

HR 2749

Food Safety Enhancement Act of 2009

Congress: 111 (2009–2011, Ended)

Chamber: House

Policy Area: Agriculture and Food

Introduced: Jun 8, 2009

Current Status: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and

Latest Action: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Aug 3, 2009)

Official Text: <https://www.congress.gov/bill/111th-congress/house-bill/2749>

Sponsor

Name: Rep. Dingell, John D. [D-MI-15]

Party: Democratic • State: MI • Chamber: House

Cosponsors (5 total)

Cosponsor	Party / State	Role	Date Joined
Rep. DeGette, Diana [D-CO-1]	D · CO		Jun 8, 2009
Rep. Pallone, Frank, Jr. [D-NJ-6]	D · NJ		Jun 8, 2009
Rep. Stupak, Bart [D-MI-1]	D · MI		Jun 8, 2009
Rep. Sutton, Betty [D-OH-13]	D · OH		Jun 8, 2009
Rep. Waxman, Henry A. [D-CA-30]	D · CA		Jun 8, 2009

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Reported by	Jun 11, 2009
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Aug 3, 2009

Subjects & Policy Tags

Policy Area:

Agriculture and Food

Related Bills

Bill	Relationship	Last Action
111 HRES 691	Procedurally related	Jul 30, 2009: Motion to reconsider laid on the table Agreed to without objection.

Food Safety Enhancement Act of 2009 - (Sec. 5) Exempts food and facilities regulated by the Secretary of Agriculture under specified acts from the requirements of this Act.

(Sec. 6) Exempts specified alcohol-related facilities from the requirements of this Act.

**Title I: Food Safety - Subtitle A: Prevention** - (Sec. 101) Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to deem a food to be misbranded if it was manufactured, processed, packed, or held in a facility that is not registered.

Declares that a facility under the FFDCA does not include private residences of individuals.

Requires annual registration of food facilities, including food facilities that export food.

Authorizes the Secretary of Health and Human Services (HHS) to suspend the registration of any food facility for a violation of the FFDCA that could result in serious adverse health consequences or death to humans or animals. Sets forth procedures for such a registration suspension.

Directs the Secretary to collect an annual fee for registration of a food facility to defray the costs of food safety activities. Terminates the authority to collect such fees after FY2014.

(Sec. 102) Deems a food to be adulterated if it has been manufactured, processed, packed, transported, or held under conditions that do not meet the requirements for hazard analysis and risk-based preventive controls.

Requires the owner, operator, or agent of a food facility to: (1) conduct a hazard analysis; (2) identify and implement effective preventive controls; (3) monitor preventive controls; (4) institute corrective actions as necessary; (5) conduct verification activities; and (6) maintain records of monitoring, corrective action, and verification.

Authorizes the Secretary to: (1) identify hazards that are reasonably likely to occur in the absence of preventive controls; and (2) establish preventive controls for specific product types to prevent unintentional contamination throughout the supply chain.

Requires the owner, operator, or agent of a food facility to implement a food safety plan before introducing any shipment of food into interstate commerce.

Directs the Secretary to establish science-based standards for conducting a hazard analysis, documenting hazards, identifying and implementing preventive controls, and documenting the implementation of the preventive controls.

Authorizes the Secretary to require the submission of finished product test results documenting the presence of contaminants in food posing a risk of severe adverse health consequences or death for certain high-risk food facilities after completion of pilot projects and a feasibility study.

Requires the owner, operator, or agent of a food facility to implement a food defense plan that includes: (1) an identification of conditions and practices that may permit a hazard to be intentionally introduced; and (2) a description of preventive measures implemented.

Authorizes the Secretary to establish by regulation or guidance preventive measures for specific product types to prevent intentional contamination throughout the supply chain. Requires the owner, operator, or agent of a facility to implement any preventive measures identified by the Secretary.

(Sec. 103) Deems a food to be adulterated if it has been manufactured, processed, packed, transported, or held under conditions that do not meet performance standards.

Requires the Secretary to: (1) issue science-based performance standards applicable to foods or food classes to minimize to an acceptable level, prevent, or eliminate the occurrence of the most significant foodborne contaminants and the most significant resulting hazards; and (2) publish a list of foodborne contaminants that have the greatest adverse impact on public health.

Authorizes the Secretary to make recommendations to industry for conducting product sampling.

(Sec. 104) Deems a food to be adulterated if it has been grown, harvested, processed, packed, sorted, transported, or held under conditions that do not meet safety standards for raw agricultural commodities.

Requires the Secretary to establish scientific and risk-based food safety standards for the growing, harvesting, packing, sorting, transporting, and holding of raw agricultural commodities: (1) that are a fruit, vegetable, nut, or fungus; and (2) for which the Secretary has determined that such standards are reasonably necessary to minimize the risk of serious adverse health consequences or death to humans or animals. Requires the Secretary to provide for effective implementation of education and compliance activities.

Requires the Secretary to update existing guidance related to minimizing microbial food safety hazards for fresh fruits and vegetables.

(Sec. 105) Requires food facilities to be inspected at a frequency determined pursuant to a risk-based schedule.

(Sec. 106) Directs each person who manufactures, processes, packs, transports, distributes, receives, or holds an article of food in the United States or for import into the United States to permit an officer or employee of the Secretary to have access to and copy all records bearing on whether the food may be adulterated, misbranded, or otherwise in violation of the FFDCA. Limits access to such records on farms.

(Sec. 107) Requires the Secretary to establish a tracing system for food that is located in the United States or is for import into the United States that enables the Secretary to quickly identify each person who grows, produces, manufactures, processes, packs, transports, holds, or sells such food.

Exempts certain food from tracing requirements, including food produced on a farm or produced through the use of a fishing vessel. Limits the tracing requirements for any grain or similarly handled commodity. Authorizes the Secretary to exempt a food or a type of facility, farm, or restaurant from tracing requirements.

Prohibits the violation of any requirement of the food tracing system under this section. Requires the refusal of admission of articles that have not complied with the requirements of the food tracing system.

(Sec. 108) Requires the Secretary to assess fees on each food facility in a fiscal year that: (1) commits a violation of the FFDCA relating to food and so requires additional inspections by the Food and Drug Administration (FDA); or (2) has been subject to a food recall.

(Sec. 109) Deems a food to be misbranded if it is part of a shipment offered for import into the United States and such shipment is in violation of provisions requiring a certification of compliance. Requires imported food to be refused admission if it is not in compliance with such certification requirements.

Authorizes the Secretary to require a qualified certifying entity to provide a certification that the imported food article complies with specified requirements of the FFDCA under certain circumstances. Requires qualified certifying entities to be free from conflicts of interest.

(Sec. 110) Sets forth requirements for analytical testing of an article of food conducted by an accredited laboratory. Requires the Secretary to establish a program for the recognition of bodies that accredit laboratories to perform analytical testing of food for import or export.

Prohibits violation of any requirement relating to testing by accredited laboratories.

(Sec. 111) Includes as a prohibited act under the FFDCA the failure to notify the Secretary of adulterated or misbranded food that presents a reasonable probability that the use or consumption of, or exposure to, such food will cause a threat of serious adverse health consequences or death to humans or animals.

Requires notification to the Secretary of the identity and location of certain adulterated or misbranded food.

Sets forth the circumstances under which the Secretary has the authority to: (1) request an immediate cease of distribution of a food; (2) order an immediate cease of distribution; or (3) issue an immediate recall. Provides for notice of affected persons.

(Sec. 112) Expands the definition of "responsible party" for purposes of reporting to the FDA's Reportable Food Registry to include farms, restaurants, retail food establishments, and importers. Requires reporting to include documentation of results from any sampling and testing of such article. Provides for the exchange of information on food exempt from disclosure under the Freedom of Information Act, as appropriate.

(Sec. 113) Authorizes the Secretary to establish a program that facilitates the movement of food through the importation process if the importer: (1) verifies that each facility is in compliance with food safety and security guidelines; and (2) ensures that appropriate safety and security controls are in place throughout the supply chain for such food.

(Sec. 114) Establishes additional requirements for any new infant formula, including information on prior approval of a new ingredient.

Deems a new infant formula to be misbranded if it does not meet the requirements of this section.

**Subtitle B: Intervention** - (Sec. 121) 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 develop and implement strategies to leverage and enhance the food safety and defense capacities of state and local agencies.

(Sec. 122) Requires the Secretary to design and implement a national public education program on food safety.

(Sec. 123) Requires the Secretary to conduct research to assist in the implementation of this Act, including studies to: (1) improve sanitation and food safety practices in the production, harvesting, and processing of food products; and (2) develop improved techniques for monitoring food and inspecting food products.

**Subtitle C: Response** - (Sec. 131) Revises procedures related to seizure of food, including to deem that exigent circumstances exist for all seizures brought under FFDCA provisions.

(Sec. 132) Provides for administrative detention of any food that is adulterated, misbranded, or otherwise in violation of the FFDCA.

(Sec. 133) Authorizes the Secretary to prohibit or restrict the movement of an article of food within a state if there is credible evidence that such food presents an imminent threat of serious adverse health consequences or death to humans or animals. Prohibits any action from being taken under this section unless there is no less drastic action that is feasible and that would be adequate to prevent such threat.

(Sec. 134) Extends the sentence for prohibited acts relating to adulterated or misbranded food from imprisonment for not more than one year to imprisonment for not more than ten years.

(Sec. 135) Expands civil penalties for FFDCA violations related to food.

(Sec. 136) Prohibits: (1) the submission of inaccurate or incomplete information relating to food that is required for import; and (2) the failure to submit such required information.

Authorizes the Secretary to require the submission of documentation or other information for articles of food that are imported or offered for import into the United States.

**Title II: Miscellaneous** - (Sec. 201) Requires the Secretary to post on the FDA's public website notice of any determination that a substance is a GRAS food substance and the supporting scientific justification. Defines "GRAS food substance" to mean a substance excluded from the term "food additive" because such substance is generally recognized to be safe under the conditions of its intended use.

(Sec. 202) Deems a processed food to be misbranded if the labeling fails to identify the country in which the final processing of the food occurs. Deems a nonprocessed food to be misbranded if the labeling fails to identify the country of the origin of the food.

(Sec. 203) Extends the export certification program currently applicable to drugs and devices to include food. Sets forth provisions regarding the fee for an export certification for food.

(Sec. 204) Directs the Secretary to require an importer of food to be registered with the Secretary and to submit appropriate unique facility identifiers as a condition of registration. Conditions maintenance of registration on compliance with good importer practices. Provides for suspension or cancellation of such registration. Requires the Secretary to establish an exemption for importation for personal use.

Requires the Secretary to assess an annual fee for the registration of an importer.

Deems a food to be misbranded if it is imported or offered for import by an importer not duly registered.

(Sec. 205) Directs the Secretary to require a customs broker, with respect to the importation of food, to be registered with the Secretary and to submit appropriate unique facility identifiers as a condition of registration. Authorizes the Secretary to cancel a registration. Provides for a personal use exemption.

(Sec. 206) Requires each registered food facility to submit a unique facility identifier for the facility or establishment.

( Sec. 207) Deems a product to be adulterated if inspection of the food facility is delayed, limited, or refused.

(Sec. 208) Requires the Secretary to establish and maintain a corps of inspectors dedicated to inspections of foreign food

facilities.

(Sec. 209) Requires the Secretary to submit a reorganization plan to the Comptroller General and relevant congressional committees before the Secretary terminates specified laboratories or district offices responsible for analyzing food or with food safety functions.

(Sec. 210) Prohibits the submission of any required report related to food that is false or misleading in any material respect.

( Sec. 211) Includes as a prohibited Act under the FFDCA the failure or refusal to obey a subpoena issued under such Act. Authorizes the Commissioner of Food and Drugs to issue subpoenas.

(Sec. 212) Prohibits any person required to submit information related to food from discriminating against an employee because of a lawful act done by the employee.

(Sec. 213) Prohibits the production, manufacture, processing, preparation, packing, holding, or distribution of an adulterated or misbranded food with the knowledge or intent that such article will be imported into the United States.

(Sec. 214) Requires the Secretary, acting through the Commissioner, to provide financial and other assistance to establish and maintain food protection training institutes.

(Sec. 215) Requires the Secretary to notify Congress whether the available scientific data supports a determination that there is a reasonable certainty of no harm for approved uses of polycarbonate plastic and epoxy resin made with bisphenol A in food and beverage containers under the conditions of use prescribed in current FDA regulations. Requires the Secretary to notify Congress of the actions the Secretary intends to take if such a determination cannot be made.

(Sec. 216) Deems ceramic tableware or cookware that includes a glaze or decorations containing lead and that is for an intended functional purpose to be misbranded unless: (1) the product and its packaging bears a warning that the product is made with lead-based glaze; or (2) the product is in compliance with requirements applicable to ornamental and decorative ceramicware.

Requires the Secretary to educate consumers on the safety of ceramicware for food.

## Actions Timeline

---

- **Aug 3, 2009:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
- **Jul 30, 2009:** Rule H. Res. 691 passed House.
- **Jul 30, 2009:** Considered under the provisions of rule H. Res. 691. (consideration: CR H9140-9165)
- **Jul 30, 2009:** Rule provides for consideration of H.R. 2749 with 1 hour of general debate. Previous question shall be considered as ordered without intervening motions except motion to recommit with or without instructions. Measure will be considered read. Bill is closed to amendments. In lieu of the amendment in the nature of a substitute recommended by the Committee on Energy and Commerce now printed in the bill, the amendment in the nature of a substitute printed in the report of the Committee on Rules shall be considered as adopted. All points of order against consideration of the bill are waived except those arising under clause 9 or 10 of rule XXI.
- **Jul 30, 2009:** DEBATE - The House proceeded with one hour of debate on H.R. 2749.
- **Jul 30, 2009:** DEBATE - The House continued with further debate on H.R. 2749.
- **Jul 30, 2009:** The previous question was ordered pursuant to the rule. (consideration: CR H9161)
- **Jul 30, 2009:** Mr. Lucas moved to recommit with instructions to Energy and Commerce. (consideration: CR H9161-9162; text: CR H9161-9162)
- **Jul 30, 2009:** DEBATE - The House proceeded with 10 minutes of debate on the Lucas(OK) motion to recommit with instructions. The instructions contained in the motion seek to require the bill to be reported back to the House with amendments, pending the reservation of a point of order.
- **Jul 30, 2009:** Mr. Dingell raised a point of order against the motion to recommit with instructions. Mr. Dingell stated that the provisions of the motion to recommit exceeds the scope of the bill. Overruled by the Chair.
- **Jul 30, 2009:** The previous question on the motion to recommit with instructions was ordered without objection. (consideration: CR H9164)
- **Jul 30, 2009:** On motion to recommit with instructions Failed by the Yeas and Nays: 186 - 240 (Roll no. 679).
- **Jul 30, 2009:** Passed/agreed to in House: On passage Passed by recorded vote: 283 - 142 (Roll no. 680).(text: CR H9140-9156)
- **Jul 30, 2009:** On passage Passed by recorded vote: 283 - 142 (Roll no. 680). (text: CR H9140-9156)
- **Jul 30, 2009:** Motion to reconsider laid on the table Agreed to without objection.
- **Jul 29, 2009:** Reported (Amended) by the Committee on Energy and Commerce. H. Rept. 111-234.
- **Jul 29, 2009:** Placed on the Union Calendar, Calendar No. 130.
- **Jul 29, 2009:** Mr. Dingell moved to suspend the rules and pass the bill, as amended.
- **Jul 29, 2009:** Considered under suspension of the rules. (consideration: CR H8990-9016)
- **Jul 29, 2009:** DEBATE - The House proceeded with forty minutes of debate on H.R. 2749.
- **Jul 29, 2009:** Failed of passage/not agreed to in House: On motion to suspend the rules and pass the bill, as amended Failed by the Yeas and Nays: (2/3 required): 280 - 150 (Roll no. 657).
- **Jul 29, 2009:** On motion to suspend the rules and pass the bill, as amended Failed by the Yeas and Nays: (2/3 required): 280 - 150 (Roll no. 657).
- **Jul 29, 2009:** Rules Committee Resolution H. Res. 691 Reported to House. Rule provides for consideration of H.R. 2749 with 1 hour of general debate. Previous question shall be considered as ordered without intervening motions except motion to recommit with or without instructions. Measure will be considered read. Bill is closed to amendments. In lieu of the amendment in the nature of a substitute recommended by the Committee on Energy and Commerce now printed in the bill, the amendment in the nature of a substitute printed in the report of the Committee on Rules shall be considered as adopted. All points of order against consideration of the bill are waived except those arising under clause 9 or 10 of rule XXI.
- **Jun 17, 2009:** Committee Consideration and Mark-up Session Held.
- **Jun 17, 2009:** Ordered to be Reported (Amended) by Voice Vote.
- **Jun 11, 2009:** Forwarded by Subcommittee to Full Committee (Amended) by Voice Vote .
- **Jun 10, 2009:** Subcommittee Consideration and Mark-up Session Held.
- **Jun 9, 2009:** Referred to the Subcommittee on Health.
- **Jun 8, 2009:** Introduced in House
- **Jun 8, 2009:** Referred to the House Committee on Energy and Commerce.