the House Calendar and ordered to be printed.

FOOD SAFETY ENHANCEMENT ACT OF 2009

Mr. DINGELL. Mr. Speaker, pursuant to H. Res. 691, I call up 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, and ask for its immediate consideration in the House.

The Clerk read the title of the bill.

The SPEAKER pro tempore. Pursuant to House Resolution 691, in lieu of the amendment in the nature of a substitute recommended by the Committee on Energy and Commerce now printed in the bill, the amendment in the nature of a substitute printed in House Report 111–235 is adopted, and the bill, as amended, is considered read.

The text of the bill, as amended, is as follows:

H.R. 2749

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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. 1. Short title.
Sec. 2. Table of contents.
Sec. 3. References.
Sec. 4. Rules of construction.
Sec. 5. USDA exemptions.
Sec. 6. Alcohol-related facilities.

TITLE I—FOOD SAFETY

Subtitle A—Prevention

Sec. 101. Changes in registration of food facilities.
Sec. 102. Hazard analysis, risk-based preventive controls, food safety plan, finished product test results from category 1 facilities.
Sec. 103. Performance standards.
Sec. 104. Safety standards for produce and certain other raw agricultural commodities.
Sec. 105. Risk-based inspection schedule.
Sec. 106. Access to records.
Sec. 107. Traceability of food.
Sec. 108. Reinspection and food recall fees applicable to facilities.
Sec. 109. Certification and accreditation.
Sec. 110. Testing by accredited laboratories.
Sec. 111. Notification, nondistribution, and recall of adulterated or misbranded food.
Sec. 112. Reportable food registry; exchange of information.
Sec. 113. Safe and secure food importation program.
Sec. 114. Infant formula.

Subtitle B—Intervention

Sec. 121. Surveillance.
Sec. 122. Public education and advisory system.
Sec. 123. Research.

Subtitle C—Response

Sec. 131. Procedures for seizure.
Sec. 132. Administrative detention.
Sec. 133. Authority to prohibit or restrict the movement of food.
Sec. 134. Criminal penalties.
Sec. 135. Civil penalties for violations relating to food.
Sec. 136. Improper import entry filings.

TITLE II—MISCELLANEOUS

Sec. 201. Food substances generally recognized as safe.
Sec. 202. Country of origin labeling.
Sec. 203. Exportation certificate program.
Sec. 204. Registration for commercial importers of food; fee.
Sec. 205. Registration for customs brokers.
Sec. 206. Unique identification number for food facilities, importers, and custom brokers.
Sec. 207. Prohibition against delaying, limiting, or refusing inspection.
Sec. 208. Dedicated foreign inspectorate.
Sec. 209. Plan and review of continued operation of field laboratories.
Sec. 210. False or misleading reporting to FDA.
Sec. 211. Subpoena authority.
Sec. 212. Whistleblower protections.
Sec. 213. Extraterritorial jurisdiction.
Sec. 214. Support for training institutes.
Sec. 215. Bisphenol A in food and beverage containers.
Sec. 216. Lead content labeling requirement for ceramic tableware and cookware.

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 the amendments 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 to the extent that such food is regulated by the Secretary of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

(b) LIVESTOCK AND POULTRY.—Livestock and poultry that are intended to be presented for slaughter pursuant to the regulations by the Secretary of Agriculture under the Federal Meat Inspection Act or the Poultry Products Inspection Act are exempt from the requirements of this Act. A cow, sheep, or goat that is used for the production of milk is exempt from the requirements of this Act.

(c) USDA-REGULATED FACILITIES.—A facility is exempt from the requirements of this Act to the extent such facility is regulated as an official establishment by the Secretary of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act or under a program recognized by the Secretary of Agriculture as at least equal to Federal regulation under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act.

(d) 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 (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5291 et seq.) 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 (21 U.S.C. 350d), as amended by this Act, is required to register as a facility because such facility is engaged in manufacturing, processing, packing, or holding 1 or more alcoholic beverages.

(b) LIMITED RECEIPT AND DISTRIBUTION OF NON-ALCOHOL FOOD.—Subsection (a) shall not apply to a facility engaged in the distributing of any non-alcohol food, except that subsection (a) shall apply to a facility described in paragraphs (1) and (2) of subsection (a) that receives and distributes non-alcohol food provided such food is received and distributed—

(1) in a prepackaged form that prevents any direct human contact with such food; and

(2) in amounts that constitute not more than 5 percent of the overall sales of such facility, as determined by the Secretary of the Treasury.

(c) 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 (27 U.S.C. 211), 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) DEFINITION OF FACILITY.—Paragraph (1) of section 415(b) (21 U.S.C. 350d(b)) is amended to read as follows:

''(1)(A) The term 'facility' means any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food.

''(B) Such term does not include farms; private residences of individuals; restaurants; other retail food establishments; nonprofit

food establishments in which food is prepared for or served directly to the consumer; or fishing vessels (except such vessels engaged in processing as defined in section 123.3(k) of title 21, Code of Federal Regulations, or any successor regulations).

''(C)(i) The term 'retail food establishment' means an establishment that, as its primary function, sells food products (including those food products that it manufactures, processes, packs, or holds) directly to consumers (including by Internet or mail order).

''(ii) Such term includes—

''(I) grocery stores;

''(II) convenience stores;

''(III) vending machine locations; and

''(IV) stores that sell bagged feed, pet food, and feed ingredients or additives over-the-counter directly to consumers and final purchasers for their own personal animals.

''(iii) A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers.

''(D)(i) The term 'farm' means an operation in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both.

''(ii) Such term includes—

''(I) such an operation that packs or holds food, provided that all food used in such activities is grown, raised, or consumed on such farm or another farm under the same ownership;

''(II) such an operation that manufactures or processes food, provided that all food used in such activities is consumed on such farm or another farm under the same ownership;

''(III) such an operation that sells food directly to consumers if the annual monetary value of sales of the food products from the farm or by an agent of the farm to consumers exceeds the annual monetary value of sales of the food products to all other buyers;

''(IV) such an operation that manufactures grains or other feed stuffs that are grown and harvested on such farm or another farm under the same ownership and are distributed directly to 1 or more farms for consumption as food by humans or animals on such farm; and

''(V) a fishery, including a wild fishery, an aquaculture operation or bed, a fresh water fishery, and a saltwater fishery.

''(iii) Such term does not include such an operation that receives manufactured feed from another farm as described in clause (ii)(IV) if the receiving farm releases the feed to another farm or facility under different ownership.

''(iv) The term 'harvesting' includes washing, trimming of outer leaves of, and cooling produce.

''(E) The term 'consumer' does not include a business.''.

(2) REGISTRATION.—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.''.

(3) 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 1011.

''(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) 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 and implement 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 or that may be unintentionally introduced.

''(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 and implement 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 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 found effective—

''(1) no affected 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 system of preventive controls identified under subsection (c) has been validated as scientifically and technically sound so that, if such system is implemented, the hazards identified in the hazard analysis under subsection (b)(3) will be prevented, eliminated, or reduced to an acceptable level;

''(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 facility 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 to the type of facility or food:

''(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 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 that the system of controls, if implemented, will prevent, eliminate, or reduce to an acceptable level the identified hazards, review of monitoring and corrective action records, and procedures for determining whether the system of controls as implemented is effectively preventing, eliminating, or reducing to an acceptable level the occurrence of identified hazards, 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 distribution or 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.), as amended, is further 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).''.

(c) FOOD DEFENSE.—

(1) ADULTERATION.—Section 402(j), as added by subsection (a), is amended by striking ''and 418A'' and inserting '', 418A, or 418C''.

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

"SEC. 418C. FOOD DEFENSE.

''(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 defense plan (in this section referred to as a 'food defense plan').

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

''(1) A food defense assessment to identify conditions and practices that may permit a hazard that may be intentionally introduced, including by an act of terrorism. This assessment shall evaluate processing security, cybersecurity, material security (including ingredients, finished product, and packaging), personnel security, storage security, shipping and receiving security, and utility security.

''(2) A description of the preventive measures being implemented as a result of such assessment to minimize the risk of intentional contamination.

''(3) A description of the procedures to check for and identify any circumstances in which the preventive measures are not fully implemented or were ineffective.

''(4) A description of the procedures for taking corrective actions to ensure that when preventive measures have not been properly implemented or have been ineffective, appropriate action is taken—

''(A) to reduce the likelihood of recurrence of the failure; and

''(B) to assess the consequences of the failure.

''(5) A description of evaluation activities for the preventive measures, including a review of records provided for under paragraph (6) and procedures to periodically test the effectiveness of the plan.

''(6) A description of the facility's recordkeeping procedures, including records documenting implementation of the procedures under paragraphs (3), (4), and (5).

''(c) HAZARD.—For purposes of this section, the term 'hazard that may be intentionally introduced, including by an act of terrorism' means a hazard for which a prudent person who, as applicable, manufactures, processes, packs, transports, or holds food, would establish preventive measures because the hazard has been identified by a food defense assessment by application of—

''(1) a targeting assessment tool recommended by the Secretary by guidance; or

''(2) a comparable targeting assessment tool.

''(d) FOOD DEFENSE HAZARDS IDENTIFIED BY THE SECRETARY.—

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

''(2) ALTERNATIVE MEASURES.—Such regulation or guidance shall allow the owner, operator, or agent of a facility to implement an alternative preventive measure 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 measure effectively addresses the hazard.

''(e) REQUIREMENT TO REASSESS AND REVISE.—

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

''(A) review the food defense assessment under subsection (b)(1) for the facility and, as necessary, revise the food defense assessment under subsection (b)(1) 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 food defense assessment; and

''(iii) if the Secretary determines that it is appropriate to protect public health; and

''(B) whenever there is a change in the food defense assessment, revise the preventive measures under subsection (b)(2) for the facility as necessary to ensure that for all hazards identified, the risk is minimized, 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 facility involved is located, or is an official senior to such director.

''(f) RECORDKEEPING.—The owner, operator, or agent of a facility shall maintain, for not less than 2 years, records documenting the activities described in subsections (b) and (e).

''(g) ACCESS TO PLAN.—

''(1) ON INSPECTION.—An officer or employee of the Secretary shall have access to the food defense plan of a facility under section 414(a) only if the Secretary, through an official who is the director of the district under this Act in which the facility is located or an official who is senior to such a director, provides notice under section 414(a)(1)(C).

''(2) NONDISCLOSURE.—A food defense plan, and any information derived from such a plan, shall be exempt from disclosure under section 552 of title 5, United States Code.''.

(3) PROHIBITION.—Section 301(j) (21 U.S.C. 331(j)) is amended by inserting after ''entitled to protection'' the following: ''or a food defense plan, or any information derived from such a plan, under section 418C''.

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. Notwithstanding the timelines set forth in this paragraph, the Secretary shall as appropriate establish such science-based performance standards for identified contaminants as necessary to protect the public health.

''(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) SAMPLING PROGRAM.—In conjunction with the establishment of a performance standard under this section, the Secretary may make recommendations to industry for conducting product sampling.

''(d) 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, in coordination with the Secretary of Agriculture, shall establish by regulation scientific and risk-based food safety standards for the growing, harvesting, processing, packing, sorting, transporting, and holding of those types of raw agricultural commodities—

''(1) that are a fruit, vegetable, nut, or fungus; and

''(2) for which the Secretary has determined that such standards are reasonably necessary to minimize the risk of serious adverse health consequences or death to humans or animals.

''(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 a fruit, vegetable, nut, or 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) EDUCATION AND COMPLIANCE.—The Secretary shall coordinate with the Secretary of Agriculture to provide for effective implementation of education and compliance activities. The Secretary 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(q); and

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

''(7) Before establishing or modifying the categorization under paragraph (4) of any food facility or type of food facility, the Secretary shall publish a notice of the proposed categorization in the Federal Register and provide a period of not less than 60 days for public comment on the proposed categorization.''.

(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—

(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.—Except as provided in paragraph (3), each person who manufactures, processes, packs, transports, distributes, receives, or holds an article of food in the United States or for import into the United States 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 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. Nothing in this subparagraph shall be construed as permitting a person to refuse to produce records required under and in accordance with subparagraph (A) due to failure of the Secretary to provide notice under this paragraph.

''(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.

''(3) LIMITED RECORDS ACCESS ON FARMS.—

''(A) APPLICATION.—Paragraphs (1) and (2) do not apply with respect to farms, except as provided in this paragraph.

''(B) IN GENERAL.—A person who is the owner, operator, or agent of a farm (as defined in section 415) shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to an article of food produced, manufactured, processed, packed, or held on such farm as specified in paragraphs (1) and (2) if—

''(i) such article of food is a fruit, vegetable, nut, or fungus that is the subject of a standard issued under section 419A; or

''(ii) such article of food is the subject of an active investigation by the Secretary of a food borne illness outbreak and is not a grain or similarly handled commodity as defined in subsection (c)(4)(C)(ii).

''(C) RECORDS ACCESS ON FARMS PRIOR TO RULEMAKING.—

''(i) IN GENERAL.—As soon as practicable after the enactment of this paragraph, the Secretary shall, in coordination with the Secretary of Agriculture, identify 1 or more fruits, vegetables, nuts, or fungi for which the Secretary shall have access to records on farms. Such identification shall be made by guidance, following notice and public comment.

''(ii) IDENTIFICATION OF RAW AGRICULTURAL COMMODITIES.—The Secretary, in coordination with the Secretary of Agriculture, shall make the identification in clause (i), based on any past food borne illness outbreak attributed to the fruit, vegetable, nut, or fungus—

''(I) in the United States and the risk that a similar outbreak could occur again in the United States; or

''(II) in a foreign country and the risk that a similar outbreak could occur in the United States.

''(iii) DURATION OF AUTHORITY.—The authority to have access to records for a fruit, vegetable, nut, or fungus under this subparagraph shall begin on the date on which the Secretary identifies such fruit, vegetable, nut, or fungus under clause (i) and shall terminate on the effective date of a final rule issued by the Secretary under section 419A.

''(iv) SCOPE OF RECORDS ACCESS.—In the guidance under clause (i), and for the period specified in clause (iii), the Secretary, in coordination with the Secretary of Agriculture, shall determine the scope of the records to which the Secretary shall have access under this subparagraph.

''(D) RULE OF CONSTRUCTION.—This paragraph shall not be construed as limiting access to any records authorized under—

''(i) this Act or the Public Health Service Act, as in effect on the day before the date of the enactment of this paragraph; or

''(ii) regulations issued under such Acts on any date before the date of the enactment of this paragraph.''.

(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, shall by regulation establish requirements regarding the establishment and maintenance, for not longer than 3 years, of records by persons who 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 subsection. The Secretary shall consult with the Secretary of Agriculture in promulgating regulations with respect to farms under this subsection and shall take into account the nature of and impact on farms in promulgating such regulations. 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 second sentence—

(A) by striking ''(excluding farms or restaurants)'' and inserting ''(excluding farms, except as provided in section 414(a)(3))'';

(B) by inserting ''receives,'' before ''holds'';

(C) by striking ''described in section 414'' and inserting ''described in or required under section 414''; and

(D) 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

(2) 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 1011; 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. The Secretary shall coordinate with the Secretary of Agriculture in conducting pilot projects with respect to farms under this subsection.

''(3) REGULATION.—

''(A) IN GENERAL.—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.

''(B) SCOPE OF REGULATION.—The Secretary may include in the regulations establishing a tracing system—

''(i) the establishment and maintenance of lot numbers;

''(ii) a standardized format for pedigree information; and

''(iii) the use of a common nomenclature for food.

''(C) COORDINATION REGARDING FARM IMPACT.—In issuing regulations under this paragraph that will impact farms, the Secretary—

''(i) shall coordinate with the Secretary of Agriculture; and

''(ii) take into account the nature of the impact of the regulations on farms.

''(4) EXEMPTIONS AND LIMITATIONS.—

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

''(i) produced on a farm; and

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

''(B) FISHING VESSELS.—Food is exempt from the requirements of this subsection if such food is produced through the use of a fishing vessel as defined in section 3(18) of the Magnuson-Stevens Fishery Conservation and Management Act until such time as the food is sold by the owner, operator, or agent in charge of such fishing vessel.

''(C) GRAINS AND SIMILARLY HANDLED COMMODITIES.—

''(i) LIMITATION ON EXTENT OF TRACING.—In addition to the exemption under subparagraph (A), any tracing system established under this subsection with regard to any grain or similarly handled commodity shall be limited to enabling the Secretary to identify persons who received, processed, packed, transported, distributed, held, or sold the grain or similarly handled commodity from the initial warehouse operator that held the grain or similarly handled commodity for any period of time to the ultimate consumer.

''(ii) DEFINITIONS.—In this subparagraph:

''(I) The term 'grain or similarly handled commodity' means wheat, corn, grain sorghum, barley, oats, rice, wild rice, rye, soybeans, legumes, sugar cane, sugar beets, sunflower seed, rapeseed, canola, safflower, flaxseed, mustard seed, crambe, sesame seed, camelina, cottonseed, cocoa beans, grass hay, and honey. The term may include any other commodity as determined by the Secretary in coordination with the Secretary of Agriculture.

''(II) The term 'warehouse operator' has the meaning given that term in section 2 of the United States Warehouse Act (7 U.S.C. 241), except that the term also includes any person or entity that handles or stores agricultural products for other persons or entities or, in the case of a cooperative, handles or stores agricultural products for its members, as determined by the Secretary in coordination with the Secretary of Agriculture.

''(D) EXEMPTION OF 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.

''(E) RECORDKEEPING REGARDING PREVIOUS SOURCES AND SUBSEQUENT RECIPIENTS.—For a food or person covered by a limitation or exemption under subparagraph (B), (C), or (D), the Secretary shall require each person who produces, receives, manufactures, processes, packs, transports, distributes, 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.

''(F) RECORDKEEPING BY 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.

''(G) RECORDKEEPING BY FARMS.—For a food covered by an exemption under subparagraph (A), farms 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(q) (requiring a certification of compliance for 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 such article is food being imported or offered for import into the United States and is not in compliance with the requirement of subsection (q) (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:

''(q) CERTIFICATIONS CONCERNING IMPORTED ARTICLES.—

''(1) IN GENERAL.—

''(A) REQUIREMENT.—The Secretary may 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 requirements of this Act as specified by the Secretary if—

''(i) for food imported from a particular country, territory, or region, the Secretary finds, based on scientific, risk-based evidence, that the government controls in such country, territory, or region are inadequate to ensure that the article is safe and that certification would assist the Secretary in determining whether to refuse to admit such article under subsection (a);

''(ii) for a type of food for which there is scientific evidence that there is a particular risk associated with the food that presents a threat of serious adverse health consequences or death, the Secretary finds that certification would assist the Secretary in determining whether to refuse to admit such article under subsection (a); or

''(iii) for an article imported from a particular country or territory, there is an agreement between the Secretary and the government of such country or territory providing for such certification.

''(B) FORM OF CERTIFICATION.—A certification under subparagraph (A) may take the form of a statement that the article or the facility or farm that manufactured, processed, packed, held, grew, harvested, sorted, or transported the article, as the case may be, complies with requirements of this Act as specified by the Secretary, or any other form as the Secretary may specify, including a listing of certified facilities or other entities. The Secretary may require that the certification include additional information regarding compliance.

''(C) ADEQUATE GOVERNMENT CONTROLS.—

''(i) PROCESS.—Before requiring a certification under clause (ii) of subparagraph (A) with respect to a food, the Secretary shall establish a process by which a country or territory may demonstrate that its government controls are adequate to ensure that such food exported from its territory to the United States is safe.

''(ii) DEMONSTRATION.—The Secretary shall not require a certification under clause (ii) of subparagraph (A) for a food exported from a country or territory, if that country or territory has demonstrated, pursuant to the process established by the Secretary under clause (i), that its government controls are adequate to ensure that such food exported from its territory to the United States is safe.

''(D) 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).

''(E) CONSISTENCY WITH INTERNATIONAL OBLIGATIONS.—The Secretary shall apply this paragraph consistently with United States obligations under international agreements.

''(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. In issuing these regulations, the Secretary may rely on or incorporate international certification standards.

''(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—

''(I) obtain and maintain annual declarations from all personnel who may be directly involved in the performance of audits as to whether they do or do not have direct financial interests in any producer, manufacturer, processor, packer, holder, supplier, or vendor of foods, and a list of any such companies in which they do have financial interests or by which they were employed in the past year; and

''(II) when an auditor is assigned to audit a facility, require that individual to affirm that he or she has no financial interest in the company that owns or operates that facility and was not employed by that facility in the previous year;

''(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) DEFINITIONS.—In this paragraph:

''(i) The term 'anything of value' includes gifts, gratuities, reimbursement of non-audit-related expenses, entertainment, loans, or any other form of compensation in cash or in kind.

''(ii) The term 'direct financial interest' does not include any ownership of mutual funds that have a financial interest in a company.

''(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) ON-SITE AUDITS.—In evaluating whether an accreditation body meets, or continues to meet, the standards for recognition under this subsection, or whether to accept certifications from a qualified certifying entity, the Secretary may—

''(A) observe on-site audits of qualified certifying entities by such accreditation body; or

''(B) for any facility that is certified by a qualified certifying entity, 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 on-site audit of the facility, which shall include access to, and copying and verification of, any related records.

''(6) ELECTRONIC SUBMISSION.—The Secretary shall provide, in coordination with the Commissioner responsible for Customs and Border Protection, for the electronic submission of certifications under this subsection.

''(7) 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:

''(uu) 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) FEDERAL LABORATORY TESTING.—If Customs and Border Protection laboratory testing concludes that an article of food is adulterated or misbranded, the Secretary shall consider and utilize as appropriate the testing results issued by the Customs and Border Protection laboratories in making a decision about the admissibility of the product.

''(j) 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:

''(vv)(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(s) 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 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 credible evidence or information 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(vv)(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(s) with respect to importation of such food.'';

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

''(3) REPORTING BY FARMS, 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 farms, 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 in coordination with the Commissioner responsible for Customs and Border Protection 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 in consultation with the Commissioner responsible for Customs and Border Protection safety and security guidelines applicable to the importation of food taking into account, to the extent appropriate, other relevant Federal programs, such as the Customs-Trade Partnership Against Terrorism (C-TPAT) programs under section 211 of the Security and Accountability for Every Port Act of 2006.

''(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 (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—

''(1) it is not the subject of a registration made pursuant to section 412(c)(1)(A);

''(2) it is not the subject of a submission made pursuant to section 412(c)(1)(B), or

''(3) at least 90 days have not passed since the making of such registration or of such submission to the Secretary.''.

(b) REQUIREMENTS.—Section 412 (21 U.S.C. 350a) is amended—

(1) in subsection (c)(1)(B), by striking ''(c)(1)'' at the end and inserting ''(d)(1), subject to subsection (d)(2)(B)'';

(2) in subsection (d)(1)—

(A) by striking ''and'' at the end of subparagraph (C);

(B) by striking the period at the end of subparagraph (D) and inserting '', and''; and

(C) by adding at the end the following:

''(E) information on any new ingredient in accordance with paragraph (2)(A).'';

(3) in subsection (d), by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(4) by inserting after paragraph (1) of subsection (d) the following:

''(2)(A) The description of any new infant formula required under paragraph (1) shall include, for any new ingredient for use in the formula—

''(i) a citation to a prior approval by the Secretary of the new ingredient for use in infant formula under section 409;

''(ii) a citation to or information showing a prior consideration of the new ingredient for use in infant formula under any program established by the Secretary for the review of ingredients used in food; or

''(iii) for a new ingredient that is not a food additive or a color additive, information equivalent to that provided under any program established by the Secretary for the review of ingredients used in food.

''(B) If the information submitted under subparagraph (A) is the information described in clause (iii) of such subparagraph, the 90 day period provided by subsection (c)(1)(B) shall not commence until the Secretary has completed review of the information submitted under such clause and has provided the submitter notice of the results of such review.''.

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 of Health and Human Services (in this subtitle referred to as 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 bio-surveillance 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 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. AUTHORITY TO PROHIBIT OR RESTRICT THE MOVEMENT OF FOOD.

(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:

''(ww) The violation of a prohibition or restriction under section 304(i).''.

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

''(i) AUTHORITY TO PROHIBIT OR RESTRICT THE MOVEMENT OF FOOD WITHIN A STATE OR PORTION OF A STATE.—

''(1) AUTHORITY TO PROHIBIT OR RESTRICT THE MOVEMENT OF FOOD.—

''(A) IN GENERAL.—

''(i) After consultation with the Governor or other appropriate official of an affected State, if the Secretary determines that there is credible evidence that an article of food presents an imminent threat of serious adverse health consequences or death to humans or animals, the Secretary may prohibit or restrict the movement of an article of food within a State or portion of a State for which the Secretary has credible evidence that such food is located within, or originated from, such State or portion thereof.

''(ii) In carrying out clause (i), the Secretary may prohibit or restrict the movement within a State or portion of a State of any article of food or means of conveyance of such article of food, if the Secretary determines that the prohibition or restriction is a necessary protection from an imminent threat of serious adverse health consequences or death to humans or animals.

''(2) NOTIFICATION PROCEDURES.—Subject to paragraph (3), before any action is taken in a State under this subsection, the Secretary shall—

''(A) notify the Governor or other appropriate official of the State affected by the proposed action;

''(B) issue a public announcement of the proposed action; and

''(C) publish in the Federal Register—

''(i) the findings of the Secretary that support the proposed action;

''(ii) a statement of the reasons for the proposed action; and

''(iii) a description of the proposed action, including—

''(I) the area affected; and

''(II) an estimate of the anticipated duration of the action.

''(3) NOTICE AFTER ACTION.—If it is not practicable to publish in the Federal Register the information required under paragraph (2)(C) before taking action under paragraph (1), the Secretary shall publish the information as soon as practicable, but not later than 10 business days, after commencement of the action.

''(4) APPLICATION OF LEAST DRASTIC ACTION.—No action shall be taken under paragraph (1) unless, in the opinion of the Secretary, there is no less drastic action that is feasible and that would be adequate to prevent the imminent threat of serious adverse health consequences or death to humans or animals.

''(5) NONDELEGATION.—An action under paragraph (1) may only be ordered by the Secretary or an official designated by the Secretary. An official may not be so designated unless the official is the Commissioner of Food and Drugs or the Principal Deputy Commissioner.

''(6) DURATION.—Fourteen days after the initiation of an action under paragraph (1), and each 14 days thereafter, if the Secretary determines that it is necessary to continue the action, the Secretary shall—

''(A) notify the Governor or other appropriate official of the State affected of the continuation of the action;

''(B) issue a public announcement of the continuation of the action; and

''(C) publish in the Federal Register the findings of the Secretary that support the continuation of the action, including an estimate of the anticipated duration of the action.

''(7) RULEMAKING.—The Secretary shall, consistent with national security interests and as appropriate for known hazards, establish by regulation standards for conducting actions under paragraph (1), including, as appropriate, sanitation standards and procedures to restore any affected equipment or means of conveyance to its status prior to an action under paragraph (1).''.

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:

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

''(yy) 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:

''(r) 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. When developing any regulation or guidance in accordance with this paragraph, to the extent that the collection of documentation or other information involves Customs and Border Protection efforts or resources, the Secretary shall consult with Customs and Border Protection.

''(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.

(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 country of origin marking 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:

''(zz) The failure to register in accordance with section 801(s).''.

(2) MISBRANDING.—Section 403 (21 U.S.C. 343) as amended by sections 101(a), 109(a), 114(a), and 202, 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(s).''.

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

''(s) 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 1011, 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 in accordance with the following:

''(A) The Secretary, in consultation with Customs and Border Protection, shall promulgate regulations to establish good importer practices that specify the measures an importer shall take to ensure imported food is in compliance with the requirements of this Act.

''(B) The measures under subparagraph (A) shall ensure that the importer of a food—

''(i) has adequate information about the food, its hazards, and the requirements of this Act applicable to such food;

''(ii) has adequate information or procedures in place to verify that both the food and each person that produced, manufactured, processed, packed, transported, or held the food, including components of the food, are in compliance with the requirements of this Act; and

''(iii) has adequate procedures in place to take corrective action, such as the ability to appropriately trace, withhold, and recall articles of food, if a food imported by the importer is not in compliance with the requirements of this Act.

''(C) In promulgating good importer practices regulations, the Secretary may, as appropriate—

''(i) incorporate certification of compliance under section 801(q) and participation in the safe and secure food importation program under section 805; and

''(ii) take into account differences among importers and the types of imports, including based on the level of risk posed by the imported food.

''(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 36 months after the date of the enactment of this Act, the Secretary of Health and Human Services in consultation with the Commissioner responsible for Customs and Border Protection shall promulgate the regulations required to carry out section 801(s) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (3). In establishing the effective date of a regulation promulgated

under section 801(s), the Secretary shall, in consultation with the Commissioner responsible for Customs and Border Protection, as appropriate, provide a reasonable period of time for importers of food to comply with good importer practices, taking into account differences among importers and the types of imports, including based on the level of risk posed by the imported food.

(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(s).

''(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(s), 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(s) 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.

(a) REGISTRATION.—

(1) PROHIBITIONS.—Section 301(zz) (21 U.S.C. 331), as added by section 204, is amended by inserting ''or 801(t)'' after ''801(s)''.

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

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

(B) by inserting ''or 801(t)'' after ''801(s)''.

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

''(t) REGISTRATION OF CUSTOMS BROKER.—

''(1) REGISTRATION.—The Secretary shall require a customs broker, 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 1011, to submit appropriate unique facility identifiers as a condition of registration.

''(2) 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 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 is updated or corrected no later than 7 days after notice is provided under subparagraph (B), the Secretary shall not cancel such registration.

''(3) NOTIFICATION.—The Secretary shall notify the Commissioner responsible for Customs and Border Protection whenever the Secretary cancels a registration under this subsection.

''(4) EXEMPTIONS.—In consultation with the Commissioner responsible for Customs and Border Protection, 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.

''(5) CIVIL PENALTIES.—Notwithstanding any other provision in this Act, a customs broker who violates section 301 because of a violation of section 403(ee), or who violates section 301(xx), 301(yy), or 301(zz), shall not be subject to a civil penalty under section 303(f)(2).''.

(4) REGULATIONS.—Not later than 24 months after the date of the enactment of this Act, the Secretary of Health and Human Services, in consultation with the Commissioner responsible for Customs and Border Protection, shall promulgate the regulations required to carry out section 801(t) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (2).

(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.—Every customs broker required to be registered with the Secretary 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, AND CUSTOM BROKERS.

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

"SEC. 1011. 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 AND CUSTOM BROKERS.—A person required to register pursuant to section 801(s) or 801(t) 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(s) or 801(t).

''(c) GUIDANCE.—The Secretary may, by guidance, and, with respect to importers and customs brokers, in consultation with the Commissioner responsible for Customs and Border Protection, 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. Development of such guidelines shall take into account the utilization of existing unique identification schemes and compatibility with customs automated systems, such as integration with the Automated Commercial Environment (ACE) and the International Trade Data System (ITDS), and any successor systems.

''(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 section 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: '', 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 ''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, or as is otherwise authorized by 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 X (21 U.S.C. 391 et seq.), as amended by section 206, is amended by adding at the end the following:

"SEC. 1012 PROTECTIONS FOR EMPLOYEES WHO REFUSE TO VIOLATE, OR WHO DISCLOSE VIOLATIONS OF, THIS 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, the employer, and the Commissioner of Food and Drugs.

''(C) BURDENS OF PROOF.—An action brought under paragraph (1)(A) or (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)(A) 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 paragraph (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 back pay); 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:

''(aaa) 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.

SEC. 216. LEAD CONTENT LABELING REQUIREMENT FOR CERAMIC TABLEWARE AND COOKWARE.

(a) IN GENERAL.—Section 403 (21 U.S.C. 343), as amended by sections 101(a), 109(a), 114(a), 202, and 204, is amended by adding at the end the following:

''(ff) If it is ceramic tableware or cookware and includes a glaze or decorations containing lead for an intended functional purpose, unless—

''(1) the product and its packaging bear the statement: 'This product is made with lead-based glaze consistent with Food and Drug Administration guidelines for such lead.'; or

''(2) the product is in compliance with the requirements applicable to ornamental and decorative ceramicware in section 109.16 of title 21, Code of Federal Regulations (or any successor regulation).''.

(b) EFFECTIVE DATE.—Section 403(ff) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall apply only to ceramic tableware or cookware that is manufactured on or after the date that is 1 year after the date of the enactment of this Act.

(c) CONSUMER EDUCATION.—Chapter IV (21 U.S.C. 341 et seq.), as amended by sections 102, 103, 104, and 111, is amended by adding at the end the following:

''SEC. 421. CONSUMER EDUCATION ON THE CONTENT OF LEAD IN CERAMICWARE AND APPLICABLE LABELING REQUIREMENTS.

''(a) IN GENERAL.—The Secretary shall educate consumers on the safety of ceramicware for food use by posting information on the Web site of the Food and Drug Administration with regard to—

''(1) the content of lead in ceramicware and its glaze;

''(2) existing Federal laws and regulations governing lead in ceramicware;

''(3) as appropriate, existing industry practices and guidelines; and

''(4) the labeling requirements applicable under this Act.

''(b) TOPICS.—The education under this section shall address—

''(1) the broad range of ceramicware types, including traditional pottery, ornamental and decorative ceramicware, cookware, and everyday dinnerware;

''(2) the safety of ceramicware that is aged or damaged;

''(3) the use of ceramicware in microwave ovens;

''(4) the storage of foods in ceramicware;

''(5) the use of home lead test kits by consumers;

''(6) the use of ceramicware by children and women of childbearing age; and

''(7) issues that are especially relevant to subpopulations of consumers who may preferentially use certain types of ceramicware made with lead.''.

The SPEAKER pro tempore. The gentleman from Michigan (Mr. DINGELL) and the gentleman from Illinois (Mr. SHIMKUS) each will control 30 minutes.

The Chair recognizes the gentleman from Michigan.

Mr. DINGELL. Mr. Speaker, I yield myself 3 minutes.

Mr. Speaker, I rise in strong support of H.R. 2749, the Food Safety Enhancement Act of 2009.

I remind my colleagues that this bill was up before us yesterday and got 280-something votes in favor of it. It is a good piece of legislation. It is bipartisan. It will fundamentally change the way in which we ensure the safety of our food supply and protect American consumers, farmers and business. I would note it came out of committee in a bipartisan fashion, unanimously, by voice vote.

A series of foodborne disease outbreaks have laid bare unacceptable gaps in our food-safety laws, and this will be the first major change in our food-safety laws with regard to food and drugs since 1938.

In the past 2 years alone, we have witnessed issues of melamine in infant formula and in milk products, and we have seen tainted peppers from Mexico, harmful seafood and shellfish from China, E. coli in spinach, and problems with strawberries and raspberries. Each year, in spite of the fact that we have the most careful and safe food in the world, we find that 76 million people contact a foodborne illness in the United States. According to CDC, some 5,000 die.

This legislation contains significant policy solutions that will address this situation. It is largely based upon legislation I introduced last year along with Energy and Commerce subcommittee Chairmen Pallone and Stupak.

We have worked for months with our Republican colleagues in a bipartisan fashion on the Committee on Energy and Commerce to get this bill right. We have worked with our colleagues on the Agriculture and the Ways and Means Committees to address their concerns, and I believe we have done so.

In the end, we have a bill that strikes an important balance; it does not create unnecessary burdens for farmers and small businesses, but it does allow FDA to retain all its existing authority. It takes no authority from the Department of Agriculture or the Committee on Agriculture, and it gives FDA new authorities that it needs to trace and prevent food-safety problems that may originate on the farm or in other sectors of the food supply chain. And we have carefully protected the farmers against intrusion by the Food and Drug Administration.

I want to talk about key provisions in the bill. Under the legislation, FDA has clear authority to issue and require manufacturers to meet strong, enforceable performance standards to ensure the safety of different types of food.

FDA will establish a food trace-back system so that the public health officials can easily determine the source of foodborne disease outbreaks and protect farmers and producers against unwise and inadequate judgments because of lack of personnel and money.

FDA is going to be required to inspect all food facilities more frequently. And the bill requires FDA to inspect the riskiest ones at least once per year.

FDA will be given new authority to ensure that imported foods are safe, a source of major concern and hazard to our people.

FDA will be given new tools—recalls, record access, penalties to punish bad actors, and the ability to act quickly when presented with a food-safety emergency.

FDA will get a new dedicated source of funding from a $500 million annual registration fee on food facilities to help it conduct its work of keeping America safe. And this provision and the rest of the bill are supported by American food producers.

FDA will not be the only cop on the beat. Our food producers will focus also on prevention and have a well-deserved and shared responsibility between FDA and food manufacturers to keep our food supplies safe.

The bill will require manufacturers to implement preventive systems to stop outbreaks before they occur. All food facilities will be required to conduct hazard analyses, assess potential food-safety risks, and develop plans to keep the food supply safe.

Mr. Speaker, there is nothing in this bill that is overly burdensome for farmers small or big. We have worked hard—and I believe we have succeeded—in protecting farms of the family size from burdens that could harm their business and their way of life. My own district has many small farms and people with whom I work closely on agricultural matters, and I believe that they will be satisfied with this legislation.

It is a fact here—and I want to address the concerns that I have heard—that farmers who sell a majority of their product direct to the consumers are exempt from the fee system in this bill. Farms that sell directly to consumers, restaurants, and grocery stores will also be exempt from the trace-back system.

Some have expressed concern that FDA will have access to confidential farm records and make them available for distribution. This is not so. FDA is already limited in the types of records they can access under the law, and they cannot access financial data, pricing data, personnel data, research data, or sales data other than shipment data regarding sales.

The SPEAKER pro tempore. The gentleman's time has expired.

Mr. DINGELL. Mr. Chairman, I yield myself 1 additional minute.

I have also heard concern that FDA will have the authority to issue safety standards that will apply to farms and interfere with organic farming practices. I want to make it clear that that is not so. In fact, FDA is prohibited from imposing safety standards unless it determines those standards are ''reasonably necessary to minimize the risk of serious adverse health consequences or death,'' a very, very high standard that they have to meet. This will ensure protection of the concerns of organic farmers and that they are taken into consideration before issuing standards. This is why it has the support of the distinguished chairman of the Agriculture Committee and members of that committee from both sides of the aisle.

Mr. Speaker, this is a product of bipartisan cooperation. It is supported by industry. It was approved unanimously by a voice vote in the Energy and Commerce Committee. It reflects findings of more than 20 hearings on the failure of our food system safety processes conducted by five different committees of the House over 3 years. It addresses weaknesses in the food-safety system at FDA that were identified under the Bush administration and included in concerns under the current administration.

H.R. 2749 it is a well-vetted, mature piece of legislation. I urge my colleagues to support H.R. 2749. It is old enough to vote; it is over 21 years old.

I urge my colleagues to support this legislation. It is a good bill. It will protect the American people, the American consumers, and it will not hurt American industry, which supports this bill.

Mr. Speaker, I reserve the balance of my time.

Mr. SHIMKUS. Mr. Speaker, I yield myself such time as I may consume.

I was a member of the Oversight and Investigation Subcommittee in the last Congress, serving 10 or 12 months in that position. And every time we had a hearing on some unsafe food product, another outbreak would occur. So we knew that we really had to get our heads together and try to address food-safety issues, and we think we've done that with this bill.

I want to thank Chairman Emeritus DINGELL and I want to thank Chairman WAXMAN, Chairman PALLONE and Chairman STUPAK for working with Ranking Member BARTON and DEAL and myself to really move the bill forward in a way that we could pass it on a voice vote. I just only wish—and I think we could do this, we could do this on energy and we could do this on health if we really sat down and tried to work out the differences.

This is not an easy bill to pass. And as Chairman Emeritus DINGELL said, 21 years he has been working on this. And this is not an easy thing to do. We did all we could. And I do appreciate the time that we spent on the floor and then with staff to work out the difficult options. And so we come here today with a pretty united bill, one that would have passed had it not been on the suspension calendar, and so we bring it up again today.

We have to have confidence in our food supply, and that's what we're trying to do in this bill. And this bill takes the necessary steps to move us forward.

The changes that we have made not just in the original text of the bill, but in addressing some of the concerns we think are very, very helpful. And I want to pledge to my ag Republican friends—and I'm from an agricultural district, and a lot of these groups that support them are good friends of mine. And we want to ensure that we continue to work forward and move forward as the bill does.

A couple of issues that Chairman Emeritus DINGELL said was, you know, the bill does not require farms to register with FDA, and as a result farms do not have to pay a registration fee. Access to farm records is significantly restricted. Livestock and poultry are exempt from the bill. Grain and related commodities are exempt from produce standards. USDA regulated farms, facilities, and products are not subject to the bill. It allows farms to be exempt from the traceability requirements.

We, as a committee, both in the Oversight and Investigation and then as a full committee, we just couldn't sit on the sidelines anymore as we saw case after case of food-borne illnesses. We had to come together in a way to address this.

□ 1630

I think we have done it. I think it's a good product. Can there be some fixes as it moves forward? Yes, there can. But I would ask all my colleagues to support this bill.

Mr. Speaker, I reserve the balance of my time.

Mr. DINGELL. I want to thank the gentleman for his hard work both in the Investigations Subcommittee and on the legislation. He and Mr. DEAL and the ranking Republican member, our good friend Mr. BARTON, have been enormously valuable in the work that has been done to bring us to where we are. I commend him and I thank him.

Mr. Speaker, I yield at this time 2 minutes to the distinguished chairwoman of the Appropriations Subcommittee of jurisdiction on this matter, Ms. DELAURO.

Ms. DELAURO. Mr. Speaker, what is this bill about? What is it about?

Food-borne illness in the United States of America kills 5,000 people every single year.

We went to war in Iraq and Afghanistan when 3,000 people, unbeknownst that when they went to work that day that they weren't coming home, and we went to war in Afghanistan as a result.

We know that 5,000 people every year die of a food-borne illness and an illness, my friends, that can be prevented.

Stand with the mother and the father of a 2-year-old child, the parents who went to the grocery store and brought home spinach or lettuce or sprouts or tomatoes and their child died because of E.coli. Stand with the son and daughter of an elderly person in a nursing home who ate a peanut-based product and wound up dying because of that, having survived illness. That's what this bill is all about.

We can prevent food-borne illness in the United States of America. We can prevent 5,000 deaths every year. That's what this bill is focused on. It is of critical importance. It is about the health and the safety of American families. That health and safety is not only threatened in airports and border checkpoints or harbor containers. It's in fridges, on kitchen tables.

And for too long the cornerstone of our food safety system, the FDA, has only rudimentary, ancient tools and an outdated mandate at its disposal. This bill rectifies that oversight. It gives the FDA the means to deal with the dangers that are posed by our global food system. It enhances the agency's ability to stem microbial illnesses, prevent contamination before it happens.

It looks at risk-based inspection and says, what are the foods that are at highest risk? Let's set up some performance standards to deal with that. Let's put mechanisms in place so that we can trace the contamination and make sure we find it and find it quickly, protect the public health, and, yes, protect industry as well. That was part of this effort as well.

Performance standards are the backbone for monitoring an effective process and a control system. I would urge the FDA to develop testing protocols for each performance standard that it sets. This would include ongoing industry testing programs, supported by periodic sampling by the FDA.

The SPEAKER pro tempore. The time of the gentlewoman has expired.

Mr. DINGELL. Mr. Speaker, I yield the distinguished gentlewoman an additional 30 seconds.

Ms. DELAURO. Thank you. We have an opportunity. The laws and the statutes at the Food and Drug Administration today are inadequate to protect the food and the safety of the American people and at the very same time they put at risk the industries that deal with these products. The industry has come forward and said, Give us standards. That's what this bill is all about.

We have an obligation today to pass this bill and to make sure that we say to the American people we are doing everything that we can to prevent 5,000 deaths every single year and particularly the most vulnerable, our children and the elderly.

Mr. SHIMKUS. Mr. Speaker, I yield such time as he may consume to the gentleman from Michigan (Mr. UPTON), who is ranking member on the Energy and Air Quality Subcommittee.

Mr. UPTON. Mr. Speaker, let's face it: the recent events have shown us that the current system regarding food safety is not working. And I want to compliment those Members that have been actively involved in this, those from our Committee on Oversight and Investigations that exposed many of the problems, obviously the leadership on both sides, Republicans and Democrats, as we moved this bill through our subcommittee and then full committee by a voice vote.

The Oversight and Investigations Subcommittee found severe problems. We are very aware of those problems because those problems have been exposed nationally. Obviously, we have a number of very bad actors, but they have jeopardized the whole food chain. We remember the peanut butter issue and spinach and tomatoes. We need to be deliberate to tackle the issue and obviously be bipartisan to resolve the issue, and that's what this legislation does.

As Mr. SHIMKUS indicated, farms are not required to register with the FDA. There are no large fees associated with this bill. There is no duplication with the USDA, as I understand it.

My district in southwest Michigan has a whole number of different food sources from fruits and vegetables to giant food processors and great companies like Kellogg's. Industry is united behind this legislation. It needs to happen so that consumers will know for sure that there is a mechanism in place to identify when a product, in fact, is bad, that needs to be recalled. And this bill, as it has moved through committee, has shown that bipartisan support.

I would urge my colleagues on both sides to support it.

Mr. DINGELL. Mr. Speaker, I yield at this time 3 minutes to the distinguished gentleman from California (Mr. FARR).

Mr. FARR. I thank the chairman for yielding.

Mr. Speaker, I rise to engage in a colloquy with my friend, the distinguished gentleman from Michigan (Mr. DINGELL).

We are passing an historic food safety measure today, and I truly appreciate the effort that you and committee staff have made to move this legislation to the floor today. As a Member of Congress who represents the Salad Bowl of the World, Salinas Valley, I feel landmark legislation is long overdue and look forward to working with my colleague as the process moves to the Senate and to the conference committee.

Also as a member of the Agriculture Appropriations Committee, I look forward to working with the gentleman to allocate the resources necessary to make the safest food in the world even safer.

I'd be remiss if I didn't mention my concerns with the fee structure in this measure, and I appreciate the effort by the chairman and the committee, and it's my preference to find a more equitable fee that does not inhibit our farm families from taking advantage of new markets. As a member of the Organic Caucus, I have concerns about the interplay between this bill and the National Organic Program.

It is my understanding, Mr. Chairman, that this bill would not establish any requirements for organically produced or processed products which are in conflict with the requirements established in the Organic Foods Production Act of 1990 and USDA's National Organic Program regulations.

Mr. DINGELL. If the gentleman would yield, the answer to that question is, yes.

Mr. FARR. Thank you. And would this bill necessarily require small farms to participate in the expensive and unworkable electronic traceability system that FDA will set up?

Mr. DINGELL. The answer to that question is, no.

Mr. FARR. I yield to Mr. BLUMENAUER from Oregon, who has worked with Ms. KAPTUR and myself to make sure that the organic and small growers and processors' concerns have a voice.

Mr. BLUMENAUER. I appreciate the gentleman's courtesy, as I appreciate the leadership of the chairman. And it's great to see food safety receive the full attention that it deserves.

I am especially concerned about the language regarding interaction between wildlife, livestock, and farming practices. Biodiversity is a prerequisite for a healthy farm. We should not penalize farmers for utilizing techniques such as naturescaping, floodplain restoration, and natural hedgerows to encourage crop health, control pests and invasive species, and enhance soil quality.

We should target reform and safety efforts towards practices which have been directly linked to food disease outbreaks rather than limiting approaches that farmers have used for centuries to reduce their dependence on pesticides, herbicides, and other carbon-intensive farming techniques.

I would like the assurance from the chairman that he will work with us as Food and Drug Administration develops these criteria so that they will consider the needs of small farms and the practices of organic farmers.

Mr. DINGELL. The answer to that question is, yes; and I will have a more detailed response.

Mr. BLUMENAUER. Thank you, Mr. Chairman, for your courtesy.

Thank you, Mr. FARR, for permitting me to participate in this colloquy.

Mr. DINGELL. If the gentleman from California would yield, I would like to give a more exhaustive response to my friends.

First, we've been hearing complaints that the bill will put unfair, inappropriate, and unnecessary burdens on farmers, particularly small, diversified, and organic farms. We have worked hard to avoid doing that. I want to tell my good friends we would be extremely concerned if this bill created a conflict between food safety and other farm practices aimed at protecting and sustaining the environment. The bill therefore has a number of important provisions designed to prevent such conflicts.

For example, it requires FDA to take into consideration the impacts of any produced food safety standards on small-scale and diversified farms or on wildlife habitat, on conservation practices, watershed protection efforts, and organic production methods. It prohibits FDA from setting any such standards unless these standards are necessary to minimize the risk of serious adverse health consequences or death.

The bill also requires FDA to work in coordination with the U.S. Department of Agriculture to issue such standards. USDA administers the National Organic Program and will be working with FDA to ensure that the safety standards are compatible with organic standards.

Let me speak now to the question about the traceability system in the bill. The traceability provisions in the bill are a critically important part because they allow FDA to quickly track down the sources of food-borne outbreaks. Before FDA can establish any traceability requirements, the bill requires FDA to go through an extensive information-gathering process with public meetings and a pilot project.

As a part of the process, it requires FDA to consider the costs and the benefits and the feasibility for different sectors of the food industry of any traceability technologies under consideration. And for any regulation that would have an impact on farms, FDA must coordinate with USDA and take into account the nature of the impact on the regulation on farms.

Additionally, FDA will be prohibited from requiring farms selling food directly to consumers, restaurants, or grocery stores to participate in this system.

So I believe we can be confident that whatever traceability system is developed will appropriately take into account the needs and interests of the farmers. And I assure my two good friends that I will work with them to see to it that these commitments are kept.

Mr. FARR. Thank you, Mr. Chairman. I really appreciate that.

Mr. BLUMENAUER. Thank you, sir.

Mr. DINGELL. I thank my two colleagues for their valuable assistance to the committee.

Mr. SHIMKUS. Mr. Speaker, before I yield time to my colleague, I yield myself 15 seconds.

Mr. Speaker, I want to recognize my colleagues Mr. PUTNAM and Mr. COSTA for their bill, the Safe FEAST Act, which I was an original cosponsor on, which got rolled into this bill, and it was of great help when they did that.

Mr. Speaker, I yield such time as he may consume to my colleague from Florida (Mr. PUTNAM).

Mr. PUTNAM. I thank my friend from Illinois for his leadership on this issue and his original cosponsorship of that Safe FEAST Act, which has had a number of its key principles incorporated into the bill that we're debating today.

I rise in support of the bill that we are debating today. It is a bipartisan bill built on a bipartisan effort and a model that could and should be followed for the other big issues facing this Congress. It's unfortunate that the process that was taken did not adequately include our Agriculture Committee, and I would hope that as we move this issue forward that it will continue to improve upon that because it is important that our Agriculture Committee and our Representatives from rural America have input into this, and the bill will benefit from their input.

□ 1645

The scares that have undermined consumer confidence in our food supply over the last several years have as oftentimes been a result of international food products, imported food goods, as they have been domestic. This bill takes an important step forward in setting the same standards on imported food that we place upon domestically produced food as well. That is a major step in the right direction.

One only need look at the controversy over baby formula, at the economic devastation that came from the misleading public statements by the FDA about tomatoes that were grown in America, which turned out to have been food-borne illness resulting from jalapeños imported from Mexico, to learn the lesson that this legislation must apply the same standards to imported foods as it does to domestic.

This legislation implements risk-based assessments, something that is very important as we look at the breadth and depth of the food industry as it has become globalized. As the world has grown smaller, as America's tastes and preferences have changed and they desire produce from Latin America and spices from Asia, these challenges will continue to grow, and this, by placing risk-based science into the bill, will allow us to build up and maintain public confidence in our food supply.

And that is really the crux of the matter between our producers and our consumers, that on this issue of food safety, there is no distinction between the interests of the farmer and the shopper in the grocery store, because the farmer loses out if FDA and USDA cannot rapidly and accurately trace back the source of food-borne illness.

If they paint the industry with a broad brush, economic losses are severe, so the interests of the farmer are that we have a modern, effective regulatory system. The interests of the consumer are that we have a modern, effective regulatory system, so that they have a high level of confidence in the items that they purchase to put on their family's kitchen table. There must be the highest possible standard and the best possible science behind that law.

As this issue moves forward, improvements can be made as it relates to the quarantine, as it relates to traceability, and, most importantly, as it relates to the implementation of this bill for State and local governments, the State Departments of Agriculture and Health, who, by definition, are delegated much of the responsibility by FDA to implement this legislation. They must have the resources and the authority and the full cooperation of FDA. There have been breakdowns in the past where FDA did not share as much as they should. This bill does much to address that, and can do a bit more.

And in an era where organic farming continues to grow in popularity, we must be sensitive to these ever-changing forms and trends in American agriculture.

With that, I am proud to support the legislation, and I appreciate the leadership of my friend from Illinois and my friend from Michigan.

Mr. DINGELL. If the gentleman will yield to me just briefly, I want to commend the gentleman not just for a fine statement, but also for the long and strong support he has given for this kind of legislation and protection for industry and for the consumers.

I would like to observe that the concerns the gentleman has expressed are very valuable and are included in the legislation, particularly in seeing to it that foreigners now have to meet the same requirement that Americans do.

Americans produce and process safe food. Foreigners do not. This will assure our people that they can rely on Food and Drug to protect them not just from American producers and from American processors, but also from the foreigners, who are slipping in dangerous substances.

I want to commend the gentleman and thank him.

Mr. PUTNAM. I thank the chairman emeritus and the dean of the House.

Mr. DINGELL. Mr. Speaker, I am delighted at this time to yield 1 minute to the distinguished gentleman from Georgia (Mr. SCOTT), the chairman of the Subcommittee on Livestock, Dairy and Poultry.

Mr. SCOTT of Georgia. I thank the chairman for yielding.

I just want to state that under the auspices of my subcommittee, food safety is a jurisdiction that we handle. It is very important as we move forward on this to understand that we have got to make our food supply safe. There is no greater thing we can do for the American people and the people of the world than to give absolute assurance that our food supply is safe.

Now, I come from a State, Georgia, where we had an outbreak from salmonella in which we lost eight lives, eight persons that would be alive today if we had this bill in place, because we would have a process of accessing records that we don't have now.

Before this bill is passed, in order to get records from a manufacturer or food processing plant, we can't get it until the food outbreak occurs. But under this bill, when we are inspecting the plant, we will be able to get access to those records. If this was in place, eight Americans would be alive today.

Mr. Speaker, 76 million Americans suffer from food poisoning from our food supply a year; 5,000 are dying.

The SPEAKER pro tempore. The time of the gentleman from Georgia has expired.

Mr. DINGLE. I yield the gentleman 30 seconds more.

Mr. SCOTT of Georgia. Five thousand are dying. There is no more plain thing we can do.

And I have heard some comments from those who oppose this bill that this bill does nothing, but it does, Mr. Speaker. It provides for us to have inspections at food plants every 6 to 12 months. Do you know how often we are inspecting them now? Once every 10 years. The American people deserve better than that. They deserve for us to have a trace-back system so that we can trace back and get the origins of the outbreak as quickly as possible.

This is a tremendous bill, a tremendous bipartisan effort, and the American people are expecting us to pass it, and pass it overwhelmingly.

Mr. SHIMKUS. Mr. Speaker, I don't have any additional speakers. I reserve my time.

Mr. DINGELL. Mr. Speaker, I yield to the distinguished gentlewoman from New York (Mrs. MALONEY) for purposes of making a unanimous consent request.

(Mrs. MALONEY asked and was given permission to revise and extend her remarks.)

Mrs. MALONEY. Mr. Speaker, I rise in strong support of this bill.

In recent years, a series of outbreaks of food-borne illnesses have made clear the need to effectively secure our nation's food supply.

From spinach to cookie dough, foods have become contaminated and have threatened the health of the American people, exposing widespread problems with the food safety system in this country. H.R. 2749 will fundamentally change the way we ensure the safety of the foods we eat.

This bipartisan bill will provide the FDA with new powers and the tools it needs to protect the food supply by providing for more frequent inspections of food-processing plants here in the U.S. and by ensuring the safety of foods imported from overseas.

H.R. 2749 will also provide a new focus on the prevention of food-borne illness by putting systems in place that allow us to better track the source of these outbreaks. This legislation is critical to the health and safety of the American people, and I urge my colleagues to support it.

Mr. SHIMKUS. Mr. Speaker, I continue to reserve.

Mr. DINGELL. Mr. Speaker, at this time I yield 2 minutes to my distinguished friend, the gentleman from Utah (Mr. MATHESON), a superb Member of this body and a great friend of mine.

Mr. MATHESON. Mr. Speaker, I thank the gentleman for yielding.

Included in this bill was the manager's amendment addressing an issue that I raised that Mr. DINGELL has worked long and hard on and helped me figure out a way to address concerns about, lead glazing on ceramic plates on which we eat our food.

This issue first came to my attention with reports in my home State of Utah when a child was sick. After they analyzed the child, they determined the child had lead poisoning. They investigated the home where this child was living and couldn't find any sources of lead.

Ultimately it was discovered that the child's mother had been heating food in the microwave oven. The ceramic bowl or plate she was using wasn't properly glazed or wasn't properly sealed, and lead was leaching out of the plate into the food. Then when she would nurse the baby, the baby would get lead poisoning.

I think we all want to take steps to prevent that type of thing from happening. What we determined is most people don't even realize lead glazing is used on these plates. These plates come in with FDA labels, because the Food and Drug Administration has authority over it, so people who see a label from the Federal Government probably assume it safe.

Included in the manager's amendment is a requirement that there is labeling, just so consumers have the right to know, that it contains a lead-glazed product. If it is properly glazed, it is not necessarily dangerous. But people have the right to know that.

I really commend my friend from Michigan, who has been working on this issue and has been aware of it for a long time. He worked with my office extensively to come up with some way to try to at least make some progress on this issue. It is included in this bill. He is a great legislator, and I am glad he helped me figure that out.

I encourage people to support this bill.

Mr. DINGELL. Mr. Speaker, if the gentleman will yield, I would appreciate it if the gentleman didn't praise me, and instead let me say good words about him.

He is a valuable member, a valuable member of our committee. He works hard. He is smart and decent and has been great on this issue. We are proud of him.

Mr. SHIMKUS. I continue to reserve, Mr. Speaker.

Mr. DINGELL. Mr. Speaker, at this time it is my privilege to yield 3 minutes to the gentleman from Minnesota (Mr. PETERSON), a very distinguished Member of this body, the chairman of the Agriculture Committee in the House and an extremely wise defender of American agriculture and American farmers.

Mr. PETERSON. Mr. Speaker, I thank the gentleman for yielding.

I first want to commend Chairman Emeritus DINGELL for all of his hard work on this issue, not only during this session of Congress but in many sessions past. We are hopeful that we can move this legislation forward and get additional safeguards in place for food safety in this country.

We also want to commend the other members of the Energy and Commerce Committee on our side of the aisle and on the Republican side of the aisle for their work on this on a bipartisan basis. It is good to see some bipartisan effort happening in the House, and there was some good work done.

We did have some concerns in the Agriculture Committee that we engaged in some discussions and negotiations with Mr. DINGELL and others on the staff of the Energy and Commerce Committee on, and we think we have further improved the bill in terms of how it relates to agriculture. We were able to clarify things in terms of livestock and grain farmers that there was some concern about the language, so that we cleared up some things in terms of performance standards and record keeping.

As the bill came out of Energy and Commerce, there were concerns registered by some of the farm groups. Some of them even indicated they might oppose it. But at this point, because of the changes that have been made, we now have groups that in the past had some concerns, they are now either neutral or supporting this bill. The United Fresh Fruit and Vegetable Group, Western Growers, the American Farm Bureau, National Association of Wheat Growers, the Cattlemen Beef Association, Turkey Federation, Chicken Council, Pork Producers, Corn Growers, Soybean Association, Rice Federation, American Food Industry Association, United Egg Producers, the American Sheep Industry, the Wheat Growers and the Barley Growers, are now either supporting the legislation or are neutral on the legislation.

We believe that we have addressed the concerns of agriculture. We believe this is a good bill. I encourage Members to support this bill, and again commend my good friend and colleague

and the chairman emeritus, Mr. DINGELL, for the great work he has done, as well as his staff.

Mr. SHIMKUS. I continue to reserve, Mr. Speaker.

Mr. DINGELL. Mr. Speaker, I am the only speaker remaining on this side, so if my good friend from Illinois would like to proceed, I will follow him in closing.

Mr. SHIMKUS. Mr. Speaker, I yield myself such time as I may consume and will just close briefly by saying this is good to see on the floor.

We did take a very difficult issue, one that has been languishing for 21 years, and worked with young Members and new Members, like ADAM PUTNAM, and with the distinguished Chairman Emeritus DINGELL, and got into a room and moved a bill that has the support of almost everybody in the food processing and agriculture community and the marketing of this.

I have sat in numerous hearings, as I said in my opening statement, and every time we would have an oversight investigation hearing there would be an alert of another food-borne illness, and we just knew we couldn't continue down that route.

As my colleague Mr. PUTNAM said, it is going to be helpful to the farmers. It is going to be helpful to the processors when we bring some more security and safety and knowledge that we continue to produce the best food supply in the world. It also will help us with the imported products, and that was a big issue in our debate.

So, with that, this has worked well. We should try this bipartisan method on things like energy and things like health, and maybe we will get there in months to come, I hope, because this is a much better process than us fighting altogether.

With that, again, I thank Chairman Emeritus DINGELL, who really led the way for us to get to where we are today.

I yield back the balance of my time.

□ 1700

Mr. DINGELL. Mr. Speaker, I yield myself such time as I may consume. First, I want to commend my friend and colleague, Mr. SHIMKUS, and I want to express my gratitude to him. I also want to express my gratitude to Chairman WAXMAN, Chairman STUPAK and Chairman PALLONE, the legislative and appropriation and investigative committee chairmen of the Commerce Committee for the outstanding work they did in preparing this legislation. Also Representative DEGETTE and Representative SUTTON.

My colleagues Mr. BARTON, Mr. DEAL and Mr. SHIMKUS on the minority side have worked very well, carefully, thoughtfully with us, and I owe them a debt of thanks and gratitude. Staff Members like Rachel Sher and Eric Flamm have worked hard on this, as has my friend, Virgil Miller. Chairman PETERSON and JIM COSTA of the Agriculture Committee have been wise advisers and helpers in coming to a bill that could be agreed on by the two committees. Representative LEVIN, Chair of the Subcommittee on Trade of the Ways and Means Committee has been extremely important, as has Representative DELAURO, the Chair of the Appropriations Subcommittee. And Jeanne Ireland, a former staff member of this committee, has been of enormous help in the drafting of the legislation.

We had a long list of supporters. The Obama administration; Grocery Manufacturers Association—the people who sell are going to understand that they're being charged a participation fee; the Wine Institute; Wine America; Distilled Spirits Council of the United States; Center for Science in the Public Interest; Consumers Union; Consumers Federation of America; Center for Foodborne Illness Research & Prevention; Food & Water Watch; Government Accountability Project; National Consumers League; Pew Charitable Trusts; and Safe Tables Our Priority are all active supporters of this legislation.

And these agencies which previously had concerns about the legislation have either lifted their opposition, become neutral or actively support H.R. 2749: United Fresh Fruit and Vegetable; Western Growers; American Farm Bureau Federation; National Association of Wheat Growers; National Cattlemen's Beef Association; National Turkey Federation; National Chicken Council; National Pork Producers Council; National Corn Growers Association; American Soybean Association; U.S. Rice Federation; American Feed Industry Association; United Egg Producers; and the American Sheep Industry.

We have seen that in the long time since legislation was passed to bring food and drug up to national needs back in 1938, that many changes have occurred that have required significant changes, both in the authority of FDA, in its moneys and its abilities to deal, not just with domestic producing problems, but with problems overseas, from which we are receiving lots of dangerous and unsafe food commodities and food products.

This legislation gives food and drug the authority that it needs, the ability to trace, the ability to hold producers abroad accountable, and it sets up a system where foreigners have to participate in the same responsibilities American producers, manufacturers and growers have to, and it enables Food and Drug, for the first time, to have real authorities to enforce the laws of the United States on food safety to protect Americans against unsafe foods coming in from abroad.

And I would remind my colleagues that Food and Drug has neither the resources at the points of entry, nor do they have the personnel at those places to inspect foods coming in. This changes that situation. It is also true that the legislation does something else of importance to our people, and that is, it sees to it that where misbehavior occurs abroad, those same penalties that would be assessed against Americans are assessed against foreigners. This is an important matter of competition to American producers and manufacturers. It sees to it that they are fairly treated, and that there is no more unfair competition by people who could market unsafe commodities to the detriment of American consumers and American growers, producers and processors.

So the legislation is good. A system of assuring responsibility and traceability is available for the first time. And Food and Drug has the authority to terminate the ability of foreigners to sell in this country for the first time in a way which is consistent with American trade laws and the obligations of American people with regard to the safety of food. So, it is a good piece of legislation, and I would urge my colleagues to support it. I would have them know that this is bipartisan, this is a good piece of legislation. It is legislation which protects American people, which sees to it that Americans will no longer be dying of dangerous foods imported into the United States, and it will see to it that American producers are treated fairly in the world marketplace without jeopardy of violation of our law.

It also will see that Food and Drug has the personnel, the resources that it needs to protect the American people, and it is kind to the budget of the American taxpayers.

I yield back the balance of my time.

The SPEAKER pro tempore. All time for debate has expired.

Pursuant to House Resolution 691, the previous question is ordered on the bill, as amended.

The question is on the engrossment and third reading of the bill.

The bill was ordered to be engrossed and read a third time, and was read the third time.

MOTION TO RECOMMIT

Mr. LUCAS. Mr. Speaker, I have a motion to recommit at the desk.

The SPEAKER pro tempore. Is the gentleman opposed to the bill?

Mr. LUCAS. I am opposed to the bill in its current form.

The SPEAKER pro tempore. The Clerk will report the motion to recommit.

The Clerk read as follows:

Mr. Lucas moves to recommit the bill H.R. 2749 to the Committee on Energy and Commerce with instructions to report the bill back to the House forthwith with the following amendments:

Page 21, lines 3 and 4, strike subparagraph (B) and insert the following:

''(B) shall only be collected and available as follows:

''(i) Fifty percent shall be available to defray the costs of additional safety inspection of food in the United States.

''(ii) Fifty percent shall be available for use under section 137 of the Food Safety Enhancement Act of 2009.

Page 23, line 8, strike ''and''.

Page 23, line 11, strike the period and insert ''; and''.

Page 23, after line 11, insert the following:

''(F) preemptive purchase of product from facilities as defined in section 415.''.

At the end of subtitle C of title I add the following (and revise the table of contents in section 2 accordingly):

SEC. 137. PREEMPTIVE PURCHASE.

(a) IN GENERAL.—From the fees collected under section 743 of the Federal Food, Drug, and Cosmetic Act, as added by section 102, the Secretary of Health and Human Services may make a preemptive purchase related to activities by the Government in carrying out any provision of this Act or an amendment made by this Act.

(b) LIMITATION.—Notwithstanding subsection (a), the Secretary shall not make any payment under such subsection in excess of the amount of fees available under section 743(e)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act, as added by section 102.

Mr. DINGELL. I reserve a point of order, Mr. Speaker.

The SPEAKER pro tempore. The point of order is reserved.

Pursuant to the rule, the gentleman from Oklahoma is recognized for 5 minutes in support of the motion.

POINT OF ORDER

Mr. DINGELL. Mr. Speaker, I raise a point of order against the motion to recommit.

The SPEAKER pro tempore. The gentleman will state his point of order.

Mr. DINGELL. Under rule XVI, clause 7, and the language of the rule, it says no motion or proposition on a subject different from that under consideration shall be admitted under color of amendment. And I'd point out that that is applicable to the questions before us. I would note that the language of the motion does take and separates the receipts that will be gotten from the registration fees, so that 50 percent are available to defray the costs of additional safety inspection of food; but 50 percent shall be available for use under section 137. But the purpose of that is, rather, for the preemptive purchase of product from facilities as defined in section 415. This allows the broadest kind of purchase of food.

The legislation itself allows certain specific actions, none of which involve purchase of food, particularly under such broad circumstances as the motion allows. The bill only allows expenditure of these registration fees for the following purpose: records access, traceability, recall authority, authority to detain, subpoena authority, prohibition or restriction on the movement of bad food. No further authorities for purchase or expenditure of this money are permitted.

This goes well beyond the fundamental purpose of the legislation and, as such, it constitutes a violation of the rules, going beyond that which is the fundamental purpose of the legislation and so constituting a violation of rule XVI, clause 7 of being not germane.

The SPEAKER pro tempore. Does any other Member wish to be heard on the point of order?

Mr. LUCAS. Mr. Speaker, the nature of this bill contemplates a number of different things that try to address and protect the supply of domestic food in this country, food in general, I should say. The bill, the language offered, the motion, refers to using 50 percent of these fees collected under section 137 of the motion, which is referenced on the second page. This is just an additional item to all of the things already outlined in the bill in its present form.

The SPEAKER pro tempore. The Chair recognizes the gentleman from Michigan.

Mr. DINGELL. Mr. Speaker, I would observe that the language of the legislation nowhere authorizes purchase of food. Under the number of the legislation appears the language, to amend the Food, Drug and Cosmetic Act to improve the safety of food in the global market and for other purposes. And then, down there where you follow, following the words, a bill, and it says, to amend the Federal Food, Drug and Cosmetic Act to improve the safety of food in the global market and for other purposes. Nowhere in the legislation, in my reading, have I been able to find the authorization for the purchase of food or the purchase of food to achieve safety.

I would observe that the language of the motion to recommit permits the purchase of the food without restriction, without restraint or limit. It is some of the grandest authority that is given and well beyond any authority which Food and Drug now has or seeks. Food and Drug has no authority in this area whatsoever for the purchase of food. And the purchasing of food is not for the purpose of protecting the American people, of seeing to it that Food and Drug can properly assure the safety of the food or the protection of the American consumers. And the language that is, I think, most particularly descriptive of what the proposal does, it follows line 3 at page 2. It says, the Secretary of Health—and this is, I'm reading at line 6—the Secretary of Health and Human Services may make a preemptive purchase related to activities by the government in carrying out any provisions of this act or amendment made by this act.

□ 1715

That might be good language for the Committee on Agriculture to present to the House, but it is no language that you will find in Food and Drug and none that would be suggested by the commerce committee.

The SPEAKER pro tempore. If no other Member wishes to be heard, the Chair is prepared to rule.

The gentleman from Michigan makes a point of order that the amendment proposed in the motion to recommit offered by the gentleman from Oklahoma is not germane. The test of germaneness in this situation is the relationship of the amendment proposed in the motion to recommit to the provisions of the bill as a whole.

The bill, as perfected, amends the Federal Food, Drug, and Cosmetic Act to improve the safety of food. It grants the Secretary of Health and Human Services authority to issue mandatory performance standards for reducing hazards and requires the Secretary to conduct risk-based inspections. It also expands the Secretary's access to food safety records and increases the Secretary's ability to oversee the safety of imported food, requiring safety-related documentation for potentially unsafe imported food as a condition of import.

In most pertinent part to the question at hand, the bill provides the Secretary with sundry tools to address an outbreak of food-borne illness. These include a system for the rapid tracing of the origin of food, authority to mandate recalls of contaminated food, and authority to quarantine geographic areas of the United States from which the Secretary reasonably believes contaminated food has originated.

The amendment proposed in the motion to recommit contemplates allowing the Secretary to preemptively purchase food as a matter of food safety, as in the context of section 415 of the Act. The amendment also would make a portion of the proceeds of certain fees contemplated by the bill available only for such preemptive purchases.

The Chair finds that the amendment pursues the same fundamental purpose of the bill by a method that dwells within the range of methods employed by the bill. The Chair therefore holds that the amendment is germane.

Accordingly, the point of order is overruled. The motion is in order.

The gentleman from Michigan may be recognized for 5 minutes in opposition.

Mr. DINGELL. Mr. Speaker, we have before us a bad motion to recommit. With all due respect for its author, we know that the FDA has been chronically starved of resources, particularly in the food area and particularly in its ability to protect the American people.

The amendment offered before us would raid that money and would use it for the purpose of purchasing food. The food is not designated as to how or why it might be purchased. I would point out that this breaks an agreement and an understanding that the committee had in this legislation with regard to the support by the food production industry, especially the parts of the industry that will pay the tax.

The bill only authorizes a modest $500 registration fee for food facilities. The motion to recommit asserts the bill does not require the FDA to spend one additional penny on the inspection of food. This is a serious untruth.

On Page 23, the bill directs the FDA to spend its registration fees on food safety activities. The bill explicitly provides that food safety activities include conducting inspections. This money will be diverted from the inspection and the protection of the American people, and it will not be available for the activities of Food and Drug. It might give relief to somebody,

and it might even be somebody who needs relief, but there's no standards whatsoever given as to who will get the money, how it will be spent, on what, and for what purposes.

The bill requires the FDA to adhere to a rigorous mandatory inspection schedule based on risk. This bill does nothing to enhance that, but it takes money away from the protection of the American consumer by having proper inspections at points of entry or inspections in other countries. That is a bad situation and one which is going to seriously hurt the safety of the American public.

The bill is carefully crafted to ensure that the American Food and Drug Administration will protect American consumers and American manufacturers, processors, growers, and the farmers of this Nation. It enables them to focus on where there is danger, and it enables them to provide the kind of protection that all of those entities need, especially the farmers, the processors and the producers, because today the broad authority that Food and Drug has is no longer sufficiently focused to enable the correct and direct focus on the dangers to the American public.

The bill gives Food and Drug modern authorities to safeguard the food supply, but it gives them the money to do the things that they have to do to protect the American industry and the American-consuming public.

This legislation diverts 50 percent of the receipts that we would get under the legislation from the protection both of producers and from the protection of the American-consuming public.

The bill has provisions that ensure that FDA cannot use its ability to stop distribution recall or to detain or to prohibit or to restrict the movement of food. The Food and Drug Administration will have to use modern authorities in a very careful way, in a way which has the support of the consuming public and of the people whose names and whose organizational structures I mentioned earlier.

We have found out what an inadequately funded FDA does. This legislation will ensure that those evils will persist. The amendment reduces funds to FDA. It thereby increases the likelihood of outbreaks and of danger to the health of the American people and of hurt to the American producers, growers, and farmers.

This is a bad amendment. It is an amendment which threatens the support of industry for this legislation by diverting the money into unwise, unnecessary and undue expenditures which threaten the basic purposes of the legislation. It is bad legislation, and it will worsen what is a carefully thought-out bipartisan bill, which has been produced in consultation, not just with the industry but with the Agriculture Committee, with the administration and with both the Department of Agriculture and the Food and Drug Administration.

I urge my colleagues to reject this amendment, which wastes money and which jeopardizes the life, safety and the well being of American consumers and the well being of American farmers, agriculture, and producers. It's a bad, bad motion to recommit.

I urge the House to reject it.

The SPEAKER pro tempore. The Chair was mis-advised that the gentleman from Oklahoma had already explained the motion.

The proponent of the motion is entitled to 5 minutes and is recognized.

Mr. LUCAS. Mr. Speaker, once again, let me express my gratitude to the chairman emeritus and to the ranking member of the Energy and Commerce Committee. They have both put a great deal of effort into developing this very important piece of legislation, and they are to be commended for their attempts to accommodate the concerns raised by members of the minority party of the Agriculture Committee.

During the past few days, I have discussed many of the more objectionable provisions of this legislation. Today, I am hopeful and optimistic, in offering this motion to recommit, that we can at the very least address two of the bill's most glaring omissions.

Specifically, I would like to focus on what I believe to be a lack of accountability on the part of the Food and Drug Administration. The legislation before us provides the agency with numerous punitive authorities as well as a new source of revenue charged to people wishing to be in the food business, but it does not require the FDA to spend one additional penny on the inspection of food.

I am hopeful that my colleagues will agree that this is something that we can and should address in this bill as it leaves the House. Therefore, I propose that FDA spend a portion of the funds collected as registration fees for additional food inspections in the United States of America. Let's face it, if we are going to call this bill the Food Safety Enhancement Act, we should probably have something in here that actually enhances food safety.

Now, another issue that is very troubling and the one we hear repeatedly from farm groups is the issue of indemnification. I would point out that the chairman emeritus and the ranking member explained that concern in a Dear Colleague that was sent out last night. The issue of indemnification can be illustrated with the example of what happened to tomato crops in 2008.

The FDA mistakenly attributed an outbreak of salmonella to tomatoes. It was later discovered that contaminated peppers were the actual source of the illness. However, the discovery came after a large part of the 2008 tomato crop was destroyed, and the industry suffered, perhaps, $100 million in losses as a result.

I appreciate that Mr. DINGELL and Mr. BARTON feel that the passage of this bill will reduce the number and the severity of these mistakes in the future. I truly hope they are right. We must not kid ourselves into believing that the FDA will not make such mistakes in the future. Wrongly implicating agriculture products to foodborne disease outbreaks can cause severe economic losses to farmers and ranchers, who can ill afford them. Unfortunately, this legislation does not address this real concern.

We attempt to address this omission in our motion to recommit. We propose that some of the money coming from the registration fees be set aside for preemptive purchase products from producers. Remember, these purchases only result from direct government action. These changes will not fix everything that we feel to be wrong with the legislation, but they will address some of the more significant problems.

Nothing in this motion adds to the cost of the bill, but it does strengthen FDA accountability, and it guarantees enhanced food safety inspection.

Once again, let's direct that half the money goes to food inspection. Let's make sure the other half of this registration money is available to correct the mistakes that the FDA may make.

I urge all of my colleagues to support this motion. Let's clean up two of the biggest problems, and let's move forward. I urge all of my colleagues to support this motion once again.

Mr. Speaker, I yield back the balance of my time.

Mr. DINGELL. Mr. Speaker, I understand that the majority on the committee that handles the bill is entitled to close; is that correct?

The SPEAKER pro tempore. That is ordinarily correct.

Mr. DINGELL. Then I ask unanimous consent that I be permitted to proceed.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Michigan?

Mr. LUCAS. I reserve the right to object, Mr. Speaker.

Mr. Speaker, could I note for the record: Has the gentleman not used his 5 minutes?

The SPEAKER pro tempore. Because recognitions to explain and oppose the motion were conferred out of sequence, if there is no objection, the gentleman from Michigan will be recognized for 1 minute to close the debate.

There was no objection.

Mr. DINGELL. Mr. Speaker, I will simply observe as follows: the motion to recommit asserts that the bill does not require FDA to spend one additional penny on the inspection of food. That is totally false.

On page 23 of the bill, it directs FDA to spend its registration fees on food safety activities. On line 18, the bill explicitly provides that food safety activities include conducting inspections. The bill also requires FDA to adhere to a rigorous mandatory inspection schedule based on risk.

I yield now to the distinguished gentleman from Georgia (Mr. SCOTT).

Mr. SCOTT of Georgia. Mr. Speaker, for the remaining seconds, the bill on two points:

It violates the rule, and it will weaken the FDA program. This bill inspects the food processing plants at an increased rate, far more than it is doing now. Again, it violates the rule, and it weakens the FDA's program. On those grounds, we reject this motion to recommit.

The SPEAKER pro tempore. Without objection, the previous question is ordered on the motion to recommit.

There was no objection.

The SPEAKER pro tempore. The question is on the motion to recommit.

The question was taken; and the Speaker pro tempore announced that the noes appeared to have it.

Mr. LUCAS. Mr. Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that a quorum is not present.

The SPEAKER pro tempore. Evidently a quorum is not present.

The Sergeant at Arms will notify absent Members.

Pursuant to clause 8 and clause 9 of rule XX, this 15-minute vote on the motion to recommit will be followed by 5-minute votes on passage of H.R. 2749, if ordered, and motions to suspend the rules with regard to:

H.R. 1752, if ordered;

H. Res. 535, if ordered;

H. Res. 550, if ordered.

The vote was taken by electronic device, and there were—yeas 186, nays 240, not voting 7, as follows:

[Roll No. 679]

YEAS—186

Aderholt
Akin
Alexander
Altmire
Arcuri
Austria
Bachmann
Bachus
Barrett (SC)
Bartlett
Barton (TX)
Biggert
Bilbray
Bilirakis
Bishop (UT)
Blackburn
Blunt
Boehner
Bonner
Bono Mack
Boozman
Boren
Boustany
Brady (TX)
Bright
Broun (GA)
Brown (SC)
Brown-Waite, Ginny
Buchanan
Burgess
Burton (IN)
Buyer
Calvert
Camp
Campbell
Cantor
Cao
Capito
Carter
Cassidy
Castle
Chaffetz
Coble
Coffman (CO)
Cole
Conaway
Crenshaw
Culberson
Davis (KY)
Deal (GA)
Dent
Diaz-Balart, L.
Diaz-Balart, M.
Dreier
Duncan
Ehlers
Emerson
Fallin
Flake
Fleming
Forbes
Fortenberry
Foxx
Franks (AZ)
Frelinghuysen
Gallegly
Garrett (NJ)
Gerlach
Gingrey (GA)
Gohmert
Goodlatte
Granger
Graves
Guthrie
Hall (TX)
Harper
Hastings (WA)
Heller
Hensarling
Herger
Hoekstra
Hunter
Inglis
Issa
Jenkins
Johnson (IL)
Johnson, Sam
Jones
Jordan (OH)
King (IA)
King (NY)
Kingston
Kirk
Kline (MN)
Lamborn
Lance
Latham
LaTourette
Latta
Lee (NY)
Lewis (CA)
LoBiondo
Lucas
Luetkemeyer
Lummis
Lungren, Daniel E.
Mack
Manzullo
Marchant
Marshall
McCarthy (CA)
McCaul
McClintock
McCotter
McHenry
McHugh
McIntyre
McKeon
McMorris Rodgers
McNerney
Mica
Miller (FL)
Miller (MI)
Miller, Gary
Moran (KS)
Murphy (NY)
Murphy, Tim
Myrick
Neugebauer
Nunes
Olson
Paul
Paulsen
Pence
Perriello
Petri
Pitts
Platts
Poe (TX)
Posey
Price (GA)
Putnam
Radanovich
Rehberg
Reichert
Roe (TN)
Rogers (AL)
Rogers (KY)
Rogers (MI)
Rohrabacher
Rooney
Ros-Lehtinen
Roskam
Royce
Ryan (WI)
Scalise
Schmidt
Schock
Sensenbrenner
Sessions
Shadegg
Shimkus
Shuster
Simpson
Smith (NE)
Smith (NJ)
Smith (TX)
Souder
Stearns
Sullivan
Terry
Thompson (PA)
Thornberry
Tiahrt
Tiberi
Turner
Upton
Walden
Wamp
Westmoreland
Whitfield
Wilson (SC)
Wittman
Wolf
Young (AK)
Young (FL)

NAYS—240

Abercrombie
Ackerman
Andrews
Baca
Baird
Baldwin
Barrow
Bean
Becerra
Berkley
Berman
Berry
Bishop (GA)
Bishop (NY)
Blumenauer
Boccieri
Boswell
Boucher
Boyd
Brady (PA)
Braley (IA)
Brown, Corrine
Butterfield
Capps
Capuano
Cardoza
Carnahan
Carney
Carson (IN)
Castor (FL)
Chandler
Childers
Chu
Clarke
Clay
Cleaver
Clyburn
Cohen
Connolly (VA)
Conyers
Cooper
Costa
Costello
Courtney
Crowley
Cuellar
Cummings
Dahlkemper
Davis (AL)
Davis (CA)
Davis (IL)
Davis (TN)
DeFazio
DeGette
Delahunt
DeLauro
Dicks
Dingell
Doggett
Donnelly (IN)
Doyle
Driehaus
Edwards (MD)
Edwards (TX)
Ellison
Ellsworth
Engel
Eshoo
Etheridge
Farr
Fattah
Filner
Foster
Frank (MA)
Fudge
Giffords
Gonzalez
Gordon (TN)
Green, Al
Green, Gene
Griffith
Grijalva
Gutierrez
Hall (NY)
Halvorson
Hare
Harman
Hastings (FL)
Heinrich
Herseth Sandlin
Higgins
Hill
Himes
Hinchey
Hinojosa
Hirono
Hodes
Holden
Holt
Honda
Hoyer
Inslee
Israel
Jackson (IL)
Jackson-Lee (TX)
Johnson (GA)
Johnson, E. B.
Kagen
Kanjorski
Kaptur
Kennedy
Kildee
Kilpatrick (MI)
Kilroy
Kind
Kirkpatrick (AZ)
Kissell
Klein (FL)
Kosmas
Kratovil
Kucinich
Langevin
Larsen (WA)
Larson (CT)
Lee (CA)
Levin
Lewis (GA)
Lipinski
Loebsack
Lofgren, Zoe
Lowey
Luján
Lynch
Maffei
Maloney
Markey (CO)
Markey (MA)
Massa
Matheson
Matsui
McCollum
McDermott
McGovern
McMahon
Meek (FL)
Meeks (NY)
Melancon
Michaud
Miller (NC)
Miller, George
Minnick
Mitchell
Mollohan
Moore (KS)
Moore (WI)
Moran (VA)
Murphy (CT)
Murphy, Patrick
Nadler (NY)
Napolitano
Neal (MA)
Nye
Oberstar
Obey
Olver
Ortiz
Pallone
Pascrell
Pastor (AZ)
Payne
Perlmutter
Peters
Peterson
Pingree (ME)
Polis (CO)
Pomeroy
Price (NC)
Quigley
Rahall
Rangel
Reyes
Richardson
Rodriguez
Ross
Rothman (NJ)
Roybal-Allard
Ruppersberger
Rush
Ryan (OH)
Sánchez, Linda T.
Sarbanes
Schakowsky
Schauer
Schiff
Schrader
Schwartz
Scott (GA)
Scott (VA)
Serrano
Sestak
Shea-Porter
Sherman
Shuler
Sires
Skelton
Slaughter
Smith (WA)
Snyder
Space
Speier
Spratt
Stark
Stupak
Sutton
Tanner
Taylor
Teague
Thompson (CA)
Thompson (MS)
Tierney
Titus
Tonko
Towns
Tsongas
Van Hollen
Velázquez
Visclosky
Walz
Wasserman Schultz
Waters
Watson
Watt
Waxman
Weiner
Welch
Wexler
Wilson (OH)
Woolsey
Wu
Yarmuth

NOT VOTING—7

Adler (NJ)
Grayson
Linder
McCarthy (NY)
Murtha
Salazar
Sanchez, Loretta

□ 1755

Messrs. MOLLOHAN, CARNEY, YARMUTH, Ms. SCHWARTZ, Messrs. BISHOP of Georgia and OBERSTAR changed their vote from ''yea'' to ''nay.''

Mr. GARY G. MILLER of California changed his vote from ''nay'' to ''yea.''

So the motion to recommit was rejected.

The result of the vote was announced as above recorded.

The SPEAKER pro tempore. The question is on the passage of the bill.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

RECORDED VOTE

Mr. SHIMKUS. Mr. Speaker, I demand a recorded vote.

A recorded vote was ordered.

The SPEAKER pro tempore. This is a 5-minute vote.

The vote was taken by electronic device, and there were—ayes 283, noes 142, not voting 8, as follows:

[Roll No. 680]

AYES—283

Abercrombie
Ackerman
Altmire
Andrews
Baca
Bachmann
Baird
Baldwin
Barrow
Barton (TX)
Bean
Becerra
Berkley
Berman
Berry
Biggert
Bilirakis
Bishop (GA)
Bishop (NY)
Blumenauer
Boccieri
Boren
Boswell
Boucher
Boyd
Brady (PA)
Braley (IA)
Brown, Corrine
Brown-Waite, Ginny
Buchanan
Burgess
Butterfield
Buyer
Camp
Cao
Capito
Capps
Capuano
Cardoza
Carnahan
Carney
Carson (IN)
Castle
Castor (FL)
Chandler
Chu
Clarke
Clay
Cleaver
Clyburn
Cohen
Connolly (VA)
Conyers
Cooper
Costa
Costello
Courtney
Crenshaw
Crowley
Cuellar
Cummings
Dahlkemper
Davis (AL)
Davis (CA)
Davis (IL)
Deal (GA)
DeFazio
DeGette
Delahunt
DeLauro
Dent
Diaz-Balart, L.
Diaz-Balart, M.
Dicks
Dingell
Doggett
Donnelly (IN)
Doyle
Driehaus
Edwards (MD)
Edwards (TX)
Ehlers
Ellison
Ellsworth
Engel
Eshoo
Etheridge
Farr
Fattah
Filner
Fortenberry
Foster
Frank (MA)
Frelinghuysen
Fudge
Gerlach
Giffords
Gingrey (GA)
Gonzalez
Gordon (TN)
Green, Al
Green, Gene
Grijalva
Guthrie
Gutierrez
Hall (NY)
Halvorson
Hare
Harman
Hastings (FL)
Herseth Sandlin
Higgins
Hill
Himes
Hinojosa
Hirono
Hodes
Holden
Holt
Honda
Hoyer
Inslee
Israel
Jackson (IL)
Jackson-Lee (TX)
Johnson (GA)
Johnson, E. B.
Kagen
Kanjorski
Kaptur
Kennedy
Kildee
Kilpatrick (MI)
Kilroy
King (NY)
Kirk
Kirkpatrick (AZ)
Kissell
Klein (FL)
Kline (MN)
Kosmas
Kucinich
Lance
Langevin
Larsen (WA)
Larson (CT)
LaTourette
Lee (CA)
Lee (NY)
Levin
Lewis (GA)
Lipinski
LoBiondo
Loebsack
Lofgren, Zoe
Lowey
Lynch
Maffei
Maloney
Markey (MA)
Matheson
Matsui
McCollum
McCotter
McDermott
McGovern
McHugh
McIntyre
McMahon

McNerney
Meek (FL)
Meeks (NY)
Melancon
Michaud
Miller (MI)
Miller (NC)
Miller, George
Mitchell
Mollohan
Moore (KS)
Moore (WI)
Moran (VA)
Murphy (CT)
Murphy (NY)
Murphy, Patrick
Murphy, Tim
Myrick
Nadler (NY)
Napolitano
Neal (MA)
Nye
Oberstar
Obey
Olver
Ortiz
Pallone
Pascrell
Pastor (AZ)
Paulsen
Payne
Perlmutter
Peters
Peterson
Platts
Polis (CO)
Pomeroy
Price (NC)
Putnam
Quigley
Rahall
Rangel
Reichert
Reyes
Richardson
Rodriguez
Rogers (KY)
Rogers (MI)
Ros-Lehtinen
Roskam
Ross
Rothman (NJ)
Roybal-Allard
Ruppersberger
Rush
Ryan (OH)
Sánchez, Linda T.
Sarbanes
Scalise
Schakowsky
Schauer
Schiff
Schrader
Schwartz
Scott (GA)
Scott (VA)
Serrano
Sestak
Shea-Porter
Sherman
Shimkus
Sires
Skelton
Slaughter
Smith (NJ)
Smith (WA)
Snyder
Space
Speier
Spratt
Stark
Stupak
Sutton
Tanner
Taylor
Terry
Thompson (CA)
Thompson (MS)
Tiberi
Tierney
Titus
Tonko
Towns
Tsongas
Turner
Upton
Van Hollen
Velázquez
Visclosky
Walden
Walz
Wasserman Schultz
Waters
Watson
Watt
Waxman
Weiner
Wexler
Whitfield
Wilson (OH)
Wolf
Wu
Yarmuth
Young (FL)

NOES—142

Aderholt
Alexander
Arcuri
Austria
Bachus
Barrett (SC)
Bartlett
Bilbray
Bishop (UT)
Blackburn
Blunt
Boehner
Bonner
Bono Mack
Boozman
Boustany
Brady (TX)
Bright
Broun (GA)
Brown (SC)
Burton (IN)
Calvert
Campbell
Cantor
Carter
Cassidy
Chaffetz
Childers
Coble
Coffman (CO)
Cole
Conaway
Culberson
Davis (KY)
Davis (TN)
Dreier
Duncan
Emerson
Fallin
Flake
Fleming
Forbes
Foxx
Franks (AZ)
Gallegly
Garrett (NJ)
Gohmert
Goodlatte
Granger
Graves
Griffith
Hall (TX)
Harper
Hastings (WA)
Heinrich
Heller
Hensarling
Herger
Hinchey
Hoekstra
Hunter
Inglis
Issa
Jenkins
Johnson (IL)
Johnson, Sam
Jones
Jordan (OH)
Kind
King (IA)
Kingston
Kratovil
Lamborn
Latham
Latta
Lewis (CA)
Lucas
Luetkemeyer
Luján
Lummis
Lungren, Daniel E.
Mack
Manzullo
Marchant
Markey (CO)
Marshall
Massa
McCarthy (CA)
McCaul
McClintock
McHenry
McKeon
McMorris Rodgers
Mica
Miller (FL)
Miller, Gary
Minnick
Moran (KS)
Neugebauer
Nunes
Olson
Paul
Pence
Perriello
Petri
Pingree (ME)
Pitts
Poe (TX)
Posey
Price (GA)
Radanovich
Rehberg
Roe (TN)
Rogers (AL)
Rohrabacher
Rooney
Royce
Ryan (WI)
Schmidt
Schock
Sensenbrenner
Sessions
Shadegg
Shuler
Shuster
Simpson
Smith (NE)
Smith (TX)
Souder
Stearns
Sullivan
Teague
Thompson (PA)
Thornberry
Tiahrt
Wamp
Welch
Westmoreland
Wilson (SC)
Wittman
Woolsey
Young (AK)

NOT VOTING—8

Adler (NJ)
Akin
Grayson
Linder
McCarthy (NY)
Murtha
Salazar
Sanchez, Loretta

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (during the vote). There are 2 minutes remaining on this vote.

□ 1802

So the bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

Stated against:

Mr. AKIN. Mr. Speaker, on rollcall No. 680, had I been present, I would have voted "no."

PERSONAL EXPLANATION

Mr. ADLER of New Jersey. Mr. Speaker, on rollcall Nos. 679 and 680, had I been present, I would have voted "no" on 679 and "yes" on 680.

PERSONAL EXPLANATION

Mr. GRAYSON. Mr. Speaker, on rollcall Nos. 679 and 680, I missed these votes unavoidably because of a meeting with the White House Chief of Staff at the White House, and heavy traffic from the White House to the Capitol. Had I been present, I would have voted "nay" on 679 and "aye" on 680.

MESSAGE FROM THE SENATE

A message from the Senate by Mr. Curtis, one of its clerks, announced that the Senate has passed with an amendment a bill of the House of the following title:

H.R. 3183. An act making appropriations for energy and water development and related agencies for the fiscal year ending September 30, 2010, and for other purposes.

The message also announced that the Senate insists upon its amendment to the bill (H.R. 3183) ''An act making appropriations for energy and water development and related agencies for the fiscal year ending September 30, 2010, and for other purposes,'' requests a conference with the House on the disagreeing votes of the two Houses thereon, and appoints Mr. DORGAN, Mr. BYRD, Mrs. MURRAY, Mrs. FEINSTEIN, Mr. JOHNSON, Ms. LANDRIEU, Mr. REED, Mr. LAUTENBERG, Mr. HARKIN, Mr. TESTER, Mr. INOUYE, Mr. BENNETT, Mr. COCHRAN, Mr. MCCONNELL, Mr. BOND, Mrs. HUTCHISON, Mr. SHELBY, Mr. ALEXANDER, and Mr. VOINOVICH, to be the conferees on the part of the Senate.

The message also announced that the Senate has passed bills of the following titles in which the concurrence of the House is requested:

S. 1391. An act to authorize appropriations for fiscal year 2010 for military activities of the Department of Defense, to prescribe military personnel strengths for such fiscal year, and for other purposes.

S. 1392. An act to authorize appropriations for fiscal year 2010 for military construction, and for other purposes.

S. 1393. An act to authorize appropriations for fiscal year 2010 for defense activities of the Department of Energy, and for other purposes.

PROVIDING FOR HOUSE OF REPRESENTATIVES STAFF PAYDAY CHANGES

The SPEAKER pro tempore. The unfinished business is the question on suspending the rules and passing the bill, H.R. 1752, as amended.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentlewoman from California (Mrs. DAVIS) that the House suspend the rules and pass the bill, H.R. 1752, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. LATHAM. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. This is a 5-minute vote.

The vote was taken by electronic device, and there were—ayes 282, noes 144, not voting 7, as follows:

[Roll No. 681]

AYES—282

Abercrombie
Ackerman
Adler (NJ)
Altmire
Andrews
Baca
Baldwin
Barrow
Bean
Becerra
Berkley
Berry
Bilbray
Bilirakis
Bishop (GA)
Bishop (NY)
Blumenauer
Blunt
Boccieri
Boren
Boswell
Boucher
Boyd
Brady (PA)
Brady (TX)
Braley (IA)
Bright
Broun (GA)
Brown (SC)
Brown, Corrine
Buchanan
Butterfield
Cao
Capps
Capuano
Cardoza
Carnahan
Carney
Carson (IN)
Castle
Castor (FL)
Chandler
Childers
Chu
Clarke
Clay
Cleaver
Cohen
Cole
Connolly (VA)
Conyers
Cooper
Costa
Costello
Courtney
Crowley
Cuellar
Culberson
Cummings
Dahlkemper
Davis (AL)
Davis (CA)
Davis (IL)
Davis (TN)
Deal (GA)
DeFazio
DeGette
Delahunt
DeLauro
Dent
Dicks
Dingell
Doggett
Donnelly (IN)
Doyle
Driehaus
Edwards (MD)
Edwards (TX)
Ellison
Ellsworth
Emerson
Engel
Eshoo
Etheridge
Fallin
Farr
Fattah
Filner
Forbes
Fortenberry
Foster
Frank (MA)
Frelinghuysen
Fudge
Gerlach
Giffords
Gonzalez
Gordon (TN)
Graves
Grayson
Green, Al
Green, Gene
Griffith
Grijalva
Gutierrez
Hall (NY)
Hall (TX)
Halvorson
Hare
Harman
Hastings (FL)
Heinrich
Herseth Sandlin
Higgins
Hill
Himes
Hinchey
Hinojosa
Hirono
Hodes
Holden
Holt
Honda
Hoyer
Inslee
Israel
Jackson-Lee (TX)
Jenkins
Johnson (GA)
Johnson, E.B.
Kagen
Kanjorski
Kaptur
Kennedy
Kildee
Kilpatrick (MI)
Kilroy
Kind
King (IA)
King (NY)
Kirk
Kirkpatrick (AZ)
Klein (FL)
Kosmas
Kucinich
Lance
Langevin
Larsen (WA)
Larson (CT)
Lee (CA)
Levin
Lewis (GA)
Lipinski
Loebsack
Lofgren, Zoe
Lowey
Lucas
Luján
Lungren, Daniel E.
Lynch
Maffei
Maloney
Markey (CO)
Markey (MA)
Marshall
Massa
Matheson
Matsui
McCarthy (CA)
McCaul
McCollum
McDermott
McGovern
McIntyre
McMahon
McMorris Rodgers
McNerney
Meek (FL)
Meeks (NY)
Melancon
Michaud
Miller (NC)
Miller, George
Minnick
Mitchell
Mollohan
Moore (KS)
Moore (WI)
Moran (VA)
Murphy (CT)
Murphy, Patrick
Murphy, Tim
Nadler (NY)
Napolitano
Neal (MA)
Nunes
Nye
Oberstar
Obey
Olver
Ortiz
Pallone
Pascrell
Pastor (AZ)