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111TH CONGRESS
1ST SESSION

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.

IN THE HOUSE OF REPRESENTATIVES

JUNE 8, 2009

Mr. DINGELL (for himself, Mr. WAXMAN, Mr. PALLONE, Mr. STUPAK, Ms. DEGETTE, and Ms. SUTTON) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food in the global market, and for other purposes.

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:

TITLE I—FOOD SAFETY

Subtitle A—Prevention

Subtitle B—Intervention

Subtitle C—Response

TITLE II—MISCELLANEOUS

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. RULE OF CONSTRUCTION.

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.).

TITLE I—FOOD SAFETY

Subtitle A—Prevention

SEC. 101. CHANGES IN REGISTRATION OF FOOD FACILITIES.

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

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

(b) ANNUAL REGISTRATION.—

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

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

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

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

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

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

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

istration is canceled by the registrant, canceled by the Secretary in accordance with this section, or suspended by the Secretary in accordance with this section.''.

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

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

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

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

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

''(E) The name, address, and 24-hour emergency contact information of the United States distribution agent for the facility, which

agent shall have access to the information required to be maintained under section 414(d) for food that is manufactured, processed, packed, or held at the facility.

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

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

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

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

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

''(5) SUSPENSION OF REGISTRATION.—

''(A) IN GENERAL.—The Secretary may suspend the registration of any facility registered under this section for a violation of this

Act that could result in serious adverse health consequences or death to humans or animals.

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

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

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

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

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

''(6) CANCELLATION OF REGISTRATION.—

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

(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, $1,000; 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).

''(c) INFLATION ADJUSTMENT.—For fiscal year 2011 and each subsequent fiscal year, the fee amount under subsection (b) 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 con-

sumers (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.

''(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, employers, 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, em-

ployees, 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, AND FOOD SAFETY PLAN.

(a) 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.''.

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

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

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

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

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

''(3) monitor preventive controls;

''(4) institute corrective actions when monitoring shows that preventive controls have not been properly implemented or were ineffective;

''(5) conduct verification activities;

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

''(7) reanalyze for hazards.

''(b) IDENTIFICATION OF HAZARDS.—

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

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

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

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

''(3) HAZARD ANALYSIS.—The owner, operator, or agent of a facility shall identify and describe the hazards evaluated under paragraph (1) or identified

under paragraph (2), to the extent applicable to the facility, in a hazard analysis.

''(c) PREVENTIVE CONTROLS.—

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

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

''(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 were ineffective, including through the use of environmental and product testing programs, as appropriate.

''(e) CORRECTIVE ACTIONS.—The owner, operator, or agent of a facility shall establish and implement proce-

dures to ensure that, if the preventive controls under subsection (c) are not fully implemented or are not effective—

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

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

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

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

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

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

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

''(g) REQUIREMENT TO REANALYZE AND REVISE.—

''(1) HAZARD ANALYSIS.—The owner, operator, or agent of a facility shall review the evaluation

under subsection (b) for the facility and, as necessary, revise the hazard analysis under subsection (b)(3) for the facility not less than every 2 years.

''(2) PREVENTIVE CONTROLS.—If there is a change that could affect the hazard analysis for a facility under subsection (b)(3) or if the Secretary determines that it is appropriate to protect public health, the owner, operator, or agent of the facility shall revise the preventive controls under subsection (c) for the facility 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.

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

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

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

''(2) PREVENTIVE CONTROLS.—The term 'preventive controls' means those risk-based procedures, practices, and processes that a person knowledgeable

about the safe manufacturing, processing, packing, transporting, or holding of food would employ to prevent, eliminate, or reduce to an acceptable level the hazards identified in the hazard analysis under subsection (b)(3) and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, transporting, or holding at the time of the analysis. Those procedures, practices, and processes shall include the following, as appropriate:

''(A) Sanitation procedures and practices.

''(B) Supervisor, manager, and employee hygiene training.

''(C) Process controls.

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

''(E) Good manufacturing practices.

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

''(G) Other procedures, practices, and processes established by the Secretary under subsection (c)(2).

''(3) REASONABLY LIKELY TO OCCUR.—The term 'reasonably likely to occur' means a hazard 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 provide a basis to conclude that there is a reasonable possibility that, in the absence of those controls, the hazard will occur in the type of food being manufactured, processed, packed, transported, or held.

"SEC. 418A. FOOD SAFETY PLAN.

''(a) IMPLEMENTATION OF FOOD SAFETY PLAN.—

''(1) 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').

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

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

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

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

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

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

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

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

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

''(I) 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.

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

(c) GUIDANCE OR REGULATIONS.—

(1) 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 subsection (b)).

(2) CONSIDERATION.—In issuing guidance or promulgating regulations under this section, the Secretary shall consider the impact of such guidance or regulations on small businesses.

(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) EFFECTIVE DATE.—

(1) GENERAL RULE.—The amendments made by this section shall take effect 18 months after the date of the enactment of this Act.

(2) EXCEPTIONS.—Notwithstanding paragraph (1)—

(A) the amendments made by this section 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

(B) the amendments made by this section 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.

SEC. 103. PERFORMANCE STANDARDS.

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

''(k) 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.

''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.''.

(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 FRESH PRODUCE AND CERTAIN OTHER RAW AGRICULTURAL COMMODITIES.

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

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

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

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

''(a) STANDARDS.—The Secretary shall establish by regulation science-based standards for the safe growing, harvesting, packing, sorting, transporting, and holding of raw agricultural commodities that—

''(1) are from a plant or a fungus; and

''(2) for which the Secretary has determined that such standards 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, in-

cluding by acts of terrorism, into raw agricultural commodities that are from a plant or a fungus; and

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

''(2) may include, with respect to growing, harvesting, packing, sorting, transporting, and storage operations, minimum 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; and

''(6) may provide for coordination of education and enforcement activities.

''(c) ENFORCEMENT.—The Secretary may coordinate with the Secretary of Agriculture and may contract and coordinate with the agency or department designated by

the Governor of each State to perform activities to ensure compliance with this section.''.

(c) TIMING.—

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

(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 one 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, including any facility that manufactures or processes raw products of animal origin (including fish and fisheries products) or other foods as designated by the Secretary. The Secretary shall randomly inspect a category 1 food facility at least every 6 to 18 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 3 to 4 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 foodborne illness outbreaks and food recalls; and

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

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

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

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

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

(A) the number of foreign and domestic facilities, by risk category, inspected under the risk-based inspection schedule established under section 704(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), in the preceding 12 months; 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—

(A) adjustments to the timing of the schedule and other ways to increase the efficiency of inspections in order to enable the Food and Drug Administration to conduct more inspections; and

(B) other methods to contribute to assuring the safety of food.

SEC. 106. ACCESS TO RECORDS.

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

''(a) RECORDS INSPECTION.—Each person who produces, manufactures, processes, packs, transports, distributes, receives, or holds an article of food in the United States or for import into the United States shall, at the

request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article bearing on whether the food is adulterated, misbranded, or otherwise in violation of this Act, including all records collected or developed to comply with section 418 or 418A. The requirement under the preceding sentence applies to all records relating to the production, manufacture, processing, packing, transporting, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.''.

(b) REGULATIONS CONCERNING RECORDKEEPING.—

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

''(b) REGULATIONS CONCERNING RECORDKEEPING.—The Secretary, in consultation and coordination, as appropriate, with other Federal departments and agencies with responsibilities for regulating food safety, may by regulation establish requirements regarding the establishment and maintenance, for not longer than 3 years, of records by persons who produce, manufacture, process, pack, transport, distribute, receive, or hold food in the

United States or for import into the United States. The Secretary shall take into account the size of a business in promulgating regulations under this section. The Secretary may require such persons to maintain such records in a standardized electronic format.''.

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

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

(1) in the first sentence—

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

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

(2) in the second sentence—

(A) by striking ''(excluding farms or restaurants)'';

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

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

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

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

(3) in the fourth sentence—

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

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

SEC. 107. TRACEABILITY OF FOOD.

(a) PROHIBITED ACT.—Section 301(e) (21 U.S.C. 331(e)) is amended by inserting '', the violation of any requirement of the food tracing system under section

414(c);'' before ''or the refusal to permit access to or verification or copying of any such required record''.

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

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

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

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

''(c) TRACING SYSTEM FOR FOOD.—

''(1) IN GENERAL.—The Secretary shall by regulation establish a tracing system for food that is located in the United States or is for import into the United States. Such regulations shall require each person who produces, manufactures, processes, packs, transports, or holds such food—

''(A) to maintain the full pedigree of the origin and previous distribution history of the food;

''(B) to link that history with the subsequent distribution history of the food;

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

''(D) to use a unique identifier for each facility owned or operated by such person for such purpose, as specified under section 911.

''(2) INFORMATION GATHERING.—

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

''(i) identify technologies for tracing the distribution history of a food that are, or may be, used by members of different sectors of the food industry; 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.—The Secretary shall conduct 1 or more pilot projects in coordination with 1 or more sectors of the food industry to explore and evaluate tracing systems for food.

''(3) ADDITIONAL AUTHORITY.—In establishing a tracing system for food, the Secretary shall require—

''(A) the establishment and maintenance of such additional information, including lot numbers, as the Secretary deems appropriate;

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

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

''(4) EXEMPTIONS.—

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

''(i) produced on a farm; and

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

''(B) OTHER FOODS.—The Secretary may by notice in the Federal Register exempt a food from the requirements of this subsection if the Secretary determines that a tracing system for such food is not necessary to protect the public health.

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

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 facility (as defined in section 415(b)) 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) USE OF FEES.—The Secretary shall make all fees collected pursuant to this section available solely to pay for the costs referred to in subsection (b).''.

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

SEC. 109. CERTIFICATION AND ACCREDITATION.

(a) MISBRANDING.—

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

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

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

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

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

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

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

''(p) CERTIFICATIONS CONCERNING IMPORTED ARTICLES.—

''(1) IN GENERAL.—

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

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

"(ii) for a type of food that could pose a significant risk to health, certification would assist the Secretary in determining whether such article poses such risk; or

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

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

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

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

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

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

''(3) NO CONFLICTS OF INTEREST.—

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

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

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

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

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

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

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

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

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

''(viii) neither the qualified certifying entity nor any of its auditors shall provide consultative services to any facility certified by the qualified certifying entity, or the owner, operator, or agent in charge of such a facility;

''(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 also ensure that any subcontractors that might be used (such as laboratories and sampling services) provide similar assurances.

"(C) ANYTHING OF VALUE.—In this paragraph, the term 'anything of value' includes

gifts, gratuities, reimbursement of expenses, entertainment, loans, or any other form of compensation in cash or in kind.

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

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

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

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

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

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

SEC. 110. TESTING BY ACCREDITED LABORATORIES.

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

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

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

''SEC. 714. TESTING BY ACCREDITED LABORATORIES.

''(a) IN GENERAL.—Whenever analytical testing of an article of food is conducted as part of testimony for the purposes of section 801(a), or for other purposes as the Secretary deems appropriate, such testing shall be conducted by a laboratory that—

''(1) is independent of the person on whose behalf such testing is conducted;

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

''(3) samples such article, itself or through an independent third party, with adequate controls for ensuring the integrity of the samples analyzed.

''(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) ON-SITE AUDITS.—In evaluating whether an accreditation body meets, or continues to meet, the standards for recognition under subsection (b), the Secretary may—

''(1) observe on-site 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 on-site 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;

''(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)(2) (relating to analytical methods) on a laboratory- or method-basis due to exigent or other circumstances.

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

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

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

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

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

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

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

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

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

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

''(1) IN GENERAL.—A responsible party as that term is defined in section 417(a)(1) or a person required to register under section 801(r) that has reason to believe that an article of food when introduced into or while in interstate commerce, or while held for sale (regardless of whether the first sale) after shipment in interstate commerce, is adulterated or misbranded in a manner that presents a reasonable probability that the use or consumption of,

or exposure to, the article (or an ingredient or component used in any such article) will cause a threat of serious adverse health consequences or death to humans or animals shall, as soon as practicable, notify the Secretary of the identity and location of the article.

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

''(b) VOLUNTARY RECALL.—The Secretary may request that any person who distributes an article of food that the Secretary has reason to believe is adulterated, misbranded, or otherwise in violation of this Act voluntarily—

''(1) recall such article, and

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

''(c) ORDER TO CEASE DISTRIBUTION.—If the Secretary has reason to believe that the use or consumption of, or exposure to, an article of food may cause 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—

''(1) to immediately cease distribution of such article; and

''(2) to immediately notify any person to whom the article was distributed of the order.

In providing for notice under paragraph (2), the Secretary may, as appropriate, allow such notice to be provided with the assistance of health care professionals, State or local health officials, or other persons designated by the Secretary.

''(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, if granted, shall be held within 10 business 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 hear-

ing, 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.

''(f) EMERGENCY RECALL ORDER.—

''(1) IN GENERAL.—If the Secretary has a reasonable belief that an article of food subject to an order under subsection (c) presents a 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, if granted, shall be held within 10 business 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 inad-

equate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) in subsection (d)(1)—

(A) in the matter preceding subparagraph (A)—

(i) by inserting ''information reasonably available to'' after ''after''; and

(ii) by striking ''determines'' and inserting ''indicates'';

(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, 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

(3) 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 pur-

suant 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 confiden-

tial, or has precluded such disclosure under other use limitations, as a condition of providing the information.

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

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

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

SEC. 113. SAFE AND SECURE FOOD IMPORTATION PROGRAM.

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

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

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

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

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

''(3) provides supporting information to the Secretary.

''(b) GUIDELINES.—

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

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

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

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

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

''(D) Vendor and supplier information.

''(E) Such other factors as the Secretary determines necessary.''.

SEC. 114. INFANT FORMULA.

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

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

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

(1) in subsection (b)(1), by adding at the end the following: ''The quality factor requirements established under this paragraph may include requirements for one or more clinical studies to demonstrate that the new infant formula supports normal physical growth of infants.'';

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

''(B) Records required under subparagraph (A) with respect to an infant formula shall be retained for at least one year after the expiration of the shelf life of such infant formula. Such records shall be made available to the Sec-

retary for review and duplication upon request of the Secretary.'';

(3) in subsection (c)(1)—

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

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

(C) by adding at the end the following:

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

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

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

''(D) scientific evidence and other evidence, as identified in regulations promulgated by the Secretary, that demonstrates that the processing of the

infant formula complies with the requirements of subsection (b)(2).''.

Subtitle B—Intervention

SEC. 121. PUBLIC HEALTH ASSESSMENT SYSTEM.

(a) SURVEILLANCE SYSTEM.—The Secretary of Health and Human Services (in this subtitle referred to as the ''Secretary'') shall build upon the existing surveillance system for food, based on a representative proportion of the population of the United States, to assess the frequency and sources of human illness in the United States associated with the consumption of food.

(b) SAMPLING AND ASSESSMENT.—

(1) IN GENERAL.—The Secretary shall utilize, as appropriate, samples of food collected and analyzed by, or on behalf of, the Secretary in carrying out the Secretary's duties under this Act and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and may collect and analyze additional samples of food to assess the nature, frequency of occurrence, and amounts of contaminants in food.

(2) REQUIREMENTS.—Assessment by the Secretary under this section may employ, in the Secretary's discretion, statistically valid monitoring, including market-basket studies, on the nature, frequency of occurrence, and amounts of contaminants

in food available to consumers, and at the request of the Secretary such other information as the Secretary determines may be useful.

(c) PUBLIC AVAILABILITY OF ASSESSMENT.—To the extent it does not impede the ability of the United States to protect against terrorist threats and other intentional attacks against the food supply, the Secretary may make publicly available, by posting on the Web site of the Department of Health and Human Services, the results of any assessment conducted under this section. To the extent feasible with the data and information available, the assessment may rank food categories based on their hazard to human health and may address—

(1) the safety of commercial harvesting and processing, as compared with the health hazards associated with food products that are harvested for recreational or subsistence purposes and prepared noncommercially;

(2) the safety of food products that are domestically harvested and processed, as compared with the health hazards associated with food products that are harvested or processed outside the United States; and

(3) contamination originating from handling practices that occur prior to or after sale of food products to consumers.

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 reduce their risk of foodborne 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.

(a) IN GENERAL.—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 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;

(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 develop new methods to reduce the transfer of antibiotic resistance to humans; and

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

(b) CONTRACT AUTHORITY.—The Secretary is authorized to enter into contracts and agreements with any State, university, government agency, or other person to carry out this section.

Subtitle C—Response

SEC. 131. PROCEDURES FOR SEIZURE.

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

SEC. 132. ADMINISTRATIVE DETENTION.

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

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

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

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

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

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

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

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

SEC. 133. QUARANTINE AUTHORITY FOR FOODS.

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

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

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

''(i) QUARANTINE OF GEOGRAPHIC LOCATION.—

''(1) AUTHORITY TO QUARANTINE.—If the Secretary determines that there is credible evidence or information that an article of food presents a threat of serious adverse health consequences or death to humans or animals, the Secretary may quarantine any geographic area within the United States where the Secretary reasonably believes such food is located or from which such food originated. The authority to quarantine includes prohibiting or restricting the movement of food or of any vehicle being used or that has been used to transport or hold such food within the geographic area.

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

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

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

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

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

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

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) $100,000, in the case of an individual; and

''(ii) $500,000, in the case of any other person.

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

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

SEC. 136. IMPROPER IMPORT ENTRY FILINGS.

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

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

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

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

''(q) DOCUMENTATION.—

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

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

TITLE II—MISCELLANEOUS

SEC. 201. TREATMENT OF CARBON MONOXIDE USED TO PRESERVE COLOR OF MEAT, POULTRY PRODUCTS, OR SEAFOOD AS COLOR ADDITIVE.

(a) IN GENERAL.—Paragraph (t) of section 201 (21 U.S.C. 321) is amended by adding at the end the following:

''(4) In the case of food that is meat within the meaning of the Federal Meat Inspection Act, a poultry product within the meaning of the Poultry Products Inspection Act, or seafood (including all fresh or saltwater fish, molluscan shellfish, crustaceans, and other forms of aquatic animal life) intended for human consumption as

food within the meaning of paragraph (f) (referred to collectively in this paragraph as 'seafood'), the term 'color additive' shall include carbon monoxide under conditions of use that may impart, maintain, preserve, stabilize, fix, or otherwise affect the color of fresh meat, poultry products, or seafood.''.

(b) ACTION BY SECRETARY.—The Secretary of Health and Human Services shall—

(1) promulgate a final regulation in accordance with section 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e) for use of carbon monoxide in or on meat, poultry products, and seafood; or

(2) publish in the Federal Register a decision against promulgating such a regulation.

(c) APPLICATION.—Section 201(t)(4) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies to the use of carbon monoxide in or on meat, poultry products, and seafood beginning on the date on which the Secretary of Health and Human Services promulgates a final regulation under subsection (b)(1) or publishes a decision under subsection (b)(2).

SEC. 202. 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 request for a substance to be determined by the Secretary to be a GRAS food substance, the Secretary shall post notice of such request 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 substances 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. 203. COUNTRY OF ORIGIN LABELING; DISCLOSURE OF SOURCE OF INGREDIENTS.

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

''(cc) In the case of a processed food if—

''(1) the labeling of the food fails to identify the country in which the final processing of the food occurs; and

''(2) the Web site for the manufacturer of the food fails to identify the country (or countries) of origin for each ingredient in the food.

''(dd) In the case of non-processed food if—

''(1) the labeling of the food fails to identify the country of origin of the food; and

''(2) the Web site for the original packer of the food fails to identify the country of origin for the food.''.

(b) REGULATIONS.—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).

(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. 204. 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. 205. REGISTRATION FOR COMMERCIAL IMPORTERS OF FOOD; FEE.

(a) REGISTRATION.—

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

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

(2) MISBRANDING.—Section 403 (21 U.S.C. 343) as amended by sections 101(a), 109(a), 114(a), and 203, is amended by adding at the end:

''(ee) If it is imported or offered for import by an importer or a customs broker or filer not duly registered under section 801(r).''.

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

''(r) REGISTRATION OF IMPORTERS AND CUSTOMS BROKERS AND FILERS.—

''(1) IMPORTERS.—

''(A) REGISTRATION.—The Secretary shall require an importer of food—

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

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

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

''(2) CUSTOMS BROKERS AND FILERS.—The Secretary shall require a customs broker or filer, with respect to the importation of food—

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

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

''(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 making of an inaccurate or incomplete statement or submission of information relating to the importation of food, drugs, or devices.

''(B) REQUEST.—The importer, customs broker, or filer whose registration is suspended may request that the Secretary vacate the suspension of registration when such importer, customs broker, or filer has corrected the violation that is the basis for such suspension.

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

"(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, customs broker, or filer of the intent to cancel the registration and the basis for such cancellation.

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

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

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

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

(4) REGULATIONS.—Not later than 24 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate the regulations required to carry out section 801(r).

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

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

''PART 7—IMPORTERS OF FOOD

''SEC. 744. IMPORTERS OF FOOD.

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

''(b) CUSTOMS BROKERS AND FILERS.—The Secretary shall assess and collect an annual fee for the registration of a customs broker or filer under section 801(r).

''(c) AMOUNT OF FEE.—

''(1) BASE AMOUNTS.—For fiscal year 2010, the Secretary shall, subject to paragraph (4), determine the amount of the fees under this section for importers, customs brokers, and filers.

''(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) COLLECTIONS AND APPROPRIATIONS ACTS.—

"(A) IN GENERAL.—The fees authorized by this section—

"(i) 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

"(ii) shall only be collected and available to cover the costs associated with registering importers, customs brokers, and

filers under section 801(r) and with ensuring compliance with good importer practices respecting food.

''(B) LIMIT.—The total amount of fees charged, as adjusted under paragraphs (2) and (3), for a fiscal year may not exceed the total costs described in subparagraph (A)(ii) for such fiscal year.''.

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

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

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

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

"SEC. 911. UNIQUE FACILITY IDENTIFIER.

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

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

''(c) GUIDANCE.—The Secretary may, by guidance, specify the unique numerical identifier system to be used to meet the requirements of subsections (a) and (b) and the form, manner, and timing of a submission under such subsections. In the absence of a specification by the Secretary, a Dunn & Bradstreet Universal Numbering System (DUNS) number shall be used as the required numerical identifier for purposes of such subsections.

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

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

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

''(m) 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''.

(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 and 205, is amended by adding at the end the following:

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

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

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

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

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

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

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

SEC. 210. FALSE OR MISLEADING REPORTING TO FDA.

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

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

SEC. 211. SUBPOENA AUTHORITY.

(a) PROHIBITED ACT.—Section 301(f) is amended by inserting before the period ''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 relating to food;

''(2) any hearing, investigation, or other proceeding to determine if a person is in violation of a specific provision of this Act relating to food; or

''(3) any other matter relative to the Commissioner's jurisdiction over food under this Act, the Public Health Service Act, or the Federal Anti-Tampering Act,

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.''.

SEC. 212. WHISTLEBLOWER PROTECTIONS.

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

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

''(a) IN GENERAL.—No person who submits or is required under this Act or the Public Health Service Act to submit any information related to a food, or any officer, employee, contractor, subcontractor, or agent of such person may discharge, demote, suspend, threaten, harass, or in any other manner discriminate against an employee in the terms and conditions of employment because of any lawful act done by the employee, including within the ordinary course of the job duties of such employee—

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

''(A) a Federal regulatory or law enforcement agency;

''(B) any Member of Congress or any committee of Congress; or

''(C) a person with supervisory authority over the employee (or such other person working for the employer who has the authority to investigate, discover, or terminate the misconduct);

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

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

''(b) ENFORCEMENT ACTION.—

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

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

''(B) if the Secretary of Labor has not issued a final decision within 210 days of the

filing of the complaint and there is no showing that such delay is due to the bad faith of the claimant, or within 90 days after receiving a final decision or order from the Secretary, bringing an action at law or equity for de novo review in the appropriate district court of the United States, which court shall have jurisdiction over such action without regard to the amount in controversy, and which action shall, at the request of either party to such action, be tried by the court with a jury.

''(2) PROCEDURE.—

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

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

''(C) BURDENS OF PROOF.—An action brought under paragraph (1)(B) shall be governed by the legal burdens of proof set forth in

section 42121(b) of title 49, United States Code.

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

''(c) REMEDIES.—

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

''(2) ISSUANCE OF ORDER.—If, in response to a complaint filed under 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 205, is amended by adding at the end the following:

''(uu) The production, manufacture, processing, preparation, packing, holding, or distribution of an adulterated

or misbranded food with the knowledge or intent that such article will be imported into the United States.''.

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

''SEC. 312. EXTRATERRITORIAL JURISDICTION.

''There is extraterritorial Federal jurisdiction over any violation of this Act relating to any article of food if such article was intended for import into the United States or if any act in furtherance of the violation was committed in the United States.''.

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