

The Safe Food Enforcement, Assessment, Standards and Targeting Act of 2009

Section-by-Section

Title I – General Provisions

Short title: *The Safe Food Enforcement, Assessment, Standards and Targeting Act of 2009* or “Safe FEAST Act”

Sec. 101. Inspection of Records During Food-Related Emergencies –

Allows FDA expanded access to food facility records if the Secretary has a reasonable belief that a related article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. Also allows for access to records in situations where there is a reasonable probability that a food, or a related article of food, will cause serious adverse health consequences or death to humans or animals.

Sec. 102. Registration of Food Facilities –

Expands current registration requirements for food facilities by requiring all food facilities and importers to register and renew registration biannually. Grants FDA authority to adjust food registration categories. Gives the Secretary authority to suspend facility registration if there is a reasonable probability that food from the facility will cause serious adverse health consequences or death to humans or animals.

Sec. 103. Mandatory Recall Authority –

Gives FDA the authority to order food recalls when firms fail to voluntarily recall products on their own, and where the Secretary determines that food is adulterated or misbranded under 403(w) of the FDCA (contains undeclared allergens), and will cause serious adverse health consequences or death to humans or animals. This authority shall only be delegated to the Commissioner of the FDA.

Sec. 104. Hazard Analysis and Risk-Based Prevention Controls –

Requires all domestic facilities to conduct a risk-based hazard analysis and have preventative controls in place to significantly minimize or prevent those identified hazards. Each owners or operator is required to maintain a written plan describing their hazard analysis and preventative controls. High risk facilities are required to submit plans to FDA’s CFSAN. CFSAN may offer guidance on plans efficacy. In addition, each owner or operator must maintain records to document the compliance with the plan. When an FDA inspector comes to a food facility, the owner or operator must make the written plan and records available to the inspector upon request. Failure to comply with this section would be a prohibited act under the FFDCA. The provision provides flexible compliance timeframes for small and very small businesses, and deems facilities in compliance with existing seafood, juice and low-acid canned foods regulations to be in compliance with this section.

Sec. 105. Performance Standards –

Requires FDA, not less than every two years, to determine the most significant food-borne contaminants and, if appropriate, the FDA may issue science-based guidance documents, action levels, and regulations to prevent adulteration. Performance standards cannot be facility-specific.

Sec. 106. Fresh Produce Standards –

Gives FDA the authority to set commodity-specific standards for the safe production, harvesting and packaging of fruits and vegetables, including mandatory standards for produce considered to be high risk, as well as Good Agricultural Practices (GAPS) for all produce. Requires the Secretary to coordinate enforcement with the U.S. Department of Agriculture and state agencies, and authorizes variances for local growing conditions.

Sec. 107. Targeting Inspection Resources –

Requires FDA to allocate food inspection resources according to the risk profile of the facility and other important criteria. Directs the Secretary to increase the frequency of inspections at all facilities, including requiring the Secretary to inspect high-risk facilities, at a minimum, every two years. Requires the FDA to submit an annual report to Congress regarding the frequency of and costs associated with food facility and import inspections.

Sec. 108. Administrative Detention –

Amends section 304(h) of the FFDCA to allow FDA to use administrative detention, an authority given FDA in 2002 but never used since then, when FDA has reason to believe that a food is adulterated or misbranded (the current standard for administrative detention of medical devices under section 304(g) of the FFDCA).

Sec. 109. National Agriculture and Food Defense Strategy –

Requires HHS and USDA, in coordination with DHS, to develop a National Agricultural and Food Defense Strategy and research agenda, including specific emergency preparedness, detection, response and recovery goals.

Sec. 110. Food and Agriculture Coordinating Councils –

Requires a report to Congress on the activities of the DHS-led government and private sector coordinating councils for agriculture and food defense which are designed to improve information sharing between government and private sector partners in protecting the food system.

Sec. 111. Fees –

Allows FDA to Assess fees for: compliance failures (recalls, reinspection) and services rendered such as issuance of export certificates, and participation in a voluntary qualifies importer program.

Title II – Detection, Surveillance, and Response

Sec. 201. Laboratory Accreditation –

Directs FDA to review laboratory accrediting bodies and establish a publicly available registry of FDA-recognized accrediting bodies for the purpose of the accrediting food testing laboratories, including State and local-run and operated laboratories. Requires all laboratory testing done for FDA regulatory purposes to be conducted by either an FDA lab or a lab accredited by an FDA-recognized accrediting body.

Sec. 202. Integrated Consortium of Laboratory Networks –

Requires DHS to work with HHS, USDA and EPA to effectively integrate laboratory networks and other relevant data sources to optimize national preparedness by quickly sharing information, conducting analyses, and alerting responders.

Sec. 203. Building Domestic Food Safety Capacity –

Requires a series of reports and actions intended to focus FDA's attention on several challenges, including information technology, data sharing, research and government capacity.

Sec. 204. Enhancing Traceback and Recordkeeping –

Requires the Secretary to establish a pilot project to test and evaluate new methods for rapidly and effectively tracking and tracing fruits and vegetables, and other raw commodities in the event of an emergency. Requires that the program develop methods that are appropriate for small businesses and technologies that enhance traceback and trace forward. Also requires the Secretary, after completion of the pilot project, to establish standards for the types of information, information format, timeframes for submission of food records to aid the Secretary in rapidly performing trace back activities in the event of a food-borne illness outbreak.

Sec. 205. Surveillance –

Requires the Secretary to enhance food-borne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on food-borne illnesses. Establishes a diverse working group of experts and stakeholders from Federal, State and local food safety and health agencies, the food industry, consumer organizations, and academia to provide recommendations on an ongoing basis regarding the improvement to food-borne illness surveillance. Also requires the Secretary to develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies.

Title III – Specific Provisions for Imported Food

Sec. 301. Foreign Supplier Verification Program –

Requires registered importers to perform food safety supplier verification activities to mitigate risks in imported foods, including sanitation, storage, handling, inspections, training, record keeping, etc. Importers required to comply with existing seafood, juice, and low-acid canned foods regulations are deemed to be in compliance with this section.

Sec. 302. Voluntary Qualified Importer Program –

Allows importers to qualify for expedited review and import of food if they go above and beyond the minimum standards to ensure the safety of imported food.

Sec. 303. Certification of Certain Imports –

Gives the Secretary the authority to require export certificates for high-risk foods from certifying entities in the exporting countries. Shipments lacking required certificates would be barred from entry.

Sec 304. Prior Notice of Imported Food Shipment –

This proposal amends section 801(m) of the FFDCa to require a prior notice for an imported food to include the name of any country that refused entry of the food. The change would be effective without FDA amending its regulations.

Sec. 305. Review of Regulatory Authority of a Foreign Government

The Secretary may review the statutes, regulations and standards and conduct onsite audits to verify compliance to determine if importing countries are can provide reasonable assurances that the food supply is equivalent in safety to that produced in the United States.

Sec. 306. Building Capacity of Foreign Governments –

Requires FDA to develop a comprehensive plan to help expand the technical, scientific, and regulatory capacity of foreign governments and their respective food industries.

Sec. 307. Inspection of Foreign Food Facilities –

Authorizes Secretary to enter into agreements and arrangements with foreign governments to facilitate the inspection of foreign facilities. Refuses entry of food from a foreign facility or country that fails to permit inspection by the United States.

Sec. 308. Accreditation of Qualified Third-Party Auditors –

Directs FDA to establish an accreditation system by which qualified third parties and duly trained auditing agents may certify that food facilities are in compliance with U.S. food safety standards. Qualified third parties auditors can include foreign governments, states and foreign or other eligible third parties. FDA is required to establish adequate protections against conflicts of interest between facilities and certifying agents. Costs of the accreditation program will be paid by applicants.

Sec. 309 Funding for Food Safety –

Such sums as are necessary to meet the requirements of this Act.

Sec 310. Jurisdiction: Authorities –

Clarifies that amendments made by this bill do not change jurisdiction between the FDA and Dept. of Agriculture, and FDA retains its current food safety authority under the FFDCa and the Public Health Service Act.