

S. 510, the FDA Food Safety Modernization Act: Substitute Amendment

While the food supply in the United States is one of the safest in the world, each year about 76 million illnesses occur, more than 300,000 persons are hospitalized, and 5,000 die from food borne illness. An increasing portion of our food now comes from overseas. Our food safety system was designed 100 years ago and was appropriate for a world in which most of our food was grown and processed domestically. Meanwhile, the FDA has struggled in recent years with outbreaks of food borne illness and nationwide recalls of contaminated food from both domestic and foreign sources. S. 510 modernizes our food safety system to better prevent food borne illness and respond to outbreaks.

Title I – Improving Capacity to Prevent Food Safety Problems

Sec. 101. Inspections of Records – If there is a reasonable probability that a food, or a related article of food, will cause serious adverse health consequences or death to humans or animals, enables the Food and Drug Administration (FDA) to access relevant records for that food and any related article of food that may be similarly contaminated.

Sec. 102. Registration of Food Facilities – Food facilities as defined in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) must register with FDA and renew registration biennially. Facility registration may be suspended if there is a reasonable probability that food from the responsible facility 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. Clarifies the existing exemption from the registration requirement for “Retail Food Establishments” that sell the majority of their food directly to consumers includes sales at roadside stands, farmers markets, and through community supported agriculture.

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 shall be made available to FDA upon request. The provision provides flexible compliance timeframes for small and very small businesses, and deems facilities 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 shall clarify under what circumstances on-farm processing activities meet the existing definition of “facility.” An alternative means of compliance is established for small businesses. Qualified small facilities are those small businesses that have either (1) met FDA’s definition of “very small business” or (2) have an average annual monetary value of food that is less than \$500,000, and sell the majority of that food directly to consumers, restaurants, or “retail food establishments” within the same state or less than 275 miles from the facility. Such facilities are exempt from the requirements of this section and must demonstrate that they are (1) in compliance with state and local food safety laws or (2) have identified potential hazards in their facilities and are implementing preventive controls to address those hazards. Qualified small facilities must prominently display the facility’s contact information directly on the product sold or at the point of sale. HHS has discretion to withdraw a qualified facility’s exemption if (1) that facility is directly linked to a foodborne illness outbreak or (2) the Secretary of HHS determines that it is necessary to protect the public health or mitigate an outbreak based on conduct or conditions associated with a facility that are material to the safety of food from such 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. Performance standards cannot be facility-specific. Requires FDA to consider the recommendations of relevant advisory committees when reviewing data and standards, and clarifies that FDA’s updated guidances or regulations may differentiate between food for humans and food for animals.

Sec. 105. Standards for Produce Safety – Gives FDA the authority to set commodity-specific standards for the safety of fresh produce. States may apply for variances from the standards due to local growing conditions. 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. FDA is also required to publish a small entity compliance guide on the new standards. Exempts qualified direct marketing farms from the requirements of this section. Qualified direct marketing farms are those farms that (1) sell the majority of their food directly to consumers, restaurants, or “retail food establishments” that are in the same state or less than 275 miles from the facility and (2) have an average annual monetary value of food less than \$500,000. Qualified direct marketing farms exempted from this section must prominently display the farm’s contact information on the product or at the point of sale. Exemptions granted under this section can be withdrawn if the farm is linked to a foodborne illness outbreak or if the Secretary determines that it is necessary to protect public health or prevent a foodborne illness outbreak based on conduct or conditions at such farm.

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. In the interests of national security, the provision gives the Department of Health and Human Services (HHS) the discretion to determine, in consultation with DHS, the time, form, and manner in which vulnerability assessments are made publicly available.

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 the Secretary of Commerce, the Secretary of Homeland Security, and the Federal Trade Commission 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. Requires a report to Congress on the implementation of the national laboratory Food Emergency Response Network, to support early detection, rapid response, and management of food-related emergencies.

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 shall, in consultation with USDA, establish a product tracing system within the FDA based on these pilots, and shall develop additional recordkeeping requirements for foods determined to be “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. Requires GAO to conduct an examination and provide recommendations regarding the effectiveness of these new requirements.

Sec. 205. Surveillance – Requires the Secretary to enhance food-borne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on food-borne illnesses. Establishes a diverse working group of experts and stakeholders from federal, state, and local food safety and health agencies, the food industry, consumer organizations, and academia to provide recommendations on an ongoing basis regarding the improvement of food-borne 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 authority shall only be delegated to the Commissioner of the FDA, and there are additional rules related to recall of alcohol products. 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. This training relates to the regulatory responsibilities and other policies established by this legislation.

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. Such notification must be displayed in a prominent and conspicuous location in the store within 24 hours of FDA release of information to stores about the recall.

Title III – Improving the Safety of Imported Food

Sec. 301. Foreign Supplier Verification Program – Requires importers to perform food safety supplier verification activities to mitigate risks in imported foods and ensure that imported foods are as safe as those manufactured and sold in the United States. Importation of a food by an importer who does not have such

a program in place is a prohibited act. 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 its 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. Third party certification may be used to participate in the Voluntary Qualified Importer Program or to fulfill import certification requirements established by FDA.

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.