

Food Defense Legislation



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H.R. 2749 and S. 510

- Lawyer & Consultant-- Not Lobbyist!
- Observations & Trends
- Increased Govt. Involvement & Oversight
- Emphasis on Farm to Fork (Process Driven)
- Develop Scientific & Performance Standards
- Connect Food Industry w/National Security
- Good News: Your job function more important
- Bad News: Your “plate” will be filled

“Food Safety Enhancement Act of 2009”

H.R. 2749

- Amends Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et 7 seq.)
- **SEC. 5. USDA REGULATED PRODUCTS EXEMPTION:**
Food is exempt from the requirements of this Act to the extent that such food is regulated by the Secretary of Agriculture under:
 - the Federal Meat Inspection Act (21 U.S.C. 601 et seq.),
 - the Poultry Products Inspection Act (21 U.S.C. 451 et 4 seq.),
 - the Egg Products Inspection Act (21 U.S.C. 1031 5 et seq.).

EXEMPTIONS

- Livestock and poultry that are intended to be presented for slaughter are exempt from the requirements of the Act.
- A farm is exempt from the requirements of this Act to the extent such farm raises animals from which food is derived that is regulated under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act.
- A cow, sheep, or goat that is used for the production of milk is exempt from the requirements of the Act.
- Facility is exempt from the requirements of this Act to the extent such facility is regulated as an official establishment by the Secretary of Agriculture.

“Food Safety Enhancement Act of 2009”

H.R. 2749

- Sec. 101. Changes in registration of food facilities.
- Sec. 102. Hazard analysis, risk-based preventive controls, & food safety plan.
- Sec. 103. Performance standards.
- Sec. 104. Safety standards for produce and certain other raw agricultural commodities.
- Sec. 105. Risk-based inspection schedule.
- Sec. 106. Access to records.
- Sec. 107. Traceability of food.
- Sec. 108. Re-inspection and food recall fees applicable to facilities.
- Sec. 109. Certification and accreditation.
- Sec. 110. Testing by accredited laboratories.
- Sec. 111. Notification, non-distribution, and recall of adulterated or misbranded food.
- Sec. 112. Reportable food registry; exchange of information.
- Sec. 113. Safe and secure food importation program.
- Sec. 114. Infant formula.

Food Safety Plan Requirements:

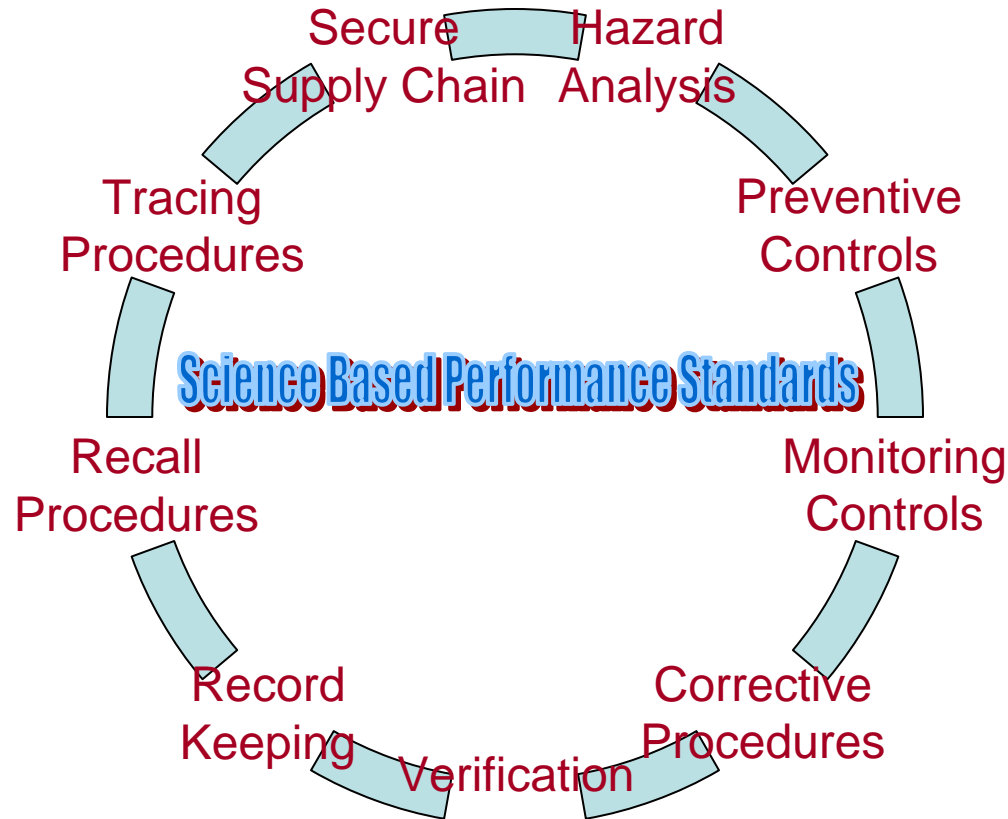
- (1) **Hazard analysis** & any re-analysis conducted.
- (2) Description of the **preventive controls** being implemented.
- (3) Description of the procedures for **monitoring** preventive controls.
- (4) Description of the **corrective procedures** implemented.
- (5) Description of **verification** activities for the preventive controls.

Food Safety Plan Requirements:

Continued

- (6) Description of the facility's **record keeping** procedures.
- (7) Description of the facility's **recall** procedures.
- (8) Description of the facility's procedures for **tracing** the distribution history of articles of food.
- (9) Description of the facility's procedures to ensure a safe and **secure supply chain** for the ingredients or components used in making the food manufactured, processed, packed, transported, or held by such facility.
- (10) Description of the facility's procedures to implement the **science-based performance standards**.

Food Safety Plan Requirements



Section 101

Registration

- Food deemed misbranded if it was manufactured, processed, packed, or held in a ***facility that is not registered***.
- Requires annual registration of food facilities, including facilities that export food (Contact/Food Category/Trade Names).
- Authorizes the Secretary of Health and Human Services (HHS) to suspend the registration of any food facility for a violation of the act that could result in serious adverse health consequences or death to humans or animals.
- Sets forth procedures for such a registration suspension:
 1. Notice
 2. Informal Hearing
 3. Request Reinstatement after Correcting Violation
- Directs the Secretary to collect an annual fee for registration of a food facility to defray the costs of food safety activities:
 - \$500.00 for 2010
 - \$175,000.00 maximum

Section 102

Hazard Analysis & Preventive Controls

- Food Deemed 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.***
- Takes effect 18 months after the enactment of the Act.

Requirements

(1) Conduct a **hazard analysis** of:

Processing security, cyber-security, material security (including ingredients, finished product, and packaging), personnel security, storage security, shipping and receiving security, and utility security.

(2) Identify and implement effective **preventive** controls;

(A) Sanitation procedures and practices

(B) Supervisor, manager, and employee hygiene training

(C) Process controls

(D) An allergen control program to minimize potential allergic reactions in humans from ingestion of, or contact with, human and animal food

(E) Good manufacturing practices

(F) Verification procedures, practices, and processes for suppliers and incoming ingredients, which may include onsite auditing of suppliers and testing of incoming ingredients

(G) Other procedures, practices, and processes established by the Secretary

Requirements

Continued

- (3) **Monitor** preventive controls;
- (4) Institute **corrective** actions as necessary;
- (5) Conduct **verification** activities (“scientifically and technically sound” system of verification);
- (6) Maintain **records** of monitoring, corrective action, and verification (not less than 2 years).
- (7) **Re-analyze** for hazards:
 - (i) not less than every 2 years;
 - (ii) if there is a change in the process or product that could affect the hazard analysis; and
 - (iii) if the Secretary determines that it is appropriate to protect public health;

Section 102

Continued

- Authorizes the Secretary by *regulation* or *guidance* 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 Food Safety Plan *before* introducing any shipment of food into interstate commerce.

Access To the Food Safety Plan

ON INSPECTION: An officer or employee of the Secretary **shall** have access to the food defense plan of a facility only if the Secretary, through an official who is the director of the district under this Act in which the facility is located or an official who is senior to such a director, provides notice.

NONDISCLOSURE: Of the food defense plan, and any information derived from such a plan.

Section 103

Performance Standards

- Food deemed 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 food borne contaminants and the most significant resulting hazards; and
 - (2) publish a list of food borne contaminants that have the greatest adverse impact on public health.
- Authorizes the Secretary to make recommendations to industry for conducting product sampling.

Section 104

Safety standards for raw agricultural commodities

- Food deemed 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.

Section 105

Inspections

- **Requires food facilities to be inspected at a frequency determined pursuant to a risk-based schedule.**
- **Shall be implemented beginning not later than 18 months after the date of the enactment.**
- **Based on the following categories & inspection frequencies:**

CATEGORY 1: randomly inspect at least every 6 to 12 months.

CATEGORY 2: randomly inspect at least every 18 months to three years.

CATEGORY 3: randomly inspect a category 3 facility at least every five years.

Section 105

Continued

- May alter the inspection frequencies based on the need to respond to food-borne illness outbreaks and food recalls; and
- May inspect a facility more frequently than the inspection frequency provided (Govt. Discretion).
- Publish in the *Federal Register* adjustments to the inspection frequencies for category 2 and category 3 food facilities based on:
 - A. The type of food manufactured, processed, packed, or held at the facility;
 - B. The compliance history of the facility;
 - C. Whether the facility importing or offering for import into the U.S. food is certified by a qualified certifying entity, and
 - D. Such other factors as the Secretary determines by guidance to be relevant to assessing the risk presented by the facility.

Section 106

Record Access Requirements

- 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 act.

Section 107

Tracing System

- Requires the Secretary to establish a tracing system for food that is located in the U.S., or is for import into the U.S.
- Goal is to enable 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 violations of any food tracing system requirements.
- Requires the refusal of admission of articles that have not complied with the requirements of the food tracing system.

Tracing Criteria

- (i) Establishment & maintenance of lot numbers;
- (ii) Standardized format for pedigree information;
and
- (iii) Use of a common nomenclature for food

Section 109

Certification and accreditation

- Food deemed misbranded if it is part of a shipment offered for import into the U.S. 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.
- Under certain circumstances, authorizes the Secretary to require a qualified certifying entity to provide a certification that the imported food article complies with specified requirements of the act.
- Requires qualified certifying entities to be free from conflicts of interest.

Section 111

Recall Requirements

- Prohibits the failure to notify the Secretary of any 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.

Section 113

Safe & secure food importation program

- 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.
- Such guidelines shall take into account the following factors:
 - (A) The personnel of the firm importing the food.
 - (B) The physical and procedural safety and security of the firm's food supply chain.
 - (C) The sufficiency of preventive controls for food and ingredients purchased by such firm.
 - (D) Vendor and supplier information.
 - (E) Other programs for certification or verification by a qualified certifying entity used by the importer.
 - (F) Such other factors as the Secretary determines necessary.

Section 134

Criminal Sanctions

- Criminal sentencing for prohibited acts relating to adulterated or misbranded food:
- Imprisonment for not more than one year (prior)
- Imprisonment for not more than ten years (new)

Section 135

Civil Penalties

- (A) Any person who violates a provision of section 301 relating to food shall be subject to civil penalty for each such violation of not more than:
 - (i) **\$20,000** in the case of an individual, not to exceed \$50,000 in a single proceeding; and
 - (ii) **\$250,000** in the case of any other person, not to exceed **\$1,000,000** in a single proceeding.
- (B) Any person who **knowingly** violates a provision of section 301 relating to food shall be subject to civil penalty for each such violation of not more than:
 - (i) **\$50,000** in the case of an individual, not to exceed **\$100,000** in a single proceeding; and
 - (ii) **\$500,000** in the case of any other person, not to exceed **\$7,500,000** in a single proceeding.

Section 212

Whistleblower protections

- Prohibits any person required to submit information related to food from discriminating against an employee because of a lawful act done by the employee.
- Prohibits discharge, demotion, suspension, threats, harassment, or in any other discrimination against an employee in the terms and conditions of employment because of any lawful act done by the employee, including within the ordinary course of the job duties of such employee:

Whistleblower protection

Continued

(1) Provided information, caused information to be provided, or otherwise assisted in any investigation regarding any conduct which the employee reasonably believes constitutes a violation of this Act, or any other provision of Federal law relating to the safety of a food, if the information or assistance is provided to, or an investigation stemming from the provided information is conducted by:

- (A) a Federal regulatory or law enforcement agency;
- (B) any Member of Congress or any committee of Congress; or
- (C) a person with supervisory authority over the employee (or such other person working for the employer who has the authority to investigate, discover, or terminate the misconduct;

Whistleblower protection

Continued

(2) To file, cause to be filed, testify, participate in, or otherwise assist in a proceeding filed, or about to be filed (with any knowledge of the employer), in any court or administrative forum relating to any such alleged violation; or

(3) To refuse to commit or assist in any such violation.

FDA Food Safety Modernization Act

S. 510

- Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to expand the authority of the Secretary of Health and Human Services to regulate food, including by authorizing the Secretary to suspend the registration of a food facility.
- Requires each food facility to evaluate hazards and implement preventive controls.

FDA Food Safety Modernization Act

S. 510

- Sec. 101. Inspections of records
- Sec. 102. Registration of food facilities
- Sec. 103. Hazard analysis & risk-based preventive controls
- Sec. 104. Performance standards
- Sec. 105. Standards for produce safety
- Sec. 106. Protection against intentional adulteration
- Sec. 107. Authority to collect fees
- Sec. 108. National agriculture and food defense strategy
- Sec. 109. Food and Agriculture Coordinating Councils
- Sec. 110. Building domestic capacity
- Sec. 111. Sanitary transportation of food
- Sec. 112. Food allergy and anaphylaxis management

Section 101

Inspections of records

- (1) ADULTERATED FOOD
- (2) USE OF OR EXPOSURE TO FOOD OF CONCERN

Section 102

Registration of Food Facilities

- BIENNIAL REGISTRATION RENEWAL
- SUSPENSION OF REGISTRATION
- HEARING ON SUSPENSION
- POST-HEARING CORRECTIVE ACTION PLAN

Section 103

Hazard Analysis & Risk Based Preventive Controls

- HAZARD ANALYSIS
- PREVENTIVE CONTROLS
- MONITORING OF EFFECTIVENESS
- CORRECTIVE ACTIONS
- VERIFICATION
- RECORDKEEPING
- WRITTEN PLAN & DOCUMENTATION
- REQUIREMENT to REANALYZE

PREVENTIVE CONTROLS

- Those procedures, practices, & processes *may* include the following:
 - (A) Sanitation procedures for food contact surfaces and utensils and food-contact surfaces of equipment
 - (B) Supervisor, manager, and employee hygiene training
 - (C) An environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment
 - (D) Food allergen control program
 - (E) Recall plan
 - (F) Good Manufacturing Practices (GMPs).
 - (G) Supplier verification activities

Section 104

Performance Standards

- The Secretary shall, not less frequently than every 2 years, review and evaluate relevant health data and other relevant information, including from toxicological and epidemiological studies and analyses, to determine the most significant food borne contaminants.
- Based on such review and evaluation, and when appropriate to reduce the risk of serious illness or death to humans or animals or to prevent adulteration of the food.

Section 107

Authority to Collect Fees

Fiscal year fees shall be based on the Secretary's estimate of 100 percent of the costs of the activities

Section 108

National Agriculture & Food Defense Strategy

- The strategy shall be consistent with:
 - (A) the National Incident Management System;
 - (B) the National Response Framework;
 - (C) the National Infrastructure Protection Plan;
 - (D) the National Preparedness Goals; and
 - (E) other relevant national strategies.

Section 109

Food & Agriculture Coordinating Councils

- (1) Facilitating partnerships between public and private entities to help coordinate and enhance the protection of the agriculture and food system of the United States;
- (2) Providing for the regular and timely interchange of information between each council relating to the security of the agriculture and food system (including intelligence information);
- (3) Identifying best practices and methods for improving the coordination among Federal, State, local, and private sector preparedness and response plans for agriculture and food defense; and
- (4) Recommending methods by which to protect the economy and the public health of the United States from the effects of:
 - (A) animal or plant disease outbreaks;
 - (B) food contamination; and
 - (C) natural disasters affecting agriculture and food.

Section 110

Building Domestic Capacity

- Secretary shall issues report including description of the following:
 - (A) Analysis of the need for further regulations or guidance to industry.
 - (B) Outreach to food industry sectors, including through the Food and Agriculture Coordinating Councils to identify potential sources of emerging threats to the safety and security of the food supply and preventive strategies to address those threats.
 - (C) Systems to ensure the prompt distribution to the food industry of information and technical assistance concerning preventive strategies.
 - (D) Communication systems to ensure that information about specific threats to the safety and security of the food supply are rapidly and effectively disseminated.
 - (E) Surveillance systems and laboratory networks to rapidly detect and respond to food borne illness outbreaks and other food-related hazards, including how such systems and networks are integrated.
 - (F) Outreach, education, and training provided to States and local governments to build State and local food safety and food defense capabilities, including progress implementing strategies.
 - (G) The estimated resources needed to effectively implement the programs and practices identified in the report developed in this section over a 5-year period.
 - (H) The impact of requirements under this Act on certified organic farms and facilities

QUESTIONS



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