

House Advances Food Safety Bill

Highlights

- ✓ Records inspections and HACCP for facilities
- ✓ Production and harvesting standards
- ✓ Reportable Food Registry for food recalls
- ✓ Imported food denied admission for lack of certification
- ✓ FDA foreign offices to facilitate inspections and compliance
- ✓ Coordinated communication and investigations during food recalls
- ✓ Staff increases and whistleblower protection

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The House of Representatives passed the Senate version of a food safety bill on December 8, 2010, as part of a trillion dollar House resolution to fund the federal government through September 2011. With a 212-206 vote and 35 Democrats crossing the aisle to join Republicans to vote “no,” H.R. 3082, Military Construction and Veterans Affairs Appropriations Act, 2010 (also referred to as the Full-Year Continuing Appropriations Act, 2011), was used as the “vehicle” to address food safety in the United States.

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 technically contained an unconstitutional provision. Article 1 requires revenue-raising provisions, such as taxes, to originate in the House. The Senate bill had 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 provision. As a result, the House included the Senate bill as part of a continuing resolution and the bill must now be re-approved by the Senate. In addition, the food safety legislation includes the Tester-Hagan amendment, a provision added to exempt small farms and producers under certain conditions, and is part of the legislation going back to the Senate for consideration.

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 and get the bill to President Obama before the end of the year.

CCH will continue to monitor the status of the legislation as the bill is prepared for the President to sign.

Food Facilities

Record 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.

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 will 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 will 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 will have inspections no less than once in the seven years following enactment and no less than every five years thereafter. The FDA will 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 will be allocated to inspect any food imported into the United States based on known safety risks.

Reports. No later than February 1 of each year, the Secretary will be responsible for submitting a Congressional report that must 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 will be required to establish pilot projects to explore and evaluate methods to rapidly identify recipients of food to prevent or mitigate a food borne illness outbreak, and address credible threats of serious adverse health consequences or death in humans or animals. The Secretary will establish a product tracing system to receive information to improve the capacity to rapidly track and trace food.

Mandatory Recall Authority. Section 206 will authorize the Secretary to cease distribution and recall articles 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 must use the regular staff and resources of the HHS 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 from being the subject of a mandatory recall.*

Reportable Food Registry Improvements. The Secretary will be required to prepare critical information for a reportable food as a standardized one page summary that will 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, must prominently display the summary near the register.

Improving Safety of Imported Food

Inspections. Title III, will 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 must 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 FDA is exempt from this section.*

Voluntary Qualified Importer Program. No later than 18 months after enactment, the Secretary must 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 will 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 must 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 provide additional detection of and response to food defense threats, and 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 will have to only prove that his or her protected actions constituted a contributing factor to the employer's adverse employment decision.

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