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111th Congress (2009 - 2010)
S.510
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S.510

Title: FDA Food Safety Modernization Act

Sponsor: [Sen Durbin, Richard](#) [IL] (introduced 3/3/2009) [Cosponsors](#) (17)

Related Bills: [H.R.1332](#)

Latest Major Action: 12/18/2009 Placed on Senate Legislative Calendar under General Orders. Calendar No. 247.

SUMMARY AS OF:

12/18/2009--Reported to Senate amended. (There is 1 [other summary](#))

FDA Food Safety Modernization Act - **Title I: Improving Capacity to Prevent Food Safety Problems** - (Sec. 101) Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to expand the authority of the Secretary of Health and Human Services (HHS) to inspect records related to food, including to: (1) allow the inspection of records of food that the Secretary reasonably believes is likely to be affected in a similar manner as an adulterated food; and (2) require that each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports an article of food permit inspection of his or her records if the Secretary believes that there is a reasonable probability that the use of or exposure to such food will cause serious adverse health consequences or death.

(Sec. 102) Authorizes the Secretary to suspend the registration of a food facility if the food manufactured, processed, packed, or held by a facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

(Sec. 103) Requires each owner, operator, or agent in charge of a food facility to: (1) evaluate the hazards that could affect food; (2) identify and implement preventive controls; (3) monitor the performance of those controls; and (4) maintain records of such monitoring. Deems facilities required to comply with certain food-specific standards to be in compliance with this section. Requires the Secretary to promulgate regulations to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting such implementation.

Prohibits the operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with this section.

Delays implementation of this section for small businesses.

(Sec. 104) Directs the Secretary to: (1) review and evaluate relevant health data and other information to determine the most significant foodborne contaminants; and (2) issue contaminant-specific and science-based guidance documents, action levels, or regulations.

(Sec. 105) Sets forth provisions related to produce safety, including to require the Secretary to: (1) establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities to minimize the risk of serious adverse health consequences or death; and (2) publish updated good agricultural practices and guidance for the safe production and harvesting of specific types of fresh produce.

(Sec. 106) Requires the Secretary to promulgate regulations to protect against the intentional adulteration of food.

(Sec. 107) Directs the Secretary to assess and collect fees related to: (1) food facility reinspection; (2) food recalls; (3) the voluntary qualified importer program; and (4) importer reinspection.

Applies export certification provisions to food.

(Sec. 108) Requires the Secretary and the Secretary of Agriculture to prepare and submit to the relevant congressional committees and make public the National Agriculture and Food Defense Strategy, which shall include: (1) an implementation plan; (2) a coordinated research agenda; and (3) a process to achieve, and evaluate progress towards, goals.

(Sec. 109) Directs the Secretary of Homeland Security (DHS) to report annually on the activities of the Food and Agriculture Government Coordinating Council and the Food and Agriculture Sector Coordinating Council.

(Sec. 110) Requires the HHS Secretary to submit to Congress: (1) a comprehensive report that identifies programs and practices that are intended to promote the safety and supply chain security of food and to prevent outbreaks of foodborne illness and other food-related hazards that can be addressed through preventive activities; and (2) biennial reports on food safety programs and practices following the submission of the comprehensive report.

Requires the HHS Secretary and the Secretary of Agriculture to submit to Congress, biennially, a joint food safety and food defense research plan.

(Sec. 111) Requires the HHS Secretary to promulgate regulations on sanitary transportation practices for the transportation of food.

(Sec. 112) Requires the Secretary to develop and make available to local educational agencies, schools, early childhood education programs, and interested entities and individuals guidelines for developing plans for individuals to manage the risk of food allergy and anaphylaxis in schools and early childhood education programs, to be implemented on a voluntary basis. Sets forth issues for such guidelines to address, including: (1) parental obligation to provide documentation of their child's food allergy; (2) the creation of an individual plan for food allergy management; (3) communication strategies between schools or childhood education programs and providers of emergency medical services; and (4) strategies to reduce the risk of exposure to anaphylactic causative agents in classrooms and common school or early childhood education program areas, such as cafeterias.

Allows the Secretary to award matching grants to assist local educational agencies in implementing such food allergy and anaphylaxis management guidelines.

Title II: Improving Capacity to Detect and Respond to Food Safety Problems - (Sec. 201) Requires the Secretary to: (1) allocate resources to inspect facilities and articles of food imported into the United States based on their risk profiles; (2) increase the frequency of inspection of all facilities; and (3) report to the appropriate congressional committees annually on food facility and food import inspections.

(Sec. 202) Requires the Secretary to: (1) recognize bodies that accredit laboratories with a demonstrated capability to conduct analytical testing of food products; (2) establish a publicly available registry of accreditation bodies; (3) develop model standards that an accreditation body shall require laboratories to meet; and (4) periodically reevaluate accreditation bodies and revoke recognition of any not in compliance with this section.

Sets forth requirements for mandatory testing, including that: (1) testing be conducted by federal laboratories or accredited nonfederal laboratories; and (2) results of such testing be sent directly to the Food and Drug Administration (FDA). Requires the Secretary to review results from any sampling and testing that lead to a state or locality issuing a food recall to evaluate the need for a national recall or other compliance and enforcement activities.

Requires the Secretary to report to the relevant congressional committees on the progress in implementing a national food emergency response laboratory network.

(Sec. 203) Directs the DHS Secretary to maintain an agreement through which relevant laboratory network members will: (1) agree on common laboratory methods in order to facilitate the sharing of knowledge and information; (2) identify means by which each member could work cooperatively to optimize national laboratory preparedness and provide surge capacity during emergencies; and (3) engage in ongoing dialogue and build relationships that will support a more effective and integrated response during emergencies. Sets forth reporting requirements.

(Sec. 204) Requires the HHS Secretary to: (1) improve tracking and tracing of fruits and vegetables that are raw agricultural commodities in the event of a foodborne illness outbreak; and (2) establish standards for the type of information, format, and timeframe for persons to submit records to aid the Secretary in such tracking and tracing.

(Sec. 205) Requires the Secretary to establish a pilot project to explore and evaluate methods for rapidly and effectively tracking and tracing processed food so that the Secretary may quickly identify the source of an outbreak involving such a processed food and the recipients of the contaminated food.

(Sec. 206) Requires the Secretary, acting through the Director of the Centers for Disease Control and Prevention (CDC), to enhance foodborne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on foodborne illnesses.

Requires the Secretary to: (1) develop and implement strategies to leverage and enhance the food safety and defense capacities of state and local agencies to achieve specified goals, including improving foodborne illness outbreak response and containment; and (2) complete a review of state and local capacities and needs for enhancement not later than one year after enactment of this Act.

Reauthorizes appropriations for grants to states and Indian tribes to expand participation in networks to enhance federal, state, and local food safety efforts, including meeting the costs of establishing and maintaining the food safety surveillance, technical, and laboratory capacity needed for such participation.

(Sec. 207) Authorizes the Secretary to: (1) provide a responsible party with an opportunity to cease distribution and recall an

adulterated or misbranded article of food if the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals; (2) order a responsible party to immediately cease distribution and provide notice to relevant persons if the responsible party does not voluntarily cease distribution of or recall such article of food; and (3) order a recall if the Secretary determines that removal of the article from commerce is necessary, but only after providing an opportunity for a hearing.

(Sec. 208) Revises the standard for the administrative detention of food to allow such a detention if the FDA has reason to believe that such article is adulterated or misbranded.

(Sec. 209) Requires the Administration of the Environmental Protection Agency (EPA) to provide support for, and technical assistance to, state, local, and tribal governments in preparing for, assessing, decontaminating, and recovering from an agriculture or food emergency.

(Sec. 210) Requires the Secretary to set standards and administer training and education programs for the employees of state, local, territorial, and tribal food safety officials relating to the regulatory responsibilities and policies established by this Act.

Authorizes and encourages the Secretary to conduct examinations, testing, and investigations for the purposes of determining compliance with the food safety provisions of this Act through the officers and employees of such state, local, territorial, or tribal agency.

(Sec. 211) Expands the program for grants to states, territories, and Indian tribes for inspections to include grants to: (1) train to HHS standards for the examination, inspection, and investigation of food manufacturing, processing, packing, holding, distribution, and importation; (2) build the capacity of the laboratories for food safety; (3) build the infrastructure and capacity of the food safety programs; and (4) take appropriate action to protect the public health in response to a recall of food under the FFDCFA.

Title III: Improving the Safety of Imported Food - (Sec. 301) Requires U.S. importers to perform risk-based foreign supplier verification activities to verify that imported food is produced in compliance with applicable requirements related to hazard analysis and standards for produce safety and is not adulterated or misbranded. Requires the Secretary to issue guidance to assist U.S. importers in developing foreign supplier verification programs.

(Sec. 302) Requires the Secretary to: (1) establish a program to provide for the expedited review and importation of food offered for importation by U.S. importers who have voluntarily agreed to participate in such program; and (2) issue a guidance document related to participation and compliance with such program.

(Sec. 303) Requires imported food that fails to meet requirements for a certification or other assurance that the food meets applicable FFDCFA requirements to be refused admission.

Authorizes the Secretary to require, as a condition of granting admission to an article of food into the United States, that an entity provide a certification or other assurances that the article of food complies with applicable FFDCFA requirements.

(Sec. 304) Directs the Secretary to require, prior to importation of an article of food, notice of any country to which such article has been refused entry.

(Sec. 305) Requires the Secretary to determine whether a country can provide reasonable assurances that the food supply of the country meets or exceeds the safety of food manufactured, processed, packed, or held in the United States.

(Sec. 306) Directs the Secretary to develop a comprehensive plan to expand the technical, scientific, and regulatory capacity of foreign governments and food industries from which foods are exported to the United States.

(Sec. 307) Authorizes the Secretary to enter into arrangements and agreements with foreign governments to facilitate the inspection of registered foreign facilities. Requires the Secretary to direct resources to inspections of foreign facilities, supplies, and food types to help ensure the safety and security of the U.S. food supply.

Requires food to be refused admission into the United States if permission to inspect the food facility is denied by the facility owner, operator, or agent or the foreign country.

(Sec. 308) Sets forth provisions governing the establishment of a system to recognize bodies that accredit third-party auditors and audit agents to certify that eligible entities meet applicable FFDCFA requirements for importation of food into the United States.

(Sec. 309) Requires the Secretary to establish offices of the Food and Drug Administration (FDA) in foreign countries to provide assistance to the appropriate governmental entities with respect to measures to provide for the safety of articles of food and other products regulated by the FDA that are exported by such countries to the United States.

(Sec. 310) Requires the Secretary to: (1) develop and implement a strategy to better identify and prevent entry into the United States of smuggled food; and (2) notify the DHS Secretary not later than ten days after identifying a smuggled food that would cause serious adverse health consequences or death to humans or animals. Requires a press release to warn consumers and vendors about a potential threat from smuggled food if certain requirements are met.

Title IV: Miscellaneous Provisions - (Sec. 401) Authorizes appropriations for FY2010-FY2014 for the activities of the Center

for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and related field activities in the Office of Regulatory Affairs of the FDA. Directs the HHS Secretary to increase the field staff of such Centers and Office.

(Sec. 402) Establishes whistleblower protections for employees of entities involved in the manufacturing, processing, packing, transporting, distribution, reception, holding, or importation of food who provide information relating to any violation of the FFDA.

(Sec. 404) Declares that nothing in this Act shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party.

(Sec. 405) Requires the Secretary to update the Fish and Fisheries Products Hazards and Control Guidance to take into account advances in technology.

(Sec. 406) Requires the Secretary, acting through the Commissioner of Food and Drugs, to study the transportation of food for consumption in the United States, including an examination of the unique needs of rural and frontier areas with regard to the delivery of safe food.

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