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 chooses to do.

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

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

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

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

I know this legislation, and this legislation is probably the largest change we have had since 1993. Members, this is a bipartisan 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, where I focused my efforts on making the Federal Government more accountable. My Subcommittee held numerous hearings in which, all too often, accounting errors such as overpayment for services or redundant payments were discovered or where programs were not effectively fulfilling their intended mission.

At a time when the national debt is nearly $14 trillion, it has never been more apparent that the Federal Government must spend taxpayer dollars wisely. Federal programs must be monitored to ensure that our investments 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 and detailed evaluations outlining how effective the agency has been in achieving their stated goals. This impartial review of Federal programs will assure that agencies are being good stewards of our Federal taxpayer dollars.

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

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

This legislation provides greater 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 issued by President 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.

□ 1520

Mr. CUELLAR. 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 read the title of the bill.

The SPEAKER pro tempore. The Clerk will designate 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 made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

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

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 guidance relating to post harvest processing of raw oysters.

Sec. 115. Port shopping.
Sec. 116. Alcohol-related facilities.
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. Administrative detention of food.
Sec. 208. Decontamination and disposal standards and plans.
Sec. 209. Improving the training of State, local, territorial, and tribal food safety officials.
Sec. 210. Enhancing food safety.
Sec. 211. Improving the reportable food registry.
TITLE III—IMPROVING THE SAFETY OF IMPORTED FOOD
Sec. 301. Foreign supplier verification program.
Sec. 302. Voluntary qualified importer program.
Sec. 303. Authority to require import 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 offices of the Food and Drug Administration.
Sec. 309. Smuggled food.
TITLE IV—MISCELLANEOUS PROVISIONS
Sec. 401. Funding for food safety.
Sec. 402. Employee protections.
Sec. 403. Jurisdiction; authorities.
Sec. 404. Compliance with international agreements.
Sec. 405. Determination of budgetary effects.

TITLE I—IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS

SEC. 101. INSPECTIONS OF RECORDS.

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

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

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

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

(3) by striking the last sentence; and

(4) by inserting at the end the following:

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

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

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

SEC. 102. REGISTRATION OF FOOD FACILITIES.

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

(1) in paragraph (2), by—

(A) striking ''conducts business and'' and inserting ''conducts business, the e-mail address for the contact person of the facility or, in the case of a foreign facility, the United States agent for the facility, and''; and

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

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

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

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

(b) SUSPENSION OF REGISTRATION.—

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

(A) in subsection (a)(2), by inserting after the first sentence the following: ''The registration shall contain an assurance that the Secretary will be permitted to inspect such facility at the times and in the manner permitted by this Act.'';

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

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

''(b) SUSPENSION OF REGISTRATION.—

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

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

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

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

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

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

''(A) CORRECTIVE ACTION PLAN.—If, after providing opportunity for an informal hearing under paragraph (2), the Secretary determines that the suspension of registration remains necessary, the Secretary shall require the registrant to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by the Secretary. The Secretary shall review such plan not later than 14 days after the submission of the corrective action plan or such other time period as determined by the Secretary.

''(B) VACATING OF ORDER.—Upon a determination by the Secretary that adequate grounds do not exist to continue the suspension actions required by the order, or that such actions should be modified, the Secretary shall promptly vacate the order and reinstate the registration of the facility subject to the order or modify the order, as appropriate.

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

''(5) REGULATIONS.—

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

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

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

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

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

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

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

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

(c) CLARIFICATION OF INTENT.—

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

(A) the sale of such food products or food directly to consumers by such establishment at a roadside stand or farmers' market where such stand or market is located other than where the food was manufactured or processed;

(B) the sale and distribution of such food through a community supported agriculture program; and

(C) the sale and distribution of such food at any other such 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 249.2 of title 7, Code of Federal Regulations (or any successor regulation); and

(B) the term ''consumer'' does not include a business.

(d) CONFORMING AMENDMENTS.—

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

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

SEC. 103. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.

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

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

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

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

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

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

''(B) hazards that occur naturally, or may be unintentionally introduced; and

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

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

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

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

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

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

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

''(e) CORRECTIVE ACTIONS.—The owner, operator, or agent in charge of a facility shall establish procedures to ensure that, if the preventive controls implemented under subsection (c) are not properly implemented or are found to be ineffective—

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

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

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

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

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

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

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

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

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

''(g) RECORDKEEPING.—The owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under subsection (c), instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under subsection (f)(4), instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.

''(h) WRITTEN PLAN AND DOCUMENTATION.—The owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of this section, including analyzing the hazards under subsection (b) and identifying the preventive controls adopted under subsection (c) to address those hazards. Such written plan, together with the documentation described in subsection (g), shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

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

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

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

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

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

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

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

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

''(l) MODIFIED REQUIREMENTS FOR QUALIFIED FACILITIES.—

''(1) QUALIFIED FACILITIES.—

''(A) IN GENERAL.—A facility is a qualified facility for purposes of this subsection if the facility meets the conditions under subparagraph (B) or (C).

''(B) VERY SMALL BUSINESS.—A facility is a qualified facility under this subparagraph—

''(i) if the facility, including any subsidiary or affiliate of the facility, is, collectively, a very small business (as defined in the regulations promulgated under subsection (n)); and

''(ii) in the case where the facility is a subsidiary or affiliate of an entity, if such subsidiaries or affiliates, are, collectively, a very small business (as so defined).

''(C) LIMITED ANNUAL MONETARY VALUE OF SALES.—

''(i) IN GENERAL.—A facility is a qualified facility under this subparagraph if clause (ii) applies—

''(I) to the facility, including any subsidiary or affiliate of the facility, collectively; and

''(II) to the subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate.

''(ii) AVERAGE ANNUAL MONETARY VALUE.—This clause applies if—

''(I) during the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility (or the collective average annual monetary value of such food at any subsidiary or affiliate, as described in clause (i)) that is sold directly to qualified end-users during such period exceeded the average annual monetary value of the food manufactured, processed, packed, or held at such facility (or the collective average annual monetary value of such food at any subsidiary or affiliate, as so described) sold by such facility (or collectively by any such subsidiary or affiliate) to all other purchasers during such period; and

''(II) the average annual monetary value of all food sold by such facility (or the collective average annual monetary value of such food sold by any subsidiary or affiliate, as described in clause (i)) during such period was less than $500,000, adjusted for inflation.

''(2) EXEMPTION.—A qualified facility—

''(A) shall not be subject to the requirements under subsections (a) through (i) and subsection (n) in an applicable calendar year; and

''(B) shall submit to the Secretary—

''(i)(I) documentation that demonstrates that the owner, operator, or agent in charge of the facility has identified potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective; or

''(II) documentation (which may include licenses, inspection reports, certificates, permits,

credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), as specified by the Secretary, that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law; and

''(ii) documentation, as specified by the Secretary in a guidance document issued not later than 1 year after the date of enactment of this section, that the facility is a qualified facility under paragraph (1)(B) or (1)(C).

''(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 qualified facility subject to an exemption under this subsection, or if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility, the Secretary may withdraw the exemption provided to such facility under this subsection.

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

''(4) DEFINITIONS.—In this subsection:

''(A) AFFILIATE.—The term 'affiliate' means any facility that controls, is controlled by, or is under common control with another facility.

''(B) QUALIFIED END-USER.—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—

''(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.

''(5) STUDY.—

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

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

''(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 hazard exists; and

''(v) the effect on foodborne illness risk 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 the regulation 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 the FDA Food Safety Modernization Act, the Secretary shall submit to Congress a report that describes the results of the study conducted under subparagraph (A).

''(6) NO PREEMPTION.—Nothing in this subsection preempts State, local, county, or other non-Federal law regarding the safe production of food. Compliance with this subsection shall not relieve any person from liability at common law or under State statutory law.

''(7) NOTIFICATION TO CONSUMERS.—

''(A) IN GENERAL.—A qualified facility that is exempt from the requirements under subsections (a) through (i) and subsection (n) and does not prepare documentation under paragraph (2)(B)(i)(I) 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 business address of the facility where the food was manufactured or processed; or

''(ii) with respect to a food for which a food packaging label is not required by the Secretary under any other provisions of this Act, prominently and conspicuously display, at the point of purchase, the name and business address of the facility where the food was manufactured or processed, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or, in the case of Internet sales, in an electronic notice.

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

''(m) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—The Secretary may, by regulation, exempt or modify the requirements for compliance under this section with respect to facilities that are solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment.

''(n) REGULATIONS.—

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

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

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

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

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

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

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

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

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

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

''(5) REVIEW.—In promulgating the regulations under paragraph (1)(A), the Secretary shall review regulatory hazard analysis and preventive control programs in existence on the date of enactment of the FDA Food Safety Modernization Act, including the Grade 'A' Pasteurized Milk Ordinance to ensure that such regulations are consistent, to the extent practicable, with applicable domestic and internationally-recognized standards in existence on such date.

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

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

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

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

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

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

''(C) An environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment.

''(D) A food allergen control program.

''(E) A recall plan.

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

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

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

(c) RULEMAKING.—

(1) PROPOSED RULEMAKING.—

(A) IN GENERAL.—Not later than 9 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall publish a notice of proposed rulemaking in the Federal Register to promulgate regulations with respect to—

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

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

(B) CLARIFICATION.—The rulemaking described under subparagraph (A) shall enhance the implementation of such section 415 and clarify the activities that are included as part of the

definition of the term ''facility'' under such section 415. Nothing in this Act authorizes the Secretary to modify the definition of the term ''facility'' under such section.

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

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

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

(D) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

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

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

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

(C) the requirements under sections 418 and 421 of the Federal Food, Drug, and Cosmetic Act, as added by this Act, from which the Secretary may issue exemptions or modifications of the requirements for certain types of facilities.

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

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

''(uu) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418.''.

(f) NO EFFECT ON HACCP AUTHORITIES.—Nothing in the amendments made by this section limits the authority of the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.) to revise, issue, or enforce Hazard Analysis Critical Control programs and the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards.

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

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

(i) EFFECTIVE DATES.—

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

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

(A) the amendments made by this section shall apply to a small business (as defined in the regulations promulgated under section 418(n) of the Federal Food, Drug, and Cosmetic Act (as added by this section)) beginning on the date that is 6 months after the effective date of such regulations; and

(B) the amendments made by this section shall apply to a very small business (as defined in such regulations) beginning on the date that is 18 months after the effective date of such regulations.

SEC. 104. PERFORMANCE STANDARDS.

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

(b) GUIDANCE DOCUMENTS AND REGULATIONS.—Based on the review and evaluation conducted under subsection (a), and when appropriate to reduce the risk of serious illness or death to humans or animals or to prevent adulteration of the food under section 402 of the Federal Food, Drug, or Cosmetic Act (21 U.S.C. 342) or to prevent the spread by food of communicable disease under section 361 of the Public Health Service Act (42 U.S.C. 264), the Secretary shall issue contaminant-specific and science-based guidance documents, including guidance documents regarding action levels, or regulations. Such guidance, including guidance regarding action levels, or regulations—

(1) shall apply to products or product classes;

(2) shall, where appropriate, differentiate between food for human consumption and food intended for consumption by animals other than humans; and

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

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

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

SEC. 105. STANDARDS FOR PRODUCE SAFETY.

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

''SEC. 419. STANDARDS FOR PRODUCE SAFETY.

''(a) PROPOSED RULEMAKING.—

''(1) IN GENERAL.—

''(A) RULEMAKING.—Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary, in coordination with the Secretary of Agriculture and representatives of State departments of agriculture (including with regard to the national organic program established under the Organic Foods Production Act of 1990), and in consultation with the Secretary of Homeland Security, shall publish a notice of proposed rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death.

''(B) DETERMINATION BY SECRETARY.—With respect to small businesses and very small businesses (as such terms are defined in the regulation promulgated under subparagraph (A)) that produce and harvest those types of fruits and vegetables that are raw agricultural commodities that the Secretary has determined are low risk and do not present a risk of serious adverse health consequences or death, the Secretary may determine not to include production and harvesting of such fruits and vegetables in such rulemaking, or may modify the applicable requirements of regulations promulgated pursuant to this section.

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

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

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

''(B) include, with respect to growing, harvesting, sorting, packing, and storage operations, science-based minimum standards related to soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water;

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

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

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

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

''(4) PRIORITIZATION.—The Secretary shall prioritize the implementation of the regulations under this section for specific fruits and vegetables that are raw agricultural commodities based

on known risks which may include a history and severity of foodborne illness outbreaks.

''(b) FINAL REGULATION.—

''(1) IN GENERAL.—Not later than 1 year after the close of the comment period for the proposed rulemaking under subsection (a), the Secretary shall adopt a final regulation to provide for minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks.

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

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

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

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

''(A) the regulations promulgated under this section shall apply to a small business (as defined in the regulation promulgated under subsection (a)(1)) after the date that is 1 year after the effective date of the final regulation under paragraph (1); and

''(B) the regulations promulgated under this section shall apply to a very small business (as defined in the regulation promulgated under subsection (a)(1)) after the date that is 2 years after the effective date of the final regulation under paragraph (1).

''(c) CRITERIA.—

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

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

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

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

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

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

''(F) permit States and foreign countries from which food is imported into the United States to request from the Secretary variances from the requirements of the regulations, subject to paragraph (2), where the State or foreign country determines that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 and to provide the same level of public health protection as the requirements of the regulations adopted under subsection (b).

''(2) VARIANCES.—

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

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

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

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

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

''(e) GUIDANCE.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall publish, after consultation with the Secretary of Agriculture, representatives of State departments of agriculture, farmer representatives, and various types of entities engaged in the production and harvesting or importing of fruits and vegetables that are raw agricultural commodities, including small businesses, updated good agricultural practices and guidance for the safe production and harvesting of specific types of fresh produce under this section.

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

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

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

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

''(f) EXEMPTION FOR DIRECT FARM MARKETING.—

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

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

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

''(2) NOTIFICATION TO CONSUMERS.—

''(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 business 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, prominently and conspicuously display, at the point of purchase, the name and business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or, in the case of Internet sales, in an electronic notice.

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

''(3) WITHDRAWAL; RULE OF CONSTRUCTION.—

''(A) IN GENERAL.—In the event of 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 the 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 be construed to expand or limit the inspection authority of the Secretary.

''(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—

''(I) 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.

''(5) NO PREEMPTION.—Nothing in this subsection preempts State, local, county, or other non-Federal law regarding the safe production, harvesting, holding, 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.

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

''(g) CLARIFICATION.—This section shall not apply to produce that is produced by an individual for personal consumption.

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

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

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

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

(d) NO EFFECT ON HACCP AUTHORITIES.—Nothing in the amendments made by this section limits the authority of the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.) to revise, issue, or enforce product and category-specific regulations, such as the Seafood Hazard Analysis Critical Controls Points Program, the Juice Hazard Analysis Critical Control Program, and the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards.

SEC. 106. PROTECTION AGAINST INTENTIONAL ADULTERATION.

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

''SEC. 420. PROTECTION AGAINST INTENTIONAL ADULTERATION.

''(a) DETERMINATIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) GUIDANCE DOCUMENTS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the Secretary of Homeland Security and the Secretary of Agriculture, shall issue guidance documents related to protection against the intentional adulteration of food, including mitigation strategies or measures to guard against such adulteration as required under section 420 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

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

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

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

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

(3) LIMITED DISTRIBUTION.—In the interest of national security, the Secretary of Health and Human Services, in consultation with the Secretary of Homeland Security, may determine the time, manner, and form in which the guidance documents issued under paragraph (1) are made public, including by releasing such documents to targeted audiences.

(c) PERIODIC REVIEW.—The Secretary of Health and Human Services shall periodically review and, as appropriate, update the regulations under section 420(b) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), and the guidance documents under subsection (b).

(d) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331 et seq.), as amended by section 105, is amended by adding at the end the following:

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

SEC. 107. AUTHORITY TO COLLECT FEES.

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

''PART 6—FEES RELATED TO FOOD

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

''(a) IN GENERAL.—

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

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

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

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

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

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

''(A) the term 'reinspection' means—

''(i) with respect to domestic facilities (as defined in section 415(b)), 1 or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified noncompliance materially related to a food safety requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction; and

''(ii) with respect to importers, 1 or more examinations conducted under section 801 subsequent to an examination conducted under such provision which identified noncompliance materially related to a food safety requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction;

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

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

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

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

''(b) ESTABLISHMENT OF FEES.—

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

''(2) FEE METHODOLOGY.—

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

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

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

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

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

''(B) OTHER CONSIDERATIONS.—

''(i) VOLUNTARY QUALIFIED IMPORTER PROGRAM.—In establishing the fee amounts under subparagraph (A)(iii) for a fiscal year, the Secretary shall provide for the number of importers who have submitted to the Secretary a notice under section 806(c) informing the Secretary of the intent of such importer to participate in the program under section 806 in such fiscal year.

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

''(ii) CREDITING OF FEES.—In establishing the fee amounts under subparagraph (A) for a fiscal year, the Secretary shall provide for the crediting of fees from the previous year to the next year if the Secretary overestimated the amount of fees needed to carry out such activities, and consider the need to account for any adjustment of fees and such other factors as the Secretary determines appropriate.

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

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

''(c) LIMITATIONS.—

''(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2010 unless the amount of the total appropriations for food safety activities at the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) is equal to or greater than the amount of appropriations for food safety activities at the Food and Drug Administration for fiscal year 2009 (excluding the amount of fees appropriated for such fiscal year), multiplied by the adjustment factor under paragraph (3).

''(2) AUTHORITY.—If—

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

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

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

''(3) ADJUSTMENT FACTOR.—

''(A) IN GENERAL.—The adjustment factor described in paragraph (1) shall be the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending June 30 preceding the fiscal year, but in no case shall such adjustment factor be negative.

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

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

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

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

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

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

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

''(e) COLLECTION OF FEES.—

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

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

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

''(g) AUTHORIZATION OF APPROPRIATIONS.—For fiscal year 2010 and each fiscal year thereafter, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under the other provisions of this section.''.

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

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

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

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

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

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

''(C) For purposes of this paragraph, a certification by the Secretary shall be made on such basis, and in such form (including a publicly available listing) as the Secretary determines appropriate.''.

(3) LIMITATIONS ON THE USE AND AMOUNT OF FEES.—Paragraph (4) of section 801(e) (21 U.S.C. 381(e)) is amended by adding at the end the following:

''(D) With regard to fees pursuant to subparagraph (B) in connection with written export certifications for food:

''(i) Such fees shall be collected and available solely for the costs of the Food and Drug Administration associated with issuing such certifications.

''(ii) Such fees may not be retained in an amount that exceeds such costs for the respective fiscal year.''

SEC. 108. NATIONAL AGRICULTURE AND FOOD DEFENSE STRATEGY.

(a) DEVELOPMENT AND SUBMISSION OF STRATEGY.—

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

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

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

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

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

(A) the National Incident Management System;

(B) the National Response Framework;

(C) the National Infrastructure Protection Plan;

(D) the National Preparedness Goals; and

(E) other relevant national strategies.

(b) COMPONENTS.—

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

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

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

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

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

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

(ii) mitigating vulnerabilities of the system;

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

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

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

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

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

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

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

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

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

(ii) preventing additional human illnesses;

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

(I) the Federal Government; and

(II) State, local, and tribal governments;

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

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

(I) the Federal Government;

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

(III) the private sector.

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

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

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

(iii) rapidly removing, and effectively disposing of—

(I) contaminated agriculture and food products; and

(II) infected plants and animals; and

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

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

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

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

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

SEC. 109. FOOD AND AGRICULTURE COORDINATING COUNCILS.

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

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

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

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

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

(A) animal or plant disease outbreaks;

(B) food contamination; and

(C) natural disasters affecting agriculture and food.

SEC. 110. BUILDING DOMESTIC CAPACITY.

(a) IN GENERAL.—

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

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

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

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

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

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

(F) Outreach, education, and training provided to States and local governments to build State and local food safety and food defense capabilities, including progress implementing strategies developed under sections 108 and 205.

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

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

(I) Specific efforts taken pursuant to the agreements authorized under section 421(c) of the Federal Food, Drug, and Cosmetic Act (as added by section 201), together with, as necessary, a description of any additional authorities necessary to improve seafood safety.

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

(A) reviews previous food safety programs and practices;

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

(C) identifies future programs and practices; and

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

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

(c) CAPABILITY FOR LABORATORY ANALYSES; RESEARCH.—The report developed under subsection (a)(1) shall provide a description of methods to increase capacity to undertake analyses of food samples promptly after collection, to identify new and rapid analytical techniques, including commercially-available techniques that can be employed at ports of entry and by Food Emergency Response Network laboratories, and to provide for well-equipped and staffed laboratory facilities and progress toward laboratory accreditation under section 422 of the Federal Food, Drug, and Cosmetic Act (as added by section 202).

(d) INFORMATION TECHNOLOGY.—The report developed under subsection (a)(1) shall include a description of such information technology systems as may be needed to identify risks and receive data from multiple sources, including foreign governments, State, local, and tribal governments, other Federal agencies, the food industry, laboratories, laboratory networks, and consumers. The information technology systems that the Secretary describes shall also provide for the integration of the facility registration system under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), and the prior notice system under section 801(m) of such Act (21 U.S.C. 381(m)) with other information technology systems that are used by the Federal Government for the processing of food offered for import into the United States.

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

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

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

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

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

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

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

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

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

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

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

(i) UNIQUE IDENTIFICATION NUMBERS.—

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

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

SEC. 111. SANITARY TRANSPORTATION OF FOOD.

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

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

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

SEC. 112. FOOD ALLERGY AND ANAPHYLAXIS MANAGEMENT.

(a) DEFINITIONS.—In this section:

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

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

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

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

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

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

(A) kindergartens;

(B) elementary schools; and

(C) secondary schools.

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

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

(1) ESTABLISHMENT.—

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

(i) develop guidelines to be used on a voluntary basis to develop plans for individuals to manage the risk of food allergy and anaphylaxis in schools and early childhood education programs; and

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

(B) APPLICABILITY OF FERPA.—Each plan described in subparagraph (A) that is developed for an individual shall be considered an education record for the purpose of section 444 of the General Education Provisions Act (commonly referred to as the ''Family Educational Rights and Privacy Act of 1974'') (20 U.S.C. 1232g).

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

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

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

(I) supporting a diagnosis of food allergy, and any risk of anaphylaxis, if applicable;

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

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

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

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

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

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

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

(B) The creation and maintenance of an individual plan for food allergy management, in consultation with the parent, tailored to the needs of each child with a documented risk for anaphylaxis, including any procedures for the self-administration of medication by such children in instances where—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) APPLICATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(D) Outreach to parents.

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

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

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

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

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

(8) MATCHING FUNDS.—

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

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

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

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

management guidelines described in subsection (b).

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

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

(d) VOLUNTARY NATURE OF GUIDELINES.—

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

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

SEC. 113. NEW DIETARY INGREDIENTS.

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

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

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

''(c) NOTIFICATION.—

''(1) IN GENERAL.—If the Secretary determines that the information in a new dietary ingredient notification submitted under this section for an article purported to be a new dietary ingredient is inadequate to establish that a dietary supplement containing such article will reasonably be expected to be safe because the article may be, or may contain, an anabolic steroid or an analogue of an anabolic steroid, the Secretary shall notify the Drug Enforcement Administration of such determination. Such notification by the Secretary shall include, at a minimum, the name of the dietary supplement or article, the name of the person or persons who marketed the product or made the submission of information regarding the article to the Secretary under this section, and any contact information for such person or persons that the Secretary has.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SEC. 115. PORT SHOPPING.

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

SEC. 116. ALCOHOL-RELATED FACILITIES.

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

(1) under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.) is required to obtain a permit or to register with the Secretary of the Treasury as a condition of doing business in the United States; and

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

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

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

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

(c) RULE OF CONSTRUCTION.—Except as provided in subsections (a) and (b), this section shall not be construed to exempt any food, other than alcoholic beverages, as defined in section 214 of the Federal Alcohol Administration Act (27 U.S.C. 214), from the requirements of this Act (including the amendments made by this Act).

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

SEC. 201. TARGETING OF INSPECTION RESOURCES FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND PORTS OF ENTRY; ANNUAL REPORT.

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

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

''(a) IDENTIFICATION AND INSPECTION OF FACILITIES.—

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

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

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

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

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

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

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

''(2) INSPECTIONS.—

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

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

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

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

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

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

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

''(D) FOREIGN FACILITIES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

''(E) a process, including the use or modification of existing processes, by which officers and employees of the National Oceanic and Atmospheric Administration may be duly designated by the Secretary to carry out seafood examinations and investigations under section 801 of this Act or section 203 of the Food Allergen Labeling and Consumer Protection Act of 2004;

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

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

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

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

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

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

''(h) ANNUAL REPORT REGARDING FOOD.—Not later than February 1 of each year, the Secretary shall submit to Congress a report, including efforts to coordinate and cooperate with other Federal agencies with responsibilities for food inspections, regarding—

''(1) information about food facilities including—

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

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

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

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

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

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

''(2) information about food imports including—

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

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

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

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

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

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

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

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

SEC. 202. LABORATORY ACCREDITATION FOR ANALYSES OF FOODS.

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

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

''(a) RECOGNITION OF LABORATORY ACCREDITATION.—

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

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

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

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

''(2) PROGRAM REQUIREMENTS.—The program established under paragraph (1)(A) shall provide for the recognition of laboratory accreditation bodies that meet criteria established by the Secretary for accreditation of laboratories, including independent private laboratories and laboratories run and operated by a Federal agency (including the Department of Commerce), State, or locality with a demonstrated capability to conduct 1 or more sampling and analytical testing methodologies for food.

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

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

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

''(6) MODEL LABORATORY STANDARDS.—The Secretary shall develop model standards that a laboratory shall meet to be accredited by a recognized accreditation body for a specified sampling or analytical testing methodology and included in the registry provided for under paragraph (1). In developing the model standards, the Secretary shall consult existing standards for guidance. The model standards shall include—

''(A) methods to ensure that—

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

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

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

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

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

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

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

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

''(b) TESTING PROCEDURES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) responds to food-related emergencies; and

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

SEC. 203. INTEGRATED CONSORTIUM OF LABORATORY NETWORKS.

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

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

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

(A) to optimize national laboratory preparedness; and

(B) to provide surge capacity during emergencies; and

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

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

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

(a) PILOT PROJECTS.—

(1) IN GENERAL.—Not later than 270 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), taking into account recommendations from the Secretary of Agriculture and representatives of State departments of health and agriculture, shall establish pilot projects in coordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) or misbranded under section 403(w) of such Act (21 U.S.C. 343(w)).

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

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

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

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

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

(b) ADDITIONAL DATA GATHERING.—

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

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

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

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

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

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

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

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

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

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

(1) IN GENERAL.—In order to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of such Act, not later than 2 years after the date of enactment of this Act, the Secretary shall publish a notice of proposed rulemaking to establish recordkeeping requirements, in addition to the requirements under section 414 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c) and subpart J of part 1 of title 21, Code of Federal Regulations (or any successor

regulations), for facilities that manufacture, process, pack, or hold foods that the Secretary designates under paragraph (2) as high-risk foods. The Secretary shall set an appropriate effective date of such additional requirements for foods designated as high risk that takes into account the length of time necessary to comply with such requirements. Such requirements shall—

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

(B) be science-based;

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

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

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

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

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

(H) allow any person subject to this subsection to maintain records required under this subsection at a central or reasonably accessible location provided that such records can be made available to the Secretary not later than 24 hours after the Secretary requests such records; and

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

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

(K) take into account international trade obligations;

(L) not require—

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

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

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

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

(2) DESIGNATION OF HIGH-RISK FOODS.—

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

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

(ii) the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food;

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

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

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

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

(B) LIST OF HIGH-RISK FOODS.—At the time the Secretary promulgates the final rules under paragraph (1), the Secretary shall publish the list of the foods designated under subparagraph (A) as high-risk foods on the Internet website of the Food and Drug Administration. The Secretary may update the list to designate new high-risk foods and to remove foods that are no longer deemed to be high-risk foods, provided that each such update to the list is consistent with the requirements of this subsection and notice of such update is published in the Federal Register.

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

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

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

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

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

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

(6) LIMITATIONS.—

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

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

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

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

(C) FISHING VESSELS.—The requirements under this subsection with respect to a food that is produced through the use of a fishing vessel (as defined in section 3(18) of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1802(18))) shall be limited to the requirements under subparagraph (F) until such time as the food is sold by the owner, operator, or agent in charge of such fishing vessel.

(D) COMMINGLED RAW AGRICULTURAL COMMODITIES.—

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

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

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

(II) the term ''commingled raw agricultural commodity'' shall not include types of fruits and vegetables that are raw agricultural commodities for which the Secretary has determined that standards promulgated under section 419 of the Federal Food, Drug, and Cosmetic Act (as added by section 105) would minimize the risk of serious adverse health consequences or death; and

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

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

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

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

(H) FARM SALES TO CONSUMERS.—The Secretary shall not require a farm to maintain any distribution records under this subsection with respect to a sale of a food described in subparagraph (I) (including a sale of a food that is produced and packaged on such farm), if such sale is made by the farm directly to a consumer.

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

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

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

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

(e) EVALUATION AND RECOMMENDATIONS.—

(1) REPORT.—Not later than 1 year after the effective date of the final rule promulgated under subsection (d)(1), the Comptroller General

of the United States shall submit to Congress a report, taking into consideration the costs of compliance and other regulatory burdens on small businesses and Federal, State, and local food safety practices and requirements, that evaluates the public health benefits and risks, if any, of limiting—

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

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

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

(f) FARMS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

(j) ENFORCEMENT.—

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

(2) IMPORTS.—Section 801(a) (21 U.S.C. 381(a)) is amended by inserting ''or (4) the 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.—

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

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

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

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

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

(E) expanding capacity of such systems, including working toward automatic electronic searches, for implementation of identification practices, including fingerprinting strategies, for foodborne infectious agents, in order to identify new or rarely documented causes of foodborne illness and submit standardized information to a centralized database;

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

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

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

(I) integrating foodborne illness surveillance systems and data with other biosurveillance and public health situational awareness capabilities at the Federal, State, and local levels, including by sharing foodborne illness surveillance data with the National Biosurveillance Integration Center; and

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

(2) WORKING GROUP.—The Secretary shall support and maintain a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food and food testing industries, consumer organizations, and academia. Such working group shall provide the Secretary, through at least annual meetings of the working group and an annual public report, advice and recommendations on an ongoing and regular basis regarding the improvement of foodborne illness surveillance and implementation of this section, including advice and recommendations on—

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

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

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

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

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

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

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

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

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

(A) Improve foodborne illness outbreak response and containment.

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

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

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

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

(F) Strengthen the capacity of State and local agencies to achieve the goals described in section 108.

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

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

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

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

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

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

(1) by striking ''2002'' and inserting ''2010''; and

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

SEC. 206. MANDATORY RECALL AUTHORITY.

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

''SEC. 423. MANDATORY RECALL AUTHORITY.

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

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

''(1) IN GENERAL.—If the responsible party refuses to or does not voluntarily cease distribution or recall such article within the time and in the manner prescribed by the Secretary (if so prescribed), the Secretary may, by order require, as the Secretary deems necessary, such person to—

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

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

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

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

''(2) REQUIRED ADDITIONAL INFORMATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

''(B) that includes, at a minimum—

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

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

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

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

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

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

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

''(j) COORDINATED COMMUNICATION.—

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

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

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

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

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

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

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

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

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

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

(2) provides a means by which an individual may locate relevant information regarding each article of food subject to a recall under section 423 of the Federal Food, Drug, and Cosmetic Act and the status of such recall (such as whether a recall is ongoing or has been completed).

(c) CIVIL PENALTY.—Section 303(f)(2)(A) (21 U.S.C. 333(f)(2)(A)) is amended by inserting ''or any person who does not comply with a recall order under section 423'' after ''section 402(a)(2)(B)''.

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

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

(e) GAO REVIEW.—

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

(A) identifies State and local agencies with the authority to require the mandatory recall of food, and evaluates use of such authority with regard to frequency, effectiveness, and appropriateness, including consideration of any new or existing mechanisms available to compensate persons for general and specific recall-related costs when a recall is subsequently determined by the relevant authority to have been an error;

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

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

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

(2) EFFECT OF REVIEW.—If the Comptroller General of the United States finds, after the review conducted under paragraph (1), that the mechanisms described in such paragraph do not exist or are inadequate, then, not later than 90 days after the conclusion of such review, the Secretary of Agriculture shall conduct a study of the feasibility of implementing a farmer indemnification program to provide restitution to agricultural producers for losses sustained as a result of a mandatory recall of an agricultural commodity by a Federal or State regulatory agency that is subsequently determined to be in error. The Secretary of Agriculture shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report that describes the results of the study, including any recommendations.

(f) ANNUAL REPORT TO CONGRESS.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act and annually thereafter, the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the use of recall authority under section 423 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) and any public health advisories issued by the Secretary that advise against the consumption of an article of food on the ground that the article of food is adulterated and poses an imminent danger to health.

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

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

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

(C) the number of responsible parties described in subparagraph (B) who did not cease distribution of or recall an article of food after given the opportunity to cease distribution or recall under section 423(a) of the Federal Food, Drug, and Cosmetic Act;

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

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

SEC. 207. ADMINISTRATIVE DETENTION OF FOOD.

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

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

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

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

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

SEC. 208. DECONTAMINATION AND DISPOSAL STANDARDS AND PLANS.

(a) IN GENERAL.—The Administrator of the Environmental Protection Agency (referred to in this section as the ''Administrator''), in coordination with the Secretary of Health and Human Services, Secretary of Homeland Security, and Secretary of Agriculture, shall provide support for, and technical assistance to, State, local, and tribal governments in preparing for, assessing, decontaminating, and recovering from an agriculture or food emergency.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

''(1) scientific training;

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

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

''(4) training that addresses best practices;

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

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

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

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

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

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

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

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

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

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

''(A) owners and operators of farms;

''(B) small food processors; and

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

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

''(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such

sums as may be necessary to carry out this section for fiscal years 2011 through 2015.''.

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

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

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

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

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

''(d) PROGRAM COORDINATION.—

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

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

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

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

''(e) GRANTS.—

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

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

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

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

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

''(f) GRANT ELIGIBILITY.—

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

''(A) a State cooperative extension service;

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

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

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

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

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

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

''(1) geographic diversity; and

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

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

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

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

SEC. 210. ENHANCING FOOD SAFETY.

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

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

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

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

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

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

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

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

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

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

''(b) ELIGIBLE ENTITIES; APPLICATION.—

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

''(A) that is—

''(i) a State;

''(ii) a locality;

''(iii) a territory;

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

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

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

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

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

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

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

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

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

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

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

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

''(2) award a grant under this section in a fiscal year for which the requirement of subsection (c) has not been met only if such requirement was not met because such funding was diverted for response to 1 or more natural disasters or in other extenuating circumstances that the Secretary may determine appropriate.

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

''(f) PROGRESS AND EVALUATION.—

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

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

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

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

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

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

''(a) IN GENERAL.—Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the working group described in subsection (b)(2), shall designate 5 Integrated Food Safety Centers of Excellence (referred to in this section as the 'Centers of Excellence') to serve as resources for Federal, State, and local public health professionals to respond to foodborne illness outbreaks. The Centers of Excellence shall be headquartered at selected State health departments.

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

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

''(A) be a State health department;

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

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

''(2) WORKING GROUP.—Not later than 180 days after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall establish a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food industry, including food retailers and food manufacturers, consumer organizations, and academia to make recommendations to the Secretary regarding designations of the Centers of Excellence.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SEC. 211. IMPROVING THE REPORTABLE FOOD REGISTRY.

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

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

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

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

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

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

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

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

''(g) GROCERY STORE NOTIFICATION.—

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

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

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

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

''(h) CONSUMER NOTIFICATION.—

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

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

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

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

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

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

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

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

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

TITLE III—IMPROVING THE SAFETY OF IMPORTED FOOD

SEC. 301. FOREIGN SUPPLIER VERIFICATION PROGRAM.

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

''SEC. 805. FOREIGN SUPPLIER VERIFICATION PROGRAM.

''(a) IN GENERAL.—

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

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

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

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

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

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

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

''(c) REGULATIONS.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall promulgate regulations to provide for the content of the foreign supplier verification program established under subsection (a).

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

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

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

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

''(B) shall include such other requirements as the Secretary deems necessary and appropriate to verify that food imported into the United States is as safe as food produced and sold within the United States.

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

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

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

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

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

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

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

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

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

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

(b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331), as amended by section 211, is amended by adding at the end the following:

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

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

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

SEC. 302. VOLUNTARY QUALIFIED IMPORTER PROGRAM.

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

''SEC. 806. VOLUNTARY QUALIFIED IMPORTER PROGRAM.

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

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

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

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

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

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

''(c) NOTICE OF INTENT TO PARTICIPATE.—An importer that intends to participate in the program under this section in a fiscal year shall submit a notice and 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 offering food for importation from a facility that has a certification described in subsection (a). In reviewing the applications and making determinations on such applications, the Secretary shall consider the risk of the food to be imported based on factors, such as the following:

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

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

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

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

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

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

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

''(e) REVIEW AND REVOCATION.—Any importer qualified by the Secretary in accordance with the eligibility criteria set forth in this section shall be reevaluated not less often than once every 3 years and the Secretary shall promptly revoke the qualified importer status of any importer found not to be in compliance with such criteria.

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

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

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

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

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

''(q) CERTIFICATIONS CONCERNING IMPORTED FOODS.—

''(1) IN GENERAL.—The Secretary may require, as a condition of granting admission to an article of food imported or offered for import into the United States, that an entity described in paragraph (3) provide a certification, or such other assurances as the Secretary determines appropriate, that the article of food complies with applicable requirements of this Act. Such certification or assurances may be provided in the form of shipment-specific certificates, a listing of certified facilities that manufacture, process, pack, or hold such food, or in such other form as the Secretary may specify.

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

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

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

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

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

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

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

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

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

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

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

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

''(B) refuse to accept any certification or assurance if the Secretary determines that such certification or assurance is not valid or reliable.

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

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

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

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

(d) NO LIMIT ON AUTHORITY.—Nothing in the amendments made by this section shall limit the authority of the Secretary to conduct inspections of imported food or to take such other steps as the Secretary deems appropriate to determine the admissibility of imported food.

SEC. 304. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.

(a) IN GENERAL.—Section 801(m)(1) (21 U.S.C. 381(m)(1)) is amended by inserting ''any country to which the article has been refused entry;'' after ''the country from which the article is shipped;''.

(b) REGULATIONS.—Not later than 120 days after the date of enactment of this Act, the Secretary shall issue an interim final rule amending subpart I of part 1 of title 21, Code of Federal Regulations, to implement the amendment made by this section.

(c) EFFECTIVE DATE.—The amendment made by this section shall take effect 180 days after the date of enactment of this Act.

SEC. 305. BUILDING CAPACITY OF FOREIGN GOVERNMENTS WITH RESPECT TO FOOD SAFETY.

(a) IN GENERAL.—The Secretary shall, not later than 2 years of the date of enactment of this Act, develop a comprehensive plan to expand the technical, scientific, and regulatory

food safety capacity of foreign governments, and their respective food industries, from which foods are exported to the United States.

(b) CONSULTATION.—In developing the plan under subsection (a), the Secretary shall consult with the Secretary of Agriculture, Secretary of State, Secretary of the Treasury, the Secretary of Homeland Security, the United States Trade Representative, and the Secretary of Commerce, representatives of the food industry, appropriate foreign government officials, nongovernmental organizations that represent the interests of consumers, and other stakeholders.

(c) PLAN.—The plan developed under subsection (a) shall include, as appropriate, the following:

(1) Recommendations for bilateral and multilateral arrangements and agreements, including provisions to provide for responsibility of exporting countries to ensure the safety of food.

(2) Provisions for secure electronic data sharing.

(3) Provisions for mutual recognition of inspection reports.

(4) Training of foreign governments and food producers on United States requirements for safe food.

(5) Recommendations on whether and how to harmonize requirements under the Codex Alimentarius.

(6) Provisions for the multilateral acceptance of laboratory methods and testing and detection techniques.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the regulation of dietary supplements under the Dietary Supplement Health and Education Act of 1994 (Public Law 103–417).

SEC. 306. INSPECTION OF FOREIGN FOOD FACILITIES.

(a) IN GENERAL.—Chapter VIII (21 U.S.C. 381 et seq.), as amended by section 302, is amended by inserting at the end the following:

''SEC. 807. INSPECTION OF FOREIGN FOOD FACILITIES.

''(a) INSPECTION.—The Secretary—

''(1) may enter into arrangements and agreements with foreign governments to facilitate the inspection of foreign facilities registered under section 415; and

''(2) shall direct resources to inspections of foreign facilities, suppliers, and food types, especially such facilities, suppliers, and food types that present a high risk (as identified by the Secretary), to help ensure the safety and security of the food supply of the United States.

''(b) EFFECT OF INABILITY TO INSPECT.—Notwithstanding any other provision of law, food shall be refused admission into the United States if it is from a foreign factory, warehouse, or other establishment of which the owner, operator, or agent in charge, or the government of the foreign country, refuses to permit entry of United States inspectors or other individuals duly designated by the Secretary, upon request, to inspect such factory, warehouse, or other establishment. For purposes of this subsection, such an owner, operator, or agent in charge shall be considered to have refused an inspection if such owner, operator, or agent in charge does not permit an inspection of a factory, warehouse, or other establishment during the 24-hour period after such request is submitted, or after such other time period, as agreed upon by the Secretary and the foreign factory, warehouse, or other establishment.''.

(b) INSPECTION BY THE SECRETARY OF COMMERCE.—

(1) IN GENERAL.—The Secretary of Commerce, in coordination with the Secretary of Health and Human Services, may send 1 or more inspectors to a country or facility of an exporter from which seafood imported into the United States originates. The inspectors shall assess practices and processes used in connection with the farming, cultivation, harvesting, preparation for market, or transportation of such seafood and may provide technical assistance related to such activities.

(2) INSPECTION REPORT.—

(A) IN GENERAL.—The Secretary of Health and Human Services, in coordination with the Secretary of Commerce, shall—

(i) prepare an inspection report for each inspection conducted under paragraph (1);

(ii) provide the report to the country or exporter that is the subject of the report; and

(iii) provide a 30-day period during which the country or exporter may provide a rebuttal or other comments on the findings of the report to the Secretary of Health and Human Services.

(B) DISTRIBUTION AND USE OF REPORT.—The Secretary of Health and Human Services shall consider the inspection reports described in subparagraph (A) in distributing inspection resources under section 421 of the Federal Food, Drug, and Cosmetic Act, as added by section 201.

SEC. 307. ACCREDITATION OF THIRD-PARTY AUDITORS.

Chapter VIII (21 U.S.C. 381 et seq.), as amended by section 306, is amended by adding at the end the following:

''SEC. 808. ACCREDITATION OF THIRD-PARTY AUDITORS.

''(a) DEFINITIONS.—In this section:

''(1) AUDIT AGENT.—The term 'audit agent' means an individual who is an employee or agent of an accredited third-party auditor and, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited third-party auditor.

''(2) ACCREDITATION BODY.—The term 'accreditation body' means an authority that performs accreditation of third-party auditors.

''(3) THIRD-PARTY AUDITOR.—The term 'third-party auditor' means a foreign government, agency of a foreign government, foreign cooperative, or any other third party, as the Secretary determines appropriate in accordance with the model standards described in subsection (b)(2), that is eligible to be considered for accreditation to conduct food safety audits to certify that eligible entities meet the applicable requirements of this section. A third-party auditor may be a single individual. A third-party auditor may employ or use audit agents to help conduct consultative and regulatory audits.

''(4) ACCREDITED THIRD-PARTY AUDITOR.—The term 'accredited third-party auditor' means a third-party auditor accredited by an accreditation body to conduct audits of eligible entities to certify that such eligible entities meet the applicable requirements of this section. An accredited third-party auditor may be an individual who conducts food safety audits to certify that eligible entities meet the applicable requirements of this section.

''(5) CONSULTATIVE AUDIT.—The term 'consultative audit' means an audit of an eligible entity—

''(A) to determine whether such entity is in compliance with the provisions of this Act and with applicable industry standards and practices; and

''(B) the results of which are for internal purposes only.

''(6) ELIGIBLE ENTITY.—The term 'eligible entity' means a foreign entity, including a foreign facility registered under section 415, in the food import supply chain that chooses to be audited by an accredited third-party auditor or the audit agent of such accredited third-party auditor.

''(7) REGULATORY AUDIT.—The term 'regulatory audit' means an audit of an eligible entity—

''(A) to determine whether such entity is in compliance with the provisions of this Act; and

''(B) the results of which determine—

''(i) whether an article of food manufactured, processed, packed, or held by such entity is eligible to receive a food certification under section 801(q); or

''(ii) whether a facility is eligible to receive a facility certification under section 806(a) for purposes of participating in the program under section 806.

''(b) ACCREDITATION SYSTEM.—

''(1) ACCREDITATION BODIES.—

''(A) RECOGNITION OF ACCREDITATION BODIES.—

''(i) IN GENERAL.—Not later than 2 years after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall establish a system for the recognition of accreditation bodies that accredit third-party auditors to certify that eligible entities meet the applicable requirements of this section.

''(ii) DIRECT ACCREDITATION.—If, by the date that is 2 years after the date of establishment of the system described in clause (i), the Secretary has not identified and recognized an accreditation body to meet the requirements of this section, the Secretary may directly accredit third-party auditors.

''(B) NOTIFICATION.—Each accreditation body recognized by the Secretary shall submit to the Secretary a list of all accredited third-party auditors accredited by such body and the audit agents of such auditors.

''(C) REVOCATION OF RECOGNITION AS AN ACCREDITATION BODY.—The Secretary shall promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of this section.

''(D) REINSTATEMENT.—The Secretary shall establish procedures to reinstate recognition of an accreditation body if the Secretary determines, based on evidence presented by such accreditation body, that revocation was inappropriate or that the body meets the requirements for recognition under this section.

''(2) MODEL ACCREDITATION STANDARDS.—Not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall develop model standards, including requirements for regulatory audit reports, and each recognized accreditation body shall ensure that third-party auditors and audit agents of such auditors meet such standards in order to qualify such third-party auditors as accredited third-party auditors under this section. In developing the model standards, the Secretary shall look to standards in place on the date of the enactment of this section for guidance, to avoid unnecessary duplication of efforts and costs.

''(c) THIRD-PARTY AUDITORS.—

''(1) REQUIREMENTS FOR ACCREDITATION AS A THIRD-PARTY AUDITOR.—

''(A) FOREIGN GOVERNMENTS.—Prior to accrediting a foreign government or an agency of a foreign government as an accredited third-party auditor, the accreditation body (or, in the case of direct accreditation under subsection (b)(1)(A)(ii), the Secretary) shall perform such reviews and audits of food safety programs, systems, and standards of the government or agency of the government as the Secretary deems necessary, including requirements under the model standards developed under subsection (b)(2), to determine that the foreign government or agency of the foreign government is capable of adequately ensuring that eligible entities or foods certified by such government or agency meet the requirements of this Act with respect to food manufactured, processed, packed, or held for import into the United States.

''(B) FOREIGN COOPERATIVES AND OTHER THIRD PARTIES.—Prior to accrediting a foreign cooperative that aggregates the products of growers or processors, or any other third party to be an accredited third-party auditor, the accreditation body (or, in the case of direct accreditation under subsection (b)(1)(A)(ii), the Secretary) shall perform such reviews and audits of the training and qualifications of audit agents used by that cooperative or party and conduct such reviews of internal systems and such other investigation of the cooperative or party as the Secretary deems necessary, including requirements under the model standards developed

under subsection (b)(2), to determine that each eligible entity certified by the cooperative or party has systems and standards in use to ensure that such entity or food meets the requirements of this Act.

''(2) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES OR FOODS.—

''(A) IN GENERAL.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(A)(ii), the Secretary) may not accredit a third-party auditor unless such third-party auditor agrees to issue a written and, as appropriate, electronic food certification, described in section 801(q), or facility certification under section 806(a), as appropriate, to accompany each food shipment for import into the United States from an eligible entity, subject to requirements set forth by the Secretary. Such written or electronic certification may be included with other documentation regarding such food shipment. The Secretary shall consider certifications under section 801(q) and participation in the voluntary qualified importer program described in section 806 when targeting inspection resources under section 421.

''(B) PURPOSE OF CERTIFICATION.—The Secretary shall use certification provided by accredited third-party auditors to—

''(i) determine, in conjunction with any other assurances the Secretary may require under section 801(q), whether a food satisfies the requirements of such section; and

''(ii) determine whether a facility is eligible to be a facility from which food may be offered for import under the voluntary qualified importer program under section 806.

''(C) REQUIREMENTS FOR ISSUING CERTIFICATION.—

''(i) IN GENERAL.—An accredited third-party auditor shall issue a food certification under section 801(q) or a facility certification described under subparagraph (B) only after conducting a regulatory audit and such other activities that may be necessary to establish compliance with the requirements of such sections.

''(ii) PROVISION OF CERTIFICATION.—Only an accredited third-party auditor or the Secretary may provide a facility certification under section 806(a). Only those parties described in 801(q)(3) or the Secretary may provide a food certification under 301(g).

''(3) AUDIT REPORT SUBMISSION REQUIREMENTS.—

''(A) REQUIREMENTS IN GENERAL.—As a condition of accreditation, not later than 45 days after conducting an audit, an accredited third-party auditor or audit agent of such auditor shall prepare, and, in the case of a regulatory audit, submit, the audit report for each audit conducted, in a form and manner designated by the Secretary, which shall include—

''(i) the identity of the persons at the audited eligible entity responsible for compliance with food safety requirements;

''(ii) the dates of the audit;

''(iii) the scope of the audit; and

''(iv) any other information required by the Secretary that relates to or may influence an assessment of compliance with this Act.

''(B) RECORDS.—Following any accreditation of a third-party auditor, the Secretary may, at any time, require the accredited third-party auditor to submit to the Secretary an onsite audit report and such other reports or documents required as part of the audit process, for any eligible entity certified by the third-party auditor or audit agent of such auditor. Such report may include documentation that the eligible entity is in compliance with any applicable registration requirements.

''(C) LIMITATION.—The requirement under subparagraph (B) shall not include any report or other documents resulting from a consultative audit by the accredited third-party auditor, except that the Secretary may access the results of a consultative audit in accordance with section 414.

''(4) REQUIREMENTS OF ACCREDITED THIRD-PARTY AUDITORS AND AUDIT AGENTS OF SUCH AUDITORS.—

''(A) RISKS TO PUBLIC HEALTH.—If, at any time during an audit, an accredited third-party auditor or audit agent of such auditor discovers a condition that could cause or contribute to a serious risk to the public health, such auditor shall immediately notify the Secretary of—

''(i) the identification of the eligible entity subject to the audit; and

''(ii) such condition.

''(B) TYPES OF AUDITS.—An accredited third-party auditor or audit agent of such auditor may perform consultative and regulatory audits of eligible entities.

''(C) LIMITATIONS.—

''(i) IN GENERAL.—An accredited third party auditor may not perform a regulatory audit of an eligible entity if such agent has performed a consultative audit or a regulatory audit of such eligible entity during the previous 13-month period.

''(ii) WAIVER.—The Secretary may waive the application of clause (i) if the Secretary determines that there is insufficient access to accredited third-party auditors in a country or region.

''(5) CONFLICTS OF INTEREST.—

''(A) THIRD-PARTY AUDITORS.—An accredited third-party auditor shall—

''(i) not be owned, managed, or controlled by any person that owns or operates an eligible entity to be certified by such auditor;

''(ii) in carrying out audits of eligible entities under this section, have procedures to ensure against the use of any officer or employee of such auditor that has a financial conflict of interest regarding an eligible entity to be certified by such auditor; and

''(iii) annually make available to the Secretary disclosures of the extent to which such auditor and the officers and employees of such auditor have maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

''(B) AUDIT AGENTS.—An audit agent shall—

''(i) not own or operate an eligible entity to be audited by such agent;

''(ii) in carrying out audits of eligible entities under this section, have procedures to ensure that such agent does not have a financial conflict of interest regarding an eligible entity to be audited by such agent; and

''(iii) annually make available to the Secretary disclosures of the extent to which such agent has maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

''(C) REGULATIONS.—The Secretary shall promulgate regulations not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act to implement this section and to ensure that there are protections against conflicts of interest between an accredited third-party auditor and the eligible entity to be certified by such auditor or audited by such audit agent. Such regulations shall include—

''(i) requiring that audits performed under this section be unannounced;

''(ii) a structure to decrease the potential for conflicts of interest, including timing and public disclosure, for fees paid by eligible entities to accredited third-party auditors; and

''(iii) appropriate limits on financial affiliations between an accredited third-party auditor or audit agents of such auditor and any person that owns or operates an eligible entity to be certified by such auditor, as described in subparagraphs (A) and (B).

''(6) WITHDRAWAL OF ACCREDITATION.—

''(A) IN GENERAL.—The Secretary shall withdraw accreditation from an accredited third-party auditor—

''(i) if food certified under section 801(q) or from a facility certified under paragraph (2)(B) by such third-party auditor is linked to an outbreak of foodborne illness that has a reasonable probability of causing serious adverse health consequences or death in humans or animals;

''(ii) following an evaluation and finding by the Secretary that the third-party auditor no longer meets the requirements for accreditation; or

''(iii) following a refusal to allow United States officials to conduct such audits and investigations as may be necessary to ensure continued compliance with the requirements set forth in this section.

''(B) ADDITIONAL BASIS FOR WITHDRAWAL OF ACCREDITATION.—The Secretary may withdraw accreditation from an accredited third-party auditor in the case that such third-party auditor is accredited by an accreditation body for which recognition as an accreditation body under subsection (b)(1)(C) is revoked, if the Secretary determines that there is good cause for the withdrawal.

''(C) EXCEPTION.—The Secretary may waive the application of subparagraph (A)(i) if the Secretary—

''(i) conducts an investigation of the material facts related to the outbreak of human or animal illness; and

''(ii) reviews the steps or actions taken by the third party auditor to justify the certification and determines that the accredited third-party auditor satisfied the requirements under section 801(q) of certifying the food, or the requirements under paragraph (2)(B) of certifying the entity.

''(7) REACCREDITATION.—The Secretary shall establish procedures to reinstate the accreditation of a third-party auditor for which accreditation has been withdrawn under paragraph (6)—

''(A) if the Secretary determines, based on evidence presented, that the third-party auditor satisfies the requirements of this section and adequate grounds for revocation no longer exist; and

''(B) in the case of a third-party auditor accredited by an accreditation body for which recognition as an accreditation body under subsection (b)(1)(C) is revoked—

''(i) if the third-party auditor becomes accredited not later than 1 year after revocation of accreditation under paragraph (6)(A), through direct accreditation under subsection (b)(1)(A)(ii) or by an accreditation body in good standing; or

''(ii) under such conditions as the Secretary may require for a third-party auditor under paragraph (6)(B).

''(8) NEUTRALIZING COSTS.—The Secretary shall establish by regulation a reimbursement (user fee) program, similar to the method described in section 203(h) of the Agriculture Marketing Act of 1946, by which the Secretary assesses fees and requires accredited third-party auditors and audit agents to reimburse the Food and Drug Administration for the work performed to establish and administer the accreditation system under this section. The Secretary shall make operating this program revenue-neutral and shall not generate surplus revenue from such a reimbursement mechanism. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to remain available until expended.

''(d) RECERTIFICATION OF ELIGIBLE ENTITIES.—An eligible entity shall apply for annual recertification by an accredited third-party auditor if such entity—

''(1) intends to participate in voluntary qualified importer program under section 806; or

''(2) is required to provide to the Secretary a certification under section 801(q) for any food from such entity.

''(e) FALSE STATEMENTS.—Any statement or representation made—

''(1) by an employee or agent of an eligible entity to an accredited third-party auditor or audit agent; or

''(2) by an accredited third-party auditor to the Secretary,

shall be subject to section 1001 of title 18, United States Code.

''(f) MONITORING.—To ensure compliance with the requirements of this section, the Secretary shall—

''(1) periodically, or at least once every 4 years, reevaluate the accreditation bodies described in subsection (b)(1);

''(2) periodically, or at least once every 4 years, evaluate the performance of each accredited third-party auditor, through the review of regulatory audit reports by such auditors, the compliance history as available of eligible entities certified by such auditors, and any other measures deemed necessary by the Secretary;

''(3) at any time, conduct an onsite audit of any eligible entity certified by an accredited third-party auditor, with or without the auditor present; and

''(4) take any other measures deemed necessary by the Secretary.

''(g) PUBLICLY AVAILABLE REGISTRY.—The Secretary shall establish a publicly available registry of accreditation bodies and of accredited third-party auditors, including the name of, contact information for, and other information deemed necessary by the Secretary about such bodies and auditors.

''(h) LIMITATIONS.—

''(1) NO EFFECT ON SECTION 704 INSPECTIONS.—The audits performed under this section shall not be considered inspections under section 704.

''(2) NO EFFECT ON INSPECTION AUTHORITY.—Nothing in this section affects the authority of the Secretary to inspect any eligible entity pursuant to this Act.''.

SEC. 308. FOREIGN OFFICES OF THE FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—The Secretary shall establish offices of the Food and Drug Administration in foreign countries selected by the Secretary, to provide assistance to the appropriate governmental entities of such countries with respect to measures to provide for the safety of articles of food and other products regulated by the Food and Drug Administration exported by such country to the United States, including by directly conducting risk-based inspections of such articles and supporting such inspections by such governmental entity.

(b) CONSULTATION.—In establishing the foreign offices described in subsection (a), the Secretary shall consult with the Secretary of State, the Secretary of Homeland Security, and the United States Trade Representative.

(c) REPORT.—Not later than October 1, 2011, the Secretary shall submit to Congress a report on the basis for the selection by the Secretary of the foreign countries in which the Secretary established offices, the progress which such offices have made with respect to assisting the governments of such countries in providing for the safety of articles of food and other products regulated by the Food and Drug Administration exported to the United States, and the plans of the Secretary for establishing additional foreign offices of the Food and Drug Administration, as appropriate.

SEC. 309. SMUGGLED FOOD.

(a) IN GENERAL.—Not later than 180 days after the enactment of this Act, the Secretary shall, in coordination with the Secretary of Homeland Security, develop and implement a strategy to better identify smuggled food and prevent entry of such food into the United States.

(b) NOTIFICATION TO HOMELAND SECURITY.—Not later than 10 days after the Secretary identifies a smuggled food that the Secretary believes would cause serious adverse health consequences or death to humans or animals, the Secretary shall provide to the Secretary of Homeland Security a notification under section 417(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350f(k)) describing the smuggled food and, if available, the names of the individuals or entities that attempted to import such food into the United States.

(c) PUBLIC NOTIFICATION.—If the Secretary—

(1) identifies a smuggled food;

(2) reasonably believes exposure to the food would cause serious adverse health consequences or death to humans or animals; and

(3) reasonably believes that the food has entered domestic commerce and is likely to be consumed,

the Secretary shall promptly issue a press release describing that food and shall use other emergency communication or recall networks, as appropriate, to warn consumers and vendors about the potential threat.

(d) EFFECT OF SECTION.—Nothing in this section shall affect the authority of the Secretary to issue public notifications under other circumstances.

(e) DEFINITION.—In this subsection, the term ''smuggled food'' means any food that a person introduces into the United States through fraudulent means or with the intent to defraud or mislead.

TITLE IV—MISCELLANEOUS PROVISIONS

SEC. 401. FUNDING FOR FOOD SAFETY.

(a) IN GENERAL.—There are authorized to be appropriated to carry out the activities of the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and related field activities in the Office of Regulatory Affairs of the Food and Drug Administration such sums as may be necessary for fiscal years 2011 through 2015.

(b) INCREASED NUMBER OF FIELD STAFF.—

(1) IN GENERAL.—To carry out the activities of the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and related field activities of the Office of Regulatory Affairs of the Food and Drug Administration, the Secretary of Health and Human Services shall increase the field staff of such Centers and Office with a goal of not fewer than—

(A) 4,000 staff members in fiscal year 2011;

(B) 4,200 staff members in fiscal year 2012;

(C) 4,600 staff members in fiscal year 2013; and

(D) 5,000 staff members in fiscal year 2014.

(2) FIELD STAFF FOR FOOD DEFENSE.—The goal under paragraph (1) shall include an increase of 150 employees by fiscal year 2011 to—

(A) provide additional detection of and response to food defense threats; and

(B) detect, track, and remove smuggled food (as defined in section 309) from commerce.

SEC. 402. EMPLOYEE PROTECTIONS.

Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.), as amended by section 209, is further amended by adding at the end the following:

''SEC. 1012. EMPLOYEE PROTECTIONS.

''(a) IN GENERAL.—No entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food may discharge an employee or otherwise discriminate against an employee with respect to compensation, terms, conditions, or privileges of employment because the employee, whether at the employee's initiative or in the ordinary course of the employee's duties (or any person acting pursuant to a request of the employee)—

''(1) provided, caused to be provided, or is about to provide or cause to be provided to the employer, the Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of any provision of this Act or any order, rule, regulation, standard, or ban under this Act, or any order, rule, regulation, standard, or ban under this Act;

''(2) testified or is about to testify in a proceeding concerning such violation;

''(3) assisted or participated or is about to assist or participate in such a proceeding; or

''(4) objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee (or other such person) reasonably believed to be in violation of any provision of this Act, or any order, rule, regulation, standard, or ban under this Act.

''(b) PROCESS.—

''(1) IN GENERAL.—A person who believes that he or she has been discharged or otherwise discriminated against by any person in violation of subsection (a) may, not later than 180 days after the date on which such violation occurs, file (or have any person file on his or her behalf) a complaint with the Secretary of Labor (referred to in this section as the 'Secretary') alleging such discharge or discrimination and identifying the person responsible for such act. Upon receipt of such a complaint, the Secretary shall notify, in writing, the person named in the complaint of the filing of the complaint, of the allegations contained in the complaint, of the substance of evidence supporting the complaint, and of the opportunities that will be afforded to such person under paragraph (2).

''(2) INVESTIGATION.—

''(A) IN GENERAL.—Not later than 60 days after the date of receipt of a complaint filed under paragraph (1) and after affording the complainant and the person named in the complaint an opportunity to submit to the Secretary a written response to the complaint and an opportunity to meet with a representative of the Secretary to present statements from witnesses, the Secretary shall initiate an investigation and determine whether there is reasonable cause to believe that the complaint has merit and notify, in writing, the complainant and the person alleged to have committed a violation of subsection (a) of the Secretary's findings.

''(B) REASONABLE CAUSE FOUND; PRELIMINARY ORDER.—If the Secretary concludes that there is reasonable cause to believe that a violation of subsection (a) has occurred, the Secretary shall accompany the Secretary's findings with a preliminary order providing the relief prescribed by paragraph (3)(B). Not later than 30 days after the date of notification of findings under this paragraph, the person alleged to have committed the violation or the complainant may file objections to the findings or preliminary order, or both, and request a hearing on the record. The filing of such objections shall not operate to stay any reinstatement remedy contained in the preliminary order. Any such hearing shall be conducted expeditiously. If a hearing is not requested in such 30-day period, the preliminary order shall be deemed a final order that is not subject to judicial review.

''(C) DISMISSAL OF COMPLAINT.—

''(i) STANDARD FOR COMPLAINANT.—The Secretary shall dismiss a complaint filed under this subsection and shall not conduct an investigation otherwise required under subparagraph (A) unless the complainant makes a prima facie showing that any behavior described in paragraphs (1) through (4) of subsection (a) was a contributing factor in the unfavorable personnel action alleged in the complaint.

''(ii) STANDARD FOR EMPLOYER.—Notwithstanding a finding by the Secretary that the complainant has made the showing required under clause (i), no investigation otherwise required under subparagraph (A) shall be conducted if the employer demonstrates, by clear and convincing evidence, that the employer would have taken the same unfavorable personnel action in the absence of that behavior.

''(iii) VIOLATION STANDARD.—The Secretary may determine that a violation of subsection (a) has occurred only if the complainant demonstrates that any behavior described in paragraphs (1) through (4) of subsection (a) was a contributing factor in the unfavorable personnel action alleged in the complaint.

''(iv) RELIEF STANDARD.—Relief may not be ordered under subparagraph (A) if the employer demonstrates by clear and convincing evidence that the employer would have taken the same unfavorable personnel action in the absence of that behavior.

''(3) FINAL ORDER.—

''(A) IN GENERAL.—Not later than 120 days after the date of conclusion of any hearing under paragraph (2), the Secretary shall issue a

final order providing the relief prescribed by this paragraph or denying the complaint. At any time before issuance of a final order, a proceeding under this subsection may be terminated on the basis of a settlement agreement entered into by the Secretary, the complainant, and the person alleged to have committed the violation.

''(B) CONTENT OF ORDER.—If, in response to a complaint filed under paragraph (1), the Secretary determines that a violation of subsection (a) has occurred, the Secretary shall order the person who committed such violation—

''(i) to take affirmative action to abate the violation;

''(ii) to reinstate the complainant to his or her former position together with compensation (including back pay) and restore the terms, conditions, and privileges associated with his or her employment; and

''(iii) to provide compensatory damages to the complainant.

''(C) PENALTY.—If such an order is issued under this paragraph, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorneys' and expert witness fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

''(D) BAD FAITH CLAIM.—If the Secretary finds that a complaint under paragraph (1) is frivolous or has been brought in bad faith, the Secretary may award to the prevailing employer a reasonable attorneys' fee, not exceeding $1,000, to be paid by the complainant.

''(4) ACTION IN COURT.—

''(A) IN GENERAL.—If the Secretary has not issued a final decision within 210 days after the filing of the complaint, or within 90 days after receiving a written determination, the complainant may bring an action at law or equity for de novo review in the appropriate district court of the United States with jurisdiction, which shall have jurisdiction over such an action without regard to the amount in controversy, and which action shall, at the request of either party to such action, be tried by the court with a jury. The proceedings shall be governed by the same legal burdens of proof specified in paragraph (2)(C).

''(B) RELIEF.—The court shall have jurisdiction to grant all relief necessary to make the employee whole, including injunctive relief and compensatory damages, including—

''(i) reinstatement with the same seniority status that the employee would have had, but for the discharge or discrimination;

''(ii) the amount of back pay, with interest; and

''(iii) compensation for any special damages sustained as a result of the discharge or discrimination, including litigation costs, expert witness fees, and reasonable attorney's fees.

''(5) REVIEW.—

''(A) IN GENERAL.—Unless the complainant brings an action under paragraph (4), any person adversely affected or aggrieved by a final order issued under paragraph (3) may obtain review of the order in the United States Court of Appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred or the circuit in which the complainant resided on the date of such violation. The petition for review must be filed not later than 60 days after the date of the issuance of the final order of the Secretary. Review shall conform to chapter 7 of title 5, United States Code. The commencement of proceedings under this subparagraph shall not, unless ordered by the court, operate as a stay of the order.

''(B) NO JUDICIAL REVIEW.—An order of the Secretary with respect to which review could have been obtained under subparagraph (A) shall not be subject to judicial review in any criminal or other civil proceeding.

''(6) FAILURE TO COMPLY WITH ORDER.—Whenever any person has failed to comply with an order issued under paragraph (3), the Secretary may file a civil action in the United States district court for the district in which the violation was found to occur, or in the United States district court for the District of Columbia, to enforce such order. In actions brought under this paragraph, the district courts shall have jurisdiction to grant all appropriate relief including, but not limited to, injunctive relief and compensatory damages.

''(7) CIVIL ACTION TO REQUIRE COMPLIANCE.—

''(A) IN GENERAL.—A person on whose behalf an order was issued under paragraph (3) may commence a civil action against the person to whom such order was issued to require compliance with such order. The appropriate United States district court shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to enforce such order.

''(B) AWARD.—The court, in issuing any final order under this paragraph, may award costs of litigation (including reasonable attorneys' and expert witness fees) to any party whenever the court determines such award is appropriate.

''(c) EFFECT OF SECTION.—

''(1) OTHER LAWS.—Nothing in this section preempts or diminishes any other safeguards against discrimination, demotion, discharge, suspension, threats, harassment, reprimand, retaliation, or any other manner of discrimination provided by Federal or State law.

''(2) RIGHTS OF EMPLOYEES.—Nothing in this section shall be construed to diminish the rights, privileges, or remedies of any employee under any Federal or State law or under any collective bargaining agreement. The rights and remedies in this section may not be waived by any agreement, policy, form, or condition of employment.

''(d) ENFORCEMENT.—Any nondiscretionary duty imposed by this section shall be enforceable in a mandamus proceeding brought under section 1361 of title 28, United States Code.

''(e) LIMITATION.—Subsection (a) shall not apply with respect to an employee of an entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food who, acting without direction from such entity (or such entity's agent), deliberately causes a violation of any requirement relating to any violation or alleged violation of any order, rule, regulation, standard, or ban under this Act.''.

SEC. 403. JURISDICTION; AUTHORITIES.

Nothing in this Act, or an amendment made by this Act, shall be construed to—

(1) alter the jurisdiction between the Secretary of Agriculture and the Secretary of Health and Human Services, under applicable statutes, regulations, or agreements regarding voluntary inspection of non-amenable species under the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.);

(2) alter the jurisdiction between the Alcohol and Tobacco Tax and Trade Bureau and the Secretary of Health and Human Services, under applicable statutes and regulations;

(3) limit the authority of the Secretary of Health and Human Services under—

(A) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) as in effect on the day before the date of enactment of this Act; or

(B) the Public Health Service Act (42 U.S.C. 301 et seq.) as in effect on the day before the date of enactment of this Act;

(4) alter or limit the authority of the Secretary of Agriculture under the laws administered by such Secretary, including—

(A) the Federal Meat Inspection Act (21 U.S.C. 601 et seq.);

(B) the Poultry Products Inspection Act (21 U.S.C. 451 et seq.);

(C) the Egg Products Inspection Act (21 U.S.C. 1031 et seq.);

(D) the United States Grain Standards Act (7 U.S.C. 71 et seq.);

(E) the Packers and Stockyards Act, 1921 (7 U.S.C. 181 et seq.);

(F) the United States Warehouse Act (7 U.S.C. 241 et seq.);

(G) the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.); and

(H) the Agricultural Adjustment Act (7 U.S.C. 601 et seq.), reenacted with the amendments made by the Agricultural Marketing Agreement Act of 1937; or

(5) alter, impede, or affect the authority of the Secretary of Homeland Security under the Homeland Security Act of 2002 (6 U.S.C. 101 et seq.) or any other statute, including any authority related to securing the borders of the United States, managing ports of entry, or agricultural import and entry inspection activities.

SEC. 404. COMPLIANCE WITH INTERNATIONAL AGREEMENTS.

Nothing in this Act (or an amendment made by this Act) shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party.

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, provided that such statement has been submitted prior to the vote on passage.

Amend the title so as to read: ''An Act to amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.''.

MOTION TO CONCUR

The SPEAKER pro tempore. The Clerk will report the motion.

The Clerk read as follows:

Mr. DINGELL moves that the House concur in the Senate amendments to H.R. 2751.

The SPEAKER pro tempore. Pursuant to House Resolution 1781, the motion shall be debatable for 1 hour equally divided and controlled by the chair and the ranking minority member of the Committee on Energy and Commerce.

The gentleman from Michigan (Mr. DINGELL) and the gentleman from Pennsylvania (Mr. PITTS) each will control 30 minutes.

The Chair recognizes the gentleman from Michigan.

GENERAL LEAVE

Mr. DINGELL. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and to insert extraneous matter into the RECORD.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Michigan?

There was no objection.

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, Congressmen PALLONE and STUPAK, Mr. BARTON and Mr. SHIMKUS, and former Representative Deal for the work on this legislation.

For a third time, today the House considers legislation that will dramatically improve the safety of our Nation's food supply. The House first passed its bill in July 2009 on a strong bipartisan vote with 283 supporters. On November 30 of this year, the Senate passed the FDA Food Safety Modernization Act on a strong bipartisan basis, by a vote of 73–25. That bill contained some constitutional defects that needed to be fixed. So on Sunday night, the Senate again passed a corrected version of the bill by voice vote.

Congress has demonstrated that food safety is a bipartisan issue. Food-borne illness outbreaks can strike each and every one of us. In recent years, foods we never would have imagined to be unsafe, everything from spinach to peanut butter, have sickened an untold number of Americans. It is time, once and for all, to enact this legislation. There is no time for any further delay.

FDA needs a modern set of authorities to deal with the effects of our increasingly globalized food supply. This legislation will give FDA the tools and resources it needs to better police the safety of the foods we eat every day. The bill makes significant improvements throughout the food chain, from the farm to the dinner table. The bill will require farmers to comply with science-based standards for safe production and harvesting. Companies that process or package foods will be required to implement preventive systems to stop outbreaks before they occur. Importers will have to demonstrate that the food they bring into the country is safe. And the bill strengthens FDA enforcement authorities, giving FDA the ability to order a food recall when companies refuse to voluntarily do so.

Many of us in the House would agree that our bill was stronger. We also would likely agree that it is regrettable that there 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. 2751.

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 priority. 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, manufacturers, and distributors do to put low-cost, high-quality food on the tables of more than 300 million people every day. We also have heard about how much our Nation's children and our Nation's farmers and small businesses can be hurt when one irresponsible actor sells adulterated, contaminated food.

Thanks to helpful testimony from hearing witnesses and hard work by our committee members, we were able to come up with some good ideas to help solve those food safety problems. Those ideas were found in the Food Safety Enhancement Act, which passed the House in July of 2009 and represented the bipartisan work of Chairman WAXMAN, Chairman Emeritus DINGELL, Chairman PALLONE, Chairman STUPAK, Governor-Elect Deal, and Ranking Member SHIMKUS.

The Food Safety Enhancement Act passed more than 16 months ago. The Senate finally passed its food safety bill, the Food Safety Modernization Act, Senate 510, during the lame duck session. The provisions of Senate 510 are contained in the bill that we are considering today with no substantive changes from what passed the Senate 3 weeks ago.

I intend to vote against this bill because it represents such a gross departure from reasonable legislating. When the Senate passed its food safety bill 3 weeks ago, we asked our 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 a great deal about 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, we should have rolled up our sleeves and gotten to work on negotiating. And now, 3 weeks and many post offices later, the majority says we have to take it or leave it.

□ 1530

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 the Tester amendment will 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. Think about what a different world it was 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 peanuts, we 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, and it's backed by a diverse 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 it contains very little that will actually contribute to the goal of food safety. It gives the Food and Drug Administration lots of additional authorities with no accountability. In fact, with the inclusion of the so-called Tester amendment, some argue that it is a step backwards.

Now, my concerns about the legislation are not limited to the unforgivable process. There are serious public policy concerns as well. The Tester amendment is an illustrative example. Intended to shield small and local producers from the burdens of the new food safety law, it is opposed by virtually all of the major organizations representing farmers and ranchers. Normally, these groups would be expected to support a provision that sought to protect their farmers and ranchers. But they oppose the Tester amendment and any legislation that contains it because it adds to the layers of food safety regulation by creating yet another tier of regulatory standards that will only confuse our consumers.

Further, by exempting small domestic companies from Federal standards, I fear, and this is a legitimate fear, that we will be required to exempt similarly sized companies in developing countries from our standards. This approach does not make food safer. It eliminates important consumer 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. New 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 commonsense way to help FDA identify facilities 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. 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 set on-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 those 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.

□ 1540

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. PALLONE 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, our food laws have not been updated 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, 325,000 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 face a lifetime of medication and bankruptcy of your family. We must act now to pass this food safety bill. This bill contains many good provisions, including the trace-back provision, which is designed to make it easier to prevent and respond to outbreaks in food-borne illnesses.

This also has mandatory recall. Most Americans are shocked to know that the FDA does not have the right to recall food or unsafe drugs in this country. They do not have the right to have that recall, especially on food. So this will now make it mandatory. The FDA can remove tainted food as soon as possible. Still, despite all these improvements, more has to be done to protect Americans.

The FDA needs subpoena power. It is probably one of the few regulatory agencies that doesn't have subpoena power. We lost that when it went to the Senate. But if you are going to trace back, if you are going to get the records, if you are going to find where the food comes from, let's give the regulatory agency the power they need. Because corporate America unfortunately too often hides their records from us.

We need an adequate funding source. For this legislation to be successful, we have to have an adequate funding source, as we had in the House but was removed in the Senate. And country of origin label. More and more of our food, especially this time of the year in the winter months, comes from other countries. We need to know exactly where those sources of food come from. So I urge the next Congress to make these improvements.

And a word of caution. Without this bill and greater improvements to this bill, we cannot fully protect Americans from food-borne illnesses, either accidentally or those intentionally put forth by America's enemies. And make no mistake about it, our enemies will exploit our weak regulatory system when they know they can harm so many Americans through food-borne illnesses.

So I hope my colleagues today will join me in supporting this legislation.

It's a great piece of legislation. I would like to thank my colleagues who have worked so hard on this over the years with me, including Ms. DELAURO of Connecticut, but especially the members of the Energy and Commerce Committee who have worked with us, especially Chairman DINGELL, Chairman WAXMAN, Mr. PALLONE, Mr. UPTON, and Mr. BARTON.

Mr. PITTS. Mr. Speaker, I reserve the balance of my time.

Mr. DINGELL. Mr. Speaker, I yield 5 minutes to the distinguished gentlewoman from Connecticut (Ms. DELAURO), the chairman of the Agriculture Appropriations Subcommittee, and very much interested in the matter before us. She has worked on it a long time.

Ms. 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 our families from food-borne illness. And I want to congratulate some of the longtime champions of food safety in this institution, such as Chairman HENRY WAXMAN, Chairman JOHN DINGELL, Subcommittee Chairman FRANK Pallone, Mr. BART STUPAK. And I say congratulations to them for successfully bringing this legislation through the House. I also want to acknowledge Senator HARKIN and Senator DURBIN for their work in facilitating passage of this bill in the Senate.

Among the critical reforms in this bill are increased inspection of high-risk facilities, expanded authority to inspect recall records, the formation of a more accurate food facility registry, improved traceability in the event of an illness outbreak, and improved surveillance of food-borne illness. The bill also requires certification of certain foreign food imports as meeting U.S. food safety requirements.

All of these tools will help improve the FDA's ability to respond to food-borne illness outbreaks and to hold industrial food production facilities to higher standards. For too long the cornerstone of our food safety system, the FDA, has had only ancient tools and an outdated mandate at its disposal. This bill will go a long way towards stemming the potential of a full-blown food-borne epidemic in the future. Recently, the CDC released an updated estimate on food-borne illness figures, and it remains a major public interest health threat. With nearly 50 million illnesses, 100,000 hospitalizations, and over 3,000 deaths each year, these estimates show that there is much work to be done in identifying and combating the pathogens that cause food-borne illness.

Just to tell you the importance of this bill, let me share with you the story of Haylee Berstein, a 17-year old girl who lives in Wilton, Connecticut. When Haylee was 3 years old, she ate unwashed lettuce that was contaminated with E. coli. She soon became extremely ill with what doctors called hemolytic uretic syndrome. The health effects of an E. coli illness are very painful. Haylee experienced traumatic damage to her kidneys and pancreas. She suffered severe bleeding in her brain. And that blood in her brain caused her to be temporarily blind. The doctors at Yale-New Haven Children's Hospital fought for 14 weeks to save her life. And to this day, Haylee still suffers from health problems such as diabetes, all because of food contaminated with E. coli. This should not happen to anyone. And as 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 on language that would 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 do leaders across the aisle, that 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, as well as 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 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 reducing 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 it home and it's safe for their children.

Mr. PITTS. I continue to reserve the balance of my time.

Mr. DINGELL. Mr. Speaker, I yield 2 minutes again to my good friend, the chairman of the Committee on Energy and Commerce, Mr. WAXMAN, for purposes of correcting the record on certain erroneous statements made.

Mr. WAXMAN. Mr. Speaker and my colleagues, the Senate only passed this bill a couple of nights ago. And so we have now the opportunity to vote to take it or reject it. Some on the other side of the aisle, Republicans, are saying we should reject the whole bill because of the Tester amendment, which exempts small farmer-producers and facilities. We didn't have that in our bill, and I would have preferred that the Senate had not adopted that provision. But I don't think it is a reason to vote against this whole bill.

This bill is a good bill. It is supported by the Consumer Federation of America, the Consumers Union, the National Consumers League, the Trust for America's Health, the American Public Health Association. And it's supported by major industry groups, the Food Marketing Institute, the Grocery Manufacturers Association, and the U.S. Chamber of Commerce.

Now, I would assume that some big operations don't like the fact that small ones are going to be exempt. They are only exempt from a couple of the provisions which Senator TESTER and the Senate Members thought were too burdensome. And some of these small operations are limited in their income, and therefore it might be too burdensome for them.

□ 1550

Republicans have suggested we should have gone to conference. If we had gone to conference, only one Senator could object and no conferees would be appointed by the Senate. So that burden we are being asked to have achieved is something we could not achieve in the short time available to us.

Let us not let this opportunity go by. We must adopt this legislation. If there are efforts to change it later on, fine. But this is an important bill that has been worked on for years. It had strong bipartisan support in the House. It had overwhelming bipartisan support in the Senate. And I want to clarify the record to point out that almost all the groups, the consumer groups and the industry groups, are urging an ''aye'' vote.

Mr. PITTS. I continue to reserve the balance of my time.

Mr. DINGELL. Mr. Speaker, I have only one further speaker on this side, so I suggest to my good friend from Pennsylvania, if he desires to speak, he should speak forthwith.

Mr. PITTS. I have no further requests for time, and I yield back the balance of my time.

Mr. DINGELL. The gentleman is a complete gentleman. I don't want to deny him any opportunity to be heard. I want to thank the gentleman. He is always courteous. I express my gratitude to him for the way he behaves.

I yield myself 5 minutes, Mr. Speaker.

Mr. Speaker, this is not the first time we have seen this bill. It came out of the Committee on Energy and Commerce unanimously. It was informally referred to the Committee on Agriculture, where they had a chance to take a look at it. It passed the House overwhelmingly on two occasions in a slightly different form. It then came back here and it was passed yet another time with the changes virtually to make it identical to that form in which it is. Those changes have been removed in some regards because they were mostly simply technical changes. So it has passed this body three times before this. This is the fourth time we have considered it. The Senate has passed it twice. On Sunday night, they passed it under a unanimous consent procedure.

The bill has enormous support, and all of the consumer organizations support it. Almost every business group in the field of food manufacturing and processing supports it: The Grocery Manufacturers Association, the National Association of Manufacturers, the Chamber of Commerce, the Consumer Federation of America, the American Public Health Association, the Bakers Association, the Beverage Association, the American Public Health Association, Pew Charitable Trust, the U.S. PIRG, and also the Food Marketing Institute as well as the Center for Science in the Public Interest. There is literally little, if any, opposition to the consideration of this legislation.

The Senate took from last summer when the House passed the bill until just a few weeks ago to pass the bill over there. It only passed for the final time on Sunday night. I want to agree with my good friend from Pennsylvania; the House's skill as a legislative body is far superior to that of the other body, and if they would leave the legislation alone, I think I could assure the House that we would pass better legislation than they do over there.

But having said these things, we are about now to be forced at the last minutes of this session to choose between not passing a superb bill and passing no bill at all because we want to achieve a greater level of perfection.

This is the first significant change in food and drug law with regard to foods 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: bad 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 salsa and caused the collapse of the American tomato industry.

These are things that will be corrected by us having people available in Food and Drug to properly investigate, to properly correct and properly see to it that these unsafe foods don't get into our food chain, with the consequences not only that they poison Americans, but, worse, that they destroy American industry and cost us the faith of the American consuming public for some of the best 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 from Michigan 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 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, 48 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 perhaps pass a different bill. 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 impinged, not by their carelessness or bad behavior but, rather, by the misbehavior of foreign producers, foreign manufacturers, and others who are sending things in here like milk products with melamine. Melamine is a constituent, believe it or not, of Formica.

□ 1600

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 beg 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 commend the staff: Katie Campbell, whose last day this is; Virgil Miller; Rachael Sher; Eric Flamm; and Emily Gibbons, who have made this possible. Our legislative counsel has labored vitally on it, and we owe real thanks to Warren Burke and Megan Renfrew.

I want to commend my Republican colleagues. I know that they're not supporting this legislation, and I grieve about that. But the harsh fact of the matter is they were very helpful in doing this in times past. And I want to pay particular tribute to Mr. SHIMKUS, Mr. Deal, and Mr. BARTON, but I do want it known that were it not for the labor of three great men in the other body, we would not be where we are. 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 I hope that the people 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 deliberate speed.

Mr. Speaker, consideration of this bill today is what I hope will be the final step of a long legislative journey. My colleagues in this body passed similar legislation last July. Some 17 months later, we are working on the same issue.

The legislative fits and starts is in no way a reflection of the policy, however, the legislation has been the hostage of political games and procedural missteps. The FDA Food Safety Modernization Act serves a necessary and admirable purpose—it will go 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 Agency with oversight of 80 percent of the nation's food supply—the authorities and resources it needs to effectively do its job.

Among other things, the legislation will:

Create a new focus on prevention, and a shared responsibility between FDA and food manufacturers to keep the food supply safe. It will require manufacturers to implement preventive systems to stop outbreaks before they occur;

Require FDA to inspect food facilities—foreign and domestic—more frequently;

Grant FDA new authority to ensure that imported foods meet U.S. safety standards and will assure foreign growers and producers must be treated with the same care that American growers and producers are; 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 ot America; Consumers 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 inspect records relating to 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 country 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. Once the origin of the salmonella outbreak was determined, the FDA and other federal agencies took action and required the responsible parties to recall all produce that they thought may have been tainted.

In the United States in 2010, at a time when we have the newest and greatest technologies at our disposal, outbreaks like the 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 traceability of the history of food in the event of a food borne illness outbreak. Often time, when our country has been faced by serious food poisoning that have affected thousands of American people, we do not know where the food was produced or cultivated. This bill would bring an end to that. It is important for us to be ever cautious that could affect the well being and health of our children, elderly and family members.

In addition to what I have mentioned, this bill would also make available a certificate of certain food imports—requiring all foods imported into the United States to meet all U.S. food safety requirements. The certificate would ensure that we are only allowing the safest and most healthy food 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 the elimination of the registration fee imposed on facilities participating in the food system. In addition, this legislation provides for a limited exemption for small food producers and processors that sell the majority of their food directly to consumers or to grocers within a circumscribed area and whose food sales are less than $500,000 per year.

The legislation before the House of Representatives is supported by a range of consumer and industry groups, including the American Public Health Association, the Center for Foodborne Illness Research and Prevention, the Center for Public Interest, the Consumer Federation of America, the Grocery Manufacturers Association, and the U.S. Chamber of Commerce.

It is time that we stand with this broad-based coalitions as we work to improve the food we eat and consume and know where exactly it's coming from. These actions will only help our country, families and our American people from having safety and consumer-friendly produce, meats and dairy.

Mr. FARR. Mr. Speaker, I would first like to thank Chairman WAXMAN and Chairman DINGELL for drafting a very strong food safety bill and leading a comprehensive debate by the House. Their legislation included three vital components that are all founded on a strong scientific base. I also want to commend them for including the teeth we need to implement mandatory recalls, as well as a commodity-specific approach to produce safety. Also important, the bill incorporated the flexibility we need to cover our growers, handlers, and processors.

Yet the Senate bill we will be voting on today, The FDA Food Safety Modernization

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 all too well. The safety 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 producer. And we need to help all growers small or large, comply with the regulations that will be promulgated from this legislation. Anything less falls short of true food safety reform, and could be a dangerous disservice to the American public.

The region I represent, California's Central Coast, is the top producing specialty crop region in the world. As such, I am proud to say that food safety is our region's industry's top priority. The men and women who grow, pack, and market fresh produce are committed to providing consumers with safe and wholesome foods from field to fork. Our local industry is constantly working to enhance and improve their performance in growing crops, harvesting and handling for distribution, packaging and processing into convenient ready-to-eat products. In addition to following all protocols to maintain the safest possible delivery chain—all the way to the consumer's table.

Mr. Speaker, Food Safety knows no price point—Salmonella, e. Coli and Listeria don't care if the food is grown conventionally or organically—or if the produce is grown on a large ranch or small farm. That's why provisions in this bill that exempt small producers from oversight are simply unacceptable and dangerous. We need policy based on sound science, and exempting certain sectors of the industry is not sound policy. Instead, we should be providing those small producers with the tools and incentives they need to meet the food safety standards we are voting on today.

Food producers are dedicated to continuously improving on-farm 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 American consumer.

Congress needs to understand—just as my growers understand—that any fruit or vegetable implicated in an outbreak taints the entire agricultural industry. And those isolated instances are cumulative. If we allow small producers to avoid oversight, the outbreaks that are likely to occur will result in the harm of all growers, handlers, processors, and shippers.

I'm committed to ensuring that when food safety regulation does come to fruition, it is developed and implemented with industry input. And that it provides pragmatic food safety guidelines that are both feasible and effective for growers, processors, handlers, and consumers.

Mr. Speaker, this legislation does offer a step forward, but be certain that today we could have taken a leap forward.

I look forward to working with my colleagues, constituents and the agencies to developing meaningful scientifically based food safety standards. But unfortunately, I can not support this bill as it is presented to us from the Senate.

Mr. VAN HOLLEN. Mr. Speaker, I rise in support of this legislation that will provide the Food and Drug Administration, FDA, muchneeded enhanced authorities to protect the American public from unsafe foods.

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. 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 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 the order of the House of today, further proceedings on this question will be postponed.

AMERICA COMPETES REAUTHORIZATION ACT OF 2010

The SPEAKER pro tempore. Pursuant to clause 1(c) of rule XIX, proceedings will now resume on the motion to concur in the Senate amendment to the bill (H.R. 5116) to invest in innovation through research and development, to improve the competitiveness of the United States, and for other purposes.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion by the gentleman from Tennessee (Mr. GORDON).

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mr. BROUN of Georgia. 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 XX, this 15-minute vote on the motion to concur in the Senate amendment to H.R. 5116 will be followed by 5-minute votes on motions to concur with respect to H.R. 2142 and H.R. 2751 and the motion to suspend on S. 3243.

The vote was taken by electronic device, and there were—yeas 228, nays 130, not voting 75, as follows:

[Roll No. 659]

YEAS—228

Ackerman	Ellison	Maloney
Altmire	Ellsworth	Markey (CO)
Andrews	Engel	Markey (MA)
Arcuri	Eshoo	Marshall
Baldwin	Etheridge	Matheson
Barrow	Farr	Matsui
Bartlett	Fattah	McCaul
Bean	Filner	McCollum
Becerra	Foster	McDermott
Berkley	Frank (MA)	McGovern
Berman	Fudge	McIntyre
Biggert	Gerlach	McNerney
Bilbray	Giffords	Meek (FL)
Bishop (GA)	Gonzalez	Meeks (NY)
Bishop (NY)	Gordon (TN)	Michaud
Boccieri	Grayson	Miller (NC)
Boren	Green, Al	Miller, George
Boswell	Green, Gene	Minnick
Boucher	Grijalva	Mollohan
Boyd	Hall (NY)	Moore (KS)
Brady (PA)	Halvorson	Moore (WI)
Braley (IA)	Hare	Moran (VA)
Brown, Corrine	Harman	Murphy (CT)
Butterfield	Hastings (FL)	Murphy (NY)
Capito	Heinrich	Murphy, Patrick
Capps	Higgins	Nadler (NY)
Capuano	Hill	Napolitano
Cardoza	Himes	Nye
Carnahan	Hinchey	Oberstar
Carney	Hinojosa	Obey
Carson (IN)	Hirono	Olver
Cassidy	Holden	Owens
Castle	Holt	Pallone
Castor (FL)	Inslee	Pascrell
Chandler	Israel	Payne
Childers	Jackson (IL)	Perlmutter
Clarke	Jackson Lee (TX)	Perriello
Clay	Johnson (GA)	Peters
Cleaver	Johnson (IL)	Peterson
Clyburn	Johnson, E. B.	Pingree (ME)
Cohen	Kagen	Polis (CO)
Connolly (VA)	Kanjorski	Pomeroy
Conyers	Kaptur	Price (NC)
Cooper	Kildee	Quigley
Costa	Kilroy	Rahall
Courtney	Kind	Rangel
Critz	Kirkpatrick (AZ)	Reed
Crowley	Kissell	Reichert
Cuellar	Klein (FL)	Richardson
Cummings	Kosmas	Rodriguez
Dahlkemper	Kratovil	Ross
Davis (CA)	Kucinich	Rothman (NJ)
Davis (TN)	Langevin	Roybal-Allard
DeFazio	Larsen (WA)	Ruppersberger
DeGette	Larson (CT)	Ryan (OH)
DeLauro	Lee (NY)	Sánchez, Linda T.
Dent	Levin	Sarbanes
Dicks	Lewis (GA)	Schakowsky
Dingell	Lipinski	Schauer
Doggett	Loebsack	Schiff
Donnelly (IN)	Lowey	Schrader
Driehaus	Luján	Schwartz
Edwards (MD)	Lynch	Scott (GA)
Edwards (TX)	Maffei	Scott (VA)
Ehlers		