110TH CONGRESS
2D SESSION

S. 3385

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

IN THE SENATE OF THE UNITED STATES

JULY 31, 2008

Mr. DURBIN (for himself, Mr. GREGG, Mr. DODD, Mr. BURR, Mr. HARKIN, and Mr. ALEXANDER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

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

SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''FDA Food Safety Modernization Act''.

(b) 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 ref-

erence 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.).

(c) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

TITLE I—GENERAL FOOD PROVISIONS

SEC. 101. INSPECTIONS OF RECORDS.

Section 414(a) (21 U.S.C. 350c(a)) is amended—

(1) by striking the heading and all follows through ''of food is'' and inserting the following: ''RECORDS INSPECTION.—

''(1) ADULTERATED FOOD.—If the Secretary has a reasonable belief that an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, is'';

(2) by inserting '', and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner,'' after ''relating to such article'';

(3) by striking the last sentence; and

(4) by inserting at the end the following:

''(2) SERIOUS ADVERSE HEALTH CONSEQUENCES.—If the Secretary believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or

animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether there is a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals.

''(3) APPLICATION.—The requirement under paragraphs (1) and (2) applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.''.

SEC. 102. REGISTRATION OF FOOD FACILITIES.

(a) UPDATING OF FOOD CATEGORY REGULATIONS; BIENNIAL REGISTRATION RENEWAL.—Section 415(a) (21 U.S.C. 350d(a)) is amended—

(1) in paragraph (2), by—

(A) striking ''conducts business and'' and inserting ''conducts business, the e-mail address for the contact person of the facility, and''; and

(B) inserting '', or any other food categories as determined appropriate by the Secretary, including by guidance)'' after ''Code of Federal Regulations'';

(2) by redesignating paragraphs (3) and (4) as paragraphs (4) and (5), respectively; and

(3) by inserting after paragraph (2) the following:

''(3) BIENNIAL REGISTRATION RENEWAL.—During the period beginning on October 1 and ending on December 31 of each even-numbered year, a registrant that has submitted a registration under paragraph (1) shall submit to the Secretary a renewal registration containing the information described in paragraph (2). The Secretary shall provide for an abbreviated registration renewal process for any registrant that has not had any changes to such information since the registrant submitted the

preceding registration or registration renewal for the facility involved.''.

(b) SUSPENSION OF REGISTRATION.—

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

(A) in subsection (a)(2), by inserting after the first sentence the following: ''The registration shall contain a consent to permit the Secretary to inspect such facility.'';

(B) by redesignating subsections (b) and (c) as subsections (c) and (d), respectively; and

(C) by inserting after subsection (a) the following:

''(b) SUSPENSION OF REGISTRATION.—

''(1) IN GENERAL.—If the Secretary determines that food manufactured, processed, packed, or held by a facility registered under this section has a reasonable probability of causing serious adverse health consequences or death to humans or animals, the Secretary may by order suspend the registration of the facility under this section in accordance with this subsection.

''(2) HEARING ON SUSPENSION.—The Secretary shall provide the registrant subject to an order under paragraph (1) with an opportunity for an in-

formal hearing, to be held as soon as possible but not later than 2 days after the issuance of the order, on the actions required for reinstatement of registration and why the registration that is subject to suspension should be reinstated. The Secretary may reinstate a registration if the Secretary determines, based on evidence presented, that adequate grounds do not exist to continue the suspension of the registration.

''(3) POST-HEARING CORRECTIVE ACTION PLAN; VACATING OF ORDER.—

''(A) CORRECTIVE ACTION PLAN.—If, after providing opportunity for an informal hearing under paragraph (2), the Secretary determines that the suspension of registration remains necessary, the Secretary shall require the registrant to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by the Secretary. The Secretary shall review such plan in a timely manner.

''(B) VACATING OF ORDER.—Upon a determination by the Secretary that adequate grounds do not exist to continue the suspension actions required by the order, or that such ac-

tions should be modified, the Secretary shall vacate the order or modify the order.

''(4) EFFECT OF SUSPENSION.—If the registration of a facility is suspended under this subsection, such facility shall not import food or offer to import food into the United States, or otherwise introduce food into interstate commerce in the United States.

''(5) REGULATIONS.—The Secretary shall promulgate regulations that describe the standards officials will use in making a determination to suspend a registration, and the format such officials will use to explain to the registrant the conditions found at the facility.

''(6) NO DELEGATION.—The authority conferred by this subsection to issue an order to suspend a registration or vacate an order of suspension shall not be delegated to any officer or employee other than the Commissioner.''.

(2) IMPORTED FOOD.—Section 801(l) (21 U.S.C. 381(l)) is amended by inserting ''(or for which a registration has been suspended under such section)'' after ''section 415''.

(c) CONFORMING AMENDMENTS.—

(1) Section 301(d) (21 U.S.C. 331(d)) is amended by inserting ''415,'' after ''404,''.

(2) Section 415(d), as redesignated by subsection (b), is amended by adding at the end before the period ''for a facility to be registered, except with respect to the reinstatement of a registration that is suspended under subsection (b)''.

SEC. 103. MANDATORY RECALL AUTHORITY.

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

''SEC. 418. MANDATORY RECALL AUTHORITY.

''(a) VOLUNTARY PROCEDURES.—If the Secretary determines, based on information gathered through the reportable food registry under section 417 or through any other means, that there is a reasonable probability that an article of food (other than infant formula) is adulterated under section 402 or misbranded under section 403(w) and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals, the Secretary shall provide the responsible party (as defined in section 417) with an opportunity to cease distribution and recall such article.

''(b) PREHEARING ORDER TO CEASE DISTRIBUTION AND GIVE NOTICE.—If the responsible party refuses to or does not voluntarily cease distribution or recall such article within the time and in the manner prescribed by the Secretary (if so prescribed), the Secretary may, by

order require, as the Secretary deems necessary, such person to—

''(1) immediately cease distribution of such article; or

''(2) immediately notify all persons—

''(A) manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such article; and

''(B) to which such article has been distributed, transported, or sold, to immediately cease distribution of such article.

''(c) HEARING ON ORDER.—The Secretary shall provide the responsible party subject to an order under subsection (b) with an opportunity for an informal hearing, to be held as soon as possible but not later than 2 days after the issuance of the order, on the actions required by the order and on why the article that is the subject of the order should not be recalled.

''(d) POST-HEARING RECALL ORDER AND MODIFICATION OF ORDER.—

''(1) AMENDMENT OF ORDER.—If, after providing opportunity for an informal hearing under subsection (c), the Secretary determines that removal of the article from commerce is necessary, the Secretary shall, as appropriate—

"(A) amend the order to require recall of such article or other appropriate action;

"(B) specify a timetable in which the recall shall occur;

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

"(D) provide notice to consumers to whom such article was, or may have been, distributed.

"(2) VACATING OF ORDER.—If, after such hearing, the Secretary determines that adequate grounds do not exist to continue the actions required by the order, or that such actions should be modified, the Secretary shall vacate the order or modify the order.

"(e) COOPERATION AND CONSULTATION.—The Secretary shall work with State and local public health officials in carrying out this section, as appropriate.

"(f) PUBLIC NOTIFICATION.—In conducting a recall under this section, the Secretary shall ensure that a press release is published regarding the recall, as well as alerts and public notices, as appropriate, in order to provide notification of the recall to consumers and retailers to whom such article was, or may have been, distributed. The notification shall include, at a minimum—

"(1) the name of the article of food subject to the recall; and

''(2) a description of the risk associated with such article.

''(g) NO DELEGATION.—The authority conferred by this section to order a recall or vacate a recall order shall not be delegated to any officer or employee other than the Commissioner.

''(h) EFFECT.—Nothing in this section shall affect the authority of the Secretary to request or participate in a voluntary recall.''.

(b) CIVIL PENALTY.—Section 303(f)(2)(A) (21 U.S.C. 333(f)(2)(A)) is amended by inserting ''or any person who does not comply with a recall order under section 418'' after ''section 402(a)(2)(B)''.

(c) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331 et seq.) is amended by adding at the end the following:

''(oo) The refusal or failure to follow an order under section 418.''.

SEC. 104. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.

(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.), as amended by section 103, is amended by adding at the end the following:

"SEC. 419. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.

"(a) IN GENERAL.—Each owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent their occurrence and provide assurances that such food is not adulterated under section 402 or misbranded under section 403(w), monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.

"(b) HAZARD ANALYSIS.—The owner, operator, or agent in charge of a facility shall—

"(1) identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including—

"(A) biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, 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; and

''(2) develop a written analysis of the hazards.

''(c) PREVENTIVE CONTROLS.—The owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that—

''(1) hazards identified in the hazard analysis conducted under subsection (b) will be significantly minimized or prevented; and

''(2) the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 or misbranded under section 403(w).

''(d) MONITORING OF EFFECTIVENESS.—The owner, operator, or agent in charge of a facility shall monitor the effectiveness of the preventive controls implemented under subsection (c) to provide assurances that the outcomes described in subsection (c) shall be achieved.

''(e) CORRECTIVE ACTIONS.—The owner, operator, or agent in charge of a facility shall establish procedures that a facility will implement if the preventive controls implemented under subsection (c) are found to be ineffective through monitoring under subsection (d).

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

''(1) the preventive controls implemented under subsection (c) are adequate to control the hazards identified under subsection (b);

''(2) the owner, operator, or agent is conducting monitoring in accordance with subsection (d);

''(3) the owner, operator, or agent is making appropriate decisions about corrective actions taken under subsection (e); and

''(4) there is documented, periodic reanalysis of the plan under subsection (i) to ensure that the plan is still relevant to the raw materials, as well as to conditions and processes in the facility, and to new and emerging threats.

''(g) RECORDKEEPING.—The owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under subsection (c), instances of nonconformance material to food safety, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.

''(h) WRITTEN PLAN AND DOCUMENTATION.—Each owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of this section, including analyzing the hazards

under subsection (b) and identifying the preventive controls adopted to address those hazards under subsection (c). Such written plan, together with documentation that the plan is being implemented, shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

''(i) REQUIREMENT TO REANALYZE.—Each owner, operator, or agent in charge of a facility shall conduct a reanalysis under subsection (b) whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or not less frequently than once every 3 years, whichever is earlier. Such reanalysis shall be completed and additional preventive controls needed to address the hazard identified, if any, shall be implemented before the change in activities at the facility is commenced. Such owner, operator, or agent shall revise the written plan required under subsection (h) if such a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed. The Secretary may require a reanalysis under this section to respond to new hazards and developments in scientific understanding.

''(j) DEEMED COMPLIANCE OF SEAFOOD, JUICE, AND LOW-ACID CANNED FOOD FACILITIES IN COMPLIANCE WITH HACCP.—An owner, operator, or agent in charge of a facility required to comply with 1 of the following standards and regulations with respect to such facility shall be deemed to be in compliance with this section, with respect to such facility:

''(1) The Seafood Hazard Analysis Critical Control Points Program of the Food and Drug Administration.

''(2) The Juice Hazard Analysis Critical Control Points Program of the Food and Drug Administration.

''(3) The Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards of the Food and Drug Administration (or any successor standards).

''(k) EXCEPTION FOR FACILITIES IN COMPLIANCE WITH SECTION 420.—This section shall not apply to a facility that is subject to section 420.

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

storage of packaged foods that are not exposed to the environment.

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

''(1) CRITICAL CONTROL POINT.—The term 'critical control point' means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

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

''(3) PREVENTIVE CONTROLS.—The term 'preventive controls' means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would have employed to significantly minimize or prevent the hazards identified under the hazard analysis conducted under subsection (a) and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis. Those procedures, practices, and processes may include the following:

''(A) Sanitation procedures for food contact surfaces and utensils and food-contact surfaces of equipment.

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

''(C) An environmental monitoring program to verify the effectiveness of pathogen controls.

''(D) An allergen control program.

''(E) A recall contingency plan.

''(F) Good Manufacturing Practices (GMPs).

''(G) Supplier verification activities.''.

(b) REGULATIONS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this Act as the ''Secretary'') shall promulgate regulations to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls under section 419 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

(2) CONTENT.—The regulations promulgated under paragraph (1) shall provide sufficient flexi-

bility to be applicable in all situations, including in the operations of small businesses.

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to provide the Secretary with the authority to apply specific technologies, practices, or critical controls to an individual facility.

(4) REVIEW.—In promulgating the regulations under paragraph (1), the Secretary shall review regulatory hazard analysis and preventive control programs in existence on the date of enactment of this Act to ensure that the program under such section 419 is consistent, to the extent practicable, with applicable internationally recognized standards in existence on such date.

(c) GUIDANCE DOCUMENT.—The Secretary shall issue a guidance document related to hazard analysis and preventive controls required under section 419 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

(d) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331), as amended by section 103, is amended by adding at the end the following:

''(pp) The operation of a facility that manufacturers, processes, packs, or holds food for sale in the United

States if the owner, operator, or agent in charge of such facility is not in compliance with section 419.''.

(e) NO EFFECT ON HACCP AUTHORITIES.—Nothing in 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.) 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.

(f) EFFECTIVE DATE.—

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

SEC. 105. PERFORMANCE STANDARDS.

The Secretary shall, not less frequently than every 2 years, review and evaluate epidemiological data and other appropriate sources of information to determine the most significant food-borne contaminants and the most significant resulting hazards, and may issue science-based guidance documents, action levels, and regulations to help prevent adulteration under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342). Such standards shall be applicable to products and product classes and shall not be written to be facility-specific.

SEC. 106. STANDARDS FOR PRODUCE SAFETY.

(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.), as amended by section 104, is amended by adding at the end the following:

"SEC. 420. STANDARDS FOR PRODUCE SAFETY.

"(a) PROPOSED RULEMAKING.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary, in consultation with the Secretary of Agriculture and representatives of State departments of agriculture, shall publish a notice of proposed rulemaking to establish science-

based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death.

''(2) PUBLIC INPUT.—During the comment period on the notice of proposed rulemaking under paragraph (1), the Secretary shall conduct not less than 3 public meetings in diverse geographical areas of the United States to provide persons in different regions an opportunity to comment.

''(3) CONTENT.—The proposed rulemaking under paragraph (1) shall—

''(A) include, with respect to growing, harvesting, sorting, and storage operations, minimum standards related to fertilizer use, nutrients, hygiene, packaging, temperature controls, animal encroachment, and water; and

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

''(4) PRIORITIZATION.—The Secretary shall prioritize the implementation of the regulations for

specific fruits and vegetables that are raw agricultural commodities that have been associated with food-borne illness outbreaks.

''(b) FINAL REGULATION.—

''(1) IN GENERAL.—Not later than 1 year after the close of the comment period for the proposed rulemaking under subsection (a), the Secretary shall adopt a final regulation to provide for minimum standards for those types of fruits and vegetables that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death.

''(2) FINAL REGULATION.—The final regulation shall—

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

''(B) provide for coordination of education and enforcement activities by State and local officials, as designated by the Governors of the respective States; and

''(C) include a description of the variance process under subsection (c) and the types of permissible variances the Secretary may grant.

''(c) CRITERIA.—

''(1) IN GENERAL.—The regulations adopted under subsection (b) shall—

''(A) set forth those procedures, processes, and practices as the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards, including hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism, into fruits and vegetables that are raw agricultural commodities and to provide reasonable assurances that the produce is not adulterated under section 402; and

''(B) permit States and foreign countries from which food is imported into the United States, subject to paragraph (2), to request from the Secretary variances from the requirements of the regulations, where upon approval of the Secretary, the variance is considered permissible under the requirements of the regulations adopted under subsection (b)(1)(C) and where the State or foreign country determines that the variance is necessary in light of local

growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 to the same extent as the requirements of the regulation adopted under subsection (b).

''(2) APPROVAL OF VARIANCES.—A State or foreign country from which food is imported into the United States shall request a variance from the Secretary in writing. The Secretary may deny such a request as not reasonably likely to ensure that the produce is not adulterated under section 402 to the same extent as the requirements of the regulation adopted under subsection (b).

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

''(e) GUIDANCE.—Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall publish, after consultation with the Secretary of Agriculture and representatives of State departments of agriculture, updated good agricultural

practices and guidance for the safe production and harvesting of specific types of fresh produce.

''(f) EXCEPTION FOR FACILITIES IN COMPLIANCE WITH SECTION 419.—This section shall not apply to a facility that is subject to section 419.''.

(b) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331), as amended by section 104, is amended by adding at the end the following:

''(qq) The production or harvesting of produce not in accordance with minimum standards as provided by regulation under section 420(b) or a variance issued under section 420(c).''.

(c) NO EFFECT ON HACCP AUTHORITIES.—Nothing in 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.) 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.

SEC. 107. TARGETING OF INSPECTION RESOURCES FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND PORTS OF ENTRY; ANNUAL REPORT.

(a) TARGETING OF INSPECTION RESOURCES FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND PORTS OF ENTRY.—Chapter IV (21 U.S.C. 341 et seq.), as amended by section 106, is amended by adding at the end the following:

"SEC. 421. TARGETING OF INSPECTION RESOURCES FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND PORTS OF ENTRY; ANNUAL REPORT.

"(a) IDENTIFICATION AND INSPECTION OF FACILITIES.—

"(1) IDENTIFICATION.—The Secretary shall allocate resources to inspect facilities according to the risk profile of the facilities, which shall be based on the following factors:

"(A) The risk profile of the food manufactured, processed, packed, or held at the facility.

"(B) The facility's history of food recalls, outbreaks, and violations of food safety standards.

"(C) The rigor of the facility's hazard analysis and risk-based preventive controls.

"(D) Whether the food manufactured, processed, packed, handled, prepared, treated,

distributed, or stored at the facility meets the criteria for priority under section 801(h)(1).

''(E) Whether the facility has received a certificate as described in section 809(b).

''(F) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

''(2) INSPECTIONS.—The Secretary shall increase the frequency of inspection of all facilities, and shall increase the frequency of inspection of facilities identified under paragraph (1) as high-risk facilities such that—

''(A) for the first 2 years after the date of enactment of the FDA Food Safety Modernization Act, each high-risk facility is inspected not less often than once every 2 years; and

''(B) for each succeeding year, each high-risk facility is inspected not less often than once each year.

''(b) IDENTIFICATION AND INSPECTION AT PORTS OF ENTRY.—The Secretary, in consultation with the Secretary of Homeland Security, shall allocate resources to inspect articles of food imported into the United States according to the risk profile of the article of food, which shall be based on the following factors:

''(1) The risk profile of the food imported.

''(2) The risk profile of the countries of origin and countries of transport of the food imported.

''(3) The history of food recalls, outbreaks, and violations of food safety standards of the food importer.

''(4) The rigor of the foreign supplier verification program under section 805.

''(5) Whether the food importer participates in the Voluntary Qualified Importer Program under section 806.

''(6) Whether the food meets the criteria for priority under section 801(h)(1).

''(7) Whether the food is from a facility that has received a certificate as described in section 809(b).

''(8) Any other criteria deemed appropriate by the Secretary for purposes of allocating inspection resources.

''(c) COORDINATION.—The Secretary shall improve coordination and cooperation with the Secretary of Agriculture to target food inspection resources.

''(d) FACILITY.—For purposes of this section, the term 'facility' means a domestic facility or a foreign facility that is required to register under section 415.''.

(b) ANNUAL REPORT.—Section 903 (21 U.S.C. 393) is amended by adding at the end the following:

''(h) ANNUAL REPORT REGARDING FOOD.—Not later than February 1 of each year, the Secretary shall submit to Congress a report regarding—

''(1) information about food facilities including—

''(A) the appropriations used to inspect facilities registered pursuant to section 415 in the previous fiscal year;

''(B) the average cost of both a non-high-risk food facility inspection and a high-risk food facility inspection, if such a difference exists, in the previous fiscal year;

''(C) the number of domestic facilities and the number of foreign facilities registered pursuant to section 415 that the Secretary inspected in the previous fiscal year;

''(D) the number of domestic facilities and the number of foreign facilities registered pursuant to section 415 that the Secretary did not inspect in the previous fiscal year;

''(E) the number of high-risk facilities identified pursuant to section 421 that the Secretary inspected in the previous fiscal year; and

''(F) the number of high-risk facilities identified pursuant to section 421 that the Secretary did not inspect in the previous fiscal year;

''(2) information about food imports including—

''(A) the number of lines of food imported into the United States that the Secretary physically inspected or sampled in the previous fiscal year;

''(B) the number of lines of food imported into the United States that the Secretary did not physically inspect or sample in the previous fiscal year; and

''(C) the average cost of physically inspecting or sampling a food line subject to this Act that is imported or offered for import into the United States; and

''(3) information on the foreign offices established under section 309 of the FDA Food Safety Modernization Act including—

''(A) the number of foreign offices established; and

''(B) the number of personnel permanently stationed in each foreign office.

''(i) PUBLIC AVAILABILITY OF ANNUAL FOOD REPORTS.—The Secretary shall make the reports required under subsection (h) available to the public on the Internet Web site of the Food and Drug Administration.''.

SEC. 108. ADMINISTRATIVE DETENTION OF FOOD.

(a) IN GENERAL.—Section 304(h)(1)(A) (21 U.S.C. 334(h)(1)(A)) is amended by—

(1) striking ''credible evidence or information indicating'' and inserting ''reason to believe''; and

(2) striking ''presents a threat of serious adverse health consequences or death to humans or animals'' and inserting ''is adulterated or misbranded''.

(b) REGULATIONS.—Not later than 120 days after the date of enactment of this Act, the Secretary shall issue an interim final rule amending subpart K of part 1 of title 21, Code of Federal Regulations, to implement the amendment made by this section.

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

SEC. 109. PROTECTION AGAINST INTENTIONAL ADULTERATION.

(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.), as amended by section 107, is amended by adding at the end the following:

"SEC. 422. PROTECTION AGAINST INTENTIONAL ADULTERATION.

''(a) IN GENERAL.—Not later than 24 months after the date of enactment of the FDA Food Safety Modernization Act, the Secretary, in consultation with the Secretary of Homeland Security and the Secretary of Agriculture, shall promulgate regulations to protect against the intentional adulteration of food subject to this Act.

''(b) CONTENT OF REGULATIONS.—Regulations under subsection (a) shall only apply to food—

''(1) for which the Secretary has identified clear vulnerabilities (such as short shelf-life or susceptibility to intentional contamination at critical control points);

''(2) in bulk or batch form, prior to being packaged for the final consumer; and

''(3) for which there is a high risk of intentional contamination, as determined by the Secretary, that could cause serious adverse health consequences or death to humans or animals.

''(c) DETERMINATIONS.—In making the determination under subsection (b)(3), the Secretary shall—

''(1) conduct vulnerability assessments of the food system;

''(2) consider the best available understanding of uncertainties, risks, costs, and benefits associated with guarding against intentional adulteration at vulnerable points; and

''(3) determine the types of science-based mitigation strategies or measures that are necessary to protect against the intentional adulteration of food.

''(d) EXCEPTION.—This section shall not apply to food produced on farms, except for milk.

''(e) DEFINITION.—For purposes of this section, the term 'farm' has the meaning given that term in section 1.227 of title 21, Code of Federal Regulations (or any successor regulation).''.

(b) GUIDANCE DOCUMENTS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary, in consultation with the Secretary of Homeland Security and the Secretary of Agriculture, shall issue guidance documents related to protection against the intentional adulteration of food, including mitigation strategies or measures to guard against such adul-

teration as required under section 422 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(2) CONTENT.—The guidance document issued under paragraph (1) shall—

(A) specify how a person shall assess whether the person is required to implement mitigation strategies or measures intended to protect against the intentional adulteration of food;

(B) specify appropriate science-based mitigation strategies or measures to prepare and protect the food supply chain at specific vulnerable points, as appropriate;

(C) include a model assessment for a person to use under subparagraph (A);

(D) include examples of mitigation strategies or measures described in subparagraph (B); and

(E) specify situations in which the examples of mitigation strategies or measures described in subparagraph (D) are appropriate.

(3) LIMITED DISTRIBUTION.—In the interest of national security, the Secretary, in consultation with the Secretary of Homeland Security, may determine

the time and manner in which the guidance documents issued under paragraph (1) are made public, including by releasing such documents to targeted audiences.

(c) PERIODIC REVIEW.—The Secretary shall periodically review and, as appropriate, update the regulation under subsection (a) and the guidance documents under subsection (b).

(d) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331 et seq.), as amended by section 106, is amended by adding at the end the following:

''(rr) The failure to comply with section 422.''.

SEC. 110. NATIONAL AGRICULTURE AND FOOD DEFENSE STRATEGY.

(a) DEVELOPMENT AND SUBMISSION OF STRATEGY.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services and the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, shall prepare and submit to the relevant committees of Congress, and make publicly available on the Internet Web site of the Department of Health and Human Services and the De-

partment of Agriculture, the National Agriculture and Food Defense Strategy.

(2) IMPLEMENTATION PLAN.—The strategy shall include an implementation plan for use by the Secretaries described under paragraph (1) in carrying out the strategy.

(3) RESEARCH.—The strategy shall include a coordinated research agenda for use by the Secretaries described under paragraph (1) in conducting research to support the goals and activities described in paragraphs (1) and (2) of subsection (b).

(4) REVISIONS.—Not later than 4 years after the date on which the strategy is submitted to the relevant committees of Congress under paragraph (1), and not less frequently than every 4 years thereafter, the Secretary of Health and Human Services and the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, shall revise and submit to the relevant committees of Congress the strategy.

(5) CONSISTENCY WITH EXISTING PLANS.—The strategy described in paragraph (1) shall be consistent with—

(A) the National Incident Management System;

(B) the National Response Framework;

(C) the National Infrastructure Protection Plan;

(D) the National Preparedness Goals; and

(E) other relevant national strategies.

(b) COMPONENTS.—

(1) IN GENERAL.—The strategy shall include a description of the process to be used by the Department of Health and Human Services, the Department of Agriculture, and the Department of Homeland Security—

(A) to achieve each goal described in paragraph (2); and

(B) to evaluate the progress made by Federal, State, local, and tribal governments towards the achievement of each goal described in paragraph (2).

(2) GOALS.—The strategy shall include a description of the process to be used by the Department of Health and Human Services, the Department of Agriculture, and the Department of Homeland Security to achieve the following goals:

(A) PREPAREDNESS GOAL.—Enhance the preparedness of the agriculture and food system by—

(i) conducting vulnerability assessments of the agriculture and food system;

(ii) mitigating vulnerabilities of the system;

(iii) improving communication and training relating to the system;

(iv) developing and conducting exercises to test decontamination and disposal plans;

(v) developing modeling tools to improve event consequence assessment and decision support; and

(vi) preparing risk communication tools and enhancing public awareness through outreach.

(B) DETECTION GOAL.—Improve agriculture and food system detection capabilities by—

(i) identifying contamination in food products at the earliest possible time; and

(ii) conducting surveillance to prevent the spread of diseases.

(C) EMERGENCY RESPONSE GOAL.—Ensure an efficient response to agriculture and food emergencies by—

(i) immediately investigating animal disease outbreaks and suspected food contamination;

(ii) preventing additional human illnesses;

(iii) organizing, training, and equipping animal, plant, and food emergency response teams of—

(I) the Federal Government; and

(II) State, local, and tribal governments;

(iv) designing, developing, and evaluating training and exercises carried out under agriculture and food defense plans; and

(v) ensuring consistent and organized risk communication to the public by—

(I) the Federal Government;

(II) State, local, and tribal governments; and

(III) the private sector.

(D) RECOVERY GOAL.—Secure agriculture and food production after an agriculture or food emergency by—

(i) working with the private sector to develop business recovery plans to rapidly resume agriculture and food production;

(ii) conducting exercises of the plans described in subparagraph (C) with the goal of long-term recovery results;

(iii) rapidly removing, and effectively disposing of—

(I) contaminated agriculture and food products; and

(II) infected plants and animals; and

(iv) decontaminating and restoring areas affected by an agriculture or food emergency.

SEC. 111. FOOD AND AGRICULTURE COORDINATING COUNCILS.

The Secretary of Homeland Security, in consultation with the Secretary of Health and Human Services and the Secretary of Agriculture, shall within 180 days of enactment of this Act, and annually thereafter, submit to the relevant committees of Congress, and make publicly available on the Internet Web site of the Department of Homeland Security, a report on the activities of the Food and Agriculture Government Coordinating Council and the

Food and Agriculture Sector Coordinating Council, including the progress of such Councils on—

(1) facilitating partnerships between public and private entities to help unify and enhance the protection of the agriculture and food system of the United States;

(2) providing for the regular and timely interchange of information between each council relating to the security of the agriculture and food system (including intelligence information);

(3) identifying best practices and methods for improving the coordination among Federal, State, local, and private sector preparedness and response plans for agriculture and food defense; and

(4) recommending methods by which to protect the economy and the public health of the United States from the effects of—

(A) animal or plant disease outbreaks;

(B) food contamination; and

(C) natural disasters affecting agriculture and food.

SEC. 112. DECONTAMINATION AND DISPOSAL STANDARDS AND PLANS.

(a) IN GENERAL.—The Administrator of the Environmental Protection Agency (referred to in this section

as the ''Administrator''), in coordination with the Secretary of Health and Human Services, Secretary of Homeland Security, and Secretary of Agriculture, shall provide support for, and technical assistance to, State, local, and tribal governments in preparing for, assessing, decontaminating, and recovering from an agriculture or food emergency.

(b) DEVELOPMENT OF STANDARDS.—In carrying out subsection (a), the Administrator, in coordination with the Secretary of Health and Human Services, Secretary of Homeland Security, Secretary of Agriculture, and State, local, and tribal governments, shall develop and disseminate specific standards and protocols to undertake clean-up, clearance, and recovery activities following the decontamination and disposal of specific threat agents and foreign animal diseases.

(c) DEVELOPMENT OF MODEL PLANS.—In carrying out subsection (a), the Administrator, the Secretary of Health and Human Services, and the Secretary of Agriculture shall jointly develop and disseminate model plans for—

(1) the decontamination of individuals, equipment, and facilities following an intentional contamination of agriculture or food; and

(2) the disposal of large quantities of animals, plants, or food products that have been infected or contaminated by specific threat agents and foreign animal diseases.

(d) EXERCISES.—In carrying out subsection (a), the Administrator, in coordination with the entities described under subsection (b), shall conduct exercises at least annually to evaluate and identify weaknesses in the decontamination and disposal model plans described in subsection (c). Such exercises shall be carried out, to the maximum extent practicable, as part of the national exercise program under section 648(b)(1) of the Post-Katrina Emergency Management Reform Act of 2006 (6 U.S.C. 748(b)(1)).

(e) MODIFICATIONS.—Based on the exercises described in subsection (d), the Administrator, in coordination with the entities described in subsection (b), shall review and modify as necessary the plans described in subsection (c) not less frequently than biennially.

(f) PRIORITIZATION.—The Administrator, in coordination with the entities described in subsection (b), shall develop standards and plans under subsections (b) and (c) in an identified order of priority that takes into account—

(1) highest-risk biological, chemical, and radiological threat agents;

(2) agents that could cause the greatest economic devastation to the agriculture and food system; and

(3) agents that are most difficult to clean or remediate.

SEC. 113. AUTHORITY TO COLLECT FEES.

(a) FEES FOR REINSPECTION, RECALL, AND IMPORTATION ACTIVITIES.—Subchapter C of chapter VII (21 U.S.C. 379f et seq.) is amended by inserting after section 740 the following:

"PART 5—FEES RELATED TO FOOD

"SEC. 740A. AUTHORITY TO COLLECT AND USE FEES.

''(a) IN GENERAL.—

''(1) PURPOSE AND AUTHORITY.—For fiscal year 2009 and each subsequent fiscal year, the Secretary shall, in accordance with this section, assess and collect fees from—

''(A) domestic facilities required to register under section 415, to cover reinspection-related costs for each such year;

''(B) domestic facilities required to register under section 415, to cover food recall activities performed by the Secretary, including technical assistance, follow-up effectiveness checks, and public notifications, for each such year;

"(C) importers required to register under section 415, to cover the administrative costs of participating in the voluntary qualified importer program under section 806 for each such year; and

"(D) importers, to cover reinspection-related costs at ports of entry for each such year.

"(2) DEFINITIONS.—For purposes of this section—

"(A) the term 'reinspection' means 1 or more inspections conducted under section 704 of this Act subsequent to an inspection conducted under such provision which identified noncompliance materially related to a food safety requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction; and

"(B) the term 'reinspection-related costs' means all expenses, including administrative expenses, incurred in connection with—

"(i) arranging, conducting, and evaluating the results of reinspections; and

"(ii) assessing and collecting reinspection fees under this section.

"(b) ESTABLISHMENT OF FEES.—

''(1) IN GENERAL.—Subject to subsections (c) and (d), the Secretary shall establish the fees to be collected under this section for each fiscal year specified in subsection (a)(1), based on the methodology described under paragraph (2), and shall publish such fees in a Federal Register notice not later than 60 days before the start of each such year.

''(2) FEE METHODOLOGY.—

''(A) FEES.—Fees amounts established for collection—

''(i) under subparagraph (A) of subsection (a)(1) for a fiscal year shall be based on the Secretary's estimate of 100 percent of the costs of the reinspection-related activities (including by type or level of reinspection activity, as the Secretary determines applicable) described in such subparagraph (A) for such year;

''(ii) under subparagraph (B) of subsection (a)(1) for a fiscal year shall be based on the Secretary's estimate of 100 percent of the costs of the activities described in such subparagraph (B) for such year;

"(iii) under subparagraph (C) of subsection (a)(1) for a fiscal year shall be based on the Secretary's estimate of 100 percent of the costs of the activities described in such subparagraph (C) for such year; and

"(iv) under subparagraph (D) of subsection (a)(1) for a fiscal year shall be based on the Secretary's estimate of 100 percent of the costs of the activities described in such subparagraph (D) for such year.

"(B) OTHER CONSIDERATIONS.—In establishing the fee amounts for a fiscal year, the Secretary shall provide for the crediting of fees from the previous year to the next year if the Secretary overestimated the amount of fees needed to carry out such activities, and consider the need to account for any adjustment of fees and such other factors as the Secretary determines appropriate.

"(3) COMPLIANCE WITH INTERNATIONAL AGREEMENTS.—Nothing in this section shall be construed to authorize the assessment of any fee inconsistent with the agreement establishing the World

Trade Organization or any other treaty or international agreement to which the United States is a party.

''(c) LIMITATIONS.—

''(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2009 unless appropriations for the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine and related activities of the Office of Regulatory Affairs at 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 Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine and related activities of the Office of Regulatory Affairs at the Food and Drug Administration for the preceding fiscal year (excluding the amount of fees appropriated for such fiscal year) multiplied by 1 plus 4.5 percent.

''(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, under subsection (a), notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

''(3) LIMITATION ON AMOUNT OF CERTAIN FEES.—Notwithstanding any other provision of this section, in no case may the amount of the fees collected for a fiscal year—

''(A) under subparagraph (B) of subsection (a)(1) exceed $20,000,000; and

''(B) under subparagraphs (A) and (D) of subsection (a)(1) exceed $25,000,000 combined.

''(d) CREDITING AND AVAILABILITY OF FEES.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided 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 account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the purpose of paying the operating expenses of the Food and Drug Administration employees and contractors performing activities associated with these food safety fees.

''(e) COLLECTION OF FEES.—

''(1) IN GENERAL.—The Secretary shall specify in the Federal Register notice described in subsection (b)(1) the time and manner in which fees assessed under this section shall be collected.

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

''(f) ANNUAL REPORT TO CONGRESS.—Not later than 120 days after each fiscal year for which fees are assessed under this section, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the United States Senate and the Committee on Energy and Commerce of the United States House of Representatives, to include a description of fees assessed and collected for each such year and a summary description of the entities paying such fees and the types of business in which such entities engage.

''(g) AUTHORIZATION OF APPROPRIATIONS.—For fiscal year 2009 and each fiscal year thereafter, there is authorized to be appropriated for fees under this section an

amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under the other provisions of this section.''.

(b) EXPORT CERTIFICATION FEES FOR FOODS AND ANIMAL FEED.—

(1) AUTHORITY FOR EXPORT CERTIFICATIONS FOR FOOD, INCLUDING ANIMAL FEED.—Section 801(e)(4)(A) (21 U.S.C. 381(e)(4)(A)) is amended—

(A) in the matter preceding clause (i), by striking ''a drug'' and inserting ''a food, drug'';

(B) in clause (i) by striking ''exported drug'' and inserting ''exported food, drug''; and

(C) in clause (ii) by striking ''the drug'' each place it appears and inserting ''the food, drug''.

(2) CLARIFICATION OF CERTIFICATION.—Section 801(e)(4) (21 U.S.C. 381(e)(4)) is amended by inserting after subparagraph (B) the following new subparagraph:

''(C) For purposes of this paragraph, a certification by the Secretary shall be made on such basis, and in such form (including a pub-

licly available listing) as the Secretary determines appropriate.''.

SEC. 114. FINAL RULE FOR PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS DURING PRODUCTION.

Not later than 1 year after the date of enactment of this Act, the Secretary shall issue a final rule based on the proposed rule issued by the Commissioner of Food and Drugs entitled ''Prevention of Salmonella Enteritidis in Shell Eggs During Production'', 69 Fed. Reg. 56824, (September 22, 2004).

SEC. 115. SANITARY TRANSPORTATION OF FOOD.

Not later than 1 year after the date of enactment of this Act, the Secretary shall promulgate regulations described in section 416(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350e(b)).

SEC. 116. FOOD ALLERGY AND ANAPHYLAXIS MANAGEMENT.

(a) DEFINITIONS.—In this section:

(1) EARLY CHILDHOOD EDUCATION PROGRAM.—The term ''early childhood education program'' means—

(A) a Head Start program or an Early Head Start program carried out under the Head Start Act (42 U.S.C. 9831 et seq.);

(B) a State licensed or regulated child care program or school; or

(C) a State prekindergarten program that serves children from birth through kindergarten.

(2) ESEA DEFINITIONS.—The terms ''local educational agency'', ''secondary school'', ''elementary school'', and ''parent'' have the meanings given the terms in section 9101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(3) SCHOOL.—The term ''school'' includes public—

(A) kindergartens;

(B) elementary schools; and

(C) secondary schools.

(b) ESTABLISHMENT OF VOLUNTARY FOOD ALLERGY AND ANAPHYLAXIS MANAGEMENT GUIDELINES.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary, in consultation with the Secretary of Education, shall—

(i) develop guidelines to be used on a voluntary basis to develop plans for individuals to manage the risk of food allergy

and anaphylaxis in schools and early childhood education programs; and

(ii) make such guidelines available to local educational agencies, schools, early childhood education programs, and other interested entities and individuals to be implemented on a voluntary basis only.

(B) APPLICABILITY OF FERPA.—Each plan described in subparagraph (A) that is developed for an individual shall be considered an education record for the purpose of the Family Educational Rights and Privacy Act of 1974 (20 U.S.C. 1232g).

(2) CONTENTS.—The voluntary guidelines developed by the Secretary under paragraph (1) shall address each of the following, and may be updated as the Secretary deems necessary:

(A) Parental obligation to provide the school or early childhood education program, prior to the start of every school year, with—

(i) documentation from their child's physician or nurse—

(I) supporting a diagnosis of food allergy and the risk of anaphylaxis;

(II) identifying any food to which the child is allergic;

(III) describing, if appropriate, any prior history of anaphylaxis;

(IV) listing any medication prescribed for the child for the treatment of anaphylaxis;

(V) detailing emergency treatment procedures in the event of a reaction;

(VI) listing the signs and symptoms of a reaction; and

(VII) assessing the child's readiness for self-administration of prescription medication; and

(ii) a list of substitute meals that may be offered to the child by school or early childhood education program food service personnel.

(B) The creation and maintenance of an individual health care plan for food allergy management, in consultation with the parent, tailored to the needs of each child with a documented risk for anaphylaxis, including any pro-

cedures for the self-administration of medication by such children in instances where—

(i) the children are capable of self-administering medication; and

(ii) such administration is not prohibited by State law.

(C) Communication strategies between individual schools or early childhood education programs and local providers of emergency medical services, including appropriate instructions for emergency medical response.

(D) Strategies to reduce the risk of exposure to anaphylactic causative agents in classrooms and common school or early childhood education program areas such as cafeterias.

(E) The dissemination of general information on life-threatening food allergies to school or early childhood education program staff, parents, and children.

(F) Food allergy management training of school or early childhood education program personnel who regularly come into contact with children with life-threatening food allergies.

(G) The authorization and training of school or early childhood education program

personnel to administer epinephrine when the nurse is not immediately available.

(H) The timely accessibility of epinephrine by school or early childhood education program personnel when the nurse is not immediately available.

(I) The creation of a plan contained in each individual health care plan for food allergy management that addresses the appropriate response to an incident of anaphylaxis of a child while such child is engaged in extracurricular programs of a school or early childhood education program, such as non-academic outings and field trips, before- and after-school programs or before- and after-early child education program programs, and school-sponsored or early childhood education program-sponsored programs held on weekends.

(J) Maintenance of information for each administration of epinephrine to a child at risk for anaphylaxis and prompt notification to parents.

(K) Other elements the Secretary deems necessary for the management of food allergies

and anaphylaxis in schools and early childhood education programs.

(3) RELATION TO STATE LAW.—Nothing in this section or the guidelines developed by the Secretary under paragraph (1) shall be construed to preempt State law, including any State law regarding whether students at risk for anaphylaxis may self-administer medication.

(c) SCHOOL-BASED FOOD ALLERGY MANAGEMENT GRANTS.—

(1) IN GENERAL.—The Secretary may award grants to local educational agencies to assist such agencies with implementing voluntary food allergy and anaphylaxis management guidelines described in subsection (b).

(2) APPLICATION.—

(A) IN GENERAL.—To be eligible to receive a grant under this subsection, a local educational agency shall submit an application to the Secretary at such time, in such manner, and including such information as the Secretary may reasonably require.

(B) CONTENTS.—Each application submitted under subparagraph (A) shall include—

(i) an assurance that the local educational agency has developed plans in accordance with the food allergy and anaphylaxis management guidelines described in subsection (b);

(ii) a description of the activities to be funded by the grant in carrying out the food allergy and anaphylaxis management guidelines, including—

(I) how the guidelines will be carried out at individual schools served by the local educational agency;

(II) how the local educational agency will inform parents and students of the guidelines in place;

(III) how school nurses, teachers, administrators, and other school-based staff will be made aware of, and given training on, when applicable, the guidelines in place; and

(IV) any other activities that the Secretary determines appropriate;

(iii) an itemization of how grant funds received under this subsection will be expended;

(iv) a description of how adoption of the guidelines and implementation of grant activities will be monitored; and

(v) an agreement by the local educational agency to report information required by the Secretary to conduct evaluations under this subsection.

(3) USE OF FUNDS.—Each local educational agency that receives a grant under this subsection may use the grant funds for the following:

(A) Purchase of materials and supplies, including limited medical supplies such as epinephrine and disposable wet wipes, to support carrying out the food allergy and anaphylaxis management guidelines described in subsection (b).

(B) In partnership with local health departments, school nurse, teacher, and personnel training for food allergy management.

(C) Programs that educate students as to the presence of, and policies and procedures in place related to, food allergies and anaphylactic shock.

(D) Outreach to parents.

(E) Any other activities consistent with the guidelines described in subsection (b).

(4) DURATION OF AWARDS.—The Secretary may award grants under this subsection for a period of not more than 2 years. In the event the Secretary conducts a program evaluation under this subsection, funding in the second year of the grant, where applicable, shall be contingent on a successful program evaluation by the Secretary after the first year.

(5) LIMITATION ON GRANT FUNDING.—The Secretary may not provide grant funding to a local educational agency under this subsection after such local educational agency has received 2 years of grant funding under this subsection.

(6) MAXIMUM AMOUNT OF ANNUAL AWARDS.—A grant awarded under this subsection may not be made in an amount that is more than $50,000 annually.

(7) PRIORITY.—In awarding grants under this subsection, the Secretary shall give priority to local educational agencies with the highest percentages of children who are counted under section 1124(c) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 6333(c)).

(8) MATCHING FUNDS.—

(A) IN GENERAL.—The Secretary may not award a grant under this subsection unless the local educational agency agrees that, with respect to the costs to be incurred by such local educational agency in carrying out the grant activities, the local educational agency shall make available (directly or through donations from public or private entities) non-Federal funds toward such costs in an amount equal to not less than 25 percent of the amount of the grant.

(B) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—Non-Federal funds required under subparagraph (A) may be cash or in kind, including plant, equipment, or services. Amounts provided by the Federal Government, and any portion of any service subsidized by the Federal Government, may not be included in determining the amount of such non-Federal funds.

(9) ADMINISTRATIVE FUNDS.—A local educational agency that receives a grant under this subsection may use not more than 2 percent of the grant amount for administrative costs related to carrying out this subsection.

(10) PROGRESS AND EVALUATIONS.—At the completion of the grant period referred to in paragraph (4), a local educational agency shall provide the Secretary with information on how grant funds were spent and the status of implementation of the food allergy and anaphylaxis management guidelines described in subsection (b).

(11) SUPPLEMENT, NOT SUPPLANT.—Grant funds received under this subsection shall be used to supplement, and not supplant, non-Federal funds and any other Federal funds available to carry out the activities described in this subsection.

(12) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $30,000,000 for fiscal year 2009 and such sums as may be necessary for each of the 4 succeeding fiscal years.

(d) VOLUNTARY NATURE OF GUIDELINES.—

(1) IN GENERAL.—The food allergy and anaphylaxis management guidelines developed by the Secretary under subsection (b) are voluntary. Nothing in this section or the guidelines developed by the Secretary under subsection (b) shall be construed to require a local educational agency to implement such guidelines.

(2) EXCEPTION.—Notwithstanding paragraph (1), the Secretary may enforce an agreement by a local educational agency to implement food allergy and anaphylaxis management guidelines as a condition of the receipt of a grant under subsection (c).

TITLE II—DETECTION AND SURVEILLANCE

SEC. 201. RECOGNITION OF LABORATORY ACCREDITATION FOR ANALYSES OF FOODS.

(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.), as amended by section 109, is amended by adding at the end the following:

"SEC. 423. RECOGNITION OF LABORATORY ACCREDITATION FOR ANALYSES OF FOODS.

''(a) RECOGNITION OF LABORATORY ACCREDITATION.—

''(1) IN GENERAL.—Not later than 2 years after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall—

''(A) provide for the recognition of accreditation bodies that accredit laboratories, including laboratories run and operated by a State or locality, with a demonstrated capability to conduct analytical testing of food products; and

''(B) establish a publicly available registry of accreditation bodies, including the name of, contact information for, and other information deemed necessary by the Secretary about such bodies.

''(2) MODEL ACCREDITATION STANDARDS.—The Secretary shall develop model standards that an accreditation body shall require laboratories to meet in order to be included in the registry provided for under paragraph (1). In developing the model standards, the Secretary shall look to existing standards for guidance. The model standards shall include methods to ensure that—

''(A) appropriate sampling and analytical procedures are followed and reports of analyses are certified as true and accurate;

''(B) internal quality systems are established and maintained;

''(C) procedures exist to evaluate and respond promptly to complaints regarding analyses and other activities for which the laboratory is recognized;

''(D) individuals who conduct the analyses are qualified by training and experience to do so; and

''(E) any other criteria determined appropriate by the Secretary.

''(3) REVIEW OF ACCREDITATION.—To assure compliance with the requirements of this section, the Secretary shall—

''(A) periodically, or at least every 5 years, reevaluate accreditation bodies recognized under paragraph (1); and

''(B) promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of this section.

''(b) TESTING PROCEDURES.—Food testing shall be conducted by either Federal laboratories or non-Federal laboratories that have been accredited by an accreditation body on the registry established by the Secretary under subsection (a) whenever such testing is either conducted by or on behalf of an owner or consignee—

''(1) in support of admission of an article of food under section 801(a);

''(2) due to a specific testing requirement in this Act or implementing regulations;

''(3) under an Import Alert that requires successful consecutive tests; or

''(4) is so required by the Secretary as the Secretary deems appropriate.

The results of any such sampling or testing shall be sent directly to the Food and Drug Administration.

''(c) REVIEW BY SECRETARY.—If food sampling and testing performed by a laboratory run and operated by a State or locality that is accredited by an accreditation body on the registry established by the Secretary under subsection (a) result in a State recalling a food, the Secretary shall review the sampling and testing results for the purpose of determining the need for a national recall or other compliance and enforcement activities.''.

(b) FOOD EMERGENCY RESPONSE NETWORK.—The Secretary, in coordination with the Secretary of Agriculture, the Secretary of Homeland Security, and State, local, and tribal governments shall, not later than 180 days after the date of enactment of this Act, and biennially thereafter, submit to the relevant committees of Congress, and make publicly available on the Internet Web site of the Department of Health and Human Services, a report on the progress in implementing a national food emergency response laboratory network that—

(1) provides ongoing surveillance, rapid detection, and surge capacity for large-scale food-related emergencies, including intentional adulteration of the food supply;

(2) coordinates the food laboratory capacities of State food laboratories, including the sharing of data between State laboratories to develop national situational awareness;

(3) provides accessible, timely, accurate, and consistent food laboratory services throughout the United States;

(4) develops and implements a methods repository for use by Federal, State, and local officials;

(5) responds to food-related emergencies; and

(6) is integrated with relevant laboratory networks administered by other Federal agencies.

SEC. 202. INTEGRATED CONSORTIUM OF LABORATORY NETWORKS.

(a) IN GENERAL.—The Secretary of Homeland Security, in consultation with the Secretary of Health and Human Services, the Secretary of Agriculture, and the Administrator of the Environmental Protection Agency, shall maintain an agreement through which relevant laboratory network members, as determined by the Secretary of Homeland Security, shall—

(1) agree on common laboratory methods in order to facilitate the sharing of knowledge and information relating to animal health, agriculture, and human health;

(2) identify the means by which each laboratory network member could work cooperatively—

(A) to optimize national laboratory preparedness; and

(B) to provide surge capacity during emergencies; and

(3) engage in ongoing dialogue and build relationships that will support a more effective and integrated response during emergencies.

(b) REPORTING REQUIREMENT.—The Secretary of Homeland Security shall, on a biennial basis, submit to the relevant committees of Congress, and make publicly available on the Internet Web site of the Department of Homeland Security, a report on the progress of the integrated consortium of laboratory networks, as established under subsection (a), in carrying out this section.

SEC. 203. BUILDING DOMESTIC CAPACITY.

(a) IN GENERAL.—

(1) INITIAL REPORT.—The Secretary shall, not later than 2 years after the date of enactment of this Act, submit to Congress a comprehensive report that identifies programs and practices that are intended to promote the safety and security of food and to prevent outbreaks of food-borne illness and other food-related hazards that can be addressed

through preventive activities. Such report shall include a description of the following:

(A) Analysis of the need for regulations or guidance to industry.

(B) Outreach to food industry sectors, including through the Food and Agriculture Coordinating Councils referred to in section 111, to identify potential sources of emerging threats to the safety and security of the food supply and preventive strategies to address those threats.

(C) Systems to ensure the prompt distribution to the food industry of information and technical assistance concerning preventive strategies.

(D) Communication systems to ensure that information about specific threats to the safety and security of the food supply are rapidly and effectively disseminated.

(E) Surveillance systems and laboratory networks to rapidly detect and respond to foodborne illness outbreaks and other food-related hazards, including how such systems and networks are integrated.

(F) Outreach, education, and training provided to States to build State food safety and food defense capabilities, including progress implementing strategies developed under sections 110 and 205.

(G) The estimated resources needed to effectively implement the programs and practices identified in the report developed in this section over a 5-year period.

(2) BIENNIAL REPORTS.—On a biennial basis following the submission of the report under paragraph (1), the Secretary shall submit to Congress a report that—

(A) reviews previous food safety programs and practices;

(B) outlines the success of those programs and practices;

(C) identifies future programs and practices; and

(D) includes information related to any matter described in subparagraphs (A) through (G) of paragraph (1), as necessary.

(b) RISK-BASED ACTIVITIES.—The report developed under subsection (a)(1) shall describe methods that seek to ensure that resources available to the Secretary for food

safety-related activities are directed at those actions most likely to reduce risks from food, including the use of preventive strategies and allocation of inspection resources. The Secretary shall promptly undertake those risk-based actions that are identified during the development of the report as likely to contribute to the safety and security of the food supply.

(c) CAPABILITY FOR LABORATORY ANALYSES; RESEARCH.—The report developed under subsection (a)(1) shall provide a description of methods to increase capacity to undertake analyses of food samples promptly after collection, to identify new and rapid analytical techniques, including techniques that can be employed at ports of entry and through Food Emergency Response Network laboratories, and to provide for well-equipped and staffed laboratory facilities.

(d) INFORMATION TECHNOLOGY.—The report developed under subsection (a)(1) shall include a description of such information technology systems as may be needed to identify risks and receive data from multiple sources, including foreign governments, State, local, and tribal governments, other Federal agencies, the food industry, laboratories, laboratory networks, and consumers. The information technology systems that the Secretary describes shall also provide for the integration of the facility reg-

istration system under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), and the prior notice system under section 801(m) of such Act (21 U.S.C. 381(m)) with other information technology systems that are used by the Federal Government for the processing of food offered for import into the United States.

(e) AUTOMATED RISK ASSESSMENT.—The report developed under subsection (a)(1) shall include a description of progress toward developing and improving an automated risk assessment system for food safety surveillance and allocation of resources.

(f) TRACEBACK AND SURVEILLANCE REPORT.—The Secretary shall include in the report developed under subsection (a)(1) an analysis of the Food and Drug Administration's performance in food-borne illness outbreaks during the 5-year period preceding the date of enactment of this Act involving fruits and vegetables that are raw agricultural commodities (as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(r)) and recommendations for enhanced surveillance, outbreak response, and traceability. Such findings and recommendations shall address communication and coordination with the public and industry, outbreak identification, and traceback.

(g) BIENNIAL FOOD SAFETY AND FOOD DEFENSE RESEARCH PLAN.—The Secretary and the Secretary of Agriculture shall, on a biennial basis, submit to Congress a joint food safety and food defense research plan which may include studying the long-term health effects of food-borne illness. Such biennial plan shall include a list and description of projects conducted during the previous 2-year period and the plan for projects to be conducted during the following 2-year period.

SEC. 204. ENHANCING TRACEBACK AND RECORDKEEPING.

(a) IN GENERAL.—The Secretary, in consultation with the Secretary of Agriculture and representatives of State departments of health and agriculture, shall improve the capacity of the Secretary to effectively and rapidly track and trace, in the event of an outbreak, fruits and vegetables that are raw agricultural commodities.

(b) PILOT PROJECT.—

(1) IN GENERAL.—Not later than 9 months after the date of enactment of this Act, the Secretary shall establish a pilot project in coordination with the produce industry to explore and evaluate new methods for rapidly and effectively tracking and tracing fruits and vegetables that are raw agricultural commodities so that, if an outbreak occurs involving such a fruit or vegetable, the Secretary may

quickly identify the source of the outbreak and the recipients of the contaminated food.

(2) CONTENT.—The Secretary shall select participants from the produce industry to run projects which overall shall include at least 3 different types of fruits or vegetables that have been the subject of outbreaks during the 5-year period preceding the date of enactment of this Act, and shall be selected in order to develop and demonstrate—

(A) methods that are applicable and appropriate for small businesses; and

(B) technologies, including existing technologies, that enhance traceback and trace forward.

(c) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary shall report to Congress on the findings of the pilot project under subsection (b) together with recommendations for establishing more effective traceback and trace forward procedures for fruits and vegetables that are raw agricultural commodities.

(d) TRACEBACK PERFORMANCE REQUIREMENTS.—Not later than 24 months after the date of enactment of this Act, the Secretary shall publish a notice of proposed rulemaking to establish standards for the type of informa-

tion, format, and timeframe for persons to submit records to aid the Secretary in effectively and rapidly tracking and tracing, in the event of an outbreak, fruits and vegetables that are raw agricultural commodities. Nothing in this section shall be construed as giving the Secretary the authority to prescribe specific technologies for the maintenance of records.

(e) PUBLIC INPUT.—During the comment period in the notice of proposed rulemaking under subsection (d), the Secretary shall conduct not less than 3 public meetings in diverse geographical areas of the United States to provide persons in different regions an opportunity to comment.

(f) RAW AGRICULTURAL COMMODITY.—In this section, the term ''raw agricultural commodity'' has the meaning given that term in section 201(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(r)).

SEC. 205. SURVEILLANCE.

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

(b) FOOD-BORNE ILLNESS SURVEILLANCE SYSTEMS.—

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

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

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

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

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

(E) expanding capacity of such systems, including working toward automatic electronic searches, for implementation of fingerprinting

strategies for food-borne infectious agents, in order to identify new or rarely documented causes of food-borne illness and submit standardized information to a centralized database;

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

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

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

(I) integrating food-borne illness surveillance systems and data with other biosurveillance and public health situational awareness capabilities at the state and federal levels; and

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

(2) PARTNERSHIPS.—The Secretary shall support and maintain a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food industry, consumer organizations, and academia. Such working group shall provide the Secretary, through at least annual meetings of the working group and an annual public report, advice and recommenda-

tions on an ongoing and regular basis regarding the improvement of food-borne illness surveillance and implementation of this section, including advice and recommendations on—

(A) the priority needs of regulatory agencies, the food industry, and consumers for information and analysis on food-borne illness and its causes;

(B) opportunities to improve the effectiveness of initiatives at the Federal, State, and local levels, including coordination and integration of activities among Federal agencies, and between the Federal, State, and local levels of government;

(C) improvement in the timeliness and depth of access by regulatory and health agencies, the food industry, academic researchers, and consumers to food-borne illness surveillance data collected by government agencies at all levels, including data compiled by the Centers for Disease Control and Prevention;

(D) key barriers to improvement in food-borne illness surveillance and its utility for preventing food-borne illness at Federal, State, and local levels;

(E) the capabilities needed for establishing automatic electronic searches of surveillance data; and

(F) specific actions to reduce barriers to improvement, implement the working group's recommendations, and achieve the purposes of this section, with measurable objectives and timelines, and identification of resource and staffing needs.

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

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

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

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

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

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

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

(F) Strengthen the capacity of State and local agencies to achieve the goals described in section 110.

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

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

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

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

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

(d) FOOD SAFETY CAPACITY BUILDING GRANTS.—Section 317R(b) of the Public Health Service Act (42 U.S.C. 247b–20(b)) is amended—

(1) by striking ''2002'' and inserting ''2009''; and

(2) by striking ''2003 through 2006'' and inserting ''2010 through 2013''.

TITLE III—SPECIFIC PROVISIONS FOR IMPORTED FOOD

SEC. 301. FOREIGN SUPPLIER VERIFICATION PROGRAM.

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

''SEC. 805. FOREIGN SUPPLIER VERIFICATION PROGRAM.

''(a) IN GENERAL.—

''(1) VERIFICATION REQUIREMENT.—Each United States importer of record shall perform risk-based foreign supplier verification activities in accordance with regulations promulgated under subsection (c) for the purpose of verifying that the food imported by the importer of record or its agent is—

''(A) produced in compliance with the requirements of section 419 or 420, as appropriate; and

''(B) is not adulterated under section 402 or misbranded under section 403(w).

''(2) IMPORTER EXCLUSION.—For purposes of this section, an 'importer of record' shall not include a person holding a valid license under section 641 of the Tariff Act of 1930 (19 U.S.C. 1641) (referred to as a 'customs broker') if the customs broker has executed a written agreement with another person who has agreed to comply with the requirements of this section with regard to food imported or offered for import by the customs broker.

''(b) GUIDANCE.—Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall issue guidance to assist United States importers of record in developing foreign supplier verification programs.

''(c) REGULATIONS.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall promulgate regulations to provide for the content of the foreign supplier verification program established under subsection (a). Such regulations shall, as appropriate, include a process for verification by a United States importer of record, with respect to each foreign supplier from which it obtains food, that the imported food is produced in compliance with the requirements of section 419 or 420, as appropriate, and is not adulterated under section 402 or misbranded under section 403(w).

''(2) VERIFICATION.—The regulations under paragraph (1) shall require that the foreign supplier verification program of each importer of record be adequate to provide assurances that each foreign supplier to the importer of record produces the imported food employing processes and procedures, including risk-based reasonably appropriate preventive controls, equivalent in preventing adulteration and reducing hazards as those required by section 419 or section 420, as appropriate.

''(3) ACTIVITIES.—Verification activities under a foreign supplier verification program under this section may include monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier, and periodically testing and sampling shipments.

''(d) RECORD MAINTENANCE AND ACCESS.—Records of a United States importer of record related to a foreign supplier verification program shall be maintained for a period of not less than 2 years and shall be made available promptly to a duly authorized representative of the Secretary upon request.

''(e) DEEMED COMPLIANCE OF SEAFOOD, JUICE, AND LOW-ACID CANNED FOOD FACILITIES IN COMPLIANCE WITH HACCP.—An owner, operator, or agent in charge of a facility required to comply with 1 of the following standards and regulations with respect to such facility shall be deemed to be in compliance with this section with respect to such facility:

''(1) The Seafood Hazard Analysis Critical Control Points Program of the Food and Drug Administration.

''(2) The Juice Hazard Analysis Critical Control Points Program of the Food and Drug Administration.

''(3) The Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards of the Food and Drug Administration (or any successor standards).

''(f) PUBLICATION OF LIST OF PARTICIPANTS.—The Secretary shall publish and maintain on the Internet Web site of the Food and Drug Administration a current list that includes the name of, location of, and other information deemed necessary by the Secretary about, importers participating under this section.''.

(b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331), as amended by section 109, is amended by adding at the end the following:

''(ss) The importation or offering for importation of a food if the importer of record does not have in place a foreign supplier verification program in compliance with section 805.''.

(c) IMPORTS.—Section 801(a) (21 U.S.C. 381(a)) is amended by adding ''or the importer of record is in violation of section 805'' after ''or in violation of section 505''.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect 2 years after the date of enactment of this Act.

SEC. 302. VOLUNTARY QUALIFIED IMPORTER PROGRAM.

Chapter VIII (21 U.S.C. 381 et seq.), as amended by section 301, is amended by adding at the end the following:

"SEC. 806. VOLUNTARY QUALIFIED IMPORTER PROGRAM.

''(a) IN GENERAL.—Beginning not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall—

''(1) establish a program, in consultation with the Department of Homeland Security, to provide for the expedited review and importation of food offered for importation by United States importers who have voluntarily agreed to participate in such program; and

''(2) issue a guidance document related to participation and compliance with such program.

''(b) VOLUNTARY PARTICIPATION.—An importer may request the Secretary to provide for the expedited review and importation of designated foods in accordance with the program procedures established by the Secretary.

''(c) ELIGIBILITY.—In order to be eligible, an importer shall be offering food for importation from a facility

that has a certification described in section 809(b). In reviewing the applications and making determinations on such requests, the Secretary shall consider the risk of the food to be imported based on factors, such as the following:

''(1) The nature of the food to be imported.

''(2) The compliance history of the foreign supplier.

''(3) The capability of the regulatory system of the country of export to ensure compliance with United States food safety standards.

''(4) The compliance of the importer with the requirements of section 805.

''(5) The recordkeeping, testing, inspections and audits of facilities, traceability of articles of food, temperature controls, and sourcing practices of the importer.

''(6) The potential risk for intentional adulteration of the food.

''(7) Any other factor that the Secretary determines appropriate.

''(d) REVIEW AND REVOCATION.—Any importer qualified by the Secretary in accordance with the eligibility criteria set forth in this section shall be reevaluated not less often than once every 3 years and the Secretary shall

promptly revoke the qualified importer status of any importer found not to be in compliance with such criteria.

''(e) DEFINITION.—For purposes of this section, the term 'importer' means the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States.''.

SEC. 303. AUTHORITY TO REQUIRE IMPORT CERTIFICATIONS FOR FOOD.

(a) IN GENERAL.—Section 801(a) (21 U.S.C. 381(a)) is amended by inserting after the third sentence the following: ''With respect to an article of food, if importation of such food is subject to, but not compliant with, the requirement under subsection (p) that such food be accompanied by a certification or other assurance that the food meets some or all applicable requirements of this Act, then such article shall be refused admission.''.

(b) ADDITION OF CERTIFICATION REQUIREMENT.—Section 801 (21 U.S.C. 381) is amended by adding at the end the following new subsection:

''(p) CERTIFICATIONS CONCERNING IMPORTED FOODS.—

''(1) IN GENERAL.—The Secretary, based on public health considerations, including risks associated with the food or its place of origin, may require as a condition of granting admission to an article of

food imported or offered for import into the United States, that an entity specified in paragraph (2) provide a certification or such other assurances as the Secretary determines appropriate that the article of food complies with some or all applicable requirements of this Act, as specified by the Secretary. Such certification or assurances may be provided in the form of shipment-specific certificates, a listing of certified entities, or in such other form as the Secretary may specify. Such certification shall be used for designated food imported from countries with which the Food and Drug Administration has an agreement to establish a certification program.

''(2) CERTIFYING ENTITIES.—For purposes of paragraph (1), entities that shall provide the certification or assurances described in such paragraph are—

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

''(B) such other persons or entities accredited pursuant to section 809 to provide such certification or assurance.

''(3) RENEWAL AND REFUSAL OF CERTIFICATIONS.—The Secretary may—

''(A) require that any certification or other assurance provided by an entity specified in paragraph (2) be renewed by such entity at such times as the Secretary determines appropriate; and

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

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

(c) CONFORMING TECHNICAL AMENDMENT.—Section 801(b) (21 U.S.C. 381(b)) is amended in the second sentence by striking ''with respect to an article included within the provision of the fourth sentence of subsection (a)'' and inserting ''with respect to an article described in subsection (a) relating to the requirements of sections 760 or 761,''.

(d) NO LIMIT ON AUTHORITY.—Nothing in the amendments made by this section shall limit the authority of the Secretary to conduct random inspections of imported food or to take such other steps as the Secretary

deems appropriate to determine the admissibility of imported food.

SEC. 304. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.

(a) IN GENERAL.—Section 801(m)(1) (21 U.S.C. 381(m)(1)) is amended by inserting ''any country to which the article has been refused entry;'' after ''the country from which the article is shipped;''.

(b) REGULATIONS.—Not later than 120 days after the date of enactment of this Act, the Secretary shall issue an interim final rule amending subpart I of part 1 of title 21, Code of Federal Regulations, to implement the amendment made by this section.

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

SEC. 305. REVIEW OF A REGULATORY AUTHORITY OF A FOREIGN COUNTRY.

Chapter VIII (21 U.S.C. 381 et seq.), as amended by section 302, is amended by adding at the end the following:

''SEC. 807. REVIEW OF A REGULATORY AUTHORITY OF A FOREIGN COUNTRY.

''The Secretary may review information from a country outlining the statutes, regulations, standards, and controls of such country, and conduct on-site audits in such

country to verify the implementation of those statutes, regulations, standards, and controls. Based on such review, the Secretary shall determine whether such country can provide reasonable assurances that the food supply of the country is equivalent in safety to food manufactured, processed, packed, or held in the United States.''.

SEC. 306. BUILDING CAPACITY OF FOREIGN GOVERNMENTS WITH RESPECT TO FOOD.

(a) IN GENERAL.—The Secretary shall, not later than 2 years of the date of enactment of this Act, develop a comprehensive plan to expand the technical, scientific, and regulatory capacity of foreign governments, and their respective food industries, from which foods are exported to the United States.

(b) CONSULTATION.—In developing the plan under subsection (a), the Secretary shall consult with the Secretary of Agriculture, Secretary of State, Secretary of the Treasury, and the Secretary of Commerce, representatives of the food industry, appropriate foreign government officials, and nongovernmental organizations that represent the interests of consumers, and other stakeholders.

(c) PLAN.—The plan developed under subsection (a) shall include, as appropriate, the following:

(1) Recommendations for bilateral and multilateral arrangements and agreements, including provi-

sions to provide for responsibility of exporting countries to ensure the safety of food.

(2) Provisions for electronic data sharing.

(3) Provisions for mutual recognition of inspection reports.

(4) Training of foreign governments and food producers on United States requirements for safe food.

(5) Recommendations to harmonize requirements under the Codex Alimentarius.

(6) Provisions for the multilateral acceptance of laboratory methods and detection techniques.

SEC. 307. INSPECTION OF FOREIGN FOOD FACILITIES.

Chapter VIII (21 U.S.C. 381 et seq.), as amended by section 305, is amended by inserting at the end the following:

"SEC. 808. INSPECTION OF FOREIGN FOOD FACILITIES.

''(a) INSPECTION.—The Secretary—

''(1) may enter into arrangements and agreements with foreign governments to facilitate the inspection of foreign facilities registered under section 415; and

''(2) shall direct resources to inspections of foreign facilities, suppliers, and food types, especially such facilities, suppliers, and food types that present

a high risk (as identified by the Secretary), to help ensure the safety and security of the food supply of the United States.

''(b) EFFECT OF INABILITY TO INSPECT.—Notwithstanding any other provision of law, food shall be refused admission into the United States if it is from a foreign facility registered under section 415 of which the owner, operator, or agent in charge of the facility, or the government of the foreign country, refuses to permit entry of United States inspectors, upon request, to inspect such facility. For purposes of this subsection, such an owner, operator, or agent in charge shall be considered to have refused an inspection if such owner, operator, or agent in charge refuses such a request to inspect a facility more than 48 hours after such request is submitted.''.

SEC. 308. ACCREDITATION OF QUALIFIED THIRD-PARTY AUDITORS.

Chapter VIII (21 U.S.C. 381 et seq.), as amended by section 307, is further amended by adding at the end the following:

''SEC. 809. ACCREDITATION OF QUALIFIED THIRD-PARTY AUDITORS.

''(a) ACCREDITATION OF CERTIFYING AGENTS.—

''(1) IN GENERAL.—Beginning not later than 2 years after the date of enactment of the FDA Food

Safety Modernization Act, the Secretary shall establish and implement an accreditation system under which a foreign government, a State or regional food authority, a foreign or domestic cooperative that aggregates the products of growers or processors, or any other third party that the Secretary determines appropriate, may request to be accredited as a certifying agent to certify that eligible entities meet the applicable requirements of this Act.

''(2) REVIEW BY SECRETARY.—When establishing the accreditation system under paragraph (1), the Secretary shall review third-party accreditation systems in existence on the date of enactment of the FDA Food Safety Modernization Act, to avoid unnecessary duplication of efforts and costs.

''(3) REQUEST BY FOREIGN GOVERNMENT.—Prior to accrediting a foreign government as a certifying agent, the Secretary shall perform such reviews and audits of food safety programs, systems, and standards of the government as the Secretary deems necessary to determine that they are adequate to ensure that eligible entities certified by such government meet the requirements of this Act with respect to food manufactured, processed, packed, or held for import to the United States.

''(4) REQUEST BY STATE OR REGIONAL FOOD AUTHORITY.—Prior to accrediting a State or regional food authority as a certifying agent, the Secretary shall perform such reviews and audits of the training and qualifications of auditors used by the authority and conduct such reviews of internal systems and such other investigation of the authority as the Secretary deems necessary to determine that each eligible entity certified by the authority has systems and standards in use to ensure that such entity meets the requirements of this Act.

''(5) COOPERATIVES AND OTHER THIRD PARTIES.—Prior to accrediting a foreign or domestic cooperative that aggregates the products of growers or processors or any other third party that the Secretary determines appropriate as a certifying agent, the Secretary shall perform such reviews and audits of the training and qualifications of auditors used by the cooperative or party and conduct such reviews of internal systems and such other investigation of the cooperative or party as the Secretary deems necessary to determine that each eligible entity certified by the cooperative or party has systems and standards in use to ensure that such entity meets the requirements of this Act.

''(6) LIMITATION ON THIRD PARTIES.—The Secretary may not accredit a third party that the Secretary determines appropriate as a certifying agent unless each auditor used by such party prepares the audit report for an audit under this section in a form and manner designated by the Secretary. An audit report shall include—

''(A) the identity of the persons at the audited eligible entity responsible for compliance with food safety requirements;

''(B) the dates of the audit;

''(C) the scope of the audit; and

''(D) any other information required by the Secretary that relate to or may influence an assessment of compliance with this Act.

''(b) IMPORTATION.—As a condition of accrediting a foreign government, a State or regional food authority, a foreign or domestic cooperative that aggregates the products of growers or processors, or any other third party that the Secretary determines appropriate as a certifying agent, such government, authority, cooperative, or party shall agree to issue a written and electronic certification to accompany each food shipment made for import from an eligible entity certified by the certifying agent, subject to requirements set forth by the Secretary. The Secretary

shall consider such certificates when targeting inspection resources under section 421.

''(c) MONITORING.—Following any accreditation of a certifying agent, the Secretary may at any time—

''(1) conduct an on-site audit of any eligible entity certified by the agent, with or without the certifying agent present; or

''(2) require the agent to submit to the Secretary, for any eligible entity certified by the agent, an onsite inspection report and such other reports or documents the agent requires as part of the audit process, including, for an eligible entity located outside the United States, documentation that the eligible is in compliance with any applicable registration requirements.

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

''(1) AUDITOR.—The term 'auditor' means an individual who—

''(A) is qualified to conduct food safety audits; and

''(B) has successfully completed any training requirements established by the Secretary for the conduct of food safety audits.

''(2) CERTIFYING AGENT.—The term 'certifying agent' means a foreign government, a State or re-

gional food authority, a foreign or domestic cooperative that aggregates the products of growers or processors, or any other third party that conducts audits of eligible entities and that is accredited by the Secretary under this section.

''(3) ELIGIBLE ENTITY.—The term 'eligible entity' means any entity in the food supply chain that chooses to be audited by a certifying agent.

''(e) AVOIDING CONFLICTS OF INTEREST WITH CERTIFYING AGENTS.—

''(1) IN GENERAL.—A certifying agent shall—

''(A) not be owned, managed, or controlled by any person that owns or operates an eligible entity to be certified by such agent;

''(B) have procedures to ensure against the use, in carrying out audits of eligible entities under this section, of any officer or employee of such agent that has a financial conflict of interest regarding an eligible entity to be certified by such agent; and

''(C) annually make available to the Secretary, disclosures of the extent to which such agent, and the officers and employees of such agent, have maintained compliance with sub-

paragraphs (A) and (B) relating to financial conflicts of interest.

''(2) REGULATIONS.—The Secretary shall promulgate regulations not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act to ensure that there are protections against conflicts of interest between a certifying agent and the eligible entity to be certified by such agent. Such regulations shall include—

''(A) requiring that domestic audits performed under this section be unannounced;

''(B) a structure, including timing and public disclosure, for fees paid by eligible entities to certifying agents to decrease the potential for conflicts of interest; and

''(C) appropriate limits on financial affiliations between a certifying agent and any person that owns or operates an eligible entity to be certified by such agent.

''(f) FALSE STATEMENTS.—Any statement of representation made by an employee or agent of an eligible entity to an auditor of a certifying agent or a certifying agent shall be subject to section 1001 of title 18, United States Code.

''(g) RISKS TO PUBLIC HEALTH.—If, at any time during an audit, an auditor of a certifying agent discovers a condition that could cause or contribute to a serious risk to the public health, the auditor shall immediately notify the Secretary of—

''(1) the identification of the eligible entity subject to the audit; and

''(2) such condition.

''(h) WITHDRAWAL OF ACCREDITATION.—The Secretary may withdraw accreditation from a certifying agent—

''(1) if food from eligible entities certified by such agent is linked to an outbreak of human or animal illness;

''(2) following a performance audit and finding by the Secretary that the agent no longer meets the requirements for accreditation; or

''(3) following a refusal to allow United States officials to conduct such audits and investigations as may be necessary to ensure continued compliance with the requirements set forth in this section.

''(i) PERFORMANCE AUDITS AND RENEWAL.—To ensure that accreditation of a certifying agent continues to meet the standards of this section and this Act and to

allow for the renewal of accreditation of such certifying agent, the Secretary shall—

"(1) audit the performance of such certifying agent on a periodic basis, not less than every 4 years, through the review of audit reports by such certifying agent and the compliance history, as available, of eligible entities certified by such certifying agent; and

"(2) any other measures deemed necessary by the Secretary.

"(j) PUBLICATION OF LIST OF CERTIFYING AGENTS.—The Secretary shall publish and maintain on the Internet Web site of the Food and Drug Administration a current list, including, the name, location and other information deemed necessary by the Secretary, of certifying agents under this section.

"(k) NEUTRALIZING COSTS.—The Secretary shall establish a method, similar to the method used by the Department of Agriculture, by which certifying agents reimburse the Food and Drug Administration for the work performed to accredit such certifying agents. The Secretary shall make operating this program revenue-neutral and shall not generate surplus revenue from such a reimbursement mechanism.

''(l) NO EFFECT ON SECTION 704 INSPECTIONS.—The audits performed under this section shall not be considered inspections under section 704.

''(m) NO EFFECT ON INSPECTION AUTHORITY.—Nothing in this section affects the authority of the Secretary to inspect any eligible entity pursuant to this Act.''.

SEC. 309. FOREIGN OFFICES OF THE FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—The Secretary shall by October 1, 2010, establish an office of the Food and Drug Administration in not less than 5 foreign countries selected by the Secretary, to provide assistance to the appropriate governmental entities of such countries with respect to measures to provide for the safety of articles of food and other products regulated by the Food and Drug Administration exported by such country to the United States, including by directly conducting risk-based inspections of such articles and supporting such inspections by such governmental entity.

(b) CONSULTATION.—In establishing the foreign offices described in subsection (a), the Secretary shall consult with the Secretary of State and the United States Trade Representative.

(c) REPORT.—Not later than October 1, 2011, the Secretary shall submit to Congress a report on the basis

for the selection by the Secretary of the foreign countries in which the Secretary established offices under subsection (a), the progress which such offices have made with respect to assisting the governments of such countries in providing for the safety of articles of food and other products regulated by the Food and Drug Administration exported to the United States, and the plans of the Secretary for establishing additional foreign offices of the Food and Drug Administration, as appropriate.

SEC. 310. FUNDING FOR FOOD SAFETY.

(a) IN GENERAL.—There are authorized to be appropriated to carry out the activities of the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and related field activities in the Office of Regulatory Affairs of the Food and Drug Administration—

(1) $775,000,000 for fiscal year 2009; and

(2) such sums as may be necessary for fiscal years 2010 through 2013.

(b) INCREASED NUMBER OF FIELD STAFF.—To carry out the activities of the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and related field activities of the Office of Regulatory Affairs of the Food and Drug Administration, the Secretary of Health and Human Services shall increase the field

staff of such Centers and Office with a goal of not fewer than—

(1) 3,600 staff members in fiscal year 2009;

(2) 3,800 staff members in fiscal year 2010;

(3) 4,000 staff members in fiscal year 2011;

(4) 4,200 staff members in fiscal year 2012; and

(5) 4,600 staff members in fiscal year 2013.

SEC. 311. JURISDICTION; AUTHORITIES.

Nothing in this Act, or an amendment made by this Act, shall be construed to—

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

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

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

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

(3) impede, minimize, or affect the authority of the Secretary of Agriculture to prevent, control, or mitigate a plant or animal health emergency, or a food emergency involving products regulated under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act.

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