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 just上周说的不完全一样。

Madam Speaker, we are better than that. In the next Congress, I certainly believe that if the House and the Senate have differences of opinion, it is appropriate that it be worked out through the processes 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 bill 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 am proud of the efforts to make 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 ensure that the results of these programs are making a difference. Federal programs 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 continue on, year after year, often with increasing funds. The Federal Government needs 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 reviews of Federal programs. This will help agencies work together to reduce duplication and improve efficiencies. The bipartisan legislation I introduced to establish a single website that will allow Congress and the American people to be aware of all the performance goals and all information would be made available to Congress and the American people.

Mr. TOWNS. Madam Speaker, I rise in support of H.R. 2142, the Government Efficiency, Effectiveness, and Performance Improvement Act. I commend Representative CUELLAR for introducing this bill to ensure that Federal resources are spent efficiently and waste is minimized. More now than ever, while American families are cutting extraneous expenses from their budgets, the Federal Government is cutting the corners. I hope that all my colleagues will join 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. I commend Representative CUELLAR for his Herculean efforts in getting this bill through the process.

This is a common sense bill that will improve the performance of the Federal Government. This bill was approved by the Committee on Oversight and Government Reform, and, as I mentioned earlier, by voice vote on May 20, 2010. The House passed the bill by voice vote on June 16, 2010. The Senate amended the bill and passed it by unanimous consent on December 16, 2010.

H.R. 2142 modernizes and strengthens the Government Performance and Results Act of 1993. This bill requires the Office of Management and Budget to develop governmentwide priority goals that cut across agency programs. This will help agencies work together to reduce duplication and improve efficiencies. This bill requires each agency to identify performance goals and to perform frequent performance reviews. This will provide agencies and Congress with the information needed to make responsible decisions regarding priorities and resources. The Senate amendments to the bill will improve the transparency of the performance management process by establishing a single website that will allow Congress and members of the public to access the results of performance assessments.

In addition, the Federal Government accountability by requiring agencies to consider input from Congress and members of the public when developing priorities and by requiring the Government Accountability Office to report to Congress on agency implementation of this legislation.

The Senate amendments retain important provisions from the House-passed bill establishing performance improvement officers at each agency and establishing a performance improvement council. These are not new ideas as they were required by an Executive Order and detailed evaluation by George W. Bush. Putting these provisions, as well as the rest of this bill in statute will provide a certain framework for both the current and future administrations.

A vote in favor of this bill is a vote in favor of an efficient, effective government. I urge my colleagues to support this legislation.

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

The SPEAKER pro tempore. All time for debate has expired. Pursuant to House Resolution 1781, the previous question is ordered.

The question is on the motion by the gentleman from Texas (Mr. CUELLAR).

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

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

The yeas and nays were ordered. The SPEAKER pro tempore. Pursuant to the order of the House of today, further proceedings on this question will be postponed.

FDA FOOD SAFETY MODERNIZATION ACT

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 polluting 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 reads the title of the bill.

The SPEAKER pro tempore. The Clerk will designating 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.—This Act may be cited as the “FDA Food Safety Modernization Act”.

(b) REFERENCES.—Except as otherwise specified, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

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

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 ports of entry; annual report.

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. Attention to prevention of food.

Sec. 208. Decontamination and disposal standards and plans.

Sec. 209. Improving the training of State, local, Tribal, and 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 certifications 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 officials 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 V—Improving Capacity to Prevent Food Safety Problems

Sec. 501. Inspections of records.

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

(1) by striking the heading and all that follows through “of food” and inserting the following: “Records Inspection.—”;

(2) by inserting “(a)(1) the Secretary, on the basis of information under subsection (b) of section 413(a), believes that food that is to be imported or exported into the United States from such facility, offer to import or export food into the United States from such facility, or otherwise introduce food from such facility into interstate or intrastate commerce in the United States.”;

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

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

“(3) Biennial registration renewal.—During the period beginning on October 1 and ending on December 31 of each even-numbered year, a registrant shall submit a registration under paragraph (1) that shall be submitted in a similar manner, as agreed upon by the Secretary and the registrant, on the actions required for reinstatement of registration under section 432, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the requirements of this subsection beginning on the earlier of—

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

(B) 100 days after the date of enactment of the FDA Food Safety Modernization Act.

(4) Application date.—Facilities shall be subject to the requirements of this subsection beginning on the earlier of—

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

(B) 100 days after the date of enactment of the FDA Food Safety Modernization Act.

(5) No delegation.—The authority conferred by this subsection to issue an order to suspend a registration or vacate an order of suspension may not be delegated to any person other than the Commissioner.”;

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

(3) Imported Food.—Section 801(l) (21 U.S.C. 361(b)) is amended by inserting “(or for which a suspension has been vacated under such section)” after “section 415”.

(4) Clarification of intent.—(a) Retail food establishment.—The Secretary shall make the amendment of the term “retail food establishment” in section 1277(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 location 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 direct 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 248.2 of title 7, Code of Federal Regulations (or any successor regulations); and
(B) the term ‘‘consumer’’ does not include a business (as so defined).
(d) CONFORMING AMENDMENTS.—
(1) Section 301(d) (21 U.S.C. 331(d)) is amended by inserting ‘‘415,’’ after ‘‘404,’’
(2) Section 415(d) (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

SEC. 414. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.

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

(2) the owner, operator, or agent in charge of a facility, collectively, a very small business (as defined in the regulations promulgated under subsection (n)); and
(2) the business (as so defined).

(3) the owner, operator, or agent is making appropriate corrections to address corrective 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 processes in the facility, and new and emerging threats.

(9) RECORDKEEPING.—The owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records of all monitoring, the results of testing and other appropriate means of verification under subsection (f)(4), instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions, including at critical control points, if any, to provide assurances that—

(f) records of periodic reanalysis of the plan under subsection (i) to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats.

(2) the owner, operator, or agent in charge of a facility shall verify that—

(3) the food manufactured, processed, packaged, or held by such facility will not be adulterated under section 402 or misbranded under section 403(w),
(4) the food was manufactured, processed, packaged, or held by such facility in accordance with the requirements of this section, including analyzing the hazards under subsection (b) and identifying the preventive controls adopted under subsection (c) to address those hazards. Such written plan, together with the documentation described in subsection (g), shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

(3) the owner, operator, or agent in charge of a facility shall perform a written analysis of the hazards.

(c) PREVENTIVE CONTROLS.—The owner, operator, or agent in charge of a facility shall:

(1) appropriate action is taken to reduce the likelihood of recurrence of the implementation failure;
(2) all affected food is evaluated for safety; and
(3) all affected food is prevented from entering into commerce of the owner, operator or agent in charge of such facility cannot ensure that the food is not adulterated and, if section 402 or misbranded under section 403(w).

(f) RECORDKEEPING.—The owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records of all monitoring, the results of testing and other appropriate means of verification under subsection (f)(4), instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions, including at critical control points, if any, to provide assurances 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 corrections to address corrective 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

(1) the food manufactured, processed, packaged, or held by such facility will not be adulterated under section 402 or misbranded under section 403(w),
(2) the owner, operator, or agent in charge of a facility shall 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. Such written plan, together with the documentation described in subsection (g), shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

(1) REQUIREMENT TO REANALYZE.—The owner, operator, or agent in charge of a facility shall conduct a reanalysis under subsection (b) whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or not less frequently than once every 3 years, whichever is earlier.

(2) the owner, operator, or agent shall review the written plan required under subsection (h) if such a significant change is made or if the written plan is no longer relevant to the raw materials, conditions and processes in the facility for purposes of this subsection if the facility meets the conditions under subparagraph (B)

(1) the owner, operator, or agent is making appropriate corrections to address corrective 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

(3) the owner, operator, or agent is making appropriate corrections to address corrective 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

(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—

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

(2) hazards that occur naturally, or may be unintentionally introduced, and

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

(1) hazards identified in the hazard analysis conducted under subsection (b)(1) will be significantly minimized or prevented and addressed, consistent with section 420, as applicable; and

(3) the food was manufactured, processed, packaged, or held by such facility in accordance with the requirements of this section, including analyzing the hazards under subsection (b) and identifying the preventive controls adopted under subsection (c) to address those hazards. Such written plan, together with the documentation described in subsection (g), shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

(2) the owner, operator, or agent is making appropriate corrections to address corrective 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

(1) appropriate action is taken to reduce the likelihood of recurrence of the implementation failure;
(2) all affected food is evaluated for safety; and
(3) all affected food is prevented from entering into commerce of the owner, operator or agent in charge of such facility cannot ensure that the food is not adulterated and, if section 402 or misbranded under section 403(w).

(f) RECORDKEEPING.—The owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records of all monitoring, the results of testing and other appropriate means of verification under subsection (f)(4), instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions, including at critical control points, if any, to provide assurances that—

(1) the food manufactured, processed, packaged, or held by such facility will not be adulterated under section 402 or misbranded under section 403(w),
(2) the owner, operator, or agent in charge of a facility shall 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. Such written plan, together with the documentation described in subsection (g), shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.
Food Safety Modernization Act, the Secretary shall submit to Congress a report that describes the results of the study conducted under subparagraph (A).

(1) 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 be required under federal law at common law or under State statutory law.

(2) Notification to consumers.—(A) In general.—A qualified facility that is exempt from the requirements under subsection (a) through (i) and subsection (n) and does not provide documentation under paragraph (2)(B)(i) or (ii) 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;

(B) rule of construction.—Nothing in this subsection shall be construed to expand or limit this subsection.

(3) Withdrawal; rule of construction.—(A) In general.—The Secretary may, by regulation, at such facility, the Secretary may withdraw the classification provided to such facility under this subsection.

(B) Rule of construction.—Nothing in this subsection shall be construed to expand or limit the implementing authority of the Secretary.

(4) Definitions.—In this subsection:

(A) Affiliate.—The term ‘affiliate’ means any company which is owned or controlled directly or indirectly by another company.

(B) Qualified end-user.—The term ‘qualified end-user’, with respect to a food, means—

(i) the 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—

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

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

(II) 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) provision of a nation-wide study of production by type and size of operation, including monetary value of food sold;

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

(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 outbreak occurred; and

(v) the effect on foodborne illness associated with commingling, processing, transporting, 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 this Act, the Secretary shall submit to Congress a report that describes the results of the study conducted under subsection (a).

(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 regulated under this Act.

(C) preliminary controls.—The term ‘preliminary controls’ means those risk-based, reasonably appropriate procedures, practices, and controls that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis and preventive controls regulations and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

(D) preventive controls.—The term ‘preventive controls’ means those risk-based, reasonably appropriate procedures, practices, and controls that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis and preventive controls regulations and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

(E) recall plan.—The term ‘recall plan’ means the procedures and practices that may include the following:

(i) Sanitation procedures for food contact surfaces and utensils and food-contact surfaces associated with food.

(ii) supervisor, manager, and employee hygiene training.

(iii) Environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment.

(iv) A food allergen control program.

(F) good current manufacturing practices (gmps) under part 110 of title 21, Code of Federal Regulations (or any equivalent).

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

(7) coordinated.—(A) in general.—The regulations promulgated under subsection (n) shall coordinate with the regulations promulgated under subsection (b)(i) 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)).

(B) rulemaking.—(1) proposed rulemaking.—(A) in general.—Not later than 9 months after the date of enactment of this Act, the Secretary shall publish a notice of proposed rulemaking in the Federal Register to promulgate regulations with respect to—

(i) facilities that constitute on-farm parking 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 another farm under common ownership for purposes of such section 415.

(2) clarification.—The promulgation 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.

(2) PROPOSED RULEMAKING.—In promulgating regulations under subparagraph (A), the Secretary shall conduct a science-based risk analysis:

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

(ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods consumed on such farm or on another farm under common ownership.

(3) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(i) IN GENERAL.—In promulgating the regulations under subparagraph (A), the Secretary shall consider the results of the science-based risk analysis conducted under subparagraph (C), and shall exempt certain facilities from the requirements in section 418 of the Federal Food, Drug, and Cosmetic Act (as added by this section), including hazard analysis and preventive controls, and the mandatory inspection frequency in section 421 of such Act (as added by section 201), or modify the requirements in such sections or 421, as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packaging, or holding activities that the Secretary determines to be low-risk involving specific foods the Secretary determines to be low-risk.

(ii) LIMITATION.—The exemptions or modifications under clause (i) shall not include an exemption from any requirement or regulation promulgated under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by this Act, if applicable, and shall apply only to small 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 under 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 packaging or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership for purposes of section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by this Act;

(B) the amendment of the regulations under section 415 of the Federal Food, Drug, and Cosmetic Act (as added by section 201, or modify the requirements in such sections or 415) 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 under section 201, or modify the requirements in such sections or 415) beginning on the date that is 18 months after the effective date of such regulations.

SEC. 105. STANDARDS FOR PRODUCE SAFETY.

(a) IN GENERAL.—The Secretary shall, in cooperation with the Secretary of Agriculture, not less than 2 years after the date of enactment of the FDA Food Safety Modernization Act, promulgate, 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, the Secretary shall promulgate, and may modify the applicable requirements of regulations promulgated pursuant to this section.

(c) PUBLIC INPUT.—During the comment period on the notice of proposed rulemaking under paragraph (1), the Secretary shall conduct no less than 3 public meetings in diverse geographic areas of the States to provide persons in different regions an opportunity to comment.

(d) 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—

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

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

(iii) be into consideration, consistent with ensuring enforceable public health protection, conservation and environmental practice standards and policies established by Federal natural resource owners, the Wildlife Conservation, and environmental agencies;

(E) inclusive of this 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 maintaining the same level of protection as the requirements under guidance documents, including guidance documents regarding action levels, and regulations under the FDA Food Safety Modernization Act;

(F) define, for purposes of this section, the terms ‘small business’ and ‘very small business’;

(G) define, for purposes of this section, the term ‘facility’ as defined by the Secretary of Agriculture to avoid issuing duplicative guidance on the same contaminants.

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

(i) EFFECTIVE DATES.—

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

(2) FINAL RULEMAKING.—Notwithstanding paragraph (1), the amendments made by this section shall apply to a small business (as defined in the regulation promulgated under this section) beginning on the date that is 6 months after the effective date of such regulations; and

(2) PROPOSED RULEMAKING.—

(a) PROPOSED RULEMAKING.—

(i) IN GENERAL.—No 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 and the Food and Drug Administration, shall publish a notice or other regulations or guidance that are not grown, raised, or consumed on such farm or another farm under common ownership.

(ii) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(iii) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(iv) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(v) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(vi) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(vii) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(viii) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(ix) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(x) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(xi) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(xii) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(xiii) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(xiv) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(xv) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

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(xvii) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(xviii) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(xix) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(xx) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(2) PROPOSED RULEMAKING.—

(a) IN GENERAL.—

(1) GENERAL RULE.—

(2) PROPOSED RULEMAKING.—

(a) IN GENERAL.—

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(a) IN GENERAL.—

(1) GENERAL RULE.—

(2) PROPOSED RULEMAKING.—

(a) IN GENERAL.—
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on known risks which may include a history and severity of foodborne illness outbreaks.

"(b) FINAL REGULATION.—

(A) IN GENERAL.—Not later than 1 year after the close of the comment period for the proposed rulemaking under subsection (a), the Secretary shall adopt a final regulation to provide for minimum science-based standards for the 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 State or official as recognized by State statute;

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

(3) FLEXIBILITY FOR SMALL BUSINESSES.—Notwithstanding paragraph (1), 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) IN GENERAL.—The regulations adopted under subsection (b) shall—

(A) set forth the procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices, as appropriate, and may specify the scope of applicability of a variance to other similarly situated persons;

(B) pursuant to section 3502(3) of title 44, United States Code (commonly known as the "Paperwork Reduction Act"), with special attention to the consumer, including small businesses such as a small food processor located on a farm;

(C) comply with chapter 35 of title 44, United States Code (commonly known as the "Paperwork Reduction Act"), with special attention to the consumer, including small businesses such as a small food processor located on a farm;

(D) include a process for small businesses to apply for variances that may include a history of foodborne illness outbreaks.

(E) the regulations promulgated under section (a)(1) for persons in different regions who apply for variances that may include a history of foodborne illness outbreaks.

(F) permit States and foreign countries from the requirements under this section in a calendar year if—

(1) IN GENERAL.—Not later than 1 year after the effective date of the final regulation under subsection (a)(1) for persons in different regions who apply for variances that may include a history of foodborne illness outbreaks.

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

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

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

(B) permit States and foreign countries from the requirements of the regulations, subject to paragraph (2), where the State or foreign country determines that the variance is necessary in light of its conditions and the types of procedures, processes, and practices to be followed under the variance are reasonable likely to ensure that the produce is not adulterated under section 402 and is not reasonably likely to provide the same level of public health protection as the requirements of the regulations adopted under subsection (b).

(2) VARIANCES.—

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

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

(C) DENIAL OF VARIANCES.—The Secretary may deny a variance request if the Secretary determines that the variance is necessary in light of local growing conditions and that the variance is not reasonably likely to ensure that the food is not adulterated under section 402 and is not reasonably likely to provide the same level of public health protection as the regulations adopted under subsection (b). The Secretary shall notify the person requesting such variance of the reasons for the denial.

(3) WITHDRAWAL; RULE OF CONSTRUCTION.—

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

(B) RULE OF CONSTRUCTION.—Nothing in this subsection shall prevent the Secretary from exercising any authority granted in the other sections of this Act.

(4) 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 415) that is located in the same State as the farm that produced the food; or

(ii) not more than 275 miles from such farm.

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

(C) NO PREEMPTION.—Nothing in this subsection preempts State, local, county, or other non-Federal law regarding the safety, processing, handling, transportation, and sale of fresh fruits and vegetables. Compliance with this subsection shall not relieve any person from liability at common law or under State statutory law.

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

(6) CLARIFICATION.—This section shall not apply to products that are produced by an individual for personal consumption.

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

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

"(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.

"(3) ADDITIONAL LABEL.—

(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 packaging label is required by the Secretary under any other provision of this Act, include prominently and conspicuously on such label the name and address of the farm where the produce was grown; 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, 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.

(5) APPLICABILITY.—This section (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.

(6) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to expand or limit the inspection authority of the Secretary.
(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 require-
ments of the Seafood Hazard Analysis Critical
Controls Points Program, the Juice Hazard
Analysis Critical Control Program, and the
Thermally Processed Low-Acid Foods Packaged
in Hermetically Sealed Containers standards.

SEC. 106. PROTECTION AGAINST INTENTIONAL
ADULTERATION.

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

“SEC. 420. PROTECTION AGAINST INTENTIONAL
ADULTERATION.

“(a) DETERMINATIONS.—

“(1) IN GENERAL.—The Secretary shall—

(A) conduct a vulnerability assessment of the food supply chain at specific vulnerable
destinations identified by the Department of Homeland Security biological,
chemical, radiological, or other terrorism risk assessments;

(B) consider the best available understanding of uncertainties, risks, costs, and benef-
fits associated with guarding against intentional adulteration of food at vulnerable points, as
appropriate.

(C) determine the types of science-based miti-
gation strategies or measures that are necessary to protect against the intentional adul-
teration 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
publicly available.

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

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

“(2) specify appropriate science-based mitigation
strategies or measures to prepare and pro-
tect the food supply chain at specific vulnerable points, as appropriate.

“(c) APPLICABILITY.—Regulations promul-
gated under subsection (b) shall apply only to
food from domestic facilities that pose a high risk of intentional contamination, as determined by the Secretary, in consultation with the Secretary of Homeland Security, under subsection (a), that could cause serious adverse health consequences or death to humans or animals and shall include those foods—

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

“(2) in a manner by considering the potential for being packed or processed for the final consumer.

“(d) EXCEPTION.—This section shall not apply
to farms, except for those that produce milk.

“(e) APPROPRIATE FOODS.—For purposes of this
section, the term ‘farm’ has the meaning given in
term section 2.227 of title 21, Code of Federal
Regulations (or any successor regulation).

“(f) DETERMINATIONS.—

“(1) IN GENERAL.—Not later than 1 year after
the date of enactment of this Act, the Secretary
of Health and Human Services, in consultation with the Secretary of Homeland Security and the Secretary of Agriculture, shall issue guid-
dance documents related to protection against the intentional adulteration of food, Drug, and Cosmetic Act, as added by subsection (a).

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

(A) include a model assessment for a person to
use under subsection (b)(1) of section 415(b) of the Federal Food, Drug, and Cosmetic Act, as
added by subsection (a);

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

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

“(3) LIMITED DISTRIBUTION.—In the interest of national security, the Secretary of Health and
Human Services, in consultation with the Sec-

retary of Homeland Security, may determine the
time, manner, and form in which the guidance
documents issued under paragraph (1) are made
publicly available.

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

(B) the responsible party for a domestic facil-
ity (as defined in section 415(b)) and an im-
porter who does not comply with a recall order
under section 422 or under section 422(f) in
such fiscal year, to cover food recall activities
associated with such recall order and the
Secretary, including technical assistance, follow-up
effectiveness checks, and public notifica-
tions, for such year;

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

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

“(2) DEFINITIONS.—For purposes of this sec-
tion—

“(A) the term ‘reinspection’ means—

(i) with respect to domestic facilities (as
de
infined in section 415(b)), 1 or more inspec-
tions conducted under such provision
which identified noncompliance materially rel-
ted to a food safety requirement of this Act,
except for inspections conducted under such provision which identified noncompliance materi-
ally related to a food safety requirement of
this Act, specifically to determine whether com-
pliance has been achieved to the Secretary’s satis-
faction;

(ii) assessing and collecting reinspection fees
under this section; and

(iii) with respect to importers, 1 or more ex-
aminations conducted under section 801 sub-
sequent to an examination conducted under such provision which identified noncompliance mate-
rially related to a food safety requirement of
this Act, specifically to determine whether com-
pliance has been achieved to the Secretary’s satis-
faction;

(iv) with respect to importers, 1 or more ex-
aminations conducted under section 801 sub-
sequent to an examination conducted under such provision which identified noncompliance mate-
rially related to a food safety requirement of
this Act, specifically to determine whether com-
pliance has been achieved to the Secretary’s satis-
faction;
FEES.—Paragraph (4) of section 801(e)(4)(A) (21 U.S.C. 381(e)(4)(A)) is amended by adding at the end the following:

"(B) in clause (i) by striking "food, drug" and inserting "food, drug, or animal feed"; and

"(C) in clause (ii) by striking "food, drug" and inserting "food, drug, or animal feed.""

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 submit to the Congress a comprehensive strategy for ensuring the nation’s ability to prevent, detect, investigate, mitigate, and respond to agricultural and food emergencies, in coordination with the Secretary of Homeland Security, to achieve the following goals:

(I) the Federal Government; and

(II) State, local, and tribal governments;

(b) IMPROVING RESPONSE 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:

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

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

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

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

(ii) providing additional human illnesses;

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

(I) the Federal Government; and

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

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

(v) ensuring consistent and organized response coordination to the process—

(I) the Federal Government; and

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

(III) the private sector.

(d) ANNUAL REPORT TO CONGRESS.—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 section (b).

(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 section (b).

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

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

(A) the National Incident Management System; and

(B) the National Preparedness Goals; and

(C) other relevant national strategies.
(iv) decontaminating and restoring areas affected by an agriculture or food emergency.

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

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

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

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

SEC. 109. FOOD AND AGRICULTURE COORDINATING COUNCILS.

The Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services and the Secretary of Agriculture, shall within 180 days of enactment of this Act, and annually thereafter, submit to the relevant appropriations committees and, if publicly available on the Internet Web site of the Department of Homeland Security, a report on the activities of the Food and Agriculture Governance Council and the Food and Agriculture Sector Coordinating Council, including the progress of such Councils on—

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

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

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

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

(A) animal or plant disease outbreaks;

(B) food contamination; and

(C) natural disasters affecting agriculture and food.

SEC. 110. BUILDING DOMESTIC CAPACITY.

(a) IN GENERAL.—

(1) INITIAL REPORT.—The Secretary, in coordination with the Secretary of Agriculture and the Secretary of Homeland Security, shall, not later than 2 years after the date of enactment of this Act, submit to Congress a comprehensive report that identifies programs and practices that are intended to promote the safety and supply chain security of food and to prevent outbreaks of foodborne illness and other food-related hazards that can be addressed through preventative activities. Such report shall include a description of the following:

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

(B) Outreach to food industry sectors, including through the Food and Agriculture Coordinating Councils referred to in section 109, to identify potential sources of emerging threats to the safety and security of the food supply and preventive strategies to address those threats.

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

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

(2) R EPORT.—Not later than 15 months after the date of enactment of this Act, the Secretary shall submit to Congress a report that—

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

(B) identifies future programs and practices; and

(D) includes information related to any matter described in subparagraphs (A) through (C) of paragraph (1).

(b) RISK-BASED ACTIVITIES.—The report developed under subsection (a)(1) shall describe methods that seek to ensure that resources are directed to those food safety-related activities that are directed at those actions most likely to reduce risks from food, including the use of preventive strategies and allocation of inspection resources, that are likely to underlie those risk-based actions that are identified during the development of the report as likely to contribute to the safety and security of the food supply.

(c) CAPABILITY FOR LABORATORY ANALYSES; RESEARCH.—The report developed under subsection (a)(1) shall include a description of methods to increase capacity to undertake analyses of food samples promptly after collection, to identify new and rapid analytical techniques, including commercially-available technology that can be employed at ports of entry and by Food Emergency Response Network laboratories, and to provide for well-equipped and staffed laboratories to accredit toward laboratory accreditation under section 422 of the Federal Food, Drug, and Cosmetic Act (as added by section 206).

(d) INFORMATION TECHNOLOGY.—The report developed under subsection (a)(1) shall include a description of such information technology systems as may be needed to identify risks and reduce or remove risks, including foreign governments, State, local, and tribal governments, other Federal agencies, the food industry, laboratories, laboratory networks, and consumers. The report shall include a description of the following:

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

(B) Outreach to food industry sectors, including through the Food and Agriculture Coordinating Councils referred to in section 109, to identify potential sources of emerging threats to the safety and security of the food supply and preventive strategies to address those threats.

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

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

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

(f) TRACEBACK AND SURVEILLANCE REPORT.—The Secretary shall include in the report developed under subsection (a)(1) an analysis of the Food and Drug Administration’s performance in foodborne illness outbreaks during the 5-year period preceding the date of enactment of this Act, including the following:

(A) A description of the cost associated with development and implementation of a program that requires a unique identifier number for each food product that is offered for import into the United States.

(B) A report on the progress measured in the manner and format in which the National Agriculture and Food Defense strategy established under sections 108 and 205.

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

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

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

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

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

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

(i) E FFECTIVENESS OF PROGRAMS ADMINISTERED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.—

(1) IN GENERAL.—To determine whether existing Federal programs administered by the Department of Health and Human Services are effective in achieving the goals of this Act, the Secretary of Homeland Security shall—

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

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

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

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

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

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

(j) EFFICIENCY REPORT.—The report described under paragraph (1) shall—

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

(2) INCLUDED.—The report shall include a description of progress toward developing and implementing an automated risk assessment system for food safety surveillance and allocation of resources.

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

(A) identifies 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 matters described in subparagraphs (A) through (C) of paragraph (1).

(l) UNIQUE IDENTIFICATION NUMBERS.—

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

SEC. 111. SANITARY TRANSPORTATION OF FOOD.

(a) IN GENERAL.—Not later than 18 months after the date of enactment of this Act, the Secretary shall promulgate regulations described in section 416(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350e(b)).

(b) F OOD TRANSPORTATION STUDY.—The Secretary, acting through the Commissioner of Food and Drugs, shall conduct a study of the

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transportation of food for consumption in the United States, including transportation by air, that includes an examination of the unique needs of rural and frontier areas with regard to the delivery of safe food.

SEC. 112. FOOD ALLERGY AND ANAPHYLAXIS MANAGEMENT.

(a) Definitions.—In this section—

(1) School-based food allergy management program.—The term ‘‘school-based food allergy management program’’ means—

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

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

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

(2) SEA definitions.—The terms ‘‘local educational agency,’’ ‘‘prekindergarten program,’’ ‘‘early education program’’ and ‘‘preschool program’’ mean—

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

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

(b) Establishment of a voluntary food allergy and anaphylaxis management program and guidelines.—

(1) Establishment.—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 school and early childhood education programs; and

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

(B) Applicability of FERPA.—Each plan described in subparagraph (A) that is developed for an individual shall be considered an education record for the purpose of section 444 of the General Education Provisions Act (commonly known as the ‘‘Pamela Education Rights and Privacy Act of 1974’’) (20 U.S.C. 1232g).

(2) Contents.—The voluntary guidelines developed under paragraph (1) shall address each of the following and may be developed by the Secretary under paragraph (1) shall be construed to include any information that is not included in any record of a private educational agency;

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

(i) documentation from their child’s physician or nurse

(ii) a description of medication currently being taken

(iii) a description of a diagnosis of food allergy, and any risk of anaphylaxis, if applicable;

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

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

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

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

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

(ix) assessing the child’s readiness for self-administration of medication by such children in instances where—

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

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

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

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

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

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

(G) The authorization and training of school or early childhood education program personnel to administer epinephrine when the nurse is not immediately available.

(H) The Development of a list of medications prescribed for the child.

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

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

(K) Other elements the Secretary determines necessary for the management of food allergies and anaphylaxis in schools and early childhood education programs.

(3) Relation to State law.—Nothing in this section or the guidelines developed by the Secretary under paragraph (1) shall be construed to preempt State law, including any State law regarding who is responsible for the administration of medication by such children.

(b) School-based food allergy management guidelines.—

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

(2) Application.—

(A) In general.—To be eligible to receive a grant under this subsection, a local educational agency shall—

(i) submit an application to the Secretary at such time, in such manner, and including such information as the Secretary may reasonably require;

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

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

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

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

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

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

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

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

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

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

(c) Use of funds.—Each local educational agency that receives a grant under this subsection may use the grant funds for the following:

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

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

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

(D) Outreach to parents.

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

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

(e) Limitation on grant funding.—The Secretary may not provide for a period of not more than 2 years of grant funding under this subsection.

(f) Maximum amount of annual awards.—A grant awarded under this subsection may not be made in an amount that is more than $50,000 annually.

(g) Priority.—In awarding grants under this subsection, the Secretary shall give priority to local educational agencies with the highest percentages of children who are counted under section 1124(c) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 6332(c)).

(h) Matching funds.—

(A) In general.—The Secretary shall not award a grant under this subsection unless the local educational agency agrees with, 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.—The amount of non-Federal contributions required under subparagraph (A) may be cash or in kind, including plant, equipment, or services. Amounts provided by the Federal Government, and any portion of any service subsidized by the Federal Government, may not be included in determining the amount of such non-Federal funds.

(i) 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 grant.

(j) Regulations and standards.—At the conclusion of the period referred to in paragraph (4), a local educational agency shall provide quarterly reports to the Secretary with regard to how grant funds were spent and the status of implementation of the food allergy and anaphylaxis...
management guidelines described in subsection (b).

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

(12) MODIFICATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $30,000,000 for fiscal year 2011 and such sums as may be necessary for each of the 4 succeeding fiscal years.

(d) VOLUNTARY NATURE OF GUIDELINES.—

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

(2) EXCEPTION.—Notwithstanding paragraph (1), the Secretary may enforce an agreement by a local educational agency to implement food allergy and anaphylaxis management guidelines established under this section 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 (a); and

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

"(c) NOTIFICATION.—"(1) In general.—If the Secretary determines that the information in a new dietary ingredient notification submitted under this section for an article purported to be a new dietary ingredient is inadequate to make a determination 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 management guideline, 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 article, the name of the person or persons who marketed the product or made the submission of information regarding the article to the Secretary under this section, and any contact information for such person or persons that the Secretary has.

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

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

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

(b) GUIDANCE.—Not later than 180 days after the date of enactment of this Act, the Secretary shall publish guidance that clarifies when a dietary supplement ingredient is a new dietary ingredient, when the manufacturer or distributor of a dietary ingredient or dietary supplement should provide the Secretary with information as described in section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act, the evidence needed to document the safety of new dietary ingredients, and appropriate methods for establishing the 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 date of enactment of this Act, the Secretary shall prepare a final rule that implements the amendments made to 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 that in which the Secretary refuses to admit a food into the United States under section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) so that the Secretary of Homeland Security, acting through the Commissioner of Customs and Border Protection, may prevent food refused admission under section 801(a) of the Federal Food, Drug, and Cosmetic Act from entering the United States.

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 that in which the Secretary refuses to admit a food into the United States under section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) so that the Secretary of Homeland Security, acting through the Commissioner of Customs and Border Protection, may prevent food refused admission under section 801(a) of the Federal Food, Drug, and Cosmetic Act from entering the United States.

SEC. 116. ALCOHOL-RELATED FACILITIES.

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

(1) under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 9001 et seq.) is required to obtain a permit under the Secretary of the Treasury, as a condition of doing business in the United States; and

(2) under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379 et seq.), is required to register as a facility because such facility is engaged in manufacturing, processing, packing, or holding 1 or more alcoholic beverages in such a manner that such facility relates to the manufacture, processing, packing, or holding of alcoholic beverages.

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

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

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

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

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

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

(a) IDENTIFICATION AND INSPECTION OF FACILITIES.—

(1) IDENTIFICATION.—The Secretary shall identify high-risk facilities and shall allocate resources to inspect facilities according to the known safety risks of the facilities, which shall be based on the following factors—

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

(B) The compliance history of a facility, including with respect to the incidence of foodborne illness, and violations of food safety standards.

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

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

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

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

(2) INSPECTIONS.—

(A) IN GENERAL.—Beginning on the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall increase the frequency of inspection of all facilities.
“(B) DOMESTIC HIGH-RISK FACILITIES.—The Secretary shall increase the frequency of inspection of domestic facilities identified under paragraph (1) as high-risk facilities such that each such facility is inspected—

(i) not less often than once in the 5-year period following the date of enactment of the Food and Drug Administration Amendments Act of 2007; and

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

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

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

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

(D) FOREIGN FACILITIES.—

(i) YEAR 1.—In the 1-period following the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall inspect not fewer than 600 foreign facilities.

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

(E) RELIANCE ON FEDERAL, STATE, OR LOCAL INSPECTIONS.—In meeting the inspection requirements specified for domestic facilities, the Secretary may rely on inspections conducted by other Federal, State, or local agencies under interagency agreements, contract, memorandum of understanding, or other obligations.

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

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

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

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

(4) The rigor and effectiveness of the activities conducted by the importer of such article of food to satisfy the requirements of the foreign supplier verification program under section 805.

(5) Whether the food importer participates in the voluntary qualified importer program under section 806.

(6) Whether the food meets the criteria for priority inspection for section 801(h).

(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, 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) arrangements 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) accreditation of seafood names, inspection records, and laboratory testing to improve interagency coordination;

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

(E) a process, including the use or modification of existing processes, by which officers and employees of the Department of Homeland Security, the Environmental Protection Agency, the Food and Drug Administration, or the National Oceanic and Atmospheric Administration may be duly designated by the Secretary to carry out seafood examinations and investigations under section 801 of this Act and the Sanitation, Drug, and Cosmetics Act of 2004; and

(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 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 415.

(J) ANNUAL REPORT.—Section 1003 (21 U.S.C. 393(c)) is amended by adding at the end the following:

(1) ANNUAL REPORT REGARDING FOOD.—Not later than 1 year after the Secretary submits a report to Congress required under subsection (h), the Secretary shall submit to Congress a report, including—

(A) information about food facilities including—

(i) the number of facilities identified pursuant to section 415 in the previous fiscal year;

(ii) the number of foreign facilities that are required to register under section 415;

(iii) the number of facilities that are participating in a foreign supplier verification program under section 805;

(iv) the number of high-risk facilities that were inspected in the previous fiscal year;

(v) the number of high-risk facilities that were not inspected in the previous fiscal year;

(vi) the number of high-risk facilities that the Secretary did not inspect in such fiscal year;

(vii) the number of high-risk facilities registered pursuant to section 415 that were scheduled for inspection in the previous fiscal year;

(viii) the number of high-risk facilities registered pursuant to section 412 that were scheduled for inspection in the previous fiscal year;

(b) ANNUAL REPORT REGARDING FOOD.—Section 1003 (21 U.S.C. 393(c)) is amended by adding at the end the following:

(1) IN GENERAL.—Not later than 1 year after the Secretary submits a report to Congress required under subsection (h), the Secretary shall submit to Congress a report, including—

(A) the number of high-risk facilities that were inspected 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;

(E) the number of high-risk facilities identified pursuant to section 421 that were scheduled for inspection in the previous fiscal year and which the Secretary did not inspect in such year;

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

(G) 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

(2) information on the foreign offices of the Food and Drug Administration including—

(A) the number of foreign offices established;

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

(C) the percentage of foreign offices located in each country; and

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

(E) the number of high-risk facilities that were inspected in the previous fiscal year;

(F) 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;

(G) the number of domestic facilities and the number of foreign facilities registered pursuant to section 415 that were scheduled for inspection in the previous fiscal year;

(H) 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;

(I) the number of high-risk facilities identified pursuant to section 421 that were scheduled for inspection in the previous fiscal year and which the Secretary did not inspect in such year;

(J) the number of high-risk facilities that were inspected in the previous fiscal year;

(K) 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

(L) information on the foreign offices of the Food and Drug Administration including—

(M) the number of foreign offices established; and

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

(2) ANNUAL REPORT.—The Secretary shall make the reports required under subsection (h) available to the public on the Internet Web site of the Food and Drug Administration.

(c) ADVISORY COMMITTEE CONSULTATION.—In allocating inspection resources as described in subsection (b), the Secretary may, as appropriate, consult with any relevant advisory committee within the Department of Homeland Security.

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.

‘‘(a) RECOGNITION OF LABORATORY ACCREDITATION.—

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

(A) establish a program for the testing of food by accredited laboratories;

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

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

‘‘(2) PROGRAM REQUIREMENTS.—The program established under paragraph (1)(A) shall provide for the recognition of laboratory accreditation bodies that meet criteria established by the Secretary for accreditation of laboratories, including independent private laboratories and laboratories run and operated by a Federal agency (including the Department of Commerce, the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), the Secretary may, as appropriate, consult with any relevant advisory committee within the Department of Homeland Security.

‘‘(1) DOMESTIC HIGH-RISK FACILITIES.—In meeting the inspection requirements specified for domestic facilities, the Secretary shall—

(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 previous fiscal year;

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

(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

(D) information on the foreign offices of the Food and Drug Administration including—

(E) the number of foreign offices established; and

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

(2) ANNUAL REPORT.—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.’’.

(4) MODEL LABORATORY STANDARDS.—The Secretary shall develop model standards that a laboratory shall meet to be accredited by a recognized accreditation body. The Secretary shall make these model standards available for guidance. The Secretary shall—

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

(6) MODEL LABORATORY STANDARDS.—The Secretary shall develop model standards that a laboratory shall meet to be accredited by a recognized accreditation body. The Secretary shall make these model standards available for guidance. The model standards shall include—

(A) methods to ensure that appropriate sampling and analytical testing procedures (including rapid analytical procedures), and commercially available techniques are followed and reports of analyses are certified as true and accurate;

(B) internal quality systems are established and maintained;
(iii) procedures exist to evaluate and respond promptly to complaints regarding analyses and other activities for which the laboratory is accredited; and

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

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

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

(A) shall periodically, and in no case less than once every 3 years, reevaluate accreditation bodies recognized under paragraph (1) and may accredit one or more such bodies from an accreditation body that is not in compliance with the criteria for recognition; and

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

(8) TESTING PROCEDURES.—

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

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

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

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

(B) on behalf of an owner or consignee—

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

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

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

(III) 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) use of such methodology or methodologies is necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak.

(IV) 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 need for a national recall or other compliance and enforcement activities.

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

(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 a network to receive complaints from Congress, and make publicly available on the Internet Web site of the Department of Health and Human Services, a report on the progress in implementing a national food emergency response laboratory network that—

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

(2) coordinates the food laboratory capacities of State, local, and tribal food laboratories, including laboratories conducting independent risk assessment and identification technologies and the sharing of data between Federal agencies and State laboratories to develop national situational awareness;

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

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

(5) responds to food-related emergencies; and

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

SEC. 203. INTEGRATED CONSORTIUM OF LABORATORY NETWORKS.

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

(1) agree on common laboratory methods in order to reduce the time required to detect and respond to foodborne illness outbreaks and facilitate the sharing of knowledge and information relating to animal health, agriculture, and human health;

(2) identify means by which laboratory network members could work cooperatively—

(A) to optimize national laboratory preparedness and

(B) to provide surge capacity during emergencies;

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

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

SEC. 204. ENHANCING TRACKING AND TRACING OF FOOD AND RECORDKEEPING.

(A) PILOT PROJECTS.—

(I) IN GENERAL.—Not later than 270 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary"), taking into account recommendations from the Secretary of Agriculture and representatives of State departments of health and agriculture, shall establish pilot projects in coordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of such Act, not later than 2 years after the date of enactment of this Act.

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

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

(B) develop and demonstrate appropriate technologies, including technologies used in the pilot projects under subsection (a); and

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

(III) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary shall report to Congress on the findings of the pilot projects under this subsection together with recommendations for improving the tracking and tracing of food.

(b) ADDITIONAL DATA GATHERING.—

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

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

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

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

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

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

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

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

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

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

(1) IN GENERAL.—In order to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of such Act, not later than 2 years after the date of enactment of this Act, the Secretary shall publish a notice of proposed rulemaking to establish recordkeeping requirements, in addition to the requirements under section 414 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 340a) and subpart 1 of part 1 of title 21, Code of Federal Regulations (or any successor
(A) relate only to information that is reasonably available and appropriate;
(B) based on science;
(C) not prescribe specific technologies for the maintenance of records;
(D) ensure that the public health benefits of imposing additional recordkeeping requirements outweigh the cost of compliance with such requirements;
(E) be scale-appropriate and practicable for facilities of varying sizes and capabilities with respect to costs and recordkeeping burdens, and not require the creation and maintenance of duplicate records where the information is contained in other company records kept in the normal course of business;
(F) minimize the number of different recordkeeping requirements for facilities that handle more than 1 type of food;
(G) to the extent practicable, not require a facility to change business systems to comply with such requirements;
(H) allow any person subject to this subsection to maintain records required under this subsection at a central or reasonably accessible location provided that such records can be made available to the Secretary not later than 24 hours after the Secretary requests such records; and
(I) include a process by which the Secretary may issue a waiver of the requirements under this subsection if the Secretary determines that such requirements would result in an economic hardship for an individual facility or a type of facility.

(3) PROTECTION OF SENSITIVE INFORMATION.—

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

(A) unauthorized reproduction of trade secret or confidential information;
(B) prevent unauthorized access to trade secret or confidential information; and
(C) maintain the confidentiality of any trade secret or confidential information.

(4) RECORDKEEPING FOR HIGH-RISK FOODS.—

In the case of high-risk foods, the Secretary may require that a facility retain records under this subsection for not more than 2 years, taking into consideration that the 2 years, taking into consideration the magnitude, location, and extent of the potential risk to public health.

(5) RECORDKEEPING REQUIREMENTS.—

The recordkeeping requirements under this subsection shall not apply to—

(i) a farm that was the source of such food.

(ii) a facility that manufactures, processes, packs, or holds such food.

(iii) the median 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 a farm.)

The requirements under this subsection shall not apply to a farm, food facility, or other person if the Secretary determines that such requirements would result in an economic hardship for an individual facility or a type of facility.

(6) EXEMPTION OF OTHER FOODS.—The Secretary may, by notice in the Federal Register, modify the requirements under this subsection with respect 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.

(7) NO IMPACT ON NON-HIGH-RISK FOODS.—The recordkeeping requirements established under this subsection with respect to any commingled raw agricultural commodity shall be limited to the requirements under subpart D of part 121 of this chapter.

(8) DEFINITIONS.—For the purposes of this paragraph—

(i) 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 streamlined 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

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

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

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 streamlined 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, grading, pasteurization, or homogenization.

(10) E XEMPTION OF OTHER FOODS.—The Secretary may, by notice in the Federal Register, modify the requirements under this subsection with respect 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.

(11) RECORDKEEPING REGARDING PREVIOUS SOURCES AND SUBSEQUENT RECIPIENTS.—In the case of a person or food to which a limitation or exemption under subparagraph (C) applies, if such person, or a person who manufactures, processes, packs, or holds such food, is required to keep records under part 121 of the Federal Food, Drug, and Cosmetic Act, the person shall maintain records with respect to a sale of a food described in subparagraph (I) (including a sale of a food that is produced and packaged on a farm.)

(12) 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 a consumer store.

(13) NO IMPACT ON NON-HIGH-RISK FOODS.—The recordkeeping requirements established under paragraph (1) shall have no effect on foods that are not designated by the Secretary under paragraph (2) as high-risk foods.

(a) The term "high-risk food" means food that is processed, manufactured, packed, or held in a facility subject to this section to maintain records required under this section, the Secretary shall take appropriate measures to ensure that there are effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section, including periodic risk assessment and planning to prevent unauthorized release and controls to—

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

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

(C) maintain the confidentiality of any trade secret or confidential information.

(b) RECORDKEEPING REQUIREMENTS.—

The recordkeeping requirements under this subsection shall not apply to a farm, food facility, or other person if the Secretary determines that such requirements would result in an economic hardship for an individual facility or a type of facility.

(c) EXEMPTION OF OTHER FOODS.—The Secretary may, by notice in the Federal Register, modify the requirements under this subsection with respect 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.

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

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 streamlined 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

(e) EVALUATION AND RECOMMENDATIONS.—

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

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

(B) the participation of restaurants in the recordkeeping requirements for restaurants and additional foods, in order to protect the public health.

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

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

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

(C) was adulterated as described in subparagraph (A) on a particular farm (as defined in section 1.227 of chapter 21, Code of Federal Regulations (or any successor regulations)).

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

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

(4) LIMITATION.—A request made under paragraph (1) shall not include a request for information, identities, prices, prices per commodities produced, personnel, research, sales (other than information relating to shipping), or other disclosures that may reveal trade secrets or confidential information from the food supply chain to which the article of food has been traced, other than information necessary to identify potential immediate recipients of such food. Section 301(j) of the Federal Food, Drug, and Cosmetic Act and the Freedom of Information Act shall apply with respect to any confidential commercial information that is disclosed to the Federal Food and Drug Administration.

(5) RECORDS.—Except with respect to identifying potential immediate recipients in response to a request under paragraph (1), this subsection shall require the establishment or maintenance by farms of new records.

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

(h) SMALL BUSINESS COMPLIANCE GUIDANCE.—Not later than 180 days after promulgation of a final rule under subsection (d), the Secretary shall issue a small entity compliance guide setting forth in understandable terms the recordkeeping requirements under such subsection in order to assist small entities, including farms and small businesses, in complying with the recordkeeping requirements under such subsection.

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

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

(j) ENFORCEMENT.—

(1) PROHIBITED ACTS.—Section 301(e) (21 U.S.C. 331(e)) is amended by inserting "or (4) the recordkeeping requirements under section 204 of the FDA Food Safety Modernization Act (except when such violation is committed by a farm)" before the period at the end of clause (2).

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

SEC. 205. SURVEILLANCE.

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

(b) FOODBORNE ILLNESS SURVEILLANCE SYSTEMS.

(I) 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 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 notification tools for foodborne infectious agents, in order to identify new or rarely documented causes of foodborne illness and submit standardized information to a centralized database; and

(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 and other research entities; (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

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

(2) WORKING GROUP.—The Secretary shall supplement 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 agencies at the Federal, State, and local levels of government;

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

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

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

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

(3) AUTHORIZATION OF APPROPRIATIONS.—To carry out the activities described in paragraph (2), there is authorized to be appropriated $24,000,000 for each fiscal years 2011 through 2015.

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

(I) IN GENERAL.—The Secretary shall develop and implement strategies to leverage and enhance food safety and defense capacities of State and local agencies 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 to appropriate agencies and conducting more standardized outbreak investigations.

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

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

(E) Share information on a timely basis among public health, food, and food testing industries, with the food industry, with health care providers, and with the public.
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(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 not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, complete a review of State and local capacities, and make recommendations, which may include a survey with respect to—

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

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

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

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

(3) Report.—The Secretary shall submit a report to Congress on the results of the review conducted under paragraph (2). The report shall be submitted not later than 1 year after the date of enactment of this Act.

(4) Implementation.—Not later than 1 year after the date of enactment of this Act, the Secretary shall submit to Congress a report that—

(A) includes a description of the progress of the implementation of the strategies required by paragraph (1); and

(B) provides a timetable for the completion of such strategies and provides an implementation plan for each strategy described in the report under paragraph (2).

SEC. 207. MODERNIZED FOOD-SAFETY INFRASTRUCTURE.

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

(A) describes the progress of the implementation of this Act; and

(B) provides recommendations for improvements to the food-safety system for the United States.

(2) Implementation.—The Secretary shall submit a report to Congress on the results of the review conducted under paragraph (1). The report shall be submitted not later than 3 years after the date of enactment of this Act.

(3) Inclusion of State and Local Government.—The report submitted under paragraph (2) shall include a summary of the views of State and local governments regarding the implementation of this Act.
SEC. 205. 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. 206. DECONTAMINATION AND DISPOSAL STANDARDS AND PLANS.

(a) IN GENERAL.—The Administrator of the Environmental Protection Agency (referred to in this section as the "Administrator"), in coordination with the Secretary of Health and Human Services, Secretary of Homeland Security, and Secretary of Agriculture, shall develop standards and plans for—

(1) preventing contamination of agriculture or food; and

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

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

(c) E XERCISES.—In carrying out subsection (a), the Administrator, in coordination with the entities described in subsection (d), shall carry out, in consultation with the Secretary of Health and Human Services, Secretary of Agriculture, and State, local, and tribal governments, an exercise or an assessment based on the national exercise program under section 648(b)(1) of the Post-Katrina Emergency Management Reform Act of 2006 (6 U.S.C. 740(b)(1)).

(d) MODIFICATIONS.—Based on the exercises described in subsection (d), the Administrator, in coordination with the entities described in subsection (b), shall develop new plans and protocols or modify existing plans and protocols to—

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

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

(e) EXERCISES.—In carrying out subsection (a), the Administrator, in coordination with the entities described in subsection (b), shall conduct and evaluate exercises and identify weaknesses in the decontamination and disposal model plans described in subsection (c). Such exercises shall be carried out, at least once but no less frequently than biennially, pursuant to the national exercise program under section 648(b)(1) of the Post-Katrina Emergency Management Reform Act of 2006 (6 U.S.C. 740(b)(1)).

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

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

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

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

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

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

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

(1) TRAINING.—The Secretary shall set standards and administer training and education programs for the employees of State, local, territorial, and tribal food safety officials responsible for the regulation and enforcement of the laws and policies established by this Act, including programs for—

(1) scientific training;

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

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

(4) training that addresses best practices;

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

(6) training in building enforcement actions focusing on inspections, examinations, testing, and investigations;

(7) partnerships with State and local officials;

(8) extension service;

(9) extension service; and

(10) national food safety training, education, extension, outreach and technical assistance program.

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

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

(4) EXTENSION SERVICE.—The Secretary shall ensure coordination with the activities of the National Institute of Food and Agriculture of the Department of Agriculture in advancing producers and small processors transitioning into new practices required as a result of the enactment of the FDA Food Safety Modernization Act and assisting regulated industry with compliance with such Act.

(5) NATIONAL FOOD SAFETY TRAINING, EDUCATION, EXTENSION, OUTREACH AND TECHNICAL ASSISTANCE PROGRAM.—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 memorandum of understanding with the Secretary of Agriculture to establish a competitive grant program within the National Institute for Food and Agriculture to provide food safety training, education, extension, outreach, and technical assistance to—

(A) owners and operators of farms;

(B) small food processors; and

(C) small fruit and vegetable merchant wholesalers.

(6) 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

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

(a) In general.—The Secretary shall award grants under this section to carry out the competitive grant program established under section 101(d) of the Food, Drug, and Cosmetic Act, pursuant to any memorandum of understanding entered into under such section.

(b) Integrated approach.—The grant program authorized under subsection (a) shall be carried out under this section in a manner that facilitates the integration of food safety standards and guidance with the variety of agricultural production systems, encompassing 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 processors, and environmental practices.

(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 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-governmenal organization, or an organization representing owners and operators of farms, small food processors, or small fruit and vegetable merchants that has a commitment to public health and expertise in administering programs that contribute to food safety;

(C) a public or private 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—

(A) geographic diversity; and

(B) 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.

(g) Program coordination.—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 processors, small food processors, and small fresh fruit and vegetable merchant wholesalers.

(h) Authorization of appropriations.—For the purposes of making grants under this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2011 through 2015.

SEC. 210. ENHANCING FOOD SAFETY.

(a) Grants to enhance food safety.—Section 1009 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 399) is amended to read as follows:

SEC. 1009. GRANTS TO ENHANCE FOOD SAFETY.

(a) In general.—The Secretary is authorized to make grants to eligible entities for—

(1) undertake examinations, inspections, and investigations, and related food safety activities under section 404 of the Agricultural Research, Extension, and Education Reform Act of 1998 as amended by section 404 (7 U.S.C. 7624) the following:

(A) geographic diversity; and

(B) diversity of types of agricultural production.

(2) 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.

(b) Multistate partnerships.—The grant program authorized under subsection (a) shall be carried out under this section in a manner that facilitates the integration of food safety standards and guidance with the variety of agricultural production systems, encompassing 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 processors, and environmental practices.

(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 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, this entity under this section after such entity has received 3 years of grant funding under this section.

(2) Multipart state partnerships.—Grants under this section may be made for projects involving more than 1 State.

(h) Program coordination.—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 processors, small food processors, and small fresh fruit and vegetable merchant wholesalers.

(i) 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. 399V–5. FOOD SAFETY INTEGRATED CENTERS OF EXCELLENCE.

(a) In general.—Not later than 1 year after the date of enactment of this Act or the FDA Food Safety Modernization Act (and any amendment made by such Act), including the grant program authorized under the FDA Food Safety Modernization Act (and any amendment made by such Act), the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the working group described in subsection (b)(2), shall designate 5 Integrated Food Safety Centers of Excellence (referred to in this section as the ‘Centers of Excellence’) to serve as resources for Federal, State, and local public health professionals to respond to foodborne illnecessaries. Such Centers of Excellence shall be headquartered at selected State health departments.
Title III—Improving the Safety of Imported Food

SEC. 301. FOREIGN SUPPLIER VERIFICATION PROGRAM.

(a) In General.—Section 301 (21 U.S.C. 331) 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 Food Safety Modernization Act, the Secretary may require a responsible party to submit to the Secretary consumer information concerning a reportable food, which shall include—

"(1) a description of the article of food as provided in subsection (a);

"(2) as provided in subsection (e)(7), affected product identification codes, such as UPC, SKU, or lot or batch numbers sufficient for the consumer to accurately identify the food;

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

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

"(g) Grocery Store Notification.—

"(1) Action by Secretary.—The Secretary shall—

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

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

"(2) Action by Grocery Store.—A notification described under paragraph (1)(B) shall include the date and time such summary was posted on the Internet website of the Food and Drug Administration;

"(h) Consumer Notification.—

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

"(2) List of Conspicuous Locations.—Not more than 1 year after the date of enactment of the Food Safety Modernization Act, the Secretary shall publish a list of acceptable conspicuous locations and manners, from which grocery stores shall select at least one, for purposes of this subsection. Such list shall include—

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

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

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

"(D) other such prominent and conspicuous locations and manners utilized by grocery stores as of the date of the date of the 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).

"(zz) Conforming Amendment.—Section 303(e) (21 U.S.C. 333(e)) is amended by striking "417(e)(2)" and inserting "417(e)(1)"

"(c) Record Maintenance and Access.—

"(1) Verification Requirement.—Except as provided under subsections (e) and (f), each importer shall perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported by the importer or agent of import is—

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

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

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

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

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

"(d) Guidance.—Not later than 1 year after the date of enactment of the Food Safety Modernization Act, the Secretary shall issue guidance to assist foreign suppliers in developing foreign supplier verification programs.

"(e) Regulations.—In General.—Not later than 1 year after the date of enactment of the Food Safety Modernization Act, the Secretary shall promulgate regulations to provide for the content of the foreign supplier verification program established under subsection (a).

"(2) Requirements.—The regulations promulgated under paragraph (1) shall require that the foreign supplier verification program of each importer be adequate to provide assurances that each foreign supplier to the importer produces the imported food in compliance with—

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

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

"(B) shall include such other requirements as the Secretary deems necessary and appropriate to ensure that foreign suppliers produce food in a manner that is safe and suitable for human consumption.

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

"(g) Record Maintenance and Access.—Records of an importer related to a foreign supplier verification program under this section may include monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier, and periodically testing and sampling shipments.

"(h) Exemption of Seafood, Juice, and Low-Acid Canned Food Facilities in Compliance with HACCP.—This section shall not apply to a facility if the owner, operator, or agent is a producer of such facility or is required to comply with, and is in compliance with, 1 of the following standards and regulations with respect to such facility:

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

"(2) The Juice Hazard Analysis Critical Control Points Program of the Food and Drug Administration.
SEC. 301. VOLUNTARY QUALIFIED IMPORTER PROGRAM.

(a) In General.—Beginning not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall—

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

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

(B) consistent with section 808, establish a process of importation of 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, relocation 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 importer 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 following factors:

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

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

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

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

(5) the recordkeeping, testing, inspections and audits of the safety history of articles of 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.

(c) ADDITIONAL REQUIREMENTS.—In addition to the requirements of subsection (b), the Secretary shall consider the following factors in determining whether the importer is eligible for the program:

(1) the prior compliance history of the importer.

(2) the compliance of the importer with the requirements of section 805.

(3) the potential risk for intentional adulteration of the food.

(4) any other factor that the Secretary determines appropriate.

(d) CERTIFICATION.—For purposes of paragraph (3), entities that provide such certification or assurances as described in such paragraph are—

(A) the Secretary or the Secretary of Agriculture; or

(B) any other person or entity accredited pursuant to section 808 to provide such certification or assurance.

(b) PROHIBITED ACT.—Section 301 (21 U.S.C. 351), as amended by section 201, is amended by adding at the end of the section the following:

(2) prohibit the importation of food, or causes food to be brought, from a foreign country into the customs territory of the United States, that an entity described in paragraph (3) provide a certification, or such other assurances as the Secretary determines appropriate, that such food complies with applicable requirements of this Act, then such article shall be refused admission.

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

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

(a) IN GENERAL.—Section 801(a) (21 U.S.C. 381(a)) is amended by adding at the end of such section the following:

(4) REQUIREMENTS.—An importer who requests the Secretary to provide for the expedited review and importation of food offered for importation by the 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 have the same force and effect as a similar statement or representation made by the importer to an agency of the United States.

(b) REGULATIONS.—Not later than 120 days after the date of enactment of this Act, the Secretary shall—

(1) establish regulations, in consultation with the Secretary of Agriculture, to carry out this subsection.

(2) issue a guidance document related to participation in, relocation of such participation in, reinstatement in, and compliance with, such program.

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

(a) IN GENERAL.—The Secretary may require, as a condition for entry into the United States, that an entity described in paragraph (4) provide a certification, or such other assurances as the Secretary determines appropriate, that the article of food complies with applicable requirements of this Act. Such certification or assurances may be provided in the form of shipment-specific certificates, a listing of certified facilities that manufacture, process, pack, or hold such food, or in such other form as the Secretary determines appropriate.

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

(3) The Secretary shall—

(A) require that any certification or other assurance if the Secretary determines that such certification or assurance is not valid or reliable.

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

(c) CONFORMING TECHNICAL AMENDMENT.—Section 801(b) (21 U.S.C. 381(b)) is amended by adding at the end of such section the following:

(4) REQUIREMENTS.—An importer may request the Secretary to provide for the expedited review and importation of food, or causes food to be brought, from a foreign country into the customs territory of the United States, that an entity described in paragraph (3) provide a certification, or such other assurances as the Secretary determines appropriate, that such food complies with applicable requirements of this Act, then such article shall be refused admission.

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

SEC. 304. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.

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

(b) REGULATIONS.—Not later than 120 days after the date of enactment of this Act, the Secretary shall, to the extent practicable, establish a process by which the foreign region, country, or territory may inform the Secretary of improvements made to such food safety system, program, system, or standard and demonstrate that those controls are adequate to ensure that an article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this Act, the Secretary shall, to the extent practicable, establish a process by which the foreign region, country, or territory may inform the Secretary of improvements made to such food safety system, program, system, or standard and demonstrate that those controls are adequate to ensure that an article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this Act.

(c) 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.

(b) CONSULTATION.—In developing the plan under subsection (a), the Secretary shall consult with the Secretary of Agriculture, the Secretary of State, the Secretary of the Treasury, the Secretary of Homeland Security, the United States Trade Representative, and the Secretary of Commerce, all representatives of the food industry, appropriate foreign government officials, nongovernmental organizations that represent the interests of consumers, and appropriate foreign trade organizations.

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

(1) Recommendations for bilateral and multilateral arrangements and agreements, including provisions to provide for responsibility of exporting countries to ensure the safety of food.

(2) Provisions for secure electronic data sharing.

(3) Provisions for mutual recognition of inspection reports.

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

(5) Recommendations on whether and how to harmonize regulatory requirements under the Codex Alimentarius.

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

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

SEC. 306. INSPECTION OF FOREIGN FOOD FACILITIES.

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

"SEC. 807. INSPECTION OF FOREIGN FOOD FACILITIES.

(1) INSPECTION.—The Secretary—

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

"(2) shall direct resources to inspections of foreign facilities, suppliers, and food types, especially such facilities, suppliers, and food types that present a high risk (as identified by the Secretary), to help ensure the safety and security of the food supply of the United States.

"(b) INSPECTION TO INSPECT.—Notwithstanding any other provision of law, food shall be refused admission into the United States if it is from a foreign factory, warehouse, or other establishment of which the owner, operator, or agent in charge, or the government of the foreign country, refuses to permit entry of United States inspectors or other individuals duly designated by the Secretary, upon request, to inspect such factory, warehouse, or other establishment. For purposes of this subsection, such an owner, operator, or agent in charge shall be considered to have refused to permit an inspection if such owner, operator, or agent in charge does not permit an inspection of a factory, warehouse, or other establishment during the 24-hour period after such request is submitted, or after such other time period, as agreed upon by the Secretary and the foreign factory, warehouse, or other establishment.

(2) BY THE SECRETARY OF COMMERCE.—

(1) IN GENERAL.—The Secretary of Commerce, in coordination with the Secretary of Health and Human Services, and the Secretary of Agriculture, shall send 1 or more individuals to a country or facility of an exporter from which seafood imported into the United States originates. The inspectors shall assess practices and procedures of such country or facility in connection with, among other things, cultivation, harvesting, preparation for market, or transportation of such seafood and may provide technical assistance related to such activities.

(2) INSPECTION REPORT.—

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

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

(ii) provide a country or exporter that is the subject of the report, and

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

(B) DISTRIBUTION AND USE OF REPORT.—The Secretary of Health and Human Services shall—

(i) 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 201.

SEC. 307. ACCREDITATION OF THIRD-PARTY AUDITORS.

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

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

(1) DEFINITIONS.—In this section:

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

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

"(3) THIRD-PARTY AUDITOR.—The term 'third-party auditor' means a foreign government, agency of a foreign government, foreign cooperative, or any other third party, as the Secretary determines appropriate in accordance with the model standards described in subsection (b)(2), that is eligible to be considered for accreditation to conduct food safety audits to certify that eligible entities meet the applicable requirements of this section. A third-party auditor may be a single individual. A third-party auditor may employ or use audit agents to help conduct consultative and regulatory audits.

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

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

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

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

"(6) ELIGIBLE ENTITY.—The term 'eligible entity' means a foreign entity, including a foreign government that meets the requirements of this section.

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

(A) 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 effectively ensuring the safety of foods certified by such government or agency meet the requirements of this Act with respect to food manufactured, processed, packed, or held for import into the United States.

(B) FOREIGN COOPERATIVES AND OTHER THIRD PARTIES.—Prior to accrediting a foreign cooperative that aggregates the products of growers or other third parties 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 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 effectively ensuring the safety of 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.

(3) ELIGIBILITY.—The term 'eligible entity' means a foreign entity, including a foreign government, that meets the applicable requirements of this section.
(A) IN GENERAL.—An accreditation body (or, if no body, an entity or accreditation under subsection (b)(1)(A)(ii), the Secretary) may not accredit a third-party auditor unless such third-party auditor agrees to issue a written and, as appropriate, electronic food certification, described in section 801(q), or facility certification under section 806(a), as appropriate, to accompany each food shipment for import into the United States. Such written or electronic certification may be included with other documentation regarding such food shipment. The Secretary shall con sider certifications under section 801(q) and participation in the voluntary qualified importer program described in section 806 when targeting inspection resources under section 421.

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

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

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

(2) 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 under subparagraph (B) only after conducting a regulatory audit and such other activities that may be necessary to establish compliance with the requirements of such sections.

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

(3) AUDIT REPORT SUBMISSION REQUIREMENTS.—

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

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

(ii) the dates of the audit;

(iii) the scope of the audit; and

(iv) any other information required by the Secretary that relates to or may influence an assessment of 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 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 of the eligible entity in compliance with any applicable registration requirements.

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

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

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

(ii) such conditions.

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

(C) LIMITATIONS.—

(i) IN GENERAL.—An accredited third-party auditor may not perform a regulatory audit of an eligible entity if such agent has performed a consultative audit or a regulatory audit of such eligible entity during the previous 12-month period.

(ii) WAIVER.—The Secretary may waive the application of clause (i) if the Secretary determines that there is insufficient access to accredited third-party auditors in a country or region.

(5) CONFLICTS OF INTEREST.—An accredited third-party auditor shall—

(i) not own or operate an eligible entity to be certified by such auditor;

(ii) in carrying out audits of eligible entities under this section, have procedures to ensure that such auditor or any person that owns or operates an eligible entity to be certified by such auditor has a financial conflict of interest regarding an eligible entity to be certified by such auditor;

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

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

(i) own or operate an eligible entity to be audited by such agent; and

(ii) in carrying out audits of eligible entities under this section, have procedures to ensure that such audit agent has maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

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

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

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

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

(6) WITHDRAWAL OF ACCREDITATION.—

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

(i) if food certified under section 801(q) or from a facility certified under this Act is used in the manufacture of food certified under section 801(q), the Secretary determines that the food or facility is not in compliance with the requirements set forth in this section.

(B) ADDITIONAL BASIS FOR WITHDRAWAL OF ACCREDITATION.—The Secretary may withdraw accreditation from an accredited third-party auditor in the case that such third-party auditor satisfied the requirements under section 801(q) of certifying the food, or the requirements under paragraph (2)(B) of certifying the eligible entity.

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

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

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

(D) NEUTRALIZING COSTS.—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 reimbursements. Such regulations shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees shall be authorized to remain available until expended.

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

(i) intends to participate in voluntary qualified importer programs under section 801(q); or

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

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

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

(ii) 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, review the accreditation bodies described in subsection (b)(1); and

(2) periodically, or at least once every 4 years, evaluate the performance of any accredited third-party auditor, through the review of regulatory audit reports by such auditors, the compliance history as available of eligible entities 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.

(2) LIMITATIONS.—The data and information described in this section shall not be considered inspections under section 704.

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

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 for the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and the Center for Food Safety and Applied Nutrition, $400,000,000 for each of fiscal years 2012 through 2015.

(b) INVESTIGATION.—If the Secretary concludes that there is reasonable cause to believe that the complainant has been discharged or otherwise discriminated against by any person in violation of subsection (a) has occurred, the Secretary shall accompany the Secretary's findings with a preliminary order providing the relief prescribed by paragraph (1)(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 under this subsection and shall not conduct an investigation otherwise required under subparagraph (A) unless the complainant makes a prima facie showing that any behavior described in paragraphs (1) through (4) of subsection (a) was a contributing factor in the unfavorable personnel action alleged in the complaint.

(2) STANDARDS FOR COMPLAINT.—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 in the absence of that behavior.

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

(2) FINAL ORDER.—Not later than 120 days after the date of conclusion of any hearing under paragraph (2), the Secretary shall issue a
final order providing the relief prescribed by this paragraph or denying the complaint. At any time before issuance of a final order, a proceeding under this subsection may be terminated on the agreement of the parties. An agreement entered into by the Secretary, the complainant, and the person alleged to have committed the violation. If, in the opinion of the Secretary, a complaint filed under paragraph (1), the Secretary determines that a violation of subsection (a) has occurred, the Secretary shall order the person alleged to have committed such a violation—

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

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

(iii) to provide compensatory damages to the complainant.

(C) PENALTY.—If such an order is issued under this paragraph, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorneys’ and expert witness fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

(D) BAD FAITH CLAIM.—If the Secretary finds that a complaint under paragraph (1) is frivolous or without merit, the Secretary may award to the prevailing employer a reasonable attorneys’ fee, not exceeding $1,000, to be paid by the complainant.

(4) IN COURT.

(A) IN GENERAL.—If the Secretary has not issued a final decision within 210 days after the filing of the complaint, or within 90 days after receiving a request for reconsideration, the complainant may bring an action at law or equity for de novo review in the appropriate district court of the United States with jurisdiction, which shall have jurisdiction over such an action without regard to the amount in controversy or the citizenship of the parties, to enforce such order.

(B) AWARD.—The court, in issuing any final order under this paragraph, may award costs of litigation (including reasonable attorneys’ and expert witness fees) to any party whenever the court determines such award is appropriate.

(C) EFFECT OF SECTION.—

(i) OTHER LAWS.—Nothing in this section preempts or diminishes any other safeguards against discrimination, demotion, discharge, suspension, threats, harassment, reprisal, re- 

termination, or any other matter of discrimination provided by Federal law.

(ii) RIGHTS OF EMPLOYEES.—Nothing in this section shall be construed to diminish the rights, privileges, or remedies of any employee under any Federal or State law or under any collective bargaining agreement. The rights and remedies in this section may not be waived by any agreement, policy, form, or condition of employment.

(D) NONDISCRETIONARY DUTY.—Nothing in this section shall be enforceable by this Act, but non discretionary duty imposed by this section shall be enforceable in a mandamus proceeding brought under section 1361 of title 28, United States Code.

(E) LIMITATION.—Subsection (a) shall not apply with respect to an employee of an entity engaged in the manufacture, processing, pack- 

ing, transporting, distribution, reception, hold- ing, or importation of food who, acting without direction from such entity (or such entity’s agent), deliberately causes a violation of any re- 

quirement relating to any violation or alleged violation of any order, rule, regulation, standard, or ban under this Act.’’.

SEC. 403. JURISDICTION; AUTHORITIES.

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

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

(2) alter the jurisdiction between the Alcohol and Tobacco Tax and Trade Bureau and the Secretary of Health and Human Services, under applicable statutes, regulations, or executive order.

(3) limit the authority of the Secretary of Health and Human Services under—

(A) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or

(B) the Public Health Service Act (42 U.S.C. 201 et seq.) as in effect on the day before the date of enactment of this Act; or

(C) the Egg Products Inspection Act (21 U.S.C. 531 et seq.);

(D) the United States Grain Standards Act (7 U.S.C. 17 et seq.); or

(E) the Packers and Stockyards Act, 1921 (7 U.S.C. 181 et seq.);

(F) the United States Warehouse Act (7 U.S.C. 214 et seq.); and

(G) the Agricultural Marketing Act of 1946 (7 U.S.C. 1521 et seq.); and

(H) the Agricultural Adjustment Act (7 U.S.C. 601 et seq.); reenacted with the amendments made by the Agricultural Marketing Agreement Act of 1937, or

amended, or extended, or otherwise affected under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or any other statute, including any au- thority relating to the administrative activities of the Federal Government, which shall have jurisdiction over such an action without regard to the amount in controversy or the citizenship of the parties, to enforce such order.

(4) ACTION IN COURT.—

(A) IN GENERAL.—A person on whose behalf an order is issued under paragraph (2) may commence a civil action against the person to whom such order was issued to require compliance with such order. The appropriate United States district court shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to enforce such order.

(B) AWARD.—The court, in issuing any final order under this paragraph, may award costs of litigation (including reasonable attorneys’ and expert witness fees) to any party whenever the court determines such award is appropriate.

(C) EFFECT OF SECTION.—

(i) OTHER LAWS.—Nothing in this section preempts or diminishes any other safeguards against discrimination, demotion, discharge, suspension, threats, harassment, reprisal, re- 
termination, or any other matter of discrimination provided by Federal law.

(ii) RIGHTS OF EMPLOYEES.—Nothing in this section shall be construed to diminish the rights, privileges, or remedies of any employee under any Federal or State law or under any collective bargaining agreement. The rights and remedies in this section may not be waived by any agreement, policy, form, or condition of employment.

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ing, transporting, distribution, reception, hold- ing, or importation of food who, acting without direction from such entity (or such entity’s agent), deliberately causes a violation of any re- 

quirement relating to any violation or alleged violation of any order, rule, regulation, standard, or ban under this Act.’’.

SEC. 404. COMPLIANCE WITH INTERNATIONAL AGREEMENTS.

Nothing in this Act (or an amendment made by this Act) shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party.

SEC. 405. DETERMINATION OF BUDGETARY EFFECTS.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled “Budgetary Effects of PAYGO Legislation” for this Act, submitted for printing in the Congressional Record by the Chairman of the Senate Budget Committee or the Appropriations Committee, as provided, if any, and if not, in accordance with the PAYGO provisions of section 251(b) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended.

MOTION TO CONCUR

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

The Clerk read as follows:

Mr. DINGELL. Mr. Speaker, I now yield 4 minutes to the gentleman from Michigan (Mr. WAXMAN) and the gentleman from Pennsylvania (Mr. PITTS) each to control 30 minutes.

The Chair recognizes the gentleman from Michigan.

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.

I move the Gentleman from Michigan (Mr. DINGELL) and the gentleman from Pennsylvania (Mr. PITTS) each be given 30 minutes.

Mr. WAXMAN. 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.

Mr. DINGELL. Mr. Speaker, I now yield 4 minutes to the gentleman from California (Mr. WAXMAN), the distinguished 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, Congresswoman RADMIRE and STUPAK, Mr. BARTON and Mr. SHIMKUS, and former Representative Deal for the work on this legislation.

Mr. DINGELL. Mr. Speaker, I now yield 4 minutes to the gentleman from Michigan (Mr. WAXMAN) and the gentleman from Pennsylvania (Mr. PITTS) each to control 30 minutes.

The Chair recognizes the gentleman from Michigan.
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 bill, and we voted on it.

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 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 Senate was 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 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 committee and staff, 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 hard work of Chairmen WAXMAN, Chairman Emeritus DINGELL, Chairman PALLONE, Chairman STUPAK, Governor-Elect Deal, and Ranking Member SHINNUS.

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, we asked the 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 that how 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 later, the majority says 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 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 it’s critical that we set up 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. The result is that we can’t do what we did 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, who can shake our heads at the vulnerability of our food supply and bemoan 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 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 backed by a broad 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 our consumers and ranchers. It will contain 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 that 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 protection 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 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 common-sense measure to improve food safety. Now, however, the law requires food facilities to register 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 to take over 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 the FDA on the farm.

The vast majority of these provisions, along with the recordkeeping requirements, traceability, mandatory recall authority, will do absolutely nothing to prevent food-borne disease outbreaks from occurring but will do plenty, do plenty, to keep Federal bureaucrats busy. And these are all the sorts of things that could be worked out through the normal legislative process, but only if there’s a process.

Mr. Speaker, let me return to where I started. We have the safest food supply in the world. Anyone who follows current events knows that our food production system faces ongoing food safety challenges, and I stand ready to work with my colleagues, all of my colleagues, to address these challenges.

Our Nation’s farmers, ranchers, packers, processors, retailers, and consumers deserve better.

Mr. DINGELL. Mr. Speaker, I yield 3 minutes to the distinguished gentleman from Michigan (Mr. STUPAK), who has been the chairman of our Oversight and Investigation Subcommittee, who’s done the wonderful investigative work that has brought us to where we are in exposing the dangers to our food supply by imports and other things, with my commendations and good wishes.

Mr. STUPAK. I thank the gentleman for yielding and for the kind words. As I wrap up my 18 years in the U.S. House of Representatives, this is a good bill in which to wrap up a career. I first introduced food safety legislation along with Mr. DINGELL and Mr. PALONE and now-Senator BROWNBACK in 1997. For 14 years we have been fighting to try to update our Nation’s food safety laws.

And then as chair of Oversight and Investigations, we have held over 13 hearings on food-borne illnesses from spinach, peanut butter, jalapenos, and most recently tainted eggs. Why was all this necessary? As has been noted, food laws have existed since 1938. And we know more and more of our foods are coming from different sources and different countries. But this year and each year approximately 77 million Americans become ill because of food-borne illnesses. Over 32,000 Americans are hospitalized, and up to 5,000 Americans will die, some of our most vulnerable Americans, such as children and senior citizens, those whose immune systems have been weakened or are not fully developed.

But if you are a young child and you do survive, what kind of life do you have after you have spent time in a hospital getting a new kidney? You won’t be able to travel, and you’re never going to be able to have that one particular piece of food you loved. And you have to live with that for the rest of your life. And then as chair of Oversight and Investigations, we have held over 13 hearings on 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. We do not have the right to take any of these products off our market, even though they are manufactured by foreign companies. This is just not right. And this is why today, I urge my colleagues to support this bill.

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 against food-borne illnesses. It’s not an accident; it’s not a matter of will; it’s not intentional; it’s not 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.
Mr. BARTON. 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 who worked with us, especially Chairman DINGELL, Chairman WAXMAN, Mr. FALLONE, Mr. UPTON, and Mr. BARTON.

Mr. MITTEN. 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. DELAURO. 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 Americans 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 Chairwoman FRANK Pallone, Mr. BART STUPAK, and colleagues in the next Congress to move this proposal forward.

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 of food-borne illnesses. The number of food-borne illnesses in the United States is more than 48 million per year. The CDC estimates that more than 128,000 suffer from health problems such as diarrhea, all because of food contaminated with E. coli. This should not happen to anyone. And 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 (FSIS) at USDA 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 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 health sector, 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 at the Government 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 under one roof. 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 a reduction in 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 they are taking care of their home and it's safe for their children.

Mr. PITTS. I continue to reserve the balance of my time.
Our manufacturers, our growers, and our processors do the best job in the world when they have 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 Consumers Union 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 are 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, and this one would leave the legislature 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 in more than 70 years 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 imported food, 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, and 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 time. 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, 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.

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

Mr. DINGELL. I yield myself 2 additional minutes.

It creates a new focus on prevention, and it shares responsibility between FDA and the food manufacturers so that they can cooperatively work to keep the food supply safe, working together.

It also is going to require manufacturers to implement preventive systems to stop outbreaks before they occur, and it is going to allow our Food and Drug Administration, for the first time in history, to police and to protect the entry into this country of foods coming from abroad, where most of the peril to our American consumers lie.

It also is going to allow our investigators and Food and Drug people to see to it, and this is a word of art, that the American law with regard to good manufacturing practices is carried forward in those other lands so that bad food cannot originate elsewhere and then come in to the United States because of shoddy manufacturing practices.

It gives Food and Drug power to ensure that foreign importers meet U.S. standards, and it will assure that foreign growers and producers will be treated with the same care and attention that American growers and producers are so that our growers and producers can know that they are facing an even and level playing field. It gives FDA new enforcement tools, mandatory recall authority, authority to detain tainted products, and protections for employees who serve as whistleblowers.

This legislation is long overdue. It will address a situation which is shameful.

Today, according to the latest statistics, 46 million Americans are sickened by bad food, some 128,000 are hospitalized, and 3,000 are killed yearly. We can dawdle around and let the House and the Senate wait until next year to perform this service to the safety of the American people. Whether it will be better or not is open to question.

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 impaired, not by their caringness 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 hope 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 Ms. DeLAURO. And I want to do a bit of 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 here where we are today. Senator HARKIN, Senator DURBIN, and Senator REID have contributed vitally to the success which we’ve had in making the American consuming public safe, and the president of the staff, Kallie, will understand we have served them well.

I urge my colleagues to vote for this bill, secure in the knowledge that you’re protecting 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 dispatch.

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 role in going a long way 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 the authority by with oversight of the 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 require 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; for foreign and domestic—more frequently; and 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 each year.

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 Shortening & 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 ensure the safety of food, while increasing inspections on high-risk on food facilities. Through passage of this bill, a more accurate registry of all food facilities serving American consumers would exist. It is important to provide safe and clean food for the American people, who deserve nothing but the best.

The safety and sanitation of food produced and distributed throughout the United States is of utmost importance. The health and well being of every person in this country hinges on the quality and effectiveness of the food inspection process. Without proper inspection, there is a possibility of contamination of foods and the spread of disease.

In the spring of 2008, a case of salmonella spread throughout the United States as a result of a single tainted pepper from a South Texas produce warehouse. This strain of salmonella sickened 1,251 people, led to the hospitalization of 229 people, and sadly, two deaths. The origin of the salmonella outbreak was never determined. In this event, federal and state agencies took action and required the responsible parties to recall all produce that they thought may have been tainted.

The United States in 2010, at a time when we have the newest and greatest technologies at our disposal, outbreaks like this one mentioned should not take place. With improved and modernized safety inspections, such outbreaks can be avoided and prevented.

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 tracking 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 certification to area areas requiring food imports into the United States to meet all safety requirements. The certificate would ensure that we are only allowing the safest and most healthy foods into our country for consumption by the American people.

Another important component of this legislation would ensure protection of whistleblowers that bring attention to important safety information pertaining to the food regulation and food safety. It is most vital that we afford those people who may know information about certain food the opportunity to inform authorities about any concerns they may have with their consumption.

The bill contains important provisions that address the industry concerns, which include elimination of the elimination of the so-called area areas responsible for 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 circle of 500 miles. For the millions of Americans who suffer from foodborne illness, 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 will being and health of our children, elderly and family members.

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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 quite high. Without the reality 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 food borne illness, the industry as a whole suffers from devastating loses in consumer confidence. In the long run, this is simply not sustainable, and it’s certainly not acceptable for growers or consumers.

At the very least, our nation needs a minimum food safety standard that applies to every American. And we need to help all growers understand—that any fruit or vegetable—be it naturally grown or if the produce is grown on a farm, the way to the consumer’s table.

Food producers are dedicated to continuously improving their food safety practices—inclusion of exemptions from food safety laws is a huge step backward, and will send the wrong message to the food industry. Even worse, it will send the wrong message to the food industry. Even worse, it will send the wrong message to the food industry. Even worse, it will send the wrong message to the food industry. Even worse, it will send the wrong message to the food industry.

Serious gaps have been exposed in the FDA’s ability to protect the American public from outbreaks of food-borne diseases. These outbreaks have shaken consumer confidence in the industry that produces one of our most basic and important commodities that Americans depend on daily—the food we eat.

While I prefer the stronger food safety bill that the House passed last year, the Senate-passed FDA Food Safety Modernization Act will make substantial improvements to our food safety system. It includes critical reforms that will improve the FDA’s ability to better prevent outbreaks and protect the safety of our food supply and it will allow the FDA to conduct increased inspections, enhance surveillance and traceability of food products, and give the FDA the authority to issue mandatory recalls.

Mr. Speaker, we must ensure that the FDA has the necessary tools and resources to fulfill its vital mission of helping protect the American public from unsafe products. This food safety bill is an important part of that effort. I urge my colleagues to support this legislation.

Mr. DINGELL. I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion by the gentleman from Michigan (Mr. DINGELL).

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

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

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XIX, this 15-minute vote on the motion to reconsider in the Senate amendment to H.R. 5116 will be followed by 5-minute votes on motions to recommit with respect to H.R. 2142 and H.R. 2751 and the motion to suspend on S. 3243.

Mr. BROWN of Georgia. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

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