bicameral when, in fact, Mr. CUELLAR’s bill was rewritten in the Senate; written by the White House, as far as I can tell, to look more like his budget process procedures that he printed back in February; sent back to us so that we could make in statute what the President chose.

Madam Speaker, we are better than that. In the next Congress, I certainly believe that if the House and the Senate have differences of opinions, it is appropriate that it be worked out through a process of conference and not simply take what the Senate sends in a closed rule without anything but meaningless debate. And, Madam Speaker, debate without the opportunity to change one line is simply talking about a foregone conclusion that last Friday the votes were counted.

With that, Madam Speaker, I yield back the balance of my time hopefully for this lame duck session.

Mr. CUELLAR. Madam Speaker, I thank the gentleman for being brief. I appreciate his consideration.

I wrote my dissertation on performance-based budgets in a comparative study of 50 States. I added about 99 percent of all the performance-based budgeting in Texas right before President Bush was the Governor there.

I know this legislation, and this legislation is probably the largest change we have had since 1993. Members, this is a bipartisan supported by both Democrats and Republicans in the House and the Senate. So, Madam Speaker, again, I urge all Members to support H.R. 2142.

Mr. PLATTS. Madam Speaker, I rise in support of this Senate-House compromise legislation, which takes important steps to eliminate Federal Government waste. For 4 years I served as the Chairman of the Oversight and Government Reform Subcommittee on Government Management, Finance, and Accountability. I’ve kept my efforts on making the Federal Government more accountable. My Subcommittee held numerous hearings in which, all too often, accounting errors such as overpayment for services or redundant payments were discovered or where programs were not effectively fulfilling their intended mission.

At a time when the national debt is nearly $14 trillion, it has never been more apparent that the Federal Government must spend taxpayer dollars wisely. Federal programs must be measured to determine that they are presenting clear results and those programs that are not performing effectively must be reformed or eliminated. One of the reasons that we find ourselves in such substantial debt today is that Federal programs never end. Both high-performing and low-performing programs need a clear evaluation process for each program, the results of which would be used to provide legislators with the information they need to determine which programs should continue on and which should not.

The legislation we are considering today, similar to legislation that I introduced in the 108th Congress, H.R. 3826, and the 109th Congress, H.R. 185, would require that all Federal agencies work with the Office of Management and Budget, OMB, to clearly identify outcome-based goals and then submit an action plan to achieve these goals. Agencies would be required to conduct quarterly performance assessments outlining how effectively they are working to meet the stated goals, and all information would be made available to Congress and the American people.

In addition, the Government Accountability Office, GAO, would be tasked with performing frequent and detailed evaluations of Federal programs. This impartial review of Federal programs will assure that agencies are being good stewards of our Federal taxpayer dollars.

I commend Representative CUELLAR for introducing this bill to ensure that Federal resources are spent efficiently and waste is minimized. Now more than ever, while American families are cutting extraneous expenses from their budgets, the Federal Government must be making wise investments. I hope that all Members of Congress will join with me in supporting this important effort.

Mr. TOWNS. Madam Speaker, I rise in support of H.R. 2142, the Government Efficiency, Effectiveness, and Performance Improvement Act of 1993.

I hope that all Members of Congress will join with me in supporting this important effort.

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

Mr. DINGELL. Mr. Speaker, pursuant to House Resolution 1781, I call up the bill (H.R. 2751) to accelerate motor fuel savings nationwide and provide incentives to registered owners of high fuel efficiency automobiles to replace such automobiles with new fuel efficient and less polluting automobiles, with the Senate amendments thereto, and I have a motion at the desk. The Clerk read the title of the bill.

The SPEAKER pro tempore. The Clerk will designates the Senate (Mr. CUELLAR) amendments.

The text of the Senate amendments is as follows:

Senate amendments: Strike all after the enacting clause and insert the following:

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

(a) SHORT TITLE.—The 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. 1 et seq.).

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

Sec. 1. Short title; references; table of contents.

TITLE I—IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS

Sec. 101. Inspections of records.
Sec. 102. Registration of food facilities.
Sec. 103. Hazard analysis and risk-based preventive controls.
Sec. 104. Performance standards.
Sec. 105. Standards for produce safety.
Sec. 106. Protection against intentional adulteration.
Sec. 107. Authority to collect fees.
Sec. 108. National agriculture and food defense strategy.
Sec. 109. Food and Agriculture Coordinating Councils.
Sec. 110. Building domestic capacity.
Sec. 111. Sanitary transportation of food.
Sec. 112. Food allergy and anaphylaxis management.
Sec. 113. New dietary ingredients.
Sec. 114. Requirement for presence relating to post harvest processing of raw oysters.
TITLE II—IMPROVING CAPACITY TO DETECT AND RESPOND TO FOOD SAFETY PROBLEMS

Sec. 201. Targeting of inspection resources for domestic facilities, foreign facilities, and tribal food safety officials.

Sec. 202. Laboratory accreditation for analyses of foods.

Sec. 203. Integrated consortium of laboratory networks.

Sec. 204. Enhancing tracking and tracing of food and recordkeeping.

Sec. 205. Surveillance.

Sec. 206. Mandatory recall authority.

Sec. 207. Administrative detention of food.

Sec. 208. Decontamination and disposal standards and plans.

Sec. 209. Improving the training of State, local, and tribal food safety officials.

Sec. 210. Enhancing food safety.

Sec. 211. Improving the reportable food registry.

TITLE III—IMPROVING THE SAFETY OF IMPORTED FOOD

Sec. 301. Foreign supplier verification program.

Sec. 302. Voluntary qualified importer program.

Sec. 303. Authority to require import certification for food.

Sec. 304. Prior notice of imported food shipments.

Sec. 305. Building capacity of foreign governments with respect to food safety.

Sec. 306. Inspection of foreign food facilities.

Sec. 307. Accreditation of third-party auditors.

Sec. 308. Foreign office of the Food and Drug Administration.

Sec. 309. Smuggled food.

TITLE IV—MISCELLANEOUS PROVISIONS

Sec. 401. Funding for food safety.

Sec. 402. Employee protections.

Sec. 403. Jurisdiction; authorities.

Sec. 404. Compliance with international agreements.

Sec. 405. Determination of budgetary effects.

TITLE I—I-MPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS

SEC. 101. INSPECTIONS OF RECORDS.

(a) In General.—Section 414(a) (21 U.S.C. 350d(a)) is amended—

(1) striking the heading and all that follows through “of food is” and inserting the following: “RECORDS INSPECTION.—(A) 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 following:

(2) USE OF OR EXPOSURE TO FOOD OF CONCERN.—The Secretary believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee 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 free and convenient access 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.

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

(3) CERN.—If the Secretary believes that there is a reasonable probability that the use of or exposure to such article 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.

(b) SUSPENSION OF REGISTRATION.—(1) In General.—Section 415 (21 U.S.C. 350d(a)) 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 provide an opportunity for an informal hearing 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

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

(2) BIENNAL REGISTRATION RENEWAL.—During the period beginning on October 1 and ending on December 31 of each even-numbered year, if a registration has been submitted under paragraph (1) shall submit to the Secretary a renewal registration and payment of the renewal fee unless the Secretary finds that the renewal registration is necessary or appropriate.

(b) CERN.—If the Secretary believes that there is a reasonable probability that the use of or exposure to such article 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.

(c) CLARIFICATION OF INTENT.—(1) RETAIL FOOD ESTABLISHMENT.—The Secretary shall amend the definition of the term “retail food establishment” in section 1.227(b)(11) of title 21, Code of Federal Regulations to clarify that, in determining the primary function of an establishment or a retail food establishment under such section, the sale of food products directly to consumers by such establishment and the sale of food directly to consumers by such retail food establishment include—

(A) the sale of such food products or food directly to consumers by such establishment at a retail food establishment located other than where the food was manufactured or processed;
(B) the sale and distribution of such food through a community supported agriculture program; and
(C) the sale and distribution of such food at any other public food sales platform as determined by the Secretary.
(2) DEFINITIONS.—For purposes of paragraph (1):
(A) the term ‘community supported agriculture program’ has the same meaning given the term ‘community supported agriculture (CSA) program’ in section 240.2 of title 7, Code of Federal Regulations (or any successor regulation); and
(B) the term ‘consumer’ does not include a business;
(d) CONFORMING AMENDMENTS.—
(1) Section 309(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 of the period before the term ‘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.—(1) Section 309(d) (21 U.S.C. 331(d)) is amended by adding at the end of the section the following:

‘‘(2) EXEMPTION.—A qualified facility—
(A) shall not be subject to the requirements under subsections (a) through (i) and subsection (m) of this section; and
(B) shall be subject to such requirements under subsection (m) of this section, and the 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, for any successful standard promulgated under subsection (n);
(4) The standards and regulations with respect to environmental and product testing programs and other appropriate means; and
(5) The requirements and regulations of the Food and Drug Administration.‘‘

(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 intentionally introduced, including by acts of terrorism; 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) appropriate actions are 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 of the owner, operator, or agent in charge of such facility.
(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 ensure that the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 or misbranded under section 403(a).
(e) 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 actions taken under subsection (c);
(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 process in the facility, and new and emerging threats.
(f) RECORDKEEPING.—The owner, operator, or agent in charge of a facility shall maintain records of the controls, and maintain records of the monitoring of the controls, and maintain records of the performance of the controls.
(g) WRITTEN PLAN AND DOCUMENTATION.—The owner, operator, or agent in charge of a facility shall—
(1) prepare a written plan that 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.
(2) keep a record of the written plan, together with the documentation described in subsection (g), at the facility, and maintain the record for 2 years.

SEC. 418. PREVENTIVE CONTROLS.
(a) IN GENERAL.—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 intentionally introduced, including by acts of terrorism; 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.
(b) PREVENTIVE CONTROLS.—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 intentionally introduced, including by acts of terrorism; 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—
(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 intentionally introduced, including by acts of terrorism; 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.
(d) MONITORING OF EFFECTIVENESS.—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 intentionally introduced, including by acts of terrorism; 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.
credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), as specified by the Secretary, that the facility is in compliance at that location, and is not otherwise subject to any other applicable non-Federal food safety law; and

(ii) documentation, as specified by the Secretary, that makes the facility a qualified facility under subparagraph (b)(1) or (b)(2)."

(D) RULE OF CONSTRUCTION.—

(A) IN GENERAL.—In the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility subject to this section, if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility, the Secretary may withdraw the determination provided to such facility under this subsection.

(B) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to expand or limit the inspection authority of the Secretary.

(C) DEFINITIONS.—In this subsection:

(A) AFFILIATE.—The term "affiliate" means any person, firm, corporation, or other entity that is controlled directly or indirectly by another person, firm, corporation, or other entity.

(B) QUALIFIED END-USER.—The term "qualified end-user", with respect to a food, means—

(i) a food; or

(ii) a restaurant or retail food establishment (as those terms are defined by the Secretary for purposes of section 415) that—

(I) is located in the same State as the qualified facility that sold the food to such restaurant or establishment; or

(II) is not more than 275 miles from such facility; and

(III) is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

(C) CONSUMER.—For purposes of subparagraph (B), the term "consumer" does not include a business.

(D) SUBSIDIARY.—The term "subsidiary" means any company which is owned or controlled directly or indirectly by another company.

(E) STUDY.—

(A) IN GENERAL.—The Secretary, in consultation with the Secretary of Agriculture, shall conduct a study of the food processing sector regulated by the Secretary to determine—

(i) the distribution of food production by type and size of operation, including monetary value of food sold; and

(ii) the proportion of food produced by each type and size of operation; and

(iii) the number and types of food facilities co-located on farms, including the number and proportion by commodity and by manufacturing or processing activity.

(iv) the incidence of foodborne illness originating from each size and type of operation and the type of food facilities for which no reported or known outbreaks occurred, and

(v) the effect on foodborne illness risk associated with handling, processing, and preparing and storing food and raw agricultural commodities, including differences in risk based on the scale and duration of such activities.

(B) SIZE.—The results of the study conducted under subparagraph (A) shall include the information necessary to enable the Secretary to define the terms "small business" and "very small business", for purposes of promulgating regulations under subsection (n). In defining such terms, the Secretary shall include consideration of harvestable acres, income, the number of employees, and the volume of food harvested.

(C) SUBMISSION OF REPORT.—Not later than 18 months after the date of enactment of the Food Safety Modernization Act, the Secretary shall submit to the Congress a report that describes the results of the study conducted under subparagraph (A).

(D) NO EXEMPTION.—Nothing in this subsection preempts State, local, county, or other non-Federal law regarding the safe production of food. Compliance with this subsection shall not relieve any person from compliance with any applicable Federal law or under State statutory law.

(E) NOTIFICATION TO CONSUMERS.—

(A) IN GENERAL.—A qualified facility that is exempted from promulgated regulations under paragraph (a) through (i) and subsection (n) and does not prepare documentation under paragraph (2)(B)(ii) shall—

(i) with respect to a food for which a food packaging label is required by the Secretary under any other provision of this Act, prominently and conspicuously on such label, the name and business address of the facility where the food was manufactured or processed; or

(ii) with respect to a food for which a food packaging label is not required by the Secretary under any other provision of this Act, prominently and conspicuously on such label, the name and business address of the facility where the food was manufactured or processed.

(B) NO ADDITIONAL LABEL.—Subparagraph (A) does not provide authority to the Secretary to require a label that is in addition to any label required under any other provision of this Act.

(C) 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 that is used for 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.

(D) REGULATIONS.—

(1) IN GENERAL.—Not later than 18 months after the date of enactment of the Food Safety Modernization Act, the Secretary shall promulgate regulations—

(A) to establish science-based minimum standards for conducting a hazard analysis and implementing, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls under this section; and

(B) to define, for purposes of this section, the terms 'small business' and 'very small business', taking into consideration the study described in subsection (c)(5).

(2) COORDINATION.—In promulgating the regulations under paragraph (1)(A), with regard to hazards that may be intentionally introduced, or hazards that are not processed under the hazard analysis requirements of this Act, the Secretary shall coordinate with the Secretary of Homeland Security, as appropriate.

(3) CONTENT.—The regulations promulgated under paragraph (1)(A) 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) on food safety hazards;

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

(D) not require 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)(A), the Secretary shall review regulatory hazard analysis and preventive control programs in existence on the date of enactment of the 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 such date.

(6) DEFINITIONS.—For purposes of this section:

(A) 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.

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

(C) PREVENTIVE CONTROLS.—The term 'preventive controls' means those risk-based, reasonably appropriate procedures, practices, and controls that a person knowledgeable about the food 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:

(1) Sanitation procedures for food contact surfaces and utensils and food-contact surfaces and equipment.

(2) Supervisor, manager, and employee hygiene training.

(3) 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.

(4) A food allergen control program.

(5) A recall plan.

(6) 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 promote regulations with respect to—

(i) facilities 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 such farm or another farm under common ownership for purposes of such section 415.

(2) CLARIFICATION.—The remaking 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) N O EFFECT ON HACCP AUTHORITY.—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.) to promulgate, 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 dietary supplements and related activities.

(h) UPDATING GUIDANCE RELATING TO FISH AND FISHERIES 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 DATES.—(1) GENERAL RULE.—(A) The amendments made by this section shall take effect 18 months after the date of enactment of this Act. (B) RULEMAKING FOR SMALL BUSINESSES.—Notwithstanding paragraph (1), (A) the amendments made by this section shall apply to a small business (as defined in the regulation promulgated under paragraph (1), beginning on the date that is 6 months after the effective date of such regulations; and (B) the amendments made by this section shall apply to a very small business (as defined in the regulation promulgated under section 418(n) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

(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 that 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, if applicable; and shall apply only to small businesses and very small businesses, as defined in the regulation promulgated under section 418(n) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

(c) REQUIREMENTS UNDER SECTIONS 418 AND 421.—(1) N O EFFECT ON HACCP AUTHORITY.—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.) to promulgate, 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 dietary supplements and related activities.

(h) UPDATING GUIDANCE RELATING TO FISH AND FISHERIES 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 DATES.—(1) GENERAL RULE.—(A) The amendments made by this section shall take effect 18 months after the date of enactment of this Act. (B) RULEMAKING FOR SMALL BUSINESSES.—Notwithstanding paragraph (1), (A) the amendments made by this section shall apply to a small business (as defined in the regulation promulgated under paragraph (1), beginning on the date that is 6 months after the effective date of such regulations; and (B) the amendments made by this section shall apply to a very small business (as defined in the regulation promulgated under paragraph (1), beginning on the date that is 18 months after the effective date of such regulations.

SEC. 105. STANDARDS FOR PRODUCE SAFETY.

(a) IN GENERAL.—(1) PROPOSED RULEMAKING.—(A) The requirements under section 423 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by this Act, shall not apply to small businesses and very small businesses, as defined in the regulation promulgated under paragraph (1), that produce and harvest those types of fruits and vegetables that are raw agricultural commodities that are substantially processed, and do not present a risk of serious adverse health consequences or death.

(B) DETERMINATION BY SECRETARY.—With respect to small businesses and very small businesses, as defined in the regulation promulgated under paragraph (1), the Secretary shall conduct not less than 3 public meetings in diverse geographic areas of the United States to provide persons in different regions an opportunity to comment.

(c) 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 operations that are necessary to prevent foodborne diseases, science-based guidance and requirements regarding the safe production and harvesting of various fruits and vegetables, including guidance regarding the control of 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) be written in language that the average person can understand, consistent with ensuring enforceable public health protection, conservation and environmental practice standards and policies established by Federal natural resources agencies, and Federal wildlife conservation and environmental agencies; (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 ensuring that the same level of food safety protection as the requirements under guidance documents, including guidance documents regarding action levels, and regulations under 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 establish national science-based standards for the safe production and harvesting of those types of fruits and vegetables, including specific breeds 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.

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

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

(h) UPDATING GUIDANCE RELATING TO FISH AND FISHERIES 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 DATES.—(1) GENERAL.—(2) 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 establish national science-based standards for the safe production and harvesting of those types of fruits and vegetables, including specific breeds 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
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 standards to prevent the growth of specific types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, based on known 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, appropriate federal officials, and the appropriate State officials 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 adopt.

"(3) FLEXIBILITY FOR SMALL BUSINESSES.—

Notwithstanding paragraph (1),

"(A) the regulations promulgated under this section shall apply to a small business (as defined in the regulation promulgated under subsection (a)(1)) 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 in the regulation promulgated under subsection (a)(1)) 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 reasonable standards, 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 and is reasonably likely to ensure that the food is not adulterated under section 402 and is 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 co-ordinate 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 Modernization Act, the Secretary shall publish, after consultation with the Secretary of Agriculture, representatives of State departments of agriculture, farmers, or other persons (including small businesses, updated good agricultural practices, 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 and is reasonably likely to ensure that the food is not adulterated under section 402 and is reasonably likely to provide the same level of public health protection as the requirements of the regulations adopted under subsection (b).

"(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 and to consumers of such food directly to consumers and farmer representatives, and for importers of fruits and vegetables that are raw agricultural commodities.

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

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

"(B) avoid creating unreasonable levels of cost or administrative burden, including in their design, implementation, and enforcement the need for more paperwork that is duplicative or unnecessary to facilitate the implementation of the regulations.

"(f) EXEMPTION FOR DIRECT FARM MARKETING.—

"(1) IN GENERAL.—A farm shall be exempt from the requirements under this section in a calendar year if—

"(A) during the previous 3-year period, the average annual monetary value of the food sold by such farm directly to qualified end-users during such period exceeded the average annual monetary value of the food sold by such farm to all other buyers during such period; and

"(B) the average annual monetary value of all food sold during such period was less than $500,000, adjusted for inflation.

"(2) EXCEPTION FOR BIG BUSINESS.—

"(A) IN GENERAL.—A farm that is exempt from the requirements under this section shall—

"(i) with respect to a food for which a food packing label is required by the Secretary under any other provision of this Act, include prominently and conspicuously on such label the name and business address of the farm where the produce was grown; or

"(ii) with respect to a food for which a food packing label is required by the Secretary under any other provision of this Act, include prominently and conspicuously, at the point of purchase, the name and business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or, in the case of Internet sales, in an electronic notice.

"(B) NO ADDITIONAL LABEL.—Subparagraph (A) does not provide authority to the Secretary to require a label that is in addition to any label required under any other provision of this Act.

"(3) WITHDRAWAL; RULE OF CONSTRUCTION.—

"(A) IN GENERAL.—In the event of the active involvement of known or reasonably foreseeable foodborne illnesses or outbreaks that are linked to a farm subject to an exemption under this section, the Secretary may withdraw the exemption provided to such farm under this subsection.

"(B) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to expand or limit the inspection authority of the Secretary.

"(g) DEFINITIONS.—

"(A) QUALIFIED END-USER.—In this subsection, the term ‘qualified end-user’, with respect to a food means—

"(i) the consumer of the food; or

"(ii) a restaurant or retail food establishment (as those terms are defined by the Secretary for purposes of section 419) that is located—

"(I) in the same State as the farm that produced the food; or

"(II) not more than 25 miles from such farm.

"(B) CONSUMER.—For purposes of subparagraph (A)(i), the term ‘consumer’ does not include a business.

"(h) EXCEPTION FOR ACTIVITIES OF FACILITIES SUBJECT TO SECTION 418.—Nothing in this subsection shall apply to activities of a facility that is subject to section 418.

"(i) LIMITATION OF EFFECT.—Nothing in this subsection shall prevent the Secretary from exercising any authority granted in the other sections of this Act.

"(j) CLASSIFICATION.—This section shall not apply to produce that is produced by an individual for personal consumption.

"(k) EXEMPTION FOR FOODS PRODUCED BY FACILITIES SUBJECT TO SECTION 418.—This section shall not apply to activities of a facility that is subject to section 418.

"(l) 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 section 415), the Secretary of Agriculture and 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 the manner in which 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:

"(cc) The failure to comply with the requirements of this section; and"

(d) 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 review, issue, or enforce product and category-specific regulations, such as the Seafood Hazard Analysis Critical Control Points Program, the Juice Hazard Analysis Critical Control Program, and the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers Program.

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 intentional 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 the guidance documents issued under paragraph (1) are made public, including by releasing such documents to targeted audiences.

(b) PERIODIC REVIEW.—The Secretary of Health and Human Services shall periodically review and update the science-based 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).

(c) 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."
(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 paid by 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 (excluding 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 the 12-month period ending June 30 preceding the fiscal year, but in no case shall such adjustment factor be negative.

(2) 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 $25,000,000; 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 subsection (a)(2)) 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) CREDIBILITY 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 fees 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 and contractors performing activities associated with these food safety fees.

(e) COLLECTION OF FEES.—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.

(f) UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under this section within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to provisions of chapter 11 of title 31, United States Code.

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

(A) the National Incident Management System;

(B) the National Response Framework;

(C) the National Infrastructure Protection Plan;

(D) the National Preparedness Goals; and

(E) other relevant national strategies.

(b) COMPONENTS.—

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

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

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

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

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

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

(ii) mitigating vulnerabilities of the system;

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

(iv) developing and conducting exercises to test vulnerability to the system; and

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

(B) RECOVERY GOAL.—Secure agriculture and food system recovery by—

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

(b) 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 the plan to achieve the goals described in paragraphs (2) and (3), and submit the plan to Congress.

(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 this subsection.

(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.

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 shall prepare an Agriculture and Food Defense Strategy, in coordination with the Secretary of Homeland Security, that shall—

(I) the Federal Government; and

(II) State, local, and tribal governments;

(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—

(A) the Federal Government; and

(B) 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;

(II) the Federal Government; and

(III) the private sector.

(2) ANNUAL REPORT TO CONGRESS.—In each fiscal year beginning after fiscal year 2011, the Secretary of Health and Human Services and the Secretary of Agriculture shall submit a report to Congress on activities performed under this section.
(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,

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

(b) submit to Congress, not later than 2 years after the date of enactment of this Act, a comprehensive report that identifies programs and practices that are likely to contribute to the safety and security of the food system of the United States.

(c) CAPABILITY FOR LABORATORY ANALYSES; RESEARCH.—The report developed under subsection (a)(1) shall include descriptions of methods to increase capacity to undertake analyses of food samples promptly after collection, to identify new and rapid analytical techniques, and to provide for well-equipped and staffed Food Emergency Response Network laboratories, and to provide for enhanced surveillance, outbreak response, and traceback and surveillance capabilities, including progress implementing strategies developed under sections 108 and 205.

(d) includes information related to any matter described in subparagraphs (A) through (D) of paragraph (1) and (1) of section 415 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) BIENNAL REPORTS.—On a biennial basis following the biennial report required 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 (D) of paragraph (1) and (1) of section 415 of the Federal Food, Drug, and Cosmetic Act (as added by section 201). Together with, as necessary, description of any additional authorities necessary to improve seafood safety.

(3) EVALUATION.—The report developed under subsection (a)(1) shall include descriptions of methods that seek to ensure that resources allocated to the Food Safety System and Food Safety Outreach, Education, and Training programs and 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 report shall highlight those risk-based activities 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 include descriptions of methods to increase capacity to undertake analyses of food samples promptly after collection, to identify new and rapid analytical techniques, and to provide for well-equipped and staffed Food Emergency Response Network laboratories, and to provide for enhanced surveillance, outbreak response, and traceback and surveillance capabilities, including progress implementing strategies developed under sections 108 and 205.

(d) includes information related to any matter described in subparagraphs (A) through (D) of paragraph (1) and (1) of section 415 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) BIENNAL REPORTS.—On a biennial basis following the biennial report required 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 (D) of paragraph (1) and (1) of section 415 of the Federal Food, Drug, and Cosmetic Act (as added by section 201). Together with, as necessary, description of any additional authorities necessary to improve seafood safety.

(3) EVALUATION.—The report developed under subsection (a)(1) shall include descriptions of methods that seek to ensure that resources allocated to the Food Safety System and Food Safety Outreach, Education, and Training programs and 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 report shall highlight those risk-based activities 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 include descriptions of methods to increase capacity to undertake analyses of food samples promptly after collection, to identify new and rapid analytical techniques, and to provide for well-equipped and staffed Food Emergency Response Network laboratories, and to provide for enhanced surveillance, outbreak response, and traceback and surveillance capabilities, including progress implementing strategies developed under sections 108 and 205.

(d) includes information related to any matter described in subparagraphs (A) through (D) of paragraph (1) and (1) of section 415 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) BIENNAL REPORTS.—On a biennial basis following the biennial report required 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) includes information related to any matter described in subparagraphs (A) through (D) of paragraph (1) and (1) of section 415 of the Federal Food, Drug, and Cosmetic Act (as added by section 201) together with, as necessary, description of any additional authorities necessary to improve seafood safety.

(3) EVALUATION.—The report developed under subsection (a)(1) shall include descriptions of methods to increase capacity to undertake analyses of food samples promptly after collection, to identify new and rapid analytical techniques, and to provide for well-equipped and staffed Food Emergency Response Network laboratories, and to provide for enhanced surveillance, outbreak response, and traceback and surveillance capabilities, including progress implementing strategies developed under sections 108 and 205.

(d) includes information related to any matter described in subparagraphs (A) through (D) of paragraph (1) and (1) of section 415 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) BIENNAL REPORTS.—On a biennial basis following the biennial report required 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) includes information related to any matter described in subparagraphs (A) through (D) of paragraph (1) and (1) of section 415 of the Federal Food, Drug, and Cosmetic Act (as added by section 201) together with, as necessary, description of any additional authorities necessary to improve seafood safety.

(3) EVALUATION.—The report developed under subsection (a)(1) shall include descriptions of methods to increase capacity to undertake analyses of food samples promptly after collection, to identify new and rapid analytical techniques, and to provide for well-equipped and staffed Food Emergency Response Network laboratories, and to provide for enhanced surveillance, outbreak response, and traceback and surveillance capabilities, including progress implementing strategies developed under sections 108 and 205.

(d) includes information related to any matter described in subparagraphs (A) through (D) of paragraph (1) and (1) of section 415 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) BIENNAL REPORTS.—On a biennial basis following the biennial report required 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) includes information related to any matter described in subparagraphs (A) through (D) of paragraph (1) and (1) of section 415 of the Federal Food, Drug, and Cosmetic Act (as added by section 201) together with, as necessary, description of any additional authorities necessary to improve seafood safety.

(3) EVALUATION.—The report developed under subsection (a)(1) shall include descriptions of methods to increase capacity to undertake analyses of food samples promptly after collection, to identify new and rapid analytical techniques, and to provide for well-equipped and staffed Food Emergency Response Network laboratories, and to provide for enhanced surveillance, outbreak response, and traceback and surveillance capabilities, including progress implementing strategies developed under sections 108 and 205.

(d) includes information related to any matter described in subparagraphs (A) through (D) of paragraph (1) and (1) of section 415 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) BIENNAL REPORTS.—On a biennial basis following the biennial report required 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) includes information related to any matter described in subparagraphs (A) through (D) of paragraph (1) and (1) of section 415 of the Federal Food, Drug, and Cosmetic Act (as added by section 201) together with, as necessary, description of any additional authorities necessary to improve seafood safety.

(3) EVALUATION.—The report developed under subsection (a)(1) shall include descriptions of methods to increase capacity to undertake analyses of food samples promptly after collection, to identify new and rapid analytical techniques, and to provide for well-equipped and staffed Food Emergency Response Network laboratories, and to provide for enhanced surveillance, outbreak response, and traceback and surveillance capabilities, including progress implementing strategies developed under sections 108 and 205.

(d) includes information related to any matter described in subparagraphs (A) through (D) of paragraph (1) and (1) of section 415 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.
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.**

**DEFINITIONS.—**In this section:

1. (A) Head Start Program or an Early Head Start Program carried out under the Head Start Act (42 U.S.C. 9331 et seq.);

2. (B) A State licensed or regulated child care program or school; or

3. (C) A State public kindergarten program that serves children from birth through kindergarten.

**2. ESRA DEFINITIONS.—**The terms “local educational agency,” “school,” “early childhood education program,” and “parents” 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. 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;

(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 developed pursuant to the guidelines is to be made available to the Secretary.

**1. IN GENERAL.—**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 the confidentiality of information maintained by the Secretary under paragraph (1). The creation and maintenance of an individual plan for food allergy management that addresses the appropriate response to an incident of anaphylaxis or of allergy, if such anaphylaxis or allergy is 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.

**2. LIMITATION ON GRANT FUNDING.—**A grant awarded under this subsection may not be made in an amount that is more than $50,000 annually.

**C. 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.—**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.

**C. 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 the activities under this subsection.

**PROGRESS AND EVALUATIONS.—**At the completion of the grant period referred to in paragraph (4), a local educational agency shall provide at least annually to the Secretary a detailed report of how grant funds were spent and the status of implementation of the food allergy and anaphylaxis management guidelines.
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 four 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) If the Secretary determines that the information in a new dietary ingredient notification submitted under this section for an article purposed to be a new dietary ingredient is insufficient to determine 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 anaphylaxis inducer as defined in section 402(21) of the Federal Food, Drug, and Cosmetic Act, the Secretary may 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 other 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 ‘anaphylaxis inducer’ means an article whose chemical structure is substantially similar to the chemical structure of an anaphylaxis inducer.

(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 containing such article will reasonably be expected to be safe because the article may be, or may contain, an anabolic steroid or an anaphylaxis inducer as defined in section 402(21) of the Federal Food, Drug, and Cosmetic Act, evidence needed to document the safety of new dietary ingredients, and appropriate methods for establishing the identity 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 relating 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, the following:

(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;

(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 appropriate governmental authorities 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 rule or regulation or guidance as described in subsection (a), the Comptroller General of the United States shall—

(1) review and evaluate the report described in subsection (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 post harvest processing measures, and make a comparison of risks the Secretary may find associated with seafood and the instances of those risks in such other regulations; 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 in advance of each inspection of a United States port of entry from being admitted by another United States port of entry, through the Commissioner of Customs and Border Protection, to the extent that 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. 341(a)) so that the Secretary of Homeland Security, acting through the Commissioner of Customs and Border Protection, may prevent food refused admission from entering the United States.

(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 post harvest processing measures, the frequency of inspection of such facility, 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 the Secretary deems 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 in the 5-year period following the date of enactment of the FDA Food Safety Modernization Act; and

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

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

(D) FOREIGN FACILITIES.—

(1) 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.

(2) 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 section for foreign facilities, the Secretary may rely on inspections conducted by other Federal, State, or local agencies under interagency agreement, contract, memorandum of understanding, or other obligation agreement.

(F) IDENTIFICATION AND INSPECTION AT PORTS OF ENTRY.—The Secretary, in consultation with the Secretary of Homeland Security, shall develop and implement a system to inspect any article of food imported into the United States according to the known safety risks of the article of food, which system 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 from 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 prioritization under section 801(i).

(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.

(G) INTERAGENCY AGREEMENTS WITH RESPECT TO SEAFOOD.—

(1) IN GENERAL.—The Secretary of Health and Human Services and 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) agreements for examining and testing seafood imports that leverage the resources, capabilities, and authorities of each party;

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

(C) agreements on seafood naming, 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 relevant agencies of the Federal Government, including the Food and Drug Administration may be duly designated by the Secretary to carry out seafood examinations and investigations under section 801 of this Act and the Act entitled "The allergen Labeling and Consumer Protection Act of 2004;"

(F) the sharing of information concerning observed non-compliance with United States food safety 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 and education efforts to enhance seafood safety and compliance with Federal food safety requirements.

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

(I) FACILITY.—For purposes of this section, the term ‘facility’ means a domestic facility or a foreign facility that is required to register under section 205.

(J) ANNUAL REPORT REGARDING FOOD.—Not later than one year after section 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 inspection activities, including—

(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 identified pursuant to section 415 that were scheduled for inspection in the previous fiscal year and which the Secretary did not inspect in such year; and

(E) the number of high-risk facilities identified pursuant to section 421 that the Secretary inspected 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 fiscal year or the period described in paragraph (1); and

(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.

(K) 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.

(L) ADVISORY COMMITTEE CONSULTATION.—In allocating inspection resources as described in paragraph (1), the Secretary shall consult existing standards recognized by the Secretary under paragraph (8) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(2) SEC. 202. LABORATORY ACCREDITATION FOR ANALYSES OF FOODS.

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

"SEC. 422. LABORATORY ACCREDITATION FOR ANALYSES OF FOODS.

(1) RECOGNITION OF LABORATORY ACCREDITATION—

(A) The Secretary shall recognize a laboratory accredited by the applicable Federal authorities; and

(B) establish a publicly available registry of laboratories accredited by the applicable Federal authorities; and

(C) require, as a condition of recognition or accreditation, that recognized laboratories present evidence to the Secretary that they have the capability to conduct and 1 or more sampling and analytical testing methodologies for food.

(2) INCREASE 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 for recognition under paragraph (1). During the year following the enactment of this Act or section 203 of the Food Allergen Labelling and Consumer Protection Act of 2004, the Secretary shall, in coordination with the Secretary of Homeland Security to target food inspection resources.

(3) 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.

(4) MODEL LABORATORY STANDARDS.—The Secretary shall develop model standards that a laboratory shall meet to be 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

(5) CONSULTATION.—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)(A) is made publicly available.

(6) MODEL LABORATORY STANDARDS.—The Secretary shall develop model standards that a laboratory shall meet to be accredited by a recognized accreditation body that meets the accreditation standards applicable to domestic laboratories accredited under this section.

 seventh year.
“(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 methodology or methodologies are necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak.

(4) 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 whether the food needs to be recalled or other compliance and enforcement activities.

(5) Review by Federal Agencies.—Nothing in this subsection 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 for the purpose of determining whether the food needs to be recalled or other compliance and enforcement activities.

(b) Food Emergency Response Network.—The Secretary, in coordination with the Secretary of Agriculture, the Secretary of Homeland Security, and State, local, and tribal governments, shall not later than 180 days after the date of enactment of this Act, and biennially thereafter, establish pilot projects in coordination with 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 food emergency response laboratory networks 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 those providing emergency response 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 methodology 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 the Secretary under subsection (a).

(2) No Limit on Secretarial Authority.—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 (21 U.S.C. 342) or misbranded under section 403(v) of such Act (21 U.S.C. 343v) or both, not later than 60 days after the date of enactment of this Act, the Secretary shall—

(a) develop and demonstrate methods for rapidly and effectively identifying recipients of food in a manner that is practicable for facilities of varying sizes, including small businesses; and

(b) develop and demonstrate appropriate techniques and procedures for rapidly and effectively identifying recipients of food on the date of enactment of this Act, that enhance the tracking and tracing of food; and

(3) food tracing and recordkeeping requirements 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 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(v) of such Act, not later than 2 years after the date of enactment of this Act, the Secretary shall—

(1) establish recordkeeping requirements, in addition to the requirements under section 414 of the Public Health Service Act (42 U.S.C. 300g–4), to ensure that—

(A) the requirements developed under this section are coordinated with the processes of other Federal agencies and 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) relating only to information that is reasonably available and appropriate;

(B) be science-based;

(C) do 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 one 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) Notwithstanding subparagraphs (A) through (k), the Secretary may, by notice in the Federal Register, require any such food to be subject to recordkeeping requirements prescribed by the Secretary under this subsection for not more than 2 years, taking into consideration the risk of spoilage, loss of freshness, and other factors relevant to the appropriate time frames.

(2) Designation of high-risk foods.—

(A) In general.—Notwithstanding the requirements under paragraph (1), the Secretary shall, in consultation with the Secretary of Agriculture, consider the impact of requirements on farm to school or farm to institution programs, and modify the requirements under this subsection, as appropriate, with respect to such programs so that the requirements do not place undue burdens on such 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 contact information (including a telephone number of the farm, the farm's postal service address, and the 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 fishing vessel that is produced through the use of a fishing vessel (as defined in section 3(18) of the Magnuson-Stevens Fishery Conservation and Management 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 the vessel in the United States.

(D) Commingled raw agricultural commodities.—

(i) Limitation on extent of tracing.—The 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 purposes of this subparagraph—

(I) the term ‘‘commingled raw agricultural commodity’’ means a 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 determined that strict, 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 regard to, or exempt from, the requirements of this subsection (other than the requirements under subparagraph (F), if applicable) if the Secretary determines that such requirements would result in an economic hardship for an individual facility or a type of facility.

(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 after the sale.

(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.

(J) 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. A food that is included 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. 350a) and 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...
Dennis Martinez
CONGRESSIONAL RECORD — HOUSE

No Limitation on Commencing of Food
Nothing in this section shall be construed to authorize the Secretary to impose any limitation on the commencing of food.

A No Limitation on Commingling of Food
(g) No Limitation on Commencing of Food—Nothing in this section shall be construed to authorize the Secretary to impose any limitation on the commencing of food.

B Foodborne Illness Surveillance System
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.

204. SURVEILLANCE
(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; (B) facilitating sharing of surveillance information on a more timely basis among government 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 and action protocols 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 information systems at the Federal, State, and local levels, including by sharing foodborne illness surveillance data with the National Biosurveillance Integration Center and other appropriate systems; (J) other activities as determined appropriate by the Secretary.

205. SURVEILLANCE
(2) Working Group.—The Secretary shall establish 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—
(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, State, and local food safety 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;
(C) any barriers to Federal, State, and local levels to improving foodborne illness surveillance and the utility of such surveillance for preventing foodborne illness;
(D) the capabilities needed for establishing electronic searches of surveillance data; and
(E) 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 strategic needs.

304. APPROPRIATIONS
(3) Authorization of Appropriations.—To carry out the activities described in paragraph (2), there is authorized $42,000,000 for each fiscal years 2011 through 2015.

404. 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 food safety and defense capacities at the State and local levels in order to achieve the following goals:
(A) Improve foodborne illness response and containment;
(B) Accelerate foodborne illness surveillance and outbreak investigation, including rapid shipment of clinical isolates from clinical laboratories and other appropriate systems, and conducting more standardized outbreak investigations.

405. SMALL ENTITY COMPLIANCE GUIDE
(1) In general.—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 101, 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); and
(2) to very small businesses (as defined by the Secretary in section 101, 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).

406. FLEXIBILITY FOR SMALL BUSINESSES
(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 101, 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); and
(2) to very small businesses (as defined by the Secretary in section 101, 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).

407. LIMITATION ON COMMINGLING OF FOOD
(4) Limitation.—A request made under paragraph (1) shall not include a request for information that is disclosed to the Food and Drug Administration in the course of responding to a request under paragraph (1).

408. PERIODIC REPORTS
(5) Periodic Reports.—Each report shall include—
(A) the participation of restaurants and other food establishments in such program;
(B) the participation of restaurants and other food establishments in such program;
(C) the participation of restaurants and other food establishments in such program;
(D) the participation of restaurants and other food establishments in such program;
(E) the participation of restaurants and other food establishments in such program;
(F) the participation of restaurants and other food establishments in such program.

504. WORKING GROUP
(6) Working Group.—The Secretary shall establish 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—
(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, State, and local food safety 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;
(C) any barriers to Federal, State, and local levels to improving foodborne illness surveillance and the utility of such surveillance for preventing foodborne illness;
(D) the capabilities needed for establishing electronic searches of surveillance data; and
(E) 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 strategic needs.
(F) Strengthen the capacity of State and local agencies to achieve the goals described in section 108.

(2) REVIEW.—In developing the strategies required under paragraph (1), the Secretary shall—

(A) assess the current capacity of the public health community to support surveillance, outbreak response, inspection, and enforcement activities; and

(B) work with counterparts at the Federal level; and

(C) provide for a review of 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–26(b)) is amended—

(1) by striking “2002” and inserting “2010”; and

(2) by striking “2002 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 food safety regulatory system, established under section 412 or by any other means, that there is a reasonable probability that an article of food (other than infant formula) is adulterated under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (as amended under section 403(w) and the use or exposure to such article will cause serious adverse health consequences or death to humans or animals, the Secretary shall provide the responsible food regulatory official at the State or local level with notice of the recall or other appropriate action; or (ii) the Secretary determines that the recall is necessary to protect public health.

(b) PREHEARING ORDER TO CEASE DISTRIBUTION AND GIVE NOTICE.—

""(1) IN GENERAL.—If the Secretary refuses to, or does not voluntarily cease distribution or recall such article within the time and manner prescribed by the Secretary as described in subsection (c), 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 whom such article has been distributed, transported, or sold, to immediately cease distribution of such article.

(c) 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 sufficient information to know or reasonably determine the precise identity of the article of food covered by a recall order under paragraph (1)(B), 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 preempt a warehouse-based third party logistics provider from being the subject of a mandatory recall order.

""(2) 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 (c)(1) as a limited geographic area, the Secretary shall provide a written notice, by certified mail, return receipt requested, to each member of the public health community involved in the investigation and related foodborne illness outbreak associated with the recall or other appropriate action.

(3) MULTIPLE RECALLS.—The Secretary may establish multiple or concurrent incident commands 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 402 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 follow a recall order under section 423” after “section 402(a)(2)(B)

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

""(22) The refusal or failure to follow an order under section 402(a)(2)(B)

(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 or food contact surfaces, and evaluates use of such authority with regard to frequency, effectiveness, and appropriateness, including consideration of any new or existing mechanisms available to compensate for such 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, completeness, 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; and

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

(D) makes recommendations to the Secretary regarding use of the authority under section 423 of the Federal Food, Drug, and Cosmetic Act of 2006 (6 U.S.C. 748(b)(1)).

SEC. 107. ADMINISTRATIVE DETENTION OF FOOD. (a) IN GENERAL.—The Administrator of Agriculture, in coordination with the Secretary of Health and Human Services, shall determine, in consultation with the Departments of Health and Human Services, Homeland Security, and Agriculture, whether the detaining of a person for up to 10 days, in order to aid in the investigation of the source of a biological, chemical, or radiological threat, is in the public interest.

(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. 108. DECONTAMINATION AND DISPOSAL OF BIOLOGICAL, CHEMICAL, AND RADIOLOGICAL THREAT AGENTS. (a) IN GENERAL.—The Administrator of Agriculture shall, in coordination with the Secretary of Health and Human Services, the Secretary of Homeland Security, and the Secretary of Agriculture, issue regulations to provide for, and technical assistance to, State, local, and tribal governments in preparing for, assessing, decontaminating, and recovering from an agricultural or food emergency.

(b) DEVELOPMENT OF STANDARDS.—In carrying out subsection (a), the Administrator, in coordination with the Secretary of Health and Human Services, shall, if necessary, develop and disseminate specific standards and protocols to protect the public health and safety of the United States, including defining the decontamination and disposal of specific threat agents and foreign animal diseases.

(c) DEDICATION OF FUNDS.—Not less frequently than biennially, the Secretary of Agriculture shall submit a report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate that describes the results of the study, including any recommendations.

(d) 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 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.

(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 (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;

(B) the number of responsible parties, as defined in section 417 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) 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 farmers in the event of a recall.

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 OF BIOLOGICAL, CHEMICAL, AND RADIOLOGICAL THREAT AGENTS. (a) IN GENERAL.—The Administrator of the Environmental Protection Agency (referred to in this section as the "Administrator"), in coordination with the Department of Health and Human Services, the Secretary of Homeland Security, and the 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, 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.—(1) CONTENT.—The report 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.

(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.

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

(2) EXTENSION SERVICE.—The Secretary shall ensure coordination with the activities of the National Institute of Food and Agriculture of the Department of Agriculture in advising producers and small processors in new and modernized production facilities as a result of the enactment of the FDA Food Safety Modernization Act and assisting regulated industry with such Acts.

(3) OFFICE OF NATIONAL FARM FOOD 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 contracts or memoranda of understanding with one or more public or private entities, including the National Institute for Food and Agriculture of the Department of Agriculture, on a cooperative basis, to carry out one or more projects 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) food processors; and

(B) 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.

(3) 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 — 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, OUT-REACH, AND TECHNICAL ASSIST-ANCE PROGRAM.

(a) IN GENERAL.—The Secretary shall award grants under this section to carry out the competitive grant program established under title 101(f) of the Food, Drug, and Cosmetic Act, pursuant to any memoranda of understandings entered into under such section.

(b) INTEGRATED APPROACH.—The grant program described in 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 conventional, 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.

(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.

(f) MAXIMUM TERM AND SIZE OF GRANT.—

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

(2) LIMITATION ON GRANT FUNDING.—The Secretary may not provide grant funding to an entity if the entity has received 3 years of grant funding under this section.

(g) 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, 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 or 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.

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

(1) geographic diversity; and

(2) diversity of types of agricultural production.

(4) 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.

(5) BENEFICIAL OUTCOMES 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.

(1) 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.

(1) IN GENERAL.—The Secretary is authorized to make grants to eligible entities for—

(A) undertake examinations, inspections, and investigations, and related food safety activities under this Act;

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

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

(D) 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

(E) take appropriate action to protect the public health in cases involving—

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

(ii) a recall of food under this Act.

(b) ELIGIBLE ENTITIES: APPLICATION.

(1) IN GENERAL.—In this section, the term ‘eligible entity’ means an entity 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 such 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 this subsection;

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

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

(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 subsequent 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.

SEC. 399V–5. FOOD SAFETY INTEGRATED CENTERS OF EXCELLENCE.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary shall—

(A) 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 illnesses;

(B) 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 illnesses;

(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 program of such entity not more than 50 percent of the funds available to any grant recipient under this section in each year of the amount equal to the level of such funding in the previous year, increased by the Consumer Price Index. Such 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 equipment, or services.

(3) 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 subsequent 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.

SEC. 210. ENHANCING FOOD SAFETY.
(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) provide for appropriate education and training of personnel; and 

(B) partner with 1 or more institutions of higher education that have demonstrated knowledge 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 shall determine to ensure that the entity is appropriately qualified to serve in this role.

(2) WORKING GROUP.—Not later than 180 days after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall establish a working group of experts and stakeholders from Federal, State, and local 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 Secretary, through the Centers of Excellence, the Centers 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 a macroregional partnership that includes—

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

(2) providing analysis of the timeliness and effectiveness of the national 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 descriptions of 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 section 417.

(f) NO DUPLICATION OF EFFORT.—In carrying out activities of the Centers of Excellence under this section, the Secretary shall not duplicate other 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.

SEC. 311. IMPORTING THE REPORTABLE FOOD REGISTRY.

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

(1) Designating 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, in a standardized format regarding a reportable food, which shall include—

(A) a description of the article of food as provided in subsection (b); 

(B) 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 food; 

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

(D) 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.

"(h) 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; 

(i) CONSUMER NOTIFICATION.—

"(1) IN GENERAL.—If a grocery store sold a reportable food, the grocery store shall post the notification required in subsection (e)(7) in a clearly visible location, prominently display such summary on its website, or otherwise notify the consumer that such information is available via at least one of the methods identified in 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 publish a list of accessible conspicuous locations and manners, from which grocery stores shall select at least one option, for provision 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 that is 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. 350e) is amended by striking "417(h)" and inserting "417(i)".

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. 305. FOREIGN SUPPLIER VERIFICATION PROGRAM.

"(a) IN GENERAL.—
“(c) Notice of Intent to Participate.—An importer may request the Secretary to provide the expedited review and importation of designated foods in accordance with the program established by the Secretary under subsection (a).”

“(d) Eligibility.—Eligibility shall be limited to an article of 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 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 presence of a satisfactory quality assurance program in 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 the facility of origin of the food, 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.

(g) 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.

“(h) 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.

“(i) 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.

SEC. 302. AUTHORITY TO REQUIRE IMPORT CERTIFICATIONS FOR FOOD.

(a) In General. — The Secretary may require, as a condition of entry, that an article of food be accompanied by a certification from the Secretary to the effect that the food meets applicable requirements of this Act, then such article shall be refused admission.

(b) Voluntary Qualified Importer Program.

Chapter VIII (21 U.S.C. 381 et seq.; 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 designated foods in accordance with the program established by the Secretary under subsection (a); 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 application 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 article of food for importation from a facility that has a certification described in subsection (a).

(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.

SEC. 303. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.

(a) In General.—Section 801(m)(1) (21 U.S.C. 381(m)) 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 1 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 after the date of enactment of this Act, develop a comprehensive plan to expand the technical, scientific, and regulatory
food safety capacity of foreign governments, and their respective food industries, from which foods are exported to the United States.

(2) INSPECTION REPORT.—In developing the plan under paragraph (1), 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.

(3) 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. 106. 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. ACCREDITATION OF THIRD-PARTY AUDITORS.

(a) DEFINITION.—In this section:

(1) AUDIT AGENT.—The term ‘audit agent’ means an individual who is employed or an 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.

(b) FOREIGN COOPERATIVES AND OTHER THIRD PARTIES.—Prior to accrediting a foreign cooperative or any other third party as an accredited third-party auditor, the accreditation body (or, in the case of an accepted model standard, the appropriate model standard) shall evaluate the foreign cooperative or other third party to determine whether the criteria for recognition under this section are satisfied.

(c) ACCREDITATION BODY.—The accreditation body 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.

(3) THIRD-PARTY AUDITORS.—(A) REQUIREMENTS FOR ACCREDITATION AS A THIRD-PARTY AUDITOR.—

(1) FOREIGN GOVERNMENTS.—Prior to accrediting 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 independently ensuring that 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.

(2) 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 cooperative or other third party to determine whether compliance with these standards is necessary, including requirements under the model standards developed

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); and

(ii) 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 inspection reports described in such paragraph (A) in distributing inspection resources under section 421 of the Federal Food, Drug, and Cosmetic Act, as added by section 207.

SEC. 107. 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) DEFINITION.—In this section:

(1) AUDIT AGENT.—The term ‘audit agent’ means an individual who is employed or an 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.

(b) FOREIGN COOPERATIVES AND OTHER THIRD PARTIES.—Prior to accrediting a foreign cooperative or other third party as an accredited third-party auditor, the accreditation body (or, in the case of an accepted model standard, the appropriate model standard) shall evaluate the foreign cooperative or other third party to determine whether the criteria for recognition under this section are satisfied.

(c) ACCREDITATION BODY.—The accreditation body 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.

(3) THIRD-PARTY AUDITORS.—(A) REQUIREMENTS FOR ACCREDITATION AS A THIRD-PARTY AUDITOR.—

(1) FOREIGN GOVERNMENTS.—Prior to accrediting 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 independently ensuring that 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.

(2) 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 cooperative or other third party to determine whether compliance with these standards is necessary, including requirements under the model standards developed

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); and

(ii) 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 inspection reports described in such paragraph (A) in distributing inspection resources under section 421 of the Federal Food, Drug, and Cosmetic Act, as added by section 207.

SEC. 107. 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) DEFINITION.—In this section:

(1) AUDIT AGENT.—The term ‘audit agent’ means an individual who is employed or an 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.

(b) FOREIGN COOPERATIVES AND OTHER THIRD PARTIES.—Prior to accrediting a foreign cooperative or other third party as an accredited third-party auditor, the accreditation body (or, in the case of an accepted model standard, the appropriate model standard) shall evaluate the foreign cooperative or other third party to determine whether the criteria for recognition under this section are satisfied.

(c) ACCREDITATION BODY.—The accreditation body 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.

(3) THIRD-PARTY AUDITORS.—(A) REQUIREMENTS FOR ACCREDITATION AS A THIRD-PARTY AUDITOR.—

(1) FOREIGN GOVERNMENTS.—Prior to accrediting 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 independently ensuring that 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.

(2) 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 cooperative or other third party to determine whether compliance with these standards is 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 an entity accredited 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 subsection (b) and determined by the Secretary that the third-party auditor satisfies the requirements under this section.

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

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

(ii) a facility, in cases in which the Secretary determines that a facility is in compliance with any applicable inspection or other documents resulting from a consultative disclosure, for fees paid by eligible entities to accredit an eligible entity against conflicts of interest between an accredited third-party auditor and the eligible entity.

(C) REQUIREMENTS FOR ISSUING CERTIFICATION.—

(i) IN GENERAL.—An accredited third-party auditor shall issue a food certification under section 801(q) or facility certification described in subsection (B) only after conducting a regulatory audit and such other activities that may be necessary to establish compliance with the requirements of this Act.

(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 section 801(q)(3) or the Secretary may provide a food certification under section 801(q).

(D) 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.

(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 under 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 onsite 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.

(3) NEUTRALIZING COSTS.—The Secretary shall neutralize costs of administering the accreditation system under this section. The Secretary shall establish by regulation a reimbursement (user fee) program, similar to the method described in section 20(h) of the Agriculture Marketing Act of 1946, whereby 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 system. Costs 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.

(4) CERTIFICATION OF ELIGIBLE ENTITIES.—An eligible entity shall apply for annual certification by an accredited third-party auditor if such entity—

(A) intends to participate in voluntary third-party program under section 806(a); or

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

(5) FALSE STATEMENTS.—Any statement or representation made—

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

(B) 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); and

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

(4) 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 provisions of 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. 398. 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 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 establishment by the Secretary of the foreign offices in the countries in which the Secretary established the offices, the progress which such offices have made with respect to assisting the governments and officials of such countries in providing 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.

SEC. 399. SMUGGLED FOOD.

(a) 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 combat 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, through a notification to Homeland Security a notification under section 417(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 359(n)) describing the smuggled food and the name of the firm, importer, or other involved persons 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 communication or recall networks, as appropriate, to inform 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 of the Regulatory Aff airs 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 Aff airs of the Food and Drug Administration such sums as may be necessary for fiscal years 2011 through 2015.

(c) REPORT.—Not later than October 1, 2011, the Secretary shall issue a report concerning the strategy to better identify smuggled food and, if available, the names of the governmental entity.

(1) field offices for direct risk-based inspections of articles of food and other products regulated by the Secretary for establishing additional foreign offices of the Food and Drug Administration, as established offices, the progress which such offices have made with respect to measures to provide for the safety of articles of food and other products regulated by the Foreign countries in which the Secretary established offices, 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 an 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.—

(1) STANDARD FOR COMPLAINT.—The Secretary may dismiss a complaint covered by 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 paragraph (1) through (4) of subsection (a) was a contributing factor in the unfavorable personnel action alleged in the complaint.

(2) STANDARD FOR EMPLOYEE.—Notwithstanding a finding by the Secretary that the complainant has made the showing required under clause (1), 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 even if the behavior described in paragraph (1) through (4) of subsection (a) was a contributing factor in the unfavorable personnel action alleged in the complaint.

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

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

(D) FINAL ORDER.—

(1) IN GENERAL.—Not later than 120 days after the date of conclusion of any hearing under paragraph (2), the Secretary shall issue a
CONGRESSIONAL RECORD — HOUSE December 21, 2010

H8884

final order providing the relief prescribed by this paragraph or denying the complaint. At any
time before issuance of a final order, a pro-
ceeding under this subsection may be terminated on
the motion or consent of the complainant and,
without prejudice to any right to seek judicial
review of the determination or order. In a pro-
ceeding under subparagraph (A) or (B), the com-
plainant shall have the burden of proving the
demand for relief, but not the burden of proving
the existence of any violation.

(3) JURISDICTION.—The Secretary shall have
jurisdiction to grant all appropriate relief includ-
ing, but not limited to, injunctive relief and
compensatory damages.

(4) PETITION FOR REVIEW.—The petition for
review must be filed not later than 60 days after
the date of the issuance of the order in the United
States Court of Appeals for the Circuit in which
the violation alleged to have committed the violation.

(5) EFFECT OF SECTION.—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.

SEC. 405. DETERMINATION OF BUDGETARY EF-
FECTS.

The budgetary effects of this Act, for the purpose
of complying with the Pay-As-You-Go Act of 2010, shall be determined by refer-
ence to the latest statement titled “Budgetary Effects of PAYGO Legislation” for this Act, sub-
mitted for printing in the Congressional Record by the Chairman of the Senate Budget Com-
mitttee, provided that such statement has been sub-
mitted prior to the vote on passage.

Amend the title so as to read: “An Act to amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.”

MOTION TO CONCUR

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

The Clerk read as follows:

Mr. DINGELL. Mr. Speaker, I ask unanimous consent that all Members
may have 5 legislative days in which to revise and extend their remarks and to
insert extraneous matter into the RECORD.

The SPEAKER pro tempore. Is there objection to the request of the gen-
tleman from Michigan?

There was no objection.

Mr. DINGELL. Mr. Speaker, I now yield 4 minutes to the gentleman from
California (Mr. WAXMAN), the distin-
guished chairman of the Committee on
Energy and Commerce.

Mr. WAXMAN. Mr. Speaker, I appreciate the gentleman from Michigan
(Mr. DINGELL) yielding to me. And I want to commend you, Representative
DELAURO, Congressmen PALLONE and
STUPAK, Mr. BARTON and Mr. SHIMKUS,
and former Representative DEAL with the
work on this legislation.
For a third time, today the House considers legislation that will dramatically improve the safety of our Nation’s food supply. The House first passed its bill in July 2009 on a strong bipartisan vote with 283 supporters. On November 30 of this year, the Senate passed the FDA Food Safety Modernization Act on a strong bipartisan basis, by a vote of 73-25. That bill contained some constitutional defects that needed to be fixed. So on Sunday night, the Senate again passed a corrected version of the same vote.

Congress has demonstrated that food safety is a bipartisan issue. Food-borne illness outbreaks can strike each and every one of us. In recent years, foods we never would have imagined to be unsafe, everything from spinach to peanut butter, have sickened an untold number of Americans. It is time, once and for all, to enact this legislation. There is no time for any further delay.

FDA needs a modern set of authorities to deal with the challenges of our increasingly globalized food supply. This legislation will give FDA the tools and resources it needs to better police the safety of the foods we eat every day. The bill makes significant improvements to the food chain, from the farm to the dinner table. The bill will require farmers to comply with science-based standards for safe production and harvesting. Companies that process or package foods will be required to implement preventive systems to stop outbreaks before they occur. Importers will have to demonstrate that the food they bring into the country is safe. And the bill strengthens FDA enforcement authorities, giving FDA the ability to order a food recall when companies refuse to voluntarily do so.

Many of us in the House would agree that our bill was stronger. We also would likely agree that it is regrettable that the votes were not time for a conference to allow us to make some improvements in the Senate bill. But this is an opportunity that will not come again for a long time. There is no question that this is a good bill and that it will provide FDA with some critical new authorities. It will fundamentally shift our food safety oversight system to one that is preventive in nature as opposed to reactive. We simply must take this chance to make our food supply safer. I urge my colleagues to vote “yes” on H.R. 2146.

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

At the Energy and Commerce Committee, food safety has been a bipartisan issue. We have held numerous hearings during the last two Congresses, examining food safety problems involving peppers and peanut butter and what we can do to solve those problems. During those hearings, we have heard about how much work our Nation’s food producers and distributors do to put low-cost, high-quality food on the tables of more than 300 million people every day. We also have heard about how much our Nation’s children and our Nation’s farmers and small businesses can be hurt when one irresponsible actor sells adulterated, contaminated food.

Thanks to helpful testimony from hearing witnesses and hard work by our colleagues, we were able to come up with some good ideas to help solve those food safety problems. Those ideas were found in the Food Safety Enhancement Act, which passed the House in July of 2009 and represented the bipartisan work of Chairman WAXMAN, Chairman Emeritus DINGELL, Chairman PALLONE, Chairman STUPAK, Governor-Elect Deal, and Ranking Member SHINUK.

The Food Safety Enhancement Act passed more than 16 months ago. The Senate finally passed its food safety bill, the Food Safety Modernization Act, Senate 510, during the lame duck session. The provisions of Senate 510 are contained in the bill that we are considering today with no substantive changes from what passed the Senate 3 weeks ago.

I intend to vote against this bill because it represents such a gross departure from reasonable legislating. When the Senate passed its food safety bill 3 weeks ago, we asked for a majority to take the bill to conference. Instead, we were forced to vote on the Senate bill with no substantive changes as part of the continuing resolution 2 weeks ago.

During the 111th Congress, we have learned great things not to do things, and this bill presents us with another example. Instead of just taking up the Senate bill, we should have held a conference. We’ve been told we couldn’t do that because there wasn’t enough time. Well, instead of naming post offices, we should have rolled up our sleeves and gotten to work on negotiating. And now, 3 weeks and many post offices later, the majority says we have to take it or leave it.

One provision that raises questions is the so-called Tester amendment that was added to the Senate food safety bill. This provision will provide exemptions from food safety requirements based on a facility’s or a farm’s size. While we do not want to overly burden small facilities and small farms, we’ve learned in our committee hearings that food-borne pathogens don’t care if you’re a big facility or a small facility, a big farm or a small farm. They affect everyone.

A food safety issue in one facility or one farm can cause hundreds of illnesses and hundreds of millions of dollars in economic losses for farmers and small businesses. By allowing facilities exemptions from food safety requirements, we’re setting our Nation up for the potential of future outbreaks. Our system is only as strong as its weakest link, and without a system full of weak links.

This is just one example of the potential problems with this bill. These are problems we could have addressed through a conference, but, instead, we wasted 3 weeks and are being told, take it or leave it.

I urge my colleagues to vote “no” on this legislation so we can do it the right way in the next Congress. I reserve the balance of my time.

Mr. DINGELL. Mr. Speaker, I yield 4 minutes to the distinguished gentleman from New Jersey (Mr. PALLONE).

Mr. PALLONE. Chairman Dingell, I want to thank you for all the hard work you have put in on this bill, and also Chairman WAXMAN. We worked on a bipartisan basis.

I rise today in strong support of the Food Safety Modernization Act. After 2 years of hard work, we’re finally on the cusp of enacting landmark comprehensive food safety legislation.

The modernization of our food safety system is desperately needed. The current food regulatory regime was established in 1938 and hasn’t been overhauled in 70 years. Since this time, the U.S. food supply has evolved into a global network made up of foreign products, processors, and growers over whom the U.S. has little or no control. There is no reason anything could not have been done then as was done in 1938. That alone should be reason enough to update our food safety laws today.

Every time we have a food safety crisis, be it eggs or spinach or peppers or peanut butter, we shake our heads at the vulnerability of our food supply and marvel the fact that we don’t have the tools to protect it. And these aren’t isolated instances. Each year, 48 million Americans are sickened from consuming contaminated food, and as many as 3,000 to 5,000 of these people die.

The Food Safety Modernization Act will give the FDA the ability, the authority, and the resources to protect American consumers from contaminated food domestically and abroad. FDA will now better ensure food safety through more frequent inspections of food processing facilities, the development of a food trace-back system to pinpoint the source of food-borne illnesses, and enhanced powers to ensure that imported foods are safe. Perhaps most notably, the bill emphasizes prevention and safety that helps ensure that food is safe before it’s distributed, before it reaches store shelves, before it reaches the kitchens of American families.

We have the most productive and most efficient food distribution system in the world, but we need to make sure that we have the safest food supply. American families need to know that the food they select from grocery stores and the meals they put on their kitchen tables are safe.

Now, I’ll say the bill before us isn’t perfect, but it is a good bill. It’s a step by step, piecemeal approach toward creating a more comprehensive food safety law. It’s a good bill, but it’s not perfect. It’s not perfect without the bipartisan coalition that includes food producers, grocery manufacturers, and consumers. It has strong bipartisan support. Last year, the
House passed its version by a vote of 283–142. The Senate passed a bill nearly identical to the one before us today by a vote of 73–25. And this is an overwhelming show of support for legislation which will significantly protect the public health.

I’m proud we’re passing this bill one more time. Today, of course, it will go to the President for his signature. He has said he would sign it. And I urge my colleagues to support this landmark legislation.

Mr. PITTS. Mr. Speaker, I yield 4 minutes to the ranking member on Agriculture, Representative LUCAS from Oklahoma.

Mr. LUCAS asked and was given permission to revise and extend his remarks.

Mr. LUCAS. Mr. Speaker, I rise again in opposition to H.R. 2751, originally dealing with the Cash for Clunkers and now containing the Senate language S. 510, the Food Safety and Modernization Act.

As I’ve stated repeatedly, I believe our Nation has the safest food supply in the world. I also believe that we must continually examine our food production and regulatory system and move forward with changes that will improve food safety.

This legislation is the product of a flawed process. It will lead to huge regulatory burdens on our Nation’s farmers and ranchers. It will raise the cost of food for consumers, and it contains very little that will actually contribute to the goal of food safety. It gives the Food and Drug Administration lots of additional authorities with no accountability. In fact, with the inclusion of the so-called Tester amendment, some argue that it is a step backwards.

Now, my concerns about the legislation are not limited to the unforgivable process. There are serious public policy concerns as well. The Tester amendment is an illustrative example. Intended to shield small and local producers from the burdens of the new food safety law, it is opposed by virtually all of the major organizations representing farmers and ranchers. Normally, these groups would be expected to support a provision that sought to protect their farmers and ranchers. But they oppose the Tester amendment and any legislation that contains it, because it adds to the layers of food safety regulation by creating yet another tier of regulatory standards that will only confuse our consumers.

Further, by exempting small domestic companies from Federal standards, I fear, and this is a legitimate fear, that we will be required to exempt similarly sized companies in developing countries from our standards. This approach does not make food safer. It eliminates important consumer protections and puts our citizens at increased risk.

With respect to the Tester amendment, I question the value of any law that is so onerous to an industry that Senators believe segments of that industry should be excluded from it. It would be wise to reconsider the entire legislative approach.

Now, there are other problems as well in the bill. The heavy regulation authority for food processing facilities will create what amounts to a Federal license to be in the food business. Registration of food processing facilities was originally envisioned as a component of food safety. The Tester amendment eliminates this level of food safety oversight under the Bioterrorism Act of 2002. This bill turns it into a license to operate, making it unlawful to sell food without a registration license, and allowing FDA to suspend the company’s registration. And this is the type of government intrusion into commerce that Americans rejected in early November of this year.

Another provision of particular concern would mandate the Food and Drug Administration use all farm production performance standards. For the first time, we’d have the Federal Government prescribing how our farmers grow crops. Farming, the growing of crops and the raising of livestock, is the first organized activity pursued by man. We’ve been doing it for a long time, and we’ve been doing it without government intrusion. In fact, with the inclusion of this so-called Tester amendment, the bill contains many good provisions, including the trace-back provision, which is designed to make it easier to prevent and respond to outbreaks in food-borne illnesses.

This also has mandatory recall. Most Americans are shocked to know that the FDA does not have the right to recall food or unsafe drugs in this country. They do not have the right to make that recall, especially on food. So this will now make it mandatory. The FDA can remove tainted food as soon as possible. Still, despite all these improvements, more has to be done to protect Americans.

The FDA needs subpoena power. It is probably one of the few regulatory agencies that doesn’t have subpoena power. We lost that when it went to the Senate. But if you are going to track back, if you are going to get the records, if you are going to find where the food comes from, let’s give the regulatory agency the power they need. Because corporate America unfortunately too often hides their records from us.

We need an adequate funding source. For this legislation to be successful, we have to have an adequate funding source. As we had in the House but was removed in the Senate. And country of origin label. More and more of our food, especially this time of the year in the winter months, comes from other countries. We need to know exactly where those sources of food come from. So I urge the next Congress to make these improvements.

And a word of caution. Without this bill and greater improvements to this bill, we cannot fully protect Americans from food-borne illnesses from our accidental or those intentionally put forth by America’s enemies. And make no mistake about it, our enemies will exploit our weak regulatory system when they know they can harm so many Americans through food-borne illnesses.

So I hope my colleagues today will join me in supporting this legislation.
It's a great piece of legislation. I would like to thank my colleagues who have worked so hard on this over the years with me, including Ms. DeLauro of Connecticut, but especially the members of the Energy and Commerce Committee, which I have worked with as especially Chairman Dingell, Chairman Waxman, Mr. Pallone, Mr. Upton, and Mr. Barton.

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

Mr. DINGELL. Mr. Speaker, I yield 5 minutes to the distinguished gentlewoman from Connecticut (Ms. DeLauro), the chairman of the Agriculture Appropriations Subcommittee, and very much interested in the matter before us. She has worked on it a long time.

Ms. DELAUGO. Mr. Speaker, I rise today in support of this bill as a good and a necessary first step in reforming our food safety system and better protecting American consumers from food-borne illness. And I want to congratulate some of the longtime champions of food safety in this institution, such as Chairman Henry Waxman, Chairman John Dingell, Subcommittee Chairman Frank Pallone, Mr. Bart Stupak. And I want to congratulate them for successfully bringing this legislation through the House. I also want to acknowledge Senator Harkin and Senator Durbin for their work in facilitating passage of this bill in the Senate.

Among the critical reforms in this bill are increased inspection of high-risk facilities, expanded authority to inspect recall records, the formation of a more accurate food facility registry, improved traceability in the event of an illness outbreak, and improved surveillance of food-borne illness. The bill also requires certification of certain foreign food imports as meeting U.S. food safety requirements.

All of these tools will help improve the FDA's ability to respond to food-borne illness outbreaks and to hold industrial food production facilities to higher standards. For too long, the cornerstone of our food safety system, the FDA, has had only ancient tools and an outdated mandate at its disposal. This bill will go a long way towards stemming the potential of a full-blown food-borne epidemic in the future. Recently, the CDC released an updated estimate on foodborne illnesses and deaths, and it remains a major public interest health threat. With nearly 50 million illnesses, 100,000 hospitalizations, and over 3,000 deaths each year, these estimates show that there is much work to be done in identifying and combating the pathogens that cause food-borne illnesses. The health effects of an E. coli illness are very painful. Haylee experienced traumatic damage to her kidneys and pancreas. She suffered severe bleeding in her brain. And that blood in her brain caused her to be temporarily blind. The Hospital fought for 14 weeks to save her life. And to this day, Haylee still suffers from health problems such as diabetes, all because of food contaminated with E. coli. This should not happen to anyone. We know in this body, it can be prevented.

With all of this in mind, our food safety efforts should not, and will not, end today. Because this piece of legislation is not about roads and bridges and parks and other things that we do in this institution. This legislation is about life and death. While the FDA is charged with protecting a large majority of our food supply, the Food Safety and Inspection Service at FSIS, is responsible for ensuring the safety of meat and poultry products. After passing this bill today, we must begin to lay the foundation for science-based reform at FSIS as well. That is why I worked with Senator Tester to create a science-based panel, supported by a wide range of stakeholders, to analyze the food safety system at FSIS and develop the concept of what a modernized system would look like there.

This collaborative proposal is supported by the pertinent industries, consumer groups, and unions. I should emphasize that this plan would not interfere with the good work currently being done by Under Secretary Elisabeth Hagen at FSIS. And I look forward to working with all of my colleagues in the next Congress to move this proposal forward.

Ultimately, I believe, as leaders across the Hill have stated, we must establish a single food safety agency. Currently, food safety responsibilities are fragmented across 15 Federal agencies and are governed by 71 interagency agreements. Food safety and public health experts in the Department of Health and Human Services, the Food and Drug Administration, the Environmental Protection Agency, and the Public Health Accountability Office, have concluded that this fragmentation has created redundancies that have weakened our food safety response. We need to consolidate all of these food safety functions into one body. This proposal will provide an updated regulatory structure and strengthen oversight and surveillance activities to better protect our food supply.

I will continue to fight for this single agency. I believe it is needed to ensure that the food in our fridges and on our kitchen tables is safe. Nonetheless, the legislation we must pass today is a strong first step toward a safer food supply and the number of preventable food-borne illnesses and deaths. I urge my colleagues to face this public health threat and to pass food safety legislation. Every parent who goes in to buy food needs to know that there is one number to call and it’s safe for their children.

Mr. PITTS. I continue to reserve the balance of my time.

Mr. DINGELL. Mr. Speaker, I yield 2 minutes again to my good friend, the chairman of the Committee on Energy and Commerce, Mr. Waxman, for purposes of correcting the record on certain erroneous statements made earlier.

Mr. WAXMAN. Mr. Speaker, on December 21, 2010, the House passed H.R. 2747, the Food Safety Modernization Act, by a vote of 250 to 178.

This bill is a good bill. It is supported by the Consumer Federation of America, the Consumers Union, the National Consumer League, the Trust for America's Health, the American Public Health Association. And it's supported by major industry groups, the Food Marketing Institute, the Grocery Manufacturers Association, and the U.S. Congress of Columbia.

Now, I would assume that some big operations don't like the fact that small ones are going to be exempt. They are only exempt from a couple of the provisions which Senator Tester and the Senate Members thought were too burdensome. And some of these small operations are limited in their income, and therefore it might be too burdensome for them.

Republicans have suggested we should have gone to conference. If we had gone to conference, only one Senator could object and no conferences would be appointed by the Senate. So that burden we are being asked to have achieved is something we could not achieve in the short time available to us.

Let us not let this opportunity go by. We must adopt this legislation. If there are efforts to change it later on, fine. But this is an important bill that has been worked on for years. It had strong bipartisan support in the House. It had overwhelming bipartisan support in the Senate. And I want to clarify the record to point out that almost all the groups, the consumer groups and the industry groups, are urging an “aye” vote.

Mr. PITTS. I continue to reserve the balance of my time.

Mr. DINGELL. Mr. Speaker, I have only one further speaker on this side, so I suggest to my good friend from Pennsylvania, if he desires to speak, he should speak forthwith.

Mr. PITTS. I have no further requests for time, and I yield back the balance of my time.

Mr. DINGELL. The gentleman is a complete gentleman. I don't want to disrupt any order. But I want to thank the gentleman. He is always courteous. I express my gratitude to him for the way he behaves.
I yield myself 5 minutes, Mr. Speaker.

Mr. Speaker, this is not the first time we have seen this bill. It came out of the Committee on Energy and Commerce unanimously. It was informally referred to the Committee on Agriculture, where they had a chance to take a look at it. It passed the House overwhelmingly on two occasions in a slightly different form. It then came back here and it was passed yet another time with the changes virtually to make it identical to that form in which it is. Those changes have been removed in some regards because they were mostly simply technical changes. So it has passed this body three times before this. This is the fourth time we have considered it. The Senate has passed it twice. On Sunday night, they passed it under a unanimous consent procedure.

The bill has enormous support, and all of the consumer organizations support it. Almost every business group in the field of food manufacturing and processing supports it: The Grocery Manufacturers Association, the National Association of Manufacturers, the Chamber of Commerce, the Consumer Federation of America, the American Public Health Association, the Bakers Association, the Beverage Association, the American Public Health Association, Pew Charitable Trust, the U.S. PIRG, and also the Food Marketing Institute as well as the Center for Science in the Public Interest. There is literally little, if any, opposition to the consideration of this legislation.

The Senate took from last summer when the House passed the bill until just a few weeks ago to pass the bill over there. It only passed for the final time on Sunday night. I want to agree with my good friend from Pennsylvania; the House's skill as a legislative body is far superior to that of the other body. I would leave the legislation alone, I think I could assure the House that we would pass better legislation than they do over there.

But having said these things, we are about now to be forced at the last minutes of this session to choose between not passing a superb bill and passing no bill at all because we want to achieve a greater level of perfection.

This is the first significant change in food safety law that America has had since 1938. At that time, you could test foods down to a few parts per thousand. Today, you can do it down to parts per billion and parts per trillion, and food is being affected by huge numbers of new, incredibly complex known and unknown molecules that are inserted.

The bill before us serves a basic and necessary and admirable purpose. It is going to have the purpose of seeing to it that the American consumer can again have confidence in the safety of their food supply.

Our manufacturers, our growers, and our processors do the best job in the world. The problem is we now import something like about one-quarter to one-third of our food supplies, and those food supplies are coming from places like China. And we have had some scandals of the most appalling character with regard to both domestic and imported food, but mostly with regard to food from China. We have seen seafood and shellfish from China, unsafe leafy vegetables like spinach and celery from China, bad berries and fruit from Chile and other places like that, peppers from Mexico that got mixed in with domestic items and have caused the collapse of the American tomato industry.

These are things that will be corrected by us having people available in Food and Drug to properly investigate, to properly correct and properly see to it that these unsafe foods don't get into our food chain, with the consequences not only that they poison Americans, but, worse, that they destroy American industry and cost us the faith of the American consuming public for some on international food manufacturers and processors in the world. The Chinese put melamine in milk. They sent us all manner of dangerous and unsafe food.

Now we are giving the agency, Food and Drug Administration, the authority it needs. This does not invade the jurisdiction of the Agriculture Committee. It was very carefully kept to see to it that it stayed within the jurisdiction of the Commerce Committee.

Mr. Speaker, this is not the first time we have seen this bill. Of course, but having said that, you're making Americans safe in spite of the fact that the U.S. Senate has to take a ride with this legislation

The SPEAKER pro tempore. The time of the gentleman has again expired.

Mr. DINGELL. I yield myself 1 additional minute.

Whether it will be better is open to question. But I will tell my colleagues, during that time there are going to be Americans sickened, there are going to be Americans killed, and there are going to be Americans hospitalized. American manufacturers and processors and growers are going to have the quality of their food products impinged, not by their carelessness or bad behavior but, rather, by the misbehavior of foreign producers, foreign manufacturers, and others who are sending things in here like milk products with melamine. Melamine is a constituent, believe it or not, of Formica.

It kills people. It kills babies. And China sells these products to their own people. If they will kill their own people with that kind of trash, imagine the glee with which they will sell that kind of trash over here to threaten the well-being and the safety and the trust of American consumers, businessmen, manufacturers, producers, and growers. I urge you, the safety of your constituents, of our people, is at stake. And I hope you will work with me to pass this legislation so that we can make our consumers not only trust the system but also to know that it is going to work to protect them.

The SPEAKER pro tempore. The time of the gentleman has again expired.

Mr. DINGELL. I yield myself 1 additional minute.

I hope if there's enthusiasm for doing further work on this, that my colleagues will join me next year in doing the same thing with regard to pharmaceuticals. And I remind you that the committee has worked not in opposition to American industry, but rather, the committee has worked with American industry, which supports the legislation.

Would it be better if we were passing the House bill? Absolutely. Is it worse and weaker because we're passing the Senate bill? Of course. But having said that, you're making Americans safe in spite of the fact that the U.S. Senate has to take a ride with this legislation
to, quite frankly, the weakening of this legislation.

I want to commend my colleagues who have participated: Mr. WAXMAN, Mr. PALLONE, Mr. STUPAK, Ms. DeGETTE, and Mr. DELAUGRO. And I want to give a special thanks to the staff: Kevin Campbell, whose last day this is; Virgil Miller; Rachael Sher; Eric Flamm; and Emily Gibbons, who have made this possible. Our legislative counsel has labored vitally on it, and we owe real thanks to Warren Burke and Megan Renfrew.

I want to commend my Republican colleagues. I know that they’re not supporting this legislation, and I grieve about that. But the harsh fact of the matter is they were very helpful in doing this in times past. And I want to pay particular tribute to Mr. SHIMKUS, Mr. Deal, and Mr. BARTON, but I do want it known that were it not for the labor of three great men in the other body, we would not be where we are.

I want to commend my colleagues to vote in favor of this legislation with due diligence.

Mr. Speaker, consideration of this bill today is what I hope will be the final step of a long legislative journey. My colleagues in this body passed similar legislation last July. Some 17 months later, we are working on the same issue.

The legislative fits and starts is in no way a reflection of the policy, however, the legislation has been the hostage of political games and procedural missteps. The FDA Food Safety Modernization Act serves a necessary and admirable purpose in boosting American consumer confidence in the safety of the nation’s food supply. The many recalls that have confronted American consumers over the years—peanuts, melamine in milk, eggs, bad seafood and shellfish, unsafe leafy vegetables like spinach, bad berries and peppers—has called into question the ability of the government to adequately protect American consumers. The FDA Food Safety Modernization Act addresses this concern head on and grants the Food and Drug Administration (FDA) the ability with oversight of 80 percent of the nation’s food supply—the authorities and resources it needs to effectively do its job.

Among other things, the legislation would create a robust system of prevention and a shared responsibility between FDA and food manufacturers to keep the food supply safe. It will require manufacturers to implement preventive systems to stop outbreaks before they occur.

Require FDA to inspect food facilities—foreign and domestic—more frequently;

Grant FDA new authority to ensure that imported foods meet U.S. safety standards and will assure foreign growers and producers must be treated with the same care that American growers and producers are;

Grant FDA new enforcement tools, including mandatory recall authority, authority to detain tainted products, and protection for employees who uncover food safety violations;

Mr. Speaker, enactment of this legislation is long overdue and necessary—necessary for the millions of Americans who suffer from foodborne illness each year, and the thousands who die from it.

We will bring to a halt a shameful situation where 48 million Americans are sickened by bad food, 128,000—yes 128,000 Americans—hospitalized and 3,000 people killed by bad food.

I strongly support the legislation before us today and urge my colleagues to cast an aye vote.

S. 510 SUPPORTERS

OBAMA ADMINISTRATION—FDA

American Bakers Association; American Beverage Association; American Public Health Association; Center for Foodborne Illness, Research & Prevention; Center for the Science In The Public Interest; Consumer Federation of America; Consumer Union; Flavor and Extract Manufacturers Association; Food Marketing Institute; Grocery Manufacturers Association; Institute of Food短ening & Edible Oils Inc.; International Dairy Foods Association; International Bottled Water Association; National Association of Manufacturers; National Coffee Association of U.S.A., Inc.; National Confectioners Association; National Consumers League; National Restaurant Association; The Pew Charitable Trusts; Snack Food Association; STOP—Safe Tables Our Priority; Trust For America’s Health; U.S. Chamber of Commerce; and U.S. PIRG: Federation of State PIRGs.

Ms. JACKSON LEE of Texas. Mr. Speaker, I rise today in strong support of the FDA Food Safety Modernization Act. H.R. 2751, the FDA Food Safety Modernization Act would help expand the FDA authority to inspect facilities participating in the food system. In addition, this legislation provides for a limited exemption for small food producers and processors that sell the majority of their food directly to consumers or to grocers within a circumscribed area and whose food sales are less than $500,000 per year.

The legislation before the House of Representatives is supported by a range of consumer and industry groups, including the American Public Health Association, the Center for Foodborne Illness Research and Prevention, the Center for Public Interest, the Consumer Federation of America, the Grocery Manufacturers Association, and the U.S. Chamber of Commerce.

It is time that we stand with this broad-based coalitions as we work to improve the food we eat and consume and know where exactly it’s coming from. These actions will only help our country, families and our American people from having safety and consumer-friendly produce, meats and dairy.

It is because of stories like this that I am ever so moved to ensure that H.R. 2751, the FDA Food Safety Modernization Act is passed in the House of Representatives and that it eventually becomes law.

Passage of the FDA Food Safety Modernization Act will prevent such salmonella scares from happening again in the future—in Texas or in any state in the country—for that matter.

This bill would also allow for improved traceability of the history of food in the event of a food borne illness outbreak. Often time, when our country has been faced by serious food poisoning that have affected thousands of American people, we do not know where the food was produced or cultivated. This bill would bring an end to that. It is important for us to be ever cautious that could affect the well being and health of our children, elderly and family members.

In addition to what I have mentioned, this bill would also make available a certificate of cGMP, a food safety standard that will assure Americans and you’re saving the lives and the health and the well-being of the American people by passing H.R. 2751.

I rise today in strong support of the FDA Food Safety Modernization Act and I urge my colleagues to vote in favor of this legislation with due diligence.

Mr. Speaker, consideration of this bill today is what I hope will be the final step of a long legislative journey. My colleagues in this body passed similar legislation last July. Some 17 months later, we are working on the same issue.

The legislative fits and starts is in no way a reflection of the policy, however, the legislation has been the hostage of political games and procedural missteps. The FDA Food Safety Modernization Act serves a necessary and admirable purpose in boosting American consumer confidence in the safety of the nation’s food supply. The many recalls that have confronted American consumers over the years—peanuts, melamine in milk, eggs, bad seafood and shellfish, unsafe leafy vegetables like spinach, bad berries and peppers—has called into question the ability of the government to adequately protect American consumers. The FDA Food Safety Modernization Act addresses this concern head on and grants the Food and Drug Administration (FDA) the ability with oversight of 80 percent of the nation’s food supply—the authorities and resources it needs to effectively do its job.

Among other things, the legislation would create a robust system of prevention and a shared responsibility between FDA and food manufacturers to keep the food supply safe. It will require manufacturers to implement preventive systems to stop outbreaks before they occur.

Require FDA to inspect food facilities—foreign and domestic—more frequently;

Grant FDA new authority to ensure that imported foods meet U.S. safety standards and
Act, fails to meet that high bar set by the original House bill. Because the version that is now before us has abandoned its original scientific base, I must sadly oppose this legislation.

Let me be clear: I understand the need for food safety reform to be well-timed. The recent Milk and Egg recalls and the fear of America's supply of fresh fruits, vegetables and nuts will always be my highest priority. I know firsthand the impact an outbreak can have on an industry, and for that reason, understand the strong need for far reaching regulations based on the best science available. The Center for Disease Control estimates, released December 15th, state that 48 million people in America—that's 1 in every 6—get sick every year from contaminated food. Furthermore, 128,000 are hospitalized and 3,000 die being exposed to this contaminated food. These are staggering numbers considering the United States still has the safest food supply in the world.

I also know each time any fruit or vegetable is implicated in an outbreak of foodborne illness, the industry as a whole suffers from devasting losses. We need to provide those small producers with the tools and incentives they need to help assuage the wrong message to the food industry. Even on today.

I also know each time any fruit or vegetable is implicated in an outbreak of foodborne illness, our nation needs a minimum food safety standard that applies to every food. We need to have on an industry, and for that reason, understand the strong need for far reaching regulations based on the best science available. The Center for Disease Control estimates, released December 15th, state that 48 million people in America—that’s 1 in every 6—get sick every year from contaminated food. Furthermore, 128,000 are hospitalized and 3,000 die being exposed to this contaminated food. These are staggering numbers considering the United States still has the safest food supply in the world.

I also know each time any fruit or vegetable is implicated in an outbreak of foodborne illness, our nation needs a minimum food safety standard that applies to every food. We need to have on an industry, and for that reason, understand the strong need for far reaching regulations based on the best science available. The Center for Disease Control estimates, released December 15th, state that 48 million people in America—that’s 1 in every 6—get sick every year from contaminated food. Furthermore, 128,000 are hospitalized and 3,000 die being exposed to this contaminated food. These are staggering numbers considering the United States still has the safest food supply in the world.

I also know each time any fruit or vegetable is implicated in an outbreak of foodborne illness, our nation needs a minimum food safety standard that applies to every food. We need to have on an industry, and for that reason, understand the strong need for far reaching regulations based on the best science available. The Center for Disease Control estimates, released December 15th, state that 48 million people in America—that’s 1 in every 6—get sick every year from contaminated food. Furthermore, 128,000 are hospitalized and 3,000 die being exposed to this contaminated food. These are staggering numbers considering the United States still has the safest food supply in the world.

I also know each time any fruit or vegetable is implicated in an outbreak of foodborne illness, our nation needs a minimum food safety standard that applies to every food. We need to have on an industry, and for that reason, understand the strong need for far reaching regulations based on the best science available. The Center for Disease Control estimates, released December 15th, state that 48 million people in America—that’s 1 in every 6—get sick every year from contaminated food. Furthermore, 128,000 are hospitalized and 3,000 die being exposed to this contaminated food. These are staggering numbers considering the United States still has the safest food supply in the world.

I also know each time any fruit or vegetable is implicated in an outbreak of foodborne illness, our nation needs a minimum food safety standard that applies to every food. We need to have on an industry, and for that reason, understand the strong need for far reaching regulations based on the best science available. The Center for Disease Control estimates, released December 15th, state that 48 million people in America—that’s 1 in every 6—get sick every year from contaminated food. Furthermore, 128,000 are hospitalized and 3,000 die being exposed to this contaminated food. These are staggering numbers considering the United States still has the safest food supply in the world.

I also know each time any fruit or vegetable is implicated in an outbreak of foodborne illness, our nation needs a minimum food safety standard that applies to every food. We need to have on an industry, and for that reason, understand the strong need for far reaching regulations based on the best science available. The Center for Disease Control estimates, released December 15th, state that 48 million people in America—that’s 1 in every 6—get sick every year from contaminated food. Furthermore, 128,000 are hospitalized and 3,000 die being exposed to this contaminated food. These are staggering numbers considering the United States still has the safest food supply in the world.