

Key provisions of the Food Safety Modernization Act:

- FDA facilities must conduct a hazard analysis to identify hazards that are likely to occur and develop food safety plans.
- FDA must develop guidance and regulations for minimum standards for effective implementation of preventive food safety plans, and stakeholders will have opportunities for input.
- FDA must improve its capacity to traceback food during a foodborne illness outbreak. The new law requires FDA to establish pilot projects (within 270 days of the bill's passage) to evaluate the efficacy of different systems for tracing packaged foods, fruits and vegetables.
- FDA has several provisions in FSMA that represent a marked increase in FDA's import oversight. For example, FDA can require, as a condition of granting admission for imports, that an entity provide certification that the food complies with FSMA.
- FDA must require importers of food to have a program to verify that imported food is produced in accordance with U.S. requirements, including the preventative controls required by the FSMA.
- FDA must develop produce safety standards.
- FDA will have more access to records, and all facilities inspected by FDA will be required to keep their records for two years.
- FDA will do more frequent inspections, and a facility's frequency of inspection is tied to its risk profile.
- High risk facilities must initially be inspected once during the first five years after the bill's passage, and then every three years thereafter.
- Low risk facilities must initially be inspected once during the first seven years after the bill's passage and then every five years thereafter.
- FDA must inspect 600 foreign facilities in the first year following passage and must double that number in each of the first five years thereafter.
- FDA may suspend a facility's registration under certain circumstances, in particular if public health is threatened.
- FDA must provide improved training for state, local, territorial and tribal food safety officials.
- The new law protects whistle-blowers who report violations.
- The new law provides FDA with mandatory recall authority and expands civil penalties for failure to follow a recall order. The new law also requires grocery stores to post recall information in a conspicuous area.
- The new law provides for increased surveillance to enhance foodborne illness surveillance systems to improve the collection, analysis, reporting, and use of data on foodborne illnesses.
- The new law provides for improved food allergy management.

- The Tester Amendment is attached to the FSMA and exempts facilities that sell the majority of their food directly to consumers, restaurants and retailers within the state or within a 275 mile radius of where it was produced AND if the exempted facility has less than \$500,000 per year in sales.

FROM: THOMAS: <http://thomas.loc.gov>

H.R.2751

Latest Title: FDA Food Safety Modernization Act

Sponsor: [Rep Sutton, Betty](#) [OH-13] (introduced 6/8/2009) [Cosponsors](#) (59)

Related Bills:

[H.RES.1781](#), [H.R.520](#), [H.R.1550](#), [H.R.1606](#), [H.R.2640](#), [S.247](#), [S.510](#), [S.1135](#), [S.1200](#), [S.1248](#)

Latest Major Action: Became Public Law No: 111-353 [GPO: [Text](#), [PDF](#)]

SUMMARY AS OF:

1/4/2011--Public Law. (There are 3 [other summaries](#))

(This measure has not been amended since it was passed by the Senate on November 30, 2010. The summary of that version is repeated here.)

FDA Food Safety Modernization Act - Title I: Improving Capacity to Prevent Food Safety Problems - Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to expand the food safety activities of the Secretary of Health and Human Services (HHS), including to authorize the Secretary to inspect records related to food.

Exempts certain establishments that sell food directly to consumers, such as roadside stands, farmers markets or participants in a community supported agriculture program, from specified requirements of this Act.

Requires each owner, operator, or agent in charge of a food facility to identify and implement preventive controls to significantly minimize or prevent hazards that could affect food manufactured, processed, packed, or held by such facility. Sets forth provisions governing exemptions from such requirements for certain facilities.

Requires the Secretary to: (1) issue guidance documents to reduce the risk from the most significant foodborne contaminants; and (2) establish

minimum standards for the safe production and harvesting of fruits and vegetables based on known safety risks. Authorizes the Secretary to issue exemptions and variances from such standards.

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.

Directs the Secretary to develop voluntary food allergy and anaphylaxis management guidelines for schools and early childhood education programs.

Title II: Improving Capacity to Detect and Respond to Food Safety Problems - Requires the Secretary to: (1) allocate resources to inspect facilities and imported food according to the known safety risks of the facilities or food; and (2) establish a product tracing system to track and trace food that is in the United States or offered for import into the United States.

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.

Gives the Secretary the authority to order a recall of an article of food.

Title III: Improving the Safety of Imported Food - 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 establish a program to expedite review and importation of food offered for importation by U.S. importers who have voluntarily agreed to participate in such program.

Authorizes the Secretary to: (1) require a certification that an article of food imported or offered for import complies with applicable requirements of this Act; and (2) enter into arrangements and agreements with foreign governments to facilitate the inspection of registered foreign facilities. 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.

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

Title IV: Miscellaneous Provisions - Authorizes appropriations for FY2011-FY2015 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 Food and Drug Administration (FDA). Directs the Secretary to increase the field staff of such Centers and Office.

Establishes whistleblower's 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 FFDCA violation.