July 2009

SECTION-BY-SECTION SUMMARY OF H.R. 2749, THE FOOD SAFETY ENHANCEMENT ACT OF 2009

Committee on Energy and Commerce

Section 1. Short title

The short title is designated as the "Food Safety Enhancement Act of 2009".

Section 2. Table of contents

Section 2 provides the table of contents.

Section 3. References

Section 3 establishes that unless otherwise specified, amendments made to a section or other provisions are considered to be made to a section or provision of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Section 4. Rules of construction

Section 4 establishes that the Food Safety Enhancement Act of 2009 shall not be construed as modifying or otherwise affecting any action or the liability of any person under the law of any state.

Section 4 further establishes that the Food Safety Enhancement Act of 2009 shall not be construed to alter the jurisdiction between the Secretary of Agriculture and the Secretary of Health and Human Services; to limit the authority of the Secretary of Health and Human Services to issue regulations related to the safety of food under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act; or to impede, minimize, or affect the authority of the Secretary of Agriculture to prevent, control, or mitigate a plant or animal health emergency, or a food emergency involving products regulated under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act.

Section 5. USDA Exemptions

Section 5 clarifies the effect of the Food Safety Enhancement Act of 2009 on USDA-regulated foods, farms, and facilities.

A food is exempt from the requirements of the Food Safety Enhancement Act of 2009 to the extent such food is regulated by the Secretary of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act.

Livestock and poultry that are intended to be presented for slaughter pursuant to the regulations by the Secretary of Agriculture under the Federal Meat Inspection Act or the Poultry Products Inspection Act are exempt from the requirements of this Act.

A facility is exempt from the requirements of this Act if such facility is regulated as an official establishment by the Secretary of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act or under a similar program recognized by the Secretary of Agriculture as at least equal to a federal program.

A farm is exempt from the requirements of this Act to the extent that 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. The portions of a farm that produce FDA-regulated foods are covered by the provisions of the bill.

Section 6. Alcohol-related facilities.
Section 6 establishes that an alcohol-related facility that is required to register as a facility under section 415 of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, solely because such facility is engaged in manufacturing, processing, packing, or holding 1 or more alcoholic beverages, is not subject to the requirements of the Food Safety Enhancement Act of 2009 if such facility is required to obtain a permit or to register with the Secretary of the Treasury as a condition of doing business. However, such facility is still subject to the registration requirements set forth in Section 101 (a) and (b) of the Food Safety Enhancement Act of 2009 and may participate in the Safe and Secure Food Importation Program established under Section 113 of the Act.

Section 6 shall not be construed to exempt any food, apart from alcoholic beverages, from the requirements of the FSEA.

TITLE I — FOOD SAFETY

Subtitle A — Prevention

Section 101. Changes in Registration of Food Facilities.
Section 101 amends section 415 of the FFDCA to require annual facility registration. Registrants are required to provide additional information pertaining to the facility, including contact information, the primary purpose and business activity of the facility, all trade names under which the facility conducts business related to food, and for foreign facilities, the United States agent for the facility. The registrant is required to notify the Secretary of any change in the submitted information no later than 30 days after the date of such change.

A "facility" is defined to include any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Facilities do not include farms; private residences of individuals; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels.

The Secretary is authorized to suspend the registration of a facility for a violation of the Act that could result in serious adverse health consequences or death. The Secretary is also granted authority to cancel a registration that the Secretary determines was not updated or otherwise contains false, incomplete, or inaccurate information, or if the required registration fee has not been paid within 30 days after the due date. However, an order to suspend or cancel a registration shall not be delegated to any officer or employee other than the Commissioner, the Principal Deputy Commissioner, Associate Commissioner for Regulatory Affairs, or the Director for the Center for Food Safety and Applied Nutrition.

The Secretary is required to provide a report to Congress annually detailing the number and type of facilities registered under this section.

Section 101 requires the Secretary to assess and collect an annual fee of $500 for the registration of a facility under section 415 of the FFDCA. The fee shall be collected and available to defray the costs of food safety activities (activities related to compliance by facilities registered under section 415 with the requirements of this Act relating to food). The registration fee shall not exceed $175,000 for an individual company. The Secretary is required to hold a public meeting to allow stakeholders to provide input into how the fee revenue will be allocated.

Section 102. Hazard Analysis, Risk-Based Preventive Controls, Food Safety Plan, and Finished Product Test Results from Category 1 Facilities.

Section 102 requires the owner, operator, or agent of a facility to develop and implement a written food safety plan. As part of this food safety plan, the owner, operator, or agent shall conduct a hazard analysis; identify, implement, and validate effective preventive controls; monitor preventive controls; institute corrective actions when monitoring shows that preventive controls have not been properly implemented or were ineffective; conduct verification activities; maintain records of monitoring, corrective action, and verification; and reanalyze for hazards. The food safety plan shall also include a description of the facility's procedures for recordkeeping; recall; trace back; supply chain safety; and science-based performance standards. When developing food safety plans under Section 102, facilities should evaluate whether there are hazards that could affect the safety, sanitation or wholesomeness of the food manufactured, processed, packed, transported, or held by the facility.

The requirements of this section shall take effect 18 months after the date of enactment. Small businesses and very small businesses will have 2 years and 3 years, respectively, to comply.

Section 102 also requires certain high-risk facilities to submit finished product test results documenting the presence of contaminants in food posing a risk of severe adverse health consequences or death. Before requiring the reporting of such test results, the Secretary must conduct 2 or more pilot projects and a study to evaluate the feasibility of such a reporting system.

Section 102 requires facilities to implement a written food defense plan to protect against intentionally introduced contaminants.

Section 103. Performance Standards.

Section 103 requires the Secretary to, not less frequently than every 2 years, identify the most significant foodborne contaminants and the most significant resulting hazards. The Secretary shall issue science-based performance standards to minimize to an acceptable level, prevent, or eliminate the occurrence of such hazards.

Section 103 also requires the Secretary to publish in the Federal Register a list of foodborne contaminants that have the greatest adverse impact on public health. In determining whether a particular foodborne contaminant should be added to such list, the Secretary is required to consider the number and severity of illnesses and the number of deaths associated with the foods associated with such contaminants.

Section 104. Safety Standards for Fresh Produce and Certain Other Raw Agricultural Commodities.

Section 104 requires the Secretary, in coordination with the Secretary of Agriculture, to establish by regulation science-based standards for the safe growing, harvesting, packing, sorting, transporting, and holding of raw agricultural commodities for which the Secretary has determined that such standards

minimize the risk of serious adverse health consequences or death to humans or animals. The Secretary shall provide a reasonable period of time for compliance, taking into account the needs of small business for additional time to comply.

Section 104 requires the Secretary, in issuing the regulations under this section, to take into consideration, consistent with ensuring enforceable public health protection, the impact of any regulations issued under this section on small-scale and diversified farms, and on wildlife habitat, conservation practices, water-shed protection efforts, and organic production methods. The Secretary is permitted to provide for coordination with other entities and provide for recognition through guidance of other existing publicly available procedures, processes, and practices that the Secretary determines to be equivalent to the goals established under this section.

Section 104 requires the Secretary to update the guidance document entitled ''Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.''

Section 105. Risk-based Inspection Schedule.
Section 105 requires that each facility registered under section 415 be inspected by the Secretary, by a federal, state, or local official in the case of a domestic facility, or by an agency or representative of a country in the case of a foreign facility, according to a risk-based schedule. The risk-based schedule shall be implemented not later than 18 months after enactment and shall provide for a frequency of inspections commensurate with the risk presented by the facility and shall be based on the following categories and inspection frequencies:

Category 1 (high-risk) -- the Secretary shall randomly inspect a category 1 food facility at least every 6 to 12 months.
Category 2 (low-risk) -- the Secretary shall randomly inspect a category 2 facility at least every 18 months to 3 years.
Category 3 (facility that holds food) -- the Secretary shall randomly inspect a category 3 facility at least every 5 years.

Prior to implementing this schedule, the Secretary must issue a notice in the Federal Register detailing the basis for ranking facilities and provide for a 60 day comment period and a public meeting to obtain input. The Secretary must undergo a similar process when the Secretary proposes to change its process for assessing high risk facilities.

Section 105 requires the Secretary to provide an annual report to Congress on the number of facilities inspected and the costs of implementing the risk-based inspection schedule for the preceding 12 months. In the third year after enactment, the Secretary is also required to submit to Congress a report describing recommendations on the risk-based inspection schedule, including recommendations for adjustments to the timing of the schedule. In making recommendations to change the inspection schedule, the Secretary shall consider the nature of the food products being processed, stored, or transported; the manner in which food products are processed, stored, or transported; the inherent likelihood that the products will contribute to the risk of foodborne illness; the best available evidence concerning reported illnesses associated with the foods processed, stored, held, or transported in the category of facilities; and the overall record of compliance with food safety law among facilities in the category, including compliance with applicable performance standards and the frequency of recalls.

Six months after submitting the Third-Year Report, the Secretary may implement the adjustments to the inspection schedule recommended in the Third Year Report with respect to Category 2 and Category 3

facilities only. The new inspection schedule and a justification for the changes must be published in the Federal Register.

Section 106. Access to Records.
Section 106 requires each person who produces, 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 duly designated by the Secretary to have access to and copy all records relating to such article bearing on whether the food may be adulterated, misbranded, or otherwise in violation of this Act during an inspection.

If the Secretary has a reasonable belief that an article of food presents a threat of serious adverse health consequences of death to human or animals, the Secretary is authorized to remotely access records reasonably related to that food. The Secretary may also remotely access records related to the food safety plan, supporting information relied on by the facility to select the preventive controls to include in its food safety plant, and documentation of corrective actions, if any, taken within the preceding two years.

The Secretary can access farm records under this Section when the Secretary has issued a safety standard for a particular food under Section 104, or for a food that is the subject of an active investigation of foodborne illness outbreak (except grains).

Section 106 requires the Secretary to issue regulations regarding the establishment and maintenance, for not longer than 3 years, of records by persons who produce, manufacture, process, pack, transport, distribute, receive, or hold food in the United States or for import into the United States. The Secretary shall take into account the size of a business in promulgating regulations under this section. The Secretary is only authorized to require restaurants to maintain distribution records showing their suppliers, and subsequent distribution other than to consumers.

Section 107. Traceability of Food.
Section 107 requires the Secretary to establish, by regulation, a tracing system for food that is located in the United States or is for import into the United States. Before issuing a proposed regulation, the Secretary shall conduct information gathering to (1) identify technologies and methodologies for tracing to enable each person who produces, manufactures, processes, packs, transports, or holds a food to maintain the full pedigree of the origin and previous distribution history of the food, link that history with the subsequent distribution of the food, establish and maintain a system for tracing the food that is interoperable with the systems established and maintained by other such persons, and to use a unique identifier; and (2) to the extent practicable, assess the costs and benefits associated with the adoption of such technologies, the feasibility of such technologies for different sectors for the food industry, and whether such technologies are compatible with the requirements of this subsection.

Section 107 requires the Secretary to take into account information obtained through this information gathering process, and to conduct at least 2 public meetings and one or more pilot projects. The Secretary shall consult with the Secretary of Agriculture in conducting pilot projects with respect to farms. After completing this public input process, the Secretary shall issue regulations establishing a tracing system that enables the Secretary to identify each person who grows, produces, manufacturers, processes, packs, transports, holds or sells such food in as short a timeframe as practicable, but in no longer than 2 business days. The Secretary may include in such regulation: the establishment and maintenance of lot numbers; a standardized format for pedigree information; and the use of a common nomenclature for food. In issuing such regulation that will impact farms, the Secretary must coordinate with the Secretary of Agriculture and take into account the impact of the regulations on farms.

Food produced on a farm and sold directly to a consumer, restaurant, or grocery store is exempt from the tracing system requirements, although restaurants and grocery stores must keep records documenting the farm that was the source of the food. If food is produced through the use of a fishing vessel, the food is exempt from the requirements of this section until the food is sold by the fishing vessel. Any tracing system with respect to grains must be limited to enabling the Secretary to identify persons who handled the grains from the initial warehouse that held the grain to the ultimate consumer. The Secretary is also granted authority to exempt a food from the tracing system requirements if the Secretary determines application of these requirements is not necessary to protect the public health. For a food so exempted, each person who produces, manufactures, processes, packs, transports, or holds such food is required to maintain records to identify the immediate previous sources of such food and its ingredients and the immediate subsequent recipients of such food.

Section 108. Reinspection and Food Recall Fees Applicable to Facilities.
Section 108 requires the Secretary to assess and collect fees from each facility in a fiscal year that undergoes additional inspection by FDA due to a violation of any requirement of the Federal Food, Drug, and Cosmetic Act or is subject to a recall.

Section 108 establishes that there will be an exemption from the fees for a recall that FDA inappropriately ordered.

Section 109. Certification and Accreditation.
Section 109 establishes that certain imported foods be accompanied by a certification that the food complies with specified requirements of the Federal Food, Drug, and Cosmetic Act. The Secretary shall require certification for food imported from a particular country or region if certification would assist the Secretary in determining whether to refuse to admit such article; for a type of food that could pose a significant risk to health, certification would assist the Secretary in determining whether such article poses such risk; or for an article imported from a particular country, there is an agreement between the Secretary and the government of such country providing for such certification. Certifications under this section must be provided by a "qualified certifying entity." A qualified certifying entity may be an agency or a representative of the government of the country from which the article originated, an individual or entity determined by the Secretary, or an accredited body recognized by the Secretary. The Secretary is required to issue regulations to ensure that any qualified certifying entity and its auditors are free from conflicts of interest.

Section 110. Testing by Accredited Laboratories.
Section 110 requires that whenever analytical testing of an article of food is conducted as part of testimony in a food import detention hearing or for other purposes as the Secretary deems appropriate, such testing shall be conducted by a laboratory that is accredited for the analytical method used, by a laboratory accreditation body that has been recognized by the Secretary; and samples such article with adequate controls for ensuring the integrity of the samples analyzed. When testing is required for purposes of a food import detention hearing, in response to a finding of non-compliance by the Secretary, or for certain products designated by the Secretary, the test must be conducted by an accredited, independent laboratory that is independent of the person on whose behalf such testing is conducted.

The Secretary shall establish and implement a program for the recognition of laboratory accreditation bodies that accredit laboratories to perform analytical testing for the purposes of this section.

Whenever such analytical testing is conducted, the laboratory conducting such testing shall submit, directly to the Secretary the results of all analyses conducted by the laboratory on each sample of such article; and all information the Secretary deems appropriate to determine whether the laboratory is accredited by a recognized laboratory accreditation body, identify the article tested, evaluate the analytical results, and determine whether the requirements of this section have been met. Section 110 requires the Secretary to consider and utilize as appropriate, the testing results issued by Customs and Border Patrol (CBP) laboratories in making a decision about the admissibility of the product if CBP laboratory testing concludes that an article of food is adulterated or misbranded.

Section 111. Notification, Nondistribution, and Recall of Adulterated or Misbranded Food.
Section 111 requires food facilities, importers, customs brokers, and filers that have reason to believe that an article of food is adulterated or misbranded in a manner that presents a reasonable probability that the use or consumption of, or exposure to, the article will cause a threat of serious adverse health consequences or death to humans or animals to notify the Secretary of the identity and location of the article as soon as practicable.

The Secretary may request that any person who distributes an article of food that the Secretary has reason to believe is adulterated, misbranded, or otherwise in violation of this Act voluntarily recall such article.

The Secretary shall have the authority to issue an order requiring any person who distributes an article of food to immediately cease distribution of such article if the Secretary has reason to believe that the use or consumption of, or exposure to, the article of food may cause serious adverse health consequences or death to humans or animals. The person subject to the order may appeal the order and request an informal hearing. If after providing an opportunity for an informal hearing under subsection (d), the Secretary determines that the order should be amended to include a recall of the article with respect to which the order was issued, the Secretary shall amend the order to require a recall. Only the Secretary or an official designated by the Secretary may order the recall. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.

If the Secretary has credible evidence or information that an article of food subject to an order to cease distribution presents an imminent threat of serious health consequences or death to humans or animals, the Secretary may issue an emergency recall order requiring any person who distributes such article to immediately recall such article. An informal hearing shall be granted following the cease distribution and emergency recall. Section 111 requires that an emergency recall order come from the FDA Commissioner, Principal Deputy Commissioner or Associate Commissioner for Regulatory Affairs.

Section 112. Reportable Food Registry; Exchange of Information.
Section 112 amends section 417 of the Federal Food, Drug, and Cosmetic Act to require an owner of a food facility, farm, or restaurant to submit a report to FDA following a timely review of any reasonably available data and information that indicates that there is a reasonable probability that use of, or exposure to, a particular article of food will cause serious adverse health consequences or death to humans or animals. Section 112 requires the report to also include analytical results from testing of such article and such additional information as the Secretary deems appropriate. Section 112 requires the Secretary to make available other means of reporting for restaurants and other retail food establishments that have limited ability to report via electronic means.

Section 112 authorizes the Secretary to share certain confidential information relating to food with any federal agency, state, local, or foreign government, or any person. This information shall not be publicly disclosed.

Section 113. Safe and Secure Food Importation Program.
Section 113 permits the Secretary to establish by regulation or guidance, in coordination with CBP, a program to facilitate the movement of food through the importation process if the importer of such food verifies that each facility involved in the production, manufacture, processing, packaging, and holding of the food has been determined to be in compliance with food safety and security guidelines developed by the Secretary, in consultation with CBP. The Secretary is required to take into account other relevant federal programs in developing food safety and security guidelines.

Section 114. Infant Formula.
Section 114 requires that no person shall introduce or deliver for introduction into interstate commerce infant formula prior to receiving a letter from the Secretary informing such person that the registration requirements and the requirements that demonstrate that the infant formula satisfies the quality factor requirements established by the Secretary.

Subtitle B — Intervention

Section 121. Public Health Assessment System.
Section 121 requires the Secretary to enhance the current food safety surveillance systems to include the collection, analysis, reporting, and usefulness of data on foodborne illnesses by coordinating federal, state, and local surveillance systems, and increasing participation in national networks of public health and food regulatory agencies and laboratories; facilitating the timely sharing of food safety findings and data with the public; developing improved epidemiological tools for obtaining better data; improving attribution of a food-borne illness outbreak to a specific food; expanding capacity of surveillance systems to identify new or rarely documented causes of foodborne illness; and other activities deemed appropriate by the Secretary. Section 121 requires the Secretary to develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies.

Section 122. Public Education and Advisory System.
Section 122 requires the Secretary, in collaboration with private and public organizations, to design and implement a national public education program on food safety that would educate the public on how to reduce their risk of foodborne illness and injury and provide information to health care professionals to improve diagnosis and treatment of foodborne illnesses. This section also directs the Secretary to work with the states and other entities to develop and distribute regional and national advisories concerning food safety; develop standardized formats for written and broadcast advisories; and incorporate state and local advisories into the national public education program.

Section 123. Research.
Section 123 requires the Secretary to conduct research to assist in the implementation of the Food Safety Enhancement Act of 2009, including studies to improve sanitation and food safety practices; develop improved monitoring and inspection techniques; develop rapid and sensitive food testing methods; determine the sources of food contamination, including critical points of risk for fresh produce and other raw agricultural commodities; develop consumption data for food products; utilize DNA matching systems to identify and control pathogens; address common and emerging zoonotic diseases; develop methods to destroy pathogens before, during and after processing; and analyze the incidence of antibiotic

resistance as it pertains to the food supply and evaluate methods to reduce the transfer of antibiotic resistance to humans.

Subtitle C — Response

Section 131. Procedures for seizure.
Section 131 amends section 304 of the FFDCA to stipulate that with respect to seizure proceedings relating to food, Rule G of the Supplemental Rules of Admiralty or Maritime Claims and Asset Forfeiture Actions shall not apply.

Section 132. Administrative detention.
Section 132 amends Section 304 of the Federal Food, Drug, and Cosmetic Act to allow an official or qualified employee of FDA to order the detention of any article of food if they have reason to believe that such article is adulterated, misbranded, or otherwise in violation of this Act.

Section 132 extends the time period during which a food may be detained from 30 to 60 days, and extends from 5 to 15 days the deadline for an informal hearing when such detention is challenged.

Section 133. Authority to Prohibit or Restrict the Movement of Food.
Section 133 permits the Secretary authority, after consultation with the Governor or other appropriate official of an affected State, to prohibit or restrict the movement of an article of food within a state or portion of a state if the Secretary determines there is credible evidence that the article of food presents an imminent threat of serious adverse health consequences or death. The authority to quarantine includes prohibiting or restricting the movement of food or of any vehicle being used to hold such food.

Section 133 requires the Secretary, prior to prohibiting or restricting the movement of food, to notify the Governor or other appropriate official of a state; issue a public announcement of the proposed action; and publish in the Federal Register a description and reasons for the proposed action. The Secretary cannot prohibit or restrict the movement of food unless he/she believes there is no less drastic action that is feasible and that would be adequate to prevent the imminent threat of serious adverse health consequences or death to humans or animals. The Secretary can only prohibit or restrict the movement of food for 14 days. The Secretary can continue the action in 14 day intervals. Each 14 days, the Secretary is required to notify the Governor or other appropriate official of the State; issue a public announcement of the continuation of the action; and publish in the Federal Register the findings of the Secretary that support the continuation of the action, including an estimate of the anticipated duration of the action.

Section 133 requires that a quarantine order must come from the Secretary, FDA Commissioner, or Principal Deputy Commissioner.

Section 133 requires the Secretary to establish, by regulation, standards for prohibiting or restricting the movement of food, sanitation standards, and procedures to restore any affected equipment or means of conveyance to status prior to the action. The Secretary is required to consider the impact on small businesses in developing such regulations.

Section 134. Criminal penalties.
Section 134 amends section 303 of the FFDCA to require that any person who knowingly violates section 301 of the Federal Food, Drug, and Cosmetic Act with respect to any food that is misbranded or adulterated shall be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.

Section 135. Civil penalties for violations relating to food.
Section 135 amends section 303 of the FFDCA to require that any person who violates a provision of section 301 relating to food shall be subject to a civil penalty for each such violation of not more than $20,000 in the case of an individual, not to exceed $50,000 in a single proceeding; $250,000 in the case of any other person, not to exceed $1,000,000 in a single proceeding. Any person who knowingly violates a provision of section 301 relating to food shall be subject to a civil penalty for each such violation of not more than $50,000 in the case of an individual, not to exceed $100,000 in a single proceeding; and $500,000 in the case of any other person, not to exceed $7,500,000 in a single proceeding.

Section 136. Improper import entry filings.
Section 136 makes the submission of information relating to imported food that is inaccurate or incomplete, or the failure to submit information that is required to be submitted related to imported food a prohibited act. Section 136 allows 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. To the extent that the collection of documentation or other information involves Customs and Border Protection (CBP) efforts or resources, Section 136 requires the Secretary to consult with CBP.

TITLE II — MISCELLANEOUS

Section 201. Food Substances Generally Recognized as Safe.
Section 201 requires the Secretary to post on FDA's website a "generally recognized as safe" (GRAS) determination as well as the supporting scientific justifications no later than 60 days after receipt by the Secretary of such determination.

Section 202. Country of Origin Labeling
Section 202 requires that all processed food labels identify the country in which the final processing occurred. If the label of a processed food is already in compliance with country of origin requirements from the U.S. Customs and Border Protection, the food will be deemed in compliance with this section. All non-processed foods must be labeled with the country of origin of the food. If a non-processed food already lists the country of origin pursuant to farm bill requirements, the food will be deemed in compliance with this section.

Section 202(b)(2)(A) requires the Secretary of Health and Human Services (HHS), acting through the Food and Drug Administration (FDA), to promulgate implementing regulations in accordance with Customs and Border Protection (CBP) laws and regulations with respect to country of origin marking to ensure that the country of origin of final processing for FDA purposes is consistent with the country of origin for CBP marking purposes.

Section 203. Exportation Certificate Program.
Section 203 authorizes the Secretary to impose a fee for the issuance of export certificates for foods and animal feeds. Such fee shall not exceed such amount as the Secretary determines is reasonably related to the cost of issuing certificates with respect to the export of food and animal feed.

Section 204. Registration for Commercial Importers of Food; Fee.
Section 204 requires all importers of foods to register with FDA annually and to pay a registration fee in the amount of $500. An importer that is also a registered facility under Section 101 is subject to only one fee. Each registered importer must comply with good importer practices, which the Secretary, in consultation with CBP, must establish through regulation. The good importer practices will specify the

measures an importer shall take to ensure imported food is in compliance with the requirements of the Act.

The Secretary may suspend an importer's registration, after notice and opportunity for an informal hearing, if the importer is found in violation of the Federal Food, Drug, and Cosmetic Act, or found to have knowingly or repeatedly made inaccurate or incomplete statements or submissions of information related to the importation of food. The Secretary may cancel an importer's registration if, after notice, the Secretary determines that the registration was not updated correctly or otherwise contains false, incomplete, or inaccurate information. If the importer's registration is updated or corrected no later than 7 days after notice is provided, the Secretary shall not cancel the importer's registration.

Section 204 requires the Secretary, in consultation with CBP, to promulgate regulations, within 36 months, required to carry out the requirements of Section 204. In establishing the effective date of the regulation, the Secretary shall consult with CBP, as appropriate, to provide a reasonable period of time for importers of food to comply with good importer practices.

Section 205. Registration for Customs Brokers.
Section 205 requires all customs brokers with respect to the importation of food to register with the FDA in a form and manner specified by the Secretary and to submit appropriate unique facility identifiers as a condition of registration. The Secretary may cancel an importer's registration, after notice to the customs broker and CBP, if the customs broker's registration is not updated or otherwise contains false, incomplete, or inaccurate information. If the registration is updated or corrected no later than seven days after notice, the Secretary shall not cancel the registration. Section 205 requires the Secretary, in consultation with CBP, to exempt importations for personal use.

Section 205 requires every customs broker required to be registered with the Secretary to, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to inspect their facilities and have access to, and to copy and verify, any related records.

Section 206. Unique Identification Number for Food Facilities, Importers, and Custom Brokers.
Section 206 requires that a person required to register a facility under section 415 or importers, and custom brokers required to register pursuant to section 801 submit, at the time of registration, a unique facility identifier. The Secretary is authorized, through guidance, to specify the unique numerical identifier system to be used to meet the requirements of Section 206. In developing such guidance, with respect to importers and customs brokers, the Secretary is required to consult with CBP and take into account the utilization of existing unique identification schemes and compatibility with customs automated systems. Section 206 requires the Secretary to refuse admission of an imported food into the U.S. for interstate commerce unless the unique facility identifiers are provided for such article.

Section 207. Prohibition Against Delaying, Limiting, or Refusing Inspection.
Section 207 makes it unlawful for the owner, operator, or agent of a farm, factory, warehouse, or establishment to delay or limit an inspection, or refuse to permit entry or inspection. In addition, Section 207 makes it unlawful for an agent of a governmental authority in the foreign country within which the farm, factory, warehouse, or establishment is located to delay, limit, or refuses to permit entry or inspection.

Section 208. Dedicated Foreign Inspectorate.
Section 208 requires the Secretary to establish and maintain inspectors dedicated to inspections of foreign food facilities.

Section 209. Plan and Review of Continued Operation of Field Laboratories.
Section 209 requires the Secretary, no later than 90 days before the Secretary terminates or consolidates any laboratory responsible for analyzing food, district office with responsibility for food safety, or the functions of any such laboratory or district office, to submit a reorganization plan to the Comptroller General of the U.S., the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate.

Section 210. False or Misleading Reporting to FDA.
Section 210 amends Section 301 of the Federal Food, Drug, and Cosmetic Act to establish that the submission of any report relating to food that is required by or under the Act that is false or misleading in any material respect is a prohibited act.

Section 211. Subpoena Authority.
Section 211 grants the Commissioner the power to issue subpoenas for the purpose of any hearing, investigation, or other proceeding respecting a violation of the Federal Food, Drug, and Cosmetic Act, the Federal Anti-Tampering Act and the Public Health Service Act relating to food; or to determine if a person is in violation of a specific provision of the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Federal Anti-Tampering Act relating to food. A subpoena may only be issued only by a district director or an individual senior to the district director.

Section 212. Whistleblower Protections.
Section 212 grants protections for employees who refuse to violate, or who disclose violations of this Act, or Section 351 of the Public Health Service Act. No person who submits any information related to a food, or any officer, employee, contractor, subcontractor, or agent may discharge, demote, suspend, threaten, harass or in any other manner discriminate against an employee in retaliation for assisting in any investigation regarding any conduct which the employee reasonably believes constitutes a violation of federal law. Section 212 ensures an employee shall be entitled to all relief necessary against retaliation by an employer.

Section 213. Extraterritorial Jurisdiction.
Section 213 establishes that there is extraterritorial federal jurisdiction over any violation of this Act relating to any article of food intended for import into the United States or if any act in furtherance of the violation was committed in the United States.

Section 214. Support for Training Institutes.
Section 214 requires the Secretary, acting through the Commissioner, to provide financial and other assistance to appropriate entities to establish and maintain one or more university-affiliated food protection training institutes in order to conduct training related to food protection activities for federal, state, local, territorial, and tribal officials; and meet standards developed by the Secretary.

Section 215. Bisphenol A in Food and Beverage Containers.
Section 215 requires the Secretary to notify Congress, no later than December 31, 2009, whether the available scientific data support a determination that there is a reasonable certainty of no harm, for infants, young children, pregnant women, and adults, for approved uses of polycarbonate plastic and epoxy resin made with bisphenol A in food and beverage containers. If the Secretary is unable to make such a determination, the Secretary must notify Congress of the actions the Secretary intends to take to protect the public health.

Section 216. Lead Content Labeling Requirement for Ceramic Tableware and Cookware.
Section 216 places new requirements on ceramic tableware or cookware which includes a glaze or decorations containing lead for an intended functional purpose. The product and its packaging must bear the statement, "This product is made with lead-based glaze consistent with Food and Drug Administration guidelines for such lead"; or the product must comply with FDA regulations applicable to ornamental and decorative ceramic ware. Section 216 requires the Secretary to educate consumers on the safety of ceramic ware for food use.