AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—111th Cong., 2d Sess.

S. 510

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

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT In the Nature of a Substitute intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

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 reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

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

TITLE IV—MISCELLANEOUS PROVISIONS

TITLE I—IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS

SEC. 101. INSPECTIONS OF RECORDS.

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

(1) by striking the heading and all that 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) USE OF OR EXPOSURE TO FOOD OF CONCERN.—If the Secretary believes that there is a rea-

sonable 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.''.

(b) CONFORMING AMENDMENT.—Section 704(a)(1)(B) (21 U.S.C. 374(a)(1)(B)) is amended by striking ''section 414 when'' and all that follows through ''subject to'' and inserting ''section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to''.

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 or, in the case of a foreign facility, the United States agent for 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 an assurance that the Secretary will be permitted to inspect such facility at the times and in the manner permitted by this Act.'';

(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, received, 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 a facility—

''(A) that created, caused, or was otherwise responsible for such reasonable probability; or

''(B)(i) that knew of, or had reason to know of, such reasonable probability; and

''(ii) packed, received, or held such food.

''(2) HEARING ON SUSPENSION.—The Secretary shall provide the registrant subject to an order under paragraph (1) with an opportunity for an informal hearing, to be held as soon as possible but not later than 2 business days after the issuance of the order or such other time period, as agreed upon by the Secretary and the registrant, on the actions required for reinstatement of registration and why the registration that is subject to suspension should be reinstated. The Secretary shall reinstate a reg-

istration 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 not later than 14 days after the submission of the corrective action plan or such other time period as determined by the Secretary.

''(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 actions should be modified, the Secretary shall promptly vacate the order and reinstate the registration of the facility subject to the order or modify the order, as appropriate.

''(4) EFFECT OF SUSPENSION.—If the registration of a facility is suspended under this subsection, no person shall import or export food into the United States from such facility, offer to import or export food into the United States from such facility, or otherwise introduce food from such facility into interstate or intrastate commerce in the United States.

''(5) REGULATIONS.—

''(A) IN GENERAL.—The Secretary shall promulgate regulations to implement this subsection. The Secretary may promulgate such regulations on an interim final basis.

''(B) REGISTRATION REQUIREMENT.—The Secretary may require that registration under this subsection be submitted in an electronic format. Such requirement may not take effect before the date that is 5 years after the date of enactment of the FDA Food Safety Modernization Act.

''(6) APPLICATION DATE.—Facilities shall be subject to the requirements of this subsection beginning on the earlier of—

''(A) the date on which the Secretary issues regulations under paragraph (5); or

''(B) 180 days after the date of enactment of the FDA Food Safety Modernization Act.

''(7) 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) SMALL ENTITY COMPLIANCE POLICY GUIDE.—Not later than 180 days after the issuance of the regulations promulgated under section 415(b)(5) of the Federal Food, Drug, and Cosmetic Act (as added by this section), the Secretary shall issue a small entity compliance policy guide setting forth in plain language the requirements of such regulations to assist small entities in complying with registration requirements and other activities required under such section.

(3) 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. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.

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

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

''(a) IN GENERAL.—The owner, operator, or agent 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 the occurrence of such hazards 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, or may be unintentionally introduced; and

''(2) identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism; and

''(3) 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)(1) will be significantly minimized or prevented;

''(2) any hazards identified in the hazard analysis conducted under subsection (b)(2) will be significantly minimized or prevented and addressed, consistent with section 420, as applicable; and

''(3) 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 to ensure that, if the preventive controls implemented under subsection (c) are not properly implemented or are found to be ineffective—

''(1) appropriate action is taken to reduce the likelihood of recurrence of the implementation failure;

''(2) all affected food is evaluated for safety; and

''(3) all affected food is prevented from entering into commerce if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 or misbranded under section 403(w).

''(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);

''(4) the preventive controls implemented under subsection (c) are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means; and

''(5) there is documented, periodic reanalysis of the plan under subsection (i) to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and 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, the results of testing and other appropriate means of verification

under subsection (f)(4), instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.

''(h) WRITTEN PLAN AND DOCUMENTATION.—The 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 under subsection (c) to address those hazards. Such written plan, together with the documentation described in subsection (g), shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

''(i) REQUIREMENT TO REANALYZE.—The 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 operative. 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, including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment.

''(j) EXEMPTION FOR SEAFOOD, JUICE, AND LOW-ACID CANNED FOOD FACILITIES SUBJECT TO HACCP.—

''(1) IN GENERAL.—This section shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, and is in compliance with, 1 of the following standards and regulations with respect to such facility:

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

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

''(C) The Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Con-

tainers standards of the Food and Drug Administration (or any successor standards).

''(2) APPLICABILITY.—The exemption under paragraph (1)(C) shall apply only with respect to microbiological hazards that are regulated under the standards for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers under part 113 of chapter 21, Code of Federal Regulations (or any successor regulations).

''(k) EXCEPTION FOR ACTIVITIES OF FACILITIES SUBJECT TO SECTION 419.—This section shall not apply to activities of a facility that are subject to section 419.

''(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 production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment.

''(m) REGULATIONS.—

''(1) IN GENERAL.—Not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act, 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 this section.

''(2) COORDINATION.—In promulgating the regulations under paragraph (1), with regard to hazards that may be intentionally introduced, including by acts of terrorism, the Secretary shall coordinate with the Secretary of Homeland Security, as appropriate.

''(3) CONTENT.—The regulations promulgated under paragraph (1) shall—

''(A) provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm;

''(B) comply with chapter 35 of title 44, United States Code (commonly known as the 'Paperwork Reduction Act'), with special attention to minimizing the burden (as defined in section 3502(2) of such Act) on the facility, and collection of information (as defined in section 3502(3) of such Act), associated with such regulations;

"(C) acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods; and

"(D) not require a facility to hire a consultant or other third party to identify, implement, certify, or audit preventative controls, except in the case of negotiated enforcement resolutions that may require such a consultant or third party.

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

"(5) 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 the FDA Food Safety Modernization Act, including the Grade 'A' Pasteurized Milk Ordinance to ensure that such regulations are consistent, to the extent practicable, with applicable domestic and internationally-recognized standards in existence on such date.

''(n) 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 such hazard 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 employ to significantly minimize or prevent the hazards identified under the hazard analysis conducted under subsection (b) 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 in processes where a food is exposed to a potential contaminant in the environment.

"(D) A food allergen control program.

"(E) A recall plan.

"(F) Current Good Manufacturing Practices (cGMPs) under part 110 of title 21, Code of Federal Regulations (or any successor regulations).

"(G) Supplier verification activities that relate to the safety of food.".

(b) GUIDANCE DOCUMENT.—The Secretary shall issue a guidance document related to the regulations promulgated under subsection (b)(1) with respect to the hazard analysis and preventive controls under section 418 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

(c) RULEMAKING.—

(1) PROPOSED RULEMAKING.—

(A) IN GENERAL.—Not later than 9 months after the date of enactment of this Act, the Secretary of Health and Human Services

(referred to in this subsection as the ''Secretary'') shall publish a notice of proposed rulemaking in the Federal Register to promulgate regulations with respect to—

(i) activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership for purposes of section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by this Act; and

(ii) activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership for purposes of such section 415.

(B) CLARIFICATION.—The rulemaking described under subparagraph (A) shall enhance the implementation of such section 415 and clarify the activities that are included as part of the definition of the term ''facility'' under such section 415. Nothing in this Act authorizes the Secretary to modify the definition of the term ''facility'' under such section.

(C) SCIENCE-BASED RISK ANALYSIS.—In promulgating regulations under subparagraph (A), the Secretary shall conduct a science-based risk analysis of—

(i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and

(ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership.

(D) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(i) IN GENERAL.—In promulgating the regulations under subparagraph (A), the Secretary shall consider the results of the science-based risk analysis conducted under subparagraph (C), and shall exempt certain facilities from the requirements in section 418 of the Federal Food, Drug, and Cosmetic Act (as added by this sec-

tion), including hazard analysis and preventive controls, and the mandatory inspection frequency in section 421 of such Act (as added by section 201), or modify the requirements in such sections 418 or 421, as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk.

(ii) LIMITATION.—

(I) IN GENERAL.—The exemptions or modifications under clause (i) shall not include an exemption from the requirement to register under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by this Act, if applicable, and shall apply only to small facilities.

(II) DEFINITION.—The Secretary shall define the term ''small facility'' for purposes of subclause (I) in the rulemaking described under this sub-

paragraph (A). In defining such term, the Secretary shall consider income, harvestable acres, the number of employees, and the volume of the food manufactured, processed, packed, or held by a facility.

(2) FINAL REGULATIONS.—Not later than 9 months after the close of the comment period for the proposed rulemaking under paragraph (1), the Secretary shall adopt final rules with respect to—

(A) activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership for purposes of section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by this Act;

(B) activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership for purposes of such section 415; and

(C) the requirements under sections 418 and 421 of the Federal Food, Drug, and Cosmetic Act, as added by this Act, from which the

Secretary may issue exemptions or modifications of the requirements for certain types of facilities.

(d) SMALL ENTITY COMPLIANCE POLICY GUIDE.—Not later than 180 days after the issuance of the regulations promulgated under subsection (m) of section 418 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), the Secretary shall issue a small entity compliance policy guide setting forth in plain language the requirements of such section 418 and this section to assist small entities in complying with the hazard analysis and other activities required under such section 418 and this section.

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

''(uu) The operation of a facility that manufactures, 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 418.''.

(f) 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 Hazard Analysis Critical Control programs and

the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards.

(g) DIETARY SUPPLEMENTS.—Nothing in the amendments made by this section shall apply to any facility with regard to the manufacturing, processing, packing, or holding of a dietary supplement that is in compliance with the requirements of sections 402(g)(2) and 761 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(g)(2), 379aa-1).

(h) UPDATING GUIDANCE RELATING TO FISH AND FISHERIES PRODUCTS HAZARDS AND CONTROLS.—The Secretary shall, not later than 180 days after the date of enactment of this Act, update the Fish and Fisheries Products Hazards and Control Guidance to take into account advances in technology that have occurred since the previous publication of such Guidance by the Secretary.

(i) 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) FLEXIBILITY FOR SMALL BUSINESSES.—Notwithstanding paragraph (1)—

(A) the amendments made by this section shall apply to a small business (as defined by the Secretary for purposes of this section, not

later than 90 days after the date of enactment of this Act) 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 for purposes of this section, not later than 90 days after the date of enactment of this Act) after the date that is 3 years after the date of enactment of this Act.

SEC. 104. PERFORMANCE STANDARDS.

(a) IN GENERAL.—The Secretary shall, in coordination with the Secretary of Agriculture, not less frequently than every 2 years, review and evaluate relevant health data and other relevant information, including from toxicological and epidemiological studies and analyses, current Good Manufacturing Practices issued by the Secretary relating to food, and relevant recommendations of relevant advisory committees, including the Food Advisory Committee, to determine the most significant foodborne contaminants.

(b) GUIDANCE DOCUMENTS AND REGULATIONS.—Based on the review and evaluation conducted under subsection (a), and when appropriate to reduce the risk of serious illness or death to humans or animals or to prevent adulteration of the food under section 402 of the Federal

Food, Drug, or Cosmetic Act (21 U.S.C. 342) or to prevent the spread by food of communicable disease under section 361 of the Public Health Service Act (42 U.S.C. 264), the Secretary shall issue contaminant-specific and science-based guidance documents, including guidance documents regarding action levels, or regulations. Such guidance, including guidance regarding action levels, or regulations—

(1) shall apply to products or product classes;

(2) may differentiate between food for human consumption and food intended for consumption by animals other than humans; and

(3) shall not be written to be facility-specific.

(c) NO DUPLICATION OF EFFORTS.—The Secretary shall coordinate with the Secretary of Agriculture to avoid issuing duplicative guidance on the same contaminants.

(d) REVIEW.—The Secretary shall periodically review and revise, as appropriate, the guidance documents, including guidance documents regarding action levels, or regulations promulgated under this section.

SEC. 105. STANDARDS FOR PRODUCE SAFETY.

(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. STANDARDS FOR PRODUCE SAFETY.

"(a) PROPOSED RULEMAKING.—

"(1) IN GENERAL.—

"(A) RULEMAKING.—Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary, in coordination with the Secretary of Agriculture and representatives of State departments of agriculture (including with regard to the national organic program established under the Organic Foods Production Act of 1990), and in consultation with the Secretary of Homeland Security, 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, including specific mixes or categories 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.

"(B) DETERMINATION BY SECRETARY.—With respect to small and very small businesses that produce and harvest those types of fruits and vegetables that are raw agricultural commodities that the Secretary has determined are

low risk and do not present a risk of serious adverse health consequences or death, the Secretary may determine not to include production and harvesting of such fruits and vegetables in such rulemaking, or may modify the applicable requirements of regulations promulgated pursuant to this section.

''(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) provide sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of fruits and vegetables that are raw agricultural commodities, including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities;

''(B) include, with respect to growing, harvesting, sorting, packing, and storage oper-

ations, science-based minimum standards related to soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water;

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

''(D) take into consideration, consistent with ensuring enforceable public health protection, conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environmental agencies; and

''(E) in the case of production that is certified organic, not include any requirements that conflict with or duplicate the requirements of the national organic program established under the Organic Foods Production Act of 1990, while providing the same level of public health protection as the requirements under guidance documents, including guidance documents regarding action levels, and regulations under the FDA Food Safety Modernization Act.

''(4) PRIORITIZATION.—The Secretary shall prioritize the implementation of the regulations under this section for specific fruits and vegetables that are raw agricultural commodities based on known risks which may include a history and severity of foodborne 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 science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks.

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

''(A) provide for coordination of education and enforcement activities by State and local officials, as designated by the Governors of the respective States or the appropriate elected State official as recognized by State statute; and

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

"(3) FLEXIBILITY FOR SMALL BUSINESSES.—Notwithstanding paragraph (1)—

"(A) the regulations promulgated under this section shall apply to a small business (as defined by the Secretary for purposes of this section, not later than 90 days after the date of enactment of the FDA Food Safety Modernization Act) after the date that is 1 year after the effective date of the final regulation under paragraph (1); and

"(B) the regulations promulgated under this section shall apply to a very small business (as defined by the Secretary for purposes of this section, not later than 90 days after the date of enactment of the FDA Food Safety Modernization Act) after the date that is 2 years after the effective date of the final regulation under paragraph (1).

"(c) CRITERIA.—

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

"(A) set forth those procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that 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, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities and to provide reasonable assurances that the produce is not adulterated under section 402;

"(B) provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm;

"(C) comply with chapter 35 of title 44, United States Code (commonly known as the 'Paperwork Reduction Act'), with special attention to minimizing the burden (as defined in section 3502(2) of such Act) on the facility, and

collection of information (as defined in section 3502(3) of such Act), associated with such regulations;

"(D) acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods; and

"(E) not require a facility to hire a consultant or other third party to identify, implement, certify, compliance with these procedures, processes, and practices, except in the case of negotiated enforcement resolutions that may require such a consultant or third party; and

"(F) permit States and foreign countries from which food is imported into the United States to request from the Secretary variances from the requirements of the regulations, subject to paragraph (2), 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 and to provide the same level of public health protection as the

requirements of the regulations adopted under subsection (b).

''(2) VARIANCES.—

''(A) REQUESTS FOR VARIANCES.—A State or foreign country from which food is imported into the United States may in writing request a variance from the Secretary. Such request shall describe the variance requested and present information demonstrating that the variance does not increase the likelihood that the food for which the variance is requested will be adulterated under section 402, and that the variance provides the same level of public health protection as the requirements of the regulations adopted under subsection (b). The Secretary shall review such requests in a reasonable timeframe.

''(B) APPROVAL OF VARIANCES.—The Secretary may approve a variance in whole or in part, as appropriate, and may specify the scope of applicability of a variance to other similarly situated persons.

''(C) DENIAL OF VARIANCES.—The Secretary may deny a variance request if the Secretary determines that such variance is not rea-

sonably likely to ensure that the food is not adulterated under section 402 and is not reasonably likely to provide the same level of public health protection as the requirements of the regulation adopted under subsection (b). The Secretary shall notify the person requesting such variance of the reasons for the denial.

''(D) MODIFICATION OR REVOCATION OF A VARIANCE.—The Secretary, after notice and an opportunity for a hearing, may modify or revoke a variance if the Secretary determines that such variance is not reasonably likely to ensure that the food is not adulterated under section 402 and is not reasonably likely to provide the same level of public health protection as the requirements of the regulations adopted under subsection (b).

''(d) ENFORCEMENT.—The Secretary may coordinate with the Secretary of Agriculture and, as appropriate, 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.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the FDA Food Safety Mod-

ernization Act, the Secretary shall publish, after consultation with the Secretary of Agriculture, representatives of State departments of agriculture, farmer representatives, and various types of entities engaged in the production and harvesting or importing of fruits and vegetables that are raw agricultural commodities, including small businesses, updated good agricultural practices and guidance for the safe production and harvesting of specific types of fresh produce under this section.

''(2) PUBLIC MEETINGS.—The Secretary shall conduct not fewer than 3 public meetings in diverse geographical areas of the United States as part of an effort to conduct education and outreach regarding the guidance described in paragraph (1) for persons in different regions who are involved in the production and harvesting of fruits and vegetables that are raw agricultural commodities, including persons that sell directly to consumers and farmer representatives.

''(3) PAPERWORK REDUCTION.—The Secretary shall ensure that any updated guidance under this section will—

''(A) provide sufficient flexibility to be practicable for all sizes and types of facilities,

including small businesses such as a small food processing facility co-located on a farm; and

''(B) acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods.

''(f) EXCEPTION FOR ACTIVITIES OF FACILITIES SUBJECT TO SECTION 418.—This section shall not apply to activities of a facility that are subject to section 418.''.

(b) SMALL ENTITY COMPLIANCE POLICY GUIDE.—Not later than 180 days after the issuance of regulations under section 419 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), the Secretary of Health and Human Services shall issue a small entity compliance policy guide setting forth in plain language the requirements of such section 419 and to assist small entities in complying with standards for safe production and harvesting and other activities required under such section.

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

''(vv) The failure to comply with the requirements under section 419.''.

(d) NO EFFECT ON HACCP AUTHORITIES.—Nothing in the amendments made by this section limits the au-

thority 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. 106. PROTECTION AGAINST INTENTIONAL ADULTERATION.

(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.), as amended by section 105, is amended by adding at the end the following:

"SEC. 420. PROTECTION AGAINST INTENTIONAL ADULTERATION.

''(a) DETERMINATIONS.—

''(1) IN GENERAL.—The Secretary shall—

''(A) conduct a vulnerability assessment of the food system, including by consideration of the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessments;

''(B) consider the best available understanding of uncertainties, risks, costs, and benefits associated with guarding against inten-

tional adulteration of food at vulnerable points; and

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

''(2) LIMITED DISTRIBUTION.—In the interest of national security, the Secretary, in consultation with the Secretary of Homeland Security, may determine the time, manner, and form in which determinations made under paragraph (1) are made publicly available.

''(b) REGULATIONS.—Not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act, the Secretary, in coordination with the Secretary of Homeland Security and in consultation with the Secretary of Agriculture, shall promulgate regulations to protect against the intentional adulteration of food subject to this Act. Such regulations shall—

''(1) 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; and

''(2) specify appropriate science-based mitigation strategies or measures to prepare and protect

the food supply chain at specific vulnerable points, as appropriate.

''(c) APPLICABILITY.—Regulations promulgated under subsection (b) shall apply only to food for which there is a high risk of intentional contamination, as determined by the Secretary, in consultation with the Secretary of Homeland Security, under subsection (a), that could cause serious adverse health consequences or death to humans or animals and shall include those foods—

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

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

''(d) EXCEPTION.—This section shall not apply to farms, except for those that produce 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 of Health and Human Services, 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 adulteration as required under section 420 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

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

(A) include a model assessment for a person to use under subsection (b)(1) of section 420 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a);

(B) include examples of mitigation strategies or measures described in subsection (b)(2) of such section; and

(C) specify situations in which the examples of mitigation strategies or measures described in subsection (b)(2) of such section are appropriate.

(3) LIMITED DISTRIBUTION.—In the interest of national security, the Secretary of Health and Human Services, in consultation with the Secretary of Homeland Security, may determine the time, manner, and form 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 of Health and Human Services shall periodically review and, as appropriate, update the regulations under section 420(b) of the Federal Food, Drug, and Cosmetic Act, as added by 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 105, is amended by adding at the end the following:

''(ww) The failure to comply with section 420.''.

SEC. 107. 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 adding at the end the following:

''PART 6—FEES RELATED TO FOOD

''SEC. 743. AUTHORITY TO COLLECT AND USE FEES.

''(a) IN GENERAL.—

''(1) PURPOSE AND AUTHORITY.—For fiscal year 2010 and each subsequent fiscal year, the Secretary shall, in accordance with this section, assess and collect fees from—

''(A) the responsible party for each domestic facility (as defined in section 415(b)) and the United States agent for each foreign facility subject to a reinspection in such fiscal year, to cover reinspection-related costs for such year;

''(B) the responsible party for a domestic facility (as defined in section 415(b)) and an importer who does not comply with a recall order under section 423 or under section 412(f) in such fiscal year, to cover food recall activities associated with such order performed by the Secretary, including technical assistance, follow-up effectiveness checks, and public notifications, for such year;

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

''(D) each importer subject to a reinspection in such fiscal year, to cover reinspection-related costs for such year.

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

''(A) the term 'reinspection' means—

"(i) with respect to domestic facilities (as defined in section 415(b)), 1 or more inspections conducted under section 704 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

"(ii) with respect to importers, 1 or more examinations conducted under section 801 subsequent to an examination 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;

"(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; and

"(C) the term 'responsible party' has the meaning given such term in section 417(a)(1).

"(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.—

"(i) VOLUNTARY QUALIFIED IMPORTER PROGRAM.—

"(I) PARTICIPATION.—In establishing the fee amounts under subparagraph (A)(iii) for a fiscal year, the Secretary shall provide for the number of importers who have submitted to the Secretary a notice under

section 806(c) informing the Secretary of the intent of such importer to participate in the program under section 806 in such fiscal year.

''(II) RECOUPMENT.—In establishing the fee amounts under subparagraph (A)(iii) for the first 5 fiscal years after the date of enactment of this section, the Secretary shall include in such fee a reasonable surcharge that provides a recoupment of the costs expended by the Secretary to establish and implement the first year of the program under section 806.

''(ii) CREDITING OF FEES.—In establishing the fee amounts under subparagraph (A) 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.

"(iii) PUBLISHED GUIDELINES.—Not later than 180 days after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall publish in the Federal Register a proposed set of guidelines in consideration of the burden of fee amounts on small business. Such consideration may include reduced fee amounts for small businesses. The Secretary shall provide for a period of public comment on such guidelines. The Secretary shall adjust the fee schedule for small businesses subject to such fees only through notice and comment rulemaking.

"(3) USE OF FEES.—The Secretary shall make all of the fees collected pursuant to clause (i), (ii), (iii), and (iv) of paragraph (2)(A) available solely to pay for the costs referred to in such clause (i), (ii), (iii), and (iv) of paragraph (2)(A), respectively.

"(c) LIMITATIONS.—

"(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2010 unless the amount of the total appropriations for food safety activities at the Food and Drug Administration for such fiscal year (ex-

cluding the amount of fees appropriated for such fiscal year) is equal to or greater than the amount of appropriations for food safety activities at the Food and Drug Administration for fiscal year 2009 (excluding the amount of fees appropriated for such fiscal year), multiplied by the adjustment factor under paragraph (3).

''(2) AUTHORITY.—If—

''(A) the Secretary does not assess fees under subsection (a) for a portion of a fiscal year because paragraph (1) applies; and

''(B) at a later date in such fiscal year, such paragraph (1) ceases to apply,

the Secretary may assess and collect such fees under subsection (a), without any modification to the rate of such fees, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

''(3) ADJUSTMENT FACTOR.—

''(A) IN GENERAL.—The adjustment factor described in paragraph (1) shall be the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending June 30 preceding the fis-

cal year, but in no case shall such adjustment factor be negative.

''(B) COMPOUNDED BASIS.—The adjustment under subparagraph (A) made each fiscal year shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2009.

''(4) LIMITATION ON AMOUNT OF CERTAIN FEES.—

''(A) IN GENERAL.—Notwithstanding any other provision of this section and subject to subparagraph (B), the Secretary may not collect fees in a fiscal year such that the amount collected—

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

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

''(B) EXCEPTION.—If a domestic facility (as defined in section 415(b)) or an importer becomes subject to a fee described in subparagraph (A), (B), or (D) of subsection (a)(1) after the maximum amount of fees has been collected by the Secretary under subparagraph

(A), the Secretary may collect a fee from such facility or importer.

''(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 provi-

sions 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 Senate and the Committee on Energy and Commerce of the 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 2010 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 publicly available listing) as the Secretary determines appropriate.''.

SEC. 108. 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 transmit to

the relevant committees of Congress, and make publicly available on the Internet Web sites of the Department of Health and Human Services and the Department 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 Depart-

ment 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, food production, and international trade;

(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.

(3) EVALUATION.—The Secretary, in coordination with the Secretary of Agriculture and the Secretary of Homeland Security, shall—

(A) develop metrics to measure progress for the evaluation process described in paragraph (1)(B); and

(B) report on the progress measured in subparagraph (A) as part of the National Agriculture and Food Defense strategy described in subsection (a)(1).

(c) LIMITED DISTRIBUTION.—In the interest of national security, the Secretary of Health and Human Services and the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, may determine the manner and format in which the National Agriculture and Food Defense strategy established under this section is made publicly available on the Internet Web sites of the Department of Health and Human Services, the Department of Homeland Security, and the Department of Agriculture, as described in subsection (a)(1).

SEC. 109. FOOD AND AGRICULTURE COORDINATING COUNCILS.

The Secretary of Homeland Security, in coordination 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 Home-

land 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 coordinate 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. 110. BUILDING DOMESTIC CAPACITY.

(a) IN GENERAL.—

(1) INITIAL REPORT.—The Secretary, in coordination with the Secretary of Agriculture and the Secretary of Homeland Security, 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 supply chain security of food and to prevent outbreaks of foodborne 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 further regulations or guidance to industry.

(B) Outreach to food industry sectors, including through the Food and Agriculture Coordinating Councils referred to in section 109, 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 and local governments to build State and local food safety and food defense capabilities, including progress implementing strategies developed under sections 108 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.

(H) The impact of requirements under this Act (including amendments made by this Act) on certified organic farms and facilities (as defined in section 415 (21 U.S.C. 350d).

(I) Specific efforts taken pursuant to the agreements authorized under section 421(c) of

the Federal Food, Drug, and Cosmetic Act (as added by section 201), together with, as necessary, a description of any additional authorities necessary to improve seafood safety.

(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 (H) 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 commercially-available techniques that can be employed at ports of entry and by Food Emergency Response Network laboratories, and to provide for well-equipped and staffed laboratory facilities and progress toward laboratory accreditation under section 422 of the Federal Food, Drug, and Cosmetic Act (as added by section 202).

(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 registration 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 foodborne 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) (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, industry, and State and local governments, as such communication and coordination relates to outbreak identification and traceback.

(g) BIENNIAL FOOD SAFETY AND FOOD DEFENSE RESEARCH PLAN.—The Secretary, the Secretary of Agriculture, and the Secretary of Homeland Security 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 foodborne 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 subsequent 2-year period.

(h) EFFECTIVENESS OF PROGRAMS ADMINISTERED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.—

(1) IN GENERAL.—To determine whether existing Federal programs administered by the Department of Health and Human Services are effective in achieving the stated goals of such programs, the Secretary shall, beginning not later than 1 year after the date of enactment of this Act—

(A) conduct an annual evaluation of each program of such Department to determine the effectiveness of each such program in achieving legislated intent, purposes, and objectives; and

(B) submit to Congress a report concerning such evaluation.

(2) CONTENT.—The report described under paragraph (1)(B) shall—

(A) include conclusions concerning the reasons that such existing programs have proven successful or not successful and what factors contributed to such conclusions;

(B) include recommendations for consolidation and elimination to reduce duplication and inefficiencies in such programs at such Department as identified during the evaluation conduct under this subsection; and

(C) be made publicly available in a publication entitled ''Guide to the U.S. Department of Health and Human Services Programs''.

(i) UNIQUE IDENTIFICATION NUMBERS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall conduct a study regarding the need for, and challenges associated with, development and implementation of a program that requires a unique identification number for each food facility registered with the Secretary and, as appropriate, each broker that imports food into the United States. Such study shall include an evaluation of the costs associated with development and implementation of such a system, and make recommendations about what new

authorities, if any, would be necessary to develop and implement such a system.

(2) REPORT.—Not later than 15 months after the date of enactment of this Act, the Secretary shall submit to Congress a report that describes the findings of the study conducted under paragraph (1) and that includes any recommendations determined appropriate by the Secretary.

SEC. 111. SANITARY TRANSPORTATION OF FOOD.

(a) IN GENERAL.—Not later than 18 months 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)).

(b) FOOD TRANSPORTATION STUDY.—The Secretary, acting through the Commissioner of Food and Drugs, shall conduct a study of the transportation of food for consumption in the United States, including transportation by air, that includes an examination of the unique needs of rural and frontier areas with regard to the delivery of safe food.

SEC. 112. 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.

(4) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(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 section 444 of the General Education Provisions Act (commonly referred to as 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 determines 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 any risk of anaphylaxis, if applicable;

(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 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 procedures 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 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 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 pro-

grams, 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 determines 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 2011 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).

SEC. 113. NEW DIETARY INGREDIENTS.

(a) IN GENERAL.—Section 413 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350b) is amended—

(1) by redesignating subsection (c) as subsection (d); and

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

''(c) NOTIFICATION.—

''(1) IN GENERAL.—If the Secretary determines that the information in a new dietary ingredient notification submitted under this section for an article purported to be a new dietary ingredient is inad-

equate to establish that a dietary supplement containing such article will reasonably be expected to be safe because the article may be, or may contain, an anabolic steroid or an analogue of an anabolic steroid, the Secretary shall notify the Drug Enforcement Administration of such determination. Such notification by the Secretary shall include, at a minimum, the name of the dietary supplement or article, the name of the person or persons who marketed the product or made the submission of information regarding the article to the Secretary under this section, and any contact information for such person or persons that the Secretary has.

''(2) DEFINITIONS.—For purposes of this subsection—

''(A) the term 'anabolic steroid' has the meaning given such term in section 102(41) of the Controlled Substances Act; and

''(B) the term 'analogue of an anabolic steroid' means a substance whose chemical structure is substantially similar to the chemical structure of an anabolic steroid.''.

(b) GUIDANCE.—Not later than 180 days after the date of enactment of this Act, the Secretary shall publish guidance that clarifies when a dietary supplement ingre-

dient is a new dietary ingredient, when the manufacturer or distributor of a dietary ingredient or dietary supplement should provide the Secretary with information as described in section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act, the evidence needed to document the safety of new dietary ingredients, and appropriate methods for establishing the identify of a new dietary ingredient.

SEC. 114. REQUIREMENT FOR GUIDANCE RELATING TO POST HARVEST PROCESSING OF RAW OYSTERS.

(a) IN GENERAL.—Not later than 90 days prior to the issuance of any guidance, regulation, or suggested amendment by the Food and Drug Administration to the National Shellfish Sanitation Program's Model Ordinance, or the issuance of any guidance or regulation by the Food and Drug Administration relating to the Seafood Hazard Analysis Critical Control Points Program of the Food and Drug Administration (parts 123 and 1240 of title 21, Code of Federal Regulations (or any successor regulations), where such guidance, regulation or suggested amendment relates to post harvest processing for raw oysters, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of

the House of Representatives a report which shall include—

(1) an assessment of how post harvest processing or other equivalent controls feasibly may be implemented in the fastest, safest, and most economical manner;

(2) the projected public health benefits of any proposed post harvest processing;

(3) the projected costs of compliance with such post harvest processing measures;

(4) the impact post harvest processing is expected to have on the sales, cost, and availability of raw oysters;

(5) criteria for ensuring post harvest processing standards will be applied equally to shellfish imported from all nations of origin;

(6) an evaluation of alternative measures to prevent, eliminate, or reduce to an acceptable level the occurrence of foodborne illness; and

(7) the extent to which the Food and Drug Administration has consulted with the States and other regulatory agencies, as appropriate, with regard to post harvest processing measures.

(b) LIMITATION.—Subsection (a) shall not apply to the guidance described in section 103(h).

(c) REVIEW AND EVALUATION.—Not later than 30 days after the Secretary issues a proposed regulation or guidance described in subsection (a), the Comptroller General of the United States shall—

(1) review and evaluate the report described in (a) and report to Congress on the findings of the estimates and analysis in the report;

(2) compare such proposed regulation or guidance to similar regulations or guidance with respect to other regulated foods, including a comparison of risks the Secretary may find associated with seafood and the instances of those risks in such other regulated foods; and

(3) evaluate the impact of post harvest processing on the competitiveness of the domestic oyster industry in the United States and in international markets.

(d) WAIVER.—The requirement of preparing a report under subsection (a) shall be waived if the Secretary issues a guidance that is adopted as a consensus agreement between Federal and State regulators and the oyster industry, acting through the Interstate Shellfish Sanitation Conference.

(e) PUBLIC ACCESS.—Any report prepared under this section shall be made available to the public.

SEC. 115. PORT SHOPPING.

Until the date on which the Secretary promulgates a final rule that implements the amendments made by section 308 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, (Public Law 107–188), the Secretary shall notify the Secretary of Homeland Security of all instances in which the Secretary refuses to admit a food into the United States under section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) so that the Secretary of Homeland Security, acting through the Commissioner of Customs and Border Protection, may prevent food refused admittance into the United States by a United States port of entry from being admitted by another United States port of entry, through the notification of other such United States ports of entry.

SEC. 116. ALCOHOL-RELATED FACILITIES.

(a) IN GENERAL.—Except as provided by sections 102, 206, 207, 302, 304, 402, 403, and 404 of this Act, and the amendments made by such sections, nothing in this Act, or the amendments made by this Act, shall be construed to apply to a facility that—

(1) under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.) is required to obtain a permit or to

register with the Secretary of the Treasury as a condition of doing business in the United States; and

(2) under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) is required to register as a facility because such facility is engaged in manufacturing, processing, packing, or holding 1 or more alcoholic beverages, with respect to the activities of such facility that relate to the manufacturing, processing, packing, or holding of alcoholic beverages.

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

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

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

(c) RULE OF CONSTRUCTION.—Except as provided in subsections (a) and (b), this section shall not be construed to exempt any food, other than alcoholic beverages, as de-

fined in section 214 of the Federal Alcohol Administration Act (27 U.S.C. 214), from the requirements of this Act (including the amendments made by this Act).

TITLE II—IMPROVING CAPACITY TO DETECT AND RESPOND TO FOOD SAFETY PROBLEMS

SEC. 201. 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 identify high-risk facilities and shall allocate resources to inspect facilities according to the known safety risks of the facilities, which shall be based on the following factors:

''(A) The known safety risks of the food manufactured, processed, packed, or held at the facility.

''(B) The compliance history of a facility, including with regard to food recalls, outbreaks of foodborne illness, and violations of food safety standards.

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

''(D) Whether the food manufactured, processed, packed, or held at the facility meets the criteria for priority under section 801(h)(1).

''(E) Whether the food or the facility that manufactured, processed, packed, or held such food has received a certification as described in section 801(q) or 806, as appropriate.

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

''(2) INSPECTIONS.—

''(A) IN GENERAL.—Beginning on the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall increase the frequency of inspection of all facilities.

"(B) DOMESTIC HIGH-RISK FACILITIES.—The Secretary shall increase the frequency of inspection of domestic facilities identified under paragraph (1) as high-risk facilities such that each such facility is inspected—

"(i) not less often than once in the 5-year period following the date of enactment of the FDA Food Safety Modernization Act; and

"(ii) not less often than once every 3 years thereafter.

"(C) DOMESTIC NON-HIGH-RISK FACILITIES.—The Secretary shall ensure that each domestic facility that is not identified under paragraph (1) as a high-risk facility is inspected—

"(i) not less often than once in the 7-year period following the date of enactment of the FDA Food Safety Modernization Act; and

"(ii) not less often than once every 5 years thereafter.

"(D) FOREIGN FACILITIES.—

"(i) YEAR 1.—In the 1-year period following the date of enactment of the FDA Food Safety Modernization Act, the

Secretary shall inspect not fewer than 600 foreign facilities.

''(ii) SUBSEQUENT YEARS.—In each of the 5 years following the 1-year period described in clause (i), the Secretary shall inspect not fewer than twice the number of foreign facilities inspected by the Secretary during the previous year.

''(E) RELIANCE ON FEDERAL, STATE, OR LOCAL INSPECTIONS.—In meeting the inspection requirements under this subsection for domestic facilities, the Secretary may rely on inspections conducted by other Federal, State, or local agencies under interagency agreement, contract, memoranda of understanding, or other obligation.

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

''(1) The known safety risks of the food imported.

''(2) The known safety risks of the countries or regions of origin and countries through which such article of food is transported.

''(3) The compliance history of the importer, including with regard to food recalls, outbreaks of foodborne illness, and violations of food safety standards.

''(4) The rigor and effectiveness of the activities conducted by the importer of such article of food to satisfy the requirements 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 or the facility that manufactured, processed, packed, or held such food received a certification as described in section 801(q) or 806.

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

''(c) INTERAGENCY AGREEMENTS WITH RESPECT TO SEAFOOD.—

''(1) IN GENERAL.—The Secretary of Health and Human Services, the Secretary of Commerce, the Secretary of Homeland Security, the Chairman of the Federal Trade Commission, and the heads of other appropriate agencies may enter into such agreements as may be necessary or appropriate to improve seafood safety.

''(2) SCOPE OF AGREEMENTS.—The agreements under paragraph (1) may include—

''(A) cooperative arrangements for examining and testing seafood imports that leverage the resources, capabilities, and authorities of each party to the agreement;

''(B) coordination of inspections of foreign facilities to increase the percentage of imported seafood and seafood facilities inspected;

''(C) standardization of data on seafood names, inspection records, and laboratory testing to improve interagency coordination;

''(D) coordination to detect and investigate violations under applicable Federal law;

''(E) a process, including the use or modification of existing processes, by which officers and employees of the National Oceanic and Atmospheric Administration may be duly des-

ignated by the Secretary to carry out seafood examinations and investigations under section 801 of this Act or section 203 of the Food Allergen Labeling and Consumer Protection Act of 2004;

''(F) the sharing of information concerning observed non-compliance with United States food requirements domestically and in foreign nations and new regulatory decisions and policies that may affect the safety of food imported into the United States;

''(G) conducting joint training on subjects that affect and strengthen seafood inspection effectiveness by Federal authorities; and

''(H) outreach on Federal efforts to enhance seafood safety and compliance with Federal food safety requirements.

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

''(e) 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 1003 (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, including efforts to coordinate and cooperate with other Federal agencies with responsibilities for food inspections, 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 were scheduled for inspection in the previous fiscal year and which the Secretary did not inspect in such 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 were scheduled for inspection in the previous fiscal year and which the Secretary did not inspect in such 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 line of food subject to this Act that is imported or offered for import into the United States; and

''(3) information on the foreign offices of the Food and Drug Administration 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.''.

(c) ADVISORY COMMITTEE CONSULTATION.—In allocating inspection resources as described in section 421 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), the Secretary may, as appropriate, consult with any relevant advisory committee within the Department of Health and Human Services.

SEC. 202. LABORATORY ACCREDITATION FOR ANALYSES OF FOODS.

(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.), as amended by section 201, is amended by adding at the end the following:

''SEC. 422. 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) establish a program for the testing of food by accredited laboratories;

''(B) establish a publicly available registry of accreditation bodies recognized by the Secretary and laboratories accredited by a recognized accreditation body, including the name of, contact information for, and other information deemed appropriate by the Secretary about such bodies and laboratories; and

''(C) require, as a condition of recognition or accreditation, as appropriate, that recognized accreditation bodies and accredited laboratories report to the Secretary any changes that would affect the recognition of such accreditation body or the accreditation of such laboratory.

''(2) PROGRAM REQUIREMENTS.—The program established under paragraph (1)(A) shall provide for the recognition of laboratory accreditation bodies that meet criteria established by the Secretary for accreditation of laboratories, including laboratories run and operated by a Federal agency (including the Department of Commerce), State, or locality with a

demonstrated capability to conduct 1 or more sampling and analytical testing methodologies for food.

''(3) INCREASING THE NUMBER OF QUALIFIED LABORATORIES.—The Secretary shall work with the laboratory accreditation bodies recognized under paragraph (1), as appropriate, to increase the number of qualified laboratories that are eligible to perform testing under subparagraph (b) beyond the number so qualified on the date of enactment of the FDA Food Safety Modernization Act.

''(4) LIMITED DISTRIBUTION.—In the interest of national security, the Secretary, in coordination with the Secretary of Homeland Security, may determine the time, manner, and form in which the registry established under paragraph (1)(B) is made publicly available.

''(5) FOREIGN LABORATORIES.—Accreditation bodies recognized by the Secretary under paragraph (1) may accredit laboratories that operate outside the United States, so long as such laboratories meet the accreditation standards applicable to domestic laboratories accredited under this section.

''(6) MODEL LABORATORY STANDARDS.—The Secretary shall develop model standards that a laboratory shall meet to be accredited by a recognized

accreditation body for a specified sampling or analytical testing methodology and included in the registry provided for under paragraph (1). In developing the model standards, the Secretary shall consult existing standards for guidance. The model standards shall include—

''(A) methods to ensure that—

''(i) appropriate sampling, analytical procedures (including rapid analytical procedures), and commercially available techniques are followed and reports of analyses are certified as true and accurate;

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

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

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

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

''(7) REVIEW OF RECOGNITION.—To ensure compliance with the requirements of this section, the Secretary—

''(A) shall periodically, and in no case less than once every 5 years, reevaluate accreditation bodies recognized under paragraph (1) and may accompany auditors from an accreditation body to assess whether the accreditation body meets the criteria for recognition; and

''(B) shall promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of this section, specifying, as appropriate, any terms and conditions necessary for laboratories accredited by such body to continue to perform testing as described in this section.

''(b) TESTING PROCEDURES.—

''(1) IN GENERAL.—Not later than 30 months after the date of enactment of the FDA Food Safety Modernization Act, food testing shall be conducted by Federal laboratories or non-Federal laboratories that have been accredited for the appropriate sampling or analytical testing methodology or methodologies by a recognized accreditation body on the registry established by the Secretary under sub-

section (a)(1)(B) whenever such testing is conducted—

"(A) by or on behalf of an owner or consignee—

"(i) in response to a specific testing requirement under this Act or implementing regulations, when applied to address an identified or suspected food safety problem; and

"(ii) as required by the Secretary, as the Secretary deems appropriate, to address an identified or suspected food safety problem; or

"(B) on behalf of an owner or consignee—

"(i) in support of admission of an article of food under section 801(a); and

"(ii) under an Import Alert that requires successful consecutive tests.

"(2) RESULTS OF TESTING.—The results of any such testing shall be sent directly to the Food and Drug Administration, except the Secretary may by regulation exempt test results from such submission requirement if the Secretary determines that such results do not contribute to the protection of public health. Test results required to be submitted

may be submitted to the Food and Drug Administration through electronic means.

''(3) EXCEPTION.—The Secretary may waive requirements under this subsection if—

''(A) a new methodology or methodologies have been developed and validated but a laboratory has not yet been accredited to perform such methodology or methodologies; and

''(B) the use of such methodology or methodologies are necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak.

''(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 a recognized 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.

''(d) NO LIMIT ON SECRETARIAL AUTHORITY.—Nothing in this section shall be construed to limit the ability of the Secretary to review and act upon information from food testing, including determining the sufficiency of such information and testing.''.

(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, local, and tribal food laboratories, including the adoption of novel surveillance and identification technologies and the sharing of data between Federal agencies and 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. 203. INTEGRATED CONSORTIUM OF LABORATORY NETWORKS.

(a) IN GENERAL.—The Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, the Secretary of Agriculture, the Secretary of Commerce, 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 reduce the time required to detect and respond to foodborne illness outbreaks and facilitate the sharing of knowledge and information relating to animal health, agriculture, and human health;

(2) identify means by which laboratory network members 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. 204. ENHANCING TRACKING AND TRACING OF FOOD AND RECORDKEEPING.

(a) PILOT PROJECTS.—

(1) IN GENERAL.—Not later than 270 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), taking into account recommendations from the Secretary of Agriculture and representatives of State departments of health and agriculture, shall establish pilot projects in coordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to hu-

mans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) or misbranded under section 403(w) of such Act (21 U.S.C. 343(w)).

(2) CONTENT.—The Secretary shall conduct 1 or more pilot projects under paragraph (1) in coordination with the processed food sector and 1 or more such pilot projects in coordination with processors or distributors of fruits and vegetables that are raw agricultural commodities. The Secretary shall ensure that the pilot projects under paragraph (1) reflect the diversity of the food supply and include at least 3 different types of foods that have been the subject of significant outbreaks during the 5-year period preceding the date of enactment of this Act, and are selected in order to—

(A) develop and demonstrate methods for rapid and effective tracking and tracing of foods in a manner that is practicable for facilities of varying sizes, including small businesses;

(B) develop and demonstrate appropriate technologies, including technologies existing on the date of enactment of this Act, that enhance the tracking and tracing of food; and

(C) inform the promulgation of regulations under subsection (d).

(3) 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 projects under this subsection together with recommendations for improving the tracking and tracing of food.

(b) ADDITIONAL DATA GATHERING.—

(1) IN GENERAL.—The Secretary, in coordination with the Secretary of Agriculture and multiple representatives of State departments of health and agriculture, shall assess—

(A) the costs and benefits associated with the adoption and use of several product tracing technologies, including technologies used in the pilot projects under subsection (a);

(B) the feasibility of such technologies for different sectors of the food industry, including small businesses; and

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

(2) REQUIREMENTS.—To the extent practicable, in carrying out paragraph (1), the Secretary shall—

(A) evaluate domestic and international product tracing practices in commercial use;

(B) consider international efforts, including an assessment of whether product tracing requirements developed under this section are compatible with global tracing systems, as appropriate; and

(C) consult with a diverse and broad range of experts and stakeholders, including representatives of the food industry, agricultural producers, and nongovernmental organizations that represent the interests of consumers.

(c) PRODUCT TRACING SYSTEM.—The Secretary, in consultation with the Secretary of Agriculture, shall, as appropriate, establish within the Food and Drug Administration a product tracing system to receive information that improves the capacity of the Secretary to effectively and rapidly track and trace food that is in the United States or offered for import into the United States. Prior to the establishment of such product tracing system, the Secretary shall examine the results of applicable pilot projects and shall ensure that the activities of such system are adequately supported by the results of such pilot projects.

(d) ADDITIONAL RECORDKEEPING REQUIREMENTS FOR HIGH RISK FOODS.—

(1) IN GENERAL.—In order to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of such Act, not later than 2 years after the date of enactment of this Act, the Secretary shall publish a notice of proposed rulemaking to establish recordkeeping requirements, in addition to the requirements under section 414 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c) and subpart J of part 1 of title 21, Code of Federal Regulations (or any successor regulations), for facilities that manufacture, process, pack, or hold foods that the Secretary designates under paragraph (2) as high-risk foods. The Secretary shall set an appropriate effective date of such additional requirements for foods designated as high risk that takes into account the length of time necessary to comply with such requirements. Such requirements shall—

(A) relate only to information that is reasonably available and appropriate;

(B) be science-based;

(C) not prescribe specific technologies for the maintenance of records;

(D) ensure that the public health benefits of imposing additional recordkeeping requirements outweigh the cost of compliance with such requirements;

(E) be scale-appropriate and practicable for facilities of varying sizes and capabilities with respect to costs and recordkeeping burdens, and not require the creation and maintenance of duplicate records where the information is contained in other company records kept in the normal course of business;

(F) minimize the number of different recordkeeping requirements for facilities that handle more than 1 type of food;

(G) to the extent practicable, not require a facility to change business systems to comply with such requirements;

(H) allow any person subject to this subsection to maintain records required under this subsection at a central or reasonably accessible

location provided that such records can be made available to the Secretary not later than 24 hours after the Secretary requests such records; and

(I) include a process by which the Secretary may issue a waiver of the requirements under this subsection if the Secretary determines that such requirements would result in an economic hardship for an individual facility or a type of facility;

(J) be commensurate with the known safety risks of the designated food;

(K) take into account international trade obligations;

(L) not require—

(i) a full pedigree, or a record of the complete previous distribution history of the food from the point of origin of such food;

(ii) records of recipients of a food beyond the immediate subsequent recipient of such food; or

(iii) product tracking to the case level by persons subject to such requirements; and

(M) include a process by which the Secretary may remove a high-risk food designation developed under paragraph (2) for a food or type of food.

(2) DESIGNATION OF HIGH-RISK FOODS.—

(A) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, and thereafter as the Secretary determines necessary, the Secretary shall designate high-risk foods for which the additional recordkeeping requirements described in paragraph (1) are appropriate and necessary to protect the public health. Each such designation shall be based on—

(i) the known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention;

(ii) the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic

microorganisms due to the nature of the food or the processes used to produce such food;

(iii) the point in the manufacturing process of the food where contamination is most likely to occur;

(iv) the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;

(v) the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and

(vi) the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.

(B) LIST OF HIGH-RISK FOODS.—At the time the Secretary promulgates the final rules under paragraph (1), the Secretary shall publish the list of the foods designated under subparagraph (A) as high-risk foods on the Internet website of the Food and Drug Administration. The Secretary may update the list to des-

ignate new high-risk foods and to remove foods that are no longer deemed to be high-risk foods, provided that each such update to the list is consistent with the requirements of this subsection and notice of such update is published in the Federal Register.

(3) PROTECTION OF SENSITIVE INFORMATION.—In promulgating regulations under this subsection, the Secretary shall take appropriate measures to ensure that there are effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section, including periodic risk assessment and planning to prevent unauthorized release and controls to—

(A) prevent unauthorized reproduction of trade secret or confidential information;

(B) prevent unauthorized access to trade secret or confidential information; and

(C) maintain records with respect to access by any person to trade secret or confidential information maintained by the agency.

(4) PUBLIC INPUT.—During the comment period in 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.

(5) RETENTION OF RECORDS.—Except as otherwise provided in this subsection, the Secretary may require that a facility retain records under this subsection for not more than 2 years, taking into consideration the risk of spoilage, loss of value, or loss of palatability of the applicable food when determining the appropriate timeframes.

(6) LIMITATIONS.—

(A) FARM TO SCHOOL PROGRAMS.—In establishing requirements under this subsection, the Secretary shall, in consultation with the Secretary of Agriculture, consider the impact of requirements on farm to school or farm to institution programs of the Department of Agriculture and other farm to school and farm to institution programs outside such agency, and shall modify the requirements under this subsection, as appropriate, with respect to such programs so that the requirements do not place undue burdens on farm to school or farm to institution programs.

(B) IDENTITY-PRESERVED LABELS WITH RESPECT TO FARM SALES OF FOOD THAT IS PRODUCED AND PACKAGED ON A FARM.—The requirements under this subsection shall not apply to a food that is produced and packaged on a farm if—

(i) the packaging of the food maintains the integrity of the product and prevents subsequent contamination or alteration of the product; and

(ii) the labeling of the food includes the name, complete address (street address, town, State, country, and zip or other postal code), and business phone number of the farm, unless the Secretary waives the requirement to include a business phone number of the farm, as appropriate, in order to accommodate a religious belief of the individual in charge of such farm.

(C) FISHING VESSELS.—The requirements under this subsection with respect to a food that is produced through the use of a fishing vessel (as defined in section 3(18) of the Magnuson-Stevens Fishery Conservation and Man-

agement Act (16 U.S.C. 1802(18))) shall be limited to the requirements under subparagraph (F) until such time as the food is sold by the owner, operator, or agent in charge of such fishing vessel.

(D) COMMINGLED RAW AGRICULTURAL COMMODITIES.—

(i) LIMITATION ON EXTENT OF TRACING.—Recordkeeping requirements under this subsection with regard to any commingled raw agricultural commodity shall be limited to the requirements under subparagraph (F).

(ii) DEFINITIONS.—For the purposes of this subparagraph—

(I) the term ''commingled raw agricultural commodity'' means any commodity that is combined or mixed after harvesting, but before processing;

(II) the term ''commingled raw agricultural commodity'' shall not include types of fruits and vegetables that are raw agricultural commodities for which the Secretary has deter-

mined that standards promulgated under section 419 of the Federal Food, Drug, and Cosmetic Act (as added by section 105) would minimize the risk of serious adverse health consequences or death; and

(III) the term ''processing'' means operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization.

(E) EXEMPTION OF OTHER FOODS.—The Secretary may, by notice in the Federal Register, modify the requirements under this subsection with respect to, or exempt a food or a type of facility from, the requirements of this subsection (other than the requirements under subparagraph (F), if applicable) if the Secretary determines that product tracing requirements for such food (such as bulk or commingled ingredients that are intended to be processed to destroy pathogens) or type of facility is not necessary to protect the public health.

(F) RECORDKEEPING REGARDING PREVIOUS SOURCES AND SUBSEQUENT RECIPIENTS.—In the case of a person or food to which a limitation or exemption under subparagraph (C), (D), or (E) applies, if such person, or a person who manufactures, processes, packs, or holds such food, is required to register with the Secretary under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) with respect to the manufacturing, processing, packing, or holding of the applicable food, the Secretary shall require such person to maintain records that identify the immediate previous source of such food and the immediate subsequent recipient of such food.

(G) GROCERY STORES.—With respect to a sale of a food described in subparagraph (H) to a grocery store, the Secretary shall not require such grocery store to maintain records under this subsection other than records documenting the farm that was the source of such food. The Secretary shall not require that such records be kept for more than 180 days.

(H) FARM SALES TO CONSUMERS.—The Secretary shall not require a farm to maintain

any distribution records under this subsection with respect to a sale of a food described in subparagraph (I) (including a sale of a food that is produced and packaged on such farm), if such sale is made by the farm directly to a consumer.

(I) SALE OF A FOOD.—A sale of a food described in this subparagraph is a sale of a food in which—

(i) the food is produced on a farm; and

(ii) the sale is made by the owner, operator, or agent in charge of such farm directly to a consumer or grocery store.

(7) NO IMPACT ON NON-HIGH-RISK FOODS.—The recordkeeping requirements established under paragraph (1) shall have no effect on foods that are not designated by the Secretary under paragraph (2) as high-risk foods. Foods described in the preceding sentence shall be subject solely to the recordkeeping requirements under section 414 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c) and subpart J of part 1 of title 21, Code of Federal Regulations (or any successor regulations).

(e) EVALUATION AND RECOMMENDATIONS.—

(1) REPORT.—Not later than 1 year after the effective date of the final rule promulgated under subsection (d)(1), the Comptroller General of the United States shall submit to Congress a report, taking into consideration the costs of compliance and other regulatory burdens on small businesses and Federal, State, and local food safety practices and requirements, that evaluates the public health benefits and risks, if any, of limiting—

(A) the product tracing requirements under subsection (d) to foods identified under paragraph (2) of such subsection, including whether such requirements provide adequate assurance of traceability in the event of intentional adulteration, including by acts of terrorism; and

(B) the participation of restaurants in the recordkeeping requirements.

(2) DETERMINATION AND RECOMMENDATIONS.—In conducting the evaluation and report under paragraph (1), if the Comptroller General of the United States determines that the limitations described in such paragraph do not adequately protect the public health, the Comptroller General shall submit to Congress recommendations, if appropriate, re-

garding recordkeeping requirements for restaurants and additional foods, in order to protect the public health.

(f) FARMS.—

(1) REQUEST FOR INFORMATION.—Notwithstanding subsection (d), during an active investigation of a foodborne illness outbreak, or if the Secretary determines it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak, the Secretary, in consultation and coordination with State and local agencies responsible for food safety, as appropriate, may request that the owner, operator, or agent of a farm identify potential immediate recipients, other than consumers, of an article of the food that is the subject of such investigation if the Secretary reasonably believes such article of food—

(A) is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;

(B) presents a threat of serious adverse health consequences or death to humans or animals; and

(C) was adulterated as described in subparagraph (A)(i) on a particular farm (as defined in section 1.227 of chapter 21, Code of

Federal Regulations (or any successor regulation)).

(2) MANNER OF REQUEST.—In making a request under paragraph (1), the Secretary, in consultation and coordination with State and local agencies responsible for food safety, as appropriate, shall issue a written notice to the owner, operator, or agent of the farm to which the article of food has been traced. The individual providing such notice shall present to such owner, operator, or agent appropriate credentials and shall deliver such notice at reasonable times and within reasonable limits and in a reasonable manner.

(3) DELIVERY OF INFORMATION REQUESTED.—The owner, operator, or agent of a farm shall deliver the information requested under paragraph (1) in a prompt and reasonable manner. Such information may consist of records kept in the normal course of business, and may be in electronic or non-electronic format.

(4) LIMITATION.—A request made under paragraph (1) shall not include a request for information relating to the finances, pricing of commodities produced, personnel, research, sales (other than information relating to shipping), or other disclosures

that may reveal trade secrets or confidential information from the farm to which the article of food has been traced, other than information necessary to identify potential immediate recipients of such food. Section 301(j) of the Federal Food, Drug, and Cosmetic Act and the Freedom of Information Act shall apply with respect to any confidential commercial information that is disclosed to the Food and Drug Administration in the course of responding to a request under paragraph (1).

(5) RECORDS.—Except with respect to identifying potential immediate recipients in response to a request under this subsection, nothing in this subsection shall require the establishment or maintenance by farms of new records.

(g) NO LIMITATION ON COMMINGLING OF FOOD.—Nothing in this section shall be construed to authorize the Secretary to impose any limitation on the commingling of food.

(h) SMALL ENTITY COMPLIANCE GUIDE.—Not later than 180 days after promulgation of a final rule under subsection (d), the Secretary shall issue a small entity compliance guide setting forth in plain language the requirements of the regulations under such subsection in order to assist small entities, including farms and small

businesses, in complying with the recordkeeping requirements under such subsection.

(i) FLEXIBILITY FOR SMALL BUSINESSES.—Notwithstanding any other provision of law, the regulations promulgated under subsection (d) shall apply—

(1) to small businesses (as defined by the Secretary in section 103, not later than 90 days after the date of enactment of this Act) beginning on the date that is 1 year after the effective date of the final regulations promulgated under subsection (d); and

(2) to very small businesses (as defined by the Secretary in section 103, not later than 90 days after the date of enactment of this Act) beginning on the date that is 2 years after the effective date of the final regulations promulgated under subsection (d).

(j) ENFORCEMENT.—

(1) PROHIBITED ACTS.—Section 301(e) (21 U.S.C. 331(e)) is amended by inserting ''; or the violation of any recordkeeping requirement under section 204 of the FDA Food Safety Modernization Act (except when such violation is committed by a farm)'' before the period at the end.

(2) IMPORTS.—Section 801(a) (21 U.S.C. 381(a)) is amended by inserting ''or (4) the record-keeping requirements under section 204 of the FDA Food Safety Modernization Act (other than the requirements under subsection (f) of such section) have not been complied with regarding such article,'' in the third sentence before ''then such article shall be refused admission''.

SEC. 205. SURVEILLANCE.

(a) DEFINITION OF FOODBORNE ILLNESS OUTBREAK.—In this Act, the term ''foodborne illness outbreak'' means the occurrence of 2 or more cases of a similar illness resulting from the ingestion of a certain food.

(b) FOODBORNE ILLNESS SURVEILLANCE SYSTEMS.—

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

(A) coordinating Federal, State and local foodborne 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 surveillance information on a more timely basis among governmental agencies, including the Food and Drug Administration, the Department of Agriculture, the Department of Homeland Security, 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 foodborne illness outbreak to a specific food;

(E) expanding capacity of such systems, including working toward automatic electronic searches, for implementation of identification practices, including fingerprinting strategies, for foodborne infectious agents, in order to identify new or rarely documented causes of foodborne 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 foodborne illness surveillance systems and data with other biosurveillance and public health situational awareness capabilities at the Federal, State, and local levels, including by sharing foodborne illness surveillance data with the National Biosurveillance Integration Center; and

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

(2) WORKING GROUP.—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 and food testing industries, 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 recommendations on an ongoing and regular basis regarding the improvement of foodborne 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 foodborne 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 foodborne illness aggregated, de-identified surveillance data collected by government agencies at all levels, including data compiled by the Centers for Disease Control and Prevention;

(D) key barriers at Federal, State, and local levels to improving foodborne illness surveillance and the utility of such surveillance for preventing foodborne illness;

(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.

(3) AUTHORIZATION OF APPROPRIATIONS.—To carry out the activities described in paragraph (1), there is authorized to be appropriated $24,000,000 for each fiscal years 2011 through 2015.

(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 foodborne illness outbreak response and containment.

(B) Accelerate foodborne illness surveillance and outbreak investigation, including rapid shipment of clinical isolates from clinical laboratories to appropriate State laboratories,

and conducting more standardized illness outbreak interviews.

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

(D) Improve the effectiveness of Federal, State, and local partnerships to coordinate food safety and defense resources and reduce the incidence of foodborne 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 108.

(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 ''2010''; and

(2) by striking ''2003 through 2006'' and inserting ''2011 through 2015''.

SEC. 206. MANDATORY RECALL AUTHORITY.

(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.), as amended by section 202, is amended by adding at the end the following:

''SEC. 423. MANDATORY RECALL AUTHORITY.

''(a) VOLUNTARY PROCEDURES.—If the Secretary determines, based on information gathered through the re-

portable 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.—

''(1) IN GENERAL.—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—

''(A) immediately cease distribution of such article; and

''(B) as applicable, immediately notify all persons—

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

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

"(2) REQUIRED ADDITIONAL INFORMATION.—

"(A) IN GENERAL.—If an article of food covered by a recall order issued under paragraph (1)(B) has been distributed to a warehouse-based third party logistics provider without providing such provider sufficient information to know or reasonably determine the precise identity of the article of food covered by a recall order that is in its possession, the notice provided by the responsible party subject to the order issued under paragraph (1)(B) shall include such information as is necessary for the warehouse-based third party logistics provider to identify the food.

"(B) RULES OF CONSTRUCTION.—Nothing in this paragraph shall be construed—

"(i) to exempt a warehouse-based third party logistics provider from the requirements of this Act, including the requirements in this section and section 414; or

"(ii) to exempt a warehouse-based third party logistics provider from being the subject of a mandatory recall order.

"(3) DETERMINATION TO LIMIT AREAS AFFECTED.—If the Secretary requires a responsible party to cease distribution under paragraph (1)(A) of an article of food identified in subsection (a), the Secretary may limit the size of the geographic area and the markets affected by such cessation if such limitation would not compromise the public health.

"(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) RULE REGARDING ALCOHOLIC BEVERAGES.—The Secretary shall not initiate a mandatory recall or take any other action under this section with respect to any alcohol beverage until the Secretary has provided the Alcohol and Tobacco Tax and Trade Bureau with a reasonable opportunity to cease distribution and recall such article under the Alcohol and Tobacco Tax and Trade Bureau authority.

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

''(g) PUBLIC NOTIFICATION.—In conducting a recall under this section, the Secretary shall—

''(1) ensure that a press release is published regarding the recall, as well as alerts and public notices, as appropriate, in order to provide notification—

''(A) of the recall to consumers and retailers to whom such article was, or may have been, distributed; and

''(B) that includes, at a minimum—

''(i) the name of the article of food subject to the recall;

''(ii) a description of the risk associated with such article; and

''(iii) to the extent practicable, information for consumers about similar articles of food that are not affected by the recall;

''(2) consult the policies of the Department of Agriculture regarding providing to the public a list of retail consignees receiving products involved in a Class I recall and shall consider providing such a list to the public, as determined appropriate by the Secretary; and

''(3) if available, publish on the Internet Web site of the Food and Drug Administration an image of the article that is the subject of the press release described in (1).

''(h) 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.

''(i) EFFECT.—Nothing in this section shall affect the authority of the Secretary to request or participate in a voluntary recall, or to issue an order to cease distribution or to recall under any other provision of this Act or under the Public Health Service Act.

''(j) COORDINATED COMMUNICATION.—

''(1) IN GENERAL.—To assist in carrying out the requirements of this subsection, the Secretary shall establish an incident command operation or a similar operation within the Department of Health and Human Services that will operate not later than 24 hours after the initiation of a mandatory recall or the recall of an article of food for which the use of, or exposure to, such article will cause serious adverse health consequences or death to humans or animals.

''(2) REQUIREMENTS.—To reduce the potential for miscommunication during recalls or regarding investigations of a food borne illness outbreak associated with a food that is subject to a recall, each incident command operation or similar operation under paragraph (1) shall use regular staff and resources of the Department of Health and Human Services to—

''(A) ensure timely and coordinated communication within the Department, including enhanced communication and coordination between different agencies and organizations within the Department;

''(B) ensure timely and coordinated communication from the Department, including public statements, throughout the duration of the investigation and related foodborne illness outbreak;

''(C) identify a single point of contact within the Department for public inquiries regarding any actions by the Secretary related to a recall;

''(D) coordinate with Federal, State, local, and tribal authorities, as appropriate, that have responsibilities related to the recall of a food or

a foodborne illness outbreak associated with a food that is subject to the recall, including notification of the Secretary of Agriculture and the Secretary of Education in the event such recalled food is a commodity intended for use in a child nutrition program (as identified in section 25(b) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1769f(b)); and

''(E) conclude operations at such time as the Secretary determines appropriate.

''(3) MULTIPLE RECALLS.—The Secretary may establish multiple or concurrent incident command operations or similar operations in the event of multiple recalls or foodborne illness outbreaks necessitating such action by the Department of Health and Human Services.''.

(b) SEARCH ENGINE.—Not later than 90 days after the date of enactment of this Act, the Secretary shall modify the Internet Web site of the Food and Drug Administration to include a search engine that—

(1) is consumer-friendly, as determined by the Secretary; and

(2) provides a means by which an individual may locate relevant information regarding each article of food subject to a recall under section 420 of

the Federal Food, Drug, and Cosmetic Act and the status of such recall (such as whether a recall is ongoing or has been completed).

(c) 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 423'' after ''section 402(a)(2)(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:

''(xx) The refusal or failure to follow an order under section 423.''.

(e) GAO REVIEW.—

(1) IN GENERAL.—Not later than 90 days after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report that—

(A) identifies State and local agencies with the authority to require the mandatory recall of food, and evaluates use of such authority with regard to frequency, effectiveness, and appropriateness, including consideration of any new or existing mechanisms available to compensate persons for general and specific recall-related

costs when a recall is subsequently determined by the relevant authority to have been an error;

(B) identifies Federal agencies, other than the Department of Health and Human Services, with mandatory recall authority and examines use of that authority with regard to frequency, effectiveness, and appropriateness, including any new or existing mechanisms available to compensate persons for general and specific recall-related costs when a recall is subsequently determined by the relevant agency to have been an error;

(C) considers models for farmer restitution implemented in other nations in cases of erroneous recalls; and

(D) makes recommendations to the Secretary regarding use of the authority under section 423 of the Federal Food, Drug, and Cosmetic Act (as added by this section) to protect the public health while seeking to minimize unnecessary economic costs.

(2) EFFECT OF REVIEW.—If the Comptroller General of the United States finds, after the review conducted under paragraph (1), that the mechanisms described in such paragraph do not exist or

are inadequate, then, not later than 90 days after the conclusion of such review, the Secretary of Agriculture shall conduct a study of the feasibility of implementing a farmer indemnification program to provide restitution to agricultural producers for losses sustained as a result of a mandatory recall of an agricultural commodity by a Federal or State regulatory agency that is subsequently determined to be in error. The Secretary of Agriculture shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report that describes the results of the study, including any recommendations.

(f) ANNUAL REPORT TO CONGRESS.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act and annually thereafter, the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the use of recall authority under section 423 of the Federal Food, Drug, and Cosmetic Act (as added by subsection

(a)) and any public health advisories issued by the Secretary that advise against the consumption of an article of food on the ground that the article of food is adulterated and poses an imminent danger to health.

(2) CONTENT.—The report under paragraph (1) shall include, with respect to the report year—

(A) the identity of each article of food that was the subject of a public health advisory described in paragraph (1), an opportunity to cease distribution and recall under subsection (a) of section 423 of the Federal Food, Drug, and Cosmetic Act, or a mandatory recall order under subsection (b) of such section;

(B) the number of responsible parties, as defined in section 417 of the Federal Food, Drug, and Cosmetic Act, formally given the opportunity to cease distribution of an article of food and recall such article, as described in section 423(a) of such Act;

(C) the number of responsible parties described in subparagraph (B) who did not cease distribution of or recall an article of food after given the opportunity to cease distribution or

recall under section 423(a) of the Federal Food, Drug, and Cosmetic Act;

(D) the number of recall orders issued under section 423(b) of the Federal Food, Drug, and Cosmetic Act; and

(E) a description of any instances in which there was no testing that confirmed adulteration of an article of food that was the subject of a recall under section 423(b) of the Federal Food, Drug, and Cosmetic Act or a public health advisory described in paragraph (1).

SEC. 207. 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. 208. 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. 209. IMPROVING THE TRAINING OF STATE, LOCAL, TERRITORIAL, AND TRIBAL FOOD SAFETY OFFICIALS.

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

"SEC. 1011. IMPROVING THE TRAINING OF STATE, LOCAL, TERRITORIAL, AND TRIBAL FOOD SAFETY OFFICIALS.

''(a) TRAINING.—The Secretary shall set standards and administer training and education programs for the employees of State, local, territorial, and tribal food safety officials relating to the regulatory responsibilities and policies established by this Act, including programs for—

''(1) scientific training;

''(2) training to improve the skill of officers and employees authorized to conduct inspections under sections 702 and 704;

''(3) training to achieve advanced product or process specialization in such inspections;

''(4) training that addresses best practices;

''(5) training in administrative process and procedure and integrity issues;

''(6) training in appropriate sampling and laboratory analysis methodology; and

''(7) training in building enforcement actions following inspections, examinations, testing, and investigations.

''(b) PARTNERSHIPS WITH STATE AND LOCAL OFFICIALS.—

''(1) IN GENERAL.—The Secretary, pursuant to a contract or memorandum of understanding between the Secretary and the head of a State, local, territorial, or tribal department or agency, is authorized and encouraged to conduct examinations, testing, and investigations for the purposes of determining compliance with the food safety provisions of this Act through the officers and employees of such

State, local, territorial, or tribal department or agency.

''(2) CONTENT.—A contract or memorandum described under paragraph (1) shall include provisions to ensure adequate training of such officers and employees to conduct such examinations, testing, and investigations. The contract or memorandum shall contain provisions regarding reimbursement. Such provisions may, at the sole discretion of the head of the other department or agency, require reimbursement, in whole or in part, from the Secretary for the examinations, testing, or investigations performed pursuant to this section by the officers or employees of the State, territorial, or tribal department or agency.

''(3) EFFECT.—Nothing in this subsection shall be construed to limit the authority of the Secretary under section 702.

''(c) EXTENSION SERVICE.—The Secretary shall ensure coordination with the extension activities of the National Institute of Food and Agriculture of the Department of Agriculture in advising producers and small processors transitioning into new practices required as a result of the enactment of the FDA Food Safety Modernization

Act and assisting regulated industry with compliance with such Act.

''(d) NATIONAL FOOD SAFETY TRAINING, EDUCATION, EXTENSION, OUTREACH AND TECHNICAL ASSISTANCE PROGRAM.—

''(1) IN GENERAL.—In order to improve food safety and reduce the incidence of foodborne illness, the Secretary shall, not later than 180 days after the date of enactment of the FDA Food Safety Modernization Act, enter into one or more memoranda of understanding, or enter into other cooperative agreements, with the Secretary of Agriculture to establish a competitive grant program within the National Institute for Food and Agriculture to provide food safety training, education, extension, outreach, and technical assistance to—

''(A) owners and operators of farms;

''(B) small food processors; and

''(C) small fruit and vegetable merchant wholesalers.

''(2) IMPLEMENTATION.—The competitive grant program established under paragraph (1) shall be carried out in accordance with section 405 of the Agricultural Research, Extension, and Education Reform Act of 1998.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section for fiscal years 2011 through 2015.''.

(b) NATIONAL FOOD SAFETY TRAINING, EDUCATION, EXTENSION, OUTREACH, AND TECHNICAL ASSISTANCE PROGRAM.—Title IV of the Agricultural Research, Extension, and Education Reform Act of 1998 is amended by inserting after section 404 (7 U.S.C. 7624) the following:

''SEC. 405. NATIONAL FOOD SAFETY TRAINING, EDUCATION, EXTENSION, OUTREACH, AND TECHNICAL ASSISTANCE PROGRAM.

''(a) IN GENERAL.—The Secretary shall award grants under this section to carry out the competitive grant program established under section 1011(d) of the Federal Food, Drug, and Cosmetic Act, pursuant to any memoranda of understanding entered into under such section.

''(b) INTEGRATED APPROACH.—The grant program described under subsection (a) shall be carried out under this section in a manner that facilitates the integration of food safety standards and guidance with the variety of agricultural production systems, encompassing conven-

tional, sustainable, organic, and conservation and environmental practices.

''(c) PRIORITY.—In awarding grants under this section, the Secretary shall give priority to projects that target small and medium-sized farms, beginning farmers, socially disadvantaged farmers, small processors, or small fresh fruit and vegetable merchant wholesalers.

''(d) PROGRAM COORDINATION.—

''(1) IN GENERAL.—The Secretary shall coordinate implementation of the grant program under this section with the National Integrated Food Safety Initiative.

''(2) INTERACTION.—The Secretary shall—

''(A) in carrying out the grant program under this section, take into consideration applied research, education, and extension results obtained from the National Integrated Food Safety Initiative; and

''(B) in determining the applied research agenda for the National Integrated Food Safety Initiative, take into consideration the needs articulated by participants in projects funded by the program under this section.

''(e) GRANTS.—

''(1) IN GENERAL.—In carrying out this section, the Secretary shall make competitive grants to support training, education, extension, outreach, and technical assistance projects that will help improve public health by increasing the understanding and adoption of established food safety standards, guidance, and protocols.

''(2) ENCOURAGED FEATURES.—The Secretary shall encourage projects carried out using grant funds under this section to include co-management of food safety, conservation systems, and ecological health.

''(3) MAXIMUM TERM AND SIZE OF GRANT.—

''(A) IN GENERAL.—A grant under this section shall have a term that is not more than 3 years.

''(B) LIMITATION ON GRANT FUNDING.—The Secretary may not provide grant funding to an entity under this section after such entity has received 3 years of grant funding under this section.

''(f) GRANT ELIGIBILITY.—

''(1) IN GENERAL.—To be eligible for a grant under this section, an entity shall be—

''(A) a State cooperative extension service;

''(B) a Federal, State, local, or tribal agency, a nonprofit community-based or non-governmental organization, or an organization representing owners and operators of farms, small food processors, or small fruit and vegetable merchant wholesalers that has a commitment to public health and expertise in administering programs that contribute to food safety;

''(C) an institution of higher education (as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a))) or a foundation maintained by an institution of higher education;

''(D) a collaboration of 2 of more eligible entities described in this subsection; or

''(E) such other appropriate entity, as determined by the Secretary.

''(2) MULTISTATE PARTNERSHIPS.—Grants under this section may be made for projects involving more than 1 State.

''(g) REGIONAL BALANCE.—In making grants under this section, the Secretary shall, to the maximum extent practicable, ensure—

''(1) geographic diversity; and

''(2) diversity of types of agricultural production.

''(h) TECHNICAL ASSISTANCE.—The Secretary may use funds made available under this section to provide technical assistance to grant recipients to further the purposes of this section.

''(i) BEST PRACTICES AND MODEL PROGRAMS.—Based on evaluations of, and responses arising from, projects funded under this section, the Secretary may issue a set of recommended best practices and models for food safety training programs for agricultural producers, small food processors, and small fresh fruit and vegetable merchant wholesalers.

''(j) AUTHORIZATION OF APPROPRIATIONS.—For the purposes of making grants under this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2011 through 2015.''.

SEC. 210. ENHANCING FOOD SAFETY.

(a) GRANTS TO ENHANCE FOOD SAFETY.—Section 1009 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 399) is amended to read as follows:

''SEC. 1009. GRANTS TO ENHANCE FOOD SAFETY.

''(a) IN GENERAL.—The Secretary is authorized to make grants to eligible entities to—

''(1) undertake examinations, inspections, and investigations, and related food safety activities under section 702;

''(2) train to the standards of the Secretary for the examination, inspection, and investigation of food manufacturing, processing, packing, holding, distribution, and importation, including as such examination, inspection, and investigation relate to retail food establishments;

''(3) build the food safety capacity of the laboratories of such eligible entity, including the detection of zoonotic diseases;

''(4) build the infrastructure and capacity of the food safety programs of such eligible entity to meet the standards as outlined in the grant application; and

''(5) take appropriate action to protect the public health in response to—

''(A) a notification under section 1008, including planning and otherwise preparing to take such action; or

''(B) a recall of food under this Act.

''(b) ELIGIBLE ENTITIES; APPLICATION.—

''(1) IN GENERAL.—In this section, the term 'eligible entity' means an entity—

''(A) that is—

''(i) a State;

''(ii) a locality;

''(iii) a territory;

''(iv) an Indian tribe (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act); or

''(v) a nonprofit food safety training entity that collaborates with 1 or more institutions of higher education; and

''(B) that submits an application to the Secretary at such time, in such manner, and including such information as the Secretary may reasonably require.

''(2) CONTENTS.—Each application submitted under paragraph (1) shall include—

''(A) an assurance that the eligible entity has developed plans to engage in the types of activities described in subsection (a);

''(B) a description of the types of activities to be funded by the grant;

''(C) an itemization of how grant funds received under this section will be expended;

''(D) a description of how grant activities will be monitored; and

''(E) an agreement by the eligible entity to report information required by the Secretary to conduct evaluations under this section.

''(c) LIMITATIONS.—The funds provided under subsection (a) shall be available to an eligible entity that receives a grant under this section only to the extent such entity funds the food safety programs of such entity independently of any grant under this section in each year of the grant at a level equal to the level of such funding in the previous year, increased by the Consumer Price Index. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

''(d) ADDITIONAL AUTHORITY.—The Secretary may—

''(1) award a grant under this section in each subsequent fiscal year without reapplication for a period of not more than 3 years, provided the requirements of subsection (c) are met for the previous fiscal year; and

''(2) award a grant under this section in a fiscal year for which the requirement of subsection (c) has not been met only if such requirement was not met because such funding was diverted for response

to 1 or more natural disasters or in other extenuating circumstances that the Secretary may determine appropriate.

''(e) DURATION OF AWARDS.—The Secretary may award grants to an individual grant recipient under this section for periods of not more than 3 years. In the event the Secretary conducts a program evaluation, funding in the second year or third year of the grant, where applicable, shall be contingent on a successful program evaluation by the Secretary after the first year.

''(f) PROGRESS AND EVALUATION.—

''(1) IN GENERAL.—The Secretary shall measure the status and success of each grant program authorized under the FDA Food Safety Modernization Act (and any amendment made by such Act), including the grant program under this section. A recipient of a grant described in the preceding sentence shall, at the end of each grant year, provide the Secretary with information on how grant funds were spent and the status of the efforts by such recipient to enhance food safety. To the extent practicable, the Secretary shall take the performance of such a grant recipient into account when determining whether to continue funding for such recipient.

''(2) NO DUPLICATION.—In carrying out paragraph (1), the Secretary shall not duplicate the efforts of the Secretary under other provisions of this Act or the FDA Food Safety Modernization Act that require measurement and review of the activities of grant recipients under either such Act.

''(g) SUPPLEMENT NOT SUPPLANT.—Grant funds received under this section 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 section.

''(h) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of making grants under this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2011 through 2015.''.

(b) CENTERS OF EXCELLENCE.—Part P of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

''SEC. 399V-5. FOOD SAFETY INTEGRATED CENTERS OF EXCELLENCE.

''(a) IN GENERAL.—Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the working group described in subsection (b)(2),

shall designate 5 Integrated Food Safety Centers of Excellence (referred to in this section as the 'Centers of Excellence') to serve as resources for Federal, State, and local public health professionals to respond to foodborne illness outbreaks. The Centers of Excellence shall be headquartered at selected State health departments.

''(b) SELECTION OF CENTERS OF EXCELLENCE.—

''(1) ELIGIBLE ENTITIES.—To be eligible to be designated as a Center of Excellence under subsection (a), an entity shall—

''(A) be a State health department;

''(B) partner with 1 or more institutions of higher education that have demonstrated knowledge, expertise, and meaningful experience with regional or national food production, processing, and distribution, as well as leadership in the laboratory, epidemiological, and environmental detection and investigation of foodborne illness; and

''(C) provide to the Secretary such information, at such time, and in such manner, as the Secretary may require.

''(2) WORKING GROUP.—Not later than 180 days after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall estab-

lish a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food industry, including food retailers and food manufacturers, consumer organizations, and academia to make recommendations to the Secretary regarding designations of the Centers of Excellence.

''(3) ADDITIONAL CENTERS OF EXCELLENCE.—The Secretary may designate eligible entities to be regional Food Safety Centers of Excellence, in addition to the 5 Centers designated under subsection (a).

''(c) ACTIVITIES.—Under the leadership of the Director of the Centers for Disease Control and Prevention, each Center of Excellence shall be based out of a selected State health department, which shall provide assistance to other regional, State, and local departments of health through activities that include—

''(1) providing resources, including timely information concerning symptoms and tests, for frontline health professionals interviewing individuals as part of routine surveillance and outbreak investigations;

''(2) providing analysis of the timeliness and effectiveness of foodborne disease surveillance and outbreak response activities;

''(3) providing training for epidemiological and environmental investigation of foodborne illness, including suggestions for streamlining and standardizing the investigation process;

''(4) establishing fellowships, stipends, and scholarships to train future epidemiological and food-safety leaders and to address critical workforce shortages;

''(5) training and coordinating State and local personnel;

''(6) strengthening capacity to participate in existing or new foodborne illness surveillance and environmental assessment information systems; and

''(7) conducting research and outreach activities focused on increasing prevention, communication, and education regarding food safety.

''(d) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall submit to Congress a report that—

''(1) describes the effectiveness of the Centers of Excellence; and

''(2) provides legislative recommendations or describes additional resources required by the Centers of Excellence.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this section.

''(f) NO DUPLICATION OF EFFORT.—In carrying out activities of the Centers of Excellence or other programs under this section, the Secretary shall not duplicate other Federal foodborne illness response efforts.''.

SEC. 211. IMPROVING THE REPORTABLE FOOD REGISTRY.

(a) IN GENERAL.—Section 417 (21 U.S.C. 350f) is amended—

(1) by redesignating subsections (f) through (k) as subsections (i) through (n), respectively; and

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

''(f) CRITICAL INFORMATION.—Except with respect to fruits and vegetables that are raw agricultural commodities, not more than 18 months after the date of enactment of the FDA Food Safety Modernization Act, the Secretary may require a responsible party to submit to the Secretary consumer-oriented information regarding a reportable food, which shall include—

''(1) a description of the article of food as provided in subsection (e)(3);

''(2) as provided in subsection (e)(7), affected product identification codes, such as UPC, SKU, or

lot or batch numbers sufficient for the consumer to identify the article of food;

''(3) contact information for the responsible party as provided in subsection (e)(8); and

''(4) any other information the Secretary determines is necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food.

''(g) GROCERY STORE NOTIFICATION.—

''(1) ACTION BY SECRETARY.—The Secretary shall—

''(A) prepare the critical information described under subsection (f) for a reportable food as a standardized one-page summary;

''(B) publish such one-page summary on the Internet website of the Food and Drug Administration in a format that can be easily printed by a grocery store for purposes of consumer notification.

''(2) ACTION BY GROCERY STORE.—A notification described under paragraph (1)(B) shall include the date and time such summary was posted on the Internet website of the Food and Drug Administration.

''(h) CONSUMER NOTIFICATION.—

''(1) IN GENERAL.—If a grocery store sold a reportable food that is the subject of the posting and such establishment is part of chain of establishments with 15 or more physical locations, then such establishment shall, not later than 24 hours after a one page summary described in subsection (g) is published, prominently display such summary or the information from such summary via at least one of the methods identified under paragraph (2) and maintain the display for 14 days.

''(2) LIST OF CONSPICUOUS LOCATIONS.—Not more than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall develop and publish a list of acceptable conspicuous locations and manners, from which grocery stores shall select at least one, for providing the notification required in paragraph (1). Such list shall include—

''(A) posting the notification at or near the register;

''(B) providing the location of the reportable food;

''(C) providing targeted recall information given to customers upon purchase of a food; and

''(D) other such prominent and conspicuous locations and manners utilized by grocery stores as of the date of the enactment of the FDA Food Safety Modernization Act to provide notice of such recalls to consumers as considered appropriate by the Secretary.''.

(b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331), as amended by section 206, is amended by adding at the end the following:

''(yy) The knowing and willful failure to comply with the notification requirement under section 417(h).''.

(c) CONFORMING AMENDMENT.—Section 301(e) (21 U.S.C. 331(e)) is amended by striking ''417(g)'' and inserting ''417(j)''.

TITLE III—IMPROVING THE SAFETY OF 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.—Except as provided under subsections (e) and (f), each importer shall perform risk-based foreign supplier verification activities for the purpose of verifying

that the food imported by the importer or agent of an importer is—

"(A) produced in compliance with the requirements of section 418 or section 419, as appropriate; and

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

"(2) IMPORTER DEFINED.—For purposes of this section, the term 'importer' means, with respect to an article of food—

"(A) the United States owner or consignee of the article of food at the time of entry of such article into the United States; or

"(B) in the case when there is no United States owner or consignee as described in subparagraph (A), the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States.

"(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 importers 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).

''(2) REQUIREMENTS.—The regulations promulgated under paragraph (1)—

''(A) shall require that the foreign supplier verification program of each importer be adequate to provide assurances that each foreign supplier to the importer produces the imported food in compliance with—

''(i) processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as those required under section 418 or section 419 (taking into consideration variances granted under section 419), as appropriate; and

''(ii) section 402 and section 403(w).

''(B) shall include such other requirements as the Secretary deems necessary and appropriate to verify that food imported into the

United States is as safe as food produced and sold within the United States.

''(3) CONSIDERATIONS.—In promulgating regulations under this subsection, the Secretary shall, as appropriate, take into account differences among importers and types of imported foods, including based on the level of risk posed by the imported food.

''(4) 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 an importer 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) EXEMPTION OF SEAFOOD, JUICE, AND LOW-ACID CANNED FOOD FACILITIES IN COMPLIANCE WITH HACCP.—This section shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, and is in compliance with, 1 of the

following standards and regulations 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).

The exemption under paragraph (3) shall apply only with respect to microbiological hazards that are regulated under the standards for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers under part 113 of chapter 21, Code of Federal Regulations (or any successor regulations).

"(f) ADDITIONAL EXEMPTIONS.—The Secretary, by notice published in the Federal Register, shall establish an exemption from the requirements of this section for articles of food imported in small quantities for research and evaluation purposes or for personal consumption, provided that such foods are not intended for retail sale and are not sold or distributed to the public.

''(g) 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 211, is amended by adding at the end the following:

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

(c) IMPORTS.—Section 801(a) (21 U.S.C. 381(a)) is amended by adding ''or the importer (as defined in section 805) is in violation of such 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 18 months after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall—

"(1) establish a program, in consultation with the Secretary of Homeland Security—

"(A) to provide for the expedited review and importation of food offered for importation by importers who have voluntarily agreed to participate in such program; and

"(B) consistent with section 808, establish a process for the issuance of a facility certification to accompany food offered for importation by importers who have voluntarily agreed to participate in such program; and

"(2) issue a guidance document related to participation in, revocation of such participation in, reinstatement in, 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 established by the Secretary under subsection (a).

"(c) NOTICE OF INTENT TO PARTICIPATE.—An importer that intends to participate in the program under this section in a fiscal year shall submit a notice and appli-

cation to the Secretary of such intent at the time and in a manner established by the Secretary.

''(d) ELIGIBILITY.—Eligibility shall be limited to an importer offering food for importation from a facility that has a certification described in subsection (a). In reviewing the applications and making determinations on such applications, the Secretary shall consider the risk of the food to be imported based on factors, such as the following:

''(1) The known safety risks of the food to be imported.

''(2) The compliance history of foreign suppliers used by the importer, as appropriate.

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

''(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.

''(e) 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.

''(f) FALSE STATEMENTS.—Any statement or representation made by an importer to the Secretary shall be subject to section 1001 of title 18, United States Code.

''(g) 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 (q) that such food be accompanied by a certification or other assurance that the food meets 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:

"(q) CERTIFICATIONS CONCERNING IMPORTED FOODS.—

"(1) IN GENERAL.—The Secretary 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 described in paragraph (3) provide a certification, or such other assurances as the Secretary determines appropriate, that the article of food complies with applicable requirements of this Act. Such certification or assurances may be provided in the form of shipment-specific certificates, a listing of certified facilities that manufacture, process, pack, or hold such food, or in such other form as the Secretary may specify.

"(2) FACTORS TO BE CONSIDERED IN REQUIRING CERTIFICATION.—The Secretary shall base the determination that an article of food is required to have a certification described in paragraph (1) on the risk of the food, including—

"(A) known safety risks associated with the food;

"(B) known food safety risks associated with the country, territory, or region of origin of the food;

"(C) a finding by the Secretary, supported by scientific, risk-based evidence, that—

"(i) the food safety programs, systems, and standards in the country, territory, or region of origin of the food are inadequate to ensure that the article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this Act; and

"(ii) the certification would assist the Secretary in determining whether to refuse or admit the article of food under subsection (a); and

"(D) information submitted to the Secretary in accordance with the process established in paragraph (7).

"(3) 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 the Secretary; or

''(B) such other persons or entities accredited pursuant to section 808 to provide such certification or assurance.

''(4) 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 not valid or reliable.

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

''(6) FALSE STATEMENTS.—Any statement or representation made by an entity described in paragraph (2) to the Secretary shall be subject to section 1001 of title 18, United States Code.

''(7) ASSESSMENT OF FOOD SAFETY PROGRAMS, SYSTEMS, AND STANDARDS.—If the Secretary determines that the food safety programs, systems, and standards in a foreign region, country, or territory are inadequate to ensure that an article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this Act, the Secretary shall, to the extent practicable, identify such inadequacies and establish a process by which the foreign region, country, or territory may inform the Secretary of improvements made to such food safety program, system, or standard and demonstrate that those controls are adequate to ensure that an article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this Act.''.

(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 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. BUILDING CAPACITY OF FOREIGN GOVERNMENTS WITH RESPECT TO FOOD SAFETY.

(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 food safety capacity of foreign govern-

ments, 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, the Secretary of Homeland Security, the United States Trade Representative, and the Secretary of Commerce, representatives of the food industry, appropriate foreign government officials, 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 provisions to provide for responsibility of exporting countries to ensure the safety of food.

(2) Provisions for secure 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 on whether and how to harmonize requirements under the Codex Alimentarius.

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

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the regulation of dietary supplements under the Dietary Supplement Health and Education Act of 1994 (Public Law 103–417).

SEC. 306. INSPECTION OF FOREIGN FOOD FACILITIES.

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

"SEC. 807. 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 factory, warehouse, or other establishment of which the owner, operator, or agent in charge, or the government of the foreign country, refuses to permit entry of United States inspectors or other individuals duly designated by the Secretary, upon request, to inspect such factory, warehouse, or other establishment. 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 does not permit an inspection of a factory, warehouse, or other establishment during the 24-hour period after such request is submitted, or after such other time period, as agreed upon by the Secretary and the foreign factory, warehouse, or other establishment.''.

(b) INSPECTION BY THE SECRETARY OF COMMERCE.—

(1) IN GENERAL.—The Secretary of Commerce, in coordination with the Secretary of Health and Human Services, may send 1 or more inspectors to a country or facility of an exporter from which sea-

food imported into the United States originates. The inspectors shall assess practices and processes used in connection with the farming, cultivation, harvesting, preparation for market, or transportation of such seafood and may provide technical assistance related to such activities.

(2) INSPECTION REPORT.—

(A) IN GENERAL.—The Secretary of Health and Human Services, in coordination with the Secretary of Commerce, shall—

(i) prepare an inspection report for each inspection conducted under paragraph (1);

(ii) provide the report to the country or exporter that is the subject of the report; and

(iii) provide a 30-day period during which the country or exporter may provide a rebuttal or other comments on the findings of the report to the Secretary of Health and Human Services.

(B) DISTRIBUTION AND USE OF REPORT.—The Secretary of Health and Human Services shall consider the inspection reports described in subparagraph (A) in distributing

inspection resources under section 421 of the Federal Food, Drug, and Cosmetic Act, as added by section 201.

SEC. 307. ACCREDITATION OF THIRD-PARTY AUDITORS.

Chapter VIII (21 U.S.C. 381 et seq.), as amended by section 306, is amended by adding at the end the following:

"SEC. 808. ACCREDITATION OF THIRD-PARTY AUDITORS.

''(a) DEFINITIONS.—In this section:

''(1) AUDIT AGENT.—The term 'audit agent' means an individual who is an employee or agent of an accredited third-party auditor and, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited third-party auditor.

''(2) ACCREDITATION BODY.—The term 'accreditation body' means an authority that performs accreditation of third-party auditors.

''(3) THIRD-PARTY AUDITOR.—The term 'third-party auditor' means a foreign government, agency of a foreign government, foreign cooperative, or any other third party, as the Secretary determines appropriate in accordance with the model standards described in subsection (b)(2), that is eligible to be considered for accreditation to conduct food safety

audits to certify that eligible entities meet the applicable requirements of this section. A third-party auditor may be a single individual. A third-party auditor may employ or use audit agents to help conduct consultative and regulatory audits.

''(4) ACCREDITED THIRD-PARTY AUDITOR.—The term 'accredited third-party auditor' means a third-party auditor accredited by an accreditation body to conduct audits of eligible entities to certify that such eligible entities meet the applicable requirements of this section. An accredited third-party auditor may be an individual who conducts food safety audits to certify that eligible entities meet the applicable requirements of this section.

''(5) CONSULTATIVE AUDIT.—The term 'consultative audit' means an audit of an eligible entity—

''(A) to determine whether such entity is in compliance with the provisions of this Act and with applicable industry standards and practices; and

''(B) the results of which are for internal purposes only.

''(6) ELIGIBLE ENTITY.—The term 'eligible entity' means a foreign entity, including a foreign fa-

cility registered under section 415, in the food import supply chain that chooses to be audited by an accredited third-party auditor or the audit agent of such accredited third-party auditor.

''(7) REGULATORY AUDIT.—The term 'regulatory audit' means an audit of an eligible entity—

''(A) to determine whether such entity is in compliance with the provisions of this Act; and

''(B) the results of which determine—

''(i) whether an article of food manufactured, processed, packed, or held by such entity is eligible to receive a food certification under section 801(q); or

''(ii) whether a facility is eligible to receive a facility certification under section 806(a) for purposes of participating in the program under section 806.

''(b) ACCREDITATION SYSTEM.—

''(1) ACCREDITATION BODIES.—

''(A) RECOGNITION OF ACCREDITATION BODIES.—

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

recognition of accreditation bodies that accredit third-party auditors to certify that eligible entities meet the applicable requirements of this section.

''(ii) DIRECT ACCREDITATION.—If, by the date that is 2 years after the date of establishment of the system described in clause (i), the Secretary has not identified and recognized an accreditation body to meet the requirements of this section, the Secretary may directly accredit third-party auditors.

''(B) NOTIFICATION.—Each accreditation body recognized by the Secretary shall submit to the Secretary a list of all accredited third-party auditors accredited by such body and the audit agents of such auditors.

''(C) REVOCATION OF RECOGNITION AS AN ACCREDITATION BODY.—The Secretary shall promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of this section.

''(D) REINSTATEMENT.—The Secretary shall establish procedures to reinstate recognition of an accreditation body if the Secretary

determines, based on evidence presented by such accreditation body, that revocation was inappropriate or that the body meets the requirements for recognition under this section.

''(2) MODEL ACCREDITATION STANDARDS.—Not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall develop model standards, including requirements for regulatory audit reports, and each recognized accreditation body shall ensure that third-party auditors and audit agents of such auditors meet such standards in order to qualify such third-party auditors as accredited third-party auditors under this section. In developing the model standards, the Secretary shall look to standards in place on the date of the enactment of this section for guidance, to avoid unnecessary duplication of efforts and costs.

''(c) THIRD-PARTY AUDITORS.—

''(1) REQUIREMENTS FOR ACCREDITATION AS A THIRD-PARTY AUDITOR.—

''(A) FOREIGN GOVERNMENTS.—Prior to accrediting a foreign government or an agency of a foreign government as an accredited third-party auditor, the accreditation body (or, in the

case of direct accreditation under subsection (b)(1)(A)(ii), the Secretary) shall perform such reviews and audits of food safety programs, systems, and standards of the government or agency of the government as the Secretary deems necessary, including requirements under the model standards developed under subsection (b)(2), to determine that the foreign government or agency of the foreign government is capable of adequately ensuring that eligible entities or foods certified by such government or agency meet the requirements of this Act with respect to food manufactured, processed, packed, or held for import into the United States.

''(B) FOREIGN COOPERATIVES AND OTHER THIRD PARTIES.—Prior to accrediting a foreign cooperative that aggregates the products of growers or processors, or any other third party to be an accredited third-party auditor, the accreditation body (or, in the case of direct accreditation under subsection (b)(1)(A)(ii), the Secretary) shall perform such reviews and audits of the training and qualifications of audit agents used by that cooperative or party and

conduct such reviews of internal systems and such other investigation of the cooperative or party as the Secretary deems necessary, including requirements under the model standards developed under subsection (b)(2), to determine that each eligible entity certified by the cooperative or party has systems and standards in use to ensure that such entity or food meets the requirements of this Act.

''(2) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES OR FOODS.—

''(A) IN GENERAL.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(A)(ii), the Secretary) may not accredit a third-party auditor unless such third-party auditor agrees to issue a written and, as appropriate, electronic food certification, described in section 801(q), or facility certification under section 806(a), as appropriate, to accompany each food shipment for import into the United States from an eligible entity, subject to requirements set forth by the Secretary. Such written or electronic certification may be included with other documentation regarding such food shipment. The Secretary shall con-

sider certifications under section 801(q) and participation in the voluntary qualified importer program described in section 806 when targeting inspection resources under section 421.

''(B) PURPOSE OF CERTIFICATION.—The Secretary shall use certification provided by accredited third-party auditors to—

''(i) determine, in conjunction with any other assurances the Secretary may require under section 801(q), whether a food satisfies the requirements of such section; and

''(ii) determine whether a facility is eligible to be a facility from which food may be offered for import under the voluntary qualified importer program under section 806.

''(C) REQUIREMENTS FOR ISSUING CERTIFICATION.—

''(i) IN GENERAL.—An accredited third-party auditor shall issue a food certification under section 801(q) or a facility certification described under subparagraph (B) only after conducting a regulatory audit and such other activities that may be

necessary to establish compliance with the requirements of such sections.

''(ii) PROVISION OF CERTIFICATION.—Only an accredited third-party auditor or the Secretary may provide a facility certification under section 806(a). Only those parties described in 801(q)(3) or the Secretary may provide a food certification under 301(g).

''(3) AUDIT REPORT SUBMISSION REQUIREMENTS.—

''(A) REQUIREMENTS IN GENERAL.—As a condition of accreditation, not later than 45 days after conducting an audit, an accredited third-party auditor or audit agent of such auditor shall prepare, and, in the case of a regulatory audit, submit, the audit report for each audit conducted, in a form and manner designated by the Secretary, which shall include—

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

''(ii) the dates of the audit;

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

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

''(B) RECORDS.—Following any accreditation of a third-party auditor, the Secretary may, at any time, require the accredited third-party auditor to submit to the Secretary an on-site audit report and such other reports or documents required as part of the audit process, for any eligible entity certified by the third-party auditor or audit agent of such auditor. Such report may include documentation that the eligible entity is in compliance with any applicable registration requirements.

''(C) LIMITATION.—The requirement under subparagraph (B) shall not include any report or other documents resulting from a consultative audit by the accredited third-party auditor, except that the Secretary may access the results of a consultative audit in accordance with section 414.

''(4) REQUIREMENTS OF ACCREDITED THIRD-PARTY AUDITORS AND AUDIT AGENTS OF SUCH AUDITORS.—

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

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

''(ii) such condition.

''(B) TYPES OF AUDITS.—An accredited third-party auditor or audit agent of such auditor may perform consultative and regulatory audits of eligible entities.

''(C) LIMITATIONS.—

''(i) IN GENERAL.—An accredited third party auditor may not perform a regulatory audit of an eligible entity if such agent has performed a consultative audit or a regulatory audit of such eligible entity during the previous 13-month period.

''(ii) WAIVER.—The Secretary may waive the application of clause (i) if the Secretary determines that there is insuffi-

cient access to accredited third-party auditors in a country or region.

''(5) CONFLICTS OF INTEREST.—

''(A) THIRD-PARTY AUDITORS.—An accredited third-party auditor shall—

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

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

''(iii) annually make available to the Secretary disclosures of the extent to which such auditor and the officers and employees of such auditor have maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

''(B) AUDIT AGENTS.—An audit agent shall—

''(i) not own or operate an eligible entity to be audited by such agent;

''(ii) in carrying out audits of eligible entities under this section, have procedures to ensure that such agent does not have a financial conflict of interest regarding an eligible entity to be audited by such agent; and

''(iii) annually make available to the Secretary disclosures of the extent to which such agent has maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

''(C) REGULATIONS.—The Secretary shall promulgate regulations not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act to implement this section and to ensure that there are protections against conflicts of interest between an accredited third-party auditor and the eligible entity to be certified by such auditor or audited by such audit agent. Such regulations shall include—

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

"(ii) a structure to decrease the potential for conflicts of interest, including timing and public disclosure, for fees paid by eligible entities to accredited third-party auditors; and

"(iii) appropriate limits on financial affiliations between an accredited third-party auditor or audit agents of such auditor and any person that owns or operates an eligible entity to be certified by such auditor, as described in subparagraphs (A) and (B).

"(6) WITHDRAWAL OF ACCREDITATION.—

"(A) IN GENERAL.—The Secretary shall withdraw accreditation from an accredited third-party auditor—

"(i) if food certified under section 801(q) or from a facility certified under paragraph (2)(B) by such third-party auditor is linked to an outbreak of foodborne illness that has a reasonable probability of causing serious adverse health consequences or death in humans or animals;

"(ii) following an evaluation and finding by the Secretary that the third-party

auditor no longer meets the requirements for accreditation; or

''(iii) 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.

''(B) ADDITIONAL BASIS FOR WITHDRAWAL OF ACCREDITATION.—The Secretary may withdraw accreditation from an accredited third-party auditor in the case that such third-party auditor is accredited by an accreditation body for which recognition as an accreditation body under subsection (b)(1)(C) is revoked, if the Secretary determines that there is good cause for the withdrawal.

''(C) EXCEPTION.—The Secretary may waive the application of subparagraph (A)(i) if the Secretary—

''(i) conducts an investigation of the material facts related to the outbreak of human or animal illness; and

''(ii) reviews the steps or actions taken by the third party auditor to justify the certification and determines that the

accredited third-party auditor satisfied the requirements under section 801(q) of certifying the food, or the requirements under paragraph (2)(B) of certifying the entity.

''(7) REACCREDITATION.—The Secretary shall establish procedures to reinstate the accreditation of a third-party auditor for which accreditation has been withdrawn under paragraph (6)—

''(A) if the Secretary determines, based on evidence presented, that the third-party auditor satisfies the requirements of this section and adequate grounds for revocation no longer exist; and

''(B) in the case of a third-party auditor accredited by an accreditation body for which recognition as an accreditation body under subsection (b)(1)(C) is revoked—

''(i) if the third-party auditor becomes accredited not later than 1 year after revocation of accreditation under paragraph (6)(A), through direct accreditation under subsection (b)(1)(A)(ii) or by an accreditation body in good standing; or

"(ii) under such conditions as the Secretary may require for a third-party auditor under paragraph (6)(B).

"(8) NEUTRALIZING COSTS.—The Secretary shall establish by regulation a reimbursement (user fee) program, similar to the method described in section 203(h) of the Agriculture Marketing Act of 1946, by which the Secretary assesses fees and requires accredited third-party auditors and audit agents to reimburse the Food and Drug Administration for the work performed to establish and administer the accreditation system under this section. The Secretary shall make operating this program revenue-neutral and shall not generate surplus revenue from such a reimbursement mechanism. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to remain available until expended.

"(d) RECERTIFICATION OF ELIGIBLE ENTITIES.—An eligible entity shall apply for annual recertification by an accredited third-party auditor if such entity—

"(1) intends to participate in voluntary qualified importer program under section 806; or

''(2) is required to provide to the Secretary a certification under section 801(q) for any food from such entity.

''(e) FALSE STATEMENTS.—Any statement or representation made—

''(1) by an employee or agent of an eligible entity to an accredited third-party auditor or audit agent; or

''(2) by an accredited third-party auditor to the Secretary,

shall be subject to section 1001 of title 18, United States Code.

''(f) MONITORING.—To ensure compliance with the requirements of this section, the Secretary shall—

''(1) periodically, or at least once every 4 years, reevaluate the accreditation bodies described in subsection (b)(1);

''(2) periodically, or at least once every 4 years, evaluate the performance of each accredited third-party auditor, through the review of regulatory audit reports by such auditors, the compliance history as available of eligible entities certified by such auditors, and any other measures deemed necessary by the Secretary;

''(3) at any time, conduct an onsite audit of any eligible entity certified by an accredited third-party auditor, with or without the auditor present; and

''(4) take any other measures deemed necessary by the Secretary.

''(g) PUBLICLY AVAILABLE REGISTRY.—The Secretary shall establish a publicly available registry of accreditation bodies and of accredited third-party auditors, including the name of, contact information for, and other information deemed necessary by the Secretary about such bodies and auditors.

''(h) LIMITATIONS.—

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

''(2) 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. 308. FOREIGN OFFICES OF THE FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—The Secretary shall establish offices of the Food and Drug Administration in 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, the Secretary of Homeland Security, 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, 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. 309. SMUGGLED FOOD.

(a) IN GENERAL.—Not later than 180 days after the enactment of this Act, the Secretary shall, in coordination with the Secretary of Homeland Security, develop and implement a strategy to better identify smuggled food and prevent entry of such food into the United States.

(b) NOTIFICATION TO HOMELAND SECURITY.—Not later than 10 days after the Secretary identifies a smuggled food that the Secretary believes would cause serious adverse health consequences or death to humans or animals, the Secretary shall provide to the Secretary of Homeland Security a notification under section 417(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350f(k)) describing the smuggled food and, if available, the names of the individuals or entities that attempted to import such food into the United States.

(c) PUBLIC NOTIFICATION.—If the Secretary—

(1) identifies a smuggled food;

(2) reasonably believes exposure to the food would cause serious adverse health consequences or death to humans or animals; and

(3) reasonably believes that the food has entered domestic commerce and is likely to be consumed,

the Secretary shall promptly issue a press release describing that food and shall use other emergency communica-

tion or recall networks, as appropriate, to warn consumers and vendors about the potential threat.

(d) EFFECT OF SECTION.—Nothing in this section shall affect the authority of the Secretary to issue public notifications under other circumstances.

(e) DEFINITION.—In this subsection, the term ''smuggled food'' means any food that a person introduces into the United States through fraudulent means or with the intent to defraud or mislead.

TITLE IV—MISCELLANEOUS PROVISIONS

SEC. 401. 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 such sums as may be necessary for fiscal years 2011 through 2015.

(b) INCREASED NUMBER OF FIELD STAFF.—

(1) IN GENERAL.—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—

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

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

(C) 4,600 staff members in fiscal year 2013; and

(D) 5,000 staff members in fiscal year 2014.

(2) FIELD STAFF FOR FOOD DEFENSE.—The goal under paragraph (1) shall include an increase of 150 employees by fiscal year 2011 to—

(A) provide additional detection of and response to food defense threats; and

(B) detect, track, and remove smuggled food (as defined in section 310) from commerce.

SEC. 402. EMPLOYEE PROTECTIONS.

Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.), as amended by section 209, is further amended by adding at the end the following:

"SEC. 1012. EMPLOYEE PROTECTIONS.

"(a) IN GENERAL.—No entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food may discharge an employee or otherwise discriminate against an employee with respect to compensation, terms, conditions, or privileges of employment because the employee, whether at the employee's initiative or in the ordinary course of the employee's duties (or any person acting pursuant to a request of the employee)—

"(1) provided, caused to be provided, or is about to provide or cause to be provided to the employer, the Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of any provision of this Act or any order, rule, regulation, standard, or ban under this Act, or any order, rule, regulation, standard, or ban under this Act;

"(2) testified or is about to testify in a proceeding concerning such violation;

"(3) assisted or participated or is about to assist or participate in such a proceeding; or

"(4) objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee (or other such person) reasonably be-

lieved to be in violation of any provision of this Act, or any order, rule, regulation, standard, or ban under this Act.

''(b) PROCESS.—

''(1) IN GENERAL.—A person who believes that he or she has been discharged or otherwise discriminated against by any person in violation of subsection (a) may, not later than 180 days after the date on which such violation occurs, file (or have any person file on his or her behalf) a complaint with the Secretary of Labor (referred to in this section as the 'Secretary') alleging such discharge or discrimination and identifying the person responsible for such act. Upon receipt of such a complaint, the Secretary shall notify, in writing, the person named in the complaint of the filing of the complaint, of the allegations contained in the complaint, of the substance of evidence supporting the complaint, and of the opportunities that will be afforded to such person under paragraph (2).

''(2) INVESTIGATION.—

''(A) IN GENERAL.—Not later than 60 days after the date of receipt of a complaint filed under paragraph (1) and after affording the complainant and the person named in the

complaint an opportunity to submit to the Secretary a written response to the complaint and an opportunity to meet with a representative of the Secretary to present statements from witnesses, the Secretary shall initiate an investigation and determine whether there is reasonable cause to believe that the complaint has merit and notify, in writing, the complainant and the person alleged to have committed a violation of subsection (a) of the Secretary's findings.

''(B) REASONABLE CAUSE FOUND; PRELIMINARY ORDER.—If the Secretary concludes that there is reasonable cause to believe that a violation of subsection (a) has occurred, the Secretary shall accompany the Secretary's findings with a preliminary order providing the relief prescribed by paragraph (3)(B). Not later than 30 days after the date of notification of findings under this paragraph, the person alleged to have committed the violation or the complainant may file objections to the findings or preliminary order, or both, and request a hearing on the record. The filing of such objections shall not operate to stay any reinstatement remedy contained in the preliminary

order. Any such hearing shall be conducted expeditiously. If a hearing is not requested in such 30-day period, the preliminary order shall be deemed a final order that is not subject to judicial review.

"(C) DISMISSAL OF COMPLAINT.—

"(i) STANDARD FOR COMPLAINANT.—The Secretary shall dismiss a complaint filed under this subsection and shall not conduct an investigation otherwise required under subparagraph (A) unless the complainant makes a prima facie showing that any behavior described in paragraphs (1) through (4) of subsection (a) was a contributing factor in the unfavorable personnel action alleged in the complaint.

"(ii) STANDARD FOR EMPLOYER.—Notwithstanding a finding by the Secretary that the complainant has made the showing required under clause (i), no investigation otherwise required under subparagraph (A) shall be conducted if the employer demonstrates, by clear and convincing evidence, that the employer would

have taken the same unfavorable personnel action in the absence of that behavior.

''(iii) VIOLATION STANDARD.—The Secretary may determine that a violation of subsection (a) has occurred only if the complainant demonstrates that any behavior described in paragraphs (1) through (4) of subsection (a) was a contributing factor in the unfavorable personnel action alleged in the complaint.

''(iv) RELIEF STANDARD.—Relief may not be ordered under subparagraph (A) if the employer demonstrates by clear and convincing evidence that the employer would have taken the same unfavorable personnel action in the absence of that behavior.

''(3) FINAL ORDER.—

''(A) IN GENERAL.—Not later than 120 days after the date of conclusion of any hearing under paragraph (2), the Secretary shall issue a final order providing the relief prescribed by this paragraph or denying the complaint. At any time before issuance of a final order, a proceeding under this subsection may be termi-

nated on the basis of a settlement agreement entered into by the Secretary, the complainant, and the person alleged to have committed the violation.

''(B) CONTENT OF ORDER.—If, in response to a complaint filed under paragraph (1), the Secretary determines that a violation of subsection (a) has occurred, the Secretary shall order the person who committed such violation—

''(i) to take affirmative action to abate the violation;

''(ii) to reinstate the complainant to his or her former position together with compensation (including back pay) and restore the terms, conditions, and privileges associated with his or her employment; and

''(iii) to provide compensatory damages to the complainant.

''(C) PENALTY.—If such an order is issued under this paragraph, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorneys' and expert

witness fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

''(D) BAD FAITH CLAIM.—If the Secretary finds that a complaint under paragraph (1) is frivolous or has been brought in bad faith, the Secretary may award to the prevailing employer a reasonable attorneys' fee, not exceeding $1,000, to be paid by the complainant.

''(4) ACTION IN COURT.—

''(A) IN GENERAL.—If the Secretary has not issued a final decision within 210 days after the filing of the complaint, or within 90 days after receiving a written determination, the complainant may bring an action at law or equity for de novo review in the appropriate district court of the United States with jurisdiction, which shall have jurisdiction over such an action without regard to the amount in controversy, and which action shall, at the request of either party to such action, be tried by the court with a jury. The proceedings shall be governed by the same legal burdens of proof specified in paragraph (2)(C).

''(B) RELIEF.—The court shall have jurisdiction to grant all relief necessary to make the employee whole, including injunctive relief and compensatory damages, including—

''(i) reinstatement with the same seniority status that the employee would have had, but for the discharge or discrimination;

''(ii) the amount of back pay, with interest; and

''(iii) compensation for any special damages sustained as a result of the discharge or discrimination, including litigation costs, expert witness fees, and reasonable attorney's fees.

''(5) REVIEW.—

''(A) IN GENERAL.—Unless the complainant brings an action under paragraph (4), any person adversely affected or aggrieved by a final order issued under paragraph (3) may obtain review of the order in the United States Court of Appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred or the circuit in which the complainant resided on the date of such viola-

tion. The petition for review must be filed not later than 60 days after the date of the issuance of the final order of the Secretary. Review shall conform to chapter 7 of title 5, United States Code. The commencement of proceedings under this subparagraph shall not, unless ordered by the court, operate as a stay of the order.

''(B) NO JUDICIAL REVIEW.—An order of the Secretary with respect to which review could have been obtained under subparagraph (A) shall not be subject to judicial review in any criminal or other civil proceeding.

''(6) FAILURE TO COMPLY WITH ORDER.—Whenever any person has failed to comply with an order issued under paragraph (3), the Secretary may file a civil action in the United States district court for the district in which the violation was found to occur, or in the United States district court for the District of Columbia, to enforce such order. In actions brought under this paragraph, the district courts shall have jurisdiction to grant all appropriate relief including, but not limited to, injunctive relief and compensatory damages.

''(7) CIVIL ACTION TO REQUIRE COMPLIANCE.—

''(A) IN GENERAL.—A person on whose behalf an order was issued under paragraph (3) may commence a civil action against the person to whom such order was issued to require compliance with such order. The appropriate United States district court shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to enforce such order.

''(B) AWARD.—The court, in issuing any final order under this paragraph, may award costs of litigation (including reasonable attorneys' and expert witness fees) to any party whenever the court determines such award is appropriate.

''(c) EFFECT OF SECTION.—

''(1) OTHER LAWS.—Nothing in this section preempts or diminishes any other safeguards against discrimination, demotion, discharge, suspension, threats, harassment, reprimand, retaliation, or any other manner of discrimination provided by Federal or State law.

''(2) RIGHTS OF EMPLOYEES.—Nothing in this section shall be construed to diminish the rights, privileges, or remedies of any employee under any Federal or State law or under any collective bargaining agreement. The rights and remedies in this section may not be waived by any agreement, policy, form, or condition of employment.

''(d) ENFORCEMENT.—Any nondiscretionary duty imposed by this section shall be enforceable in a mandamus proceeding brought under section 1361 of title 28, United States Code.

''(e) LIMITATION.—Subsection (a) shall not apply with respect to an employee of an entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food who, acting without direction from such entity (or such entity's agent), deliberately causes a violation of any requirement relating to any violation or alleged violation of any order, rule, regulation, standard, or ban under this Act.''.

SEC. 403. 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, regula-

tions, or agreements regarding voluntary inspection of non-amenable species under the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.);

(2) alter the jurisdiction between the Alcohol and Tobacco Tax and Trade Bureau and the Secretary of Health and Human Services, under applicable statutes and regulations;

(3) limit the authority of the Secretary of Health and Human Services 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;

(4) alter or limit the authority of the Secretary of Agriculture under the laws administered by such Secretary, including—

(A) the Federal Meat Inspection Act (21 U.S.C. 601 et seq.);

(B) the Poultry Products Inspection Act (21 U.S.C. 451 et seq.);

(C) the Egg Products Inspection Act (21 U.S.C. 1031 et seq.);

(D) the United States Grain Standards Act (7 U.S.C. 71 et seq.);

(E) the Packers and Stockyards Act, 1921 (7 U.S.C. 181 et seq.);

(F) the United States Warehouse Act (7 U.S.C. 241 et seq.);

(G) the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.); and

(H) the Agricultural Adjustment Act (7 U.S.C. 601 et seq.), reenacted with the amendments made by the Agricultural Marketing Agreement Act of 1937; or

(5) alter, impede, or affect the authority of the Secretary of Homeland Security under the Homeland Security Act of 2002 (6 U.S.C. 101 et seq.) or any other statute, including any authority related to securing the borders of the United States, managing ports of entry, or agricultural import and entry inspection activities.

SEC. 404. COMPLIANCE WITH INTERNATIONAL AGREEMENTS.

Nothing in this Act (or an amendment made by this Act) shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or

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