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REPORT
111–234

FOOD SAFETY ENHANCEMENT ACT OF 2009

JULY 29, 2009.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. WAXMAN, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 2749]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2749) to amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food in the global market, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Food Safety Enhancement Act of 2009".

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

SEC. 3. REFERENCES.

Except as otherwise specified, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 4. RULES OF CONSTRUCTION.

(a) Nothing in this Act or any amendment made by this Act shall be construed to prohibit or limit—

(1) any cause of action under State law; or

(2) the introduction of evidence of compliance or noncompliance with the requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) Nothing in this Act or any amendment made by this Act shall be construed to—

(1) alter the jurisdiction between the Secretary of Agriculture and the Secretary of Health and Human Services, under applicable statutes and regulations;

(2) limit the authority of the Secretary of Health and Human Services to issue regulations related to the safety of food under—

(A) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) as in effect on the day before the date of the enactment of this Act; or

(B) the Public Health Service Act (42 U.S.C. 301 et seq.) as in effect on the day before the date of the enactment of this Act; or

(3) 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 (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

SEC. 5. USDA EXEMPTIONS.

(a) USDA-REGULATED PRODUCTS.—Food is exempt from the requirements of this Act if 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.

(b) USDA-REGULATED FACILITIES.—A facility is exempt from the requirements of this Act if such facility is regulated exclusively 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.

(c) FARMS.—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.

SEC. 6. ALCOHOL-RELATED FACILITIES.

(a) IN GENERAL.—With the exception of the amendments made by section 101(a) and (b) and section 113 of this Act, nothing in this Act, or the amendments made by this Act, shall be construed to apply to a facility that—

(1) under the Federal Alcohol Administration Act or chapter 51 of subtitle E of the Internal Revenue Code, is required to obtain a permit or to register with the Secretary of the Treasury as a condition of doing business in the United States; and

(2) under section 415 of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, is required to register as a facility solely because such facility is engaged in manufacturing, processing, packing, or holding 1 or more alcoholic beverages.

(b) RULE OF CONSTRUCTION.—This section shall not be construed to exempt any food, apart from distilled spirits, wine, and malt beverages, as defined in section 211 of the Federal Alcohol Administration Act, from the requirements of this Act and the amendments made by this Act.

TITLE I—FOOD SAFETY

Subtitle A—Prevention

SEC. 101. CHANGES IN REGISTRATION OF FOOD FACILITIES.

(a) MISBRANDING.—Section 403 (21 U.S.C. 343) is amended by adding at the end the following:

"(z) If it was manufactured, processed, packed, or held in a facility that is not duly registered under section 415, including a facility whose registration is canceled or suspended under such section.".

(b) ANNUAL REGISTRATION.—

(1) IN GENERAL.—Section 415(a) (21 U.S.C. 350d(a)) is amended—

(A) in the first sentence of paragraph (1)—

(i) by striking "require that" and inserting "require that, on or before December 31 of each year,"; and

(ii) by striking "food for consumption in the United States" and inserting "food for consumption in the United States or for export from the United States";

(B) in subparagraphs (A) and (B) of paragraph (1), by inserting "and pay the registration fee required under section 743" after "submit a registration to the Secretary" each place it appears;

(C) in the first sentence of paragraph (2), by inserting "in electronic format" after "submit"; and

(D) in paragraph (4), by inserting after the first sentence the following: "The Secretary shall remove from such list the name of any facility that fails to reregister in accordance with this section, that fails to pay the registration fee required under section 743, or whose registration is canceled by the registrant, canceled by the Secretary in accordance with this section, or suspended by the Secretary in accordance with this section.".

(2) CONTENTS OF REGISTRATION.—Paragraph (2) of section 415(a) (21 U.S.C. 350d(a)), as amended by paragraph (1), is amended by striking "containing information" and all that follows and inserting the following: "containing information that identifies the following:

"(A) The name, address, and emergency contact information of the facility being registered.

"(B) The primary purpose and business activity of the facility, including the dates of operation if the facility is seasonal.

"(C) The general food category (as defined by the Secretary by guidance) of each food manufactured, processed, packed, or held at the facility.

"(D) All trade names under which the facility conducts business related to food.

"(E) The name, address, and 24-hour emergency contact information of the United States distribution agent for the facility, which agent shall have access to the information required to be maintained under section 414(d) for food that is manufactured, processed, packed, or held at the facility.

"(F) If the facility is located outside of the United States, the name, address, and emergency contact information for a United States agent.

"(G) The unique facility identifier of the facility, as specified under section 911.

"(H) Such additional information pertaining to the facility as the Secretary may require by regulation.

The registrant shall notify the Secretary of any change in the submitted information not later than 30 days after the date of such change, unless otherwise specified by the Secretary.".

(3) SUSPENSION AND CANCELLATION AUTHORITY.—Section 415(a) (21 U.S.C. 350d(a)), as amended by paragraphs (1) and (2), is further amended by adding at the end the following:

"(5) SUSPENSION OF REGISTRATION.—

"(A) IN GENERAL.—The Secretary may suspend the registration of any facility registered under this section for a violation of this Act that could result in serious adverse health consequences or death to humans or animals.

"(B) NOTICE OF SUSPENSION.—Suspension of a registration shall be preceded by—

"(i) notice to the facility of the intent to suspend the registration; and

"(ii) an opportunity for an informal hearing, as defined in guidance or regulations issued by the Secretary, concerning the suspension of such registration for such facility.

"(C) REQUEST.—The owner, operator, or agent in charge of a facility whose registration is suspended may request that the Secretary vacate the suspension of registration when such owner, operator, or agent has corrected the violation that is the basis for such suspension.

"(D) VACATING OF SUSPENSION.—If, based on an inspection of the facility or other information, the Secretary determines that adequate reasons do not exist to continue the suspension of a registration, the Secretary shall vacate such suspension.

"(6) CANCELLATION OF REGISTRATION.—

"(A) IN GENERAL.—Not earlier than 10 days after providing the notice under subparagraph (B), the Secretary may cancel a registration if the Secretary determines that—

"(i) the registration was not updated in accordance with this section or otherwise contains false, incomplete, or inaccurate information; or

"(ii) the required registration fee has not been paid within 30 days after the date due.

"(B) NOTICE OF CANCELLATION.—Cancellation shall be preceded by notice to the facility of the intent to cancel the registration and the basis for such cancellation.

"(C) TIMELY UPDATE OR CORRECTION.—If the registration for the facility is updated or corrected no later than 7 days after notice is provided under subparagraph (B), the Secretary shall not cancel such registration.

"(7) REPORT TO CONGRESS.—Not later than March 30th of each year, the Secretary shall submit to the Congress a report, based on the registrations on or before December 31 of the previous year, on the following:

"(A) The number of facilities registered under this section.

"(B) The number of such facilities that are domestic.

"(C) The number of such facilities that are foreign.

"(D) The number of such facilities that are high-risk.

"(E) The number of such facilities that are low-risk.

"(F) The number of such facilities that hold food.

"(8) LIMITATION ON DELEGATION.—The authority conferred by this subsection to issue an order to suspend a registration or cancel a registration shall not be delegated to any officer or employee other than the Commissioner of Food and Drugs, the Principal Deputy Commissioner, the Associate Commissioner for Regulatory Affairs, or the Director for the Center for Food Safety and Applied Nutrition, of the Food and Drug Administration.".

(c) REGISTRATION FEE.—Chapter VII (21 U.S.C. 371 et seq.) is amended by adding at the end of subchapter C the following:

"PART 6—FEES RELATING TO FOOD

"SEC. 743. FACILITY REGISTRATION FEE.

"(a) IN GENERAL.—

"(1) ASSESSMENT AND COLLECTION.—Beginning in fiscal year 2010, the Secretary shall assess and collect an annual fee for the registration of a facility under section 415.

"(2) PAYABLE DATE.—A fee under this section shall be payable—

"(A) for a facility that was not registered under section 415 for the preceding fiscal year, on the date of registration; and

"(B) for any other facility—

"(i) for fiscal year 2010, not later than the sooner of 90 days after the date of the enactment of this part or December 31, 2009; and

"(ii) for a subsequent fiscal year, not later than December 31 of such fiscal year.

"(b) FEE AMOUNTS.—

"(1) IN GENERAL.—The registration fee under subsection (a) shall be—

"(A) for fiscal year 2010, $500; and

"(B) for fiscal year 2011 and each subsequent fiscal year, the fee for fiscal year 2010 as adjusted under subsection (c).

"(2) ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the start of fiscal year 2011 and each subsequent fiscal year, establish, for the next fiscal year, registration fees under subsection (a), as described in paragraph (1).

"(3) MAXIMUM AMOUNT.—Notwithstanding paragraph (1), a person who owns or operates multiple facilities for which a fee must be paid under this section for a fiscal year shall be liable for not more than $175,000 in aggregate fees under this section for such fiscal year.

"(c) INFLATION ADJUSTMENT.—For fiscal year 2011 and each subsequent fiscal year, the fee amount under subsection (b)(1) shall be adjusted by the Secretary by notice, published in the Federal Register, to reflect the greater of—

"(1) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; U.S. city average) for the 12-month period ending June 30 preceding the fiscal year for which fees are being established;

"(2) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia; or

"(3) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 5 years of the preceding 6 fiscal years.

The adjustment made each fiscal year under this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2010 under this subsection.

"(d) LIMITATIONS.—

"(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2010 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for fiscal year 2010 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

"(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may

assess and collect such fees, without any modification in the rate, for registration under section 415 at any time in such fiscal year.

"(3) ADJUSTMENT FACTOR.—In this subsection, the term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2009.

"(e) CREDITING AND AVAILABILITY OF FEES.—

"(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

"(2) COLLECTIONS AND APPROPRIATIONS ACTS.—The fees authorized by this section—

"(A) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year; and

"(B) shall only be collected and available to defray the costs of food safety activities.

"(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2010 through 2014, there are authorized to be appropriated for fees under this section such sums as may be necessary.

"(4) PUBLIC MEETINGS.—For each fiscal year, the Secretary shall hold a public meeting on how fees collected under this section will be used to defray the costs of food safety activities in order to solicit the views of the regulated industry, consumers, and other interested stakeholders.

"(f) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

"(g) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in food safety activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

"(h) ANNUAL FISCAL REPORTS.—Beginning with fiscal year 2011, not later than 120 days after the end of each fiscal year for which fees are collected under this section, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

"(i) DEFINITIONS.—In this section:

"(1) The term 'costs of food safety activities' means the expenses incurred in connection with food safety activities for—

"(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and to contracts with such contractors;

"(B) laboratory capacity;

"(C) management of information, and the acquisition, maintenance, and repair of technology resources;

"(D) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

"(E) collecting fees under this section and accounting for resources allocated for food safety activities.

"(2) The term 'food safety activities' means activities related to compliance by facilities registered under section 415 with the requirements of this Act relating to food (including research related to and the development of standards (such as performance standards and preventive controls), risk assessments, hazard analyses, inspection planning and inspections, third-party inspections, compliance review and enforcement, import review, information technology support, test development, product sampling, risk communication, and administrative detention).".

(d) TRANSITIONAL PROVISIONS.—

(1) FEES.—The Secretary of Health and Human Services shall first impose the fee established under section 743 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (c), for fiscal years beginning with fiscal year 2010.

(2) MODIFICATION OF REGISTRATION FORM.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall modify the registration form under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) to comply with the amendments made by this section.

(3) APPLICATION.—The amendments made by this section, other than subsections (b)(2) and (c), shall take effect on the date that is 30 days after the date on which such modified registration form takes effect, but not later than 210 days after the date of the enactment of this Act.

(4) SUNSET DATE.—Section 743 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (c), does not authorize the assessment or collection of a fee for registration under section 415 of such Act (21 U.S.C. 360) occurring after fiscal year 2014.

SEC. 102. HAZARD ANALYSIS, RISK-BASED PREVENTIVE CONTROLS, FOOD SAFETY PLAN, FINISHED PRODUCT TEST RESULTS FROM CATEGORY 1 FACILITIES.

(a) HAZARD ANALYSIS, RISK-BASED PREVENTIVE CONTROLS, FOOD SAFETY PLAN.—

(1) ADULTERATED FOOD.—Section 402 (21 U.S.C. 342) is amended by adding at the end the following:

"(j) If it has been manufactured, processed, packed, transported, or held under conditions that do not meet the requirements of sections 418 and 418A.".

(2) REQUIREMENTS.—Chapter IV (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

"SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.

"(a) IN GENERAL.—The owner, operator, or agent of a facility shall, in accordance with this section—

"(1) conduct a hazard analysis (or more than one if appropriate);

"(2) identify, implement, and validate effective preventive controls;

"(3) monitor preventive controls;

"(4) institute corrective actions when—

"(A) monitoring shows that preventive controls have not been properly implemented; or

"(B) monitoring and verification show that such controls were ineffective;

"(5) conduct verification activities;

"(6) maintain records of monitoring, corrective action, and verification; and

"(7) reanalyze for hazards.

"(b) IDENTIFICATION OF HAZARDS.—

"(1) IN GENERAL.—The owner, operator, or agent of a facility shall evaluate whether there are any hazards, including hazards due to the source of the ingredients, that are reasonably likely to occur in the absence of preventive controls that may affect the safety, wholesomeness, or sanitation of the food manufactured, processed, packed, transported, or held by the facility, including—

"(A) biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, filth, decomposition, parasites, allergens, and unapproved food and color additives; and

"(B) hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism.

"(2) IDENTIFIED BY THE SECRETARY.—The Secretary may, by regulation or guidance, identify hazards that are reasonably likely to occur in the absence of preventive controls.

"(3) HAZARD ANALYSIS.—The owner, operator, or agent of a facility shall identify and describe the hazards evaluated under paragraph (1) or identified under paragraph (2), to the extent applicable to the facility, in a hazard analysis.

"(c) PREVENTIVE CONTROLS.—

"(1) IN GENERAL.—The owner, operator, or agent of a facility shall identify, implement, and validate effective preventive controls to prevent, eliminate, or reduce to acceptable levels the occurrence of any hazards identified in the hazard analysis under subsection (b)(3).

"(2) IDENTIFIED BY THE SECRETARY.—

"(A) ESTABLISHMENT.—The Secretary may establish by regulation or guidance preventive controls for specific product types to prevent intentional or unintentional contamination throughout the supply chain. The owner, operator, or agent of a facility shall implement any preventive controls identified by the Secretary under this paragraph.

"(B) ALTERNATIVE CONTROLS.—Such regulation or guidance shall allow the owner, operator, or agent of a facility to implement an alternative pre-

ventive control to one established by the Secretary, provided that, in response to a request by the Secretary, the owner, operator, or agent can present to the Secretary data or other information sufficient to demonstrate that the alternative control effectively addresses the hazard, including meeting any applicable performance standard.

"(C) LIMITATION.—Subparagraph (B) shall not apply to any preventive control described in subparagraph (A), (B), or (E) of subsection (i)(2).

"(d) MONITORING.—The owner, operator, or agent of a facility shall monitor the implementation of preventive controls under subsection (c) to identify any circumstances in which the preventive controls are not fully implemented or verification shows that such controls were ineffective.

"(e) CORRECTIVE ACTIONS.—The owner, operator, or agent of a facility shall establish and implement procedures to ensure that, if the preventive controls under subsection (c) are not fully implemented or are not effective—

"(1) no product from such facility enters commerce; and

"(2) appropriate action is taken to reduce the likelihood of recurrence of the implementation failure.

"(f) VERIFICATION.—The owner, operator, or agent of a facility shall ensure that—

"(1) the preventive controls identified under subsection (c) have been validated as adequate to control the hazards identified in the hazard analysis under subsection (b)(3);

"(2) the facility is conducting monitoring in accordance with subsection (d);

"(3) the facility is taking effective corrective actions under subsection (e); and

"(4) the preventive controls are effectively preventing, eliminating, or reducing to an acceptable level the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means.

"(g) REQUIREMENT TO REANALYZE AND REVISE.—

"(1) REQUIREMENT.—The owner, operator, or agent of a facility shall—

"(A) review the evaluation under subsection (b) for the facility and, as necessary, revise the hazard analysis under subsection (b)(3) for the facility—

"(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; and

"(B) whenever there is a change in the hazard analysis, revise the preventive controls under subsection (c) for the facility as necessary to ensure that all hazards that are reasonably likely to occur are prevented, eliminated, or reduced to an acceptable level, or document the basis for the conclusion that no such revision is needed.

"(2) NONDELEGATION.—Any revisions ordered by the Secretary under this subsection shall be ordered by the Secretary or an official designated by the Secretary. 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.

"(h) RECORDKEEPING.—The owner, operator, or agent of a facility shall maintain, for not less than 2 years, records documenting the activities described in subsections (a) through (g).

"(i) DEFINITIONS.—For purposes of this section:

"(1) FACILITY.—The term 'facility' means a domestic facility or a foreign facility that is required to be registered under section 415.

"(2) PREVENTIVE CONTROLS.—The term 'preventive controls' means those risk-based procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, transporting, or holding of food would employ to prevent, eliminate, or reduce to an acceptable level the hazards identified in the hazard analysis under subsection (b)(3) and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, transporting, or holding at the time of the analysis. Those procedures, practices, and processes shall include the following, as appropriate:

"(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 under subsection (c)(2).

"(3) HAZARD THAT IS REASONABLY LIKELY TO OCCUR.—A food safety hazard that is reasonably likely to occur is one for which a prudent person who, as applicable, manufactures, processes, packs, transports, or holds food, would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, transported, or held in the absence of those controls.

"SEC. 418A. FOOD SAFETY PLAN.

"(a) IN GENERAL.—Before a facility (as defined in section 418(i)) introduces or delivers for introduction into interstate commerce any shipment of food, the owner, operator, or agent of the facility shall develop and implement a written food safety plan (in this section referred to as a 'food safety plan').

"(b) CONTENTS.—The food safety plan shall include each of the following elements:

"(1) The hazard analysis and any reanalysis conducted under section 418.

"(2) A description of the preventive controls being implemented under subsection 418(c), including those to address hazards or conditions identified by the Secretary under subsection 418(b)(2).

"(3) A description of the procedures for monitoring preventive controls.

"(4) A description of the procedures for taking corrective actions.

"(5) A description of verification activities for the preventive controls, including validation, review of monitoring and corrective action records, and procedures for determining whether the preventive controls are effectively preventing, eliminating, or reducing to an acceptable level the occurrence of identified hazards or conditions, including the use of environmental and product testing programs.

"(6) A description of the facility's recordkeeping procedures.

"(7) A description of the facility's procedures for the recall of articles of food, whether voluntarily or when required under section 422.

"(8) A description of the facility's procedures for tracing the distribution history of articles of food, whether voluntarily or when required under section 414.

"(9) A 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) A description of the facility's procedures to implement the science-based performance standards issued under section 419.".

(3) GUIDANCE OR REGULATIONS.—

(A) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the "Secretary") shall issue guidance or promulgate regulations 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, including verification and corrective actions under sections 418 and 418A of the Federal Food, Drug, and Cosmetic Act (as added by paragraph (2)).

(B) INTERNATIONAL STANDARDS.—In issuing guidance or regulations under subparagraph (A), the Secretary shall review international hazard analysis and preventive control standards that are in existence on the date of the enactment of this Act and relevant to such guidelines or regulations to ensure that the programs under sections 418 and 418A of the Federal Food, Drug, and Cosmetic Act (as added by paragraph (2)) are consistent, to the extent the Secretary determines practicable and appropriate, with such standards.

(C) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—The Secretary may, by regulation, exempt or modify the requirements for compliance under this section and the amendments made by this section with respect to facilities that are solely engaged in—

(i) the production of food for animals other than man or the storage of packaged foods that are not exposed to the environment; or

(ii) the storage of raw agricultural commodities for further processing.

(D) SMALL BUSINESSES.—The Secretary—

(i) shall consider the impact of any guidance or regulations under this section on small businesses; and

(ii) shall issue guidance to assist small businesses in complying with the requirements of this section and the amendments made by this section.

(4) NO EFFECT ON EXISTING HACCP AUTHORITIES.—Nothing in this section or the amendments made by this section limits the authority of the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.), as in effect on the day before the date of the enactment of this Act, to revise, issue, or enforce product- and category-specific regulations, such as the Seafood Hazard Analysis Critical Controls Points Program, the Juice Hazard Analysis Critical Control Program, and the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards.

(5) CONSIDERATION.—When implementing sections 418 and 418A of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (2), the Secretary may take into account differences between food intended for human consumption and food intended for consumption by animals other than man.

(6) EFFECTIVE DATE.—

(A) GENERAL RULE.—The amendments made by subsection (a) and this subsection shall take effect 18 months after the date of the enactment of this Act.

(B) EXCEPTIONS.—Notwithstanding subparagraph (A)—

(i) the amendments made by subsection (a) and this subsection shall apply to a small business (as defined by the Secretary) after the date that is 2 years after the date of the enactment of this Act; and

(ii) the amendments made by subsection (a) and this subsection shall apply to a very small business (as defined by the Secretary) after the date that is 3 years after the date of the enactment of this Act.

(b) FINISHED PRODUCT TEST RESULTS FROM CATEGORY 1 FACILITIES.—

(1) ADULTERATION.—Section 402 (21 U.S.C. 342), as amended by subsection (a), is amended by adding at the end the following:

"(k) If it is manufactured or processed in a facility that is in violation of section 418B.".

(2) REQUIREMENTS.—Chapter IV (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

"SEC. 418B. FINISHED PRODUCT TEST RESULTS FROM CATEGORY 1 FACILITIES.

"(a) AUTHORITY.—Beginning on the date specified in subsection (c), the Secretary shall require, after public notice and an opportunity for comment, the submission to the Secretary of finished product test results by the owner, operator, or agent of each category 1 facility subject to good manufacturing practices regulations documenting the presence of contaminants in food in the possession or control of such facility posing a risk of severe adverse health consequences or death.

"(b) CONSIDERATIONS.—The Secretary shall require submissions under subsection (a)—

"(1) as the Secretary determines feasible and appropriate; and

"(2) taking into consideration available data and information on the potential risks posed by the facility.

"(c) BEGINNING DATE.—The date specified in this subsection is the sooner of—

"(1) the date of completion of the pilot projects and feasibility study under subsections (d) and (e); and

"(2) the date that is 2 years after the date of the enactment of this section.

"(d) PILOT PROJECTS.—The Secretary shall conduct 2 or more pilot projects to evaluate the feasibility of collecting positive finished product testing results from category 1 facilities, including the value and feasibility of reporting corrective actions taken when positive finished product test results are reported to the Secretary.

"(e) FEASIBILITY STUDY.—The Secretary shall assess the feasibility and benefits of the reporting by facilities subject to good manufacturing practices regulations of appropriate finished product testing results from category 1 facilities to the Secretary, including the extent to which the collection of such finished product testing results will help the Secretary assess the risk presented by a facility or product category.

"(f) LIMITATIONS.—Nothing in this section shall be construed—

"(1) to require the Secretary to mandate testing or submission of test results that the Secretary determines would not provide useful information in assessing the potential risk presented by a facility or product category; or

"(2) to limit the Secretary's authority under any other provisions of law to require any person to provide access, or to submit information or test results, to the Secretary, including the ability of the Secretary to require field or other testing and to obtain test results in the course of an investigation of a potential food-borne illness or contamination incident.

"(g) DEFINITION.—In this section, the term 'category 1 facility' means a category 1 facility within the meaning of section 704(h).".

SEC. 103. PERFORMANCE STANDARDS.

(a) ADULTERATED FOOD.—Section 402 (21 U.S.C. 342), as amended by section 102, is amended by adding at the end the following:

"(l) If it has been manufactured, processed, packed, transported, or held under conditions that do not meet the standards issued under section 419.".

(b) REQUIREMENTS.—Chapter IV (21 U.S.C. 341 et seq.), as amended by section 102(b), is further amended by adding at the end the following:

"SEC. 419. PERFORMANCE STANDARDS.

"(a) PERFORMANCE STANDARDS.—The Secretary shall, not less frequently than every 2 years, review and evaluate epidemiological data and other appropriate sources of information, including research under section 123 of the Food Safety Enhancement Act of 2009, to identify the most significant food-borne contaminants and the most significant resulting hazards. The Secretary shall issue, as soon as practicable, through guidance or by regulation, science-based performance standards (which may include action levels) applicable to foods or food classes, as appropriate, to minimize to an acceptable level, prevent, or eliminate the occurrence of such hazards. Such standards shall be applicable to foods and food classes.

"(b) LIST OF CONTAMINANTS.—Following each review under subsection (a), the Secretary shall publish in the Federal Register a list of food-borne contaminants that have the greatest adverse impact on public health. In determining whether a particular food-borne contaminant should be added to such list, the Secretary shall consider the number and severity of illnesses and the number of deaths associated with the foods associated with such contaminants.

"(c) REVOCATION BY SECRETARY.—All performance standards of the Food and Drug Administration applicable to foods or food classes in effect on the date of the enactment of this section, or issued under this section, shall remain in effect until revised or revoked by the Secretary.".

(c) REPORT TO CONGRESS.—The Secretary of Health and Human Services shall submit to the Congress by March 30th of the year following each review under section 419 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), a report on the results of such review and the Secretary's plans to address the significant food-borne hazards identified, or the basis for not addressing any significant food-borne hazards identified, including any resource limitations or limitations in data that preclude further action at that time.

SEC. 104. SAFETY STANDARDS FOR PRODUCE AND CERTAIN OTHER RAW AGRICULTURAL COMMODITIES.

(a) ADULTERATED FOOD.—Section 402 (21 U.S.C. 342), as amended by sections 102 and 103(a), is amended by adding at the end the following:

"(m) If it has been grown, harvested, processed, packed, sorted, transported, or held under conditions that do not meet the standards established under section 419A.".

(b) STANDARDS.—Chapter IV (21 U.S.C. 341 et seq.), as amended by sections 102(b) and 103(b), is amended by adding at the end the following:

"SEC. 419A. SAFETY STANDARDS FOR PRODUCE AND CERTAIN OTHER RAW AGRICULTURAL COMMODITIES.

"(a) STANDARDS.—The Secretary shall establish by regulation scientific and risk-based standards for the safe growing, harvesting, processing, packing, sorting, transporting, and holding of those types of raw agricultural commodities—

"(1) that are from a plant or a 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.

"(b) CONTENTS.—The regulations under subsection (a)—

"(1) may set forth such procedures, processes, and practices as the Secretary determines to be reasonably necessary—

"(A) to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards, including hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism, into raw agricultural commodities that are from a plant or a fungus; and

"(B) to provide reasonable assurances that such commodity is not adulterated under section 402;

"(2) may include, with respect to growing, harvesting, processing, packing, sorting, transporting, and storage operations, standards for safety as the Secretary determines to be reasonably necessary;

"(3) may include standards addressing manure use, water quality, employee hygiene, sanitation and animal control, and temperature controls, as the Secretary determines to be reasonably necessary;

"(4) may include standards for such other elements as the Secretary determines necessary to carry out subsection (a);

"(5) shall provide a reasonable period of time for compliance, taking into account the needs of small businesses for additional time to comply;

"(6) may provide for coordination of education and enforcement activities;

"(7) shall take into consideration, consistent with ensuring enforceable public health protection, the impact on small-scale and diversified farms, and on wildlife habitat, conservation practices, watershed-protection efforts, and organic production methods;

"(8) may provide for coordination of education and training with other government agencies, universities, private entities, and others with experience working directly with farmers; and

"(9) may provide for recognition through guidance of other existing publicly available procedures, processes, and practices that the Secretary determines to be equivalent to those established under paragraph (1).

"(c) ENFORCEMENT.—The Secretary may coordinate with the Secretary of Agriculture and may contract and coordinate with the agency or department designated by the Governor of each State to perform activities to ensure compliance with this section.".

(c) TIMING.—

(1) PROPOSED RULE.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue a proposed rule to carry out section 419A of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b).

(2) FINAL RULE.—Not later than 3 years after such date, the Secretary of Health and Human Services shall issue a final rule under such section.

(d) NO EFFECT ON EXISTING HACCP AUTHORITIES.—Nothing in this section or the amendments made by this section limits the authority of the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.), as in effect on the day before the date of the enactment of this Act, to revise, issue, or enforce product- and category-specific regulations, such as the Seafood Hazard Analysis Critical Controls Points Program, the Juice Hazard Analysis Critical Control Program, and the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards.

(e) UPDATE EXISTING GUIDANCE.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall update the guidance document entitled "Guidance For Industry: Guide To Minimize Microbial Food Safety Hazards For Fresh Fruits And Vegetables" (issued on October 26, 1998) in accordance with this section and the amendments made by this section.

SEC. 105. RISK-BASED INSPECTION SCHEDULE.

(a) IN GENERAL.—Section 704 (21 U.S.C. 374) is amended by adding at the end the following:

"(h)(1) Each facility registered under section 415 shall be inspected—

"(A)(i) by one or more officers duly designated under section 702 or other statutory authority by the Secretary;

"(ii) for domestic facilities, by a Federal, State, or local official recognized by the Secretary under paragraph (2); or

"(iii) for foreign facilities, by an agency or a representative of a country that is recognized by the Secretary under paragraph (2); and

"(B) at a frequency determined pursuant to a risk-based schedule.

"(2) For purposes of paragraph (1)(A), the Secretary—

"(A) may recognize Federal, State, and local officials and agencies and representatives of foreign countries as meeting standards established by the Secretary for conducting inspections under this Act; and

"(B) may limit such recognition to inspections of specific commodities or food types.

"(3) The risk-based schedule under paragraph (1)(B) shall be implemented beginning not later than 18 months after the date of the enactment of this subsection.

"(4) Such risk-based schedule 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:

"(A) CATEGORY 1.—A category 1 food facility is a high-risk facility that manufactures or processes food. The Secretary shall randomly inspect a category 1 food facility at least every 6 to 12 months.

"(B) CATEGORY 2.—A category 2 food facility is a low-risk facility that manufactures or processes food or a facility that packs or labels food. The Secretary shall randomly inspect a category 2 facility at least every 18 months to 3 years.

"(C) CATEGORY 3.—A category 3 food facility is a facility that holds food. The Secretary shall randomly inspect a category 3 facility at least every 5 years.

"(5) The Secretary—

"(A) may, by guidance, modify the types of food facilities within a category under paragraph (4);

"(B) may alter the inspection frequencies specified in paragraph (4) based on the need to respond to food-borne illness outbreaks and food recalls; and

"(C) may inspect a facility more frequently than the inspection frequency provided by paragraph (4);

"(D) beginning 6 months after submitting the report required by section 105(b)(2) of the Food Safety Enhancement Act of 2009, may—

"(i) publish in the Federal Register adjustments to the inspection frequencies specified in subparagraphs (B) and (C) of paragraph (4) for category 2 and category 3 food facilities, which adjustments shall be in accordance with the Secretary's recommendations in such report; and

"(ii) after such publication, implement the adjustments; and

"(E) except as provided in subparagraphs (B) and (C), may not alter the inspection frequency specified in paragraph (4)(A) for category 1 food facilities.

"(6) In determining the appropriate frequency of inspection, the Secretary shall consider—

"(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 United States food is certified by a qualified certifying entity in accordance with section 801(p); and

"(D) such other factors as the Secretary determines by guidance to be relevant to assessing the risk presented by the facility.".

(b) REPORTS ON RISK-BASED INSPECTIONS OF FOOD FACILITIES.—

(1) ANNUAL REPORT.—Not later than December 31 of each year, the Secretary of Health and Human Services shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate describing—

(A) the number of foreign and domestic facilities, by risk category, inspected under the risk-based inspection schedule established under section 704(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), in the preceding fiscal year; and

(B) the costs of implementing the risk-based inspection schedule for the preceding 12 months.

(2) THIRD-YEAR REPORT.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate describing recommendations on the risk-based inspection schedule under section 704(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), including recommendations for adjustments to the timing of the schedule and other ways to improve the risk-based allocation of resources by the Food and Drug Administration. In making such recommendations, the Secretary shall consider the following—

(A) the nature of the food products being processed, stored, or transported;

(B) the manner in which food products are processed, stored, or transported;

(C) the inherent likelihood that the products will contribute to the risk of food-borne illness;

(D) the best available evidence concerning reported illnesses associated with the foods processed, stored, held, or transported in the category of facilities; and

(E) 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.

SEC. 106. ACCESS TO RECORDS.

(a) RECORDS ACCESS.—Subsection (a) of section 414 (21 U.S.C. 350c) is amended to read as follows:

"(a) RECORDS ACCESS.—

"(1) RECORDS ACCESS DURING AN INSPECTION.—

"(A) IN GENERAL.—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 shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials, at reasonable times and within reasonable limits and in a reasonable manner, 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, including all records collected or developed to comply with section 418 or 418A.

"(B) SCOPE OF RECORDS.—The requirement under subparagraph (A) applies to all records relating to the production, manufacture, processing, packing, transporting, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.

"(C) IMMEDIATE AVAILABILITY WITH NOTICE.—Records not required to be made available immediately on commencement of an inspection under subparagraph (A) shall nonetheless be made available immediately on commencement of such an inspection if, by a reasonable time before such inspection, the Secretary by letter to the person identifies the records to be made available during such inspection.

"(2) ADDITIONAL AUTHORITIES TO ACCESS RECORDS REMOTELY; SUBMISSION OF RECORDS TO THE SECRETARY.—

"(A) REMOTE ACCESS IN EMERGENCIES.—If the Secretary has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death to humans or animals, the Secretary may require each person who manufactures, processes, packs, transports, distributes, receives, holds, or imports such article of food, or any article of food that the Secretary determines may be affected in a similar manner, to submit to the Secretary all records reasonably related to such article of food as soon as is reasonably practicable, after receiving written notice (including by notice served personally and outside normal business hours to an agent identified under subparagraph (E) or (F) of section 415(a)(2)) of such requirement.

"(B) REMOTE ACCESS TO RECORDS RELATED TO FOOD SAFETY PLANS.—With respect to a facility subject to section 418 and 418A, the Secretary may require the owner, operator, or agent of such facility to submit to the Secretary, as soon as reasonably practicable after receiving written notice of such requirement, the food safety plan, supporting information relied on by the facility to select the preventive controls to include in its food safety plan, and documentation of corrective actions, if any, taken under section 418(e) within the preceding 2 years

"(C) ELECTRONIC SUBMISSION.—If the records required to be submitted to the Secretary under subparagraph (A) or (B) are available in electronic format, such records shall be submitted electronically unless the Secretary specifies otherwise in the notice under such subparagraph.".

(b) REGULATIONS CONCERNING RECORDKEEPING.—

(1) AMENDMENT.—Subsection (b) of section 414 (21 U.S.C. 350c) is amended to read as follows:

"(b) REGULATIONS CONCERNING RECORDKEEPING.—The Secretary, in consultation and coordination, as appropriate, with other Federal departments and agencies with responsibilities for regulating food safety, may by regulation establish requirements 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 only distribution records which may be required of restaurants under this subsection are those showing the restaurant's suppliers and subsequent distribution other than to consumers.".

(2) APPLICATION.—The Secretary of Health and Human Services shall promulgate revised regulations to implement section 414(b) of the Federal Food, Drug, and Cosmetic Act, as amended by this subsection. Section 414(b) of the Federal Food, Drug, and Cosmetic Act and regulations thereunder, as in effect on the day before the date of the enactment of this Act, shall apply to acts and omissions occurring before the effective date of such revised regulations.

(c) CONFORMING AMENDMENTS.—Section 704(a)(1) (21 U.S.C. 374(a)(1)) is amended—

(1) in the first sentence—

(A) by inserting "farm," before "factory" each place it appears; and

(B) by inserting "produced," before "manufactured";

(2) in the second sentence—

(A) by striking "(excluding farms and restaurants)";

(B) by inserting "produces," before "manufactures";

(C) by inserting "receives," before "holds";

(D) by striking "described in section 414" and inserting "described in or required under section 414"; and

(E) by striking "when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals" and inserting "bearing on whether such food is adulterated, misbranded, or otherwise in violation of this Act, including all records collected or developed to comply with section 418 or 418A"; and

(3) in the fourth sentence—

(A) by striking "the preceding sentence" and inserting "either of the preceding two sentences"; and

(B) by inserting "recipes for food," before "financial data,".

SEC. 107. TRACEABILITY OF FOOD.

(a) PROHIBITED ACT.—Section 301(e) (21 U.S.C. 331(e)) is amended by inserting ", the violation of any requirement of the food tracing system under section 414(c);" before "or the refusal to permit access to or verification or copying of any such required record".

(b) IMPORTS.—Section 801(a) (21 U.S.C. 381(a)) is amended by inserting "or (4) the requirements of section 414 have not been complied with regarding such article," before "then such article shall be refused admission".

(c) PRODUCT TRACING FOR FOOD.—Section 414 (21 U.S.C. 350c), as amended by section 106, is amended—

(1) by redesignating subsections (c) and (d) as subsections (d) and (e), respectively; and

(2) by inserting after subsection (b) the following:

"(c) TRACING SYSTEM FOR FOOD.—

"(1) IN GENERAL.—The Secretary shall by regulation establish a tracing system for food that is located in the United States or is for import into the United States.

"(2) INFORMATION GATHERING.—

"(A) TRACING TECHNOLOGIES.—Before issuing a proposed regulation under this subsection, the Secretary shall—

"(i) identify technologies and methodologies for tracing the distribution history of a food that are, or may be, used by members of different sectors of the food industry, including technologies and methodologies to enable each person who produces, manufactures, processes, pack, transports, or holds a food to—

"(I) maintain the full pedigree of the origin and previous distribution history of the food;

"(II) link that history with the subsequent distribution of the food;

"(III) establish and maintain a system for tracing the food that is interoperable with the systems established and maintained by other such persons; and

"(IV) use a unique identifier for each facility owned or operated by such person for such purpose, as specified under section 911; and

"(ii) to the extent practicable, assess—

"(I) the costs and benefits associated with the adoption and use of such technologies;

"(II) the feasibility of such technologies for different sectors of the food industry; and

"(III) whether such technologies are compatible with the requirements of this subsection.

"(B) PUBLIC MEETINGS.—Before issuing a proposed regulation under this subsection, the Secretary shall conduct not less than 2 public meetings in diverse geographical areas of the United States to provide persons in different regions an opportunity to provide input and information to the Secretary.

"(C) PILOT PROJECTS.—Before issuing a proposed regulation under this subsection, the Secretary shall conduct 1 or more pilot projects in coordination with 1 or more sectors of the food industry to explore and evaluate tracing systems for food.

"(3) REGULATION.—Taking into account information obtained through information gathering under paragraph (2), the Secretary shall issue regulations establishing a tracing system that enables the Secretary to identify each person who grows, produces, manufactures, processes, packs, transports, holds, or sells such food in as short a timeframe as practicable but no longer than 2 business days. The Secretary may include in such regulation—

"(A) the establishment and maintenance of lot numbers;

"(B) a standardized format for pedigree information; and

"(C) the use of a common nomenclature for food.

"(4) EXEMPTIONS.—

"(A) DIRECT SALES BY FARMS.—Food is exempt from the requirements of this subsection if such food is—

"(i) produced on a farm or fishery (including an oyster bed, a wild fishery, an aquaculture facility, a fresh water fishery, and a saltwater fishery); and

"(ii) sold by the owner, operator, or agent in charge of such farm or fishery directly to a consumer or to a restaurant or grocery store.

"(B) OTHER FOODS.—The Secretary may by notice in the Federal Register exempt a food or a type of facility, farm, or restaurant from, or modify the requirements with respect to, the requirements of this subsection if the Secretary determines that a tracing system for such food or type of facility, farm, or restaurant is not necessary to protect the public health.

"(C) PREVIOUS SOURCES AND SUBSEQUENT RECIPIENTS.—For a food covered by an exemption under subparagraph (B), the Secretary shall require each person who produces, manufactures, processes, packs, transports, or holds such food to maintain records to identify the immediate previous sources of such food and its ingredients and the immediate subsequent recipients of such food.

"(D) RESTAURANTS AND GROCERY STORES.—For a food covered by an exemption under subparagraph (A), restaurants and grocery stores shall keep records documenting the farm that was the source of the food.

"(E) FARMS AND FISHERIES.—For a food covered by an exemption under subparagraph (A), farms and fisheries shall keep records, in electronic or non-electronic format, for at least 6 months documenting the restaurant or grocery store to which the food was sold.".

SEC. 108. REINSPECTION AND FOOD RECALL FEES APPLICABLE TO FACILITIES.

(a) IN GENERAL.—Part 6 of subchapter C of chapter VII (21 U.S.C. 371 et seq.), as added by section 101(c), is amended by adding at the end the following:

"SEC. 743A. REINSPECTION AND FOOD RECALL FEES APPLICABLE TO FACILITIES.

"(a) IN GENERAL.—The Secretary shall assess and collect fees from each entity in a fiscal year—

"(1) that—

"(A) during such fiscal year commits a violation of any requirement of this Act relating to food, including any such requirement relating to good manufacturing practices; and

"(B) because of such violation, undergoes additional inspection by the Food and Drug Administration; or

"(2) during such fiscal year is subject to a food recall.

"(b) AMOUNT OF FEES.—The Secretary shall set the amount of the fees under this section to fully cover the costs of—

"(1) in the case of fees collected under subsection (a)(1), conducting the additional inspections referred to in such subsection; and

"(2) in the case of fees collected under subsection (a)(2), conducting food recall activities, including technical assistance, follow-up effectiveness checks, and public notifications, during the fiscal year involved.

"(c) CREDITING AND AVAILABILITY OF FEES.—

"(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

"(2) COLLECTIONS AND APPROPRIATIONS ACTS.—The fees authorized by this section—

"(A) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year; and

"(B) shall only be collected and available to defray the costs referred to in subsection (b).

"(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2010 through 2014, there are authorized to be appropriated for fees under this section such sums as may be necessary.

"(d) WAIVER.—The Secretary shall waive and, if applicable, refund the amount of any fee collected under this section from an entity as a result of a food recall that the Secretary determines was inappropriately ordered.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to additional inspections and food recall activities occurring after the date of the enactment of this Act.

SEC. 109. CERTIFICATION AND ACCREDITATION.

(a) MISBRANDING.—

(1) IN GENERAL.—Section 403 (21 U.S.C. 343), as amended by section 101(a), is amended by adding at the end the following:

"(aa) If it is part of a shipment offered for import into the United States and such shipment is in violation of section 801(p) (requiring a certification to accompany certain food shipments).".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to shipments offered for import on or after the date that is 3 years after the date of the enactment of this Act.

(b) CERTIFICATION OF COMPLIANCE FOR IMPORTS.—Chapter VIII (21 U.S.C. 381 et seq.) is amended—

(1) in section 801(a), as amended by section 107(b), by inserting after the third sentence the following: "If an article of food being imported or offered for import into the United States is not in compliance with the requirement of subsection (p) (relating to certifications of compliance with this Act), then such article shall be refused admission.";

(2) in the second sentence of section 801(b), by striking "the fourth sentence" and inserting "the fifth sentence"; and

(3) by adding at the end of section 801 the following:

"(p) CERTIFICATIONS CONCERNING IMPORTED ARTICLES.—

"(1) IN GENERAL.—

"(A) REQUIREMENT.—The Secretary shall require, as an additional condition of granting admission to an article of food being imported or offered for import into the United States, that a qualified certifying entity provide a certification that the article complies with specified requirements of this Act if—

"(i) for food imported from a particular country or region, based on the adequacy of government controls in such country or region or other information relevant to such food, certification would assist the Secretary in determining whether to refuse to admit such article under subsection (a);

"(ii) 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

"(iii) 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.

"(B) CONTENTS OF CERTIFICATION.—Such certification shall include such information regarding compliance as the Secretary may specify, and may be provided in the form of shipment-specific certificates, a listing of certified facilities or other entities, or in such other form as the Secretary may specify.

"(C) NOTICE OF CANCELLATION OR SUSPENSION OF CERTIFICATION.—As a condition on acceptance of certifications from a qualified certifying entity, the Secretary shall require the qualified certifying entity to notify the Secretary whenever the qualified certifying entity cancels or suspends the certification of any facility or other entity included in a listing under subparagraph (B).

"(2) QUALIFIED CERTIFYING ENTITY.—For purposes of this subsection, the term 'qualified certifying entity' means—

"(A) an agency or a representative of the government of the country from which the article originated, as designated by such government or the Secretary; or

"(B) an individual or entity determined by the Secretary or an accredited body recognized by the Secretary to be qualified to provide a certification under paragraph (1).

"(3) NO CONFLICTS OF INTEREST.—

"(A) IN GENERAL.—The Secretary shall issue regulations to ensure that any qualified certifying entity and its auditors are free from conflicts of interest.

"(B) REGULATIONS.—Such regulations shall require that—

"(i) the qualified certifying entity shall have a committee or management structure for safeguarding impartiality;

"(ii) conflict of interest policies for a qualified certifying entity and auditors acting for the qualified certifying entity shall be written;

"(iii) the qualified certifying entity shall not be owned, operated, or controlled by a producer, manufacturer, processor, packer, holder, supplier, or vendor of any article of the type it certifies;

"(iv) the qualified certifying entity shall not have any ownership or financial interest in any product, producer, manufacturer, processor, packer, holder, supplier or vendor of the type it certifies;

"(v) no auditor acting for the qualified certifying entity (or spouse or minor children) shall have any significant ownership or other financial interest regarding any product of the type it certifies;

"(vi) the qualified certifying entity shall maintain records pertaining to the financial interests of the personnel involved in audits;

"(vii) neither the qualified certifying entity nor any of its auditors acting for the qualified certifying entity shall participate in the production, manufacture, processing, packing, holding, promotion, or sale of any product of the type it certifies;

"(viii) neither the qualified certifying entity nor any of its auditors shall provide consultative services to any facility certified by the qualified certifying entity, or the owner, operator, or agent in charge of such a facility, unless the qualified certifying entity has procedures in place, approved by the Secretary, to ensure separation of functions between auditors providing consultative services and auditors providing certification services under this subsection;

"(ix) no auditors acting for the qualified certifying entity shall participate in an audit of a facility they were employed by within the last 12 months;

"(x) fees charged or accepted shall not be contingent or based upon the report made by the qualified certifying entity or any personnel involved in the audit process;

"(xi) neither the qualified certifying entity nor any of its auditors shall accept anything of value from anyone in connection with the facility being audited other than the audit fee;

"(xii) the qualified certifying entity shall not be owned, operated, or controlled by a trade association whose member companies operate facilities that it certifies;

"(xiii) the qualified certifying entity and its auditors shall be free from any other conflicts of interest that threaten impartiality;

"(xiv) the qualified certifying entity and its auditors shall sign a statement attesting to compliance with the conflict of interests requirements under this paragraph; and

"(xv) the qualified certifying entity shall ensure that any subcontractors that might be used (such as laboratories and sampling services) provide similar assurances, except that it shall not be a violation of this subsection to the extent such subcontractors perform additional nutritional testing services unrelated to the testing under this subsection.

"(C) ANYTHING OF VALUE.—In this paragraph, the term 'anything of value' includes gifts, gratuities, reimbursement of expenses, entertainment, loans, or any other form of compensation in cash or in kind.

"(4) RENEWAL AND REFUSAL OF CERTIFICATIONS.—The Secretary shall—

"(A) require that, to the extent applicable, any certification provided by a qualified certifying entity be renewed by such entity at such times as the Secretary determines appropriate; and

"(B) refuse to accept any certification if the Secretary determines that such certification is no longer valid or reliable.

"(5) ELECTRONIC SUBMISSION.—The Secretary shall provide for the electronic submission of certifications under this subsection.

"(6) NO LIMIT ON AUTHORITY.—This subsection shall not be construed to limit the authority of the Secretary to conduct random inspections of imported articles or facilities of importers, issue import alerts for detention without physical examination, require submission to the Secretary of documentation or other information about an article imported or offered for import, or to take such other

steps as the Secretary deems appropriate to determine the admissibility of imported articles.".

SEC. 110. TESTING BY ACCREDITED LABORATORIES.

(a) PROHIBITED ACT.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

"(oo) The violation of any requirement of section 714 (relating to testing by accredited laboratories).".

(b) LABORATORY ACCREDITATION.—Subchapter A of chapter VII (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

"SEC. 714. TESTING BY ACCREDITED LABORATORIES.

"(a) IN GENERAL.—

"(1) REQUIREMENT.—Whenever analytical testing of an article of food is conducted as part of testimony for the purposes of section 801(a), or for such other purposes as the Secretary deems appropriate through regulation or guidance, such testing shall be conducted by a laboratory that—

"(A) is accredited, for the analytical method used, by a laboratory accreditation body that has been recognized by the Secretary; and

"(B) samples such article with adequate controls for ensuring the integrity of the samples analyzed.

"(2) INDEPENDENCE OF LABORATORY.—

"(A) CERTAIN TESTS.—Tests required for purposes of section 801(a) or in response to a finding of noncompliance by the Secretary shall be conducted by a laboratory independent of the person on whose behalf such testing is conducted and analyzed.

"(B) CERTAIN PRODUCTS.—The Secretary may require that testing for certain products under paragraph (1) be conducted by a laboratory independent of the person on whose behalf such testing is conducted.

"(b) RECOGNITION OF LABORATORY ACCREDITATION BODIES.—The Secretary shall establish and implement a program for the recognition, based on standards the Secretary deems appropriate, of laboratory accreditation bodies that accredit laboratories to perform analytical testing for the purposes of this section. The Secretary shall issue regulations or guidance to implement this program.

"(c) ONSITE AUDITS.—In evaluating whether an accreditation body meets, or continues to meet, the standards for recognition under subsection (b), the Secretary may—

"(1) observe onsite audits of laboratories by such accreditation bodies; or

"(2) for any laboratory that is accredited by such accreditation body under this section, upon request of an officer or employee designated by the Secretary and upon presentation of appropriate credentials, at reasonable times and within reasonable limits and in a reasonable manner, conduct an onsite audit of the laboratory, which shall include access to, and copying and verification of, any related records.

"(d) PUBLICATION OF LIST OF RECOGNIZED ACCREDITATION BODIES.—The Secretary shall publish and maintain on the public Web site of the Food and Drug Administration a list of accreditation bodies recognized by the Secretary under subsection (b).

"(e) NOTIFICATION OF ACCREDITATION OF LABORATORY.—An accreditation body that has been recognized pursuant to this section shall promptly notify the Secretary whenever it accredits a laboratory for the purposes of this section and whenever it withdraws or suspends such accreditation.

"(f) ADVANCE NOTICE.—Whenever analytical testing is conducted pursuant to subsection (a), the person on whose behalf the testing is conducted shall notify the Secretary before any sample of the article is collected. Such notice shall contain information the Secretary determines is appropriate to identify the article, the location of the article, and each laboratory that will analyze the sample on the person's behalf.

"(g) CONTENTS OF LABORATORY PACKAGES.—Whenever analytical testing is conducted pursuant to subsection (a), the laboratory conducting such testing shall submit, directly to the Secretary—

"(1) the results of all analyses conducted by the laboratory on each sample of such article; and

"(2) all information the Secretary deems appropriate to—

"(A) determine whether the laboratory is accredited by a recognized laboratory accreditation body;

"(B) identify the article tested;

"(C) evaluate the analytical results; and

"(D) determine whether the requirements of this section have been met.

"(h) EXIGENT CIRCUMSTANCES.—The Secretary may waive the requirement of subsection (a)(1)(A) (relating to analytical methods) on a laboratory or method basis due to exigent or other circumstances.

"(i) NO LIMIT ON AUTHORITY.—Nothing in this section shall be construed to limit—

"(1) the ability of the Secretary to review and act upon information from the analytical testing of food (including under this section), including determining the sufficiency of such information and testing; or

"(2) the authority of the Secretary to conduct, require, or consider the results of analytical testing pursuant to any other provision of law.".

SEC. 111. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED FOOD.

(a) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331), as amended by section 110, is amended by adding at the end the following:

"(pp)(1) The failure to notify the Secretary in violation of section 420(a).

"(2) The failure to comply with any order issued under section 420.".

(b) NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED FOOD.—Chapter IV (21 U.S.C. 341 et seq.), as amended by sections 102, 103, and 104, is amended by adding at the end the following:

"SEC. 420. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED FOOD.

"(a) NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED FOOD.—

"(1) IN GENERAL.—A responsible party as that term is defined in section 417(a)(1) or a person required to register under section 801(r) that has reason to believe that an article of food when introduced into or while in interstate commerce, or while held for sale (regardless of whether the first sale) after shipment in interstate commerce, is adulterated or misbranded in a manner that presents a reasonable probability that the use or consumption of, or exposure to, the article (or an ingredient or component used in any such article) will cause a threat of serious adverse health consequences or death to humans or animals shall, as soon as practicable, notify the Secretary of the identity and location of the article.

"(2) MANNER OF NOTIFICATION.—Notification under paragraph (1) shall be made in such manner and by such means as the Secretary may require by regulation or guidance.

"(b) VOLUNTARY RECALL.—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—

"(1) recall such article; and

"(2) provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

"(c) ORDER TO CEASE DISTRIBUTION.—If the Secretary has reason to believe that the use or consumption of, or exposure to, an article of food may cause serious adverse health consequences or death to humans or animals, the Secretary shall have the authority to issue an order requiring any person who distributes such article to immediately cease distribution of such article.

"(d) ACTION FOLLOWING ORDER.—Any person who is subject to an order under subsection (c) shall immediately cease distribution of such article and provide notification as required by such order, and may appeal within 24 hours of issuance such order to the Secretary. Such appeal may include a request for an informal hearing and a description of any efforts to recall such article undertaken voluntarily by the person, including after a request under subsection (b). Except as provided in subsection (f), an informal hearing shall be held within as soon as practicable, but not later than 5 calendar days, or less as determined by the Secretary, after such an appeal is filed, unless the parties jointly agree to an extension. After affording an opportunity for an informal hearing, the Secretary shall determine whether the order should be amended to require a recall of such article. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(e) ORDER TO RECALL.—

"(1) AMENDMENT.—Except as provided under subsection (f), 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.

"(2) CONTENTS.—An amended order under paragraph (1) shall—

"(A) specify a timetable in which the recall will occur;

"(B) require periodic reports to the Secretary describing the progress of the recall; and

"(C) provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

In providing for such notice, the Secretary may allow for the assistance of health professionals, State or local officials, or other individuals designated by the Secretary.

"(3) NONDELEGATION.—An amended order under this subsection shall be ordered by the Secretary or an official designated by the Secretary. 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.

"(f) EMERGENCY RECALL ORDER.—

"(1) IN GENERAL.—If the Secretary has a reasonable belief that an article of food subject to an order under subsection (c) presents an imminent threat of serious adverse health consequences or death to humans or animals, the Secretary may issue an order requiring any person who distributes such article—

"(A) to immediately recall such article; and

"(B) to provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

"(2) ACTION FOLLOWING ORDER.—Any person who is subject to an emergency recall order under this subsection shall immediately recall such article and provide notification as required by such order, and may appeal within 24 hours after issuance such order to the Secretary. An informal hearing shall be held within as soon as practicable but not later than 5 calendar days, or less as determined by the Secretary, after such an appeal is filed, unless the parties jointly agree to an extension. After affording an opportunity for an informal hearing, the Secretary shall determine whether the order should be amended pursuant to subsection (e)(1). If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(3) NONDELEGATION.—An order under this subsection shall be issued by the Commissioner of Food and Drugs, the Principal Deputy Commissioner, or the Associate Commissioner for Regulatory Affairs of the Food and Drug Administration.

"(g) NOTICE TO CONSUMERS AND HEALTH OFFICIALS.—The Secretary shall, as the Secretary determines to be necessary, provide notice of a recall order under this section to consumers to whom the article was, or may have been, distributed and to appropriate State and local health officials.

"(h) SAVINGS CLAUSE.—Nothing contained in this section shall be construed as limiting—

"(1) the authority of the Secretary to issue an order to cease distribution of, or to recall, an article under any other provision of this Act or the Public Health Service Act; or

"(2) the ability of the Secretary to request any person to perform a voluntary activity related to any article subject to this Act or the Public Health Service Act.".

(c) ARTICLES SUBJECT TO REFUSAL.—The third sentence of subsection (a) of section 801 (21 U.S.C. 381), as amended by section 107(b), is amended by inserting "or (5) such article is subject to an order under section 420 to cease distribution of or recall the article," before "then such article shall be refused admission".

(d) EFFECTIVE DATE.—Sections 301(pp)(1) and 420 of the Federal Food, Drug, and Cosmetic Act, as added by subsections (a) and (b), shall apply with respect to articles of food as of such date, not later than 1 year after the date of the enactment of this Act, as the Secretary of Health and Human Services shall specify.

SEC. 112. REPORTABLE FOOD REGISTRY; EXCHANGE OF INFORMATION.

(a) REPORTABLE FOOD REGISTRY.—Section 417 (21 U.S.C. 350f) is amended—

(1) in subsection (a)(1), by striking "means a person" and all that follows through the end of paragraph (1) and inserting the following: "means—

"(A) a person who submits the registration under section 415(a) for a food facility that is required to be registered under section 415(a), at which such food is manufactured, processed, packed, or held;

"(B) a person who owns, operates, is an agent of, or is otherwise responsible for such food on a farm (as such term is defined in section 1.227(b)(3) of title 21, Code of Federal Regulations, or successor regulations) at which such food is produced for sale or distribution in interstate commerce;

"(C) a person who owns, operates, or is an agent of a restaurant or other retail food establishment (as such terms are defined in section 1.227(b)(11) and (12), respectively, of title 21, Code of Federal Regulations, or successor regulations) at which such food is offered for sale; or

"(D) a person that is required to register pursuant to section 801(r) with respect to importation of such food.";

(2) in subsection (b), by adding at the end the following:

"(3) REPORTING BY RESTAURANTS AND RETAIL FOOD ESTABLISHMENTS.—In addition to the electronic portal described in paragraph (1), the Secretary shall make available alternative means of reporting under this section with respect to restaurants and other retail food establishments with limited ability for such reporting.";

(3) in subsection (d)(1)—

(A) in the matter preceding subparagraph (A), by inserting "following a timely review of any reasonably available data and information," after "reportable food,";

(B) in subparagraph (A), by striking "and" at the end;

(C) by redesignating subparagraph (B) as subparagraph (C); and

(D) by inserting after subparagraph (A) the following:

"(B) submit, with such report, through the electronic portal, documentation of results from any sampling and testing of such article, including—

"(i) analytical results from testing of such article conducted by or on behalf of the responsible party under section 418, 418A, 419, 419A, or 714;

"(ii) analytical results from testing conducted by or on behalf of such responsible party of a component of such article;

"(iii) analytical results of environmental testing of any facility at which such article, or a component of such article, is manufactured, processed, packed, or held; and

"(iv) any other information the Secretary determines is necessary to evaluate the adulteration of such article, any component of such article, any other article of food manufactured, processed, packed or held in the same manner as, or at the same facility as, such article, or any other article containing a component from the same source as a component of such article; and"; and

(4) in subsection (e)—

(A) in paragraph (1), by inserting "if the responsible party is required to register" after "415(a)(3)"; and

(B) by adding at the end the following:

"(12) Such additional information as the Secretary deems appropriate.".

(b) EXCHANGE OF INFORMATION.—Section 708 (21 U.S.C. 379) is amended—

(1) by striking "The Secretary" and inserting "(a) The Secretary"; and

(2) by adding at the end the following:

"(b)(1)(A) The Secretary may provide to any Federal agency acting within the scope of its jurisdiction any information relating to food that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section, or that is referred to in section 301(j) or 415(a)(4).

"(B) Any such information provided to another Federal agency shall not be disclosed by such agency except in any action or proceeding under the laws of the United States to which the receiving agency or the United States is a party.

"(2)(A) In carrying out this Act, the Secretary may provide to a State or local government agency any information relating to food that is exempt from disclosure pursuant to section 552(a) of title 5, United States Code, by reason of subsection (b)(4) of such section, or that is referred to in section 301(j) or 415(a)(4).

"(B) Any such information provided to a State or local government agency shall not be disclosed by such agency.

"(3) In carrying out this Act, the Secretary may provide to any person any information relating to food that is exempt from disclosure pursuant to section 552(a) of title 5, United States Code, by reason of subsection (b)(4) of such section, if the Secretary determines that providing the information to the person is appropriate under the circumstances and the recipient provides adequate assurances to the Secretary that the recipient will preserve the confidentiality of the information.

"(4) In carrying out this Act, the Secretary may provide any information relating to food that is exempt from disclosure pursuant to section 552(a) of title 5, United States Code, by reason of subsection (b)(4) of such section, or that is referred to in section 301(j)—

"(A) to any foreign government agency; or

"(B) any international organization established by law, treaty, or other governmental action and having responsibility—

"(i) to facilitate global or regional harmonization of standards and requirements in an area of responsibility of the Food and Drug Administration; or

"(ii) to promote and coordinate public health efforts,

if the agency or organization provides adequate assurances to the Secretary that the agency or organization will preserve the confidentiality of the information.

"(c) Except where specifically prohibited by statute, the Secretary may disclose to the public any information relating to food that is exempt from disclosure pursuant to section 552(a) of title 5, United States Code, by reason of subsection (b)(4) of such section, if the Secretary determines that such disclosure is necessary to protect the public health.

"(d) Except as provided in subsection (e), the Secretary shall not be required to disclose under section 552 of title 5, United States Code, or any other provision of law any information relating to food obtained from a Federal, State, or local government agency, or from a foreign government agency, or from an international organization described in subsection (b)(4), if the agency or organization has requested that the information be kept confidential, or has precluded such disclosure under other use limitations, as a condition of providing the information.

"(e) Nothing in subsection (d) authorizes the Secretary to withhold information from the Congress or prevents the Secretary from complying with an order of a court of the United States.

"(f) This section shall not affect the authority of the Secretary to provide or disclose information under any other provision of law.".

(c) CONFORMING AMENDMENT.—Section 301(j) (21 U.S.C. 331(j)) is amended by striking "or to the courts when relevant in any judicial proceeding under this Act," and inserting "to the courts when relevant in any judicial proceeding under this Act, or as specified in section 708,".

SEC. 113. SAFE AND SECURE FOOD IMPORTATION PROGRAM.

Chapter VIII (21 U.S.C. 381 et seq.) is amended by adding at the end the following:

"SEC. 805. SAFE AND SECURE FOOD IMPORTATION PROGRAM.

"(a) IN GENERAL.—The Secretary may establish by regulation or guidance a program that facilitates the movement of food through the importation process under this Act if the importer of such food—

"(1) verifies that each facility involved in the production, manufacture, processing, packaging, and holding of the food is in compliance with the food safety and security guidelines developed under subsection (b) with respect to such food;

"(2) ensures that appropriate safety and security controls are in place throughout the supply chain for such food; and

"(3) provides supporting information to the Secretary.

"(b) GUIDELINES.—

"(1) DEVELOPMENT.—For purposes of the program established under subsection (a), the Secretary shall develop safety and security guidelines applicable to the importation of food.

"(2) FACTORS.—Such guidelines shall take into account the following factors:

"(A) The personnel of the person importing the food.

"(B) The physical and procedural safety and security of such person's food supply chain.

"(C) The sufficiency of preventive controls for food and ingredients purchased by such person.

"(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.".

SEC. 114. INFANT FORMULA.

(a) MISBRANDING.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) as amended by sections 101(a) and 109(a), is amended by adding at the end the following:

"(bb) If it is a new infant formula and it is not the subject of a letter from the Secretary provided pursuant to section 412(c)(1)(C).".

(b) REQUIREMENTS.—Section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) is amended—

(1) in subsection (b)(1), by adding at the end the following: "The quality factor requirements established under this paragraph may include requirements for

one or more clinical studies to demonstrate that the new infant formula supports normal physical growth of infants.";

(2) in subsection (b)(4), by amending subparagraph (B) to read as follows:

"(B) Records required under subparagraph (A) with respect to an infant formula shall be retained for at least one year after the expiration of the shelf life of such infant formula. Such records shall be made available to the Secretary for review and duplication upon request of the Secretary.";

(3) in subsection (c)(1)—

(A) in subparagraph (A), by striking "and" at the end;

(B) in subparagraph (B), by striking "(c)(1)." at the end and inserting "(d)(1), and"; and

(C) by adding at the end the following:

"(C) the Secretary has by letter informed such person that the registration requirements and the requirements in subsection (d)(1) have been satisfied."; and

(4) in subsection (d)(1), by striking subparagraphs (C) and (D) and inserting the following:

"(C) scientific evidence and other evidence, as identified in regulations promulgated by the Secretary, that demonstrates that the infant formula satisfies the requirements of subsection (b)(1), and, as demonstrated by the testing required under subsection (b)(3), that it satisfies the requirements of subsection (i), and

"(D) scientific evidence and other evidence, as identified in regulations promulgated by the Secretary, that demonstrate that the processing of the infant formula complies with the requirements of subsection (b)(2).".

Subtitle B—Intervention

SEC. 121. SURVEILLANCE.

(a) DEFINITION OF FOOD-BORNE ILLNESS OUTBREAK.—In this section, the term "food-borne illness outbreak" means the occurrence of 2 or more cases of a similar illness resulting from the ingestion of a food.

(b) FOOD-BORNE ILLNESS SURVEILLANCE SYSTEMS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall enhance food-borne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on food-borne illnesses by—

(1) coordinating Federal, State, and local food-borne illness surveillance systems, including complaint systems, and increasing participation in national networks of public health and food regulatory agencies and laboratories;

(2) facilitating sharing of findings on a more timely basis among governmental agencies, including the Food and Drug Administration, the Department of Agriculture, and State and local agencies, and with the public;

(3) developing improved epidemiological tools for obtaining quality exposure data, and microbiological methods for classifying cases;

(4) augmenting such systems to improve attribution of a food-borne illness outbreak to a specific food;

(5) expanding capacity of such systems, including fingerprinting and other detection strategies for food-borne infectious agents, in order to identify new or rarely documented causes of food-borne illness;

(6) allowing timely public access to aggregated, de-identified surveillance data;

(7) at least annually, publishing current reports on findings from such systems;

(8) establishing a flexible mechanism for rapidly initiating scientific research by academic institutions;

(9) integrating food-borne illness surveillance systems and data with other biosurveillance and public health situational awareness capabilities at the Federal, State, and local levels; and

(10) other activities as determined appropriate by the Secretary.

(c) IMPROVING FOOD SAFETY AND DEFENSE CAPACITY AT THE STATE AND LOCAL LEVEL.—

(1) IN GENERAL.—The Secretary shall develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies in order to achieve the following goals:

(A) Improve food-borne illness outbreak response and containment.

(B) Accelerate food-borne illness surveillance and outbreak investigation, including rapid shipment of clinical isolates from clinical laboratories to appropriate State laboratories, and conducting more standardized illness outbreak interviews.

(C) Strengthen the capacity of State and local agencies to carry out inspections and enforce safety standards.

(D) Improve the effectiveness of Federal, State, and local partnerships to coordinate food safety and defense resources and reduce the incidence of food-borne illness.

(E) Share information on a timely basis among public health and food regulatory agencies, with the food industry, with health care providers, and with the public.

(2) REVIEW.—In developing of the strategies required by paragraph (1), the Secretary shall, not later than 1 year after the date of enactment of this Act, complete a review of State and local capacities, and needs for enhancement, which may include a survey with respect to—

(A) staffing levels and expertise available to perform food safety and defense functions;

(B) laboratory capacity to support surveillance, outbreak response, inspection, and enforcement activities;

(C) information systems to support data management and sharing of food safety and defense information among State and local agencies and with counterparts at the Federal level; and

(D) other State and local activities and needs as determined appropriate by the Secretary.

SEC. 122. PUBLIC EDUCATION AND ADVISORY SYSTEM.

(a) PUBLIC EDUCATION.—The Secretary, in cooperation with private and public organizations, including the appropriate State entities, shall design and implement a national public education program on food safety. The program shall provide—

(1) information to the public so that individuals can understand the potential impact and risk of food-borne illness, take action to reduce their risk of food-borne illness and injury, and make healthy dietary choices;

(2) information to health professionals so that they may improve diagnosis and treatment of food-related illness and advise individuals whose health conditions place them in particular risk; and

(3) such other information or advice to consumers and other persons as the Secretary determines will promote the purposes of this Act.

(b) HEALTH ADVISORIES.—The Secretary shall work with the States and other appropriate entities to—

(1) develop and distribute regional and national advisories concerning food safety;

(2) develop standardized formats for written and broadcast advisories; and

(3) incorporate State and local advisories into the national public education program required under subsection (a).

SEC. 123. RESEARCH.

The Secretary shall 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;

(2) develop improved techniques for the monitoring of food and inspection of food products;

(3) develop efficient, rapid, and sensitive methods for determining and detecting the presence of contaminants in food products;

(4) determine the sources of contamination of food and food products, including critical points of risk for fresh produce and other raw agricultural commodities;

(5) develop consumption data with respect to food products;

(6) draw upon research and educational programs that exist at the State and local level;

(7) utilize the DNA matching system and other processes to identify and control pathogens;

(8) address common and emerging zoonotic diseases;

(9) develop methods to reduce or destroy pathogens before, during, and after processing;

(10) 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; and

(11) conduct other research that supports the purposes of this Act.

Subtitle C—Response

SEC. 131. PROCEDURES FOR SEIZURE.

Section 304(b) (21 U.S.C. 334(b)) is amended by inserting "and except that, with respect to proceedings relating to food, Rule G of the Supplemental Rules of Admiralty or Maritime Claims and Asset Forfeiture Actions shall not apply in any such case, exigent circumstances shall be deemed to exist for all seizures brought under this section, and the summons and arrest warrant shall be issued by the clerk of the court without court review in any such case" after "in any such case shall be tried by jury".

SEC. 132. ADMINISTRATIVE DETENTION.

(a) AMENDMENTS.—Section 304(h) (21 U.S.C. 334(h)) is amended—

(1) in paragraph (1)(A), by striking "credible evidence or information indicating" and inserting "reason to believe";

(2) in paragraph (1)(A), by striking "presents a threat of serious adverse health consequences or death to humans or animals" and inserting "is adulterated, misbranded, or otherwise in violation of this Act";

(3) in paragraph (2), by striking "30" and inserting "60";

(4) in paragraph (3), by striking the third sentence; and

(5) in paragraph (4)(A) by striking the terms "five" and "five-day" and inserting "fifteen" and "fifteen-day", respectively.

(b) REGULATIONS.—The Secretary shall issue regulations or guidance to implement the amendments made by this section.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect 180 days after the date of the enactment of this Act.

SEC. 133. QUARANTINE AUTHORITY FOR FOODS.

(a) PROHIBITED ACT.—Section 301 (21 U.S.C. 331), as amended by sections 110 and 111, is amended by adding at the end by adding the following:

"(qq) The violation of a quarantine under section 304(i).".

(b) IN GENERAL.—Section 304 (21 U.S.C. 334) is amended by adding at the end the following:

"(i) QUARANTINE OF GEOGRAPHIC LOCATION.—

"(1) AUTHORITY TO QUARANTINE.—If the Secretary determines that there is credible evidence or information that an article of food presents an imminent threat of serious adverse health consequences or death to humans or animals, the Secretary may quarantine any geographic area within the United States where the Secretary reasonably believes such food is located or from which such food originated. The authority to quarantine includes prohibiting or restricting the movement of food or of any vehicle being used or that has been used to transport or hold such food within the geographic area. Any quarantine under this paragraph shall be no greater than is appropriate, as determined by the Secretary, to protect the public health.

"(2) NOTIFICATION PROCEDURES.—Before any quarantine action is taken in any State under this subsection, the Secretary shall notify an appropriate official of the State affected and shall issue a public announcement of—

"(A) the Secretary's findings that support the quarantine action;

"(B) the area affected by the intended quarantine action;

"(C) the reasons for the intended quarantine action; and

"(D) where practicable, an estimate of the anticipated duration of the quarantine.

The Secretary is not required to make such announcement by publication in the Federal Register, but may use a newspaper, radio or television, the Internet, or any reasonable means to make such announcement.

"(3) NONDELEGATION.—The authority to quarantine under this subsection is limited to the Commissioner of Food and Drugs, the Principal Deputy Commissioner, and the Associate Commissioner for Regulatory Affairs of the Food and Drug Administration.".

SEC. 134. CRIMINAL PENALTIES.

Section 303(a) (21 U.S.C. 333) is amended—

(1) in paragraph (1), by striking "Any" and inserting "Except as provided in paragraph (2) or (3), any"; and

(2) by adding at the end the following:

"(3) Notwithstanding paragraph (1), any person who knowingly violates paragraph (a), (b), (c), (k), or (v) of section 301 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.".

SEC. 135. CIVIL PENALTIES FOR VIOLATIONS RELATING TO FOOD.

(a) IN GENERAL.—Paragraph (2) of section 303(f) (21 U.S.C. 331 et seq.) is amended to read as follows:

"(2)(A) 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—

"(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 a 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.

"(C) Each violation described in subparagraph (A) or (B) and each day during which the violation continues shall be considered to be a separate offense.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) applies to violations committed on or after the date of the enactment of this Act.

SEC. 136. IMPROPER IMPORT ENTRY FILINGS.

(a) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331), as amended by sections 110, 111, and 133, is amended by adding at the end the following:

"(rr) The submission of information relating to food that is required by or under section 801 that is inaccurate or incomplete.

"(ss) The failure to submit information relating to food that is required by or under section 801.".

(b) DOCUMENTATION FOR IMPORTS.—Section 801 (21 U.S.C. 381), as amended by section 109, is amended by adding at the end the following:

"(q) DOCUMENTATION.—

"(1) SUBMISSION.—The Secretary may require by regulation or guidance the submission of documentation or other information for articles of food that are imported or offered for import into the United States.

"(2) FORMAT.—A regulation or guidance under paragraph (1) may specify the format for submission of the documentation or other information.".

TITLE II—MISCELLANEOUS

SEC. 201. FOOD SUBSTANCES GENERALLY RECOGNIZED AS SAFE.

Section 409 (21 U.S.C. 348) is amended by adding at the end the following:

"Substances Generally Recognized as Safe

"(k)(1) Not later than 60 days after the date of receipt by the Secretary, after the date of the enactment of this subsection, of a determination that a substance is a GRAS food substance, the Secretary shall post notice of such determination and the supporting scientific justifications on the Food and Drug Administration's public Web site.

"(2) Not later than 60 days after the date of receipt of a request under paragraph (1), the Secretary shall acknowledge receipt of such request by informing the requester in writing of the date on which the request was received.

"(3) In this subsection, the term 'GRAS food substance' means a substance excluded from the definition of the term 'food additive' in section 201(s) because such substance is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.".

SEC. 202. COUNTRY OF ORIGIN LABELING; DISCLOSURE OF SOURCE OF INGREDIENTS.

(a) MISBRANDING.—Section 403 (21 U.S.C. 343), as amended by sections 101(a), 109(a), and 114(a), is amended by adding at the end the following:

"(cc) In the case of a processed food, if the labeling of the food fails to identify the country in which the final processing of the food occurs.

"(dd) In the case of nonprocessed food, if the labeling of the food fails to identify the country of origin of the food.".

(b) REGULATIONS.—

(1) PROMULGATION.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate final

regulations to carry out paragraphs (cc) and (dd) of section 403 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(2) RELATION TO OTHER REQUIREMENTS.—Regulations promulgated under paragraph (1) shall provide that labeling meets the requirements of paragraphs (cc) and (dd) of section 403 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), if—

(A) in the case of a processed food, the label of the food informs the consumer of the country where the final processing of the food occurred in accordance with labeling requirements of the United States Customs and Border Protection; or

(B) in the case of a nonprocessed food, the label of the food informs the consumer of the country of origin of the food in accordance with labeling requirements of the Department of Agriculture.

(c) EFFECTIVE DATE.—The requirements of paragraphs (cc) and (dd) of section 403 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), take effect on the date that is 2 years after the date of the enactment of this Act.

SEC. 203. EXPORTATION CERTIFICATE PROGRAM.

Section 801(e)(4) (21 U.S.C. 381) is amended—

(1) in the matter preceding clause (i) in subparagraph (A)—

(A) by inserting "from the United States" after "exports"; and

(B) by striking "a drug, animal drug, or device" and inserting "a food (including animal feed), drug, animal drug, or device";

(2) in subparagraph (A)(i)—

(A) by striking "in writing"; and

(B) by striking "exported drug, animal drug, or device" and inserting "exported food, drug, animal drug, or device";

(3) in subparagraph (A)(ii)—

(A) by striking "in writing";

(B) by striking "the drug, animal drug, or device" and inserting "the food, drug, animal drug, or device"; and

(C) by striking "the drug or device" and inserting "the food, drug, or device";

(4) by redesignating subparagraph (B) as subparagraph (C);

(5) by inserting after subparagraph (A) the following:

"(B) For purposes of this paragraph, a certification by the Secretary shall be made on such basis and in such form (such as a publicly available listing) as the Secretary determines appropriate."; and

(6) by adding at the end the following:

"(D) Notwithstanding subparagraph (C), if the Secretary issues an export certification within the 20 days prescribed by subparagraph (A) with respect to the export of food, a fee for such certification shall not exceed such amount as the Secretary determines is reasonably related to the cost of issuing certificates under subparagraph (A) with respect to the export of food. The Secretary may adjust this fee annually to account for inflation and other cost adjustments. Fees collected for a fiscal year pursuant to this subparagraph shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriations Acts until expended, without fiscal year limitation. Such fees shall be collected in each fiscal year in an amount equal to the amount specified in appropriations Acts for such fiscal year and shall only be collected and available for the costs of the Food and Drug Administration to cover the cost of issuing such certifications. Such sums as necessary may be transferred from such appropriation account for salaries and expenses of the Food and Drug Administration without fiscal year limitation to such appropriation account for salaries and expenses with fiscal year limitation.".

SEC. 204. REGISTRATION FOR COMMERCIAL IMPORTERS OF FOOD; FEE.

(a) REGISTRATION.—

(1) PROHIBITIONS.—Section 301 (21 U.S.C. 331), as amended by sections 110, 111, 133, and 136, is amended by adding at the end the following:

"(tt) The failure to register in accordance with section 801(r).".

(2) MISBRANDING.—Section 403 (21 U.S.C. 343) as amended by sections 101(a), 109(a), 114(a), and 202(a), is amended by adding at the end the following:

"(ee) If it is imported or offered for import by an importer not duly registered under section 801(r).".

(3) REGISTRATION.—Section 801, as amended by sections 109 and 136, is amended by adding at the end the following:

"(r) REGISTRATION OF IMPORTERS.—

"(1) REGISTRATION.—The Secretary shall require an importer of food—

"(A) to be registered with the Secretary in a form and manner specified by the Secretary; and

"(B) consistent with section 911, to submit appropriate unique facility identifiers as a condition of registration.

"(2) GOOD IMPORTER PRACTICES.—The maintenance of registration under this subsection is conditioned on compliance with good importer practices. Good importer practices shall include the verification of good manufacturing practices and preventive controls of the importer's foreign suppliers, as applicable.

"(3) SUSPENSION OF REGISTRATION.—

"(A) IN GENERAL.—Registration under this subsection is subject to suspension upon a finding by the Secretary, after notice and an opportunity for an informal hearing, of—

"(i) a violation of this Act; or

"(ii) the knowing or repeated making of an inaccurate or incomplete statement or submission of information relating to the importation of food.

"(B) REQUEST.—The importer whose registration is suspended may request that the Secretary vacate the suspension of registration when such importer has corrected the violation that is the basis for such suspension.

"(C) VACATING OF SUSPENSION.—If the Secretary determines that adequate reasons do not exist to continue the suspension of a registration, the Secretary shall vacate such suspension.

"(4) CANCELLATION OF REGISTRATION.—

"(A) IN GENERAL.—Not earlier than 10 days after providing the notice under subparagraph (B), the Secretary may cancel a registration that the Secretary determines was not updated in accordance with this section or otherwise contains false, incomplete, or inaccurate information.

"(B) NOTICE OF CANCELLATION.—Cancellation shall be preceded by notice to the importer of the intent to cancel the registration and the basis for such cancellation.

"(C) TIMELY UPDATE OR CORRECTION.—If the registration for the importer is updated or corrected no later than 7 days after notice is provided under subparagraph (B), the Secretary shall not cancel such registration.

"(5) EXEMPTIONS.—The Secretary, by notice published in the Federal Register—

"(A) shall establish an exemption from the requirements of this subsection for importations for personal use; and

"(B) may establish other exemptions from the requirements of this subsection.".

(4) REGULATIONS.—Not later than 24 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate the regulations required to carry out section 801(r) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (3).

(5) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date that is 24 months after the date of enactment of this Act.

(b) FEE.—Subchapter C of chapter VII (21 U.S.C. 379f et seq.) as added and amended by sections 101 and 108, is amended by adding at the end the following:

"PART 7—IMPORTERS OF FOOD

"SEC. 744. IMPORTERS OF FOOD.

"(a) IMPORTERS.—The Secretary shall assess and collect an annual fee for the registration of an importer of food under section 801(r).

"(b) AMOUNT OF FEE.—

"(1) BASE AMOUNTS.—The registration fee under subsection (a) shall be—

"(A) for fiscal year 2010, $500; and

"(B) for fiscal year 2011 and each subsequent fiscal year, the fee for fiscal year 2010 as adjusted under paragraph (2).

"(2) ADJUSTMENT.—For fiscal year 2011 and subsequent fiscal years, the fees established pursuant to paragraph (1) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

"(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average), for the 12-month period ending June 30 preceding the fiscal year for which fees are being established;

"(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5,

United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia; or

"(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 5 years of the preceding 6 fiscal years.

"(3) COMPOUNDED BASIS.—The adjustment made each fiscal year pursuant this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2010 under this subsection.

"(4) WAIVER FOR IMPORTERS REQUIRED TO PAY REGISTRATION FEE.—In the case of a person who is required to pay both a fee under section 743 for registration of one or more facilities under section 415 and a fee under this section for registration as an importer of food under section 801(r), the Secretary shall waive the fees applicable to such person under section 743 or the fee applicable to such person under this section.

"(c) CREDITING AND AVAILABILITY OF FEES.—

"(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

"(2) COLLECTIONS AND APPROPRIATIONS ACTS.—The fees authorized by this section—

"(A) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year; and

"(B) shall only be collected and available to cover the costs associated with registering importers under section 801(r) and with ensuring compliance with good importer practices respecting food.

"(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2010 through 2014, there are authorized to be appropriated for fees under this section such sums as may be necessary.".

(c) INSPECTION.—Section 704 (21 U.S.C. 374), as amended by section 105, is amended by adding at the end the following:

"(i) IMPORTERS.—Every person engaged in the importing of any food shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to inspect the facilities of such person and have access to, and to copy and verify, any related records.".

SEC. 205. REGISTRATION FOR CUSTOMS BROKERS AND FILERS; FEE.

(a) REGISTRATION.—

(1) PROHIBITIONS.—Section 301(tt) (21 U.S.C. 331), as added by section 204, is amended by inserting "or 801(s)" after "801(r)".

(2) MISBRANDING.—Section 403(ee) (21 U.S.C. 343), as added by section 204, is amended—

(A) by inserting "or a customs broker or filer" after "by an importer"; and

(B) by inserting "or 801(s)" after "801(r)".

(3) REGISTRATION.—Section 801, as amended by sections 109, 136, and 204, is amended by adding at the end the following:

"(s) REGISTRATION OF CUSTOMS BROKERS AND FILERS.—

"(1) REGISTRATION.—The Secretary shall require a customs broker or filer, with respect to the importation of food—

"(A) to be registered with the Secretary in a form and manner specified by the Secretary; and

"(B) consistent with section 911, to submit appropriate unique facility identifiers as a condition of registration.

"(2) SUSPENSION OF REGISTRATION.—

"(A) IN GENERAL.—Registration under this subsection is subject to suspension upon a finding by the Secretary, after notice and an opportunity for an informal hearing, of—

"(i) a violation of this Act; or

"(ii) the knowing or repeated making of an inaccurate or incomplete statement or submission of information relating to the importation of food.

"(B) REQUEST.—The customs broker or filer whose registration is suspended may request that the Secretary vacate the suspension of registra-

tion when such customs broker or filer has corrected the violation that is the basis for such suspension.

"(C) VACATING OF SUSPENSION.—If the Secretary determines that adequate reasons do not exist to continue the suspension of a registration, the Secretary shall vacate such suspension.

"(3) CANCELLATION OF REGISTRATION.—

"(A) IN GENERAL.—Not earlier than 10 days after providing the notice under subparagraph (B), the Secretary may cancel a registration that the Secretary determines was not updated in accordance with this section or otherwise contains false, incomplete, or inaccurate information.

"(B) NOTICE OF CANCELLATION.—Cancellation shall be preceded by notice to the customs broker or filer of the intent to cancel the registration and the basis for such cancellation.

"(C) TIMELY UPDATE OR CORRECTION.—If the registration for the customs broker or filer is updated or corrected no later than 7 days after notice is provided under subparagraph (B), the Secretary shall not cancel such registration.

"(4) EXEMPTIONS.—The Secretary, by notice published in the Federal Register—

"(A) shall establish an exemption from the requirements of this subsection for importations for personal use; and

"(B) may establish other exemptions from the requirements of this subsection.".

(4) REGULATIONS.—Not later than 24 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate the regulations required to carry out section 801(s) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (3).

(5) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date that is 24 months after the date of enactment of this Act.

(b) INSPECTION.—Section 704 (21 U.S.C. 374), as amended by sections 105 and 204, is amended by adding at the end the following:

"(j) BROKERS AND FILERS.—Every person engaged in the brokering for import or filing for import of any food shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to inspect the facilities of such person and have access to, and to copy and verify, any related records.".

SEC. 206. UNIQUE IDENTIFICATION NUMBER FOR FOOD FACILITIES, IMPORTERS, CUSTOM BROKERS, AND FILERS.

Chapter IX (21 U.S.C. 391 et seq) is amended by adding at the end the following:

"SEC. 911. UNIQUE FACILITY IDENTIFIER.

"(a) REGISTRATION OF FACILITY OR ESTABLISHMENT.—A person required to register a facility pursuant to section 415 shall submit, at the time of registration, a unique facility identifier for the facility or establishment.

"(b) REGISTRATION OF IMPORTERS, CUSTOM BROKERS, AND FILERS.—A person required to register pursuant to section 801(r) or 801(s) shall submit, at the time of registration, a unique facility identifier for the principal place of business for which such person is required to register under section 801(r) or 801(s).

"(c) GUIDANCE.—The Secretary may, by guidance, specify the unique numerical identifier system to be used to meet the requirements of subsections (a) and (b) and the form, manner, and timing of a submission under such subsections.

"(d) IMPORTATION.—An article of food imported or offered for import shall be refused admission unless the appropriate unique facility identifiers, as specified by the Secretary, are provided for such article.".

SEC. 207. PROHIBITION AGAINST DELAYING, LIMITING, OR REFUSING INSPECTION.

(a) ADULTERATION.—Section 402 (21 U.S.C. 342), as amended by sections 102, 103(a), and 104(a), is amended by adding at the end the following:

"(n) If it has been produced, manufactured, processed, packed, or held in any farm, factory, warehouse, or establishment and the owner, operator, or agent of such farm, factory, warehouse, or establishment, or any agent of a governmental authority in the foreign country within which such farm, factory, warehouse, or establishment is located, delays or limits an inspection, or refuses to permit entry or inspection, under section 414 or 704.".

(b) FOREIGN INSPECTIONS.—Section 704(a)(1) (21 U.S.C. 374(a)(1)), as amended by section 106(c), is amended—

(1) in the first sentence, by inserting ", including any such food factory, warehouse, or establishment whether foreign or domestic," after "factory, warehouse, or establishment"; and

(2) in the third sentence, by inserting ", including any food factory, warehouse, establishment, or consulting laboratory whether foreign or domestic," after "factory, warehouse, establishment, or consulting laboratory".

SEC. 208. DEDICATED FOREIGN INSPECTORATE.

Section 704 (21 U.S.C. 374), as amended by sections 105, 204, and 205, is amended by adding at the end the following:

"(k) DEDICATED FOREIGN INSPECTORATE.—The Secretary shall establish and maintain a corps of inspectors dedicated to inspections of foreign food facilities. This corps shall be staffed and funded by the Secretary at a level sufficient to enable it to assist the Secretary in achieving the frequency of inspections for food facilities as described in this Act.".

SEC. 209. PLAN AND REVIEW OF CONTINUED OPERATION OF FIELD LABORATORIES.

(a) SUBMISSION OF PLAN.—Not later than 90 days before the Secretary terminates or consolidates any laboratory, district office, or the functions (including the inspection and compliance functions) of any such laboratory or district office, specified in subsection (b), the Secretary shall submit a reorganization plan to the Comptroller General of the United States, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate.

(b) SPECIFIED LABORATORIES AND OFFICES.—The laboratories and offices specified in this subsection are the following:

(1) Any of the 13 field laboratories responsible for analyzing food that were operated by the Office of Regulatory Affairs of the Food and Drug Administration as of January 1, 2007.

(2) Any of the 20 district offices of the Food and Drug Administration with responsibility for food safety functioning as of January 1, 2007.

(c) CONGRESSIONAL REVIEW.—A reorganization plan described in subsection (a) is deemed to be a major rule (as defined in section 804(2) of title 5, United States Code) for purposes of chapter 8 of such title.

SEC. 210. FALSE OR MISLEADING REPORTING TO FDA.

(a) IN GENERAL.—Section 301(q)(2) (21 U.S.C. 331(q)(2)) is amended by inserting after "device" the following: "or food".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to submissions made on or after the date of the enactment of this Act.

SEC. 211. SUBPOENA AUTHORITY.

(a) PROHIBITED ACT.—Section 301(f) is amended by inserting before the period the following: "or the failure or refusal to obey a subpoena issued pursuant to section 311".

(b) AMENDMENT.—Chapter III (21 U.S.C. 331 et seq.) is amended by adding at the end the following:

"SEC. 311. EXERCISE OF SUBPOENA AUTHORITY.

"(a) IN GENERAL.—For the purpose of—

"(1) any hearing, investigation, or other proceeding respecting a violation of a provision of this Act, the Public Health Service Act, or the Federal Anti-Tampering Act, relating to food; or

"(2) any hearing, investigation, or other proceeding to determine if a person is in violation of a specific provision of this Act, the Public Health Service Act, or the Federal Anti-Tampering Act, relating to food,

the Commissioner may issue subpoenas requiring the attendance and testimony of witnesses and the production of records and other things.

"(b) TIMING OF COMPLIANCE.—When the Commissioner deems that immediate compliance with a subpoena issued under this section is necessary to address a threat of serious adverse health consequences or death, the subpoena may require immediate production.

"(c) SERVICE OF SUBPOENA.—

"(1) IN GENERAL.—Subpoenas of the Commissioner shall be served by a person authorized by the Commissioner by delivering a copy thereof to the person named therein or by certified mail addressed to such person at such person's last known dwelling place or principal place of business.

"(2) CORPORATIONS AND OTHER ENTITIES.—Service on a domestic or foreign corporation, partnership, unincorporated association, or other entity that is subject to suit under a common name may be made by delivering the subpoena to an officer, a managing or general agent, or any other agent authorized by appointment or by law to receive service of process.

"(3) PERSON OUTSIDE U.S. JURISDICTION.—Service on any person not found within the territorial jurisdiction of any court of the United States may be made

in any manner as the Federal Rules of Civil Procedure prescribe for service in a foreign nation.

"(4) PROOF OF SERVICE.—A verified return by the person so serving the subpoena setting forth the manner of service, or, in the case of service by certified mail, the return post office receipt therefor signed by the person so served, shall be proof of service.

"(d) PAYMENT OF WITNESSES.—Witnesses subpoenaed under subsection (a) shall be paid the same fees and mileage as are paid witnesses in the district courts of the United States.

"(e) ENFORCEMENT.—In the case of a refusal to obey a subpoena duly served upon any person under subsection (a), any district court of the United States for the judicial district in which such person charged with refusal to obey is found, resides, or transacts business, upon application by the Commissioner, shall have jurisdiction to issue an order compelling compliance with the subpoena and requiring such person to appear and give testimony or to appear and produce records and other things, or both. The failure to obey such order of the court may be punished by the court as contempt thereof. If the person charged with failure or refusal to obey is not found within the territorial jurisdiction of the United States, the United States District Court for the District of Columbia shall have the same jurisdiction, consistent with due process, to take any action respecting compliance with the subpoena by such person that such district court would have if such person were personally within the jurisdiction of such district court.

"(f) NONDISCLOSURE.—A United States district court for the district in which the subpoena is or will be served, upon application of the Commissioner, may issue an ex parte order that no person or entity disclose to any other person or entity (other than to an attorney to obtain legal advice) the existence of such subpoena for a period of up to 90 days. Such order may be issued on a showing that the records or things being sought may be relevant to the hearing, investigation, proceeding, or other matter and that there is reason to believe that such disclosure may result in—

"(1) furtherance of a potential violation under investigation;

"(2) endangerment to the life or physical safety of any person;

"(3) flight or other action to avoid prosecution or other enforcement remedies;

"(4) destruction of or tampering with evidence; or

"(5) intimidation of potential witnesses.

An order under this subsection may be renewed for additional periods of up to 90 days upon a showing that any of the circumstances described in paragraphs (1) through (5) continue to exist.

"(g) RELATION TO OTHER PROVISIONS.—The subpoena authority vested in the Commissioner and the district courts of the United States by this section is in addition to any such authority vested in the Commissioner or such courts by other provisions of law.

"(h) NONDELEGATION.—The authority to issue a subpoena under this section is limited to the Secretary or an official designated by the Secretary. 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.".

SEC. 212. WHISTLEBLOWER PROTECTIONS.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 206, is amended by adding at the end the following:

"SEC. 912. PROTECTIONS FOR EMPLOYEES WHO REFUSE TO VIOLATE, OR WHO DISCLOSE VIOLATIONS OF, THIS ACT OR SECTION 351 OF THE PUBLIC HEALTH SERVICE ACT.

"(a) IN GENERAL.—No person who submits or is required under this Act or the Public Health Service Act to submit any information related to a food, or any officer, employee, contractor, subcontractor, or agent of such person may discharge, demote, suspend, threaten, harass, or in any other manner discriminate 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—

"(1) to provide information, cause information to be provided, or otherwise assist 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);

"(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.

"(b) ENFORCEMENT ACTION.—

"(1) IN GENERAL.—An employee who alleges discharge or other discrimination in violation of subsection (a) may seek relief in accordance with the provisions of subsection (c) by—

"(A) filing a complaint with the Secretary of Labor; or

"(B) if the Secretary of Labor has not issued a final decision within 210 days of the filing of the complaint and there is no showing that such delay is due to the bad faith of the claimant, or within 90 days after receiving a final decision or order from the Secretary, bringing an action at law or equity for de novo review in the appropriate district court of the United States, which court shall have jurisdiction over such action without regard to the amount in controversy, and which action shall, at the request of either party to such action, be tried by the court with a jury.

"(2) PROCEDURE.—

"(A) IN GENERAL.—Any action under paragraph (1) shall be governed under the rules and procedures set forth in section 42121(b) of title 49, United States Code.

"(B) EXCEPTION.—Notification in an action under paragraph (1) shall be made in accordance with section 42121(b)(1) of title 49, United States Code, except that such notification shall be made to the person named in the complaint and to the employer.

"(C) BURDENS OF PROOF.—An action brought under paragraph (1)(B) shall be governed by the legal burdens of proof set forth in section 42121(b) of title 49, United States Code.

"(D) STATUTE OF LIMITATIONS.—An action under paragraph (1) shall be commenced not later than 180 days after the date on which the violation occurs.

"(c) REMEDIES.—

"(1) IN GENERAL.—An employee prevailing in any action under subsection (b)(1) shall be entitled to all relief necessary to make the employee whole.

"(2) ISSUANCE OF ORDER.—If, in response to a complaint filed under subsection (b)(1), the Secretary of Labor or the district court, as applicable, determines that a violation of subsection (a) has occurred, the Secretary or the court shall order the person who committed such violation—

"(A) to take affirmative action to abate the violation;

"(B) to—

"(i) reinstate the complainant to his or her former position together with compensation (including backpay); and

"(ii) restore the terms, conditions, and privileges associated with his or her employment; and

"(C) to provide compensatory damages to the complainant.

If such an order is issued under this paragraph, the Secretary or the court, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorney and expert witness fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

"(d) RIGHTS RETAINED BY EMPLOYEE.—Nothing in this section shall be deemed to diminish the rights, privileges, or remedies of any employee under any Federal or State law or under any collective bargaining agreement. The rights and remedies in this section may not be waived by any agreement, policy, form, or condition of employment.".

SEC. 213. EXTRATERRITORIAL JURISDICTION.

(a) PROHIBITED ACT.—Section 301 (21 U.S.C. 331), as amended by sections 110, 111, 133, 136, and 204, is amended by adding at the end the following:

"(uu) 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.".

(b) JURISDICTION.—Chapter III (21 U.S.C. 331 et seq.), as amended by section 211, is amended by adding at the end the following:

"SEC. 312. EXTRATERRITORIAL JURISDICTION.

"There is extraterritorial Federal jurisdiction over any violation of this Act relating to any article of food if such article was intended for import into the United

States or if any act in furtherance of the violation was committed in the United States.".

SEC. 214. SUPPORT FOR TRAINING INSTITUTES.

The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall provide financial and other assistance to appropriate entities to establish and maintain one or more university-affiliated food protection training institutes that—

(1) conduct training related to food protection activities for Federal, State, local, territorial, and tribal officials; and

(2) meet standards developed by the Secretary.

SEC. 215. BISPHENOL A IN FOOD AND BEVERAGE CONTAINERS.

(a) NOTICE OF DETERMINATION.—No later than December 31, 2009, the Secretary of Health and Human Services shall notify the Congress 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, including reusable food and beverage containers, under the conditions of use prescribed in current Food and Drug Administration regulations.

(b) NOTICE OF ACTIONS TO BE TAKEN.—If the Secretary concludes that such a determination cannot be made for any approved use, the Secretary shall notify the Congress of the actions the Secretary intends to take under the Secretary's authority to regulate food additives to protect the public health, which may include—

(1) revoking or modifying any of the approved uses of bisphenol A in food and beverage containers, including reusable food and beverage containers; and

(2) ensuring that the public is sufficiently informed of such determination and the steps the public may take in response to such determination.

(c) RULE OF CONSTRUCTION.—Nothing herein is intended or shall be construed to modify existing Food and Drug Administration authority, procedures, or policies for assessing scientific data, making safety determinations, or regulating the safe use of food additives.

PURPOSE AND SUMMARY

H.R. 2749, the Food Safety Enhancement Act of 2009, is to amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food, and for other purposes.

A primary focus of H.R. 2749 is preventing food safety problems before they occur. Under the legislation, food facilities must implement preventive food safety plans in order to identify potential food hazards and take steps to prevent them from occurring. H.R. 2749 grants the Secretary the authority to issue mandatory performance standards for reducing hazards. The legislation also requires the Secretary to conduct more frequent risk-based inspections and expands the Secretary's access to food safety records. H.R. 2749 increases the Secretary's ability to oversee the safety of imported food by permitting the Secretary to require safety-related documentation for potentially unsafe imported food as a condition of import.

H.R. 2749 provides the Secretary with enhanced tools to address food-borne illness outbreaks when they do occur. H.R. 2749 requires the Secretary to establish, by regulation after a public input process, a system for the rapid tracing of the origin of food. The legislation also grants the Secretary the authority to mandate recalls of contaminated food and to quarantine geographic areas of the United States from which the Secretary reasonably believes contaminated food originated.

To enable the Secretary to better account for entities involved in the manufacture, processing, packing, holding, and import of food, H.R. 2749 requires food facilities, importers, custom brokers, and filers to register with the Secretary annually and to provide certain information related to the entity. Facilities and importers are also required to pay an annual registration fee in the amount of $500.

To increase the development and dissemination of food safety information, H.R. 2749 requires the Secretary to enhance food-borne illness surveillance systems, to design and implement a national public education program on food safety, and to conduct extensive food safety-related research.

H.R. 2749 provides the Secretary with enhanced enforcement tools for food-related violations, including civil monetary penalties, increased criminal penalties, and subpoena authority.

BACKGROUND AND NEED FOR LEGISLATION

There is substantial evidence that the nation's food safety system could be improved to better address potential food safety threats. There has been a string of food-borne illness outbreaks in recent years in foods consumed by millions of Americans each day such as pistachios, peanuts, and spinach. As numerous reports and congressional hearings have shown, the ability of the Food and Drug Administration (FDA) to oversee the safety of our food supply is compromised by inadequate authorities and insufficient resources.[1]

LEGISLATIVE HISTORY

H.R. 2749 was introduced on June 8, 2009, by Chairman Emeritus Dingell, Chairman Waxman, Subcommittee on Health Chairman Pallone, and Reps. DeGette and Sutton. H.R. 2749 builds upon the food-related provisions in H.R. 759, the Food and Drug Administration Globalization Act of 2009, introduced by Chairmen Dingell, Pallone, and Stupak on January 28, 2009. Prior to the bill's introduction, the Subcommittee on Health held a legislative hearing on the discussion draft of the Food Safety Enhancement Act of 2009 on June 3, 2009. There were three hearings on food safety held in the 111th Congress by the Subcommittee on Oversight and Investigations (February 11, 2009, and March 19, 2009) and by the Subcommittee on Health (March 11, 2009). These hearings built upon the hearings held in the 110th Congress on the safety of the nation's food supply.

COMMITTEE CONSIDERATION

The Subcommittee on Health met in open markup session on Wednesday, June 10, 2009, to consider H.R. 2749. An amendment in the nature of a substitute, offered as a manager's amendment

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[1] See, e.g., Food and Drug Administration, Science and Mission at Risk, Report of the Subcommittee on Science and Technology (Nov. 2007) (online at *www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b__02__01__FDA%20Report%20on%20 Science%20and%20Technology.pdf*); U.S. Government Accountability Office, High Risk Series: An Update (Jan. 2009) (online at *www.gao.gov/new.items/d09271.pdf*); U.S. Government Accountability Office, Food Safety: Improvements Needed in FDA Oversight of Fresh Produce (Sept. 26, 2008) (online at *www.gao.gov/new.items/d081047.pdf*); House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, The Salmonella Outbreak: The Continued Failure to Protect the Food Supply, 111th Cong. (Feb. 11, 2009) (online at *http://energycommerce.house.gov/index.php?option=com__content&task=view&id=1492&Itemid=95*); House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, The Recent Salmonella Outbreak: Lessons Learned and Consequences to Industry and Public Health (July 31, 2008); House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, American Lives Still at Risk: When Will FDA's Food Protection Plan Be Fully Funded and Implemented? (June 12, 2008) (online at *http://energycommerce.house.gov/index.php?option=com__content&task=view&id=1392&Itemid=106*); House Committee on Energy and Commerce, Subcommittee on Health, Discussion Draft of the 'Food and Drug Administration Globalization Act' Legislation: Food Provisions (Apr. 24, 2008) (online at *http://energycommerce.house.gov/index.php?option=com__content&task=view&id=655&Itemid=106*).

by Chairman Pallone to H.R. 2749, made substantive changes to the bill as introduced. The Pallone manager's amendment was adopted by a voice vote. The Subcommittee favorably forwarded H.R. 2749, amended, to the full Committee by a voice vote.

The Committee on Energy and Commerce met in open markup session on Wednesday, June 17, 2009, to consider H.R. 2749, as amended by the Subcommittee on Health on June 10, 2009. An amendment in the nature of a substitute, offered by Mr. Waxman as a manager's amendment, to the bill as forwarded by the Subcommittee on Health, was adopted by a voice vote. H.R. 2749 was then ordered favorably reported to the House, amended, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The Committee agreed to a motion by Mr. Waxman to order H.R. 2749 favorably reported to the House, amended, by a voice vote. There were no record votes during consideration of the legislation.

COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

In compliance with clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portions of this report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Regarding compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate prepared on H.R. 2749 by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

In accordance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the performance goals and objectives of the Committee are reflected in the descriptive portions of this report.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the constitutional authority for this legislation is provided in Article I, section 8, clause 18 of the Constitution of the United States.

EARMARKS AND TAX AND TARIFF BENEFITS

H.R. 2749 does not include any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(e), 9(f), or 9(g) of rule XXI of the Rules of the House of Representatives.

ADVISORY COMMITTEE STATEMENT

The Committee finds that the legislation does not establish or authorize the establishment of advisory committees within the definition of section 5 U.S.C. App., section 5(b) of the Federal Advisory Committee Act.

APPLICABILITY OF LAW TO THE LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act of 1985.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimates of federal mandates on H.R. 2749 prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate on H.R. 2749 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate on H.R. 2749 provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 24, 2009.

Hon. HENRY A. WAXMAN,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2749, the Food Safety Enhancement Act of 2009.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Ellen Werble.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

H.R. 2749—Food Safety Enhancement Act of 2009

Summary: H.R. 2749 would require the Department of Health and Human Services (HHS) to strengthen federal efforts related to ensuring the safety of commercially distributed food. H.R. 2749 would also broaden the Food and Drug Administration's (FDA's) authority to regulate food products, and would require the agency to assess fees on food facilities, as well as importers and exporters of food products to cover the costs of registering and inspecting facilities authorized in the bill. Such fees could be collected and made

available for obligation only to the extent and in the amounts provided in advance in appropriations acts.

CBO estimates that:

- Implementing the bill would increase spending subject to appropriation, on net, by about $2.0 billion over the 2010–2014 period, assuming annual appropriation action consistent with the bill; and
- Federal revenues from civil penalties for food related violations of the Federal Food, Drug, and Cosmetic Act would increase by $10 million over the 2010–2014 period and by $20 million over the 2010–2019 period.

H.R. 2749 would impose a number of mandates, as defined in the Unfunded Mandates Reform Act (UMRA), on individuals and entities involved in producing, manufacturing, processing, packing, transporting, distributing, receiving, holding, importing, or exporting articles of food. CBO estimates that the total cost of those mandates would exceed the threshold established in UMRA for private-sector entities ($139 million in 2009, adjusted annually for inflation) in each year, beginning with 2010. Given the limited number of public entities affected by the requirements, CBO estimates that the costs of intergovernmental mandates would fall below the threshold established in UMRA ($69 million in 2009, adjusted annually for inflation).

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 2749 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2010	2011	2012	2013	2014	2010–2014
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Food and Drug Administration (FDA):						
Collection of New Fees:						
Estimated Authorization Level	−209	−241	−290	−333	−368	−1,441
Estimated Outlays	−209	−241	−290	−333	−368	−1,441
Spending of New Fees:						
Estimated Authorization Level	209	241	290	333	368	1,441
Estimated Outlays	66	199	309	352	372	1,298
Net Changes from Fee Authority:						
Estimated Authorization Level	0	0	0	0	0	0
Estimated Outlays	−143	−43	19	19	4	−144
FDA Activities Not Supported by Fees:						
Estimated Authorization Level	−35	4	459	777	1,109	2,314
Estimated Outlays	−35	−9	368	749	1,084	2,157
Total Changes in Spending Subject to Appropriation:						
Estimated Authorization Level	−35	4	459	777	1,109	2,314
Estimated Outlays	−178	−51	387	768	1,088	2,014
CHANGES IN REVENUES						
Estimated Revenues from Civil Penalties	2	2	2	2	2	10

Note: Components may not sum to totals because of rounding.

Basis of estimate: For this estimate, CBO assumes that H.R. 2749 will be enacted near the start of fiscal year 2010, that the full amounts authorized will be collected (starting in fiscal year 2010) to fund FDA's regulatory activities authorized under the bill, and that outlays will follow historical patterns for similar activities.

H.R. 2749 would broaden the FDA's authority to regulate food facilities. Such authority would include:

- Mandating the annual registration of all establishments that import, export, manufacture, process, pack, or hold food for consumption in the United States, and specifying certain inspection, recordkeeping, and reporting requirements for such facilities;
- Requiring any person who produces, manufactures, processes, packs, transports, distributes, receives, imports, or holds an article of food to permit an officer or employee designated by the Secretary of HHS to have access to their records relating to articles of food that may be adulterated, misbranded, or otherwise in violation of the Federal Food, Drug, and Cosmetic Act;
- Requiring any food facility that violates a food-related requirement of the Federal Food, Drug, and Cosmetic Act that consequently requires a reinspection or food recall shall pay a fee to cover the costs of the reinspection or food recall; and
- Reviewing and evaluating epidemiological data every two years to identify the most significant food-borne contaminants and resulting hazards, and setting national performance standards to minimize the occurrence of such hazards, and establishing national standards for risk-based preventive controls, hazard analysis, safe growing, harvesting, processing, packing, sorting, transporting, and holding of raw agricultural products.

H.R. 2749 also would require the FDA to inspect registered food facilities on a risk-based schedule beginning no later than 18 months after enactment. The Secretary of Health and Human Services may recognize federal, state, and local officials, and agencies and representatives of foreign countries to conduct inspections. The frequency of the inspections shall be determined by the category of the facility:

- A category 1 facility is a high-risk facility that manufactures or processes food and must be inspected at least once every 6 to 12 months;
- A category 2 facility is a low-risk facility that manufactures or processes food and must be inspected at least every 18 months to 3 years; and
- A category 3 facility is a facility that holds food and must be inspected at least every 5 years.

Based on information from the FDA, CBO estimates this bill would require about 360,000 domestic and foreign food facilities be inspected on a risk-based frequency schedule. This estimate assumes the magnitude of the inspections required in the risk-based inspection schedule will lead the FDA to recognize agencies and representatives of foreign countries to help fulfill the bill's requirements for inspection frequency.

The bill also would require the Secretary of HHS to design and implement a tracing system for food located in the United States or for import into the country. The bill would explicitly exempt all food products and facilities regulated by the Secretary of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act from the requirements in H.R. 2749.

Spending subject to appropriation

CBO estimates that implementing H.R. 2749 would increase spending subject to appropriation, on net, by $2.0 billion over the 2010–2014 period, assuming appropriation action consistent with the bill. The effect on discretionary spending by federal programs reflects the authorized funding relating to the federal regulation of food products.

The gross costs for FDA to administer the new regulatory activities authorized under the legislation—about $3.5 billion over the 2010–2014 period—would be partially covered by fees assessed on registered food facilities, importers, and exporters.

Collection of new fees

H.R. 2749 would amend and modify the Federal Food, Drug, and Cosmetic Act to authorize the FDA to collect fees to help defray some of FDA's costs of performing food safety activities. The bill would create two new fee programs: a facility reinspection and recall fee program, and an importer registration fee program. The bill also would amend two current categories of fees: food facility registration fees, and export certification fees.

Under current law, both domestic and foreign food facilities are required to register with the FDA; however, periodic renewal is not required and the FDA does not have authority to collect fees. The bill would mandate annual registration for all food facilities and require an annual fee of $500 adjusted for inflation. The legislation also would authorize the FDA to collect fees for food (including animal feed) export certificates under the current export certification program. Fees authorized by the bill would be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriations acts. As a result, those collections would be credited as an offset to discretionary spending.

Spending of fees by FDA to regulate food products

Spending of the new fees assessed by FDA to regulate food products would be classified as discretionary spending because the authorized amounts would be available for obligation subject to appropriation action. Amounts collected would be available to cover FDA's administrative costs to regulate food products at any point in the future.

Importer registration fees could only be collected and made available to defray the costs of registering importers and enforcing compliance with good importer practices. Export certification fees could only be collected and made available to cover the cost of issuing such certifications. Reinspection and recall fees could also only be collected and made available to cover the costs of such activities. The fees program for food facility registration could be collected and made available to defray the costs of food safety activities, which are defined in the bill as expenses incurred in connection with food safety activities.

Assuming appropriation action consistent with the bill, CBO estimates that implementing the program to assess fees to cover new FDA costs associated with regulating food products would increase collections and subsequent spending of those fees by about $1.4 billion over five years, and would result in a net decrease in discre-

tionary outlays of about $140 million over the 2010–2014 period. (Spending of fees would lag slightly behind their collection.)

FDA activities not supported by fees

Because of the magnitude of the inspections required under the bill, CBO estimates the fees collected would not offset all of the costs of the new requirements. The net additional inspections and administrative activities not covered by fees would increase discretionary outlays, on net, by $2.2 billion over five years. This amount incorporates savings to the FDA for food safety activities conducted under current law that would be replaced by fees in the bill. For example, in 2010, CBO anticipates the FDA will save $35 million relative to its current appropriation level for activities that would be funded through new fees.

Revenues

The bill would expand the FDA's authority to assess civil penalties for food related violations of the Federal Food, Drug, and Cosmetic Act. Such violations include the introduction into interstate commerce of certain adulterated or misbranded foods. Based on information provided by the FDA regarding recent enforcement activity, CBO estimates that the bill would increase revenues from civil penalties by $20 million over the 2010–2019 period.

The bill could also increase revenues from criminal penalties, which are recorded as revenues, deposited in the Crime Victims Fund, and later spent. CBO expects that any additional revenues from criminal penalties would not be significant.

Intergovernmental and Private-Sector Impact: H.R. 2749 would impose a number of mandates, as defined in the UMRA, on individuals and entities involved in producing, manufacturing, processing, packing, transporting, distributing, receiving, holding, importing, or exporting articles of food. CBO estimates that the total cost of those mandates would exceed the threshold established in UMRA for private-sector entities ($139 million in 2009, adjusted annually for inflation) in each year, beginning with 2010. Given the limited number of public entities affected by the requirements, CBO estimates that the costs of intergovernmental mandates would fall below the threshold established in UMRA ($69 million in 2009, adjusted annually for inflation).

The bill would require facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States or export to other countries to register with the Secretary of HHS and pay an annual fee. Under current law, all of those facilities are required to register with the Secretary except for facilities holding food for export, but the annual fee would be a new requirement. CBO estimates fees would total almost $210 million in 2010 and rise to almost $370 million by 2014. The costs of those payments alone would exceed the threshold established by UMRA.

The bill also would place new requirements on entities involved in producing, manufacturing, processing, packing, transporting, distributing, receiving, holding, importing, or exporting articles of food. In general, the costs of those mandates on the private sector would depend on future guidance and regulations established by the Secretary. For example, the Secretary would be required to develop science- and risk-based standards, to establish a tracing sys-

tem for food located in the United States or for import into the country, and to develop safety and security guidelines for the importation of food. It is unclear how those requirements would be implemented and how they would affect the food industry. Therefore, CBO cannot estimate the cost to private entities of those provisions.

The bill would require owners, operators, and agents of facilities to conduct hazard analyses, implement and monitor preventive controls, institute corrective actions when necessary, repeat hazard analyses at least every two years, and maintain records of these activities. They also would have to develop food safety plans that outline how facilities would meet these requirements. High-risk facilities that manufacture or process food, also referred to as "category 1 facilities," would be required to test finished products for the presence of contaminants and submit the results of the tests to the Secretary. The Secretary would have the option to establish guidance or regulations, which would determine the extent of the requirements for complying with these provisions of the legislation.

The bill also would require entities, among other things, to be prepared to present all records related to the production, manufacture, processing, packing, transporting, distribution, receipt, holding or importation of an article of food; to report to a food registry; to use accredited laboratories recognized by the Secretary for analytical testing of an article of food; to notify the Secretary of the identity and location of an article of food that is believed to be adulterated or misbranded; to maintain records with respect to infant formula for at least one year after the expiration of the shelf life; and to identify the country in which the final processing occurred and for unprocessed food to identify the country of origin of the food. Under current law, many entities may already have the capability to meet some of those requirements, but entities such as farms and restaurants that are not currently subject to any of those requirements previously could incur significant costs to comply with their respective mandates.

Mandates in the bill would extend to some public entities, including public colleges and universities that operate farms and a limited number of tribal entities that produce and package food items for resale. Given the limited number of public entities affected, however, CBO estimates that the costs of the mandates would fall below the intergovernmental threshold ($69 million in 2009, adjusted annually for inflation).

Estimate prepared by: Federal Spending: Ellen Werble, Rebecca Yip; Federal Revenues: Zachary Epstein; Impact on State, Local, and Tribal Governments: Leo Lex; Impact on the Private Sector: Keisuke Nakagawa.

Estimate approved by: Peter H. Fontaine, Assistant Director for Budget Analysis.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

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 if 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.

A facility is exempt from the requirements of this Act if such facility is regulated exclusively 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.

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 by the Secretary of Agriculture 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 one 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. Such facility is, however, 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.

The Committee does not intend to alter FDA's current regulatory definition of "facility" governing which entities must register. For example, the Committee believes that any storage facility located on a farm does not need to be registered with the FDA if the commodities stored in such facility originate on that farm or another farm under the same ownership.

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, the 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.

The bill provides that revenues generated by new registration fees be directed to specified food safety activities. Because an effective food safety program must be a combined effort of the scientific and regulatory food safety activities of the Center for Food Safety and Applied Nutrition (CFSAN) and support for the food safety inspection-related activities of the Office of Regulatory Affairs (ORA),

the Committee expresses its intent that the agency give highest priority for use of these funds to activities that directly support implementation of this bill, including: (1) regulations and guidance, particularly with respect to hazard analyses, preventive controls, and food safety plans, both with respect to packaged food and to fresh produce; (2) risk assessment activities underlying development of performance standards; (3) information gathering steps prior to developing regulations on traceability and reporting results of finished product testing, including required pilot projects, technology assessments, and feasibility studies; (4) maintenance of an enhanced registration system; (5) maintenance of an up-to-date reportable food registry; (6) information technology systems to support domestic and import inspectional activities; (7) scientific equipment to conduct needed research and perform product sampling; (8) training of agency and state officials in the proper conduct of inspectional activities; (9) development of an expedited safe and secure importation program; (10) surveillance, public education, and research activities in support of improving food safety; (11) review of infant formula and GRAS submissions; and (12) creation and implementation of a risk-based inspection schedule.

The bill seeks to ensure that the revenues collected from registration fees be additive to the existing FDA appropriated resource base for food safety activities, adjusted for inflation in future years, and that funds from food safety-related activities not be redirected to meet responsibilities of other FDA programs. The bill seeks to accomplish this by stating that user fees may not be collected in any fiscal year in which the salaries and expenses for the Food and Drug Administration do not equal that for fiscal year 2010, adjusted for inflation.

Section 102. Hazard analysis, risk-based preventive controls, food safety plan, 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 and implement 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. This analysis should include consideration of biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, filth, decomposition, parasites, allergens, and unapproved food and color additives, and should include consideration of such contamination on surfaces or in the air or from other possible vectors.

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 two or more pilot projects and a study to evaluate the feasibility of such a reporting system.

Section 103. Performance standards

Section 103 requires the Secretary, not less frequently than every 2 years, to identify the most significant food-borne contaminants and the most significant resulting hazards. The Secretary shall issue science-based performance standards, as appropriate, 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 food-borne contaminants that have the greatest adverse impact on public health. In determining whether a particular food-borne 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 produce and certain other raw agricultural commodities

Section 104 requires the Secretary 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.

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 food-borne 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 plan, and documentation of corrective actions, if any, taken within the preceding two years. The Committee expects FDA, when notifying the company of the need for such "remote access" to records, to specify which types of food safety records FDA seeks, including for what product(s) and over what time frame. This will ensure that the records collection

process is properly tailored to assist FDA in its investigation and that the agency will not waste time sorting through a broader array of records that are not pertinent to its investigation.

This authority is intended to provide FDA with a mechanism to gain a better understanding of a facility's food safety program, but it is not intended as a substitute for an on-site inspection. The Committee expects that FDA would use this authority as an initial survey and triage tool, to help the agency prioritize which facilities to inspect and where to focus the inspection, when conducted. The Committee underscores the importance of on-site inspections for FDA to have a clear and complete understanding of the facility's food safety program.

The Committee recognizes that large document productions are not the most efficient way to provide FDA with information, and that additional mechanisms are needed if FDA is to accomplish its public health goal in a timely way. Therefore, it is the Committee's view that when FDA believes it can accomplish its goal of conducting smarter investigations by first sending a food company written questions for the company to answer, with a request for supporting documentation, as needed, it should do so. The Committee expects companies to respond in a timely manner to FDA's questions by providing information reasonably known at the time. The Committee expects companies to supply such information as soon as reasonably possible. The Committee's goal is to facilitate good communication between FDA and the company to help FDA determine whether appropriate preventive controls are in place, whether there is a need for additional preventive controls, guidance, or regulations, and what circumstances caused food contamination. This provision should be applied by FDA with that goal in mind.

Section 106 allows the Secretary to establish requirements regarding the establishment and maintenance, for not longer than three 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 the information gathering process, and to conduct at least two public meetings and one or more pilot projects. After completing this public input process, the Secretary shall issue proposed 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 two 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.

Food produced on a farm or a fishery 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. The Secretary is also granted authority to exempt a food or type of facility 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 the 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 being 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 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, nor is an official senior to such director.

If the Secretary has a reasonable belief 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 and a determination 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 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.

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 following have been satisfied: (1) the registration requirement and (2) a demonstration that the infant formula satisfies the quality factor requirements established by the Secretary. The Committee anticipates that the language of this section will change as this legislation moves through the legislative process.

Subtitle B—Intervention

Section 121. Surveillance

Section 121 requires the Secretary to enhance the current food safety surveillance systems to include the collection, analysis, reporting, and usefulness of data on food-borne 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 food-borne 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 food-borne illness and injury and provide information to health care professionals to improve diagnosis and treatment of food-borne 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 the 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. Quarantine authority for foods

Section 133 permits the Secretary authority to quarantine any geographic area within the United States if the Secretary determines that there is credible evidence or information that an article of food that is located in such area presents an imminent threat of serious adverse health consequences or death to humans or animals. The authority to quarantine includes prohibiting or restricting the movement of food or of any vehicle being used to hold such food.

Before exercising authority to quarantine a geographic area, the Secretary is required to notify an appropriate official of the state affected and to issue a public announcement of the Secretary's findings that support the action; the area affected by the intended quarantine; the reasons for the quarantine; and where practicable, an estimate of the anticipated duration of the quarantine.

Section 133 requires that a quarantine order must come from the FDA Commissioner, Principal Deputy Commissioner, or Associate Commissioner for Regulatory Affairs.

Section 134. Criminal penalties

Section 134 amends section 303 of the Federal Food, Drug, and Cosmetic Act to require that any person who knowingly violates section 301 of the FFDCA 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.

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; disclosure of source of ingredients

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 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 the 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 must establish through regulation. 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 205. Registration for customs brokers and filers

Section 205 requires all customs brokers or filers with respect to the importation of foods 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 suspend an importer's registration, after notice and opportunity for an informal hearing, if the customs broker or filer is found in violation of Federal Food, Drug, and Cosmetic Act, or found to have knowingly or repeatedly made inaccurate or incom-

plete 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.

Section 206. Unique identification number for food facilities, importers, custom brokers, and filers

Section 206 requires that a person required to register a facility under section 415 or importers, custom brokers, and filers required to register pursuant to section 801 submit, at the time of registration, a unique facility identifier. 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 Public Health Service Act, or the Federal Anti-Tampering 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 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.

EXPLANATION OF AMENDMENTS

During full Committee markup, the Chairman offered a manager's amendment (amendment in the nature of a substitute) making several changes to the bill, which was adopted by the Committee on a voice vote. The manager's amendment clarifies that the bill applies to FDA-regulated farms and facilities and delineates the ways in which the bill applies—and does not apply—to facilities manufacturing alcoholic beverages.

In the area of preventive food safety plans, the manager's amendment clarifies that the Secretary must permit the use of alternative preventive controls which have sufficiently demonstrated to effectively address the hazard. The manager's amendment clarifies that the Secretary may require finished product testing at high-risk facilities if such testing or reporting would provide useful

risk information. Before doing so, the Secretary must complete two or more pilot projects and a feasibility study.

The manager's amendment clarifies the circumstances under which the Secretary may access food records remotely.

The manager's amendment specifies that importers must pay a $500 annual registration fee as other registered facilities are required to do in the bill.

The manager's amendment revises section 205 to require customs brokers to register with the Secretary but removes the requirement that customs brokers pay a fee.

The manager's amendment adds two new sections. Section 214 requires the Secretary to support and provide assistance to establish and maintain one or more university-affiliated food protection training institutes that conduct training related to food protection activities for Federal, State, local, territorial, and tribal officials. Section 215 requires the Secretary to assess the risks associated with bisphenol A in food and beverage containers, to report back to Congress on the findings, and to take appropriate actions to address any risks identified.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) * * *

* * * * * * *

(e) The refusal to permit access to or copying of any record as required by section 412, 414, 417(g), 416, 504, 564, 703, 704(a), 760, or 761; or the failure to establish or maintain any record, or make any report, required under section 412, 414(b), 417, 416, 504, 505 (i) or (k), 512(a)(4)(C), 512 (j), (l) or (m), 572(i), 515(f), 519, 564, 760, or 761*, the violation of any requirement of the food tracing system under section 414(c);* or the refusal to permit access to or verification or copying of any such required record.

(f) The refusal to permit entry or inspection as authorized by section 704 *or the failure or refusal to obey a subpoena issued pursuant to section 311.*

* * * * * * *

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, [or to the courts when relevant in any judicial proceeding under this Act,] *to the courts when relevant in any judicial pro-*

ceeding under this Act, or as specified in section 708, any information acquired under authority of section 404, 409, 412, 414, 505, 510, 512, 513, 514, 515, 516, 518, 519, 520, 571, 572, 573., 704, 708, or 721 concerning any method or process which as a trade secret is entitled to protection; or the violating of section 408(i)(2) or any regulation issued under that section.. This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

* * * * * * *

(q)(1) * * *

(2) With respect to any device *or food*, the submission of any report that is required by or under this Act that is false or misleading in any material respect.

* * * * * * *

(oo) The violation of any requirement of section 714 (relating to testing by accredited laboratories).

(pp)(1) The failure to notify the Secretary in violation of section 420(a).

(2) The failure to comply with any order issued under section 420.

(qq) The violation of a quarantine under section 304(i).

(rr) The submission of information relating to food that is required by or under section 801 that is inaccurate or incomplete.

(ss) The failure to submit information relating to food that is required by or under section 801.

(tt) The failure to register in accordance with section 801(r) or 801(s).

(uu) 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.

* * * * * * *

PENALTIES

SEC. 303. (a)(1) ⟦Any⟧ *Except as provided in paragraph (2) or (3), any* person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both.

* * * * * * *

(3) Notwithstanding paragraph (1), any person who knowingly violates paragraph (a), (b), (c), (k), or (v) of section 301 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.

* * * * * * *

(f)(1) * * *

⟦(2)(A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 402(a)(2)(B) shall be subject to a civil money penalty of not more than $50,000 in the case of an individual and $250,000 in the case of any other person

for such introduction or delivery, not to exceed $500,000 for all such violations adjudicated in a single proceeding.

[(B) This paragraph shall not apply to any person who grew the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the criminal authorities under this section to sanction such person for the introduction or delivery for introduction into interstate commerce of the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the seizure authorities of section 304 or the injunction authorities of section 302 with respect to the article of food that is adulterated.

[(C) In a hearing to assess a civil penalty under this paragraph, the presiding officer shall have the same authority with regard to compelling testimony or production of documents as a presiding officer has under section 408(g)(2)(B). The third sentence of paragraph (5)(A) shall not apply to any investigation under this paragraph.]

(2)(A) 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—

(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 a 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.

(C) Each violation described in subparagraph (A) or (B) and each day during which the violation continues shall be considered to be a separate offense.

* * * * * * *

SEIZURE

SEC. 304. (a) * * *

(b) The article, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury *and except that, with respect to proceedings relating to food, Rule G of the Supplemental Rules of Admiralty or Maritime Claims and Asset Forfeiture Actions shall not apply in any such case, exigent circumstances shall be deemed to exist for all seizures brought under this section, and the summons and arrest warrant shall be issued by the clerk of the court without court review in any such case*. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made

to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

* * * * * * *

(h) ADMINISTRATIVE DETENTION OF FOODS.—

(1) DETENTION AUTHORITY.—

(A) IN GENERAL.—An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has **[**credible evidence or information indicating**]** *reason to believe* that such article **[**presents a threat of serious adverse health consequences or death to humans or animals**]** *is adulterated, misbranded, or otherwise in violation of this Act*.

* * * * * * *

(2) PERIOD OF DETENTION.—An article of food may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed **[**30**]** *60* days, is necessary, to enable the Secretary to institute an action under subsection (a) or section 302. The Secretary shall by regulation provide for procedures for instituting such action on an expedited basis with respect to perishable foods.

(3) SECURITY OF DETAINED ARTICLE.—An order under paragraph (1) with respect to an article of food may require that such article be labeled or marked as detained, and shall require that the article be removed to a secure facility, as appropriate. An article subject to such an order shall not be transferred by any person from the place at which the article is ordered detained, or from the place to which the article is so removed, as the case may be, until released by the Secretary or until the expiration of the detention period applicable under such order, whichever occurs first. **[**This subsection may not be construed as authorizing the delivery of the article pursuant to the execution of a bond while the article is subject to the order, and section 801(b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is subject to the order.**]**

(4) APPEAL OF DETENTION ORDER.—

(A) IN GENERAL.—With respect to an article of food ordered detained under paragraph (1), any person who

would be entitled to be a claimant for such article if the article were seized under subsection (a) may appeal the order to the Secretary. Within [five] *fifteen* days after such an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Secretary shall be considered a final agency action for purposes of section 702 of title 5, United States Code. If during such [five-day] *fifteen-day* period the Secretary fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

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(i) QUARANTINE OF GEOGRAPHIC LOCATION.—

(1) AUTHORITY TO QUARANTINE.—If the Secretary determines that there is credible evidence or information that an article of food presents an imminent threat of serious adverse health consequences or death to humans or animals, the Secretary may quarantine any geographic area within the United States where the Secretary reasonably believes such food is located or from which such food originated. The authority to quarantine includes prohibiting or restricting the movement of food or of any vehicle being used or that has been used to transport or hold such food within the geographic area. Any quarantine under this paragraph shall be no greater than is appropriate, as determined by the Secretary, to protect the public health.

(2) NOTIFICATION PROCEDURES.—Before any quarantine action is taken in any State under this subsection, the Secretary shall notify an appropriate official of the State affected and shall issue a public announcement of—

(A) the Secretary's findings that support the quarantine action;

(B) the area affected by the intended quarantine action;

(C) the reasons for the intended quarantine action; and

(D) where practicable, an estimate of the anticipated duration of the quarantine.

The Secretary is not required to make such announcement by publication in the Federal Register, but may use a newspaper, radio or television, the Internet, or any reasonable means to make such announcement.

(3) NONDELEGATION.—The authority to quarantine under this subsection is limited to the Commissioner of Food and Drugs, the Principal Deputy Commissioner, and the Associate Commissioner for Regulatory Affairs of the Food and Drug Administration.

* * * * * * *

SEC. 311. EXERCISE OF SUBPOENA AUTHORITY.

(a) IN GENERAL.—For the purpose of—

(1) any hearing, investigation, or other proceeding respecting a violation of a provision of this Act, the Public Health Service Act, or the Federal Anti-Tampering Act, relating to food; or

(2) any hearing, investigation, or other proceeding to determine if a person is in violation of a specific provision of this Act, the Public Health Service Act, or the Federal Anti-Tampering Act, relating to food,

the Commissioner may issue subpoenas requiring the attendance and testimony of witnesses and the production of records and other things.

(b) TIMING OF COMPLIANCE.—When the Commissioner deems that immediate compliance with a subpoena issued under this section is necessary to address a threat of serious adverse health consequences or death, the subpoena may require immediate production.

(c) SERVICE OF SUBPOENA.—

(1) IN GENERAL.—Subpoenas of the Commissioner shall be served by a person authorized by the Commissioner by delivering a copy thereof to the person named therein or by certified mail addressed to such person at such person's last known dwelling place or principal place of business.

(2) CORPORATIONS AND OTHER ENTITIES.—Service on a domestic or foreign corporation, partnership, unincorporated association, or other entity that is subject to suit under a common name may be made by delivering the subpoena to an officer, a managing or general agent, or any other agent authorized by appointment or by law to receive service of process.

(3) PERSON OUTSIDE U.S. JURISDICTION.—Service on any person not found within the territorial jurisdiction of any court of the United States may be made in any manner as the Federal Rules of Civil Procedure prescribe for service in a foreign nation.

(4) PROOF OF SERVICE.—A verified return by the person so serving the subpoena setting forth the manner of service, or, in the case of service by certified mail, the return post office receipt therefor signed by the person so served, shall be proof of service.

(d) PAYMENT OF WITNESSES.—Witnesses subpoenaed under subsection (a) shall be paid the same fees and mileage as are paid witnesses in the district courts of the United States.

(e) ENFORCEMENT.—In the case of a refusal to obey a subpoena duly served upon any person under subsection (a), any district court of the United States for the judicial district in which such person charged with refusal to obey is found, resides, or transacts business, upon application by the Commissioner, shall have jurisdiction to issue an order compelling compliance with the subpoena and requiring such person to appear and give testimony or to appear and produce records and other things, or both. The failure to obey such order of the court may be punished by the court as contempt thereof. If the person charged with failure or refusal to obey is not found within the territorial jurisdiction of the United States, the United States District Court for the District of Columbia shall have the same jurisdiction, consistent with due process, to take any action respecting compliance with the subpoena by such person that such district court would have if such person were personally within the jurisdiction of such district court.

(f) NONDISCLOSURE.—A United States district court for the district in which the subpoena is or will be served, upon application of the Commissioner, may issue an ex parte order that no person or entity disclose to any other person or entity (other than to an attorney to obtain legal advice) the existence of such subpoena for a period of up to 90 days. Such order may be issued on a showing that the records or things being sought may be relevant to the hearing,

investigation, proceeding, or other matter and that there is reason to believe that such disclosure may result in—

(1) furtherance of a potential violation under investigation;

(2) endangerment to the life or physical safety of any person;

(3) flight or other action to avoid prosecution or other enforcement remedies;

(4) destruction of or tampering with evidence; or

(5) intimidation of potential witnesses.

An order under this subsection may be renewed for additional periods of up to 90 days upon a showing that any of the circumstances described in paragraphs (1) through (5) continue to exist.

(g) RELATION TO OTHER PROVISIONS.—The subpoena authority vested in the Commissioner and the district courts of the United States by this section is in addition to any such authority vested in the Commissioner or such courts by other provisions of law.

(h) NONDELEGATION.—The authority to issue a subpoena under this section is limited to the Secretary or an official designated by the Secretary. 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.

SEC. 312. EXTRATERRITORIAL JURISDICTION.

There is extraterritorial Federal jurisdiction over any violation of this Act relating to any article of food if such article was intended for import into the United States or if any act in furtherance of the violation was committed in the United States.

CHAPTER IV—FOOD

* * * * * * *

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a) * * *

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(j) If it has been manufactured, processed, packed, transported, or held under conditions that do not meet the requirements of sections 418 and 418A.

(k) If it is manufactured or processed in a facility that is in violation of section 418B.

(l) If it has been manufactured, processed, packed, transported, or held under conditions that do not meet the standards issued under section 419.

(m) If it has been grown, harvested, processed, packed, sorted, transported, or held under conditions that do not meet the standards established under section 419A.

(n) If it has been produced, manufactured, processed, packed, or held in any farm, factory, warehouse, or establishment and the owner, operator, or agent of such farm, factory, warehouse, or establishment, or any agent of a governmental authority in the foreign country within which such farm, factory, warehouse, or establishment is located, delays or limits an inspection, or refuses to permit entry or inspection, under section 414 or 704.

MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—
(a) * * *

* * * * * * *

(z) If it was manufactured, processed, packed, or held in a facility that is not duly registered under section 415, including a facility whose registration is canceled or suspended under such section.

(aa) If it is part of a shipment offered for import into the United States and such shipment is in violation of section 801(p) (requiring a certification to accompany certain food shipments).

(bb) If it is a new infant formula and it is not the subject of a letter from the Secretary provided pursuant to section 412(c)(1)(C).

(cc) In the case of a processed food, if the labeling of the food fails to identify the country in which the final processing of the food occurs.

(dd) In the case of nonprocessed food, if the labeling of the food fails to identify the country of origin of the food.

(ee) If it is imported or offered for import by an importer or a customs broker or filer not duly registered under section 801(r) or 801(s).

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FOOD ADDITIVES

SEC. 409. (a) * * *

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Substances Generally Recognized as Safe

(k)(1) Not later than 60 days after the date of receipt by the Secretary, after the date of the enactment of this subsection, of a determination that a substance is a GRAS food substance, the Secretary shall post notice of such determination and the supporting scientific justifications on the Food and Drug Administration's public Web site.

(2) Not later than 60 days after the date of receipt of a request under paragraph (1), the Secretary shall acknowledge receipt of such request by informing the requester in writing of the date on which the request was received.

(3) In this subsection, the term "GRAS food substance" means a substance excluded from the definition of the term "food additive" in section 201(s) because such substance is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

* * * * * * *

REQUIREMENTS FOR INFANT FORMULAS

SEC. 412. (a) * * *

(b)(1) The Secretary shall by regulation establish requirements for quality factors for infant formulas to the extent possible consistent with current scientific knowledge, including quality factor requirements for the nutrients required by subsection (i). *The quality factor requirements established under this paragraph may include requirements for one or more clinical studies to demonstrate that the new infant formula supports normal physical growth of infants.*

* * * * * * *

(4)(A) * * *

[(B)(i) Records required under subparagraph (A) with respect to an infant formula shall be retained for at least one year after the expiration of the shelf life of such infant formula. Except as provided in clause (ii), such records shall be made available to the Secretary for review and duplication upon request of the Secretary.

[(ii) A manufacturer need only provide written assurances to the Secretary that the regularly scheduled audits required by paragraph (2)(B)(iv) are being conducted by the manufacturer, and need not make available to the Secretary the actual written reports of such audits.**]**

(B) Records required under subparagraph (A) with respect to an infant formula shall be retained for at least one year after the expiration of the shelf life of such infant formula. Such records shall be made available to the Secretary for review and duplication upon request of the Secretary.

(c)(1) No person shall introduce or deliver for introduction into interstate commerce any new infant formula unless—

(A) such person has, before introducing such new infant formula, or delivering such new infant formula for introduction, into interstate commerce, registered with the Secretary the name of such person, the place of business of such person, and all establishments at which such person intends to manufacture such new infant formula, **[**and**]**

(B) such person has at least 90 days before marketing such new infant formula, made the submission to the Secretary required by subsection **[**(c)(1).**]** *(d)(1), and*

(C) the Secretary has by letter informed such person that the registration requirements and the requirements in subsection (d)(1) have been satisfied.

* * * * * * *

(d)(1) A person shall, with respect to any infant formula subject to subsection (c), make a submission to the Secretary which shall include—

(A) * * *

* * * * * * *

[(C) assurances that the infant formula will not be marketed unless it meets the requirements of subsections (b)(1) and (i), as demonstrated by the testing required under subsection (b)(3), and

[(D) assurances that the processing of the infant formula complies with subsection (b)(2).**]**

(C) scientific evidence and other evidence, as identified in regulations promulgated by the Secretary, that demonstrates that

the infant formula satisfies the requirements of subsection (b)(1), and, as demonstrated by the testing required under subsection (b)(3), that it satisfies the requirements of subsection (i), and

(D) scientific evidence and other evidence, as identified in regulations promulgated by the Secretary, that demonstrate that the processing of the infant formula complies with the requirements of subsection (b)(2).

* * * * * * *

SEC. 414. MAINTENANCE AND INSPECTION OF RECORDS.

[(a) RECORDS INSPECTION.—If the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. The requirement under the preceding sentence applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.

[(b) REGULATIONS CONCERNING RECORDKEEPING.—The Secretary, in consultation and coordination, as appropriate, with other Federal departments and agencies with responsibilities for regulating food safety, may by regulation establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, which records are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. The Secretary shall take into account the size of a business in promulgating regulations under this section.]

(a) RECORDS ACCESS.—

(1) RECORDS ACCESS DURING AN INSPECTION.—

(A) IN GENERAL.—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 shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials, at reasonable times and within reasonable limits and in a reasonable manner, 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, including all records collected or developed to comply with section 418 or 418A.

(B) SCOPE OF RECORDS.—The requirement under subparagraph (A) applies to all records relating to the production, manufacture, processing, packing, transporting, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.

(C) IMMEDIATE AVAILABILITY WITH NOTICE.—Records not required to be made available immediately on commencement of an inspection under subparagraph (A) shall nonetheless be made available immediately on commencement of such an inspection if, by a reasonable time before such inspection, the Secretary by letter to the person identifies the records to be made available during such inspection.

(2) ADDITIONAL AUTHORITIES TO ACCESS RECORDS REMOTELY; SUBMISSION OF RECORDS TO THE SECRETARY.—

(A) REMOTE ACCESS IN EMERGENCIES.—If the Secretary has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death to humans or animals, the Secretary may require each person who manufactures, processes, packs, transports, distributes, receives, holds, or imports such article of food, or any article of food that the Secretary determines may be affected in a similar manner, to submit to the Secretary all records reasonably related to such article of food as soon as is reasonably practicable, after receiving written notice (including by notice served personally and outside normal business hours to an agent identified under subparagraph (E) or (F) of section 415(a)(2)) of such requirement.

(B) REMOTE ACCESS TO RECORDS RELATED TO FOOD SAFETY PLANS.—With respect to a facility subject to section 418 and 418A, the Secretary may require the owner, operator, or agent of such facility to submit to the Secretary, as soon as reasonably practicable after receiving written notice of such requirement, the food safety plan, supporting information relied on by the facility to select the preventive controls to include in its food safety plan, and documentation of corrective actions, if any, taken under section 418(e) within the preceding 2 years

(C) ELECTRONIC SUBMISSION.—If the records required to be submitted to the Secretary under subparagraph (A) or (B) are available in electronic format, such records shall be submitted electronically unless the Secretary specifies otherwise in the notice under such subparagraph.

(b) REGULATIONS CONCERNING RECORDKEEPING.—The Secretary, in consultation and coordination, as appropriate, with other Federal departments and agencies with responsibilities for regulating food safety, may by regulation establish requirements 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 sec-

tion. The only distribution records which may be required of restaurants under this subsection are those showing the restaurant's suppliers and subsequent distribution other than to consumers.

(c) TRACING SYSTEM FOR FOOD.—

(1) IN GENERAL.—The Secretary shall by regulation establish a tracing system for food that is located in the United States or is for import into the United States.

(2) INFORMATION GATHERING.—

(A) TRACING TECHNOLOGIES.—Before issuing a proposed regulation under this subsection, the Secretary shall—

(i) identify technologies and methodologies for tracing the distribution history of a food that are, or may be, used by members of different sectors of the food industry, including technologies and methodologies to enable each person who produces, manufactures, processes, pack, transports, or holds a food to—

(I) maintain the full pedigree of the origin and previous distribution history of the food;

(II) link that history with the subsequent distribution of the food;

(III) establish and maintain a system for tracing the food that is interoperable with the systems established and maintained by other such persons; and

(IV) use a unique identifier for each facility owned or operated by such person for such purpose, as specified under section 911; and

(ii) to the extent practicable, assess—

(I) the costs and benefits associated with the adoption and use of such technologies;

(II) the feasibility of such technologies for different sectors of the food industry; and

(III) whether such technologies are compatible with the requirements of this subsection.

(B) PUBLIC MEETINGS.—Before issuing a proposed regulation under this subsection, the Secretary shall conduct not less than 2 public meetings in diverse geographical areas of the United States to provide persons in different regions an opportunity to provide input and information to the Secretary.

(C) PILOT PROJECTS.—Before issuing a proposed regulation under this subsection, the Secretary shall conduct 1 or more pilot projects in coordination with 1 or more sectors of the food industry to explore and evaluate tracing systems for food.

(3) REGULATION.—Taking into account information obtained through information gathering under paragraph (2), the Secretary shall issue regulations establishing a tracing system that enables the Secretary to identify each person who grows, produces, manufactures, processes, packs, transports, holds, or sells such food in as short a timeframe as practicable but no longer than 2 business days. The Secretary may include in such regulation—

(A) the establishment and maintenance of lot numbers;

(B) a standardized format for pedigree information; and

(C) the use of a common nomenclature for food.

(4) EXEMPTIONS.—

(A) DIRECT SALES BY FARMS.—Food is exempt from the requirements of this subsection if such food is—

(i) produced on a farm or fishery (including an oyster bed, a wild fishery, an aquaculture facility, a fresh water fishery, and a saltwater fishery); and

(ii) sold by the owner, operator, or agent in charge of such farm or fishery directly to a consumer or to a restaurant or grocery store.

(B) OTHER FOODS.—The Secretary may by notice in the Federal Register exempt a food or a type of facility, farm, or restaurant from, or modify the requirements with respect to, the requirements of this subsection if the Secretary determines that a tracing system for such food or type of facility, farm, or restaurant is not necessary to protect the public health.

(C) PREVIOUS SOURCES AND SUBSEQUENT RECIPIENTS.—For a food covered by an exemption under subparagraph (B), the Secretary shall require each person who produces, manufactures, processes, packs, transports, or holds such food to maintain records to identify the immediate previous sources of such food and its ingredients and the immediate subsequent recipients of such food.

(D) RESTAURANTS AND GROCERY STORES.—For a food covered by an exemption under subparagraph (A), restaurants and grocery stores shall keep records documenting the farm that was the source of the food.

(E) FARMS AND FISHERIES.—For a food covered by an exemption under subparagraph (A), farms and fisheries shall keep records, in electronic or non-electronic format, for at least 6 months documenting the restaurant or grocery store to which the food was sold.

[(c)**]** *(d)* PROTECTION OF SENSITIVE INFORMATION.—The Secretary shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section.

[(d)**]** *(e)* LIMITATIONS.—This section shall not be construed—

(1) * * *

* * * * * * *

SEC. 415. REGISTRATION OF FOOD FACILITIES.

(a) REGISTRATION.—

(1) IN GENERAL.—The Secretary shall by regulation **[**require that**]** *require that, on or before December 31 of each year,* any facility engaged in manufacturing, processing, packing, or holding **[**food for consumption in the United States**]** *food for consumption in the United States or for export from the United States* be registered with the Secretary. To be registered—

(A) for a domestic facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary *and pay the registration fee required under section 743*; and

(B) for a foreign facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary *and pay the registration fee required under section 743* and shall include with the registration the name of the United States agent for the facility.

(2) REGISTRATION.—An entity (referred to in this section as the "registrant") shall submit *in electronic format* a registration under paragraph (1) to the Secretary [containing information necessary to notify the Secretary of the name and address of each facility at which, and all trade names under which, the registrant conducts business and, when determined necessary by the Secretary through guidance, the general food category (as identified under section 170.3 of title 21, Code of Federal Regulations) of any food manufactured, processed, packed, or held at such facility. The registrant shall notify the Secretary in a timely manner of changes to such information.] *containing information that identifies the following:*

(A) The name, address, and emergency contact information of the facility being registered.

(B) The primary purpose and business activity of the facility, including the dates of operation if the facility is seasonal.

(C) The general food category (as defined by the Secretary by guidance) of each food manufactured, processed, packed, or held at the facility.

(D) All trade names under which the facility conducts business related to food.

(E) The name, address, and 24-hour emergency contact information of the United States distribution agent for the facility, which agent shall have access to the information required to be maintained under section 414(d) for food that is manufactured, processed, packed, or held at the facility.

(F) If the facility is located outside of the United States, the name, address, and emergency contact information for a United States agent.

(G) The unique facility identifier of the facility, as specified under section 911.

(H) Such additional information pertaining to the facility as the Secretary may require by regulation.

The registrant shall notify the Secretary of any change in the submitted information not later than 30 days after the date of such change, unless otherwise specified by the Secretary.

* * * * * * *

(4) LIST.—The Secretary shall compile and maintain an up-to-date list of facilities that are registered under this section. *The Secretary shall remove from such list the name of any facility that fails to reregister in accordance with this section, that fails to pay the registration fee required under section 743, or whose registration is canceled by the registrant, canceled by the Secretary in accordance with this section, or suspended by the Secretary in accordance with this section.* Such list and any registration documents submitted pursuant to this subsection shall not be subject to disclosure under section 552 of title 5, United States Code. Information derived from such list or reg-

istration documents shall not be subject to disclosure under section 552 of title 5, United States Code, to the extent that it discloses the identity or location of a specific registered person.

(5) SUSPENSION OF REGISTRATION.—

(A) IN GENERAL.—The Secretary may suspend the registration of any facility registered under this section for a violation of this Act that could result in serious adverse health consequences or death to humans or animals.

(B) NOTICE OF SUSPENSION.—Suspension of a registration shall be preceded by—

(i) notice to the facility of the intent to suspend the registration; and

(ii) an opportunity for an informal hearing, as defined in guidance or regulations issued by the Secretary, concerning the suspension of such registration for such facility.

(C) REQUEST.—The owner, operator, or agent in charge of a facility whose registration is suspended may request that the Secretary vacate the suspension of registration when such owner, operator, or agent has corrected the violation that is the basis for such suspension.

(D) VACATING OF SUSPENSION.—If, based on an inspection of the facility or other information, the Secretary determines that adequate reasons do not exist to continue the suspension of a registration, the Secretary shall vacate such suspension.

(6) CANCELLATION OF REGISTRATION.—

(A) IN GENERAL.—Not earlier than 10 days after providing the notice under subparagraph (B), the Secretary may cancel a registration if the Secretary determines that—

(i) the registration was not updated in accordance with this section or otherwise contains false, incomplete, or inaccurate information; or

(ii) the required registration fee has not been paid within 30 days after the date due.

(B) NOTICE OF CANCELLATION.—Cancellation shall be preceded by notice to the facility of the intent to cancel the registration and the basis for such cancellation.

(C) TIMELY UPDATE OR CORRECTION.—If the registration for the facility is updated or corrected no later than 7 days after notice is provided under subparagraph (B), the Secretary shall not cancel such registration.

(7) REPORT TO CONGRESS.—Not later than March 30th of each year, the Secretary shall submit to the Congress a report, based on the registrations on or before December 31 of the previous year, on the following:

(A) The number of facilities registered under this section.

(B) The number of such facilities that are domestic.

(C) The number of such facilities that are foreign.

(D) The number of such facilities that are high-risk.

(E) The number of such facilities that are low-risk.

(F) The number of such facilities that hold food.

(8) LIMITATION ON DELEGATION.—The authority conferred by this subsection to issue an order to suspend a registration or

cancel a registration shall not be delegated to any officer or employee other than the Commissioner of Food and Drugs, the Principal Deputy Commissioner, the Associate Commissioner for Regulatory Affairs, or the Director for the Center for Food Safety and Applied Nutrition, of the Food and Drug Administration.

* * * * * * *

SEC. 417. REPORTABLE FOOD REGISTRY.

(a) DEFINITIONS.—In this section:

(1) RESPONSIBLE PARTY.—The term "responsible party", with respect to an article of food, **[**means a person that submits the registration under section 415(a) for a food facility that is required to register under section 415(a), at which such article of food is manufactured, processed, packed, or held.**]** *means—*

(A) a person who submits the registration under section 415(a) for a food facility that is required to be registered under section 415(a), at which such food is manufactured, processed, packed, or held;

(B) a person who owns, operates, is an agent of, or is otherwise responsible for such food on a farm (as such term is defined in section 1.227(b)(3) of title 21, Code of Federal Regulations, or successor regulations) at which such food is produced for sale or distribution in interstate commerce;

(C) a person who owns, operates, or is an agent of a restaurant or other retail food establishment (as such terms are defined in section 1.227(b)(11) and (12), respectively, of title 21, Code of Federal Regulations, or successor regulations) at which such food is offered for sale; or

(D) a person that is required to register pursuant to section 801(r) with respect to importation of such food.

* * * * * * *

(b) ESTABLISHMENT.—

(1) * * *

* * * * * * *

(3) REPORTING BY RESTAURANTS AND RETAIL FOOD ESTABLISHMENTS.—In addition to the electronic portal described in paragraph (1), the Secretary shall make available alternative means of reporting under this section with respect to restaurants and other retail food establishments with limited ability for such reporting.

* * * * * * *

(d) REPORTING AND NOTIFICATION.—

(1) IN GENERAL.—Except as provided in paragraph (2), as soon as practicable, but in no case later than 24 hours after a responsible party determines that an article of food is a reportable food, *following a timely review of any reasonably available data and information,* the responsible party shall—

(A) submit a report to the Food and Drug Administration through the electronic portal established under subsection (b) that includes the data elements described in subsection (e) (except the elements described in paragraphs (8), (9), and (10) of such subsection); **[**and**]**

(B) submit, with such report, through the electronic portal, documentation of results from any sampling and testing of such article, including—

(i) analytical results from testing of such article conducted by or on behalf of the responsible party under section 418, 418A, 419, 419A, or 714;

(ii) analytical results from testing conducted by or on behalf of such responsible party of a component of such article;

(iii) analytical results of environmental testing of any facility at which such article, or a component of such article, is manufactured, processed, packed, or held; and

(iv) any other information the Secretary determines is necessary to evaluate the adulteration of such article, any component of such article, any other article of food manufactured, processed, packed or held in the same manner as, or at the same facility as, such article, or any other article containing a component from the same source as a component of such article; and

[(B)] *(C)* investigate the cause of the adulteration if the adulteration of the article of food may have originated with the responsible party.

* * * * * * *

(e) DATA ELEMENTS.—The data elements described in this subsection are the following:

(1) The registration numbers of the responsible party under section 415(a)(3) *if the responsible party is required to register*.

* * * * * * *

(12) Such additional information as the Secretary deems appropriate.

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SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.

(a) IN GENERAL.—The owner, operator, or agent of a facility shall, in accordance with this section—

(1) conduct a hazard analysis (or more than one if appropriate);

(2) identify, implement, and validate effective preventive controls;

(3) monitor preventive controls;

(4) institute corrective actions when—

(A) monitoring shows that preventive controls have not been properly implemented; or

(B) monitoring and verification show that such controls were ineffective;

(5) conduct verification activities;

(6) maintain records of monitoring, corrective action, and verification; and

(7) reanalyze for hazards.

(b) IDENTIFICATION OF HAZARDS.—

(1) IN GENERAL.—The owner, operator, or agent of a facility shall evaluate whether there are any hazards, including haz-

ards due to the source of the ingredients, that are reasonably likely to occur in the absence of preventive controls that may affect the safety, wholesomeness, or sanitation of the food manufactured, processed, packed, transported, or held by the facility, including—

(A) biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, filth, decomposition, parasites, allergens, and unapproved food and color additives; and

(B) hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism.

(2) IDENTIFIED BY THE SECRETARY.—The Secretary may, by regulation or guidance, identify hazards that are reasonably likely to occur in the absence of preventive controls.

(3) HAZARD ANALYSIS.—The owner, operator, or agent of a facility shall identify and describe the hazards evaluated under paragraph (1) or identified under paragraph (2), to the extent applicable to the facility, in a hazard analysis.

(c) PREVENTIVE CONTROLS.—

(1) IN GENERAL.—The owner, operator, or agent of a facility shall identify, implement, and validate effective preventive controls to prevent, eliminate, or reduce to acceptable levels the occurrence of any hazards identified in the hazard analysis under subsection (b)(3).

(2) IDENTIFIED BY THE SECRETARY.—

(A) ESTABLISHMENT.—The Secretary may establish by regulation or guidance preventive controls for specific product types to prevent intentional or unintentional contamination throughout the supply chain. The owner, operator, or agent of a facility shall implement any preventive controls identified by the Secretary under this paragraph.

(B) ALTERNATIVE CONTROLS.—Such regulation or guidance shall allow the owner, operator, or agent of a facility to implement an alternative preventive control to one established by the Secretary, provided that, in response to a request by the Secretary, the owner, operator, or agent can present to the Secretary data or other information sufficient to demonstrate that the alternative control effectively addresses the hazard, including meeting any applicable performance standard.

(C) LIMITATION.—Subparagraph (B) shall not apply to any preventive control described in subparagraph (A), (B), or (E) of subsection (i)(2).

(d) MONITORING.—The owner, operator, or agent of a facility shall monitor the implementation of preventive controls under subsection (c) to identify any circumstances in which the preventive controls are not fully implemented or verification shows that such controls were ineffective.

(e) CORRECTIVE ACTIONS.—The owner, operator, or agent of a facility shall establish and implement procedures to ensure that, if the preventive controls under subsection (c) are not fully implemented or are not effective—

(1) no product from such facility enters commerce; and

(2) appropriate action is taken to reduce the likelihood of recurrence of the implementation failure.

(f) VERIFICATION.—The owner, operator, or agent of a facility shall ensure that—

(1) the preventive controls identified under subsection (c) have been validated as adequate to control the hazards identified in the hazard analysis under subsection (b)(3);

(2) the facility is conducting monitoring in accordance with subsection (d);

(3) the facility is taking effective corrective actions under subsection (e); and

(4) the preventive controls are effectively preventing, eliminating, or reducing to an acceptable level the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means.

(g) REQUIREMENT TO REANALYZE AND REVISE.—

(1) REQUIREMENT.—The owner, operator, or agent of a facility shall—

(A) review the evaluation under subsection (b) for the facility and, as necessary, revise the hazard analysis under subsection (b)(3) for the facility—

(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; and

(B) whenever there is a change in the hazard analysis, revise the preventive controls under subsection (c) for the facility as necessary to ensure that all hazards that are reasonably likely to occur are prevented, eliminated, or reduced to an acceptable level, or document the basis for the conclusion that no such revision is needed.

(2) NONDELEGATION.—Any revisions ordered by the Secretary under this subsection shall be ordered by the Secretary or an official designated by the Secretary. 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.

(h) RECORDKEEPING.—The owner, operator, or agent of a facility shall maintain, for not less than 2 years, records documenting the activities described in subsections (a) through (g).

(i) DEFINITIONS.—For purposes of this section:

(1) FACILITY.—The term "facility" means a domestic facility or a foreign facility that is required to be registered under section 415.

(2) PREVENTIVE CONTROLS.—The term "preventive controls" means those risk-based procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, transporting, or holding of food would employ to prevent, eliminate, or reduce to an acceptable level the hazards identified in the hazard analysis under subsection (b)(3) and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, transporting, or holding at the time of the analysis. Those pro-

cedures, practices, and processes shall include the following, as appropriate:

(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 under subsection (c)(2).

(3) HAZARD THAT IS REASONABLY LIKELY TO OCCUR.—A food safety hazard that is reasonably likely to occur is one for which a prudent person who, as applicable, manufactures, processes, packs, transports, or holds food, would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, transported, or held in the absence of those controls.

SEC. 418A. FOOD SAFETY PLAN.

(a) IN GENERAL.—Before a facility (as defined in section 418(i)) introduces or delivers for introduction into interstate commerce any shipment of food, the owner, operator, or agent of the facility shall develop and implement a written food safety plan (in this section referred to as a "food safety plan").

(b) CONTENTS.—The food safety plan shall include each of the following elements:

(1) The hazard analysis and any reanalysis conducted under section 418.

(2) A description of the preventive controls being implemented under subsection 418(c), including those to address hazards or conditions identified by the Secretary under subsection 418(b)(2).

(3) A description of the procedures for monitoring preventive controls.

(4) A description of the procedures for taking corrective actions.

(5) A description of verification activities for the preventive controls, including validation, review of monitoring and corrective action records, and procedures for determining whether the preventive controls are effectively preventing, eliminating, or reducing to an acceptable level the occurrence of identified hazards or conditions, including the use of environmental and product testing programs.

(6) A description of the facility's recordkeeping procedures.

(7) A description of the facility's procedures for the recall of articles of food, whether voluntarily or when required under section 422.

(8) A description of the facility's procedures for tracing the distribution history of articles of food, whether voluntarily or when required under section 414.

(9) A 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) A description of the facility's procedures to implement the science-based performance standards issued under section 419.

SEC. 418B. FINISHED PRODUCT TEST RESULTS FROM CATEGORY 1 FACILITIES.

(a) AUTHORITY.—Beginning on the date specified in subsection (c), the Secretary shall require, after public notice and an opportunity for comment, the submission to the Secretary of finished product test results by the owner, operator, or agent of each category 1 facility subject to good manufacturing practices regulations documenting the presence of contaminants in food in the possession or control of such facility posing a risk of severe adverse health consequences or death.

(b) CONSIDERATIONS.—The Secretary shall require submissions under subsection (a)—

(1) as the Secretary determines feasible and appropriate; and

(2) taking into consideration available data and information on the potential risks posed by the facility.

(c) BEGINNING DATE.—The date specified in this subsection is the sooner of—

(1) the date of completion of the pilot projects and feasibility study under subsections (d) and (e); and

(2) the date that is 2 years after the date of the enactment of this section.

(d) PILOT PROJECTS.—The Secretary shall conduct 2 or more pilot projects to evaluate the feasibility of collecting positive finished product testing results from category 1 facilities, including the value and feasibility of reporting corrective actions taken when positive finished product test results are reported to the Secretary.

(e) FEASIBILITY STUDY.—The Secretary shall assess the feasibility and benefits of the reporting by facilities subject to good manufacturing practices regulations of appropriate finished product testing results from category 1 facilities to the Secretary, including the extent to which the collection of such finished product testing results will help the Secretary assess the risk presented by a facility or product category.

(f) LIMITATIONS.—Nothing in this section shall be construed—

(1) to require the Secretary to mandate testing or submission of test results that the Secretary determines would not provide useful information in assessing the potential risk presented by a facility or product category; or

(2) to limit the Secretary's authority under any other provisions of law to require any person to provide access, or to submit information or test results, to the Secretary, including the ability of the Secretary to require field or other testing and to obtain test results in the course of an investigation of a potential food-borne illness or contamination incident.

(g) DEFINITION.—In this section, the term "category 1 facility" means a category 1 facility within the meaning of section 704(h).

SEC. 419. PERFORMANCE STANDARDS.

(a) PERFORMANCE STANDARDS.—The Secretary shall, not less frequently than every 2 years, review and evaluate epidemiological data and other appropriate sources of information, including research under section 123 of the Food Safety Enhancement Act of 2009, to identify the most significant food-borne contaminants and the most significant resulting hazards. The Secretary shall issue, as soon as practicable, through guidance or by regulation, science-based performance standards (which may include action levels) applicable to foods or food classes, as appropriate, to minimize to an acceptable level, prevent, or eliminate the occurrence of such hazards. Such standards shall be applicable to foods and food classes.

(b) LIST OF CONTAMINANTS.—Following each review under subsection (a), the Secretary shall publish in the Federal Register a list of food-borne contaminants that have the greatest adverse impact on public health. In determining whether a particular food-borne contaminant should be added to such list, the Secretary shall consider the number and severity of illnesses and the number of deaths associated with the foods associated with such contaminants.

(c) REVOCATION BY SECRETARY.—All performance standards of the Food and Drug Administration applicable to foods or food classes in effect on the date of the enactment of this section, or issued under this section, shall remain in effect until revised or revoked by the Secretary.

SEC. 419A. SAFETY STANDARDS FOR PRODUCE AND CERTAIN OTHER RAW AGRICULTURAL COMMODITIES.

(a) STANDARDS.—The Secretary shall establish by regulation scientific and risk-based standards for the safe growing, harvesting, processing, packing, sorting, transporting, and holding of those types of raw agricultural commodities—

(1) that are from a plant or a 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.

(b) CONTENTS.—The regulations under subsection (a)—

(1) may set forth such procedures, processes, and practices as the Secretary determines to be reasonably necessary—

(A) to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards, including hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism, into raw agricultural commodities that are from a plant or a fungus; and

(B) to provide reasonable assurances that such commodity is not adulterated under section 402;

(2) may include, with respect to growing, harvesting, processing, packing, sorting, transporting, and storage operations, standards for safety as the Secretary determines to be reasonably necessary;

(3) may include standards addressing manure use, water quality, employee hygiene, sanitation and animal control, and temperature controls, as the Secretary determines to be reasonably necessary;

(4) may include standards for such other elements as the Secretary determines necessary to carry out subsection (a);

(5) shall provide a reasonable period of time for compliance, taking into account the needs of small businesses for additional time to comply;

(6) may provide for coordination of education and enforcement activities;

(7) shall take into consideration, consistent with ensuring enforceable public health protection, the impact on small-scale and diversified farms, and on wildlife habitat, conservation practices, watershed-protection efforts, and organic production methods;

(8) may provide for coordination of education and training with other government agencies, universities, private entities, and others with experience working directly with farmers; and

(9) may provide for recognition through guidance of other existing publicly available procedures, processes, and practices that the Secretary determines to be equivalent to those established under paragraph (1).

(c) ENFORCEMENT.—The Secretary may coordinate with the Secretary of Agriculture and may contract and coordinate with the agency or department designated by the Governor of each State to perform activities to ensure compliance with this section.

SEC. 420. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED FOOD.

(a) NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED FOOD.—

(1) IN GENERAL.—A responsible party as that term is defined in section 417(a)(1) or a person required to register under section 801(r) that has reason to believe that an article of food when introduced into or while in interstate commerce, or while held for sale (regardless of whether the first sale) after shipment in interstate commerce, is adulterated or misbranded in a manner that presents a reasonable probability that the use or consumption of, or exposure to, the article (or an ingredient or component used in any such article) will cause a threat of serious adverse health consequences or death to humans or animals shall, as soon as practicable, notify the Secretary of the identity and location of the article.

(2) MANNER OF NOTIFICATION.—Notification under paragraph (1) shall be made in such manner and by such means as the Secretary may require by regulation or guidance.

(b) VOLUNTARY RECALL.—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—

(1) recall such article; and

(2) provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

(c) ORDER TO CEASE DISTRIBUTION.—If the Secretary has reason to believe that the use or consumption of, or exposure to, an article of food may cause serious adverse health consequences or death to humans or animals, the Secretary shall have the authority to issue an order requiring any person who distributes such article to immediately cease distribution of such article.

(d) ACTION FOLLOWING ORDER.—Any person who is subject to an order under subsection (c) shall immediately cease distribution of

such article and provide notification as required by such order, and may appeal within 24 hours of issuance such order to the Secretary. Such appeal may include a request for an informal hearing and a description of any efforts to recall such article undertaken voluntarily by the person, including after a request under subsection (b). Except as provided in subsection (f), an informal hearing shall be held within as soon as practicable, but not later than 5 calendar days, or less as determined by the Secretary, after such an appeal is filed, unless the parties jointly agree to an extension. After affording an opportunity for an informal hearing, the Secretary shall determine whether the order should be amended to require a recall of such article. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

(e) ORDER TO RECALL.—

(1) AMENDMENT.—Except as provided under subsection (f), 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.

(2) CONTENTS.—An amended order under paragraph (1) shall—

(A) specify a timetable in which the recall will occur;

(B) require periodic reports to the Secretary describing the progress of the recall; and

(C) provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

In providing for such notice, the Secretary may allow for the assistance of health professionals, State or local officials, or other individuals designated by the Secretary.

(3) NONDELEGATION.—An amended order under this subsection shall be ordered by the Secretary or an official designated by the Secretary. 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.

(f) EMERGENCY RECALL ORDER.—

(1) IN GENERAL.—If the Secretary has a reasonable belief that an article of food subject to an order under subsection (c) presents an imminent threat of serious adverse health consequences or death to humans or animals, the Secretary may issue an order requiring any person who distributes such article—

(A) to immediately recall such article; and

(B) to provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

(2) ACTION FOLLOWING ORDER.—Any person who is subject to an emergency recall order under this subsection shall immediately recall such article and provide notification as required by such order, and may appeal within 24 hours after issuance such order to the Secretary. An informal hearing shall be held within as soon as practicable but not later than 5 calendar days, or less as determined by the Secretary, after such an ap-

peal is filed, unless the parties jointly agree to an extension. After affording an opportunity for an informal hearing, the Secretary shall determine whether the order should be amended pursuant to subsection (e)(1). If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

(3) NONDELEGATION.—An order under this subsection shall be issued by the Commissioner of Food and Drugs, the Principal Deputy Commissioner, or the Associate Commissioner for Regulatory Affairs of the Food and Drug Administration.

(g) NOTICE TO CONSUMERS AND HEALTH OFFICIALS.—The Secretary shall, as the Secretary determines to be necessary, provide notice of a recall order under this section to consumers to whom the article was, or may have been, distributed and to appropriate State and local health officials.

(h) SAVINGS CLAUSE.—Nothing contained in this section shall be construed as limiting—

(1) the authority of the Secretary to issue an order to cease distribution of, or to recall, an article under any other provision of this Act or the Public Health Service Act; or

(2) the ability of the Secretary to request any person to perform a voluntary activity related to any article subject to this Act or the Public Health Service Act.

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CHAPTER VII—GENERAL AUTHORITY

SUBCHAPTER A—GENERAL ADMINISTRATIVE PROVISIONS

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FACTORY INSPECTION

SEC. 704. (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any *farm,* factory, warehouse, or establishment*, including any such food factory, warehouse, or establishment whether foreign or domestic,* in which food, drugs, devices, or cosmetics are *produced,* manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle, being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such *farm,* factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person **[**(excluding farms and restaurants)**]** who *produces,* manufactures, processes, packs, transports, distributes, *receives,* holds, or imports foods, the inspection shall extend to all records and other information **[**described in section 414 when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals**]** *described in or required under section 414 bearing on whether such food is adul-*

terated, misbranded, or otherwise in violation of this Act, including all records collected or developed to comply with section 418 or 418A, subject to the limitations established in section 414(d). In the case of any *farm,* factory, warehouse, establishment, or consulting laboratory*, including any food factory, warehouse, establishment, or consulting laboratory whether foreign or domestic,* in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by **[**the preceding sentence**]** *either of the preceding two sentences* or by paragraph (3) shall extend to *recipes for food,* financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k) section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

* * * * * * *

(h)(1) Each facility registered under section 415 shall be inspected—

(A)(i) by one or more officers duly designated under section 702 or other statutory authority by the Secretary;

(ii) for domestic facilities, by a Federal, State, or local official recognized by the Secretary under paragraph (2); or

(iii) for foreign facilities, by an agency or a representative of a country that is recognized by the Secretary under paragraph (2); and

(B) at a frequency determined pursuant to a risk-based schedule.

(2) For purposes of paragraph (1)(A), the Secretary—

(A) may recognize Federal, State, and local officials and agencies and representatives of foreign countries as meeting standards established by the Secretary for conducting inspections under this Act; and

(B) may limit such recognition to inspections of specific commodities or food types.

(3) The risk-based schedule under paragraph (1)(B) shall be implemented beginning not later than 18 months after the date of the enactment of this subsection.

(4) Such risk-based schedule 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:

(A) CATEGORY 1.—A category 1 food facility is a high-risk facility that manufactures or processes food. The Secretary shall randomly inspect a category 1 food facility at least every 6 to 12 months.

(B) CATEGORY 2.—A category 2 food facility is a low-risk facility that manufactures or processes food or a facility that packs or labels food. The Secretary shall randomly inspect a category 2 facility at least every 18 months to 3 years.

(C) CATEGORY 3.—A category 3 food facility is a facility that holds food. The Secretary shall randomly inspect a category 3 facility at least every 5 years.

(5) The Secretary—

(A) may, by guidance, modify the types of food facilities within a category under paragraph (4);

(B) may alter the inspection frequencies specified in paragraph (4) based on the need to respond to food-borne illness outbreaks and food recalls; and

(C) may inspect a facility more frequently than the inspection frequency provided by paragraph (4);

(D) beginning 6 months after submitting the report required by section 105(b)(2) of the Food Safety Enhancement Act of 2009, may—

(i) publish in the Federal Register adjustments to the inspection frequencies specified in subparagraphs (B) and (C) of paragraph (4) for category 2 and category 3 food facilities, which adjustments shall be in accordance with the Secretary's recommendations in such report; and

(ii) after such publication, implement the adjustments; and

(E) except as provided in subparagraphs (B) and (C), may not alter the inspection frequency specified in paragraph (4)(A) for category 1 food facilities.

(6) In determining the appropriate frequency of inspection, the Secretary shall consider—

(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 United States food is certified by a qualified certifying entity in accordance with section 801(p); and

(D) such other factors as the Secretary determines by guidance to be relevant to assessing the risk presented by the facility.

(i) IMPORTERS.—Every person engaged in the importing of any food shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to inspect the facilities of such person and have access to, and to copy and verify, any related records.

(j) BROKERS AND FILERS.—Every person engaged in the brokering for import or filing for import of any food shall, upon request of an officer or employee designated by the Secretary, permit such officer

or employee at all reasonable times to inspect the facilities of such person and have access to, and to copy and verify, any related records.

(k) DEDICATED FOREIGN INSPECTORATE.—The Secretary shall establish and maintain a corps of inspectors dedicated to inspections of foreign food facilities. This corps shall be staffed and funded by the Secretary at a level sufficient to enable it to assist the Secretary in achieving the frequency of inspections for food facilities as described in this Act.

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CONFIDENTIAL INFORMATION

SEC. 708. [The Secretary] *(a) The Secretary* may provide any information which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section to a person other than an officer or employee of the Department if the Secretary determines such other person requires the information in connection with an activity which is undertaken under contract with the Secretary, which relates to the administration of this Act, and with respect to which the Secretary (or an officer or employee of the Department) is not prohibited from using such information. The Secretary shall require as a condition to the provision of information under this section that the person receiving it take such security precautions respecting the information as the Secretary may by regulation prescribe.

(b)(1)(A) The Secretary may provide to any Federal agency acting within the scope of its jurisdiction any information relating to food that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section, or that is referred to in section 301(j) or 415(a)(4).

(B) Any such information provided to another Federal agency shall not be disclosed by such agency except in any action or proceeding under the laws of the United States to which the receiving agency or the United States is a party.

(2)(A) In carrying out this Act, the Secretary may provide to a State or local government agency any information relating to food that is exempt from disclosure pursuant to section 552(a) of title 5, United States Code, by reason of subsection (b)(4) of such section, or that is referred to in section 301(j) or 415(a)(4).

(B) Any such information provided to a State or local government agency shall not be disclosed by such agency.

(3) In carrying out this Act, the Secretary may provide to any person any information relating to food that is exempt from disclosure pursuant to section 552(a) of title 5, United States Code, by reason of subsection (b)(4) of such section, if the Secretary determines that providing the information to the person is appropriate under the circumstances and the recipient provides adequate assurances to the Secretary that the recipient will preserve the confidentiality of the information.

(4) In carrying out this Act, the Secretary may provide any information relating to food that is exempt from disclosure pursuant to section 552(a) of title 5, United States Code, by reason of subsection (b)(4) of such section, or that is referred to in section 301(j)—

(A) to any foreign government agency; or

(B) any international organization established by law, treaty, or other governmental action and having responsibility—

(i) to facilitate global or regional harmonization of standards and requirements in an area of responsibility of the Food and Drug Administration; or

(ii) to promote and coordinate public health efforts,

if the agency or organization provides adequate assurances to the Secretary that the agency or organization will preserve the confidentiality of the information.

(c) Except where specifically prohibited by statute, the Secretary may disclose to the public any information relating to food that is exempt from disclosure pursuant to section 552(a) of title 5, United States Code, by reason of subsection (b)(4) of such section, if the Secretary determines that such disclosure is necessary to protect the public health.

(d) Except as provided in subsection (e), the Secretary shall not be required to disclose under section 552 of title 5, United States Code, or any other provision of law any information relating to food obtained from a Federal, State, or local government agency, or from a foreign government agency, or from an international organization described in subsection (b)(4), if the agency or organization has requested that the information be kept confidential, or has precluded such disclosure under other use limitations, as a condition of providing the information.

(e) Nothing in subsection (d) authorizes the Secretary to withhold information from the Congress or prevents the Secretary from complying with an order of a court of the United States.

(f) This section shall not affect the authority of the Secretary to provide or disclose information under any other provision of law.

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SEC. 714. TESTING BY ACCREDITED LABORATORIES.

(a) IN GENERAL.—

(1) REQUIREMENT.—Whenever analytical testing of an article of food is conducted as part of testimony for the purposes of section 801(a), or for such other purposes as the Secretary deems appropriate through regulation or guidance, such testing shall be conducted by a laboratory that—

(A) is accredited, for the analytical method used, by a laboratory accreditation body that has been recognized by the Secretary; and

(B) samples such article with adequate controls for ensuring the integrity of the samples analyzed.

(2) INDEPENDENCE OF LABORATORY.—

(A) CERTAIN TESTS.—Tests required for purposes of section 801(a) or in response to a finding of noncompliance by the Secretary shall be conducted by a laboratory independent of the person on whose behalf such testing is conducted and analyzed.

(B) CERTAIN PRODUCTS.—The Secretary may require that testing for certain products under paragraph (1) be conducted by a laboratory independent of the person on whose behalf such testing is conducted.

(b) RECOGNITION OF LABORATORY ACCREDITATION BODIES.—The Secretary shall establish and implement a program for the recognition, based on standards the Secretary deems appropriate, of laboratory accreditation bodies that accredit laboratories to perform analytical testing for the purposes of this section. The Secretary shall issue regulations or guidance to implement this program.

(c) ONSITE AUDITS.—In evaluating whether an accreditation body meets, or continues to meet, the standards for recognition under subsection (b), the Secretary may—

(1) observe onsite audits of laboratories by such accreditation bodies; or

(2) for any laboratory that is accredited by such accreditation body under this section, upon request of an officer or employee designated by the Secretary and upon presentation of appropriate credentials, at reasonable times and within reasonable limits and in a reasonable manner, conduct an onsite audit of the laboratory, which shall include access to, and copying and verification of, any related records.

(d) PUBLICATION OF LIST OF RECOGNIZED ACCREDITATION BODIES.—The Secretary shall publish and maintain on the public Web site of the Food and Drug Administration a list of accreditation bodies recognized by the Secretary under subsection (b).

(e) NOTIFICATION OF ACCREDITATION OF LABORATORY.—An accreditation body that has been recognized pursuant to this section shall promptly notify the Secretary whenever it accredits a laboratory for the purposes of this section and whenever it withdraws or suspends such accreditation.

(f) ADVANCE NOTICE.—Whenever analytical testing is conducted pursuant to subsection (a), the person on whose behalf the testing is conducted shall notify the Secretary before any sample of the article is collected. Such notice shall contain information the Secretary determines is appropriate to identify the article, the location of the article, and each laboratory that will analyze the sample on the person's behalf.

(g) CONTENTS OF LABORATORY PACKAGES.—Whenever analytical testing is conducted pursuant to subsection (a), the laboratory conducting such testing shall submit, directly to the Secretary—

(1) the results of all analyses conducted by the laboratory on each sample of such article; and

(2) all information the Secretary deems appropriate to—

(A) determine whether the laboratory is accredited by a recognized laboratory accreditation body;

(B) identify the article tested;

(C) evaluate the analytical results; and

(D) determine whether the requirements of this section have been met.

(h) EXIGENT CIRCUMSTANCES.—The Secretary may waive the requirement of subsection (a)(1)(A) (relating to analytical methods) on a laboratory or method basis due to exigent or other circumstances.

(i) NO LIMIT ON AUTHORITY.—Nothing in this section shall be construed to limit—

(1) the ability of the Secretary to review and act upon information from the analytical testing of food (including under this section), including determining the sufficiency of such information and testing; or

(2) the authority of the Secretary to conduct, require, or consider the results of analytical testing pursuant to any other provision of law.

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SUBCHAPTER C—FEES

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PART 6—FEES RELATING TO FOOD

SEC. 743. FACILITY REGISTRATION FEE.

(a) IN GENERAL.—

(1) ASSESSMENT AND COLLECTION.—Beginning in fiscal year 2010, the Secretary shall assess and collect an annual fee for the registration of a facility under section 415.

(2) PAYABLE DATE.—A fee under this section shall be payable—

(A) for a facility that was not registered under section 415 for the preceding fiscal year, on the date of registration; and

(B) for any other facility—

(i) for fiscal year 2010, not later than the sooner of 90 days after the date of the enactment of this part or December 31, 2009; and

(ii) for a subsequent fiscal year, not later than December 31 of such fiscal year.

(b) FEE AMOUNTS.—

(1) IN GENERAL.—The registration fee under subsection (a) shall be—

(A) for fiscal year 2010, $500; and

(B) for fiscal year 2011 and each subsequent fiscal year, the fee for fiscal year 2010 as adjusted under subsection (c).

(2) ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the start of fiscal year 2011 and each subsequent fiscal year, establish, for the next fiscal year, registration fees under subsection (a), as described in paragraph (1).

(3) MAXIMUM AMOUNT.—Notwithstanding paragraph (1), a person who owns or operates multiple facilities for which a fee must be paid under this section for a fiscal year shall be liable for not more than $175,000 in aggregate fees under this section for such fiscal year.

(c) INFLATION ADJUSTMENT.—For fiscal year 2011 and each subsequent fiscal year, the fee amount under subsection (b)(1) shall be adjusted by the Secretary by notice, published in the Federal Register, to reflect the greater of—

(1) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; U.S. city average) for the 12-month period ending June 30 preceding the fiscal year for which fees are being established;

(2) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of

such title for Federal employees stationed in the District of Columbia; or

(3) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 5 years of the preceding 6 fiscal years.

The adjustment made each fiscal year under this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2010 under this subsection.

(d) LIMITATIONS.—

(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2010 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for fiscal year 2010 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for registration under section 415 at any time in such fiscal year.

(3) ADJUSTMENT FACTOR.—In this subsection, the term "adjustment factor" applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2009.

(e) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

(2) COLLECTIONS AND APPROPRIATIONS ACTS.—The fees authorized by this section—

(A) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year; and

(B) shall only be collected and available to defray the costs of food safety activities.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2010 through 2014, there are authorized to be appropriated for fees under this section such sums as may be necessary.

(4) PUBLIC MEETINGS.—For each fiscal year, the Secretary shall hold a public meeting on how fees collected under this sec-

tion will be used to defray the costs of food safety activities in order to solicit the views of the regulated industry, consumers, and other interested stakeholders.

(f) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(g) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in food safety activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(h) ANNUAL FISCAL REPORTS.—Beginning with fiscal year 2011, not later than 120 days after the end of each fiscal year for which fees are collected under this section, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

(i) DEFINITIONS.—In this section:

(1) The term "costs of food safety activities" means the expenses incurred in connection with food safety activities for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and to contracts with such contractors;

(B) laboratory capacity;

(C) management of information, and the acquisition, maintenance, and repair of technology resources;

(D) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(E) collecting fees under this section and accounting for resources allocated for food safety activities.

(2) The term "food safety activities" means activities related to compliance by facilities registered under section 415 with the requirements of this Act relating to food (including research related to and the development of standards (such as performance standards and preventive controls), risk assessments, hazard analyses, inspection planning and inspections, third-party inspections, compliance review and enforcement, import review, information technology support, test development, product sampling, risk communication, and administrative detention).

SEC. 743A. REINSPECTION AND FOOD RECALL FEES APPLICABLE TO FACILITIES.

(a) IN GENERAL.—The Secretary shall assess and collect fees from each entity in a fiscal year—

(1) that—

(A) during such fiscal year commits a violation of any requirement of this Act relating to food, including any such requirement relating to good manufacturing practices; and

(B) because of such violation, undergoes additional inspection by the Food and Drug Administration; or

(2) during such fiscal year is subject to a food recall.

(b) AMOUNT OF FEES.—The Secretary shall set the amount of the fees under this section to fully cover the costs of—

(1) in the case of fees collected under subsection (a)(1), conducting the additional inspections referred to in such subsection; and

(2) in the case of fees collected under subsection (a)(2), conducting food recall activities, including technical assistance, follow-up effectiveness checks, and public notifications, during the fiscal year involved.

(c) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

(2) COLLECTIONS AND APPROPRIATIONS ACTS.—The fees authorized by this section—

(A) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year; and

(B) shall only be collected and available to defray the costs referred to in subsection (b).

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2010 through 2014, there are authorized to be appropriated for fees under this section such sums as may be necessary.

(d) WAIVER.—The Secretary shall waive and, if applicable, refund the amount of any fee collected under this section from an entity as a result of a food recall that the Secretary determines was inappropriately ordered.

PART 7—IMPORTERS OF FOOD

SEC. 744. IMPORTERS OF FOOD.

(a) IMPORTERS.—The Secretary shall assess and collect an annual fee for the registration of an importer of food under section 801(r).

(b) AMOUNT OF FEE.—

(1) BASE AMOUNTS.—The registration fee under subsection (a) shall be—

(A) for fiscal year 2010, $500; and

(B) for fiscal year 2011 and each subsequent fiscal year, the fee for fiscal year 2010 as adjusted under paragraph (2).

(2) ADJUSTMENT.—For fiscal year 2011 and subsequent fiscal years, the fees established pursuant to paragraph (1) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average), for the 12-month period ending June 30 preceding the fiscal year for which fees are being established;

(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia; or

(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 5 years of the preceding 6 fiscal years.

(3) COMPOUNDED BASIS.—The adjustment made each fiscal year pursuant this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2010 under this subsection.

(4) WAIVER FOR IMPORTERS REQUIRED TO PAY REGISTRATION FEE.—In the case of a person who is required to pay both a fee under section 743 for registration of one or more facilities under section 415 and a fee under this section for registration as an importer of food under section 801(r), the Secretary shall waive the fees applicable to such person under section 743 or the fee applicable to such person under this section.

(c) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

(2) COLLECTIONS AND APPROPRIATIONS ACTS.—The fees authorized by this section—

(A) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year; and

(B) shall only be collected and available to cover the costs associated with registering importers under section 801(r) and with ensuring compliance with good importer practices respecting food.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2010 through 2014, there are authorized to be appro-

priated for fees under this section such sums as may be necessary.

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CHAPTER VIII—IMPORTS AND EXPORTS

IMPORTS AND EXPORTS

SEC. 801. (a) The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. The Secretary of Health and Human Services shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 510 and shall request that if any drugs or devices manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs or devices be delivered to the Secretary of Health and Human Services, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 520(f), or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, or prohibited from introduction or delivery for introduction into interstate commerce under section 301(ll), *or (4) the requirements of section 414 have not been complied with regarding such article, or (5) such article is subject to an order under section 420 to cease distribution of or recall the article,* then such article shall be refused admission, except as provided in subsection (b) of this section. *If an article of food being imported or offered for import into the United States is not in compliance with the requirement of subsection (p) (relating to certifications of compliance with this Act), then such article shall be refused admission.* If such article is subject to a requirement under section 760 or 761 and if the Secretary has credible evidence or information indicating that the responsible person (as defined in such section 760 or 761) has not complied with a requirement of such section 760 or 761 with respect to any such article, or has not allowed access to records described in such section 760 or 761, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations. Clause (2) of the third sentence of this paragraph shall not

be construed to prohibit the admission of narcotic drugs the importation of which is permitted under the Controlled Substances Import and Export Act.

(b) Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury. If it appears to the Secretary of Health and Human Services that (1) an article included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with the Act or rendered other than a food, drug, device, or cosmetic, or (2) with respect to an article included within the provision of **[**the fourth sentence**]** *the fifth sentence* of subsection (a), the responsible person (as defined in section 760 or 761) can take action that would assure that the responsible person is in compliance with section 760 or 761, as the case may be, final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this subsection, the Secretary may, in accordance with regulations, authorize the applicant, or, with respect to clause (2), the responsible person, to perform such relabeling or other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Secretary's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Department of Health and Human Services designated by the Secretary, or an officer or employee of the Department of the Treasury designated by the Secretary of the Treasury.

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(e)(1) * * *

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(4)(A) Any person who exports **[**a drug, animal drug, or device**]** *from the United States a food (including animal feed), drug, animal drug, or device* may request that the Secretary—

(i) certify **[**in writing**]** that the **[**exported drug, animal drug, or device**]** *exported food, drug, animal drug, or device* meets the requirements of paragraph (1) or section 802; or

(ii) certify **[**in writing**]** that **[**the drug, animal drug, or device**]** *the food, drug, animal drug, or device* being exported meets the applicable requirements of this Act upon a showing that **[**the drug or device**]** *the food, drug, or device* meets the applicable requirements of this Act.

The Secretary shall issue such a certification within 20 days of the receipt of a request for such certification.

(B) For purposes of this paragraph, a certification by the Secretary shall be made on such basis and in such form (such as a publicly available listing) as the Secretary determines appropriate.

[(B)**]** *(C)* If the Secretary issues a written export certification within the 20 days prescribed by subparagraph (A), a fee for such certification may be charged but shall not exceed $175 for each cer-

tification. Fees collected for a fiscal year pursuant to this subparagraph shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriations Acts until expended without fiscal year limitation. Such fees shall be collected in each fiscal year in an amount equal to the amount specified in appropriations Acts for such fiscal year and shall only be collected and available for the costs of the Food and Drug Administration.

(D) Notwithstanding subparagraph (C), if the Secretary issues an export certification within the 20 days prescribed by subparagraph (A) with respect to the export of food, a fee for such certification shall not exceed such amount as the Secretary determines is reasonably related to the cost of issuing certificates under subparagraph (A) with respect to the export of food. The Secretary may adjust this fee annually to account for inflation and other cost adjustments. Fees collected for a fiscal year pursuant to this subparagraph shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriations Acts until expended, without fiscal year limitation. Such fees shall be collected in each fiscal year in an amount equal to the amount specified in appropriations Acts for such fiscal year and shall only be collected and available for the costs of the Food and Drug Administration to cover the cost of issuing such certifications. Such sums as necessary may be transferred from such appropriation account for salaries and expenses of the Food and Drug Administration without fiscal year limitation to such appropriation account for salaries and expenses with fiscal year limitation.

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(p) CERTIFICATIONS CONCERNING IMPORTED ARTICLES.—

(1) IN GENERAL.—

(A) REQUIREMENT.—The Secretary shall require, as an additional condition of granting admission to an article of food being imported or offered for import into the United States, that a qualified certifying entity provide a certification that the article complies with specified requirements of this Act if—

(i) for food imported from a particular country or region, based on the adequacy of government controls in such country or region or other information relevant to such food, certification would assist the Secretary in determining whether to refuse to admit such article under subsection (a);

(ii) 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

(iii) 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.

(B) CONTENTS OF CERTIFICATION.—Such certification shall include such information regarding compliance as the Secretary may specify, and may be provided in the form of shipment-specific certificates, a listing of certified facilities

or other entities, or in such other form as the Secretary may specify.

(C) NOTICE OF CANCELLATION OR SUSPENSION OF CERTIFICATION.—As a condition on acceptance of certifications from a qualified certifying entity, the Secretary shall require the qualified certifying entity to notify the Secretary whenever the qualified certifying entity cancels or suspends the certification of any facility or other entity included in a listing under subparagraph (B).

(2) QUALIFIED CERTIFYING ENTITY.—For purposes of this subsection, the term "qualified certifying entity" means—

(A) an agency or a representative of the government of the country from which the article originated, as designated by such government or the Secretary; or

(B) an individual or entity determined by the Secretary or an accredited body recognized by the Secretary to be qualified to provide a certification under paragraph (1).

(3) NO CONFLICTS OF INTEREST.—

(A) IN GENERAL.—The Secretary shall issue regulations to ensure that any qualified certifying entity and its auditors are free from conflicts of interest.

(B) REGULATIONS.—Such regulations shall require that—

(i) the qualified certifying entity shall have a committee or management structure for safeguarding impartiality;

(ii) conflict of interest policies for a qualified certifying entity and auditors acting for the qualified certifying entity shall be written;

(iii) the qualified certifying entity shall not be owned, operated, or controlled by a producer, manufacturer, processor, packer, holder, supplier, or vendor of any article of the type it certifies;

(iv) the qualified certifying entity shall not have any ownership or financial interest in any product, producer, manufacturer, processor, packer, holder, supplier or vendor of the type it certifies;

(v) no auditor acting for the qualified certifying entity (or spouse or minor children) shall have any significant ownership or other financial interest regarding any product of the type it certifies;

(vi) the qualified certifying entity shall maintain records pertaining to the financial interests of the personnel involved in audits;

(vii) neither the qualified certifying entity nor any of its auditors acting for the qualified certifying entity shall participate in the production, manufacture, processing, packing, holding, promotion, or sale of any product of the type it certifies;

(viii) neither the qualified certifying entity nor any of its auditors shall provide consultative services to any facility certified by the qualified certifying entity, or the owner, operator, or agent in charge of such a facility, unless the qualified certifying entity has procedures in place, approved by the Secretary, to ensure separation of functions between auditors providing consultative

services and auditors providing certification services under this subsection;

(ix) no auditors acting for the qualified certifying entity shall participate in an audit of a facility they were employed by within the last 12 months;

(x) fees charged or accepted shall not be contingent or based upon the report made by the qualified certifying entity or any personnel involved in the audit process;

(xi) neither the qualified certifying entity nor any of its auditors shall accept anything of value from anyone in connection with the facility being audited other than the audit fee;

(xii) the qualified certifying entity shall not be owned, operated, or controlled by a trade association whose member companies operate facilities that it certifies;

(xiii) the qualified certifying entity and its auditors shall be free from any other conflicts of interest that threaten impartiality;

(xiv) the qualified certifying entity and its auditors shall sign a statement attesting to compliance with the conflict of interests requirements under this paragraph; and

(xv) the qualified certifying entity shall ensure that any subcontractors that might be used (such as laboratories and sampling services) provide similar assurances, except that it shall not be a violation of this subsection to the extent such subcontractors perform additional nutritional testing services unrelated to the testing under this subsection.

(C) ANYTHING OF VALUE.—In this paragraph, the term "anything of value" includes gifts, gratuities, reimbursement of expenses, entertainment, loans, or any other form of compensation in cash or in kind.

(4) RENEWAL AND REFUSAL OF CERTIFICATIONS.—The Secretary shall—

(A) require that, to the extent applicable, any certification provided by a qualified certifying entity be renewed by such entity at such times as the Secretary determines appropriate; and

(B) refuse to accept any certification if the Secretary determines that such certification is no longer valid or reliable.

(5) ELECTRONIC SUBMISSION.—The Secretary shall provide for the electronic submission of certifications under this subsection.

(6) NO LIMIT ON AUTHORITY.—This subsection shall not be construed to limit the authority of the Secretary to conduct random inspections of imported articles or facilities of importers, issue import alerts for detention without physical examination, require submission to the Secretary of documentation or other information about an article imported or offered for import, or to take such other steps as the Secretary deems appropriate to determine the admissibility of imported articles.

(q) DOCUMENTATION.—

(1) SUBMISSION.—The Secretary may require by regulation or guidance the submission of documentation or other information for articles of food that are imported or offered for import into the United States.

(2) FORMAT.—A regulation or guidance under paragraph (1) may specify the format for submission of the documentation or other information.

(r) REGISTRATION OF IMPORTERS.—

(1) REGISTRATION.—The Secretary shall require an importer of food—

(A) to be registered with the Secretary in a form and manner specified by the Secretary; and

(B) consistent with section 911, to submit appropriate unique facility identifiers as a condition of registration.

(2) GOOD IMPORTER PRACTICES.—The maintenance of registration under this subsection is conditioned on compliance with good importer practices. Good importer practices shall include the verification of good manufacturing practices and preventive controls of the importer's foreign suppliers, as applicable.

(3) SUSPENSION OF REGISTRATION.—

(A) IN GENERAL.—Registration under this subsection is subject to suspension upon a finding by the Secretary, after notice and an opportunity for an informal hearing, of—

(i) a violation of this Act; or

(ii) the knowing or repeated making of an inaccurate or incomplete statement or submission of information relating to the importation of food.

(B) REQUEST.—The importer whose registration is suspended may request that the Secretary vacate the suspension of registration when such importer has corrected the violation that is the basis for such suspension.

(C) VACATING OF SUSPENSION.—If the Secretary determines that adequate reasons do not exist to continue the suspension of a registration, the Secretary shall vacate such suspension.

(4) CANCELLATION OF REGISTRATION.—

(A) IN GENERAL.—Not earlier than 10 days after providing the notice under subparagraph (B), the Secretary may cancel a registration that the Secretary determines was not updated in accordance with this section or otherwise contains false, incomplete, or inaccurate information.

(B) NOTICE OF CANCELLATION.—Cancellation shall be preceded by notice to the importer of the intent to cancel the registration and the basis for such cancellation.

(C) TIMELY UPDATE OR CORRECTION.—If the registration for the importer is updated or corrected no later than 7 days after notice is provided under subparagraph (B), the Secretary shall not cancel such registration.

(5) EXEMPTIONS.—The Secretary, by notice published in the Federal Register—

(A) shall establish an exemption from the requirements of this subsection for importations for personal use; and

(B) may establish other exemptions from the requirements of this subsection.

(s) REGISTRATION OF CUSTOMS BROKERS AND FILERS.—

(1) REGISTRATION.—The Secretary shall require a customs broker or filer, with respect to the importation of food—

(A) to be registered with the Secretary in a form and manner specified by the Secretary; and

(B) consistent with section 911, to submit appropriate unique facility identifiers as a condition of registration.

(2) SUSPENSION OF REGISTRATION.—

(A) IN GENERAL.—Registration under this subsection is subject to suspension upon a finding by the Secretary, after notice and an opportunity for an informal hearing, of—

(i) a violation of this Act; or

(ii) the knowing or repeated making of an inaccurate or incomplete statement or submission of information relating to the importation of food.

(B) REQUEST.—The customs broker or filer whose registration is suspended may request that the Secretary vacate the suspension of registration when such customs broker or filer has corrected the violation that is the basis for such suspension.

(C) VACATING OF SUSPENSION.—If the Secretary determines that adequate reasons do not exist to continue the suspension of a registration, the Secretary shall vacate such suspension.

(3) CANCELLATION OF REGISTRATION.—

(A) IN GENERAL.—Not earlier than 10 days after providing the notice under subparagraph (B), the Secretary may cancel a registration that the Secretary determines was not updated in accordance with this section or otherwise contains false, incomplete, or inaccurate information.

(B) NOTICE OF CANCELLATION.—Cancellation shall be preceded by notice to the customs broker or filer of the intent to cancel the registration and the basis for such cancellation.

(C) TIMELY UPDATE OR CORRECTION.—If the registration for the customs broker or filer is updated or corrected no later than 7 days after notice is provided under subparagraph (B), the Secretary shall not cancel such registration.

(4) EXEMPTIONS.—The Secretary, by notice published in the Federal Register—

(A) shall establish an exemption from the requirements of this subsection for importations for personal use; and

(B) may establish other exemptions from the requirements of this subsection.

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SEC. 805. SAFE AND SECURE FOOD IMPORTATION PROGRAM.

(a) IN GENERAL.—The Secretary may establish by regulation or guidance a program that facilitates the movement of food through the importation process under this Act if the importer of such food—

(1) verifies that each facility involved in the production, manufacture, processing, packaging, and holding of the food is in compliance with the food safety and security guidelines developed under subsection (b) with respect to such food;

(2) ensures that appropriate safety and security controls are in place throughout the supply chain for such food; and

(3) provides supporting information to the Secretary.

(b) GUIDELINES.—

(1) DEVELOPMENT.—For purposes of the program established under subsection (a), the Secretary shall develop safety and security guidelines applicable to the importation of food.

(2) FACTORS.—Such guidelines shall take into account the following factors:

(A) The personnel of the person importing the food.

(B) The physical and procedural safety and security of such person's food supply chain.

(C) The sufficiency of preventive controls for food and ingredients purchased by such person.

(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.

CHAPTER IX—MISCELLANEOUS

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SEC. 911. UNIQUE FACILITY IDENTIFIER.

(a) REGISTRATION OF FACILITY OR ESTABLISHMENT.—A person required to register a facility pursuant to section 415 shall submit, at the time of registration, a unique facility identifier for the facility or establishment.

(b) REGISTRATION OF IMPORTERS, CUSTOM BROKERS, AND FILERS.—A person required to register pursuant to section 801(r) or 801(s) shall submit, at the time of registration, a unique facility identifier for the principal place of business for which such person is required to register under section 801(r) or 801(s).

(c) GUIDANCE.—The Secretary may, by guidance, specify the unique numerical identifier system to be used to meet the requirements of subsections (a) and (b) and the form, manner, and timing of a submission under such subsections.

(d) IMPORTATION.—An article of food imported or offered for import shall be refused admission unless the appropriate unique facility identifiers, as specified by the Secretary, are provided for such article.

SEC. 912. PROTECTIONS FOR EMPLOYEES WHO REFUSE TO VIOLATE, OR WHO DISCLOSE VIOLATIONS OF, THIS ACT OR SECTION 351 OF THE PUBLIC HEALTH SERVICE ACT.

(a) IN GENERAL.—No person who submits or is required under this Act or the Public Health Service Act to submit any information related to a food, or any officer, employee, contractor, subcontractor, or agent of such person may discharge, demote, suspend, threaten, harass, or in any other manner discriminate 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—

(1) to provide information, cause information to be provided, or otherwise assist 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);

(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.

(b) ENFORCEMENT ACTION.—

(1) IN GENERAL.—An employee who alleges discharge or other discrimination in violation of subsection (a) may seek relief in accordance with the provisions of subsection (c) by—

(A) filing a complaint with the Secretary of Labor; or

(B) if the Secretary of Labor has not issued a final decision within 210 days of the filing of the complaint and there is no showing that such delay is due to the bad faith of the claimant, or within 90 days after receiving a final decision or order from the Secretary, bringing an action at law or equity for de novo review in the appropriate district court of the United States, which court shall have jurisdiction over such action without regard to the amount in controversy, and which action shall, at the request of either party to such action, be tried by the court with a jury.

(2) PROCEDURE.—

(A) IN GENERAL.—Any action under paragraph (1) shall be governed under the rules and procedures set forth in section 42121(b) of title 49, United States Code.

(B) EXCEPTION.—Notification in an action under paragraph (1) shall be made in accordance with section 42121(b)(1) of title 49, United States Code, except that such notification shall be made to the person named in the complaint and to the employer.

(C) BURDENS OF PROOF.—An action brought under paragraph (1)(B) shall be governed by the legal burdens of proof set forth in section 42121(b) of title 49, United States Code.

(D) STATUTE OF LIMITATIONS.—An action under paragraph (1) shall be commenced not later than 180 days after the date on which the violation occurs.

(c) REMEDIES.—

(1) IN GENERAL.—An employee prevailing in any action under subsection (b)(1) shall be entitled to all relief necessary to make the employee whole.

(2) ISSUANCE OF ORDER.—If, in response to a complaint filed under subsection (b)(1), the Secretary of Labor or the district court, as applicable, determines that a violation of subsection (a) has occurred, the Secretary or the court shall order the person who committed such violation—

(A) to take affirmative action to abate the violation;

(B) to—

(i) reinstate the complainant to his or her former position together with compensation (including backpay); and

(ii) restore the terms, conditions, and privileges associated with his or her employment; and

(C) to provide compensatory damages to the complainant.

If such an order is issued under this paragraph, the Secretary or the court, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorney and expert witness fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

(d) RIGHTS RETAINED BY EMPLOYEE.—Nothing in this section shall be deemed to diminish the rights, privileges, or remedies of any employee under any Federal or State law or under any collective bargaining agreement. The rights and remedies in this section may not be waived by any agreement, policy, form, or condition of employment.

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