

Congress Approves Food Safety Bill

Highlights

- ✓ Records inspections and HACCP for facilities
- ✓ Production and harvesting standards
- ✓ Food recall reporting and registry
- ✓ Imported food to meet U.S. safety standards
- ✓ FDA foreign offices for inspections and compliance
- ✓ Coordinated communication and investigations
- ✓ Staff increases and whistleblower protection

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The House of Representatives reapproved the Senate version of a food safety bill on December 21, 2010, authorizing the FDA with some of the most significant changes to food safety regulation in 70 years, on a vote of 215-144. President Obama is expected to sign the bill shortly. The bill is expected to cost \$1.4 billion over the next four years.

The House vote marked the final hurdle for a bill that cleared various obstacles, despite bipartisan support. Although the Senate had approved virtually the same measure December 3, 2010, on a 73-25 vote, S. 510, FDA Food Safety Modernization Act, was voided because it contained technically an unconstitutional provision. Article 1 requires revenue-raising provisions, such as taxes, to originate in the House. The Senate bill has a provision that authorizes the FDA to assess fees on food importers and food producers that have recalls or fail inspections, which could possibly be interpreted as a revenue-raising.

The constitutional setback, among other issues, repeatedly sent the bill back to both chambers.

A few days prior to the House reapproval, the bill was believed to be tabled for the remainder of the 111th Congress, because of Republican disapproval over the spending measure to which it had been attached. The Senate surprised the legislation's advocates by allowing the bill to advance on December 19, 2010, by unanimous consent. In the end, the House voted on it three times and the Senate twice.

In July 2009, the House passed a more sweeping version of the bill, which also contained broader FDA authority for records access and more frequent inspections of high risk facilities, but with a time-limited 111th Congress, the House leadership decided to take up the Senate version to expedite the process. CCH will continue to monitor the legislation as it is prepared for the President to sign.

Food facilities

Records inspections. The Secretary of Health and Human Services (HHS) will have expanded authority to inspect records related to food, including: (1) allowing the inspection of records of foods that the FDA reasonably believes is likely to be affected in a similar manner as adulterated food; and (2) requiring that each person who manufactures, processes, packs, distributes, receives, holds, or imports an article of food permit inspection of records if the FDA believes there is a reasonable probability that the use or exposure to the food will cause serious health consequences.

Registration. The FDA will be authorized to suspend the registration of a food facility if the food manufactured, processed, packed, or held by a facility has reasonable probability of causing serious adverse health consequences.

Hazards analysis and control points. Owners of food facilities must also implement detailed “hazard analysis and risk-based preventive controls,” to prevent “hazards that could affect food” and provide assurances that such food is not adulterated or misbranded under current FDA food regulations.

Comment: An amendment sponsored by Senator Jon Tester (D-Mont.) will exempt certain small, local food processors and producers. Food facilities would qualify for an exemption if (1) they are a “very small business” as defined by the FDA or (2) the facility averages less than \$500,000 of food sold directly to consumers, restaurants, or grocery stores during the previous three years. For purposes of the exemption, the FDA would conduct a study in order to define “very small business.”

Farms

Food Standards. Farms will be required to comply with minimum standards for the safe production and harvesting of types of fruits and vegetables that are raw agricultural commodities, as well as comply with standards on good agricultural practices. The FDA will

Comment: Under the Tester Amendment, farms would also be exempt from the food standards provision if the value of food sales to consumers, restaurants, or grocery stores is less than \$500,000 over a three year period. Additionally in order to qualify for exemption, the majority of sales would have to be in the same state where the farm harvested or produced the food or within 275 miles of the farm.

Detecting and Responding to Food Safety Problems

Inspections. Title II, Section 201 would require the Secretary to allocate resources for food facility inspection and the inspection of imported food based risk profiles. Risk profiles will be based on the known safety risks of the food that is manufactured, processed or held at the facility, the compliance history of the facility, the rigor and effectiveness of the facility’s hazard analysis and risk-based prevention, or if the food being is manufactured, processed or held at the facility is determined to be a priority. Inspections for all facilities would be increased and for high risk facilities, inspections will be held no less than once in the five years after enactment and no

less than once every three years after. Non-high-risk facilities would have inspections no less than once in the seven years following enactment and no less than every five years thereafter. The FDA would be responsible for inspecting no less than 600 foreign food facilities within a year of enactment, and within each year of the five years following, the FDA will inspect no fewer than twice the number inspected in the previous year. Resources would be allocated to inspect any food imported into the United States based on known safety risks.

Inspection Reports. No later than February 1 of each year, the Secretary would be responsible for submitting a Congressional report that would include the efforts of coordination and cooperation with other Federal agencies responsible for food inspections (USDA), with information including the average cost of inspections, the difference in cost for inspection of a high or low risk facility, the number of facilities inspected and other statistics pertinent.

Tracking and Tracing. No later than 270 days after the date of enactment, the Secretary would be required to establish pilot projects to explore and evaluate methods to rapidly identify recipients of food to prevent or mitigate a foodborne illness outbreak, and address credible threats of serious adverse health consequences or death in humans or animals. The Secretary would establish a product tracing system to receive information to improve the capacity to rapidly track and trace food.

Mandatory Recall Authority. Section 206 would authorize the Secretary to cease distribution and recall articles that of food if the responsible party refuses or does not voluntarily cease distribution of products (other than infant formula) that are adulterated or misbranded if there is a probability the article will cause serious adverse health consequences or death in humans or animals. If the food covered by the recall has been distributed to a third-party warehouse based logistics provider, information will be given to the provider to identify the food. The Secretary may limit the size of the geographic area of a recall to the markets affected. If a mandatory recall is ordered, it will have a specific timetable. The public will be informed of the recall through press releases and alerts and notices, and will include the name and article of the food subject to the recall, a description of the risk associated with the article, and information about similar articles of food that are not affected. To reduce miscommunication during recalls or investigations, each incident will have an incident

command operation and shall use the regular staff and resources of the Department of Human Health and Services to ensure timely and coordinated communication between agencies and to the public.

Comment: *Warehouse-based third party logistics providers are not exempt from recalls or the subject of a mandatory recall.*

Reportable Food Registry Improvements. The Secretary would be required to prepare critical information for a reportable food as a standardized one page summary that would be published on the FDA website in a format that can easily be printed by a grocery store for purposes of consumer notification. Grocery stores that sold a reportable food that is the subject of the posting, and have 15 or more physical locations shall prominently display the summary near the register.

Improving Safety of Imported Food

Inspections. Title III, would require importers of food to perform a risk-based foreign supplier verification to ensure its imported food is produced in compliance with applicable requirements related to hazard analysis and standards for produce safety, and to show it is not adulterated or misbranded. No later than one year after enactment, the Secretary would issue a guidance to assist importers to develop foreign supplier verification programs.

Comment: *A facility that is required to comply with, and is in compliance with the Seafood Hazard Analysis Critical Control Points Program of the FDA, the Juice Hazard Analysis Critical Control Points Program of the FDA, or the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards of the DFA are exempt from this section.*

Voluntary Qualified Importer Program. No later than 18 months after enactment, the Secretary shall establish a program in consultation with the Department of Homeland Security to provide an expedited

review and importation of food offered for importation by importers who have voluntarily agreed, and issue a guidance document related to the participation, revocation and compliance with the program.

Import Certification. Food that fails to meet the requirement for certification or other assurance that it meets requirements will be refused admission into the United States.

Foreign Offices. The Secretary would be responsible for establishing foreign offices of the FDA in foreign countries, selected by the Secretary in consultation with the United States Trade Representative, Secretary of State and Secretary of Homeland Security to provide assistance to the appropriate governmental entities of such countries with respect to food safety measures. The Secretary shall submit a report to Congress regarding the selection of foreign countries no later than October 1, 2011.

Administration

Staff increases. The FDA will increase field staff by 150 employees by fiscal year 2011 to (1) provide additional detection of and response to food defense threats; and (B) detect, track, and remove smuggled food from commerce. The FDA also is mandated to have no fewer than 5,000 staff members in 2014 to carry out the activities of the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and related field activities of the Office of Regulatory Affairs.

Whistleblower protections. A whistleblower protection provision in section 402 protects workers engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food from discharge or discrimination with respect to compensation, terms, conditions, or privileges of employment. The employee would have to prove only that his or her protected actions constituted a contributing factor to the employer's adverse employment decision.

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