275 miles from the facility and (2) have food sales with an average annual monetary value of less than \$500,000.

Sec. 106. Protection Against Intentional Adulteration –Requires FDA, working with the Department of Homeland Security (DHS) and the United States Department of Agriculture (USDA), to conduct vulnerability assessments and issue regulations to protect against the intentional adulteration of food by terrorists.

Sec. 107. Authority to Collect Fees –Allows FDA to assess fees for compliance failures (recalls and re-inspections) and participation in a voluntary qualified importer program. Appropriations must keep pace in order for fees to be collected.

Sec. 108. National Agriculture and Food Defense Strategy –Requires HHS and USDA, in coordination with DHS, to develop a National Agriculture and Food Defense Strategy and research agenda, including specific emergency preparedness, detection, response, and recovery goals.

Sec. 109. Food and Agriculture Coordinating Councils –Requires DHS, in coordination with HHS and USDA, to report to Congress on the activities of the government and private sector coordinating councils for agriculture and food defense, which are designed to improve information sharing between government and private sector partners in protecting the food system.

Sec. 110. Building Domestic Food Safety Capacity –Requires a series of reports and actions intended to focus FDA's attention on several challenges, including information technology, data sharing, research, and government capacity.

Sec. 111. Sanitary Transportation of Food –Requires FDA to promulgate regulations on the sanitary transportation of food. Also requires FDA to conduct a study on the unique needs of rural and frontier areas with regard to the delivery of safe food.

Sec. 112. Food Allergy and Anaphylaxis Management for Children –Directs HHS, in consultation with the Department of Education, to develop voluntary food allergy management guidelines to manage the risk of food allergy and anaphylaxis in schools or early childhood education programs. Provides for non-renewable food allergy management incentive grants for up to two years to assist local educational agencies (LEAs) with adoption and implementation of the voluntary food allergy management guidelines.

Sec. 113. New Dietary Ingredients –Directs FDA to submit information to DEA if it denies a New Dietary Ingredient notification on the grounds that the dietary ingredient may contain an illegal steroid, and FDA must publish a guidance that clarifies regulation of new dietary ingredients in 180 days.

Sec. 114. Post Harvest Processing of Raw Oysters –Requires FDA to conduct public health and cost assessments before issuing any guidance or rulemaking related to post harvest processing of raw oysters.

Sec. 115. Port Shopping –Until FDA publishes its final rule on the marking of food imports that are refused entry into the United States (as required by the Bioterrorism Act), FDA is required to notify

DHS of all instances in which it refuses to admit a food into the United States so that DHS, acting through Customs and Border Patrol, can notify all ports in the United States and thereby prevent food that is refused in one port from being admitted into the country by another.

Sec. 116. Alcohol-Related Facilities –Exempts facilities that manufacture alcoholic beverages from several sections of the bill, including the preventive control requirements in section 418.

Title II – Improving Capacity to Detect and Respond to Food Safety Problems

Sec. 201. Targeting Inspection Resources –Requires FDA to allocate food inspection resources according to the risk profile of the facility and other important criteria. Requires FDA to increase the frequency of inspections at foreign and domestic facilities, and authorizes FDA to enter into agreements with other federal agencies to improve seafood safety. Requires FDA to submit an annual report to Congress regarding the frequency of, and costs associated with, inspections.

Sec. 202. Laboratory Accreditation –Directs FDA to recognize laboratory accreditation bodies that accredit food testing laboratories and establishes a publicly available registry of these bodies. Requires all laboratory testing done for FDA regulatory purposes to be conducted by either an FDA lab or a lab accredited by an FDA-recognized accreditation body.

Sec. 203. Integrated Consortium of Laboratory Networks –Requires DHS to work with HHS, USDA, and the Environmental Protection Agency (EPA) to effectively integrate laboratory networks and other relevant data sources to optimize national preparedness by quickly sharing information, conducting analyses, and alerting responders.

Sec. 204. Enhancing Tracking and Tracing of Food and Recordkeeping –Requires FDA, in coordination with the food industry, to establish pilot projects to test and evaluate new methods for rapidly and effectively tracking and tracing food products to prevent and mitigate foodborne illness outbreaks. FDA must establish a product tracing system within the FDA based on these pilots, and develop additional recordkeeping requirements for foods that are “high risk.” Ensures methods and requirements are appropriate for small businesses, and exempts or limits requirements for farms, restaurants, raw agricultural commodities, and fishing vessels.

Sec. 205. Surveillance –Requires the Secretary to enhance foodborne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on foodborne illnesses. Establishes a diverse working group of experts and stakeholders to provide recommendations on an ongoing basis regarding the improvement of foodborne illness surveillance. Requires the Secretary to develop and implement strategies to leverage and enhance the food safety and defense capacities of state and local agencies.

Sec. 206. Mandatory Recall Authority –Gives FDA the authority to order food recalls when firms fail to voluntarily recall products that are either adulterated or contain undeclared allergens and which will cause serious adverse health consequences or death to humans or animals. This section also establishes an incident command operation to improve communication within the Department during a mandatory recall or Class I (serious) recall, and requires FDA to submit an annual report to Congress about its use of this authority.

Sec. 207. Administrative Detention –Allows FDA to use administrative detention to hold food for a short period of time when FDA has reason to believe that a food is adulterated or misbranded.

Sec. 208. Decontamination and Disposal Standards and Plans –Requires EPA, in coordination with HHS, DHS, and USDA, to develop decontamination and disposal standards and protocols to help state and local governments prepare for a food or agriculture emergency.

Sec. 209. Improving the training of State, local, territorial, and tribal food safety officials – Requires the Secretary to administer training and education programs for State, local, territorial, and tribal food safety official employees.

Sec. 210. Enhancing Food Safety –Authorizes the HHS to make grants to states, localities, and Indian tribes to improve local food safety programs, improve state laboratories and train state officials to conduct food safety inspections. University-affiliated projects are eligible to receive food safety capacity building grants, and FDA may use grants to support centers of excellence to serve as resources to public health officials in response to outbreaks.

Sec. 211. Improving the Reportable Food Registry –Provides for consumer notification of Class I (serious) recalls in grocery stores.

Title III – Improving the Safety of Imported Food

Sec. 301. Foreign Supplier Verification Program –Requires importers to perform food safety supplier verification activities to ensure that imported foods are as safe as those manufactured and sold in the United States. Importers required to comply with existing seafood, juice, and low-acid canned foods regulations are exempted from this section if they are in compliance with those other requirements.

Sec. 302. Voluntary Qualified Importer Program –Allows importers to qualify for expedited review and importation of food if they go above and beyond the minimum standards to ensure the safety of imported food.

Sec 303. Authority to Require Import Certifications for Food –Allows FDA to require certification or other assurance of safety for high-risk food imports. Requires Secretary to consider public health factors when requiring certifications for high risk foods, including (1) known safety risks of the food, (2) known safety risks of the country of origin, (3) inadequate government controls in country of origin, and (4) information submitted by the country of origin related to the quality of it government controls. FDA may refuse admission of a food import lacking required certification.

Sec. 304. Prior Notice of Imported Food Shipments –Requires prior notice for an imported food to include the name of any country that refused entry of the food.

Sec. 305. Building Capacity of Foreign Governments with Respect to Food Safety –Requires FDA to develop a comprehensive plan to help expand the technical, scientific, and regulatory capacity of foreign governments and their respective food industries.

Sec. 306 . Inspection of Foreign Food Facilities – Allows FDA to enter into agreements and arrangements with foreign governments to facilitate the inspection of foreign facilities. Prohibits entry of food from a foreign facility or country that fails to permit inspection by the United States. Also authorizes the Department of Commerce, in coordination with HHS, to assess foreign facilities that import seafood into the United States and provide technical assistance.

Sec. 307. Accreditation of Third-Party Auditors –Directs FDA to recognize accreditation bodies to accredit third parties to certify that foreign food facilities and foods are in compliance with U.S. food safety standards.

Sec. 308. Foreign Offices of the FDA –Directs FDA to establish offices in at least five foreign nations to improve the agency’s presence overseas and positively impact the safety of FDA-regulated products.

Sec. 309. Smuggled food –Requires the Secretary of HHS, in coordination with the Secretary of DHS, to develop and implement a strategy to better identify smuggled food and prevent its entry into the United States.

Title IV – Miscellaneous Provisions

Sec. 401. Funding for Food Safety –Increases funding for FDA food safety functions and directs the FDA to incrementally increase field staff by 2015.

Sec. 402. Employee protections –Prohibits retaliation by manufacturers, processors, packagers, transporters, distributors, receivers, holders, or importers against their employees who have, in relation to potential or real food safety violations, provided information to officials, assisted or testified in violation proceedings, or refused to participate in any work-related activity that they believe may be a food safety violation.

Sec. 403. Jurisdiction –Clarifies that amendments made by this bill do not change jurisdiction between FDA, USDA, and DHS, and that FDA retains its current food safety authority under the Food, Drug, and Cosmetic Act and the Public Health Service Act.

Sec. 404. Compliance with international agreements –Provides that nothing in the act is to be construed in a manner that is inconsistent with agreements with the World Trade Organization or other international treaties or agreements.

