

**Calendar No. 247**111<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION**S. 510**

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

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## IN THE SENATE OF THE UNITED STATES

MARCH 3, 2009

Mr. DURBIN (for himself, Mr. GREGG, Mr. KENNEDY, Mr. BURR, Mr. DODD, Mr. ALEXANDER, Mr. ISAKSON, Ms. KLOBUCHAR, Mr. CHAMBLISS, Mr. BURRIS, Mr. UDALL of New Mexico, Mrs. GILLIBRAND, Mr. HATCH, Mr. BINGAMAN, Mr. HARKIN, and Mr. ENZI) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

DECEMBER 18, 2009

Reported by Mr. HARKIN, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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**A BILL**

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

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CON-**  
 2 **TENTS.**

3 (a) **SHORT TITLE.**—This Act may be cited as the  
 4 “FDA Food Safety Modernization Act”.

5 (b) **REFERENCES.**—Except as otherwise specified,  
 6 whenever in this Act an amendment is expressed in terms  
 7 of an amendment to a section or other provision, the ref-  
 8 erence shall be considered to be made to a section or other  
 9 provision of the Federal Food, Drug, and Cosmetic Act  
 10 (21 U.S.C. 301 et seq.).

11 (c) **TABLE OF CONTENTS.**—The table of contents for  
 12 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. Final rule for prevention of Salmonella Enteritidis in shell eggs dur-  
 ing production.

Sec. 112. Sanitary transportation of food.

Sec. 113. Food allergy and anaphylaxis management.

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

Sec. 201. Targeting of inspection resources for domestic facilities, foreign facili-  
 ties, and ports of entry; annual report.

Sec. 202. Recognition of laboratory accreditation for analyses of foods.

Sec. 203. Integrated consortium of laboratory networks.

Sec. 204. Enhancing traceback and recordkeeping.

Sec. 205. Surveillance.

Sec. 206. Mandatory recall authority.

Sec. 207. Administrative detention of food.  
 Sec. 208. Decontamination and disposal standards and plans.

#### 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. Review of a regulatory authority of a foreign country.  
 Sec. 306. Building capacity of foreign governments with respect to food.  
 Sec. 307. Inspection of foreign food facilities.  
 Sec. 308. Accreditation of qualified third-party auditors and audit agents.  
 Sec. 309. Foreign offices of the Food and Drug Administration.

#### TITLE IV—MISCELLANEOUS PROVISIONS

Sec. 401. Funding for food safety.  
 Sec. 402. Jurisdiction; authorities.

# 1 **TITLE I—IMPROVING CAPACITY** 2 **TO PREVENT FOOD SAFETY** 3 **PROBLEMS**

## 4 **SEC. 101. INSPECTIONS OF RECORDS.**

5 (a) IN GENERAL.—Section 414(a) (21 U.S.C.  
 6 350e(a)) is amended—

7 (1) by striking the heading and all follows  
 8 through “of food is” and inserting the following:  
 9 “RECORDS INSPECTION.—

10 “(1) ADULTERATED FOOD.—If the Secretary  
 11 has a reasonable belief that an article of food, and  
 12 any other article of food that the Secretary reason-  
 13 ably believes is likely to be affected in a similar man-  
 14 ner, is”;

15 (2) by inserting “, and to any other article of  
 16 food that the Secretary reasonably believes is likely

1 to be affected in a similar manner,” after “relating  
2 to such article”;

3 (3) by striking the last sentence; and

4 (4) by inserting at the end the following:

5 “(2) USE OF OR EXPOSURE TO FOOD OF CON-  
6 CERN.—If the Secretary believes that there is a rea-  
7 sonable probability that the use of or exposure to an  
8 article of food, and any other article of food that the  
9 Secretary reasonably believes is likely to be affected  
10 in a similar manner, will cause serious adverse  
11 health consequences or death to humans or animals,  
12 each person (excluding farms and restaurants) who  
13 manufactures, processes, packs, distributes, receives,  
14 holds, or imports such article shall, at the request of  
15 an officer or employee duly designated by the Sec-  
16 retary, permit such officer or employee, upon presen-  
17 tation of appropriate credentials and a written notice  
18 to such person, at reasonable times and within rea-  
19 sonable limits and in a reasonable manner, to have  
20 access to and copy all records relating to such article  
21 and to any other article of food that the Secretary  
22 reasonably believes is likely to be affected in a simi-  
23 lar manner, that are needed to assist the Secretary  
24 in determining whether there is a reasonable prob-  
25 ability that the use of or exposure to the food will

1       cause serious adverse health consequences or death  
2       to humans or animals.

3           ~~“(3) APPLICATION.—~~The requirement under  
4       paragraphs (1) and (2) applies to all records relating  
5       to the manufacture, processing, packing, distribu-  
6       tion, receipt, holding, or importation of such article  
7       maintained by or on behalf of such person in any  
8       format (including paper and electronic formats) and  
9       at any location.”.

10       (b)       ~~CONFORMING        AMENDMENT.—~~Section  
11       704(a)(1)(B) (~~21 U.S.C. 374(a)(1)(B)~~) is amended by  
12       striking “section 414 when” and all that follows through  
13       “subject to” and inserting “section 414, when the stand-  
14       ard for record inspection under paragraph (1) or (2) of  
15       section 414(a) applies, subject to”.

16       **SEC. 102. REGISTRATION OF FOOD FACILITIES.**

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

20           (1) in paragraph (2), by—

21                   (A) striking “conducts business and” and  
22                   inserting “conducts business, the e-mail address  
23                   for the contact person of the facility or, in the  
24                   ease of a foreign facility, the United States  
25                   agent for the facility, and”; and

1           (B) inserting “, or any other food cat-  
 2           egories as determined appropriate by the Sec-  
 3           retary, including by guidance)” after “Code of  
 4           Federal Regulations”;

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

7           (3) by inserting after paragraph (2) the fol-  
 8           lowing:

9           “(3) BIENNIAL REGISTRATION RENEWAL.—

10          During the period beginning on October 1 and end-  
 11          ing on December 31 of each even-numbered year, a  
 12          registrant that has submitted a registration under  
 13          paragraph (1) shall submit to the Secretary a re-  
 14          newal registration containing the information de-  
 15          scribed in paragraph (2). The Secretary shall pro-  
 16          vide for an abbreviated registration renewal process  
 17          for any registrant that has not had any changes to  
 18          such information since the registrant submitted the  
 19          preceding registration or registration renewal for the  
 20          facility involved.”.

21          (b) SUSPENSION OF REGISTRATION.—

22          (1) IN GENERAL.—Section 415 (21 U.S.C.  
 23          350d) is amended—

24                 (A) in subsection (a)(2), by inserting after  
 25                 the first sentence the following: “The registra-

1           tion shall contain an assurance that the Sec-  
 2           retary will be permitted to inspect such facility  
 3           at the times and in the manner permitted by  
 4           this Act.”;

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

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

9           “(b) **SUSPENSION OF REGISTRATION.**—

10           “(1) **IN GENERAL.**—If the Secretary determines  
 11           that food manufactured, processed, packed, or held  
 12           by a facility registered under this section has a rea-  
 13           sonable probability of causing serious adverse health  
 14           consequences or death to humans or animals, the  
 15           Secretary may by order suspend the registration of  
 16           the facility under this section in accordance with this  
 17           subsection.

18           “(2) **HEARING ON SUSPENSION.**—The Secretary  
 19           shall provide the registrant subject to an order  
 20           under paragraph (1) with an opportunity for an in-  
 21           formal hearing, to be held as soon as possible but  
 22           not later than 2 days after the issuance of the order,  
 23           on the actions required for reinstatement of registra-  
 24           tion and why the registration that is subject to sus-  
 25           pension should be reinstated. The Secretary shall re-

1 instate a registration if the Secretary determines,  
2 based on evidence presented, that adequate grounds  
3 do not exist to continue the suspension of the reg-  
4 istration.

5 “(3) POST-HEARING CORRECTIVE ACTION PLAN;  
6 VACATING OF ORDER.—

7 “(A) CORRECTIVE ACTION PLAN.—If, after  
8 providing opportunity for an informal hearing  
9 under paragraph (2), the Secretary determines  
10 that the suspension of registration remains nec-  
11 essary, the Secretary shall require the reg-  
12 istrant to submit a corrective action plan to  
13 demonstrate how the registrant plans to correct  
14 the conditions found by the Secretary. The Sec-  
15 retary shall review such plan in a timely man-  
16 ner.

17 “(B) VACATING OF ORDER.—Upon a de-  
18 termination by the Secretary that adequate  
19 grounds do not exist to continue the suspension  
20 actions required by the order, or that such ac-  
21 tions should be modified, the Secretary shall va-  
22 cate the order or modify the order.

23 “(4) EFFECT OF SUSPENSION.—If the registra-  
24 tion of a facility is suspended under this subsection,  
25 such facility shall not import food or offer to import



1 food into the United States, or otherwise introduce  
2 food into interstate commerce in the United States.

3 ~~“(5) REGULATIONS.—~~The Secretary shall pro-  
4 mulgate regulations that describe the standards offi-  
5 cials will use in making a determination to suspend  
6 a registration, and the format such officials will use  
7 to explain to the registrant the conditions found at  
8 the facility.

9 ~~“(6) NO DELEGATION.—~~The authority con-  
10 ferred by this subsection to issue an order to sus-  
11 pend a registration or vacate an order of suspension  
12 shall not be delegated to any officer or employee  
13 other than the Commissioner.”.

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

18 ~~(c) CONFORMING AMENDMENTS.—~~

19 ~~(1) Section 301(d) (21 U.S.C. 331(d)) is~~  
20 ~~amended by inserting “415,” after “404,”.~~

21 ~~(2) Section 415(d), as redesignated by sub-~~  
22 ~~section (b), is amended by adding at the end before~~  
23 ~~the period “for a facility to be registered, except~~  
24 ~~with respect to the reinstatement of a registration~~  
25 ~~that is suspended under subsection (b)”.~~

1 **SEC. 103. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE**  
 2 **CONTROLS.**

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

5 **“SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVEN-**  
 6 **TIVE CONTROLS.**

7 “(a) **IN GENERAL.**—Each owner, operator, or agent  
 8 in charge of a facility shall, in accordance with this sec-  
 9 tion, evaluate the hazards that could affect food manufac-  
 10 tured, processed, packed, or held by such facility, identify  
 11 and implement preventive controls to significantly mini-  
 12 mize or prevent their occurrence and provide assurances  
 13 that such food is not adulterated under section 402 or  
 14 misbranded under section 403(w); monitor the perform-  
 15 ance of those controls; and maintain records of this moni-  
 16 toring as a matter of routine practice.

17 “(b) **HAZARD ANALYSIS.**—The owner, operator, or  
 18 agent in charge of a facility shall—

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

22 “(A) biological, chemical, physical, and ra-  
 23 diological hazards; natural toxins; pesticides;  
 24 drug residues; decomposition; parasites; aller-  
 25 gens; and unapproved food and color additives;  
 26 and

1           “(B) hazards that occur naturally, may be  
2           unintentionally introduced, or may be inten-  
3           tionally introduced, including by acts of ter-  
4           rorism; and

5           “(2) develop a written analysis of the hazards.

6           “(e) PREVENTIVE CONTROLS.—The owner, operator,  
7           or agent in charge of a facility shall identify and imple-  
8           ment preventive controls, including at critical control  
9           points, if any, to provide assurances that—

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

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

16           “(d) MONITORING OF EFFECTIVENESS.—The owner,  
17           operator, or agent in charge of a facility shall monitor the  
18           effectiveness of the preventive controls implemented under  
19           subsection (e) to provide assurances that the outcomes de-  
20           scribed in subsection (e) shall be achieved.

21           “(e) CORRECTIVE ACTIONS.—The owner, operator,  
22           or agent in charge of a facility shall establish procedures  
23           that a facility will implement if the preventive controls im-  
24           plemented under subsection (e) are found to be ineffective  
25           through monitoring under subsection (d).

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

3           “(1) the preventive controls implemented under  
4 subsection (c) are adequate to control the hazards  
5 identified under subsection (b);

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

8           “(3) the owner, operator, or agent is making  
9 appropriate decisions about corrective actions taken  
10 under subsection (c); and

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

16       “(g) RECORDKEEPING.—The owner, operator, or  
17 agent in charge of a facility shall maintain, for not less  
18 than 2 years, records documenting the monitoring of the  
19 preventive controls implemented under subsection (c), in-  
20 stances of nonconformance material to food safety, in-  
21 stances when corrective actions were implemented, and the  
22 efficacy of preventive controls and corrective actions.

23       “(h) WRITTEN PLAN AND DOCUMENTATION.—Each  
24 owner, operator, or agent in charge of a facility shall pre-  
25 pare a written plan that documents and describes the pro-

1 cedures used by the facility to comply with the require-  
2 ments of this section, including analyzing the hazards  
3 under subsection (b) and identifying the preventive con-  
4 trols adopted to address those hazards under subsection  
5 (e). Such written plan, together with documentation that  
6 the plan is being implemented, shall be made promptly  
7 available to a duly authorized representative of the Sec-  
8 retary upon oral or written request.

9       “(i) REQUIREMENT TO REANALYZE.—Each owner,  
10 operator, or agent in charge of a facility shall conduct a  
11 reanalysis under subsection (b) whenever a significant  
12 change is made in the activities conducted at a facility  
13 operated by such owner, operator, or agent if the change  
14 creates a reasonable potential for a new hazard or a sig-  
15 nificant increase in a previously identified hazard or not  
16 less frequently than once every 3 years, whichever is ear-  
17 lier. Such reanalysis shall be completed and additional pre-  
18 ventive controls needed to address the hazard identified,  
19 if any, shall be implemented before the change in activities  
20 at the facility is commenced. Such owner, operator, or  
21 agent shall revise the written plan required under sub-  
22 section (h) if such a significant change is made or docu-  
23 ment the basis for the conclusion that no additional or  
24 revised preventive controls are needed. The Secretary may

1 require a reanalysis under this section to respond to new  
2 hazards and developments in scientific understanding.

3       “(j) ~~DEEMED COMPLIANCE OF SEAFOOD, JUICE,~~  
4 ~~AND LOW-ACID CANNED FOOD FACILITIES IN COMPLI-~~  
5 ~~ANCE WITH HACCP.~~—An owner, operator, or agent in  
6 charge of a facility required to comply with 1 of the fol-  
7 lowing standards and regulations with respect to such fa-  
8 cility shall be deemed to be in compliance with this section,  
9 with respect to such facility:

10           “(1) The Seafood Hazard Analysis Critical  
11 Control Points Program of the Food and Drug Ad-  
12 ministration.

13           “(2) The Juice Hazard Analysis Critical Con-  
14 trol Points Program of the Food and Drug Adminis-  
15 tration.

16           “(3) The Thermally Processed Low-Acid Foods  
17 Packaged in Hermetically Sealed Containers stand-  
18 ards of the Food and Drug Administration (or any  
19 successor standards).

20       “(k) ~~EXCEPTION FOR FACILITIES IN COMPLIANCE~~  
21 ~~WITH SECTION 419.~~—This section shall not apply to a  
22 facility that is subject to section 419.

23       “(l) ~~AUTHORITY WITH RESPECT TO CERTAIN FA-~~  
24 ~~CILITIES.~~—The Secretary may, by regulation, exempt or  
25 modify the requirements for compliance under this section

1 with respect to facilities that are solely engaged in the pro-  
2 duction of food for animals other than man or the storage  
3 of packaged foods that are not exposed to the environ-  
4 ment.

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

6 “(1) CRITICAL CONTROL POINT.—The term  
7 ‘critical control point’ means a point, step, or proce-  
8 dure in a food process at which control can be ap-  
9 plied and is essential to prevent or eliminate a food  
10 safety hazard or reduce it to an acceptable level.

11 “(2) FACILITY.—The term ‘facility’ means a  
12 domestic facility or a foreign facility that is required  
13 to register under section 415.

14 “(3) PREVENTIVE CONTROLS.—The term ‘pre-  
15 ventive controls’ means those risk-based, reasonably  
16 appropriate procedures, practices, and processes that  
17 a person knowledgeable about the safe manufac-  
18 turing, processing, packing, or holding of food would  
19 have employed to significantly minimize or prevent  
20 the hazards identified under the hazard analysis con-  
21 ducted under subsection (a) and that are consistent  
22 with the current scientific understanding of safe  
23 food manufacturing, processing, packing, or holding  
24 at the time of the analysis. Those procedures, prac-  
25 tices, and processes may include the following:

1           “(A) Sanitation procedures for food con-  
2           tact surfaces and utensils and food-contact sur-  
3           faces of equipment.

4           “(B) Supervisor, manager, and employee  
5           hygiene training.

6           “(C) An environmental monitoring pro-  
7           gram to verify the effectiveness of pathogen  
8           controls.

9           “(D) An allergen control program.

10          “(E) A recall contingency plan.

11          “(F) Good Manufacturing Practices  
12          (GMPs).

13          “(G) Supplier verification activities.”.

14          (b) REGULATIONS.—

15           (1) IN GENERAL.—The Secretary of Health and  
16           Human Services (referred to in this Act as the “Sec-  
17           retary”) shall promulgate regulations to establish  
18           science-based minimum standards for conducting a  
19           hazard analysis, documenting hazards, implementing  
20           preventive controls, and documenting the implemen-  
21           tation of the preventive controls under section 418  
22           of the Federal Food, Drug, and Cosmetic Act (as  
23           added by subsection (a)).

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



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

3 ~~(3) RULE OF CONSTRUCTION.~~—Nothing in this  
4 subsection shall be construed to provide the Sec-  
5 retary with the authority to apply specific tech-  
6 nologies, practices, or critical controls to an indi-  
7 vidual facility.

8 (4) REVIEW.—In promulgating the regulations  
9 under paragraph (1), the Secretary shall review reg-  
10 ulatory hazard analysis and preventive control pro-  
11 grams in existence on the date of enactment of this  
12 Act to ensure that the program under such section  
13 418 is consistent, to the extent practicable, with ap-  
14 plicable internationally recognized standards in exist-  
15 ence on such date.

16 ~~(c) GUIDANCE DOCUMENT.~~—The Secretary shall  
17 issue a guidance document related to hazard analysis and  
18 preventive controls required under section 418 of the Fed-  
19 eral Food, Drug, and Cosmetic Act (as added by sub-  
20 section (a)).

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

23 “(oo) The operation of a facility that manufacturers,  
24 processes, packs, or holds food for sale in the United

1 States if the owner, operator, or agent in charge of such  
 2 facility is not in compliance with section 418.”.

3 (e) NO EFFECT ON HACCP AUTHORITIES.—Noth-  
 4 ing in the amendments made by this section limits the au-  
 5 thority of the Secretary under the Federal Food, Drug,  
 6 and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public  
 7 Health Service Act (42 U.S.C. 201 et seq.) to revise, issue,  
 8 or enforce product and category-specific regulations, such  
 9 as the Seafood Hazard Analysis Critical Controls Points  
 10 Program, the Juice Hazard Analysis Critical Control Pro-  
 11 gram, and the Thermally Processed Low-Acid Foods  
 12 Packaged in Hermetically Sealed Containers standards.

13 (f) EFFECTIVE DATE.—

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

17 (2) EXCEPTIONS.—Notwithstanding paragraph  
 18 (1)—

19 (A) the amendments made by this section  
 20 shall apply to a small business (as defined by  
 21 the Secretary) after the date that is 2 years  
 22 after the date of enactment of this Act; and

23 (B) the amendments made by this section  
 24 shall apply to a very small business (as defined

1           by the Secretary) after the date that is 3 years  
2           after the date of enactment of this Act.

3 **SEC. 104. PERFORMANCE STANDARDS.**

4           The Secretary shall, not less frequently than every  
5 2 years, review and evaluate relevant health data and  
6 other relevant information, including from toxicological  
7 and epidemiological studies and analyses, to determine the  
8 most significant food-borne contaminants and, when ap-  
9 propriate to reduce the risk of serious illness or death to  
10 humans or animals or to prevent the adulteration of the  
11 food under section 402 of the Federal Food, Drug, or Cos-  
12 metic Act, (21 U.S.C. 342) or to prevent the spread of  
13 communicable disease under section 361 of the Public  
14 Health Service Act (42 U.S.C. 264), shall issue contami-  
15 nant-specific and science-based guidance documents, ac-  
16 tions levels, or regulations. Such guidance, action levels,  
17 or regulations shall apply to products or product classes  
18 and shall not be written to be facility-specific.

19 **SEC. 105. STANDARDS FOR PRODUCE SAFETY.**

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

23 **“SEC. 419. STANDARDS FOR PRODUCE SAFETY.**

24           “(a) PROPOSED RULEMAKING.—

1           “(1) IN GENERAL.—Not later than 1 year after  
2 the date of enactment of the FDA Food Safety Mod-  
3 ernization Act, the Secretary, in consultation with  
4 the Secretary of Agriculture and representatives of  
5 State departments of agriculture, shall publish a no-  
6 tice of proposed rulemaking to establish science-  
7 based minimum standards for the safe production  
8 and harvesting of those types of fruits and vegeta-  
9 bles that are raw agricultural commodities for which  
10 the Secretary has determined that such standards  
11 minimize the risk of serious adverse health con-  
12 sequences or death.

13           “(2) PUBLIC INPUT.—During the comment pe-  
14 riod on the notice of proposed rulemaking under  
15 paragraph (1), the Secretary shall conduct not less  
16 than 3 public meetings in diverse geographical areas  
17 of the United States to provide persons in different  
18 regions an opportunity to comment.

19           “(3) CONTENT.—The proposed rulemaking  
20 under paragraph (1) shall—

21           “(A) include, with respect to growing, har-  
22 vesting, sorting, and storage operations, min-  
23 imum standards related to soil amendments,  
24 hygiene, packaging, temperature controls, ani-  
25 mal encroachment, and water; and

1           “(B) consider hazards that occur naturally,  
2           may be unintentionally introduced, or may be  
3           intentionally introduced, including by acts of  
4           terrorism.

5           “(4) PRIORITIZATION.—The Secretary shall  
6           prioritize the implementation of the regulations for  
7           specific fruits and vegetables that are raw agricul-  
8           tural commodities that have been associated with  
9           food-borne illness outbreaks.

10          “(b) FINAL REGULATION.—

11           “(1) IN GENERAL.—Not later than 1 year after  
12           the close of the comment period for the proposed  
13           rulemaking under subsection (a), the Secretary shall  
14           adopt a final regulation to provide for minimum  
15           standards for those types of fruits and vegetables  
16           that are raw agricultural commodities for which the  
17           Secretary has determined that such standards mini-  
18           mize the risk of serious adverse health consequences  
19           or death.

20           “(2) FINAL REGULATION.—The final regulation  
21           shall—

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

1           “(B) provide for coordination of education  
2           and enforcement activities by State and local  
3           officials, as designated by the Governors of the  
4           respective States; and

5           “(C) include a description of the variance  
6           process under subsection (e) and the types of  
7           permissible variances the Secretary may grant.

8           “(e) CRITERIA.—

9           “(1) IN GENERAL.—The regulations adopted  
10          under subsection (b) shall—

11           “(A) set forth those procedures, processes,  
12           and practices as the Secretary determines to be  
13           reasonably necessary to prevent the introduc-  
14           tion of known or reasonably foreseeable biologi-  
15           cal, chemical, and physical hazards, including  
16           hazards that occur naturally, may be uninten-  
17           tionally introduced, or may be intentionally in-  
18           troduced, including by acts of terrorism, into  
19           fruits and vegetables that are raw agricultural  
20           commodities and to provide reasonable assur-  
21           ances that the produce is not adulterated under  
22           section 402; and

23           “(B) permit States and foreign countries  
24           from which food is imported into the United  
25           States, subject to paragraph (2), to request

1 from the Secretary variances from the require-  
2 ments of the regulations, where upon approval  
3 of the Secretary, the variance is considered per-  
4 missible under the requirements of the regula-  
5 tions adopted under subsection (b)(2)(C) and  
6 where the State or foreign country determines  
7 that the variance is necessary in light of local  
8 growing conditions and that the procedures,  
9 processes, and practices to be followed under  
10 the variance are reasonably likely to ensure that  
11 the produce is not adulterated under section  
12 402 to the same extent as the requirements of  
13 the regulation adopted under subsection (b).

14 “(2) APPROVAL OF VARIANCES.—A State or  
15 foreign country from which food is imported into the  
16 United States shall request a variance from the Sec-  
17 retary in writing. The Secretary may deny such a re-  
18 quest as not reasonably likely to ensure that the  
19 produce is not adulterated under section 402 to the  
20 same extent as the requirements of the regulation  
21 adopted under subsection (b).

22 “(d) ENFORCEMENT.—The Secretary may coordinate  
23 with the Secretary of Agriculture and shall contract and  
24 coordinate with the agency or department designated by

1 the Governor of each State to perform activities to ensure  
2 compliance with this section.

3       “(e) GUIDANCE.—Not later than 1 year after the  
4 date of enactment of the FDA Food Safety Modernization  
5 Act, the Secretary shall publish, after consultation with  
6 the Secretary of Agriculture and representatives of State  
7 departments of agriculture, updated good agricultural  
8 practices and guidance for the safe production and har-  
9 vesting of specific types of fresh produce.

10       “(f) EXCEPTION FOR FACILITIES IN COMPLIANCE  
11 WITH SECTION 418.—This section shall not apply to a  
12 facility that is subject to section 418.”.

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

16       “(pp) The production or harvesting of produce not  
17 in accordance with minimum standards as provided by  
18 regulation under section 419(b) or a variance issued under  
19 section 419(c).”.

20       (e) NO EFFECT ON HACCP AUTHORITIES.—Nothing  
21 in the amendments made by this section limits the author-  
22 ity of the Secretary under the Federal Food, Drug, and  
23 Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health  
24 Service Act (42 U.S.C. 201 et seq.) to revise, issue, or  
25 enforce product and category-specific regulations, such as



1 the Seafood Hazard Analysis Critical Controls Points Pro-  
 2 gram, the Juice Hazard Analysis Critical Control Pro-  
 3 gram, and the Thermally Processed Low-Acid Foods  
 4 Packaged in Hermetically Sealed Containers standards.

5 **SEC. 106. PROTECTION AGAINST INTENTIONAL ADULTERA-**  
 6 **TION.**

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

10 **“SEC. 420. PROTECTION AGAINST INTENTIONAL ADULTERA-**  
 11 **TION.**

12 “(a) **IN GENERAL.**—Not later than 24 months after  
 13 the date of enactment of the FDA Food Safety Moderniza-  
 14 tion Act, the Secretary, in consultation with the Secretary  
 15 of Homeland Security and the Secretary of Agriculture,  
 16 shall promulgate regulations to protect against the inten-  
 17 tional adulteration of food subject to this Act.

18 “(b) **CONTENT OF REGULATIONS.**—Regulations  
 19 under subsection (a) shall only apply to food—

20 “(1) for which the Secretary has identified clear  
 21 vulnerabilities (such as short shelf-life or suscepti-  
 22 bility to intentional contamination at critical control  
 23 points);

24 “(2) in bulk or batch form, prior to being pack-  
 25 aged for the final consumer, and

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

5           “(e) DETERMINATIONS.—In making the determina-  
6           tion under subsection (b)(3), the Secretary shall—

7           “(1) conduct vulnerability assessments of the  
8           food system;

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

13           “(3) determine the types of science-based miti-  
14           gation strategies or measures that are necessary to  
15           protect against the intentional adulteration of food.

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

18           “(e) DEFINITION.—For purposes of this section, the  
19           term ‘farm’ has the meaning given that term in section  
20           1.227 of title 21, Code of Federal Regulations (or any suc-  
21           cessor regulation).”.

22           (b) GUIDANCE DOCUMENTS.—

23           (1) IN GENERAL.—Not later than 1 year after  
24           the date of enactment of this Act, the Secretary, in  
25           consultation with the Secretary of Homeland Secu-

1 rity and the Secretary of Agriculture, shall issue  
2 guidance documents related to protection against the  
3 intentional adulteration of food, including mitigation  
4 strategies or measures to guard against such adul-  
5 teration as required under section 420 of the Fed-  
6 eral Food, Drug, and Cosmetic Act, as added by  
7 subsection (a):

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

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

15 (B) specify appropriate science-based miti-  
16 gation strategies or measures to prepare and  
17 protect the food supply chain at specific vulner-  
18 able points, as appropriate;

19 (C) include a model assessment for a per-  
20 son to use under subparagraph (A);

21 (D) include examples of mitigation strate-  
22 gies or measures described in subparagraph  
23 (B); and

1           ~~(E)~~ specify situations in which the exam-  
 2           ples of mitigation strategies or measures de-  
 3           scribed in subparagraph ~~(D)~~ are appropriate.

4           ~~(3)~~ LIMITED DISTRIBUTION.—In the interest of  
 5           national security, the Secretary, in consultation with  
 6           the Secretary of Homeland Security, may determine  
 7           the time and manner in which the guidance docu-  
 8           ments issued under paragraph ~~(1)~~ are made public,  
 9           including by releasing such documents to targeted  
 10          audiences.

11          ~~(c)~~ PERIODIC REVIEW.—The Secretary shall periodi-  
 12          cally review and, as appropriate, update the regulation  
 13          under subsection ~~(a)~~ and the guidance documents under  
 14          subsection ~~(b)~~.

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

18          “~~(qq)~~ The failure to comply with section 420.”.

19          **SEC. 107. AUTHORITY TO COLLECT FEES.**

20          ~~(a)~~ FEES FOR REINSPECTION, RECALL, AND IMPOR-  
 21          TATION ACTIVITIES.—Subchapter C of chapter VII (21  
 22          U.S.C. 379f et seq.) is amended by inserting after section  
 23          740 the following:

1                   **“PART 5—FEES RELATED TO FOOD**

2                   **“SEC. 740A. AUTHORITY TO COLLECT AND USE FEES.**

3                   ~~“(a) IN GENERAL.—~~

4                   ~~“(1) PURPOSE AND AUTHORITY.—For fiscal~~  
5                   ~~year 2010 and each subsequent fiscal year, the Sec-~~  
6                   ~~retary shall, in accordance with this section, assess~~  
7                   ~~and collect fees from—~~

8                   ~~“(A) each domestic facility (as defined in~~  
9                   ~~section 415(b)) subject to a reinspection in such~~  
10                  ~~fiscal year, to cover reinspection-related costs~~  
11                  ~~for such year;~~

12                  ~~“(B) each domestic facility (as defined in~~  
13                  ~~section 415(b)) and importer subject to a food~~  
14                  ~~recall in such fiscal year, to cover food recall ac-~~  
15                  ~~tivities performed by the Secretary, including~~  
16                  ~~technical assistance, follow-up effectiveness~~  
17                  ~~checks, and public notifications, for such year;~~

18                  ~~“(C) each importer participating in the~~  
19                  ~~voluntary qualified importer program under sec-~~  
20                  ~~tion 806 in such year, to cover the administra-~~  
21                  ~~tive costs such program for such year; and~~

22                  ~~“(D) each importer subject to a reinspec-~~  
23                  ~~tion in such fiscal year at a port of entry, to~~  
24                  ~~cover reinspection-related costs at ports of entry~~  
25                  ~~for such year.~~

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

3                   “(A) the term ‘reinspection’ means—

4                           “(i) with respect to domestic facilities  
5                           (as defined in section 415(b)), 1 or more  
6                           inspections conducted under section 704  
7                           subsequent to an inspection conducted  
8                           under such provision which identified non-  
9                           compliance materially related to a food  
10                           safety requirement of this Act, specifically  
11                           to determine whether compliance has been  
12                           achieved to the Secretary’s satisfaction;  
13                           and

14                           “(ii) with respect to importers, 1 or  
15                           more examinations conducted under sec-  
16                           tion 801 subsequent to an examination  
17                           conducted under such provision which  
18                           identified noncompliance materially related  
19                           to a food safety requirement of this Act,  
20                           specifically to determine whether compli-  
21                           ance has been achieved to the Secretary’s  
22                           satisfaction; and

23                           “(B) the term ‘reinspection-related costs’  
24                           means all expenses, including administrative ex-  
25                           penses, incurred in connection with—

1           “(i) arranging, conducting, and evalu-  
2           ating the results of reinspections; and

3           “(ii) assessing and collecting reinspec-  
4           tion fees under this section.

5       “(b) ESTABLISHMENT OF FEES.—

6           “(1) IN GENERAL.—Subject to subsections (c)  
7           and (d), the Secretary shall establish the fees to be  
8           collected under this section for each fiscal year speci-  
9           fied in subsection (a)(1), based on the methodology  
10          described under paragraph (2), and shall publish  
11          such fees in a Federal Register notice not later than  
12          60 days before the start of each such year.

13          “(2) FEE METHODOLOGY.—

14               “(A) FEES.—Fees amounts established for  
15               collection—

16                   “(i) under subparagraph (A) of sub-  
17                   section (a)(1) for a fiscal year shall be  
18                   based on the Secretary’s estimate of 100  
19                   percent of the costs of the reinspection-re-  
20                   lated activities (including by type or level  
21                   of reinspection activity, as the Secretary  
22                   determines applicable) described in such  
23                   subparagraph (A) for such year;

24                   “(ii) under subparagraph (B) of sub-  
25                   section (a)(1) for a fiscal year shall be

1 based on the Secretary's estimate of 100  
2 percent of the costs of the activities de-  
3 scribed in such subparagraph (B) for such  
4 year;

5 “(iii) under subparagraph (C) of sub-  
6 section (a)(1) for a fiscal year shall be  
7 based on the Secretary's estimate of 100  
8 percent of the costs of the activities de-  
9 scribed in such subparagraph (C) for such  
10 year; and

11 “(iv) under subparagraph (D) of sub-  
12 section (a)(1) for a fiscal year shall be  
13 based on the Secretary's estimate of 100  
14 percent of the costs of the activities de-  
15 scribed in such subparagraph (D) for such  
16 year.

17 “(B) OTHER CONSIDERATIONS.—

18 “(i) VOLUNTARY QUALIFIED IM-  
19 PORTER PROGRAM.—

20 “(I) PARTICIPATION.—In estab-  
21 lishing the fee amounts under sub-  
22 subparagraph (A)(iii) for a fiscal year,  
23 the Secretary shall provide for the  
24 number of importers who have sub-  
25 mitted to the Secretary a notice under



1 section 806(e) informing the Sec-  
2 retary of the intent of such importer  
3 to participate in the program under  
4 section 806 in such fiscal year.

5 “(II) RECOUPMENT.—In estab-  
6 lishing the fee amounts under sub-  
7 paragraph (A)(iii) for the first 5 fiscal  
8 years after the date of enactment of  
9 this section, the Secretary shall in-  
10 clude in such fee a reasonable sur-  
11 charge that provides a recoupment of  
12 the costs expended by the Secretary to  
13 establish and implement the first year  
14 of the program under section 806.

15 “(ii) CREDITING OF FEES.—In estab-  
16 lishing the fee amounts under subpara-  
17 graph (A) for a fiscal year, the Secretary  
18 shall provide for the crediting of fees from  
19 the previous year to the next year if the  
20 Secretary overestimated the amount of fees  
21 needed to carry out such activities, and  
22 consider the need to account for any ad-  
23 justment of fees and such other factors as  
24 the Secretary determines appropriate.

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

6           “(4) COMPLIANCE WITH INTERNATIONAL  
7 AGREEMENTS.—Nothing in this section shall be con-  
8 strued to authorize the assessment of any fee incon-  
9 sistent with the agreement establishing the World  
10 Trade Organization or any other treaty or inter-  
11 national agreement to which the United States is a  
12 party.

13           “(c) LIMITATIONS.—

14           “(1) IN GENERAL.—Fees under subsection (a)  
15 shall be refunded for a fiscal year beginning after  
16 fiscal year 2010 unless appropriations for the Center  
17 for Food Safety and Applied Nutrition and the Cen-  
18 ter for Veterinary Medicine and related activities of  
19 the Office of Regulatory Affairs at the Food and  
20 Drug Administration for such fiscal year (excluding  
21 the amount of fees appropriated for such fiscal year)  
22 are equal to or greater than the amount of appro-  
23 priations for the Center for Food Safety and Applied  
24 Nutrition and the Center for Veterinary Medicine  
25 and related activities of the Office of Regulatory Af-

1       fairs at the Food and Drug Administration for the  
2       preceding fiscal year (excluding the amount of fees  
3       appropriated for such fiscal year) multiplied by 1  
4       plus 4.5 percent.

5           “(2) AUTHORITY.—If the Secretary does not  
6       assess fees under subsection (a) during any portion  
7       of a fiscal year because of paragraph (1) and if at  
8       a later date in such fiscal year the Secretary may as-  
9       sess such fees, the Secretary may assess and collect  
10      such fees, without any modification in the rate,  
11      under subsection (a), notwithstanding the provisions  
12      of subsection (a) relating to the date fees are to be  
13      paid.

14           “(3) LIMITATION ON AMOUNT OF CERTAIN  
15      FEES.—

16           “(A) IN GENERAL.—Notwithstanding any  
17      other provision of this section and subject to  
18      subparagraph (B), the Secretary may not col-  
19      lect fees in a fiscal year such that the amount  
20      collected—

21           “(i) under subparagraph (B) of sub-  
22      section (a)(1) exceeds \$20,000,000; and

23           “(ii) under subparagraphs (A) and  
24      (D) of subsection (a)(1) exceeds  
25      \$25,000,000 combined.

1           “(B) EXCEPTION.—If a domestic facility  
2           (as defined in section 415(b)) or an importer  
3           becomes subject to a fee described in subpara-  
4           graph (A), (B), or (D) of subsection (a)(1)  
5           after the maximum amount of fees has been  
6           collected by the Secretary under subparagraph  
7           (A), the Secretary may collect a fee from such  
8           facility or importer.

9           “(d) CREDITING AND AVAILABILITY OF FEES.—Fees  
10          authorized under subsection (a) shall be collected and  
11          available for obligation only to the extent and in the  
12          amount provided in appropriations Acts. Such fees are au-  
13          thorized to remain available until expended. Such sums  
14          as may be necessary may be transferred from the Food  
15          and Drug Administration salaries and expenses account  
16          without fiscal year limitation to such appropriation ac-  
17          count for salaries and expenses with such fiscal year limi-  
18          tation. The sums transferred shall be available solely for  
19          the purpose of paying the operating expenses of the Food  
20          and Drug Administration employees and contractors per-  
21          forming activities associated with these food safety fees.

22          “(e) COLLECTION OF FEES.—

23                 “(1) IN GENERAL.—The Secretary shall specify  
24                 in the Federal Register notice described in sub-

1 section (b)(1) the time and manner in which fees as-  
2 sessed under this section shall be collected.

3 “(2) COLLECTION OF UNPAID FEES.—In any  
4 ease where the Secretary does not receive payment  
5 of a fee assessed under this section within 30 days  
6 after it is due, such fee shall be treated as a claim  
7 of the United States Government subject to provi-  
8 sions of subchapter II of chapter 37 of title 31,  
9 United States Code.

10 “(f) ANNUAL REPORT TO CONGRESS.—Not later  
11 than 120 days after each fiscal year for which fees are  
12 assessed under this section, the Secretary shall submit a  
13 report to the Committee on Health, Education, Labor, and  
14 Pensions of the United States Senate and the Committee  
15 on Energy and Commerce of the United States House of  
16 Representatives, to include a description of fees assessed  
17 and collected for each such year and a summary descrip-  
18 tion of the entities paying such fees and the types of busi-  
19 ness in which such entities engage.

20 “(g) AUTHORIZATION OF APPROPRIATIONS.—For fis-  
21 cal year 2010 and each fiscal year thereafter, there is au-  
22 thorized to be appropriated for fees under this section an  
23 amount equal to the total revenue amount determined  
24 under subsection (b) for the fiscal year, as adjusted or

1 otherwise affected under the other provisions of this sec-  
2 tion.”.

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

5 (1) AUTHORITY FOR EXPORT CERTIFICATIONS  
6 FOR FOOD, INCLUDING ANIMAL FEED.—Section  
7 801(e)(4)(A) (~~21 U.S.C. 381(e)(4)(A)~~) is amend-  
8 ed—

9 (A) in the matter preceding clause (i), by  
10 striking “a drug” and inserting “a food, drug”;

11 (B) in clause (i) by striking “exported  
12 drug” and inserting “exported food, drug”; and

13 (C) in clause (ii) by striking “the drug”  
14 each place it appears and inserting “the food,  
15 drug”.

16 (2) CLARIFICATION OF CERTIFICATION.—Sec-  
17 tion 801(e)(4) (~~21 U.S.C. 381(e)(4)~~) is amended by  
18 inserting after subparagraph (B) the following new  
19 subparagraph:

20 “(C) For purposes of this paragraph, a  
21 certification by the Secretary shall be made on  
22 such basis, and in such form (including a pub-  
23 licly available listing) as the Secretary deter-  
24 mines appropriate.”.

1 **SEC. 108. NATIONAL AGRICULTURE AND FOOD DEFENSE**  
2 **STRATEGY.**

3 (a) DEVELOPMENT AND SUBMISSION OF STRAT-  
4 EGY.—

5 (1) IN GENERAL.—Not later than 1 year after  
6 the date of enactment of this Act, the Secretary of  
7 Health and Human Services and the Secretary of  
8 Agriculture, in coordination with the Secretary of  
9 Homeland Security, shall prepare and submit to the  
10 relevant committees of Congress, and make publicly  
11 available on the Internet Web site of the Depart-  
12 ment of Health and Human Services and the De-  
13 partment of Agriculture, the National Agriculture  
14 and Food Defense Strategy.

15 (2) IMPLEMENTATION PLAN.—The strategy  
16 shall include an implementation plan for use by the  
17 Secretaries described under paragraph (1) in ear-  
18 rying out the strategy.

19 (3) RESEARCH.—The strategy shall include a  
20 coordinated research agenda for use by the Secre-  
21 taries described under paragraph (1) in conducting  
22 research to support the goals and activities described  
23 in paragraphs (1) and (2) of subsection (b).

24 (4) REVISIONS.—Not later than 4 years after  
25 the date on which the strategy is submitted to the  
26 relevant committees of Congress under paragraph

1 (1), and not less frequently than every 4 years there-  
2 after, the Secretary of Health and Human Services  
3 and the Secretary of Agriculture, in coordination  
4 with the Secretary of Homeland Security, shall re-  
5 vise and submit to the relevant committees of Con-  
6 gress the strategy.

7 (5) CONSISTENCY WITH EXISTING PLANS.—The  
8 strategy described in paragraph (1) shall be con-  
9 sistent with—

10 (A) the National Incident Management  
11 System;

12 (B) the National Response Framework;

13 (C) the National Infrastructure Protection  
14 Plan;

15 (D) the National Preparedness Goals; and

16 (E) other relevant national strategies.

17 (b) COMPONENTS.—

18 (1) IN GENERAL.—The strategy shall include a  
19 description of the process to be used by the Depart-  
20 ment of Health and Human Services, the Depart-  
21 ment of Agriculture, and the Department of Home-  
22 land Security—

23 (A) to achieve each goal described in para-  
24 graph (2); and



1           (B) to evaluate the progress made by Fed-  
2           eral, State, local, and tribal governments to-  
3           wards the achievement of each goal described in  
4           paragraph (2).

5           (2) GOALS.—The strategy shall include a de-  
6           scription of the process to be used by the Depart-  
7           ment of Health and Human Services, the Depart-  
8           ment of Agriculture, and the Department of Home-  
9           land Security to achieve the following goals:

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

13                   (i) conducting vulnerability assess-  
14                   ments of the agriculture and food system;

15                   (ii) mitigating vulnerabilities of the  
16                   system;

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

19                   (iv) developing and conducting exer-  
20                   cises to test decontamination and disposal  
21                   plans;

22                   (v) developing modeling tools to im-  
23                   prove event consequence assessment and  
24                   decision support; and

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

4                   (B) DETECTION GOAL.—Improve agri-  
5                   culture and food system detection capabilities  
6                   by—

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

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

11                  (C) EMERGENCY RESPONSE GOAL.—En-  
12                  sure an efficient response to agriculture and  
13                  food emergencies by—

14                  (i) immediately investigating animal  
15                  disease outbreaks and suspected food con-  
16                  tamination;

17                  (ii) preventing additional human ill-  
18                  nesses;

19                  (iii) organizing, training, and equip-  
20                  ping animal, plant, and food emergency re-  
21                  sponse teams of—

22                               (I) the Federal Government; and

23                               (II) State, local, and tribal gov-  
24                               ernments;

1 (iv) designing, developing, and evalu-  
2 ating training and exercises carried out  
3 under agriculture and food defense plans;  
4 and

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

7 (I) the Federal Government;

8 (II) State, local, and tribal gov-  
9 ernments; and

10 (III) the private sector.

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

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

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

20 (iii) rapidly removing, and effectively  
21 disposing of—

22 (I) contaminated agriculture and  
23 food products; and

24 (II) infected plants and animals;  
25 and

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

4 **SEC. 109. FOOD AND AGRICULTURE COORDINATING COUN-**  
5 **CILS.**

6           The Secretary of Homeland Security, in consultation  
7 with the Secretary of Health and Human Services and the  
8 Secretary of Agriculture, shall within 180 days of enact-  
9 ment of this Act, and annually thereafter, submit to the  
10 relevant committees of Congress, and make publicly avail-  
11 able on the Internet Web site of the Department of Home-  
12 land Security, a report on the activities of the Food and  
13 Agriculture Government Coordinating Council and the  
14 Food and Agriculture Sector Coordinating Council, includ-  
15 ing the progress of such Councils on—

16                   (1) facilitating partnerships between public and  
17                   private entities to help unify and enhance the protec-  
18                   tion of the agriculture and food system of the  
19                   United States;

20                   (2) providing for the regular and timely inter-  
21                   change of information between each council relating  
22                   to the security of the agriculture and food system  
23                   (including intelligence information);

24                   (3) identifying best practices and methods for  
25                   improving the coordination among Federal, State,

1 local, and private sector preparedness and response  
2 plans for agriculture and food defense; and

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

6 (A) animal or plant disease outbreaks;

7 (B) food contamination; and

8 (C) natural disasters affecting agriculture  
9 and food.

10 **SEC. 110. BUILDING DOMESTIC CAPACITY.**

11 (a) IN GENERAL.—

12 (1) INITIAL REPORT.—The Secretary shall, not  
13 later than 2 years after the date of enactment of  
14 this Act, submit to Congress a comprehensive report  
15 that identifies programs and practices that are in-  
16 tended to promote the safety and security of food  
17 and to prevent outbreaks of food-borne illness and  
18 other food-related hazards that can be addressed  
19 through preventive activities. Such report shall in-  
20 clude a description of the following:

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

23 (B) Outreach to food industry sectors, in-  
24 cluding through the Food and Agriculture Co-  
25 ordinating Councils referred to in section 109;

1 to identify potential sources of emerging threats  
2 to the safety and security of the food supply  
3 and preventive strategies to address those  
4 threats.

5 (C) Systems to ensure the prompt distribu-  
6 tion to the food industry of information and  
7 technical assistance concerning preventive strat-  
8 egies.

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

13 (E) Surveillance systems and laboratory  
14 networks to rapidly detect and respond to food-  
15 borne illness outbreaks and other food-related  
16 hazards, including how such systems and net-  
17 works are integrated.

18 (F) Outreach, education, and training pro-  
19 vided to States and local governments to build  
20 State and local food safety and food defense ca-  
21 pabilities, including progress implementing  
22 strategies developed under sections 108 and  
23 205.

24 (G) The estimated resources needed to ef-  
25 fectively implement the programs and practices

1 identified in the report developed in this section  
2 over a 5-year period.

3 ~~(2) BIENNIAL REPORTS.~~—On a biennial basis  
4 following the submission of the report under para-  
5 graph (1), the Secretary shall submit to Congress a  
6 report that—

7 (A) reviews previous food safety programs  
8 and practices;

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

11 (C) identifies future programs and prac-  
12 tices; and

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

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

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

10           (d) INFORMATION TECHNOLOGY.—The report devel-  
11 oped under subsection (a)(1) shall include a description  
12 of such information technology systems as may be needed  
13 to identify risks and receive data from multiple sources,  
14 including foreign governments, State, local, and tribal gov-  
15 ernments, other Federal agencies, the food industry, lab-  
16 oratories, laboratory networks, and consumers. The infor-  
17 mation technology systems that the Secretary describes  
18 shall also provide for the integration of the facility reg-  
19 istration system under section 415 of the Federal Food,  
20 Drug, and Cosmetic Act (21 U.S.C. 350d), and the prior  
21 notice system under section 801(m) of such Act (21  
22 U.S.C. 381(m)) with other information technology systems  
23 that are used by the Federal Government for the proe-  
24 essing of food offered for import into the United States.



1           (e) ~~AUTOMATED RISK ASSESSMENT.~~—The report de-  
2 veloped under subsection (a)(1) shall include a description  
3 of progress toward developing and improving an auto-  
4 mated risk assessment system for food safety surveillance  
5 and allocation of resources.

6           (f) ~~TRACEBACK AND SURVEILLANCE REPORT.~~—The  
7 Secretary shall include in the report developed under sub-  
8 section (a)(1) an analysis of the Food and Drug Adminis-  
9 tration’s performance in food-borne illness outbreaks dur-  
10 ing the 5-year period preceding the date of enactment of  
11 this Act involving fruits and vegetables that are raw agri-  
12 cultural commodities (as defined in section 201(r) of the  
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(r))  
14 and recommendations for enhanced surveillance, outbreak  
15 response, and traceability. Such findings and rec-  
16 ommendations shall address communication and coordina-  
17 tion with the public, industry, and State and local govern-  
18 ments, outbreak identification, and traceback.

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

1 year period and the plan for projects to be conducted during the following 2-year period.

3 **SEC. 111. FINAL RULE FOR PREVENTION OF SALMONELLA**  
 4 **ENTERITIDIS IN SHELL EGGS DURING PRO-**  
 5 **DUCTION.**

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

12 **SEC. 112. SANITARY TRANSPORTATION OF FOOD.**

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

17 **SEC. 113. FOOD ALLERGY AND ANAPHYLAXIS MANAGE-**  
 18 **MENT.**

19 (a) DEFINITIONS.—In this section:

20 (1) EARLY CHILDHOOD EDUCATION PRO-  
 21 GRAM.—The term “early childhood education pro-  
 22 gram” means—

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

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

3           (C) a State prekindergarten program that  
4 serves children from birth through kinder-  
5 garten.

6           (2) ESEA DEFINITIONS.—The terms “local  
7 educational agency”, “secondary school”, “elemen-  
8 tary school”, and “parent” have the meanings given  
9 the terms in section 9101 of the Elementary and  
10 Secondary Education Act of 1965 (20 U.S.C. 7801).

11           (3) SCHOOL.—The term “school” includes pub-  
12 lic—

13                   (A) kindergartens;

14                   (B) elementary schools; and

15                   (C) secondary schools.

16           (4) SECRETARY.—The term “Secretary” means  
17 the Secretary of Health and Human Services.

18           (b) ESTABLISHMENT OF VOLUNTARY FOOD AL-  
19 LERGY AND ANAPHYLAXIS MANAGEMENT GUIDELINES.—

20                   (1) ESTABLISHMENT.—

21                           (A) IN GENERAL.—Not later than 1 year  
22 after the date of enactment of this Act, the Sec-  
23 retary, in consultation with the Secretary of  
24 Education, shall—

1           (i) develop guidelines to be used on a  
2           voluntary basis to develop plans for indi-  
3           viduals to manage the risk of food allergy  
4           and anaphylaxis in schools and early child-  
5           hood education programs; and

6           (ii) make such guidelines available to  
7           local educational agencies, schools, early  
8           childhood education programs, and other  
9           interested entities and individuals to be im-  
10          plemented on a voluntary basis only.

11          (B) APPLICABILITY OF FERPA.—Each plan  
12          described in subparagraph (A) that is developed  
13          for an individual shall be considered an edu-  
14          cation record for the purpose of the Family  
15          Educational Rights and Privacy Act of 1974  
16          (20 U.S.C. 1232g).

17          (2) CONTENTS.—The voluntary guidelines de-  
18          veloped by the Secretary under paragraph (1) shall  
19          address each of the following, and may be updated  
20          as the Secretary determines necessary:

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

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

- 1                   (I) supporting a diagnosis of food  
2                   allergy, and any risk of anaphylaxis, if  
3                   applicable;
- 4                   (II) identifying any food to which  
5                   the child is allergic;
- 6                   (III) describing, if appropriate,  
7                   any prior history of anaphylaxis;
- 8                   (IV) listing any medication pre-  
9                   scribed for the child for the treatment  
10                  of anaphylaxis;
- 11                  (V) detailing emergency treat-  
12                  ment procedures in the event of a re-  
13                  action;
- 14                  (VI) listing the signs and symp-  
15                  toms of a reaction; and
- 16                  (VII) assessing the child's readi-  
17                  ness for self-administration of pre-  
18                  scription medication; and
- 19                  (ii) a list of substitute meals that may  
20                  be offered to the child by school or early  
21                  childhood education program food service  
22                  personnel.
- 23                  (B) The creation and maintenance of an  
24                  individual plan for food allergy management, in  
25                  consultation with the parent, tailored to the

1 needs of each child with a documented risk for  
2 anaphylaxis, including any procedures for the  
3 self-administration of medication by such chil-  
4 dren in instances where—

5 (i) the children are capable of self-ad-  
6 ministering medication; and

7 (ii) such administration is not prohib-  
8 ited by State law.

9 (C) Communication strategies between in-  
10 dividual schools or early childhood education  
11 programs and providers of emergency medical  
12 services, including appropriate instructions for  
13 emergency medical response.

14 (D) Strategies to reduce the risk of expo-  
15 sure to anaphylactic causative agents in class-  
16 rooms and common school or early childhood  
17 education program areas such as cafeterias.

18 (E) The dissemination of general informa-  
19 tion on life-threatening food allergies to school  
20 or early childhood education program staff, par-  
21 ents, and children.

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

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

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

9           (I) The creation of a plan contained in  
10 each individual plan for food allergy manage-  
11 ment that addresses the appropriate response to  
12 an incident of anaphylaxis of a child while such  
13 child is engaged in extracurricular programs of  
14 a school or early childhood education program,  
15 such as non-academic outings and field trips,  
16 before- and after-school programs or before-  
17 and after-early child education program pro-  
18 grams, and school-sponsored or early childhood  
19 education program-sponsored programs held on  
20 weekends.

21           (J) Maintenance of information for each  
22 administration of epinephrine to a child at risk  
23 for anaphylaxis and prompt notification to par-  
24 ents.

1           ~~(K)~~ Other elements the Secretary deter-  
 2           mines necessary for the management of food al-  
 3           lergies and anaphylaxis in schools and early  
 4           childhood education programs.

5           ~~(3) RELATION TO STATE LAW.—~~Nothing in this  
 6           section or the guidelines developed by the Secretary  
 7           under paragraph ~~(1)~~ shall be construed to preempt  
 8           State law, including any State law regarding wheth-  
 9           er students at risk for anaphylaxis may self-admin-  
 10          ister medication.

11          ~~(e) SCHOOL-BASED FOOD ALLERGY MANAGEMENT~~  
 12          ~~GRANTS.—~~

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

18           ~~(2) APPLICATION.—~~

19           ~~(A) IN GENERAL.—~~To be eligible to receive  
 20           a grant under this subsection, a local edu-  
 21           cational agency shall submit an application to  
 22           the Secretary at such time, in such manner,  
 23           and including such information as the Secretary  
 24           may reasonably require.



1           (B) CONTENTS.—Each application sub-  
2           mitted under subparagraph (A) shall include—

3                   (i) an assurance that the local edu-  
4                   cational agency has developed plans in ac-  
5                   cordance with the food allergy and anaphy-  
6                   laxis management guidelines described in  
7                   subsection (b);

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

12                           (I) how the guidelines will be ear-  
13                           ried out at individual schools served  
14                           by the local educational agency;

15                           (II) how the local educational  
16                           agency will inform parents and stu-  
17                           dents of the guidelines in place;

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

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

1 (iii) an itemization of how grant funds  
 2 received under this subsection will be ex-  
 3 pended;

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

7 (v) an agreement by the local edu-  
 8 cational agency to report information re-  
 9 quired by the Secretary to conduct evalua-  
 10 tions under this subsection.

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

14 (A) Purchase of materials and supplies, in-  
 15 cluding limited medical supplies such as epi-  
 16 nephrine and disposable wet wipes, to support  
 17 carrying out the food allergy and anaphylaxis  
 18 management guidelines described in subsection  
 19 ~~(b)~~.

20 (B) In partnership with local health de-  
 21 partments, school nurse, teacher, and personnel  
 22 training for food allergy management.

23 (C) Programs that educate students as to  
 24 the presence of, and policies and procedures in

1 place related to, food allergies and anaphylactic  
2 shock.

3 ~~(D) Outreach to parents.~~

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

6 ~~(4) DURATION OF AWARDS.—The Secretary~~  
7 ~~may award grants under this subsection for a period~~  
8 ~~of not more than 2 years. In the event the Secretary~~  
9 ~~conducts a program evaluation under this sub-~~  
10 ~~section, funding in the second year of the grant,~~  
11 ~~where applicable, shall be contingent on a successful~~  
12 ~~program evaluation by the Secretary after the first~~  
13 ~~year.~~

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

19 ~~(6) MAXIMUM AMOUNT OF ANNUAL AWARDS.—~~  
20 ~~A grant awarded under this subsection may not be~~  
21 ~~made in an amount that is more than \$50,000 an-~~  
22 ~~nually.~~

23 ~~(7) PRIORITY.—In awarding grants under this~~  
24 ~~subsection, the Secretary shall give priority to local~~  
25 ~~educational agencies with the highest percentages of~~

1 children who are counted under section 1124(e) of  
2 the Elementary and Secondary Education Act of  
3 1965 (20 U.S.C. 6333(e)).

4 (8) MATCHING FUNDS.—

5 (A) IN GENERAL.—The Secretary may not  
6 award a grant under this subsection unless the  
7 local educational agency agrees that, with re-  
8 spect to the costs to be incurred by such local  
9 educational agency in carrying out the grant ac-  
10 tivities, the local educational agency shall make  
11 available (directly or through donations from  
12 public or private entities) non-Federal funds to-  
13 ward such costs in an amount equal to not less  
14 than 25 percent of the amount of the grant.

15 (B) DETERMINATION OF AMOUNT OF NON-  
16 FEDERAL CONTRIBUTION.—Non-Federal funds  
17 required under subparagraph (A) may be cash  
18 or in kind, including plant, equipment, or serv-  
19 ices. Amounts provided by the Federal Govern-  
20 ment, and any portion of any service subsidized  
21 by the Federal Government, may not be in-  
22 cluded in determining the amount of such non-  
23 Federal funds.

24 (9) ADMINISTRATIVE FUNDS.—A local edu-  
25 cational agency that receives a grant under this sub-

1 section may use not more than 2 percent of the  
 2 grant amount for administrative costs related to ear-  
 3 rying out this subsection.

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

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

16 (12) AUTHORIZATION OF APPROPRIATIONS.—  
 17 There is authorized to be appropriated to carry out  
 18 this subsection \$30,000,000 for fiscal year 2010 and  
 19 such sums as may be necessary for each of the 4  
 20 succeeding fiscal years.

21 (d) VOLUNTARY NATURE OF GUIDELINES.—

22 (1) IN GENERAL.—The food allergy and ana-  
 23 naphylaxis management guidelines developed by the  
 24 Secretary under subsection (b) are voluntary. Noth-  
 25 ing in this section or the guidelines developed by the

1 Secretary under subsection (b) shall be construed to  
 2 require a local educational agency to implement such  
 3 guidelines.

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

9 **TITLE II—IMPROVING CAPACITY**  
 10 **TO DETECT AND RESPOND TO**  
 11 **FOOD SAFETY PROBLEMS**

12 **SEC. 201. TARGETING OF INSPECTION RESOURCES FOR DO-**  
 13 **MESTIC FACILITIES, FOREIGN FACILITIES,**  
 14 **AND PORTS OF ENTRY; ANNUAL REPORT.**

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

20 **“SEC. 421. TARGETING OF INSPECTION RESOURCES FOR**  
 21 **DOMESTIC FACILITIES, FOREIGN FACILITIES,**  
 22 **AND PORTS OF ENTRY; ANNUAL REPORT.**

23 **“(a) IDENTIFICATION AND INSPECTION OF FACILI-**  
 24 **TIES.—**

1           “(1) IDENTIFICATION.—The Secretary shall al-  
2 locate resources to inspect facilities according to the  
3 risk profile of the facilities, which shall be based on  
4 the following factors:

5           “(A) The risk profile of the food manufac-  
6 tured, processed, packed, or held at the facility.

7           “(B) The facility’s history of food recalls,  
8 outbreaks, and violations of food safety stand-  
9 ards.

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

12           “(D) Whether the food manufactured,  
13 processed, packed, handled, prepared, treated,  
14 distributed, or stored at the facility meets the  
15 criteria for priority under section 801(h)(1).

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

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

21           “(2) INSPECTIONS.—

22           “(A) IN GENERAL.—Beginning on the date  
23 of enactment of the FDA Food Safety Mod-  
24 ernization Act, the Secretary shall increase the  
25 frequency of inspection of all facilities.

1           “(B) ~~HIGH-RISK FACILITIES.~~—The Sec-  
2           retary shall increase the frequency of inspection  
3           of facilities identified under paragraph (1) as  
4           high-risk facilities such that—

5                   “(i) for the first 2 years after the date  
6                   of enactment of the FDA Food Safety  
7                   Modernization Act, each high-risk facility  
8                   is inspected not less often than once every  
9                   2 years; and

10                   “(ii) for each succeeding year, each  
11                   high-risk facility is inspected not less often  
12                   than once each year.

13           “(C) ~~NON-HIGH-RISK FACILITIES.~~—The  
14           Secretary shall ensure that each facility that is  
15           not identified under paragraph (1) as a high-  
16           risk facility is inspected not less often than once  
17           every 4 years.

18           “(b) ~~IDENTIFICATION AND INSPECTION AT PORTS OF~~  
19 ~~ENTRY.~~—The Secretary, in consultation with the Sec-  
20           retary of Homeland Security, shall allocate resources to  
21           inspect articles of food imported into the United States  
22           according to the risk profile of the article of food, which  
23           shall be based on the following factors:

24                   “(1) The risk profile of the food imported.



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

3           “(3) The history of food recalls, outbreaks, and  
4           violations of food safety standards of the food im-  
5           porter.

6           “(4) The rigor of the foreign supplier  
7           verification program under section 805.

8           “(5) Whether the food importer participates in  
9           the voluntary qualified importer program under sec-  
10          tion 806.

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

13          “(7) Whether the food is from a facility that  
14          has received a certificate as described in section  
15          809(b).

16          “(8) Any other criteria deemed appropriate by  
17          the Secretary for purposes of allocating inspection  
18          resources.

19          “(e) COORDINATION.—The Secretary shall improve  
20          coordination and cooperation with the Secretary of Agri-  
21          culture to target food inspection resources.

22          “(d) FACILITY.—For purposes of this section, the  
23          term ‘facility’ means a domestic facility or a foreign facil-  
24          ity that is required to register under section 415.”.

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

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

6           “(1) information about food facilities includ-  
7 ing—

8           “(A) the appropriations used to inspect fa-  
9 cilities registered pursuant to section 415 in the  
10 previous fiscal year;

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

15           “(C) the number of domestic facilities and  
16 the number of foreign facilities registered pur-  
17 suant to section 415 that the Secretary in-  
18 spected in the previous fiscal year;

19           “(D) the number of domestic facilities and  
20 the number of foreign facilities registered pur-  
21 suant to section 415 that the Secretary did not  
22 inspect in the previous fiscal year;

23           “(E) the number of high-risk facilities  
24 identified pursuant to section 421 that the Sec-  
25 retary inspected in the previous fiscal year; and

1           “(F) the number of high-risk facilities  
2 identified pursuant to section 421 that the Sec-  
3 retary did not inspect in the previous fiscal  
4 year;

5           “(2) information about food imports includ-  
6 ing—

7           “(A) the number of lines of food imported  
8 into the United States that the Secretary phys-  
9 ically inspected or sampled in the previous fiscal  
10 year;

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

15           “(C) the average cost of physically inspect-  
16 ing or sampling a food line subject to this Act  
17 that is imported or offered for import into the  
18 United States; and

19           “(3) information on the foreign offices estab-  
20 lished under section 309 of the FDA Food Safety  
21 Modernization Act including—

22           “(A) the number of foreign offices estab-  
23 lished; and

24           “(B) the number of personnel permanently  
25 stationed in each foreign office.

1       “(i) PUBLIC AVAILABILITY OF ANNUAL FOOD RE-  
 2 PORTS.—The Secretary shall make the reports required  
 3 under subsection (h) available to the public on the Internet  
 4 Web site of the Food and Drug Administration.”.

5 **SEC. 202. RECOGNITION OF LABORATORY ACCREDITATION**  
 6 **FOR ANALYSES OF FOODS.**

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

10 **“SEC. 422. RECOGNITION OF LABORATORY ACCREDITATION**  
 11 **FOR ANALYSES OF FOODS.**

12       “(a) RECOGNITION OF LABORATORY ACCREDITA-  
 13 TION.—

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

17                       “(A) provide for the recognition of accredi-  
 18 tation bodies that accredit laboratories, includ-  
 19 ing laboratories run and operated by a State or  
 20 locality, with a demonstrated capability to con-  
 21 duct analytical testing of food products; and

22                       “(B) establish a publicly available registry  
 23 of accreditation bodies, including the name of,  
 24 contact information for, and other information

1           deemed necessary by the Secretary about such  
2           bodies.

3           “(2) FOREIGN LABORATORIES.—Accreditation  
4           bodies may accredit laboratories that operate outside  
5           the United States, so long as such laboratories meet  
6           the accreditation standards applicable to domestic  
7           laboratories accredited under this section.

8           “(3) MODEL ACCREDITATION STANDARDS.—  
9           The Secretary shall develop model standards that an  
10          accreditation body shall require laboratories to meet  
11          in order to be included in the registry provided for  
12          under paragraph (1). In developing the model stand-  
13          ards, the Secretary shall look to existing standards  
14          for guidance. The model standards shall include  
15          methods to ensure that—

16                 “(A) appropriate sampling and analytical  
17                 procedures are followed and reports of analyses  
18                 are certified as true and accurate;

19                 “(B) internal quality systems are estab-  
20                 lished and maintained;

21                 “(C) procedures exist to evaluate and re-  
22                 spond promptly to complaints regarding anal-  
23                 yses and other activities for which the labora-  
24                 tory is recognized;

1           “(D) individuals who conduct the analyses  
2           are qualified by training and experience to do  
3           so; and

4           “(E) any other criteria determined appro-  
5           priate by the Secretary.

6           “(4) REVIEW OF ACCREDITATION.—To assure  
7           compliance with the requirements of this section, the  
8           Secretary shall—

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

12          “(B) promptly revoke the recognition of  
13          any accreditation body found not to be in com-  
14          pliance with the requirements of this section.

15          “(b) TESTING PROCEDURES.—

16          “(1) IN GENERAL.—Food testing shall be con-  
17          ducted by either Federal laboratories or non-Federal  
18          laboratories that have been accredited by an accredi-  
19          tation body on the registry established by the Sec-  
20          retary under subsection (a) whenever such testing is  
21          either conducted by or on behalf of an owner or con-  
22          signee—

23                 “(A) in support of admission of an article  
24                 of food under section 801(a);

1           “(B) due to a specific testing requirement  
2           in this Act or implementing regulations, when  
3           applied to address an identified or suspected  
4           food safety problem;

5           “(C) under an Import Alert that requires  
6           successful consecutive tests; or

7           “(D) is so required by the Secretary as the  
8           Secretary deems appropriate to address an  
9           identified or suspected food safety problem.

10          “(2) RESULTS OF TESTING.—The results of  
11          any such testing shall be sent directly to the Food  
12          and Drug Administration. Such results may be sub-  
13          mitted to the Food and Drug Administration  
14          through electronic means.

15          “(e) REVIEW BY SECRETARY.—If food sampling and  
16          testing performed by a laboratory run and operated by a  
17          State or locality that is accredited by an accreditation  
18          body on the registry established by the Secretary under  
19          subsection (a) result in a State recalling a food, the Sec-  
20          retary shall review the sampling and testing results for  
21          the purpose of determining the need for a national recall  
22          or other compliance and enforcement activities.

23          “(d) NO LIMIT ON SECRETARIAL AUTHORITY.—  
24          Nothing in this section shall be construed to limit the abil-  
25          ity of the Secretary to review and act upon information

1 from food testing, including determining the sufficiency of  
2 such information and testing.”.

3 (b) ~~FOOD EMERGENCY RESPONSE NETWORK~~.—The  
4 Secretary, in coordination with the Secretary of Agri-  
5 culture, the Secretary of Homeland Security, and State,  
6 local, and tribal governments shall, not later than 180  
7 days after the date of enactment of this Act, and biennially  
8 thereafter, submit to the relevant committees of Congress,  
9 and make publicly available on the Internet Web site of  
10 the Department of Health and Human Services, a report  
11 on the progress in implementing a national food emer-  
12 gency response laboratory network that—

13 (1) provides ongoing surveillance, rapid detec-  
14 tion, and surge capacity for large-scale food-related  
15 emergencies, including intentional adulteration of  
16 the food supply;

17 (2) coordinates the food laboratory capacities of  
18 State food laboratories, including the sharing of data  
19 between State laboratories to develop national situa-  
20 tional awareness;

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

24 (4) develops and implements a methods reposi-  
25 tory for use by Federal, State, and local officials;



1           (5) responds to food-related emergencies; and

2           (6) is integrated with relevant laboratory net-  
3       works administered by other Federal agencies.

4 **SEC. 203. INTEGRATED CONSORTIUM OF LABORATORY**  
5 **NETWORKS.**

6       (a) **IN GENERAL.**—The Secretary of Homeland Secu-  
7 rity, in consultation with the Secretary of Health and  
8 Human Services, the Secretary of Agriculture, and the  
9 Administrator of the Environmental Protection Agency,  
10 shall maintain an agreement through which relevant lab-  
11 oratory network members, as determined by the Secretary  
12 of Homeland Security, shall—

13           (1) agree on common laboratory methods in  
14       order to facilitate the sharing of knowledge and in-  
15       formation relating to animal health, agriculture, and  
16       human health;

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

19                   (A) to optimize national laboratory pre-  
20       paredness; and

21                   (B) to provide surge capacity during emer-  
22       gencies; and

23           (3) engage in ongoing dialogue and build rela-  
24       tionships that will support a more effective and inte-  
25       grated response during emergencies.

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

8 **SEC. 204. ENHANCING TRACEBACK AND RECORDKEEPING.**

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

15 (b) PILOT PROJECT.—

16 (1) IN GENERAL.—Not later than 9 months  
17 after the date of enactment of this Act, the Sec-  
18 retary shall establish a pilot project in coordination  
19 with the produce industry to explore and evaluate  
20 methods for rapidly and effectively tracking and  
21 tracing fruits and vegetables that are raw agricul-  
22 tural commodities so that, if an outbreak occurs in-  
23 volving such a fruit or vegetable, the Secretary may  
24 quickly identify the source of the outbreak and the  
25 recipients of the contaminated food.

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

8                     (A) methods that are applicable and appro-  
9                     priate for small businesses; and

10                    (B) technologies, including existing tech-  
11                    nologies, that enhance traceback and trace for-  
12                    ward.

13           (c) ~~REPORT.~~—Not later than 18 months after the  
14           date of enactment of this Act, the Secretary shall report  
15           to Congress on the findings of the pilot project under sub-  
16           section (b) together with recommendations for establishing  
17           more effective traceback and trace forward procedures for  
18           fruits and vegetables that are raw agricultural commod-  
19           ities.

20           (d) ~~TRACEBACK PERFORMANCE REQUIREMENTS.~~—  
21           Not later than 24 months after the date of enactment of  
22           this Act, the Secretary shall publish a notice of proposed  
23           rulemaking to establish standards for the type of informa-  
24           tion, format, and timeframe for persons to submit records  
25           to aid the Secretary in effectively and rapidly tracking and

1 tracing, in the event of an outbreak, fruits and vegetables  
2 that are raw agricultural commodities. Nothing in this sec-  
3 tion shall be construed as giving the Secretary the author-  
4 ity to prescribe specific technologies for the maintenance  
5 of records.

6 (e) PUBLIC INPUT.—During the comment period in  
7 the notice of proposed rulemaking under subsection (d),  
8 the Secretary shall conduct not less than 3 public meetings  
9 in diverse geographical areas of the United States to pro-  
10 vide persons in different regions an opportunity to com-  
11 ment.

12 (f) RAW AGRICULTURAL COMMODITY.—In this sec-  
13 tion, the term “raw agricultural commodity” has the  
14 meaning given that term in section 201(r) of the Federal  
15 Food, Drug, and Cosmetic Act (21 U.S.C. 321(r)).

16 **SEC. 205. SURVEILLANCE.**

17 (a) DEFINITION OF FOOD-BORNE ILLNESS OUT-  
18 BREAK.—In this section, the term “food-borne illness out-  
19 break” means the occurrence of 2 or more cases of a simi-  
20 lar illness resulting from the ingestion of a food.

21 (b) FOOD-BORNE ILLNESS SURVEILLANCE SYS-  
22 TEMS.—

23 (1) IN GENERAL.—The Secretary, acting  
24 through the Director of the Centers for Disease  
25 Control and Prevention, shall enhance food-borne ill-

1       ness surveillance systems to improve the collection,  
2       analysis, reporting, and usefulness of data on food-  
3       borne illnesses by—

4               (A) coordinating Federal, State and local  
5       food-borne illness surveillance systems, includ-  
6       ing complaint systems, and increasing participa-  
7       tion in national networks of public health and  
8       food regulatory agencies and laboratories;

9               (B) facilitating sharing of findings on a  
10       more timely basis among governmental agen-  
11       cies, including the Food and Drug Administra-  
12       tion, the Department of Agriculture, and State  
13       and local agencies, and with the public;

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

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

20              (E) expanding capacity of such systems,  
21       including working toward automatic electronic  
22       searches, for implementation of fingerprinting  
23       strategies for food-borne infectious agents, in  
24       order to identify new or rarely documented

1 causes of food-borne illness and submit stand-  
2 ardized information to a centralized database;

3 (F) allowing timely public access to aggre-  
4 gated, de-identified surveillance data;

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

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

10 (I) integrating food-borne illness surveil-  
11 lance systems and data with other biosurveil-  
12 lance and public health situational awareness  
13 capabilities at the Federal, State, and local lev-  
14 els; and

15 (J) other activities as determined appro-  
16 priate by the Secretary.

17 (2) PARTNERSHIPS.—The Secretary shall sup-  
18 port and maintain a diverse working group of ex-  
19 perts and stakeholders from Federal, State, and  
20 local food safety and health agencies, the food indus-  
21 try, consumer organizations, and academia. Such  
22 working group shall provide the Secretary, through  
23 at least annual meetings of the working group and  
24 an annual public report, advice and recommenda-  
25 tions on an ongoing and regular basis regarding the

1 improvement of food-borne illness surveillance and  
2 implementation of this section, including advice and  
3 recommendations on—

4 (A) the priority needs of regulatory agen-  
5 cies, the food industry, and consumers for infor-  
6 mation and analysis on food-borne illness and  
7 its causes;

8 (B) opportunities to improve the effective-  
9 ness of initiatives at the Federal, State, and  
10 local levels, including coordination and integra-  
11 tion of activities among Federal agencies, and  
12 between the Federal, State, and local levels of  
13 government;

14 (C) improvement in the timeliness and  
15 depth of access by regulatory and health agen-  
16 cies, the food industry, academic researchers,  
17 and consumers to food-borne illness surveillance  
18 data collected by government agencies at all lev-  
19 els, including data compiled by the Centers for  
20 Disease Control and Prevention;

21 (D) key barriers to improvement in food-  
22 borne illness surveillance and its utility for pre-  
23 venting food-borne illness at Federal, State, and  
24 local levels;

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

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

10       ~~(c) IMPROVING FOOD SAFETY AND DEFENSE CAPAC-~~  
11 ~~ITY AT THE STATE AND LOCAL LEVEL.—~~

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

16           ~~(A)~~ Improve food-borne illness outbreak re-  
17           sponse and containment.

18           ~~(B)~~ Accelerate food-borne illness surveil-  
19           lance and outbreak investigation, including  
20           rapid shipment of clinical isolates from clinical  
21           laboratories to appropriate State laboratories,  
22           and conducting more standardized illness out-  
23           break interviews.



1           (C) Strengthen the capacity of State and  
2 local agencies to carry out inspections and en-  
3 force safety standards.

4           (D) Improve the effectiveness of Federal,  
5 State, and local partnerships to coordinate food  
6 safety and defense resources and reduce the in-  
7 cidence of food-borne illness.

8           (E) Share information on a timely basis  
9 among public health and food regulatory agen-  
10 cies, with the food industry, with health care  
11 providers, and with the public.

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

15           (2) REVIEW.—In developing of the strategies  
16 required by paragraph (1), the Secretary shall, not  
17 later than 1 year after the date of enactment of the  
18 FDA Food Safety Modernization Act, complete a re-  
19 view of State and local capacities, and needs for en-  
20 hancement, which may include a survey with respect  
21 to—

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

1           (B) laboratory capacity to support surveil-  
 2           lance, outbreak response, inspection, and en-  
 3           forcement activities;

4           (C) information systems to support data  
 5           management and sharing of food safety and de-  
 6           fense information among State and local agen-  
 7           cies and with counterparts at the Federal level;  
 8           and

9           (D) other State and local activities and  
 10          needs as determined appropriate by the Sec-  
 11          retary.

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

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

17               (2) by striking “2003 through 2006” and in-  
 18          serting “2011 through 2014”.

19          **SEC. 206. MANDATORY RECALL AUTHORITY.**

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

23          **“SEC. 423. MANDATORY RECALL AUTHORITY.**

24               “(a) **VOLUNTARY PROCEDURES.**—If the Secretary  
 25          determines, based on information gathered through the re-

1 portable food registry under section 417 or through any  
 2 other means, that there is a reasonable probability that  
 3 an article of food (other than infant formula) is adulter-  
 4 ated under section 402 or misbranded under section  
 5 403(w) and the use of or exposure to such article will  
 6 cause serious adverse health consequences or death to hu-  
 7 mans or animals, the Secretary shall provide the respon-  
 8 sible party (as defined in section 417) with an opportunity  
 9 to cease distribution and recall such article.

10       “(b) PREHEARING ORDER TO CEASE DISTRIBUTION  
 11 AND GIVE NOTICE.—If the responsible party refuses to  
 12 or does not voluntarily cease distribution or recall such  
 13 article within the time and in the manner prescribed by  
 14 the Secretary (if so prescribed), the Secretary may, by  
 15 order require, as the Secretary deems necessary, such per-  
 16 son to—

17               “(1) immediately cease distribution of such arti-  
 18 cle; or

19               “(2) immediately notify all persons—

20                       “(A) manufacturing, processing, packing,  
 21 transporting, distributing, receiving, holding, or  
 22 importing and selling such article; and

23                       “(B) to which such article has been dis-  
 24 tributed, transported, or sold, to immediately  
 25 cease distribution of such article.

1       “(e) HEARING ON ORDER.—The Secretary shall pro-  
 2 vide the responsible party subject to an order under sub-  
 3 section (b) with an opportunity for an informal hearing;  
 4 to be held as soon as possible but not later than 2 days  
 5 after the issuance of the order, on the actions required  
 6 by the order and on why the article that is the subject  
 7 of the order should not be recalled.

8       “(d) POST-HEARING RECALL ORDER AND MODIFICA-  
 9 TION OF ORDER.—

10           “(1) AMENDMENT OF ORDER.—If, after pro-  
 11 viding opportunity for an informal hearing under  
 12 subsection (e), the Secretary determines that re-  
 13 moval of the article from commerce is necessary, the  
 14 Secretary shall, as appropriate—

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

17           “(B) specify a timetable in which the recall  
 18 shall occur;

19           “(C) require periodic reports to the Sec-  
 20 retary describing the progress of the recall; and

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

23       “(2) VACATING OF ORDER.—If, after such hear-  
 24 ing, the Secretary determines that adequate grounds  
 25 do not exist to continue the actions required by the

1 order, or that such actions should be modified; the  
2 Secretary shall vacate the order or modify the order.

3 “(e) COOPERATION AND CONSULTATION.—The Sec-  
4 retary shall work with State and local public health offi-  
5 cials in carrying out this section, as appropriate.

6 “(f) PUBLIC NOTIFICATION.—In conducting a recall  
7 under this section, the Secretary shall—

8 “(1) ensure that a press release is published re-  
9 garding the recall, as well as alerts and public no-  
10 tices, as appropriate, in order to provide notifica-  
11 tion—

12 “(A) of the recall to consumers and retail-  
13 ers to whom such article was, or may have  
14 been, distributed; and

15 “(B) that includes, at a minimum—

16 “(i) the name of the article of food  
17 subject to the recall; and

18 “(ii) a description of the risk associ-  
19 ated with such article; and

20 “(2) consult the policies of the Department of  
21 Agriculture regarding providing to the public a list  
22 of retail consignees receiving products involved in a  
23 Class I recall and shall consider providing such a list  
24 to the public, as determined appropriate by the Sec-  
25 retary.

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

5       “(h) EFFECT.—Nothing in this section shall affect  
6 the authority of the Secretary to request or participate  
7 in a voluntary recall.”.

8       (b) CIVIL PENALTY.—Section 303(f)(2)(A) (21  
9 U.S.C. 303(f)(2)(A)) is amended by inserting “or any per-  
10 son who does not comply with a recall order under section  
11 423” after “section 402(a)(2)(B)”.

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

15       “(r) The refusal or failure to follow an order under  
16 section 423.”.

17 **SEC. 207. ADMINISTRATIVE DETENTION OF FOOD.**

18       (a) IN GENERAL.—Section 304(h)(1)(A) (21 U.S.C.  
19 304(h)(1)(A)) is amended by—

20           (1) striking “credible evidence or information  
21 indicating” and inserting “reason to believe”; and

22           (2) striking “presents a threat of serious ad-  
23 verse health consequences or death to humans or  
24 animals” and inserting “is adulterated or mis-  
25 branded”.



1 up, clearance, and recovery activities following the decon-  
2 tamination and disposal of specific threat agents and for-  
3 eign animal diseases.

4 (c) DEVELOPMENT OF MODEL PLANS.—In carrying  
5 out subsection (a), the Administrator, the Secretary of  
6 Health and Human Services, and the Secretary of Agri-  
7 culture shall jointly develop and disseminate model plans  
8 for—

9 (1) the decontamination of individuals, equip-  
10 ment, and facilities following an intentional contami-  
11 nation of agriculture or food; and

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

16 (d) EXERCISES.—In carrying out subsection (a), the  
17 Administrator, in coordination with the entities described  
18 under subsection (b), shall conduct exercises at least annu-  
19 ally to evaluate and identify weaknesses in the decon-  
20 tamination and disposal model plans described in sub-  
21 section (c). Such exercises shall be carried out, to the max-  
22 imum extent practicable, as part of the national exercise  
23 program under section 648(b)(1) of the Post-Katrina  
24 Emergency Management Reform Act of 2006 (6 U.S.C.  
25 748(b)(1)).



1 (e) MODIFICATIONS.—Based on the exercises de-  
 2 scribed in subsection (d), the Administrator, in coordina-  
 3 tion with the entities described in subsection (b), shall re-  
 4 view and modify as necessary the plans described in sub-  
 5 section (e) not less frequently than biennially.

6 (f) PRIORITIZATION.—The Administrator, in coordi-  
 7 nation with the entities described in subsection (b), shall  
 8 develop standards and plans under subsections (b) and (e)  
 9 in an identified order of priority that takes into account—

10 (1) highest-risk biological, chemical, and radio-  
 11 logical threat agents;

12 (2) agents that could cause the greatest eco-  
 13 nomic devastation to the agriculture and food sys-  
 14 tem; and

15 (3) agents that are most difficult to clean or re-  
 16 mediate.

## 17 **TITLE III—IMPROVING THE** 18 **SAFETY OF IMPORTED FOOD**

### 19 **SEC. 301. FOREIGN SUPPLIER VERIFICATION PROGRAM.**

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

#### 22 **“SEC. 805. FOREIGN SUPPLIER VERIFICATION PROGRAM.**

23 **“(a) IN GENERAL.—**

24 **“(1) VERIFICATION REQUIREMENT.—**Each  
 25 United States importer shall perform risk-based for-

1       eign supplier verification activities in accordance  
2       with regulations promulgated under subsection (e)  
3       for the purpose of verifying that the food imported  
4       by the importer or its agent is—

5               “(A) produced in compliance with the re-  
6               quirements of section 418 or 419, as appro-  
7               priate; and

8               “(B) is not adulterated under section 402  
9               or misbranded under section 403(w).

10       “(2) IMPORTER DEFINED.—For purposes of  
11       this section, the term ‘importer’ means, with respect  
12       to an article of food—

13               “(A) the United States owner or consignee  
14               of the article of food at the time of entry of  
15               such article into the United States; or

16               “(B) in the case when there is no United  
17               States owner or consignee as described in sub-  
18               paragraph (A); the United States agent or rep-  
19               resentative of a foreign owner or consignee of  
20               the article of food at the time of entry of such  
21               article into the United States.

22       “(b) GUIDANCE.—Not later than 1 year after the  
23       date of enactment of the FDA Food Safety Modernization  
24       Act, the Secretary shall issue guidance to assist United

1 States importers in developing foreign supplier verification  
2 programs.

3 “(c) REGULATIONS.—

4 “(1) IN GENERAL.—Not later than 1 year after  
5 the date of enactment of the FDA Food Safety Mod-  
6 ernization Act, the Secretary shall promulgate regu-  
7 lations to provide for the content of the foreign sup-  
8 plier verification program established under sub-  
9 section (a). Such regulations shall, as appropriate,  
10 include a process for verification by a United States  
11 importer, with respect to each foreign supplier from  
12 which it obtains food, that the imported food is pro-  
13 duced in compliance with the requirements of section  
14 418 or 419, as appropriate, and is not adulterated  
15 under section 402 or misbranded under section  
16 403(w).

17 “(2) VERIFICATION.—The regulations under  
18 paragraph (1) shall require that the foreign supplier  
19 verification program of each importer be adequate to  
20 provide assurances that each foreign supplier to the  
21 importer produces the imported food employing  
22 processes and procedures, including risk-based rea-  
23 sonably appropriate preventive controls, equivalent  
24 in preventing adulteration and reducing hazards as

1 those required by section 418 or section 419, as ap-  
2 propriate.

3 ~~“(3) ACTIVITIES.—~~Verification activities under  
4 a foreign supplier verification program under this  
5 section may include monitoring records for ship-  
6 ments, lot-by-lot certification of compliance, annual  
7 on-site inspections, checking the hazard analysis and  
8 risk-based preventive control plan of the foreign sup-  
9 plier, and periodically testing and sampling ship-  
10 ments.

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

17 ~~“(e) DEEMED COMPLIANCE OF SEAFOOD, JUICE,~~  
18 ~~AND LOW-ACID CANNED FOOD FACILITIES IN COMPLI-~~  
19 ~~ANCE WITH HACCP.—~~An owner, operator, or agent in  
20 charge of a facility required to comply with 1 of the fol-  
21 lowing standards and regulations with respect to such fa-  
22 cility shall be deemed to be in compliance with this section  
23 with respect to such facility:

1           ~~“(1) The Seafood Hazard Analysis Critical~~  
2           ~~Control Points Program of the Food and Drug Ad-~~  
3           ~~ministration.~~

4           ~~“(2) The Juice Hazard Analysis Critical Con-~~  
5           ~~trol Points Program of the Food and Drug Adminis-~~  
6           ~~tration.~~

7           ~~“(3) The Thermally Processed Low-Acid Foods~~  
8           ~~Packaged in Hermetically Sealed Containers stand-~~  
9           ~~ards of the Food and Drug Administration (or any~~  
10          ~~successor standards).~~

11          ~~“(f) PUBLICATION OF LIST OF PARTICIPANTS.—The~~  
12          ~~Secretary shall publish and maintain on the Internet Web~~  
13          ~~site of the Food and Drug Administration a current list~~  
14          ~~that includes the name of, location of, and other informa-~~  
15          ~~tion deemed necessary by the Secretary about, importers~~  
16          ~~participating under this section.”.~~

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

20          ~~“(ss) The importation or offering for importation of~~  
21          ~~a food if the importer (as defined in section 805) does~~  
22          ~~not have in place a foreign supplier verification program~~  
23          ~~in compliance with such section 805.”.~~

24          ~~(c) IMPORTS.—Section 801(a) (21 U.S.C. 381(a)) is~~  
25          ~~amended by adding “or the importer (as defined in section~~

1 805) is in violation of such section 805” after “or in viola-  
2 tion of section 505”.

3 (d) **EFFECTIVE DATE.**—The amendments made by  
4 this section shall take effect 2 years after the date of en-  
5 actment of this Act.

6 **SEC. 302. VOLUNTARY QUALIFIED IMPORTER PROGRAM.**

7 Chapter VIII (21 U.S.C. 381 et seq.), as amended  
8 by section 301, is amended by adding at the end the fol-  
9 lowing:

10 **“SEC. 806. VOLUNTARY QUALIFIED IMPORTER PROGRAM.**

11 “(a) **IN GENERAL.**—Beginning not later than 1 year  
12 after the date of enactment of the FDA Food Safety Mod-  
13 ernization Act, the Secretary shall—

14 “(1) establish a program, in consultation with  
15 the Department of Homeland Security, to provide  
16 for the expedited review and importation of food of-  
17 fered for importation by United States importers  
18 who have voluntarily agreed to participate in such  
19 program; and

20 “(2) issue a guidance document related to par-  
21 ticipation and compliance with such program.

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

1       “(c) ELIGIBILITY.—In order to be eligible, an im-  
2 porter shall be offering food for importation from a facility  
3 that has a certification described in section 809(b). In re-  
4 viewing the applications and making determinations on  
5 such requests, the Secretary shall consider the risk of the  
6 food to be imported based on factors, such as the fol-  
7 lowing:

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

9               “(2) The compliance history of the foreign sup-  
10 plier.

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

14              “(4) The compliance of the importer with the  
15 requirements of section 805.

16              “(5) The recordkeeping, testing, inspections  
17 and audits of facilities, traceability of articles of  
18 food, temperature controls, and sourcing practices of  
19 the importer.

20              “(6) The potential risk for intentional adultera-  
21 tion of the food.

22              “(7) Any other factor that the Secretary deter-  
23 mines appropriate.

24       “(d) REVIEW AND REVOCATION.—Any importer  
25 qualified by the Secretary in accordance with the eligibility

1 criteria set forth in this section shall be reevaluated not  
 2 less often than once every 3 years and the Secretary shall  
 3 promptly revoke the qualified importer status of any im-  
 4 porter found not to be in compliance with such criteria.

5 “(e) NOTICE OF INTENT TO PARTICIPATE.—An im-  
 6 porter that intends to participate in the program under  
 7 this section in a fiscal year shall submit a notice to the  
 8 Secretary of such intent at time and in a manner estab-  
 9 lished by the Secretary.

10 “(f) FALSE STATEMENTS.—Any statement or rep-  
 11 resentation made by an importer to the Secretary shall  
 12 be subject to section 1001 of title 18, United States Code.

13 “(g) DEFINITION.—For purposes of this section, the  
 14 term ‘importer’ means the person that brings food, or  
 15 causes food to be brought, from a foreign country into the  
 16 customs territory of the United States.”.

17 **SEC. 303. AUTHORITY TO REQUIRE IMPORT CERTIFI-**  
 18 **CATIONS FOR FOOD.**

19 (a) IN GENERAL.—Section 801(a) (21 U.S.C.  
 20 381(a)) is amended by inserting after the third sentence  
 21 the following: “With respect to an article of food, if impor-  
 22 tation of such food is subject to, but not compliant with,  
 23 the requirement under subsection (p) that such food be  
 24 accompanied by a certification or other assurance that the



1 food meets some or all applicable requirements of this Act,  
2 then such article shall be refused admission.”.

3 (b) ADDITION OF CERTIFICATION REQUIREMENT.—

4 Section 801 (21 U.S.C. 381) is amended by adding at the  
5 end the following new subsection:

6 “(p) CERTIFICATIONS CONCERNING IMPORTED  
7 FOODS.—

8 “(1) IN GENERAL.—The Secretary, based on  
9 public health considerations, including risks associ-  
10 ated with the food or its place of origin, may require  
11 as a condition of granting admission to an article of  
12 food imported or offered for import into the United  
13 States, that an entity specified in paragraph (2) pro-  
14 vide a certification or such other assurances as the  
15 Secretary determines appropriate that the article of  
16 food complies with some or all applicable require-  
17 ments of this Act, as specified by the Secretary.  
18 Such certification or assurances may be provided in  
19 the form of shipment-specific certificates, a listing of  
20 certified entities, or in such other form as the Sec-  
21 retary may specify. Such certification shall be used  
22 for designated food imported from countries with  
23 which the Food and Drug Administration has an  
24 agreement to establish a certification program.

1           “(2) CERTIFYING ENTITIES.—For purposes of  
2 paragraph (1), entities that shall provide the certifi-  
3 cation or assurances described in such paragraph  
4 are—

5           “(A) an agency or a representative of the  
6 government of the country from which the arti-  
7 cle of food at issue originated, as designated by  
8 such government or the Secretary; or

9           “(B) such other persons or entities accred-  
10 ited pursuant to section 809 to provide such  
11 certification or assurance.

12           “(3) RENEWAL AND REFUSAL OF CERTIFI-  
13 CATIONS.—The Secretary may—

14           “(A) require that any certification or other  
15 assurance provided by an entity specified in  
16 paragraph (2) be renewed by such entity at  
17 such times as the Secretary determines appro-  
18 priate; and

19           “(B) refuse to accept any certification or  
20 assurance if the Secretary determines that such  
21 certification or assurance is no longer valid or  
22 reliable.

23           “(4) ELECTRONIC SUBMISSION.—The Secretary  
24 shall provide for the electronic submission of certifi-  
25 cations under this subsection.

1           “(5) FALSE STATEMENTS.—Any statement or  
2           representation made by an entity described in para-  
3           graph (2) to the Secretary shall be subject to section  
4           1001 of title 18, United States Code.”.

5           (e) CONFORMING TECHNICAL AMENDMENT.—See-  
6           tion 801(b) (21 U.S.C. 381(b)) is amended in the second  
7           sentence by striking “with respect to an article included  
8           within the provision of the fourth sentence of subsection  
9           (a)” and inserting “with respect to an article described  
10          in subsection (a) relating to the requirements of sections  
11          760 or 761,”.

12          (d) NO LIMIT ON AUTHORITY.—Nothing in the  
13          amendments made by this section shall limit the authority  
14          of the Secretary to conduct random inspections of im-  
15          ported food or to take such other steps as the Secretary  
16          deems appropriate to determine the admissibility of im-  
17          ported food.

18          **SEC. 304. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.**

19          (a) IN GENERAL.—Section 801(m)(1) (21 U.S.C.  
20          381(m)(1)) is amended by inserting “any country to which  
21          the article has been refused entry;” after “the country  
22          from which the article is shipped;”.

23          (b) REGULATIONS.—Not later than 120 days after  
24          the date of enactment of this Act, the Secretary shall issue  
25          an interim final rule amending subpart I of part 1 of title

1 21, Code of Federal Regulations, to implement the amend-  
 2 ment made by this section.

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

6 **SEC. 305. REVIEW OF A REGULATORY AUTHORITY OF A**  
 7 **FOREIGN COUNTRY.**

8 Chapter VIII (21 U.S.C. 381 et seq.), as amended  
 9 by section 302, is amended by adding at the end the fol-  
 10 lowing:

11 **“SEC. 807. REVIEW OF A REGULATORY AUTHORITY OF A**  
 12 **FOREIGN COUNTRY.**

13 “The Secretary may review information from a coun-  
 14 try outlining the statutes, regulations, standards, and con-  
 15 trols of such country, and conduct on-site audits in such  
 16 country to verify the implementation of those statutes,  
 17 regulations, standards, and controls. Based on such re-  
 18 view, the Secretary shall determine whether such country  
 19 can provide reasonable assurances that the food supply of  
 20 the country is equivalent in safety to food manufactured,  
 21 processed, packed, or held in the United States.”.

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

24 (a) **IN GENERAL.**—The Secretary shall, not later  
 25 than 2 years of the date of enactment of this Act, develop

1 a comprehensive plan to expand the technical, scientific,  
2 and regulatory capacity of foreign governments, and their  
3 respective food industries, from which foods are exported  
4 to the United States.

5 (b) CONSULTATION.—In developing the plan under  
6 subsection (a), the Secretary shall consult with the Sec-  
7 retary of Agriculture, Secretary of State, Secretary of the  
8 Treasury, and the Secretary of Commerce, representatives  
9 of the food industry, appropriate foreign government offi-  
10 cials, and nongovernmental organizations that represent  
11 the interests of consumers, and other stakeholders.

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

14 (1) Recommendations for bilateral and multilat-  
15 eral arrangements and agreements, including provi-  
16 sions to provide for responsibility of exporting coun-  
17 tries to ensure the safety of food.

18 (2) Provisions for electronic data sharing.

19 (3) Provisions for mutual recognition of inspec-  
20 tion reports.

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

24 (5) Recommendations to harmonize require-  
25 ments under the Codex Alimentarius.

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

3 **SEC. 307. INSPECTION OF FOREIGN FOOD FACILITIES.**

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

7 **“SEC. 808. INSPECTION OF FOREIGN FOOD FACILITIES.**

8           “(a) INSPECTION.—The Secretary—

9           “(1) may enter into arrangements and agree-  
10           ments with foreign governments to facilitate the in-  
11           spection of foreign facilities registered under section  
12           415; and

13           “(2) shall direct resources to inspections of for-  
14           eign facilities, suppliers, and food types, especially  
15           such facilities, suppliers, and food types that present  
16           a high risk (as identified by the Secretary), to help  
17           ensure the safety and security of the food supply of  
18           the United States.

19           “(b) EFFECT OF INABILITY TO INSPECT.—Notwith-  
20           standing any other provision of law, food shall be refused  
21           admission into the United States if it is from a foreign  
22           facility registered under section 415 of which the owner,  
23           operator, or agent in charge of the facility, or the govern-  
24           ment of the foreign country, refuses to permit entry of  
25           United States inspectors, upon request, to inspect such fa-

1 cility. For purposes of this subsection, such an owner, op-  
 2 erator, or agent in charge shall be considered to have re-  
 3 fused an inspection if such owner, operator, or agent in  
 4 charge refuses such a request to inspect a facility more  
 5 than 48 hours after such request is submitted.”.

6 **SEC. 308. ACCREDITATION OF THIRD-PARTY AUDITORS**  
 7 **AND AUDIT AGENTS.**

8 Chapter VIII (21 U.S.C. 381 et seq.), as amended  
 9 by section 307, is amended by adding at the end the fol-  
 10 lowing:

11 **“SEC. 809. ACCREDITATION OF THIRD-PARTY AUDITORS**  
 12 **AND AUDIT AGENTS.**

13 “(a) **DEFINITIONS.**—In this section:

14 “(1) **ACCREDITED AUDIT AGENT.**—The term  
 15 ‘accredited audit agent’ means an audit agent ac-  
 16 credited by an accreditation body under this section.

17 “(2) **AUDIT AGENT.**—The term ‘audit agent’  
 18 means an individual who is qualified to conduct food  
 19 safety audits, and who may be an employee or an  
 20 agent of a third-party auditor.

21 “(3) **ACCREDITATION BODY.**—The term ‘ac-  
 22 creditation body’ means a recognized authority that  
 23 performs accreditation of third-party auditors and  
 24 audit agents.

1           “(4) ACCREDITED THIRD-PARTY AUDITOR.—

2           The term ‘accredited third-party auditor’ means a  
3           third-party auditor accredited by an accreditation  
4           body under this section.

5           “(5) CONSULTATIVE AUDIT.—The term ‘con-  
6           sultative audit’ means an audit of an eligible enti-  
7           ty—

8                       “(A) to determine whether such entity is in  
9                       compliance with the provisions of this Act and  
10                      with applicable industry standards and prac-  
11                      tices; and

12                     “(B) the results of which are for internal  
13                     facility purposes only.

14           “(6) ELIGIBLE ENTITY.—The term ‘eligible en-  
15           tity’ means a foreign entity, including foreign facili-  
16           ties registered under section 415, in the food import  
17           supply chain that chooses to be audited by an ac-  
18           credited third-party auditor or audit agent.

19           “(7) REGULATORY AUDIT.—The term ‘regu-  
20           latory audit’ means an audit of an eligible entity—

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

23                     “(B) the results of which determine—



1           “(i) whether an entity is eligible to re-  
2           ceive a certification under section 801(p);  
3           and

4           “(ii) whether the entity is eligible to  
5           participate in the voluntary qualified im-  
6           porter program under section 806.

7           “(8) THIRD-PARTY AUDITOR.—The term ‘third-  
8           party auditor’ means a foreign government, foreign  
9           cooperative, or any other qualified third party, as  
10          the Secretary determines appropriate, that conducts  
11          audits of eligible entities to certify that such eligible  
12          entities meet the applicable requirements of this sec-  
13          tion.

14          “(b) ACCREDITATION SYSTEM.—

15                 “(1) ACCREDITATION BODIES.—

16                         “(A) RECOGNITION OF ACCREDITATION  
17                         BODIES.—Beginning not later than 2 years  
18                         after the date of enactment of the FDA Food  
19                         Safety Modernization Act, the Secretary shall  
20                         establish a system for the recognition of accred-  
21                         itation bodies that accredit third-party auditors  
22                         and audit agents to certify that eligible entities  
23                         meet the applicable requirements of this Act.

24                         “(B) NOTIFICATION.—Each accreditation  
25                         body recognized by the Secretary shall submit

1 to the Secretary a list of all accredited third-  
 2 party auditors and audit agents accredited by  
 3 such body.

4 “(C) REVOCATION OF RECOGNITION AS AN  
 5 ACCREDITATION BODY.—The Secretary shall  
 6 promptly revoke the recognition of any accredi-  
 7 tation body found not to be in compliance with  
 8 the requirements of this section.

9 “(2) MODEL ACCREDITATION STANDARDS.—  
 10 The Secretary shall develop model standards, includ-  
 11 ing audit report requirements, and each recognized  
 12 accreditation body shall ensure that third-party  
 13 auditors and audit agents meet such standards in  
 14 order to qualify as an accredited third-party auditor  
 15 or audit agent under this section. In developing the  
 16 model standards, the Secretary shall look to stand-  
 17 ards in place on the date of the enactment of this  
 18 section for guidance, to avoid unnecessary duplica-  
 19 tion of efforts and costs.

20 “(e) THIRD-PARTY AUDITORS AND AUDIT AGEN-  
 21 CIES.—

22 “(1) REQUIREMENTS FOR ACCREDITATION AS A  
 23 THIRD-PARTY AUDITOR OR AUDIT AGENT.—

24 “(A) FOREIGN GOVERNMENTS.—Prior to  
 25 accrediting a foreign government as an accred-

1           ited third-party auditor, the accreditation body  
2           shall perform such reviews and audits of food  
3           safety programs, systems, and standards of the  
4           government as the Secretary deems necessary  
5           to determine that the foreign government is ca-  
6           pable of adequately ensuring that eligible enti-  
7           ties certified by such government meet the re-  
8           quirements of this Act with respect to food  
9           manufactured, processed, packed, or held for  
10          import to the United States.

11           “(B) FOREIGN COOPERATIVES AND OTHER  
12          THIRD PARTIES.—Prior to accrediting a foreign  
13          cooperative that aggregates the products of  
14          growers or processors, or any other third party  
15          that the Secretary determines appropriate to be  
16          an accredited third-party auditor or audit  
17          agent, the accreditation body shall perform such  
18          reviews and audits of the training and qualifica-  
19          tions of auditors used by that cooperative or  
20          party and conduct such reviews of internal sys-  
21          tems and such other investigation of the cooper-  
22          ative or party as the Secretary deems necessary  
23          to determine that each eligible entity certified  
24          by the cooperative or party has systems and

1 standards in use to ensure that such entity  
2 meets the requirements of this Act.

3 ~~“(2) REQUIREMENT TO ISSUE CERTIFICATION~~  
4 ~~OF ELIGIBLE ENTITIES.—~~

5 ~~“(A) IN GENERAL.—An accreditation body~~  
6 ~~may not accredit a third-party auditor or audit~~  
7 ~~agent unless such third-party auditor or audit~~  
8 ~~agent agrees to issue a written and electronic~~  
9 ~~certification to accompany each food shipment~~  
10 ~~for import into the United States from an eligi-~~  
11 ~~ble entity certified by the third-party auditor or~~  
12 ~~audit agent, subject to requirements set forth~~  
13 ~~by the Secretary. The Secretary shall consider~~  
14 ~~such certificates when targeting inspection re-~~  
15 ~~sources under section 421.~~

16 ~~“(B) PURPOSE OF CERTIFICATION.—The~~  
17 ~~Secretary shall use evidence of certification pro-~~  
18 ~~vided by accredited third-party auditors and~~  
19 ~~audit agents—~~

20 ~~“(i) to determined the eligibility of an~~  
21 ~~importer to receive a certification under~~  
22 ~~section 801(p); and~~

23 ~~“(ii) determine the eligibility of an im-~~  
24 ~~porter to participate in the voluntary quali-~~  
25 ~~fied importer program under section 806.~~

1           ~~“(3) AUDIT REPORT REQUIREMENTS.—~~

2           ~~“(A) REQUIREMENTS IN GENERAL.—As a~~  
3           ~~condition of accreditation, an accredited third-~~  
4           ~~party auditor or audit agent shall prepare the~~  
5           ~~audit report for an audit, in a form and manner~~  
6           ~~designated by the Secretary, which shall in-~~  
7           ~~clude—~~

8                   ~~“(i) the identity of the persons at the~~  
9                   ~~audited eligible entity responsible for com-~~  
10                  ~~pliance with food safety requirements;~~

11                   ~~“(ii) the dates of the audit;~~

12                   ~~“(iii) the scope of the audit; and~~

13                   ~~“(iv) any other info required by the~~  
14                  ~~Secretary that relate to or may influence~~  
15                  ~~an assessment of compliance with this Act.~~

16           ~~“(B) SUBMISSION OF REPORTS TO THE~~  
17           ~~SECRETARY.—~~

18                   ~~“(i) IN GENERAL.—Following any ac-~~  
19                  ~~creditation of a third-party auditor or~~  
20                  ~~audit agent, the Secretary may, at any~~  
21                  ~~time, require the accredited third-party~~  
22                  ~~auditor or audit agent to submit to the~~  
23                  ~~Secretary an onsite audit report and such~~  
24                  ~~other reports or documents required as~~  
25                  ~~part of the audit process, for any eligible~~

1           entity certified by the third-party auditor  
2           or audit agent. Such report may include  
3           documentation that the eligible entity is in  
4           compliance with any applicable registration  
5           requirements.

6           “(ii) LIMITATION.—The requirement  
7           under clause (i) shall not include any re-  
8           port or other documents resulting from a  
9           consultative audit by the accredited third-  
10          party auditor or audit agent, except that  
11          the Secretary may access the results of a  
12          consultative audit in accordance with sec-  
13          tion 414.

14          “(4) REQUIREMENTS OF AUDIT AGENTS.—

15          “(A) RISKS TO PUBLIC HEALTH.—If, at  
16          any time during an audit, an accredited audit  
17          agent discovers a condition that could cause or  
18          contribute to a serious risk to the public health,  
19          the audit agent shall immediately notify the  
20          Secretary of—

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

23                  “(ii) such condition.

1           “(B) TYPES OF AUDITS.—An accredited  
2           audit agent may perform consultative and regu-  
3           latory audits of eligible entities.

4           “(C) LIMITATIONS.—An accredited audit  
5           agent may not perform a regulatory audit of an  
6           eligible entity if such agent has performed a  
7           consultative audit or a regulatory audit of such  
8           eligible entity during the previous 24-month pe-  
9           riod.

10          “(5) CONFLICTS OF INTEREST.—

11           “(A) THIRD-PARTY AUDITORS.—An ac-  
12          credited third-party auditor shall—

13                   “(i) not be owned, managed, or con-  
14                   trolled by any person that owns or operates  
15                   an eligible entity to be certified by such  
16                   auditor;

17                   “(ii) in carrying out audits of eligible  
18                   entities under this section, have procedures  
19                   to ensure against the use of any officer or  
20                   employee of such auditor that has a finan-  
21                   cial conflict of interest regarding an eligi-  
22                   ble entity to be certified by such auditor;  
23                   and

24                   “(iii) annually make available to the  
25                   Secretary disclosures of the extent to

1           which such auditor and the officers and  
2           employees of such auditor have maintained  
3           compliance with clauses (i) and (ii) relat-  
4           ing to financial conflicts of interest.

5           “(B) AUDIT AGENTS.—An accredited audit  
6           agent shall—

7                   “(i) not own or operate an eligible en-  
8                   tity to be certified by such agent;

9                   “(ii) in carrying out audits of eligible  
10                  entities under this section, have procedures  
11                  to ensure that such agent does not have a  
12                  financial conflict of interest regarding an  
13                  eligible entity to be certified by such agent;  
14                  and

15                  “(iii) annually make available to the  
16                  Secretary disclosures of the extent to  
17                  which such agent has maintained compli-  
18                  ance with clauses (i) and (ii) relating to fi-  
19                  nancial conflicts of interest.

20           “(C) REGULATIONS.—The Secretary shall  
21           promulgate regulations not later than 18  
22           months after the date of enactment of the FDA  
23           Food Safety Modernization Act to ensure that  
24           there are protections against conflicts of inter-  
25           est between an accredited third-party auditor or



1           audit agent and the eligible entity to be cer-  
2           tified by such auditor or audit agent. Such reg-  
3           ulations shall include—

4                   “(i) requiring that audits performed  
5                   under this section be unannounced;

6                   “(ii) a structure, including timing and  
7                   public disclosure, for fees paid by eligible  
8                   entities to accredited third-party auditors  
9                   or audit agents to decrease the potential  
10                  for conflicts of interest; and

11                  “(iii) appropriate limits on financial  
12                  affiliations between an accredited third-  
13                  party auditor or audit agent and any per-  
14                  son that owns or operates an eligible entity  
15                  to be certified by such auditor or audit  
16                  agent.

17           “(6) WITHDRAWAL OF ACCREDITATION.—The  
18           Secretary shall withdraw accreditation from an ac-  
19           credited third-party auditor or audit agent—

20                   “(A) if food from an eligible entity cer-  
21                   tified by such third-party auditor or audit agent  
22                   is linked to an outbreak of human or animal ill-  
23                   ness;

24                   “(B) following a performance audit and  
25                   finding by the Secretary that the third-party

1 auditor or audit agent no longer meets the re-  
2 quirements for accreditation; or

3 “(C) following a refusal to allow United  
4 States officials to conduct such audits and in-  
5 vestigations as may be necessary to ensure con-  
6 tinued compliance with the requirements set  
7 forth in this section.

8 “(7) NEUTRALIZING COSTS.—The Secretary  
9 shall establish a method, similar to the method used  
10 by the Department of Agriculture, by which accred-  
11 ited third-party auditors and audit agents reimburse  
12 the Food and Drug Administration for the work per-  
13 formed to establish and administer the accreditation  
14 system under this section. The Secretary shall make  
15 operating this program revenue-neutral and shall not  
16 generate surplus revenue from such a reimburse-  
17 ment mechanism.

18 “(d) RECERTIFICATION OF ELIGIBLE ENTITIES.—An  
19 eligible entity shall apply for annual recertification by an  
20 accredited third-party auditor or audit agent if such enti-  
21 ty—

22 “(1) intends to participate in voluntary quali-  
23 fied importer program under section 806; or

1           “(2) must provide to the Secretary a certifi-  
2           cation under section 801(p) for any food from such  
3           entity.

4           “(e) FALSE STATEMENTS.—Any statement or rep-  
5           resentation made—

6           “(1) by an employee or agent of an eligible enti-  
7           ty to an accredited third-party auditor or audit  
8           agent; or

9           “(2) by an accredited third-party auditor or an  
10          audit agent to the Secretary,

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

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

15         “(1) periodically, or at least once every 4 years,  
16         reevaluate the accreditation bodies described in sub-  
17         section (b)(1);

18         “(2) periodically, or at least once every 4 years,  
19         audit the performance of each accredited third-party  
20         auditor and audit agent, through the review of audit  
21         reports by such auditors and audit agents, the com-  
22         pliance history as available of eligible entities cer-  
23         tified by such auditors and audit agents, and any  
24         other measures deemed necessary by the Secretary;



1 tration in not less than 5 foreign countries selected by the  
2 Secretary, to provide assistance to the appropriate govern-  
3 mental entities of such countries with respect to measures  
4 to provide for the safety of articles of food and other prod-  
5 ucts regulated by the Food and Drug Administration ex-  
6 ported by such country to the United States, including by  
7 directly conducting risk-based inspections of such articles  
8 and supporting such inspections by such governmental en-  
9 tity.

10 (b) CONSULTATION.—In establishing the foreign of-  
11 fices described in subsection (a), the Secretary shall con-  
12 sult with the Secretary of State and the United States  
13 Trade Representative.

14 (c) REPORT.—Not later than October 1, 2011, the  
15 Secretary shall submit to Congress a report on the basis  
16 for the selection by the Secretary of the foreign countries  
17 in which the Secretary established offices under subsection  
18 (a), the progress which such offices have made with re-  
19 spect to assisting the governments of such countries in  
20 providing for the safety of articles of food and other prod-  
21 ucts regulated by the Food and Drug Administration ex-  
22 ported to the United States, and the plans of the Secretary  
23 for establishing additional foreign offices of the Food and  
24 Drug Administration, as appropriate.

1           **TITLE IV—MISCELLANEOUS**  
 2                           **PROVISIONS**

3   **SEC. 401. FUNDING FOR FOOD SAFETY.**

4           (a) **IN GENERAL.**—There are authorized to be appro-  
 5   priated to carry out the activities of the Center for Food  
 6   Safety and Applied Nutrition, the Center for Veterinary  
 7   Medicine, and related field activities in the Office of Regu-  
 8   latory Affairs of the Food and Drug Administration—

9                   (1) \$825,000,000 for fiscal year 2010; and

10                   (2) such sums as may be necessary for fiscal  
 11   years 2011 through 2014.

12           (b) **INCREASED NUMBER OF FIELD STAFF.**—To  
 13   carry out the activities of the Center for Food Safety and  
 14   Applied Nutrition, the Center for Veterinary Medicine,  
 15   and related field activities of the Office of Regulatory Af-  
 16   fairs of the Food and Drug Administration, the Secretary  
 17   of Health and Human Services shall increase the field  
 18   staff of such Centers and Office with a goal of not fewer  
 19   than—

20                   (1) 3,800 staff members in fiscal year 2010;

21                   (2) 4,000 staff members in fiscal year 2011;

22                   (3) 4,200 staff members in fiscal year 2012;

23                   (4) 4,600 staff members in fiscal year 2013;

24                   and

25                   (5) 5,000 staff members in fiscal year 2014.

1 **SEC. 402. JURISDICTION; AUTHORITIES.**

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

4 (1) alter the jurisdiction between the Secretary  
5 of Agriculture and the Secretary of Health and  
6 Human Services, under applicable statutes and regu-  
7 lations;

8 (2) limit the authority of the Secretary of  
9 Health and Human Services to issue regulations re-  
10 lated to the safety of food under—

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

14 (B) the Public Health Service Act (42  
15 U.S.C. 301 et seq.) as in effect on the day be-  
16 fore the date of enactment of this Act; or

17 (3) impede, minimize, or affect the authority of  
18 the Secretary of Agriculture to prevent, control, or  
19 mitigate a plant or animal health emergency, or a  
20 food emergency involving products regulated under  
21 the Federal Meat Inspection Act, the Poultry Prod-  
22 ucts Inspection Act, or the Egg Products Inspection  
23 Act.

1 **SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CON-**  
 2 **TENTS.**

3 (a) *SHORT TITLE.*—*This Act may be cited as the*  
 4 *“FDA Food Safety Modernization Act”.*

5 (b) *REFERENCES.*—*Except as otherwise specified,*  
 6 *whenever in this Act an amendment is expressed in terms*  
 7 *of an amendment to a section or other provision, the ref-*  
 8 *erence shall be considered to be made to a section or other*  
 9 *provision of the Federal Food, Drug, and Cosmetic Act (21*  
 10 *U.S.C. 301 et seq.).*

11 (c) *TABLE OF CONTENTS.*—*The table of contents for*  
 12 *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.*

**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. Recognition of laboratory accreditation for analyses of foods.*
- Sec. 203. Integrated consortium of laboratory networks.*
- Sec. 204. Enhancing traceback and recordkeeping.*
- Sec. 205. Pilot project to enhance traceback and recordkeeping with respect to processed food.*
- Sec. 206. Surveillance.*
- Sec. 207. Mandatory recall authority.*



*Sec. 208. Administrative detention of food.*

*Sec. 209. Decontamination and disposal standards and plans.*

*Sec. 210. Improving the training of State, local, territorial, and tribal food safety officials.*

*Sec. 211. Grants to enhance food safety.*

**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. Review of a regulatory authority of a foreign country.*

*Sec. 306. Building capacity of foreign governments with respect to food.*

*Sec. 307. Inspection of foreign food facilities.*

*Sec. 308. Accreditation of third-party auditors and audit agents.*

*Sec. 309. Foreign offices of the Food and Drug Administration.*

*Sec. 310. Smuggled food.*

**TITLE IV—MISCELLANEOUS PROVISIONS**

*Sec. 401. Funding for food safety.*

*Sec. 402. Whistleblower protections.*

*Sec. 403. Jurisdiction; authorities.*

*Sec. 404. Compliance with international agreements.*

1 **TITLE I—IMPROVING CAPACITY**  
 2 **TO PREVENT FOOD SAFETY**  
 3 **PROBLEMS**

4 **SEC. 101. INSPECTIONS OF RECORDS.**

5 (a) *IN GENERAL.*—Section 414(a) (21 U.S.C. 350c(a))

6 *is amended—*

7 (1) *by striking the heading and all that follows*  
 8 *through “of food is” and inserting the following:*

9 *“RECORDS INSPECTION.—*

10 *“(1) ADULTERATED FOOD.—If the Secretary has*  
 11 *a reasonable belief that an article of food, and any*  
 12 *other article of food that the Secretary reasonably be-*  
 13 *lieves is likely to be affected in a similar manner, is”;*

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

5           (3) by striking the last sentence; and

6           (4) by inserting at the end the following:

7           “(2) *USE OF OR EXPOSURE TO FOOD OF CON-*  
8 *CERN.—If the Secretary believes that there is a rea-*  
9 *sonable probability that the use of or exposure to an*  
10 *article of food, and any other article of food that the*  
11 *Secretary reasonably believes is likely to be affected in*  
12 *a similar manner, will cause serious adverse health*  
13 *consequences or death to humans or animals, each*  
14 *person (excluding farms and restaurants) who manu-*  
15 *factures, processes, packs, distributes, receives, holds,*  
16 *or imports such article shall, at the request of an offi-*  
17 *cer or employee duly designated by the Secretary, per-*  
18 *mit such officer or employee, upon presentation of ap-*  
19 *propriate credentials and a written notice to such*  
20 *person, at reasonable times and within reasonable*  
21 *limits and in a reasonable manner, to have access to*  
22 *and copy all records relating to such article and to*  
23 *any other article of food that the Secretary reasonably*  
24 *believes is likely to be affected in a similar manner,*  
25 *that are needed to assist the Secretary in determining*

1       *whether there is a reasonable probability that the use*  
 2       *of or exposure to the food will cause serious adverse*  
 3       *health consequences or death to humans or animals.*

4           “(3) *APPLICATION.*—*The requirement under*  
 5       *paragraphs (1) and (2) applies to all records relating*  
 6       *to the manufacture, processing, packing, distribution,*  
 7       *receipt, holding, or importation of such article main-*  
 8       *tained by or on behalf of such person in any format*  
 9       *(including paper and electronic formats) and at any*  
 10       *location.”.*

11       “(b) *CONFORMING AMENDMENT.*—*Section 704(a)(1)(B)*  
 12       *(21 U.S.C. 374(a)(1)(B)) is amended by striking “section*  
 13       *414 when” and all that follows through “subject to” and*  
 14       *inserting “section 414, when the standard for records in-*  
 15       *spection under paragraph (1) or (2) of section 414(a) ap-*  
 16       *plies, subject to”.*

17       **SEC. 102. REGISTRATION OF FOOD FACILITIES.**

18       “(a) *UPDATING OF FOOD CATEGORY REGULATIONS; BI-*  
 19       *ENNIAL REGISTRATION RENEWAL.*—*Section 415(a) (21*  
 20       *U.S.C. 350d(a)) is amended—*

21           (1) *in paragraph (2), by—*

22                   (A) *striking “conducts business and” and*  
 23                   *inserting “conducts business, the e-mail address*  
 24                   *for the contact person of the facility or, in the*

1           *case of a foreign facility, the United States agent*  
2           *for the facility, and”;* and

3           *(B) inserting “, or any other food categories*  
4           *as determined appropriate by the Secretary, in-*  
5           *cluding by guidance” after “Code of Federal*  
6           *Regulations”;*

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

9           *(3) by inserting after paragraph (2) the fol-*  
10          *lowing:*

11           *“(3) BIENNIAL REGISTRATION RENEWAL.—Dur-*  
12          *ing the period beginning on October 1 and ending on*  
13          *December 31 of each even-numbered year, a registrant*  
14          *that has submitted a registration under paragraph*  
15          *(1) shall submit to the Secretary a renewal registra-*  
16          *tion containing the information described in para-*  
17          *graph (2). The Secretary shall provide for an abbrev-*  
18          *viated registration renewal process for any registrant*  
19          *that has not had any changes to such information*  
20          *since the registrant submitted the preceding registra-*  
21          *tion or registration renewal for the facility involved.”.*

22          *(b) SUSPENSION OF REGISTRATION.—*

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

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

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

9           (C) by inserting after subsection (a) the fol-  
10          lowing:

11         “(b) *SUSPENSION OF REGISTRATION.*—

12           “(1) *IN GENERAL.*—If the Secretary determines  
13           that food manufactured, processed, packed, or held by  
14           a facility registered under this section has a reason-  
15           able probability of causing serious adverse health con-  
16           sequences or death to humans or animals, the Sec-  
17           retary may by order suspend the registration of the  
18           facility under this section in accordance with this  
19           subsection.

20           “(2) *HEARING ON SUSPENSION.*—The Secretary  
21           shall provide the registrant subject to an order under  
22           paragraph (1) with an opportunity for an informal  
23           hearing, to be held as soon as possible but not later  
24           than 2 business days after the issuance of the order  
25           or such other time period, as agreed upon by the Sec-

1        *retary and the registrant, on the actions required for*  
2        *reinstatement of registration and why the registration*  
3        *that is subject to suspension should be reinstated. The*  
4        *Secretary shall reinstate a registration if the Sec-*  
5        *retary determines, based on evidence presented, that*  
6        *adequate grounds do not exist to continue the suspen-*  
7        *sion of the registration.*

8                *“(3) POST-HEARING CORRECTIVE ACTION PLAN;*  
9        *VACATING OF ORDER.—*

10                *“(A) CORRECTIVE ACTION PLAN.—If, after*  
11                *providing opportunity for an informal hearing*  
12                *under paragraph (2), the Secretary determines*  
13                *that the suspension of registration remains nec-*  
14                *essary, the Secretary shall require the registrant*  
15                *to submit a corrective action plan to demonstrate*  
16                *how the registrant plans to correct the conditions*  
17                *found by the Secretary. The Secretary shall re-*  
18                *view such plan in a timely manner.*

19                *“(B) VACATING OF ORDER.—Upon a deter-*  
20                *mination by the Secretary that adequate grounds*  
21                *do not exist to continue the suspension actions*  
22                *required by the order, or that such actions should*  
23                *be modified, the Secretary shall vacate the order*  
24                *or modify the order.*

1           “(4) *EFFECT OF SUSPENSION.*—If the registra-  
2           tion of a facility is suspended under this subsection,  
3           such facility shall not import food or offer to import  
4           food into the United States, or otherwise introduce  
5           food into interstate or intrastate commerce in the  
6           United States.

7           “(5) *REGULATIONS.*—The Secretary shall pro-  
8           mulgate regulations that describe the standards the  
9           Commissioner will use in making a determination to  
10          suspend a registration, and the format the Commis-  
11          sioner will use to explain to the registrant the condi-  
12          tions found at the facility. The Secretary may pro-  
13          mulgate such regulations on an interim final basis.

14          “(6) *APPLICATION DATE.*—Facilities shall be  
15          subject to the requirements of this subsection begin-  
16          ning on the earlier of—

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

19                 “(B) 180 days after the date of enactment  
20                 of the *FDA Food Safety Modernization Act*.

21          “(7) *NO DELEGATION.*—The authority conferred  
22          by this subsection to issue an order to suspend a reg-  
23          istration or vacate an order of suspension shall not  
24          be delegated to any officer or employee other than the  
25          Commissioner.”.

1           (2) *IMPORTED FOOD.*—Section 801(l) (21 U.S.C.  
2           381(l)) is amended by inserting “(or for which a reg-  
3           istration has been suspended under such section)”  
4           after “section 415”.

5           (c) *CONFORMING AMENDMENTS.*—

6           (1) Section 301(d) (21 U.S.C. 331(d)) is amend-  
7           ed by inserting “415,” after “404,”.

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

13   **SEC. 103. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE**  
14                                   **CONTROLS.**

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

17   **“SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVEN-**  
18                                   **TIVE CONTROLS.**

19          “(a) *IN GENERAL.*—The owner, operator, or agent in  
20          charge of a facility shall, in accordance with this section,  
21          evaluate the hazards that could affect food manufactured,  
22          processed, packed, or held by such facility, identify and im-  
23          plement preventive controls to significantly minimize or  
24          prevent the occurrence of such hazards and provide assur-  
25          ances that such food is not adulterated under section 402



1 *or misbranded under section 403(w), monitor the perform-*  
2 *ance of those controls, and maintain records of this moni-*  
3 *toring as a matter of routine practice.*

4       “(b) *HAZARD ANALYSIS.—The owner, operator, or*  
5 *agent in charge of a facility shall—*

6               “(1) *identify and evaluate known or reasonably*  
7 *foreseeable hazards that may be associated with the*  
8 *facility, including—*

9                       “(A) *biological, chemical, physical, and ra-*  
10 *diological hazards, natural toxins, pesticides,*  
11 *drug residues, decomposition, parasites, aller-*  
12 *gens, and unapproved food and color additives;*  
13 *and*

14                       “(B) *hazards that occur naturally, may be*  
15 *unintentionally introduced, or may be inten-*  
16 *tionally introduced, including by acts of ter-*  
17 *rorism; and*

18               “(2) *develop a written analysis of the hazards.*

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

23               “(1) *hazards identified in the hazard analysis*  
24 *conducted under subsection (b) will be significantly*  
25 *minimized or prevented; and*

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

4           “(d) *MONITORING OF EFFECTIVENESS.—The owner,*  
5           *operator, or agent in charge of a facility shall monitor the*  
6           *effectiveness of the preventive controls implemented under*  
7           *subsection (c) to provide assurances that the outcomes de-*  
8           *scribed in subsection (c) shall be achieved.*

9           “(e) *CORRECTIVE ACTIONS.—The owner, operator, or*  
10          *agent in charge of a facility shall establish procedures that*  
11          *a facility will implement if the preventive controls imple-*  
12          *mented under subsection (c) are found to be ineffective*  
13          *through monitoring under subsection (d).*

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

16                 “(1) *the preventive controls implemented under*  
17                 *subsection (c) are adequate to control the hazards*  
18                 *identified under subsection (b);*

19                 “(2) *the owner, operator, or agent is conducting*  
20                 *monitoring in accordance with subsection (d);*

21                 “(3) *the owner, operator, or agent is making ap-*  
22                 *propriate decisions about corrective actions taken*  
23                 *under subsection (e);*

24                 “(4) *the preventive controls implemented under*  
25                 *subsection (c) are effectively and significantly mini-*

1        *mizing or preventing the occurrence of identified haz-*  
2        *ards, including through the use of environmental and*  
3        *product testing programs and other appropriate*  
4        *means; and*

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

10          *“(g) RECORDKEEPING.—The owner, operator, or agent*  
11        *in charge of a facility shall maintain, for not less than 2*  
12        *years, records documenting the monitoring of the preventive*  
13        *controls implemented under subsection (c), instances of non-*  
14        *conformance material to food safety, the results of testing*  
15        *and other appropriate means of verification under sub-*  
16        *section (f)(4), instances when corrective actions were imple-*  
17        *mented, and the efficacy of preventive controls and correc-*  
18        *tive actions.*

19          *“(h) WRITTEN PLAN AND DOCUMENTATION.—The*  
20        *owner, operator, or agent in charge of a facility shall pre-*  
21        *pare a written plan that documents and describes the proce-*  
22        *dures used by the facility to comply with the requirements*  
23        *of this section, including analyzing the hazards under sub-*  
24        *section (b) and identifying the preventive controls adopted*  
25        *under subsection (c) to address those hazards. Such written*

1 *plan, together with the documentation described in sub-*  
2 *section (g), shall be made promptly available to a duly au-*  
3 *thorized representative of the Secretary upon oral or written*  
4 *request.*

5       “(i) *REQUIREMENT TO REANALYZE.*—*The owner, op-*  
6 *erator, or agent in charge of a facility shall conduct a rea-*  
7 *nalysis under subsection (b) whenever a significant change*  
8 *is made in the activities conducted at a facility operated*  
9 *by such owner, operator, or agent if the change creates a*  
10 *reasonable potential for a new hazard or a significant in-*  
11 *crease in a previously identified hazard or not less fre-*  
12 *quently than once every 3 years, whichever is earlier. Such*  
13 *reanalysis shall be completed and additional preventive*  
14 *controls needed to address the hazard identified, if any,*  
15 *shall be implemented before the change in activities at the*  
16 *facility is operative. Such owner, operator, or agent shall*  
17 *revise the written plan required under subsection (h) if such*  
18 *a significant change is made or document the basis for the*  
19 *conclusion that no additional or revised preventive controls*  
20 *are needed. The Secretary may require a reanalysis under*  
21 *this section to respond to new hazards and developments*  
22 *in scientific understanding.*

23       “(j) *DEEMED COMPLIANCE OF SEAFOOD, JUICE, AND*  
24 *LOW-ACID CANNED FOOD FACILITIES SUBJECT TO*  
25 *HACCP.*—*The owner, operator, or agent in charge of a fa-*

1 *cility required to comply with 1 of the following standards*  
2 *and regulations with respect to such facility shall be deemed*  
3 *to be in compliance with this section, with respect to such*  
4 *facility:*

5           “(1) *The Seafood Hazard Analysis Critical Con-*  
6           *trol Points Program of the Food and Drug Adminis-*  
7           *tration.*

8           “(2) *The Juice Hazard Analysis Critical Control*  
9           *Points Program of the Food and Drug Administra-*  
10          *tion.*

11          “(3) *The Thermally Processed Low-Acid Foods*  
12          *Packaged in Hermetically Sealed Containers stand-*  
13          *ards of the Food and Drug Administration (or any*  
14          *successor standards).*

15          “(k) *EXCEPTION FOR FACILITIES SUBJECT TO SEC-*  
16          *TION 419.—This section shall not apply to a facility that*  
17          *is subject to section 419.*

18          “(l) *AUTHORITY WITH RESPECT TO CERTAIN FACILI-*  
19          *TIES.—The Secretary may, by regulation, exempt or modify*  
20          *the requirements for compliance under this section with re-*  
21          *spect to facilities that are solely engaged in the production*  
22          *of food for animals other than man, the storage of raw agri-*  
23          *cultural commodities (other than fruits and vegetables) in-*  
24          *tended for further distribution or processing, or the storage*  
25          *of packaged foods that are not exposed to the environment.*

1       “(m) *DEFINITIONS.*—*For purposes of this section:*

2               “(1) *CRITICAL CONTROL POINT.*—*The term ‘crit-*  
3       *ical control point’ means a point, step, or procedure*  
4       *in a food process at which control can be applied and*  
5       *is essential to prevent or eliminate a food safety haz-*  
6       *ard or reduce such hazard to an acceptable level.*

7               “(2) *FACILITY.*—*The term ‘facility’ means a do-*  
8       *mestic facility or a foreign facility that is required to*  
9       *register under section 415.*

10              “(3) *PREVENTIVE CONTROLS.*—*The term ‘preven-*  
11       *tive controls’ means those risk-based, reasonably ap-*  
12       *propriate procedures, practices, and processes that a*  
13       *person knowledgeable about the safe manufacturing,*  
14       *processing, packing, or holding of food would employ*  
15       *to significantly minimize or prevent the hazards iden-*  
16       *tified under the hazard analysis conducted under sub-*  
17       *section (a) and that are consistent with the current*  
18       *scientific understanding of safe food manufacturing,*  
19       *processing, packing, or holding at the time of the*  
20       *analysis. Those procedures, practices, and processes*  
21       *may include the following:*

22                      “(A) *Sanitation procedures for food contact*  
23       *surfaces and utensils and food-contact surfaces of*  
24       *equipment.*

1           “(B) Supervisor, manager, and employee  
2 hygiene training.

3           “(C) An environmental monitoring pro-  
4 gram to verify the effectiveness of pathogen con-  
5 trols in processes where a food is exposed to a po-  
6 tential contaminant in the environment.

7           “(D) A food allergen control program.

8           “(E) A recall plan.

9           “(F) Good Manufacturing Practices  
10 (GMPs).

11           “(G) Supplier verification activities.”.

12       (b) REGULATIONS.—

13           (1) IN GENERAL.—Not later than 18 months  
14 after the date of enactment of this Act, the Secretary  
15 of Health and Human Services (referred to in this  
16 Act as the “Secretary”) shall promulgate regulations  
17 to establish science-based minimum standards for con-  
18 ducting a hazard analysis, documenting hazards, im-  
19 plementing preventive controls, and documenting the  
20 implementation of the preventive controls under sec-  
21 tion 418 of the Federal Food, Drug, and Cosmetic Act  
22 (as added by subsection (a)).

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

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

3            (3) *RULE OF CONSTRUCTION.*—*Nothing in this*  
4        *subsection shall be construed to provide the Secretary*  
5        *with the authority to apply specific technologies,*  
6        *practices, or critical controls to an individual facil-*  
7        *ity.*

8            (4) *REVIEW.*—*In promulgating the regulations*  
9        *under paragraph (1), the Secretary shall review regu-*  
10       *latory hazard analysis and preventive control pro-*  
11       *grams in existence on the date of enactment of this*  
12       *Act to ensure that the program under such section*  
13       *418 is consistent, to the extent practicable, with ap-*  
14       *plicable domestic and internationally-recognized*  
15       *standards in existence on such date.*

16          (c) *GUIDANCE DOCUMENT.*—*The Secretary shall issue*  
17       *a guidance document related to hazard analysis and pre-*  
18       *ventive controls related to the regulations promulgated*  
19       *under section 418 of the Federal Food, Drug, and Cosmetic*  
20       *Act (as added by subsection (a)).*

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

23            “(uu) *The operation of a facility that manufacturers,*  
24        *processes, packs, or holds food for sale in the United States*



1 *if the owner, operator, or agent in charge of such facility*  
2 *is not in compliance with section 418.”*

3       (e) *NO EFFECT ON HACCP AUTHORITIES.*—*Nothing*  
4 *in the amendments made by this section limits the author-*  
5 *ity of the Secretary under the Federal Food, Drug, and Cos-*  
6 *metic Act (21 U.S.C. 301 et seq.) or the Public Health Serv-*  
7 *ice Act (42 U.S.C. 201 et seq.) to revise, issue, or enforce*  
8 *product and category-specific regulations, such as the Sea-*  
9 *food Hazard Analysis Critical Controls Points Program,*  
10 *the Juice Hazard Analysis Critical Control Program, and*  
11 *the Thermally Processed Low-Acid Foods Packaged in Her-*  
12 *metically Sealed Containers standards.*

13       (f) *DIETARY SUPPLEMENTS.*—*Nothing in the amend-*  
14 *ments made by this section shall apply to any dietary sup-*  
15 *plement that is in compliance with the requirements of sec-*  
16 *tions 402(g)(2) and 761 of the Federal Food, Drug, and*  
17 *Cosmetic Act (21 U.S.C. 342(g)(2), 379aa-1).*

18       (g) *NO EFFECT ON ALCOHOL-RELATED FACILITIES.*—

19           (1) *IN GENERAL.*—*Nothing in the amendments*  
20 *made by this section shall apply to a facility that—*

21                   (A) *under the Federal Alcohol Administra-*  
22 *tion Act (27 U.S.C. 201 et seq.) or chapter 51 of*  
23 *subtitle E of the Internal Revenue Code of 1986*  
24 *(26 U.S.C. 5291 et seq.) is required to obtain a*  
25 *permit or to register with the Secretary of the*

1           *Treasury as a condition of doing business in the*  
2           *United States; and*

3                   *(B) is required to register as a facility*  
4                   *under section 415 of the Federal Food, Drug,*  
5                   *and Cosmetic Act (21 U.S.C. 350d) because such*  
6                   *facility is engaged in manufacturing, processing,*  
7                   *packing, or holding 1 or more alcoholic bev-*  
8                   *erages,*  
9           *with respect to the activities of such facility that re-*  
10           *late to the manufacturing, processing, packing, or*  
11           *holding of alcoholic beverages.*

12                   (2) *LIMITED RECEIPT AND DISTRIBUTION OF*  
13                   *NON-ALCOHOL FOOD.—Paragraph (1) shall not apply*  
14                   *to a facility engaged in the receipt or distribution of*  
15                   *any non-alcohol food, except that such paragraph*  
16                   *shall apply to a facility described in such paragraph*  
17                   *that receives and distributes non-alcohol food, pro-*  
18                   *vided such food is received and distributed—*

19                           *(A) in a prepackaged form that prevents*  
20                           *any direct human contact with such food; and*

21                           *(B) in amounts that constitute not more*  
22                           *than 5 percent of the overall sales of such facil-*  
23                           *ity, as determined by the Secretary of the Treas-*  
24                           *ury.*

1           (3) *RULE OF CONSTRUCTION.*—*Except as pro-*  
2 *vided in paragraphs (1) and (2), this subsection shall*  
3 *not be construed to exempt any food, other than dis-*  
4 *tilled spirits, wine, and malt beverages, as defined in*  
5 *section 211 of the Federal Alcohol Administration Act*  
6 *(27 U.S.C. 211), from the requirements of this Act*  
7 *(including the amendments made by this Act).*

8           (h) *EFFECTIVE DATE.*—

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

12           (2) *EXCEPTIONS.*—*Notwithstanding paragraph*  
13 *(1)—*

14           (A) *the amendments made by this section*  
15 *shall apply to a small business (as defined by the*  
16 *Secretary for purposes of this section, not later*  
17 *than 90 days after the date of enactment of this*  
18 *Act) after the date that is 2 years after the date*  
19 *of enactment of this Act; and*

20           (B) *the amendments made by this section*  
21 *shall apply to a very small business (as defined*  
22 *by the Secretary for purposes of this section, not*  
23 *later than 90 days after the date of enactment of*  
24 *this Act) after the date that is 3 years after the*  
25 *date of enactment of this Act.*

1 **SEC. 104. PERFORMANCE STANDARDS.**

2       *The Secretary shall, not less frequently than every 2*  
3 *years, review and evaluate relevant health data and other*  
4 *relevant information, including from toxicological and epi-*  
5 *demiological studies and analyses, to determine the most*  
6 *significant foodborne contaminants. Based on such review*  
7 *and evaluation, and when appropriate to reduce the risk*  
8 *of serious illness or death to humans or animals or to pre-*  
9 *vent adulteration of the food under section 402 of the Fed-*  
10 *eral Food, Drug, or Cosmetic Act (21 U.S.C. 342) or to pre-*  
11 *vent the spread of communicable disease under section 361*  
12 *of the Public Health Service Act (42 U.S.C. 264), the Sec-*  
13 *retary shall issue contaminant-specific and science-based*  
14 *guidance documents, action levels, or regulations. Such*  
15 *guidance, action levels, or regulations shall apply to prod-*  
16 *ucts or product classes and shall not be written to be facil-*  
17 *ity-specific.*

18 **SEC. 105. STANDARDS FOR PRODUCE SAFETY.**

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

22 **“SEC. 419. STANDARDS FOR PRODUCE SAFETY.**

23       *“(a) PROPOSED RULEMAKING.—*

24               *“(1) IN GENERAL.—Not later than 1 year after*  
25 *the date of enactment of the FDA Food Safety Mod-*  
26 *ernization Act, the Secretary, in coordination with*

1        *the Secretary of Agriculture and representatives of*  
2        *State departments of agriculture (including with re-*  
3        *gard to the national organic program established*  
4        *under the Organic Foods Production Act of 1990 (7*  
5        *U.S.C. 6501 et seq.)), shall publish a notice of pro-*  
6        *posed rulemaking to establish science-based minimum*  
7        *standards for the safe production and harvesting of*  
8        *those types of fruits and vegetables that are raw agri-*  
9        *cultural commodities for which the Secretary has de-*  
10       *termined that such standards minimize the risk of se-*  
11       *rious adverse health consequences or death.*

12                *“(2) PUBLIC INPUT.—During the comment pe-*  
13        *riod on the notice of proposed rulemaking under*  
14        *paragraph (1), the Secretary shall conduct not less*  
15        *than 3 public meetings in diverse geographical areas*  
16        *of the United States to provide persons in different*  
17        *regions an opportunity to comment.*

18                *“(3) CONTENT.—The proposed rulemaking under*  
19        *paragraph (1) shall—*

20                        *“(A) provide sufficient flexibility to be ap-*  
21        *plicable to various types of entities engaged in*  
22        *the production and harvesting of raw agricul-*  
23        *tural commodities, including small businesses*  
24        *and entities that sell directly to consumers, and*

1           *be appropriate to the scale and diversity of the*  
2           *production and harvesting of such commodities;*

3           “(B) *include, with respect to growing, har-*  
4           *vesting, sorting, packing, and storage operations,*  
5           *minimum standards related to soil amendments,*  
6           *hygiene, packaging, temperature controls, animal*  
7           *encroachment, and water;*

8           “(C) *consider hazards that occur naturally,*  
9           *may be unintentionally introduced, or may be*  
10          *intentionally introduced, including by acts of*  
11          *terrorism;*

12          “(D) *take into consideration, consistent*  
13          *with ensuring enforceable public health protec-*  
14          *tion, conservation and environmental practice*  
15          *standards and policies established by Federal*  
16          *natural resource conservation, wildlife conserva-*  
17          *tion, and environmental agencies; and*

18          “(E) *in the case of production that is cer-*  
19          *tified organic, not include any requirements that*  
20          *conflict with or duplicate the requirements of the*  
21          *national organic program established under the*  
22          *Organic Foods Production Act of 1990 (7 U.S.C.*  
23          *6501 et seq.), while providing for public health*  
24          *protection consistent with the requirements of*  
25          *this Act.*

1           “(4) *PRIORITIZATION.*—*The Secretary shall*  
2           *prioritize the implementation of the regulations for*  
3           *specific fruits and vegetables that are raw agricul-*  
4           *tural commodities that have been associated with*  
5           *foodborne illness outbreaks.*

6           “(b) *FINAL REGULATION.*—

7           “(1) *IN GENERAL.*—*Not later than 1 year after*  
8           *the close of the comment period for the proposed rule-*  
9           *making under subsection (a), the Secretary shall*  
10           *adopt a final regulation to provide for minimum*  
11           *standards for those types of fruits and vegetables that*  
12           *are raw agricultural commodities for which the Sec-*  
13           *retary has determined that such standards minimize*  
14           *the risk of serious adverse health consequences or*  
15           *death.*

16           “(2) *FINAL REGULATION.*—*The final regulation*  
17           *shall—*

18           “(A) *provide a reasonable period of time for*  
19           *compliance, taking into account the needs of*  
20           *small businesses for additional time to comply;*

21           “(B) *provide for coordination of education*  
22           *and enforcement activities by State and local of-*  
23           *ficials, as designated by the Governors of the re-*  
24           *spective States; and*

1           “(C) include a description of the variance  
2           process under subsection (c) and the types of per-  
3           missible variances the Secretary may grant.

4           “(c) CRITERIA.—

5           “(1) IN GENERAL.—The regulations adopted  
6           under subsection (b) shall—

7           “(A) set forth those procedures, processes,  
8           and practices as the Secretary determines to be  
9           reasonably necessary to prevent the introduction  
10          of known or reasonably foreseeable biological,  
11          chemical, and physical hazards, including haz-  
12          ards that occur naturally, may be unintention-  
13          ally introduced, or may be intentionally intro-  
14          duced, including by acts of terrorism, into fruits  
15          and vegetables that are raw agricultural com-  
16          modities and to provide reasonable assurances  
17          that the produce is not adulterated under section  
18          402; and

19          “(B) permit States and foreign countries  
20          from which food is imported into the United  
21          States, subject to paragraph (2), to request from  
22          the Secretary variances from the requirements of  
23          the regulations, where upon approval of the Sec-  
24          retary, the variance is considered permissible  
25          under the requirements of the regulations adopt-



1           *ed under subsection (b)(2)(C) and where the*  
2           *State or foreign country determines that the*  
3           *variance is necessary in light of local growing*  
4           *conditions and that the procedures, processes,*  
5           *and practices to be followed under the variance*  
6           *are reasonably likely to ensure that the produce*  
7           *is not adulterated under section 402 to the same*  
8           *extent as the requirements of the regulation*  
9           *adopted under subsection (b).*

10           “(2) *APPROVAL OF VARIANCES.*—*A State or for-*  
11           *ign country from which food is imported into the*  
12           *United States shall request a variance from the Sec-*  
13           *retary in writing. The Secretary may deny such a re-*  
14           *quest as not reasonably likely to ensure that the*  
15           *produce is not adulterated under section 402 to the*  
16           *same extent as the requirements of the regulation*  
17           *adopted under subsection (b).*

18           “(d) *ENFORCEMENT.*—*The Secretary may coordinate*  
19           *with the Secretary of Agriculture and, as appropriate, shall*  
20           *contract and coordinate with the agency or department des-*  
21           *ignated by the Governor of each State to perform activities*  
22           *to ensure compliance with this section.*

23           “(e) *GUIDANCE.*—

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

1        *ernization Act, the Secretary shall publish, after con-*  
2        *sultation with the Secretary of Agriculture, represent-*  
3        *atives of State departments of agriculture, farmer*  
4        *representatives, and various types of entities engaged*  
5        *in the production and harvesting of fruits and vegeta-*  
6        *bles that are raw agricultural commodities, including*  
7        *small businesses, updated good agricultural practices*  
8        *and guidance for the safe production and harvesting*  
9        *of specific types of fresh produce.*

10        “(2) *PUBLIC MEETINGS.*—*The Secretary shall*  
11        *conduct not fewer than 3 public meetings in diverse*  
12        *geographical areas of the United States as part of an*  
13        *effort to conduct education and outreach regarding*  
14        *the guidance described in paragraph (1) for persons*  
15        *in different regions who are involved in the produc-*  
16        *tion and harvesting of fruits and vegetables that are*  
17        *raw agricultural commodities, including persons that*  
18        *sell directly to consumers and farmer representatives.*

19        “(f) *EXCEPTION FOR FACILITIES SUBJECT TO SEC-*  
20        *TION 418.*—*This section shall not apply to a facility that*  
21        *is subject to section 418.”.*

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

1       “(vv) *The failure to comply with the requirements*  
2 *under section 419.*”.

3       (c) **NO EFFECT ON HACCP AUTHORITIES.**—*Nothing*  
4 *in the amendments made by this section limits the author-*  
5 *ity of the Secretary under the Federal Food, Drug, and Cos-*  
6 *metic Act (21 U.S.C. 301 et seq.) or the Public Health Serv-*  
7 *ice Act (42 U.S.C. 201 et seq.) to revise, issue, or enforce*  
8 *product and category-specific regulations, such as the Sea-*  
9 *food Hazard Analysis Critical Controls Points Program,*  
10 *the Juice Hazard Analysis Critical Control Program, and*  
11 *the Thermally Processed Low-Acid Foods Packaged in Her-*  
12 *metically Sealed Containers standards.*

13 **SEC. 106. PROTECTION AGAINST INTENTIONAL ADULTERA-**  
14 **TION.**

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

18 **“SEC. 420. PROTECTION AGAINST INTENTIONAL ADULTERA-**  
19 **TION.**

20       “(a) **IN GENERAL.**—*Not later than 2 years after the*  
21 *date of enactment of the FDA Food Safety Modernization*  
22 *Act, the Secretary, in consultation with the Secretary of*  
23 *Homeland Security and the Secretary of Agriculture, shall*  
24 *promulgate regulations to protect against the intentional*  
25 *adulteration of food subject to this Act.*

1       “(b) *APPLICABILITY.*—Regulations under subsection  
2 (a) shall apply only to food—

3               “(1) for which the Secretary has identified clear  
4 vulnerabilities (including short shelf-life or suscepti-  
5 bility to intentional contamination at critical control  
6 points);

7               “(2) in bulk or batch form, prior to being pack-  
8 aged for the final consumer; and

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

13       “(c) *DETERMINATIONS.*—In making the determination  
14 under subsection (b)(3), the Secretary shall—

15               “(1) conduct vulnerability assessments of the food  
16 system;

17               “(2) consider the best available understanding of  
18 uncertainties, risks, costs, and benefits associated with  
19 guarding against intentional adulteration at vulner-  
20 able points; and

21               “(3) determine the types of science-based mitiga-  
22 tion strategies or measures that are necessary to pro-  
23 tect against the intentional adulteration of food.

24       “(d) *CONTENT OF REGULATIONS.*—Regulations under  
25 subsection (a) shall—

1           “(1) *specify how a person shall assess whether*  
2           *the person is required to implement mitigation strate-*  
3           *gies or measures intended to protect against the in-*  
4           *tentional adulteration of food; and*

5           “(2) *specify appropriate science-based mitigation*  
6           *strategies or measures to prepare and protect the food*  
7           *supply chain at specific vulnerable points, as appro-*  
8           *priate.*

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

11          “(f) *DEFINITION.—For purposes of this section, the*  
12          *term ‘farm’ has the meaning given that term in section*  
13          *1.227 of title 21, Code of Federal Regulations (or any suc-*  
14          *cessor regulation).’.*

15          (b) *GUIDANCE DOCUMENTS.—*

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

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

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

7                   (B) *include examples of mitigation strate-*  
8                   *gies or measures described in subsection (d)(2) of*  
9                   *such section; and*

10                  (C) *specify situations in which the examples*  
11                  *of mitigation strategies or measures described in*  
12                  *subsection (d)(2) of such section are appropriate.*

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

20           (c) *PERIODIC REVIEW.*—*The Secretary of Health and*  
21           *Human Services shall periodically review and, as appro-*  
22           *priate, update the regulations under subsection (a) and the*  
23           *guidance documents under subsection (b).*

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

4       “(ww) *The failure to comply with section 420.*”.

5       **SEC. 107. AUTHORITY TO COLLECT FEES.**

6       (a) *FEES FOR REINSPECTION, RECALL, AND IMPORTA-*  
 7 *TION ACTIVITIES.*—Subchapter C of chapter VII (21 U.S.C.  
 8 379f *et seq.*) is amended by adding at the end the following:

9               **“PART 6—FEES RELATED TO FOOD**

10       **“SEC. 743. AUTHORITY TO COLLECT AND USE FEES.**

11       “(a) *IN GENERAL.*—

12               “(1) *PURPOSE AND AUTHORITY.*—For fiscal year  
 13 2010 and each subsequent fiscal year, the Secretary  
 14 shall, in accordance with this section, assess and col-  
 15 lect fees from—

16                       “(A) *the responsible party for each domestic*  
 17 *facility (as defined in section 415(b)) and the*  
 18 *United States agent for each foreign facility sub-*  
 19 *ject to a reinspection in such fiscal year, to cover*  
 20 *reinspection-related costs for such year;*

21                       “(B) *the responsible party for a domestic*  
 22 *facility (as defined in section 415(b)) and an*  
 23 *importer who does not comply with a recall*  
 24 *order under section 423 or under section 412(f)*  
 25 *in such fiscal year, to cover food recall activities*

1 associated with such order performed by the Sec-  
2 retary, including technical assistance, follow-up  
3 effectiveness checks, and public notifications, for  
4 such year;

5 “(C) each importer participating in the vol-  
6 untary qualified importer program under section  
7 806 in such year, to cover the administrative  
8 costs of such program for such year; and

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

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

14 “(A) the term ‘reinspection’ means—

15 “(i) with respect to domestic facilities  
16 (as defined in section 415(b)), 1 or more in-  
17 spections conducted under section 704 subse-  
18 quent to an inspection conducted under  
19 such provision which identified noncompli-  
20 ance materially related to a food safety re-  
21 quirement of this Act, specifically to deter-  
22 mine whether compliance has been achieved  
23 to the Secretary’s satisfaction; and

24 “(ii) with respect to importers, 1 or  
25 more examinations conducted under section



1           801 subsequent to an examination con-  
2           ducted under such provision which identi-  
3           fied noncompliance materially related to a  
4           food safety requirement of this Act, specifi-  
5           cally to determine whether compliance has  
6           been achieved to the Secretary's satisfaction;

7           “(B) the term ‘reinspection-related costs’  
8           means all expenses, including administrative ex-  
9           penses, incurred in connection with—

10                   “(i) arranging, conducting, and evalu-  
11                   ating the results of reinspections; and

12                   “(ii) assessing and collecting reinspec-  
13                   tion fees under this section; and

14           “(C) the term ‘responsible party’ has the  
15           meaning given such term in section 417(a)(1).

16           “(b) *ESTABLISHMENT OF FEES.*—

17                   “(1) *IN GENERAL.*—Subject to subsections (c)  
18                   and (d), the Secretary shall establish the fees to be col-  
19                   lected under this section for each fiscal year specified  
20                   in subsection (a)(1), based on the methodology de-  
21                   scribed under paragraph (2), and shall publish such  
22                   fees in a *Federal Register* notice not later than 60  
23                   days before the start of each such year.

24           “(2) *FEE METHODOLOGY.*—

1           “(A) *FEEES.—Fees amounts established for*  
2           *collection—*

3                   “(i) *under subparagraph (A) of sub-*  
4                   *section (a)(1) for a fiscal year shall be based*  
5                   *on the Secretary’s estimate of 100 percent of*  
6                   *the costs of the reinspection-related activi-*  
7                   *ties (including by type or level of reinspec-*  
8                   *tion activity, as the Secretary determines*  
9                   *applicable) described in such subparagraph*  
10                   *(A) for such year;*

11                   “(ii) *under subparagraph (B) of sub-*  
12                   *section (a)(1) for a fiscal year shall be based*  
13                   *on the Secretary’s estimate of 100 percent of*  
14                   *the costs of the activities described in such*  
15                   *subparagraph (B) for such year;*

16                   “(iii) *under subparagraph (C) of sub-*  
17                   *section (a)(1) for a fiscal year shall be based*  
18                   *on the Secretary’s estimate of 100 percent of*  
19                   *the costs of the activities described in such*  
20                   *subparagraph (C) for such year; and*

21                   “(iv) *under subparagraph (D) of sub-*  
22                   *section (a)(1) for a fiscal year shall be based*  
23                   *on the Secretary’s estimate of 100 percent of*  
24                   *the costs of the activities described in such*  
25                   *subparagraph (D) for such year.*

1                   “(B) *OTHER CONSIDERATIONS.*—

2                   “*(i) VOLUNTARY QUALIFIED IMPORTER*  
3                   *PROGRAM.*—

4                   “*(I) PARTICIPATION.*—*In estab-*  
5                   *lishing the fee amounts under subpara-*  
6                   *graph (A)(iii) for a fiscal year, the*  
7                   *Secretary shall provide for the number*  
8                   *of importers who have submitted to the*  
9                   *Secretary a notice under section 806(e)*  
10                  *informing the Secretary of the intent of*  
11                  *such importer to participate in the*  
12                  *program under section 806 in such fis-*  
13                  *cal year.*

14                  “*(II) RECOUPMENT.*—*In estab-*  
15                  *lishing the fee amounts under subpara-*  
16                  *graph (A)(iii) for the first 5 fiscal*  
17                  *years after the date of enactment of*  
18                  *this section, the Secretary shall include*  
19                  *in such fee a reasonable surcharge that*  
20                  *provides a recoupment of the costs ex-*  
21                  *pended by the Secretary to establish*  
22                  *and implement the first year of the*  
23                  *program under section 806.*

24                  “*(ii) CREDITING OF FEES.*—*In estab-*  
25                  *lishing the fee amounts under subparagraph*

1           (A) for a fiscal year, the Secretary shall  
2           provide for the crediting of fees from the  
3           previous year to the next year if the Sec-  
4           retary overestimated the amount of fees  
5           needed to carry out such activities, and con-  
6           sider the need to account for any adjust-  
7           ment of fees and such other factors as the  
8           Secretary determines appropriate.

9           “(iii) *PUBLISHED GUIDELINES.*—Not  
10          later than June 30, 2010, the Secretary  
11          shall publish in the *Federal Register* a pro-  
12          posed set of guidelines in consideration of  
13          the burden of fee amounts on small business.  
14          Such consideration may include reduced fee  
15          amounts for small businesses. The Secretary  
16          shall provide for a period of public com-  
17          ment on such guidelines. The Secretary  
18          shall adjust the fee schedule for small busi-  
19          nesses subject to such fees only through no-  
20          tice and comment rulemaking.

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

1       “(c) *LIMITATIONS.*—

2               “(1) *IN GENERAL.*—*Fees under subsection (a)*  
3 *shall be refunded for a fiscal year beginning after fis-*  
4 *cal year 2010 unless the amount of the total appro-*  
5 *priations for food safety activities at the Food and*  
6 *Drug Administration for such fiscal year (excluding*  
7 *the amount of fees appropriated for such fiscal year)*  
8 *is equal to or greater than the amount of appropria-*  
9 *tions for food safety activities at the Food and Drug*  
10 *Administration for fiscal year 2009 (excluding the*  
11 *amount of fees appropriated for such fiscal year),*  
12 *multiplied by the adjustment factor under paragraph*  
13 *(3).*

14               “(2) *AUTHORITY.*—*If—*

15                       “(A) *the Secretary does not assess fees under*  
16 *subsection (a) for a portion of a fiscal year be-*  
17 *cause paragraph (1) applies; and*

18                       “(B) *at a later date in such fiscal year,*  
19 *such paragraph (1) ceases to apply,*  
20 *the Secretary may assess and collect such fees under*  
21 *subsection (a), without any modification to the rate*  
22 *of such fees, notwithstanding the provisions of sub-*  
23 *section (a) relating to the date fees are to be paid.*

24               “(3) *ADJUSTMENT FACTOR.*—

1           “(A) *IN GENERAL.*—*The adjustment factor*  
2           *described in paragraph (1) shall be the total per-*  
3           *centage change that occurred in the Consumer*  
4           *Price Index for all urban consumers (all items;*  
5           *United States city average) for the 12-month pe-*  
6           *riod ending June 30 preceding the fiscal year,*  
7           *but in no case shall such adjustment factor be*  
8           *negative.*

9           “(B) *COMPOUNDED BASIS.*—*The adjustment*  
10           *under subparagraph (A) made each fiscal year*  
11           *shall be added on a compounded basis to the sum*  
12           *of all adjustments made each fiscal year after fis-*  
13           *cal year 2009.*

14           “(4) *LIMITATION ON AMOUNT OF CERTAIN*  
15           *FEES.*—

16           “(A) *IN GENERAL.*—*Notwithstanding any*  
17           *other provision of this section and subject to sub-*  
18           *paragraph (B), the Secretary may not collect fees*  
19           *in a fiscal year such that the amount collected—*

20                   “(i) *under subparagraph (B) of sub-*  
21                   *section (a)(1) exceeds \$20,000,000; and*

22                   “(ii) *under subparagraphs (A) and (D)*  
23                   *of subsection (a)(1) exceeds \$25,000,000*  
24                   *combined.*

1           “(B) *EXCEPTION.*—*If a domestic facility*  
2           *(as defined in section 415(b)) or an importer be-*  
3           *comes subject to a fee described in subparagraph*  
4           *(A), (B), or (D) of subsection (a)(1) after the*  
5           *maximum amount of fees has been collected by*  
6           *the Secretary under subparagraph (A), the Sec-*  
7           *retary may collect a fee from such facility or im-*  
8           *porter.*

9           “(d) *CREDITING AND AVAILABILITY OF FEES.*—*Fees*  
10          *authorized under subsection (a) shall be collected and avail-*  
11          *able for obligation only to the extent and in the amount*  
12          *provided in appropriations Acts. Such fees are authorized*  
13          *to remain available until expended. Such sums as may be*  
14          *necessary may be transferred from the Food and Drug Ad-*  
15          *ministration salaries and expenses account without fiscal*  
16          *year limitation to such appropriation account for salaries*  
17          *and expenses with such fiscal year limitation. The sums*  
18          *transferred shall be available solely for the purpose of pay-*  
19          *ing the operating expenses of the Food and Drug Adminis-*  
20          *tration employees and contractors performing activities as-*  
21          *sociated with these food safety fees.*

22          “(e) *COLLECTION OF FEES.*—

23                 “(1) *IN GENERAL.*—*The Secretary shall specify*  
24                 *in the Federal Register notice described in subsection*

1       **(b)(1)** *the time and manner in which fees assessed*  
2       *under this section shall be collected.*

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

10              **“(f) ANNUAL REPORT TO CONGRESS.—***Not later than*  
11       *120 days after each fiscal year for which fees are assessed*  
12       *under this section, the Secretary shall submit a report to*  
13       *the Committee on Health, Education, Labor, and Pensions*  
14       *of the Senate and the Committee on Energy and Commerce*  
15       *of the House of Representatives, to include a description*  
16       *of fees assessed and collected for each such year and a sum-*  
17       *mary description of the entities paying such fees and the*  
18       *types of business in which such entities engage.*

19              **“(g) AUTHORIZATION OF APPROPRIATIONS.—***For fis-*  
20       *cal year 2010 and each fiscal year thereafter, there is au-*  
21       *thorized to be appropriated for fees under this section an*  
22       *amount equal to the total revenue amount determined under*  
23       *subsection (b) for the fiscal year, as adjusted or otherwise*  
24       *affected under the other provisions of this section.”.*



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

3           (1) *AUTHORITY FOR EXPORT CERTIFICATIONS*  
 4 *FOR FOOD, INCLUDING ANIMAL FEED.*—Section  
 5 *801(e)(4)(A) (21 U.S.C. 381(e)(4)(A)) is amended—*

6           (A) *in the matter preceding clause (i), by*  
 7 *striking “a drug” and inserting “a food, drug”;*

8           (B) *in clause (i) by striking “exported*  
 9 *drug” and inserting “exported food, drug”; and*

10          (C) *in clause (ii) by striking “the drug”*  
 11 *each place it appears and inserting “the food,*  
 12 *drug”.*

13          (2) *CLARIFICATION OF CERTIFICATION.*—Section  
 14 *801(e)(4) (21 U.S.C. 381(e)(4)) is amended by insert-*  
 15 *ing after subparagraph (B) the following new sub-*  
 16 *paragraph:*

17           “(C) *For purposes of this paragraph, a cer-*  
 18 *tification by the Secretary shall be made on such*  
 19 *basis, and in such form (including a publicly*  
 20 *available listing) as the Secretary determines ap-*  
 21 *propriate.”.*

22 **SEC. 108. NATIONAL AGRICULTURE AND FOOD DEFENSE**  
 23 **STRATEGY.**

24          (a) *DEVELOPMENT AND SUBMISSION OF STRATEGY.*—

1           (1) *IN GENERAL.*—Not later than 1 year after  
2           the date of enactment of this Act, the Secretary of  
3           Health and Human Services and the Secretary of Ag-  
4           riculture, in coordination with the Secretary of  
5           Homeland Security, shall prepare and submit to the  
6           relevant committees of Congress, and make publicly  
7           available on the Internet Web sites of the Department  
8           of Health and Human Services and the Department  
9           of Agriculture, the National Agriculture and Food De-  
10          fense Strategy.

11           (2) *IMPLEMENTATION PLAN.*—The strategy shall  
12          include an implementation plan for use by the Secre-  
13          taries described under paragraph (1) in carrying out  
14          the strategy.

15           (3) *RESEARCH.*—The strategy shall include a co-  
16          ordinated research agenda for use by the Secretaries  
17          described under paragraph (1) in conducting research  
18          to support the goals and activities described in para-  
19          graphs (1) and (2) of subsection (b).

20           (4) *REVISIONS.*—Not later than 4 years after the  
21          date on which the strategy is submitted to the relevant  
22          committees of Congress under paragraph (1), and not  
23          less frequently than every 4 years thereafter, the Sec-  
24          retary of Health and Human Services and the Sec-  
25          retary of Agriculture, in coordination with the Sec-

1        *retary of Homeland Security, shall revise and submit*  
2        *to the relevant committees of Congress the strategy.*

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

6            (A) *the National Incident Management Sys-*  
7        *tem;*

8            (B) *the National Response Framework;*

9            (C) *the National Infrastructure Protection*  
10        *Plan;*

11          (D) *the National Preparedness Goals; and*

12          (E) *other relevant national strategies.*

13        (b) *COMPONENTS.—*

14            (1) *IN GENERAL.—The strategy shall include a*  
15        *description of the process to be used by the Depart-*  
16        *ment of Health and Human Services, the Department*  
17        *of Agriculture, and the Department of Homeland Se-*  
18        *curity—*

19            (A) *to achieve each goal described in para-*  
20        *graph (2); and*

21            (B) *to evaluate the progress made by Fed-*  
22        *eral, State, local, and tribal governments to-*  
23        *wards the achievement of each goal described in*  
24        *paragraph (2).*

1           (2) *GOALS.—The strategy shall include a de-*  
2           *scription of the process to be used by the Department*  
3           *of Health and Human Services, the Department of*  
4           *Agriculture, and the Department of Homeland Secu-*  
5           *urity to achieve the following goals:*

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

9                           (i) *conducting vulnerability assess-*  
10                           *ments of the agriculture and food system;*

11                           (ii) *mitigating vulnerabilities of the*  
12                           *system;*

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

15                           (iv) *developing and conducting exer-*  
16                           *cises to test decontamination and disposal*  
17                           *plans;*

18                           (v) *developing modeling tools to im-*  
19                           *prove event consequence assessment and de-*  
20                           *cision support; and*

21                           (vi) *preparing risk communication*  
22                           *tools and enhancing public awareness*  
23                           *through outreach.*

1           (B) *DETECTION GOAL.—Improve agri-*  
2 *culture and food system detection capabilities*  
3 *by—*

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

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

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

11           (i) *immediately investigating animal*  
12 *disease outbreaks and suspected food con-*  
13 *tamination;*

14           (ii) *preventing additional human ill-*  
15 *nesses;*

16           (iii) *organizing, training, and equip-*  
17 *ping animal, plant, and food emergency re-*  
18 *sponse teams of—*

19           (I) *the Federal Government; and*

20           (II) *State, local, and tribal gov-*  
21 *ernments;*

22           (iv) *designing, developing, and evalu-*  
23 *ating training and exercises carried out*  
24 *under agriculture and food defense plans;*  
25 *and*

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

3                               (I) *the Federal Government;*

4                               (II) *State, local, and tribal gov-*  
5                               *ernments; and*

6                               (III) *the private sector.*

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

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

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

17                               (iii) *rapidly removing, and effectively*  
18                               *disposing of—*

19                                       (I) *contaminated agriculture and*  
20                                       *food products; and*

21                                       (II) *infected plants and animals;*  
22                                       *and*

23                                       (iv) *decontaminating and restoring*  
24                                       *areas affected by an agriculture or food*  
25                                       *emergency.*

1           (c) *LIMITED DISTRIBUTION.*—*In the interest of na-*  
 2 *tional security, the Secretary of Health and Human Serv-*  
 3 *ices and the Secretary of Agriculture, in coordination with*  
 4 *the Secretary of Homeland Security, may determine the*  
 5 *manner and format in which the National Agriculture and*  
 6 *Food Defense strategy established under this section is made*  
 7 *publicly available on the Internet Web sites of the Depart-*  
 8 *ment of Health and Human Services, the Department of*  
 9 *Homeland Security, and the Department of Agriculture, as*  
 10 *described in subsection (a)(1).*

11 **SEC. 109. FOOD AND AGRICULTURE COORDINATING COUN-**  
 12 **CILS.**

13           *The Secretary of Homeland Security, in coordination*  
 14 *with the Secretary of Health and Human Services and the*  
 15 *Secretary of Agriculture, shall within 180 days of enact-*  
 16 *ment of this Act, and annually thereafter, submit to the*  
 17 *relevant committees of Congress, and make publicly avail-*  
 18 *able on the Internet Web site of the Department of Home-*  
 19 *land Security, a report on the activities of the Food and*  
 20 *Agriculture Government Coordinating Council and the*  
 21 *Food and Agriculture Sector Coordinating Council, includ-*  
 22 *ing the progress of such Councils on—*

23                   (1) *facilitating partnerships between public and*  
 24           *private entities to help coordinate and enhance the*

1       *protection of the agriculture and food system of the*  
2       *United States;*

3             (2) *providing for the regular and timely inter-*  
4       *change of information between each council relating*  
5       *to the security of the agriculture and food system (in-*  
6       *cluding intelligence information);*

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

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

14                    (A) *animal or plant disease outbreaks;*

15                    (B) *food contamination; and*

16                    (C) *natural disasters affecting agriculture*  
17       *and food.*

18       **SEC. 110. BUILDING DOMESTIC CAPACITY.**

19        (a) *IN GENERAL.—*

20             (1) *INITIAL REPORT.—The Secretary shall, not*  
21       *later than 2 years after the date of enactment of this*  
22       *Act, submit to Congress a comprehensive report that*  
23       *identifies programs and practices that are intended to*  
24       *promote the safety and supply chain security of food*  
25       *and to prevent outbreaks of foodborne illness and*



1     *other food-related hazards that can be addressed*  
2     *through preventive activities. Such report shall in-*  
3     *clude a description of the following:*

4             *(A) Analysis of the need for further regula-*  
5             *tions or guidance to industry.*

6             *(B) Outreach to food industry sectors, in-*  
7             *cluding through the Food and Agriculture Co-*  
8             *ordinating Councils referred to in section 109, to*  
9             *identify potential sources of emerging threats to*  
10            *the safety and security of the food supply and*  
11            *preventive strategies to address those threats.*

12            *(C) Systems to ensure the prompt distribu-*  
13            *tion to the food industry of information and*  
14            *technical assistance concerning preventive strate-*  
15            *gies.*

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

20            *(E) Surveillance systems and laboratory*  
21            *networks to rapidly detect and respond to*  
22            *foodborne illness outbreaks and other food-related*  
23            *hazards, including how such systems and net-*  
24            *works are integrated.*

1           (F) *Outreach, education, and training pro-*  
2 *vided to States and local governments to build*  
3 *State and local food safety and food defense ca-*  
4 *pabilities, including progress implementing*  
5 *strategies developed under sections 108 and 206.*

6           (G) *The estimated resources needed to effec-*  
7 *tively implement the programs and practices*  
8 *identified in the report developed in this section*  
9 *over a 5-year period.*

10           (H) *The impact of requirements under this*  
11 *Act (including amendments made by this Act)*  
12 *on certified organic farms and facilities (as de-*  
13 *finied in section 415 (21 U.S.C. 350d).*

14           (2) *BIENNIAL REPORTS.*—*On a biennial basis*  
15 *following the submission of the report under para-*  
16 *graph (1), the Secretary shall submit to Congress a*  
17 *report that—*

18           (A) *reviews previous food safety programs*  
19 *and practices;*

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

22           (C) *identifies future programs and prac-*  
23 *tices; and*

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

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

14           (c) *CAPABILITY FOR LABORATORY ANALYSES; RE-*  
15 *SEARCH.*—The report developed under subsection (a)(1)  
16 shall provide a description of methods to increase capacity  
17 to undertake analyses of food samples promptly after collec-  
18 tion, to identify new and rapid analytical techniques, in-  
19 cluding commercially-available techniques that can be em-  
20 ployed at ports of entry and by Food Emergency Response  
21 Network laboratories, and to provide for well-equipped and  
22 staffed laboratory facilities.

23           (d) *INFORMATION TECHNOLOGY.*—The report devel-  
24 oped under subsection (a)(1) shall include a description of  
25 such information technology systems as may be needed to

1 *identify risks and receive data from multiple sources, in-*  
2 *cluding foreign governments, State, local, and tribal govern-*  
3 *ments, other Federal agencies, the food industry, labora-*  
4 *tories, laboratory networks, and consumers. The informa-*  
5 *tion technology systems that the Secretary describes shall*  
6 *also provide for the integration of the facility registration*  
7 *system under section 415 of the Federal Food, Drug, and*  
8 *Cosmetic Act (21 U.S.C. 350d), and the prior notice system*  
9 *under section 801(m) of such Act (21 U.S.C. 381(m)) with*  
10 *other information technology systems that are used by the*  
11 *Federal Government for the processing of food offered for*  
12 *import into the United States.*

13       (e) *AUTOMATED RISK ASSESSMENT.*—*The report de-*  
14 *veloped under subsection (a)(1) shall include a description*  
15 *of progress toward developing and improving an automated*  
16 *risk assessment system for food safety surveillance and allo-*  
17 *cation of resources.*

18       (f) *TRACEBACK AND SURVEILLANCE REPORT.*—*The*  
19 *Secretary shall include in the report developed under sub-*  
20 *section (a)(1) an analysis of the Food and Drug Adminis-*  
21 *tration’s performance in foodborne illness outbreaks during*  
22 *the 5-year period preceding the date of enactment of this*  
23 *Act involving fruits and vegetables that are raw agricul-*  
24 *tural commodities (as defined in section 201(r) (21 U.S.C.*  
25 *321(r)) and recommendations for enhanced surveillance,*

1 *outbreak response, and traceability. Such findings and rec-*  
 2 *ommendations shall address communication and coordina-*  
 3 *tion with the public, industry, and State and local govern-*  
 4 *ments, as such communication and coordination relates to*  
 5 *outbreak identification and traceback.*

6       (g) **BIENNIAL FOOD SAFETY AND FOOD DEFENSE RE-**  
 7 **SEARCH PLAN.**—*The Secretary and the Secretary of Agri-*  
 8 *culture shall, on a biennial basis, submit to Congress a joint*  
 9 *food safety and food defense research plan which may in-*  
 10 *clude studying the long-term health effects of foodborne ill-*  
 11 *ness. Such biennial plan shall include a list and description*  
 12 *of projects conducted during the previous 2-year period and*  
 13 *the plan for projects to be conducted during the subsequent*  
 14 *2-year period.*

15 **SEC. 111. SANITARY TRANSPORTATION OF FOOD.**

16       *Not later than 1 year after the date of enactment of*  
 17 *this Act, the Secretary shall promulgate regulations de-*  
 18 *scribed in section 416(b) of the Federal Food, Drug, and*  
 19 *Cosmetic Act (21 U.S.C. 350e(b)).*

20 **SEC. 112. FOOD ALLERGY AND ANAPHYLAXIS MANAGE-**  
 21 **MENT.**

22       (a) **DEFINITIONS.**—*In this section:*

23               (1) **EARLY CHILDHOOD EDUCATION PROGRAM.**—  
 24       *The term “early childhood education program”*  
 25       *means—*

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

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

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

8           (2) *ESEA DEFINITIONS*.—The terms “local edu-  
 9           cational agency”, “secondary school”, “elementary  
 10          school”, and “parent” have the meanings given the  
 11          terms in section 9101 of the *Elementary and Sec-*  
 12          *ondary Education Act of 1965* (20 U.S.C. 7801).

13          (3) *SCHOOL*.—The term “school” includes pub-  
 14          lic—

15               (A) kindergartens;

16               (B) elementary schools; and

17               (C) secondary schools.

18          (4) *SECRETARY*.—The term “Secretary” means  
 19          the Secretary of Health and Human Services.

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

22               (1) *ESTABLISHMENT*.—

23                   (A) *IN GENERAL*.—Not later than 1 year  
 24                   after the date of enactment of this Act, the Sec-

1           *retary, in consultation with the Secretary of*  
2           *Education, shall—*

3                     *(i) develop guidelines to be used on a*  
4                     *voluntary basis to develop plans for indi-*  
5                     *viduals to manage the risk of food allergy*  
6                     *and anaphylaxis in schools and early child-*  
7                     *hood education programs; and*

8                     *(ii) make such guidelines available to*  
9                     *local educational agencies, schools, early*  
10                    *childhood education programs, and other*  
11                    *interested entities and individuals to be im-*  
12                    *plemented on a voluntary basis only.*

13                    *(B) APPLICABILITY OF FERPA.—Each plan*  
14                    *described in subparagraph (A) that is developed*  
15                    *for an individual shall be considered an edu-*  
16                    *cation record for the purpose of section 444 of the*  
17                    *General Education Provisions Act (commonly re-*  
18                    *ferred to as the “Family Educational Rights and*  
19                    *Privacy Act of 1974”) (20 U.S.C. 1232g).*

20                    *(2) CONTENTS.—The voluntary guidelines devel-*  
21                    *oped by the Secretary under paragraph (1) shall ad-*  
22                    *dress each of the following and may be updated as the*  
23                    *Secretary determines necessary:*

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

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

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

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

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

13           (IV) *listing any medication pre-*  
14 *scribed for the child for the treatment*  
15 *of anaphylaxis;*

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

18           (VI) *listing the signs and symp-*  
19 *toms of a reaction; and*

20           (VII) *assessing the child's readi-*  
21 *ness for self-administration of prescrip-*  
22 *tion medication; and*

23           (ii) *a list of substitute meals that may*  
24 *be offered to the child by school or early*



1           *childhood education program food service*  
2           *personnel.*

3           *(B) The creation and maintenance of an in-*  
4           *dividual plan for food allergy management, in*  
5           *consultation with the parent, tailored to the*  
6           *needs of each child with a documented risk for*  
7           *anaphylaxis, including any procedures for the*  
8           *self-administration of medication by such chil-*  
9           *dren in instances where—*

10                   *(i) the children are capable of self-ad-*  
11                   *ministering medication; and*

12                   *(ii) such administration is not prohib-*  
13                   *ited by State law.*

14           *(C) Communication strategies between indi-*  
15           *vidual schools or early childhood education pro-*  
16           *grams and providers of emergency medical serv-*  
17           *ices, including appropriate instructions for*  
18           *emergency medical response.*

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

23           *(E) The dissemination of general informa-*  
24           *tion on life-threatening food allergies to school or*

1           *early childhood education program staff, parents,*  
2           *and children.*

3           *(F) Food allergy management training of*  
4           *school or early childhood education program per-*  
5           *sonnel who regularly come into contact with chil-*  
6           *dren with life-threatening food allergies.*

7           *(G) The authorization and training of*  
8           *school or early childhood education program per-*  
9           *sonnel to administer epinephrine when the nurse*  
10          *is not immediately available.*

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

15          *(I) The creation of a plan contained in each*  
16          *individual plan for food allergy management*  
17          *that addresses the appropriate response to an in-*  
18          *cident of anaphylaxis of a child while such child*  
19          *is engaged in extracurricular programs of a*  
20          *school or early childhood education program,*  
21          *such as non-academic outings and field trips,*  
22          *before- and after-school programs or before- and*  
23          *after-early child education program programs,*  
24          *and school-sponsored or early childhood edu-*

1            *cation program-sponsored programs held on*  
2            *weekends.*

3            *(J) Maintenance of information for each*  
4            *administration of epinephrine to a child at risk*  
5            *for anaphylaxis and prompt notification to par-*  
6            *ents.*

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

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

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

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

24           *(2) APPLICATION.—*

1           (A) *IN GENERAL.*—*To be eligible to receive*  
2 *a grant under this subsection, a local edu-*  
3 *cational agency shall submit an application to*  
4 *the Secretary at such time, in such manner, and*  
5 *including such information as the Secretary may*  
6 *reasonably require.*

7           (B) *CONTENTS.*—*Each application sub-*  
8 *mitted under subparagraph (A) shall include—*

9                   (i) *an assurance that the local edu-*  
10 *cational agency has developed plans in ac-*  
11 *cordance with the food allergy and anaphy-*  
12 *laxis management guidelines described in*  
13 *subsection (b);*

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

18                           (I) *how the guidelines will be car-*  
19 *ried out at individual schools served by*  
20 *the local educational agency;*

21                           (II) *how the local educational*  
22 *agency will inform parents and stu-*  
23 *dents of the guidelines in place;*

24                           (III) *how school nurses, teachers,*  
25 *administrators, and other school-based*

1           *staff will be made aware of, and given*  
2           *training on, when applicable, the*  
3           *guidelines in place; and*

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

6           *(iii) an itemization of how grant funds*  
7           *received under this subsection will be ex-*  
8           *pende;d;*

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

12                    *(v) an agreement by the local edu-*  
13          *cational agency to report information re-*  
14          *quired by the Secretary to conduct evalua-*  
15          *tions under this subsection.*

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

19                    (A) *Purchase of materials and supplies, in-*  
20          *cluding limited medical supplies such as epi-*  
21          *nephrine and disposable wet wipes, to support*  
22          *carrying out the food allergy and anaphylaxis*  
23          *management guidelines described in subsection*  
24          *(b).*

1           (B) *In partnership with local health depart-*  
2           *ments, school nurse, teacher, and personnel*  
3           *training for food allergy management.*

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

8           (D) *Outreach to parents.*

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

11          (4) *DURATION OF AWARDS.—The Secretary may*  
12          *award grants under this subsection for a period of not*  
13          *more than 2 years. In the event the Secretary con-*  
14          *ducts a program evaluation under this subsection,*  
15          *funding in the second year of the grant, where appli-*  
16          *cable, shall be contingent on a successful program*  
17          *evaluation by the Secretary after the first year.*

18          (5) *LIMITATION ON GRANT FUNDING.—The Sec-*  
19          *retary may not provide grant funding to a local edu-*  
20          *cational agency under this subsection after such local*  
21          *educational agency has received 2 years of grant*  
22          *funding under this subsection.*

23          (6) *MAXIMUM AMOUNT OF ANNUAL AWARDS.—A*  
24          *grant awarded under this subsection may not be*

1       *made in an amount that is more than \$50,000 annu-*  
2       *ally.*

3           (7) *PRIORITY.*—*In awarding grants under this*  
4       *subsection, the Secretary shall give priority to local*  
5       *educational agencies with the highest percentages of*  
6       *children who are counted under section 1124(c) of the*  
7       *Elementary and Secondary Education Act of 1965*  
8       *(20 U.S.C. 6333(c)).*

9           (8) *MATCHING FUNDS.*—

10           (A) *IN GENERAL.*—*The Secretary may not*  
11       *award a grant under this subsection unless the*  
12       *local educational agency agrees that, with respect*  
13       *to the costs to be incurred by such local edu-*  
14       *cational agency in carrying out the grant activi-*  
15       *ties, the local educational agency shall make*  
16       *available (directly or through donations from*  
17       *public or private entities) non-Federal funds to-*  
18       *ward such costs in an amount equal to not less*  
19       *than 25 percent of the amount of the grant.*

20           (B) *DETERMINATION OF AMOUNT OF NON-*  
21       *FEDERAL CONTRIBUTION.*—*Non-Federal funds*  
22       *required under subparagraph (A) may be cash or*  
23       *in kind, including plant, equipment, or services.*  
24       *Amounts provided by the Federal Government,*  
25       *and any portion of any service subsidized by the*

1           *Federal Government, may not be included in de-*  
2           *termining the amount of such non-Federal funds.*

3           (9) *ADMINISTRATIVE FUNDS.*—*A local edu-*  
4           *cational agency that receives a grant under this sub-*  
5           *section may use not more than 2 percent of the grant*  
6           *amount for administrative costs related to carrying*  
7           *out this subsection.*

8           (10) *PROGRESS AND EVALUATIONS.*—*At the com-*  
9           *pletion of the grant period referred to in paragraph*  
10          *(4), a local educational agency shall provide the Sec-*  
11          *retary with information on how grant funds were*  
12          *spent and the status of implementation of the food al-*  
13          *lergy and anaphylaxis management guidelines de-*  
14          *scribed in subsection (b).*

15          (11) *SUPPLEMENT, NOT SUPPLANT.*—*Grant*  
16          *funds received under this subsection shall be used to*  
17          *supplement, and not supplant, non-Federal funds and*  
18          *any other Federal funds available to carry out the ac-*  
19          *tivities described in this subsection.*

20          (12) *AUTHORIZATION OF APPROPRIATIONS.*—  
21          *There is authorized to be appropriated to carry out*  
22          *this subsection \$30,000,000 for fiscal year 2010 and*  
23          *such sums as may be necessary for each of the 4 suc-*  
24          *ceeding fiscal years.*

25          (d) *VOLUNTARY NATURE OF GUIDELINES.*—



1           (1) *IN GENERAL.*—*The food allergy and anaphy-*  
 2           *laxis management guidelines developed by the Sec-*  
 3           *retary under subsection (b) are voluntary. Nothing in*  
 4           *this section or the guidelines developed by the Sec-*  
 5           *retary under subsection (b) shall be construed to re-*  
 6           *quire a local educational agency to implement such*  
 7           *guidelines.*

8           (2) *EXCEPTION.*—*Notwithstanding paragraph*  
 9           *(1), the Secretary may enforce an agreement by a*  
 10          *local educational agency to implement food allergy*  
 11          *and anaphylaxis management guidelines as a condi-*  
 12          *tion of the receipt of a grant under subsection (c).*

13       ***TITLE II—IMPROVING CAPACITY***  
 14       ***TO DETECT AND RESPOND TO***  
 15       ***FOOD SAFETY PROBLEMS***

16       ***SEC. 201. TARGETING OF INSPECTION RESOURCES FOR DO-***  
 17                       ***MESTIC FACILITIES, FOREIGN FACILITIES,***  
 18                       ***AND PORTS OF ENTRY; ANNUAL REPORT.***

19           (a) *TARGETING OF INSPECTION RESOURCES FOR DO-*  
 20       *MESTIC FACILITIES, FOREIGN FACILITIES, AND PORTS OF*  
 21       *ENTRY.*—*Chapter IV (21 U.S.C. 341 et seq.), as amended*  
 22       *by section 106, is amended by adding at the end the fol-*  
 23       *lowing:*

1 **“SEC. 421. TARGETING OF INSPECTION RESOURCES FOR**  
2 **DOMESTIC FACILITIES, FOREIGN FACILITIES,**  
3 **AND PORTS OF ENTRY; ANNUAL REPORT.**

4 “(a) *IDENTIFICATION AND INSPECTION OF FACILI-*  
5 *TIES.—*

6 “(1) *IDENTIFICATION.—The Secretary shall allo-*  
7 *cate resources to inspect facilities according to the*  
8 *risk profile of the facilities, which shall be based on*  
9 *the following factors:*

10 “(A) *The risk profile of the food manufac-*  
11 *tured, processed, packed, or held at the facility.*

12 “(B) *The facility’s compliance history, in-*  
13 *cluding with regard to food recalls, outbreaks,*  
14 *and violations of food safety standards.*

15 “(C) *The rigor and effectiveness of the fa-*  
16 *cility’s hazard analysis and risk-based preven-*  
17 *tive controls.*

18 “(D) *Whether the food manufactured, proc-*  
19 *essed, packed, handled, prepared, treated, distrib-*  
20 *uted, or stored at the facility meets the criteria*  
21 *for priority under section 801(h)(1).*

22 “(E) *Whether the facility has received a cer-*  
23 *tificate as described in section 809(b).*

24 “(F) *Any other criteria deemed necessary*  
25 *and appropriate by the Secretary for purposes of*  
26 *allocating inspection resources.*

1           “(2) *INSPECTIONS.*—

2                   “(A) *IN GENERAL.*—*Beginning on the date*  
3 *of enactment of the FDA Food Safety Moderniza-*  
4 *tion Act, the Secretary shall increase the fre-*  
5 *quency of inspection of all facilities.*

6                   “(B) *HIGH-RISK FACILITIES.*—*The Sec-*  
7 *retary shall increase the frequency of inspection*  
8 *of facilities identified under paragraph (1) as*  
9 *high-risk facilities such that—*

10                           “(i) *for the first 2 years after the date*  
11 *of enactment of the FDA Food Safety Mod-*  
12 *ernization Act, each high-risk facility is in-*  
13 *spected not less often than once every 2*  
14 *years; and*

15                           “(ii) *for each succeeding year, each*  
16 *high-risk facility is inspected not less often*  
17 *than once each year.*

18                   “(C) *NON-HIGH-RISK FACILITIES.*—*The Sec-*  
19 *retary shall ensure that each facility that is not*  
20 *identified under paragraph (1) as a high-risk fa-*  
21 *cility is inspected not less often than once every*  
22 *4 years.*

23           “(b) *IDENTIFICATION AND INSPECTION AT PORTS OF*  
24 *ENTRY.*—*The Secretary, in consultation with the Secretary*  
25 *of Homeland Security, shall allocate resources to inspect ar-*

1 *ticles of food imported into the United States according to*  
2 *the risk profile of the article of food, which shall be based*  
3 *on the following factors:*

4           “(1) *The risk profile of the food imported.*

5           “(2) *The risk profile of the countries or regions*  
6 *of origin and countries of transport of the food im-*  
7 *ported.*

8           “(3) *The compliance history of the importer, in-*  
9 *cluding with regard to food recalls, outbreaks, and*  
10 *violations of food safety standards.*

11           “(4) *The rigor and effectiveness of the foreign*  
12 *supplier verification program under section 805.*

13           “(5) *Whether the food importer participates in*  
14 *the voluntary qualified importer program under sec-*  
15 *tion 806.*

16           “(6) *Whether the food meets the criteria for pri-*  
17 *ority under section 801(h)(1).*

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

20           “(8) *Any other criteria deemed appropriate by*  
21 *the Secretary for purposes of allocating inspection re-*  
22 *sources.*

23           “(c) *COORDINATION.—The Secretary shall improve co-*  
24 *ordination and cooperation with the Secretary of Agri-*  
25 *culture to target food inspection resources.*

1       “(d) *FACILITY*.—For purposes of this section, the term  
2 ‘facility’ means a domestic facility or a foreign facility that  
3 is required to register under section 415.”

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

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

9               “(1) information about food facilities includ-  
10 ing—

11                       “(A) the appropriations used to inspect fa-  
12 cilities registered pursuant to section 415 in the  
13 previous fiscal year;

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

18                       “(C) the number of domestic facilities and  
19 the number of foreign facilities registered pursu-  
20 ant to section 415 that the Secretary inspected in  
21 the previous fiscal year;

22                       “(D) the number of domestic facilities and  
23 the number of foreign facilities registered pursu-  
24 ant to section 415 that were scheduled for inspec-

1            *tion in the previous fiscal year and which the*  
2            *Secretary did not inspect in such year;*

3            *“(E) the number of high-risk facilities iden-*  
4            *tified pursuant to section 421 that the Secretary*  
5            *inspected in the previous fiscal year; and*

6            *“(F) the number of high-risk facilities iden-*  
7            *tified pursuant to section 421 that were sched-*  
8            *uled for inspection in the previous fiscal year*  
9            *and which the Secretary did not inspect in such*  
10           *year.*

11           *“(2) information about food imports including—*

12           *“(A) the number of lines of food imported*  
13           *into the United States that the Secretary phys-*  
14           *ically inspected or sampled in the previous fiscal*  
15           *year;*

16           *“(B) the number of lines of food imported*  
17           *into the United States that the Secretary did not*  
18           *physically inspect or sample in the previous fis-*  
19           *cal year; and*

20           *“(C) the average cost of physically inspect-*  
21           *ing or sampling a food line subject to this Act*  
22           *that is imported or offered for import into the*  
23           *United States; and*

24           *“(3) information on the foreign offices of the*  
25           *Food and Drug Administration including—*

1           “(A) the number of foreign offices estab-  
2           lished; and

3           “(B) the number of personnel permanently  
4           stationed in each foreign office.

5           “(i) *PUBLIC AVAILABILITY OF ANNUAL FOOD RE-*  
6 *PORTS.*—The Secretary shall make the reports required  
7 under subsection (h) available to the public on the Internet  
8 Web site of the Food and Drug Administration.”.

9   **SEC. 202. RECOGNITION OF LABORATORY ACCREDITATION**  
10           **FOR ANALYSES OF FOODS.**

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

14   **“SEC. 422. RECOGNITION OF LABORATORY ACCREDITATION**  
15           **FOR ANALYSES OF FOODS.**

16           “(a) *RECOGNITION OF LABORATORY ACCREDITA-*  
17 *TION.*—

18           “(1) *IN GENERAL.*—Not later than 2 years after  
19 the date of enactment of the FDA Food Safety Mod-  
20 ernization Act, the Secretary shall—

21           “(A) provide for the recognition of accredi-  
22 tation bodies that accredit laboratories, includ-  
23 ing laboratories run and operated by a State or  
24 locality, with a demonstrated capability to con-

1           *duct sampling and analytical testing of food*  
2           *products; and*

3           “(B) *establish a publicly available registry*  
4           *of accreditation bodies, including the name of,*  
5           *contact information for, and other information*  
6           *deemed necessary by the Secretary about such*  
7           *bodies.*

8           “(2) *FOREIGN LABORATORIES.—Accreditation*  
9           *bodies recognized by the Secretary under paragraph*  
10          *(1) may accredit laboratories that operate outside the*  
11          *United States, so long as such laboratories meet the*  
12          *accreditation standards applicable to domestic labora-*  
13          *tories accredited under this section.*

14          “(3) *MODEL ACCREDITATION STANDARDS.—The*  
15          *Secretary shall develop model standards that an ac-*  
16          *creditation body shall require laboratories to meet in*  
17          *order to be included in the registry provided for*  
18          *under paragraph (1). In developing the model stand-*  
19          *ards, the Secretary shall look to existing standards for*  
20          *guidance. The model standards shall include methods*  
21          *to ensure that—*

22                  “(A) *appropriate sampling and rapid ana-*  
23                  *lytical procedures and commercially available*  
24                  *techniques are followed and reports of analyses*  
25                  *are certified as true and accurate;*



1           “(B) *internal quality systems are estab-*  
2           *lished and maintained;*

3           “(C) *procedures exist to evaluate and re-*  
4           *spond promptly to complaints regarding anal-*  
5           *yses and other activities for which the laboratory*  
6           *is recognized;*

7           “(D) *individuals who conduct the sampling*  
8           *and analyses are qualified by training and expe-*  
9           *rience to do so; and*

10          “(E) *any other criteria determined appro-*  
11          *priate by the Secretary.*

12          “(4) *REVIEW OF ACCREDITATION.—To ensure*  
13          *compliance with the requirements of this section, the*  
14          *Secretary shall—*

15                 “(A) *periodically, or at least every 5 years,*  
16                 *reevaluate accreditation bodies recognized under*  
17                 *paragraph (1); and*

18                 “(B) *promptly revoke the recognition of any*  
19                 *accreditation body found not to be in compliance*  
20                 *with the requirements of this section, specifying,*  
21                 *as appropriate, any terms and conditions nec-*  
22                 *essary for laboratories accredited by such body to*  
23                 *continue to perform testing as described in this*  
24                 *section.*

25          “(b) *TESTING PROCEDURES.—*

1           “(1) *IN GENERAL.*—*Food testing shall be con-*  
2           *ducted by Federal laboratories or non-Federal labora-*  
3           *tories that have been accredited by an accreditation*  
4           *body on the registry established by the Secretary*  
5           *under subsection (a)(1)(B) whenever such testing is*  
6           *conducted—*

7                   “(A) *by or on behalf of an owner or con-*  
8                   *signee—*

9                           “(i) *in response to a specific testing re-*  
10                           *quirement under this Act or implementing*  
11                           *regulations, when applied to address an*  
12                           *identified or suspected food safety problem;*  
13                           *and*

14                           “(ii) *as required by the Secretary, as*  
15                           *the Secretary deems appropriate, to address*  
16                           *an identified or suspected food safety prob-*  
17                           *lem; and*

18                   “(B) *on behalf of an owner or consignee—*

19                           “(i) *in support of admission of an ar-*  
20                           *ticle of food under section 801(a); and*

21                           “(ii) *under an Import Alert that re-*  
22                           *quires successful consecutive tests.*

23           “(2) *RESULTS OF TESTING.*—*The results of any*  
24           *such testing shall be sent directly to the Food and*  
25           *Drug Administration, except the Secretary may by*

1 regulation exempt test results that do not have to be  
2 so submitted if the Secretary determines that such re-  
3 sults do not contribute to the protection of public  
4 health. Test results required to be submitted may be  
5 submitted to the Food and Drug Administration  
6 through electronic means.

7 “(c) *REVIEW BY SECRETARY.*—If food sampling and  
8 testing performed by a laboratory run and operated by a  
9 State or locality that is accredited by an accreditation body  
10 on the registry established by the Secretary under subsection  
11 (a) result in a State recalling a food, the Secretary shall  
12 review the sampling and testing results for the purpose of  
13 determining the need for a national recall or other compli-  
14 ance and enforcement activities.

15 “(d) *NO LIMIT ON SECRETARIAL AUTHORITY.*—Noth-  
16 ing in this section shall be construed to limit the ability  
17 of the Secretary to review and act upon information from  
18 food testing, including determining the sufficiency of such  
19 information and testing.”.

20 (b) *FOOD EMERGENCY RESPONSE NETWORK.*—The  
21 Secretary, in coordination with the Secretary of Agri-  
22 culture, the Secretary of Homeland Security, and State,  
23 local, and tribal governments shall, not later than 180 days  
24 after the date of enactment of this Act, and biennially there-  
25 after, submit to the relevant committees of Congress, and

1 *make publicly available on the Internet Web site of the De-*  
 2 *partment of Health and Human Services, a report on the*  
 3 *progress in implementing a national food emergency re-*  
 4 *sponse laboratory network that—*

5           (1) *provides ongoing surveillance, rapid detec-*  
 6 *tion, and surge capacity for large-scale food-related*  
 7 *emergencies, including intentional adulteration of the*  
 8 *food supply;*

9           (2) *coordinates the food laboratory capacities of*  
 10 *State, local, and private food laboratories, including*  
 11 *the sharing of data between State laboratories to de-*  
 12 *velop national situational awareness;*

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

16           (4) *develops and implements a methods reposi-*  
 17 *tory for use by Federal, State, and local officials;*

18           (5) *responds to food-related emergencies; and*

19           (6) *is integrated with relevant laboratory net-*  
 20 *works administered by other Federal agencies.*

21 **SEC. 203. INTEGRATED CONSORTIUM OF LABORATORY NET-**  
 22 **WORKS.**

23           (a) *IN GENERAL.—The Secretary of Homeland Secu-*  
 24 *rity, in coordination with the Secretary of Health and*  
 25 *Human Services, the Secretary of Agriculture, and the Ad-*

1 *administrator of the Environmental Protection Agency, shall*  
2 *maintain an agreement through which relevant laboratory*  
3 *network members, as determined by the Secretary of Home-*  
4 *land Security, shall—*

5           (1) *agree on common laboratory methods in*  
6 *order to facilitate the sharing of knowledge and infor-*  
7 *mation relating to animal health, agriculture, and*  
8 *human health;*

9           (2) *identify means by which each laboratory net-*  
10 *work member could work cooperatively—*

11                   (A) *to optimize national laboratory pre-*  
12 *paredness; and*

13                   (B) *to provide surge capacity during emer-*  
14 *gencies; and*

15           (3) *engage in ongoing dialogue and build rela-*  
16 *tionships that will support a more effective and inte-*  
17 *grated response during emergencies.*

18           (b) *REPORTING REQUIREMENT.—The Secretary of*  
19 *Homeland Security shall, on a biennial basis, submit to*  
20 *the relevant committees of Congress, and make publicly*  
21 *available on the Internet Web site of the Department of*  
22 *Homeland Security, a report on the progress of the inte-*  
23 *grated consortium of laboratory networks, as established*  
24 *under subsection (a), in carrying out this section.*

1 **SEC. 204. ENHANCING TRACEBACK AND RECORDKEEPING.**

2 (a) *IN GENERAL.*—*The Secretary, in consultation with*  
3 *the Secretary of Agriculture and representatives of State de-*  
4 *partments of health and agriculture, shall improve the ca-*  
5 *capacity of the Secretary to effectively and rapidly track and*  
6 *trace, in the event of an outbreak, fruits and vegetables that*  
7 *are raw agricultural commodities.*

8 (b) *PILOT PROJECTS.*—

9 (1) *IN GENERAL.*—*Not later than 9 months after*  
10 *the date of enactment of this Act, the Secretary shall*  
11 *establish at least 3 pilot projects in coordination with*  
12 *the produce industry to explore and evaluate methods*  
13 *for rapidly and effectively tracking and tracing fruits*  
14 *and vegetables that are raw agricultural commodities*  
15 *so that, if an outbreak occurs involving such a fruit*  
16 *or vegetable, the Secretary may quickly identify, as*  
17 *soon as practicable, the source of the outbreak and the*  
18 *recipients of the contaminated food.*

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

1           (A) *methods that are applicable and appro-*  
2           *priate for small businesses; and*

3           (B) *technologies, including existing tech-*  
4           *nologies, that enhance traceback and trace for-*  
5           *ward.*

6           (c) *REPORT.—Not later than 18 months after the date*  
7           *of enactment of this Act, the Secretary shall report to Con-*  
8           *gress on the findings of the pilot projects under subsection*  
9           *(b) together with recommendations for establishing more ef-*  
10          *fective traceback and trace forward procedures for fruits*  
11          *and vegetables that are raw agricultural commodities.*

12          (d) *TRACEBACK PERFORMANCE REQUIREMENTS.—*

13           (1) *IN GENERAL.—Not later than 3 years after*  
14          *the date of enactment of this Act, the Secretary shall*  
15          *publish a notice of proposed rulemaking to establish*  
16          *standards for the type of information, format, and*  
17          *timeframe for persons to submit records to aid the*  
18          *Secretary in effectively and rapidly tracking and*  
19          *tracing, in the event of a foodborne illness outbreak,*  
20          *fruits and vegetables that are raw agricultural com-*  
21          *modities. In promulgating the regulations under this*  
22          *paragraph, the Secretary shall consider—*

23           (A) *the impact of such regulations on farms*  
24          *and small businesses;*

1           (B) *the findings in the report submitted*  
2           *under subsection (c); and*

3           (C) *existing international trade obligations.*

4           (2) *LIMITATIONS.—*

5           (A) *TYPE OF RECORDS.—The Secretary*  
6           *shall not require an entity that is subject to the*  
7           *requirements of section 419 of the Federal Food,*  
8           *Drug, and Cosmetic Act (as added by section*  
9           *105), but which is not a facility (as such term*  
10           *is defined by section 415 of such Act), to submit*  
11           *to the Secretary distribution records under this*  
12           *section other than distribution records that are*  
13           *kept in the normal course of business and that*  
14           *show the immediate subsequent recipient, other*  
15           *than a consumer.*

16           (B) *MAINTENANCE OF RECORDS.—Nothing*  
17           *in this section shall be construed as giving the*  
18           *Secretary the authority to prescribe specific tech-*  
19           *nologies for the maintenance of records.*

20           (e) *PUBLIC INPUT.—During the comment period in the*  
21           *notice of proposed rulemaking under subsection (d), the Sec-*  
22           *retary shall conduct not less than 3 public meetings in di-*  
23           *verse geographical areas of the United States to provide per-*  
24           *sons in different regions an opportunity to comment.*



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

5 **SEC. 205. PILOT PROJECT TO ENHANCE TRACEBACK AND**  
6                           **RECORDKEEPING WITH RESPECT TO PROC-**  
7                           **ESSED FOOD.**

8           (a) *IN GENERAL*.—*As soon as practicable after the*  
9 *date of enactment of this Act, the Secretary shall establish*  
10 *a pilot project to explore and evaluate methods for rapidly*  
11 *and effectively tracking and tracing processed food so that,*  
12 *if an outbreak occurs involving such a processed food, the*  
13 *Secretary may quickly identify the source of the outbreak*  
14 *and the recipients of the contaminated food.*

15           (b) *CONSULTATION*.—*In establishing the pilot project*  
16 *under subsection (a), the Secretary shall consult with food*  
17 *processors and relevant businesses of varying size.*

18           (c) *CONTENT*.—*The Secretary shall select participants*  
19 *from the processed food industry to run a project which*  
20 *overall shall include 1 or more different types of processed*  
21 *food that have been the subject of outbreaks during the 5-*  
22 *year period preceding the date of enactment of this Act and*  
23 *shall be selected in order to develop and demonstrate—*

24                   (1) *methods that are applicable and appropriate*  
25           *for small businesses; and*

1           (2) *technologies, including existing technologies,*  
2           *that enhance traceback and trace forward.*

3           (d) *REPORT.*—*The Secretary shall report to Congress*  
4 *on the findings of the pilot project under this section, to-*  
5 *gether with recommendations for establishing more effective*  
6 *traceback and trace forward procedures for processed food.*

7           (e) *PROCESSED FOOD.*—*In this section, the term*  
8 *“processed food” has the meaning given such term in section*  
9 *201(gg) of the Federal Food, Drug, and Cosmetic Act (21*  
10 *U.S.C. 321(gg)).*

11 **SEC. 206. SURVEILLANCE.**

12           (a) *DEFINITION OF FOODBORNE ILLNESS OUT-*  
13 *BREAK.*—*In this section, the term “foodborne illness out-*  
14 *break” means the occurrence of 2 or more cases of a similar*  
15 *illness resulting from the ingestion of a food.*

16           (b) *FOODBORNE ILLNESS SURVEILLANCE SYSTEMS.*—

17           (1) *IN GENERAL.*—*The Secretary, acting through*  
18 *the Director of the Centers for Disease Control and*  
19 *Prevention, shall enhance foodborne illness surveil-*  
20 *lance systems to improve the collection, analysis, re-*  
21 *porting, and usefulness of data on foodborne illnesses*  
22 *by—*

23           (A) *coordinating Federal, State and local*  
24 *foodborne illness surveillance systems, including*  
25 *complaint systems, and increasing participation*

1           *in national networks of public health and food*  
2           *regulatory agencies and laboratories;*

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

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

11          *(D) augmenting such systems to improve at-*  
12          *tribution of a foodborne illness outbreak to a spe-*  
13          *cific food;*

14          *(E) expanding capacity of such systems, in-*  
15          *cluding working toward automatic electronic*  
16          *searches, for implementation of identification*  
17          *practices, including fingerprinting strategies, for*  
18          *foodborne infectious agents, in order to identify*  
19          *new or rarely documented causes of foodborne ill-*  
20          *ness and submit standardized information to a*  
21          *centralized database;*

22          *(F) allowing timely public access to aggre-*  
23          *gated, de-identified surveillance data;*

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

1           (H) *establishing a flexible mechanism for*  
2           *rapidly initiating scientific research by aca-*  
3           *demie institutions;*

4           (I) *integrating foodborne illness surveillance*  
5           *systems and data with other biosurveillance and*  
6           *public health situational awareness capabilities*  
7           *at the Federal, State, and local levels; and*

8           (J) *other activities as determined appro-*  
9           *priate by the Secretary.*

10          (2) *PARTNERSHIPS.—The Secretary shall sup-*  
11          *port and maintain a diverse working group of experts*  
12          *and stakeholders from Federal, State, and local food*  
13          *safety and health agencies, the food and food testing*  
14          *industries, consumer organizations, and academia.*  
15          *Such working group shall provide the Secretary,*  
16          *through at least annual meetings of the working*  
17          *group and an annual public report, advice and rec-*  
18          *ommendations on an ongoing and regular basis re-*  
19          *garding the improvement of foodborne illness surveil-*  
20          *lance and implementation of this section, including*  
21          *advice and recommendations on—*

22               (A) *the priority needs of regulatory agen-*  
23               *cies, the food industry, and consumers for infor-*  
24               *mation and analysis on foodborne illness and its*  
25               *causes;*

1           (B) opportunities to improve the effective-  
2           ness of initiatives at the Federal, State, and  
3           local levels, including coordination and integra-  
4           tion of activities among Federal agencies, and  
5           between the Federal, State, and local levels of  
6           government;

7           (C) improvement in the timeliness and  
8           depth of access by regulatory and health agen-  
9           cies, the food industry, academic researchers, and  
10          consumers to foodborne illness aggregated, de-  
11          identified surveillance data collected by govern-  
12          ment agencies at all levels, including data com-  
13          piled by the Centers for Disease Control and Pre-  
14          vention;

15          (D) key barriers to improvement in  
16          foodborne illness surveillance and its utility for  
17          preventing foodborne illness at Federal, State,  
18          and local levels;

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

22          (F) specific actions to reduce barriers to im-  
23          provement, implement the working group's rec-  
24          ommendations, and achieve the purposes of this

1            *section, with measurable objectives and timelines,*  
2            *and identification of resource and staffing needs.*

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

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

9                    *(A) Improve foodborne illness outbreak re-*  
10                   *sponse and containment.*

11                   *(B) Accelerate foodborne illness surveillance*  
12                   *and outbreak investigation, including rapid*  
13                   *shipment of clinical isolates from clinical labora-*  
14                   *tories to appropriate State laboratories, and con-*  
15                   *ducting more standardized illness outbreak inter-*  
16                   *views.*

17                   *(C) Strengthen the capacity of State and*  
18                   *local agencies to carry out inspections and en-*  
19                   *force safety standards.*

20                   *(D) Improve the effectiveness of Federal,*  
21                   *State, and local partnerships to coordinate food*  
22                   *safety and defense resources and reduce the inci-*  
23                   *dence of foodborne illness.*

24                   *(E) Share information on a timely basis*  
25                   *among public health and food regulatory agen-*

1            *cies, with the food industry, with health care*  
2            *providers, and with the public.*

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

6            *(2) REVIEW.—In developing of the strategies re-*  
7            *quired by paragraph (1), the Secretary shall, not*  
8            *later than 1 year after the date of enactment of the*  
9            *FDA Food Safety Modernization Act, complete a re-*  
10           *view of State and local capacities, and needs for en-*  
11           *hancement, which may include a survey with respect*  
12           *to—*

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

15           *(B) laboratory capacity to support surveil-*  
16           *lance, outbreak response, inspection, and enforce-*  
17           *ment activities;*

18           *(C) information systems to support data*  
19           *management and sharing of food safety and de-*  
20           *fense information among State and local agen-*  
21           *cies and with counterparts at the Federal level;*  
22           *and*

23           *(D) other State and local activities and*  
24           *needs as determined appropriate by the Sec-*  
25           *retary.*

1           (d) *FOOD SAFETY CAPACITY BUILDING GRANTS.*—*Sec-*  
 2 *tion 317R(b) of the Public Health Service Act (42 U.S.C.*  
 3 *247b–20(b)) is amended—*

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

6                   (2) *by striking “2003 through 2006” and insert-*  
 7 *ing “2011 through 2014”.*

8 **SEC. 207. MANDATORY RECALL AUTHORITY.**

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

12 **“SEC. 423. MANDATORY RECALL AUTHORITY.**

13           “(a) *VOLUNTARY PROCEDURES.*—*If the Secretary de-*  
 14 *termines, based on information gathered through the report-*  
 15 *able food registry under section 417 or through any other*  
 16 *means, that there is a reasonable probability that an article*  
 17 *of food (other than infant formula) is adulterated under sec-*  
 18 *tion 402 or misbranded under section 403(w) and the use*  
 19 *of or exposure to such article will cause serious adverse*  
 20 *health consequences or death to humans or animals, the Sec-*  
 21 *retary shall provide the responsible party (as defined in sec-*  
 22 *tion 417) with an opportunity to cease distribution and re-*  
 23 *call such article.*

24           “(b) *PREHEARING ORDER TO CEASE DISTRIBUTION*  
 25 *AND GIVE NOTICE.*—*If the responsible party refuses to or*



1 *does not voluntarily cease distribution or recall such article*  
2 *within the time and in the manner prescribed by the Sec-*  
3 *retary (if so prescribed), the Secretary may, by order re-*  
4 *quire, as the Secretary deems necessary, such person to—*

5           “(1) *immediately cease distribution of such arti-*  
6 *cle; and*

7           “(2) *as applicable, immediately notify all per-*  
8 *sons—*

9                   “(A) *manufacturing, processing, packing,*  
10 *transporting, distributing, receiving, holding, or*  
11 *importing and selling such article; and*

12                   “(B) *to which such article has been distrib-*  
13 *uted, transported, or sold, to immediately cease*  
14 *distribution of such article.*

15           “(c) *HEARING ON ORDER.—The Secretary shall pro-*  
16 *vide the responsible party subject to an order under sub-*  
17 *section (b) with an opportunity for an informal hearing,*  
18 *to be held as soon as possible, but not later than 2 days*  
19 *after the issuance of the order, on the actions required by*  
20 *the order and on why the article that is the subject of the*  
21 *order should not be recalled.*

22           “(d) *POST-HEARING RECALL ORDER AND MODIFICA-*  
23 *TION OF ORDER.—*

24                   “(1) *AMENDMENT OF ORDER.—If, after pro-*  
25 *viding opportunity for an informal hearing under*

1        *subsection (c), the Secretary determines that removal*  
2        *of the article from commerce is necessary, the Sec-*  
3        *retary shall, as appropriate—*

4                *“(A) amend the order to require recall of*  
5                *such article or other appropriate action;*

6                *“(B) specify a timetable in which the recall*  
7                *shall occur;*

8                *“(C) require periodic reports to the Sec-*  
9                *retary describing the progress of the recall; and*

10               *“(D) provide notice to consumers to whom*  
11               *such article was, or may have been, distributed.*

12               *“(2) VACATING OF ORDER.—If, after such hear-*  
13               *ing, the Secretary determines that adequate grounds*  
14               *do not exist to continue the actions required by the*  
15               *order, or that such actions should be modified, the*  
16               *Secretary shall vacate the order or modify the order.*

17               *“(e) COOPERATION AND CONSULTATION.—The Sec-*  
18               *retary shall work with State and local public health officials*  
19               *in carrying out this section, as appropriate.*

20               *“(f) PUBLIC NOTIFICATION.—In conducting a recall*  
21               *under this section, the Secretary shall—*

22               *“(1) ensure that a press release is published re-*  
23               *garding the recall, as well as alerts and public no-*  
24               *tices, as appropriate, in order to provide notifica-*  
25               *tion—*

1           “(A) of the recall to consumers and retailers  
2           to whom such article was, or may have been, dis-  
3           tributed; and

4           “(B) that includes, at a minimum—

5                 “(i) the name of the article of food sub-  
6                 ject to the recall; and

7                 “(ii) a description of the risk associ-  
8                 ated with such article;

9           “(2) consult the policies of the Department of Ag-  
10          riculture regarding providing to the public a list of  
11          retail consignees receiving products involved in a  
12          Class I recall and shall consider providing such a list  
13          to the public, as determined appropriate by the Sec-  
14          retary; and

15          “(3) if available, publish on the Internet Web  
16          site of the Food and Drug Administration an image  
17          of the article that is the subject of the press release de-  
18          scribed in (1).

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

23          “(h) *EFFECT.*—Nothing in this section shall affect the  
24          authority of the Secretary to request or participate in a  
25          voluntary recall.”.

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

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

7           (2) provides a means by which an individual  
8 may locate relevant information regarding each arti-  
9 cle of food subject to a recall under section 420 of the  
10 Federal Food, Drug, and Cosmetic Act and the status  
11 of such recall (such as whether a recall is ongoing or  
12 has been completed).

13       (c) *CIVIL PENALTY.*—Section 303(f)(2)(A) (21 U.S.C.  
14 333(f)(2)(A)) is amended by inserting “or any person who  
15 does not comply with a recall order under section 423” after  
16 “section 402(a)(2)(B)”.

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

20           “(xx) The refusal or failure to follow an order under  
21 section 423.”.

22 **SEC. 208. ADMINISTRATIVE DETENTION OF FOOD.**

23       (a) *IN GENERAL.*—Section 304(h)(1)(A) (21 U.S.C.  
24 334(h)(1)(A)) is amended by—



1 *Secretary of Health and Human Services, Secretary of*  
2 *Homeland Security, Secretary of Agriculture, and State,*  
3 *local, and tribal governments, shall develop and disseminate*  
4 *specific standards and protocols to undertake clean-up,*  
5 *clearance, and recovery activities following the decon-*  
6 *tamination and disposal of specific threat agents and for-*  
7 *ign animal diseases.*

8       (c) *DEVELOPMENT OF MODEL PLANS.*—*In carrying*  
9 *out subsection (a), the Administrator, the Secretary of*  
10 *Health and Human Services, and the Secretary of Agri-*  
11 *culture shall jointly develop and disseminate model plans*  
12 *for—*

13           (1) *the decontamination of individuals, equip-*  
14 *ment, and facilities following an intentional contami-*  
15 *nation of agriculture or food; and*

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

20       (d) *EXERCISES.*—*In carrying out subsection (a), the*  
21 *Administrator, in coordination with the entities described*  
22 *under subsection (b), shall conduct exercises at least annu-*  
23 *ally to evaluate and identify weaknesses in the decon-*  
24 *tamination and disposal model plans described in sub-*  
25 *section (c). Such exercises shall be carried out, to the max-*

1 *imum extent practicable, as part of the national exercise*  
 2 *program under section 648(b)(1) of the Post-Katrina Emer-*  
 3 *gency Management Reform Act of 2006 (6 U.S.C.*  
 4 *748(b)(1)).*

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

10 *(f) PRIORITIZATION.—The Administrator, in coordi-*  
 11 *nation with the entities described in subsection (b), shall*  
 12 *develop standards and plans under subsections (b) and (c)*  
 13 *in an identified order of priority that takes into account—*

14 *(1) highest-risk biological, chemical, and radio-*  
 15 *logical threat agents;*

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

18 *(3) agents that are most difficult to clean or re-*  
 19 *mediate.*

20 **SEC. 210. IMPROVING THE TRAINING OF STATE, LOCAL,**  
 21 **TERRITORIAL, AND TRIBAL FOOD SAFETY OF-**  
 22 **FICIALS.**

23 *Chapter X (21 U.S.C.391 et seq.) is amended by add-*  
 24 *ing at the end the following:*

1 **“SEC. 1011. IMPROVING THE TRAINING OF STATE, LOCAL,**  
2 **TERRITORIAL, AND TRIBAL FOOD SAFETY OF-**  
3 **FICIALS.**

4 “(a) *TRAINING.—The Secretary shall set standards*  
5 *and administer training and education programs for the*  
6 *employees of State, local, territorial, and tribal food safety*  
7 *officials relating to the regulatory responsibilities and poli-*  
8 *cies established by this Act, including programs for—*

9 “(1) *scientific training;*

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

13 “(3) *training to achieve advanced product or*  
14 *process specialization in such inspections;*

15 “(4) *training that addresses best practices;*

16 “(5) *training in administrative process and pro-*  
17 *cedure and integrity issues;*

18 “(6) *training in appropriate sampling and lab-*  
19 *oratory analysis methodology; and*

20 “(7) *training in building enforcement actions*  
21 *following inspections, examinations, testing, and in-*  
22 *vestigations.*

23 “(b) *PARTNERSHIPS WITH STATE AND LOCAL OFFI-*  
24 *CIALS.—*

25 “(1) *IN GENERAL.—The Secretary, pursuant to a*  
26 *contract or memorandum of understanding between*



1       *the Secretary and the head of a State, local, terri-*  
2       *torial, or tribal department or agency, is authorized*  
3       *and encouraged to conduct examinations, testing, and*  
4       *investigations for the purposes of determining compli-*  
5       *ance with the food safety provisions of this Act*  
6       *through the officers and employees of such State, local,*  
7       *territorial, or tribal department or agency.*

8               “(2) *CONTENT.*—*A contract or memorandum de-*  
9       *scribed under paragraph (1) shall include provisions*  
10       *to ensure adequate training of such officers and em-*  
11       *ployees to conduct such examinations, testing, and in-*  
12       *vestigations. The contract or memorandum shall con-*  
13       *tain provisions regarding reimbursement. Such provi-*  
14       *sions may, at the sole discretion of the head of the*  
15       *other department or agency, require reimbursement,*  
16       *in whole or in part, from the Secretary for the exami-*  
17       *nations, testing, or investigations performed pursuant*  
18       *to this section by the officers or employees of the*  
19       *State, territorial, or tribal department or agency.*

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

23               “(c) *EXTENSION SERVICE.*—*The Secretary shall ensure*  
24       *coordination with the extension activities of the National*  
25       *Institute of Food and Agriculture of the Department of Ag-*

1 *riculture in advising producers and small processors*  
2 *transitioning into new practices required as a result of the*  
3 *enactment of the FDA Food Safety Modernization Act and*  
4 *assisting regulated industry with compliance with such Act.*

5       “(d) *AUTHORIZATION OF APPROPRIATIONS.—There*  
6 *are authorized to be appropriated such sums as may be nec-*  
7 *essary to carry out this section for fiscal years 2011 through*  
8 *2015.”.*

9 **SEC. 211. GRANTS TO ENHANCE FOOD SAFETY.**

10       *Section 1009 of the Federal Food, Drug, and Cosmetic*  
11 *Act (21 U.S.C. 399) is amended to read as follows:*

12 **“SEC. 1009. GRANTS TO ENHANCE FOOD SAFETY.**

13       “(a) *IN GENERAL.—The Secretary is authorized to*  
14 *make grants to States, localities, territories, and Indian*  
15 *tribes (as defined in section 4(e) of the Indian Self-Deter-*  
16 *mination and Education Assistance Act (25 U.S.C.*  
17 *450b(e))) to—*

18               “(1) *undertake examinations, inspections, and*  
19 *investigations, and related food safety activities under*  
20 *section 702;*

21               “(2) *train to the standards of the Secretary for*  
22 *the examination, inspection, and investigation of food*  
23 *manufacturing, processing, packing, holding, dis-*  
24 *tribution, and importation, including as such exam-*

1        *ination, inspection, and investigation relate to retail*  
2        *food establishments;*

3            *“(3) build the capacity of the laboratories of such*  
4        *State, locality, territory, or Indian tribe for food safe-*  
5        *ty;*

6            *“(4) build the infrastructure and capacity of the*  
7        *food safety programs of such State, locality, territory,*  
8        *or Indian tribe to meet the standards as outlined in*  
9        *the grant application; and*

10           *“(5) take appropriate action to protect the public*  
11        *health in response to—*

12                *“(A) a notification under section 1008, in-*  
13                *cluding planning and otherwise preparing to*  
14                *take such action; or*

15                *“(B) a recall of food under this Act.*

16        *“(b) APPLICATION.—*

17                *“(1) IN GENERAL.—To be eligible to receive a*  
18        *grant under this section, a State, locality, territory,*  
19        *or Indian tribe shall submit an application to the*  
20        *Secretary at such time, in such manner, and includ-*  
21        *ing such information as the Secretary may reason-*  
22        *ably require.*

23                *“(2) CONTENTS.—Each application submitted*  
24        *under paragraph (1) shall include—*

1           “(A) an assurance that the State, locality,  
2           territory, or Indian tribe has developed plans to  
3           engage in the types of activities described in sub-  
4           section (a);

5           “(B) a description of the types of activities  
6           to be funded by the grant;

7           “(C) an itemization of how grant funds re-  
8           ceived under this section will be expended;

9           “(D) a description of how grant activities  
10          will be monitored; and

11          “(E) an agreement by the State, locality,  
12          territory, or Indian tribe to report information  
13          required by the Secretary to conduct evaluations  
14          under this section.

15          “(c) *LIMITATIONS.*—The funds provided under sub-  
16          section (a) shall be available to a State, locality, territory,  
17          or Indian tribe only to the extent such State, locality, terri-  
18          tory, or Indian tribe funds its food safety programs inde-  
19          pendently of any grant under this section in each year of  
20          the grant at a level equal to the level of such funding in  
21          the previous year, increased by the Consumer Price Index.

22          “(d) *ADDITIONAL AUTHORITY.*—The Secretary may—

23                 “(1) award a grant under this section in each  
24                 subsequent fiscal year without reapplication for a pe-  
25                 riod of not more than 3 years, provided the require-

1        *ments of subsection (c) are met for the previous fiscal*  
2        *year; and*

3            *“(2) award a grant under this section in a fiscal*  
4        *year for which the requirement of subsection (c) has*  
5        *not been met only if such requirement was not met*  
6        *because such funding was diverted for response to 1*  
7        *or more natural disasters or in other extenuating cir-*  
8        *cumstances that the Secretary may determine appro-*  
9        *priate.*

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

17        *“(f) PROGRESS AND EVALUATION.—A grant recipient*  
18        *shall at the end of each year provide the Secretary with*  
19        *information on how grant funds were spent and the status*  
20        *of the efforts by such recipient to enhance food safety.*

21        *“(g) SUPPLEMENT NOT SUPPLANT.—Grant funds re-*  
22        *ceived under this section shall be used to supplement, and*  
23        *not supplant, non-Federal funds and any other Federal*  
24        *funds available to carry out the activities described in this*  
25        *section.*

1       “(h) *AUTHORIZATION OF APPROPRIATIONS.*—For the  
 2 *purpose of making grants under this section, there are au-*  
 3 *thorized to be appropriated such sums as may be necessary*  
 4 *for fiscal years 2011 through 2015.*”.

5           ***TITLE III—IMPROVING THE***  
 6           ***SAFETY OF IMPORTED FOOD***

7   ***SEC. 301. FOREIGN SUPPLIER VERIFICATION PROGRAM.***

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

10   ***“SEC. 805. FOREIGN SUPPLIER VERIFICATION PROGRAM.***

11       “(a) *IN GENERAL.*—

12           “(1) *VERIFICATION REQUIREMENT.*—Each im-  
 13 *porter shall perform risk-based foreign supplier*  
 14 *verification activities for the purpose of verifying that*  
 15 *the food imported by the importer or its agent is—*

16                   “(A) *produced in compliance with the re-*  
 17                   *quirements of section 418 or 419, as appropriate;*  
 18                   *and*

19                   “(B) *is not adulterated under section 402 or*  
 20                   *misbranded under section 403(w).*

21           “(2) *IMPORTER DEFINED.*—For purposes of this  
 22 *section, the term ‘importer’ means, with respect to an*  
 23 *article of food—*

1           “(A) *the United States owner or consignee*  
2           *of the article of food at the time of entry of such*  
3           *article into the United States; or*

4           “(B) *in the case when there is no United*  
5           *States owner or consignee as described in sub-*  
6           *paragraph (A), the United States agent or rep-*  
7           *resentative of a foreign owner or consignee of the*  
8           *article of food at the time of entry of such article*  
9           *into the United States.*

10          “(b) *GUIDANCE.—Not later than 1 year after the date*  
11          *of enactment of the FDA Food Safety Modernization Act,*  
12          *the Secretary shall issue guidance to assist importers in de-*  
13          *veloping foreign supplier verification programs.*

14          “(c) *REGULATIONS.—*

15                 “(1) *IN GENERAL.—Not later than 1 year after*  
16                 *the date of enactment of the FDA Food Safety Mod-*  
17                 *ernization Act, the Secretary shall promulgate regula-*  
18                 *tions to provide for the content of the foreign supplier*  
19                 *verification program established under subsection (a).*  
20                 *Such regulations shall, as appropriate, include a*  
21                 *process for verification by an importer, with respect*  
22                 *to each foreign supplier from which it obtains food,*  
23                 *that the imported food is produced in compliance*  
24                 *with the requirements of section 418 or 419, as appro-*

1        *appropriate, and is not adulterated under section 402 or*  
2        *misbranded under section 403(w).*

3            “(2) *VERIFICATION.*—*The regulations under*  
4        *paragraph (1) shall require that the foreign supplier*  
5        *verification program of each importer be adequate to*  
6        *provide assurances that each foreign supplier to the*  
7        *importer produces the imported food employing proc-*  
8        *esses and procedures, including risk-based reasonably*  
9        *appropriate preventive controls, equivalent in pre-*  
10       *venting adulteration and reducing hazards to those*  
11       *required by section 418 or section 419, as appro-*  
12       *priate.*

13            “(3) *ACTIVITIES.*—*Verification activities under a*  
14        *foreign supplier verification program under this sec-*  
15        *tion may include monitoring records for shipments,*  
16        *lot-by-lot certification of compliance, annual on-site*  
17        *inspections, checking the hazard analysis and risk-*  
18        *based preventive control plan of the foreign supplier,*  
19        *and periodically testing and sampling shipments.*

20            “(d) *RECORD MAINTENANCE AND ACCESS.*—*Records of*  
21        *an importer related to a foreign supplier verification pro-*  
22        *gram shall be maintained for a period of not less than 2*  
23        *years and shall be made available promptly to a duly au-*  
24        *thorized representative of the Secretary upon request.*



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

8                   “(1) *The Seafood Hazard Analysis Critical Con-*  
9 *trol Points Program of the Food and Drug Adminis-*  
10 *tration.*

11                   “(2) *The Juice Hazard Analysis Critical Control*  
12 *Points Program of the Food and Drug Administra-*  
13 *tion.*

14                   “(3) *The Thermally Processed Low-Acid Foods*  
15 *Packaged in Hermetically Sealed Containers stand-*  
16 *ards of the Food and Drug Administration (or any*  
17 *successor standards).*

18           “(f) *PUBLICATION OF LIST OF PARTICIPANTS.*—*The*  
19 *Secretary shall publish and maintain on the Internet Web*  
20 *site of the Food and Drug Administration a current list*  
21 *that includes the name of, location of, and other informa-*  
22 *tion deemed necessary by the Secretary about, importers*  
23 *participating under this section.”.*

1       (b) *PROHIBITED ACT.*—Section 301 (21 U.S.C. 331),  
 2 as amended by section 207, is amended by adding at the  
 3 end the following:

4       “(yy) The importation or offering for importation of  
 5 a food if the importer (as defined in section 805) does not  
 6 have in place a foreign supplier verification program in  
 7 compliance with such section 805.”.

8       (c) *IMPORTS.*—Section 801(a) (21 U.S.C. 381(a)) is  
 9 amended by adding “or the importer (as defined in section  
 10 805) is in violation of such section 805” after “or in viola-  
 11 tion of section 505”.

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

15 **SEC. 302. VOLUNTARY QUALIFIED IMPORTER PROGRAM.**

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

18 **“SEC. 806. VOLUNTARY QUALIFIED IMPORTER PROGRAM.**

19       “(a) *IN GENERAL.*—Beginning not later than 1 year  
 20 after the date of enactment of the FDA Food Safety Mod-  
 21 ernization Act, the Secretary shall—

22               “(1) establish a program, in consultation with  
 23 the Secretary of Homeland Security, to provide for  
 24 the expedited review and importation of food offered

1       *for importation by importers who have voluntarily*  
2       *agreed to participate in such program; and*

3               “(2) *issue a guidance document related to par-*  
4       *ticipation and compliance with such program.*

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

9       “(c) *ELIGIBILITY.—Eligibility shall be limited to an*  
10       *importer offering food for importation from a facility that*  
11       *has a certification described in section 809(b). In reviewing*  
12       *the applications and making determinations on such re-*  
13       *quests, the Secretary shall consider the risk of the food to*  
14       *be imported based on factors, such as the following:*

15               “(1) *The nature of the food to be imported.*

16               “(2) *The compliance history of the foreign sup-*  
17       *plier.*

18               “(3) *The capability of the regulatory system of*  
19       *the country of export to ensure compliance with*  
20       *United States food safety standards.*

21               “(4) *The compliance of the importer with the re-*  
22       *quirements of section 805.*

23               “(5) *The recordkeeping, testing, inspections and*  
24       *audits of facilities, traceability of articles of food,*

1        *temperature controls, and sourcing practices of the*  
2        *importer.*

3            “(6) *The potential risk for intentional adultera-*  
4        *tion of the food.*

5            “(7) *Any other factor that the Secretary deter-*  
6        *mines appropriate.*

7            “(d) *REVIEW AND REVOCATION.—Any importer quali-*  
8        *fied by the Secretary in accordance with the eligibility cri-*  
9        *teria set forth in this section shall be reevaluated not less*  
10       *often than once every 3 years and the Secretary shall*  
11       *promptly revoke the qualified importer status of any im-*  
12       *porter found not to be in compliance with such criteria.*

13          “(e) *NOTICE OF INTENT TO PARTICIPATE.—An im-*  
14       *porter that intends to participate in the program under this*  
15       *section in a fiscal year shall submit a notice to the Sec-*  
16       *retary of such intent at time and in a manner established*  
17       *by the Secretary.*

18          “(f) *FALSE STATEMENTS.—Any statement or represen-*  
19       *tation made by an importer to the Secretary shall be subject*  
20       *to section 1001 of title 18, United States Code.*

21          “(g) *DEFINITION.—For purposes of this section, the*  
22       *term ‘importer’ means the person that brings food, or causes*  
23       *food to be brought, from a foreign country into the customs*  
24       *territory of the United States.’’.*

1 **SEC. 303. AUTHORITY TO REQUIRE IMPORT CERTIFI-**  
2 **CATIONS FOR FOOD.**

3 (a) *IN GENERAL.*—Section 801(a) (21 U.S.C. 381(a))  
4 is amended by inserting after the third sentence the fol-  
5 lowing: “With respect to an article of food, if importation  
6 of such food is subject to, but not compliant with, the re-  
7 quirement under subsection (q) that such food be accom-  
8 panied by a certification or other assurance that the food  
9 meets some or all applicable requirements of this Act, then  
10 such article shall be refused admission.”.

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

14 “(q) *CERTIFICATIONS CONCERNING IMPORTED*  
15 *FOODS.*—

16 “(1) *IN GENERAL.*—The Secretary, based on pub-  
17 lic health considerations, including risks associated  
18 with the food or its place of origin, may require as  
19 a condition of granting admission to an article of  
20 food imported or offered for import into the United  
21 States, that an entity specified in paragraph (2) pro-  
22 vide a certification or such other assurances as the  
23 Secretary determines appropriate that the article of  
24 food complies with some or all applicable require-  
25 ments of this Act, as specified by the Secretary. Such  
26 certification or assurances may be provided in the

1 *form of shipment-specific certificates, a listing of cer-*  
2 *tified entities, or in such other form as the Secretary*  
3 *may specify. Such certification shall be used for des-*  
4 *ignated food imported from countries with which the*  
5 *Food and Drug Administration has an agreement to*  
6 *establish a certification program.*

7 “(2) *CERTIFYING ENTITIES.*—*For purposes of*  
8 *paragraph (1), entities that shall provide the certifi-*  
9 *cation or assurances described in such paragraph*  
10 *are—*

11 “(A) *an agency or a representative of the*  
12 *government of the country from which the article*  
13 *of food at issue originated, as designated by such*  
14 *government or the Secretary; or*

15 “(B) *such other persons or entities accred-*  
16 *ited pursuant to section 809 to provide such cer-*  
17 *tification or assurance.*

18 “(3) *RENEWAL AND REFUSAL OF CERTIFI-*  
19 *CATIONS.*—*The Secretary may—*

20 “(A) *require that any certification or other*  
21 *assurance provided by an entity specified in*  
22 *paragraph (2) be renewed by such entity at such*  
23 *times as the Secretary determines appropriate;*  
24 *and*

1           “(B) refuse to accept any certification or  
2           assurance if the Secretary determines that such  
3           certification or assurance is not valid or reliable.

4           “(4) *ELECTRONIC SUBMISSION.*—The Secretary  
5           shall provide for the electronic submission of certifi-  
6           cations under this subsection.

7           “(5) *FALSE STATEMENTS.*—Any statement or  
8           representation made by an entity described in para-  
9           graph (2) to the Secretary shall be subject to section  
10          1001 of title 18, United States Code.”.

11          (c) *CONFORMING TECHNICAL AMENDMENT.*—Section  
12          801(b) (21 U.S.C. 381(b)) is amended in the second sentence  
13          by striking “with respect to an article included within the  
14          provision of the fourth sentence of subsection (a)” and in-  
15          serting “with respect to an article described in subsection  
16          (a) relating to the requirements of sections 760 or 761,”.

17          (d) *NO LIMIT ON AUTHORITY.*—Nothing in the amend-  
18          ments made by this section shall limit the authority of the  
19          Secretary to conduct inspections of imported food or to take  
20          such other steps as the Secretary deems appropriate to de-  
21          termine the admissibility of imported food.

22          **SEC. 304. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.**

23          (a) *IN GENERAL.*—Section 801(m)(1) (21 U.S.C.  
24          381(m)(1)) is amended by inserting “any country to which

1 *the article has been refused entry;*” after “*the country from*  
2 *which the article is shipped;*”.

3 (b) *REGULATIONS.*—Not later than 120 days after the  
4 date of enactment of this Act, the Secretary shall issue an  
5 interim final rule amending subpart I of part 1 of title  
6 21, Code of Federal Regulations, to implement the amend-  
7 ment made by this section.

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

11 **SEC. 305. REVIEW OF A REGULATORY AUTHORITY OF A FOR-**  
12 **EIGN COUNTRY.**

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

15 **“SEC. 807. REVIEW OF A REGULATORY AUTHORITY OF A**  
16 **FOREIGN COUNTRY.**

17 “The Secretary may review information from a coun-  
18 try outlining the statutes, regulations, standards, and con-  
19 trols of such country, and conduct on-site audits in such  
20 country to verify the implementation of those statutes, regu-  
21 lations, standards, and controls. Based on such review, the  
22 Secretary shall determine whether such country can provide  
23 reasonable assurances that the food supply of the country  
24 meets or exceeds the safety of food manufactured, processed,  
25 packed, or held in the United States.”.



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

3 (a) *IN GENERAL.*—*The Secretary shall, not later than*  
4 *2 years of the date of enactment of this Act, develop a com-*  
5 *prehensive plan to expand the technical, scientific, and reg-*  
6 *ulatory capacity of foreign governments, and their respec-*  
7 *tive food industries, from which foods are exported to the*  
8 *United States.*

9 (b) *CONSULTATION.*—*In developing the plan under*  
10 *subsection (a), the Secretary shall consult with the Sec-*  
11 *retary of Agriculture, Secretary of State, Secretary of the*  
12 *Treasury, the United States Trade Representative, and the*  
13 *Secretary of Commerce, representatives of the food industry,*  
14 *appropriate foreign government officials, nongovernmental*  
15 *organizations that represent the interests of consumers, and*  
16 *other stakeholders.*

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

19 (1) *Recommendations for bilateral and multilat-*  
20 *eral arrangements and agreements, including provi-*  
21 *sions to provide for responsibility of exporting coun-*  
22 *tries to ensure the safety of food.*

23 (2) *Provisions for secure electronic data sharing.*

24 (3) *Provisions for mutual recognition of inspec-*  
25 *tion reports.*

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

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

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

8           (d) *RULE OF CONSTRUCTION.*—*Nothing in this section*  
9           *shall be construed to affect the regulation of dietary supple-*  
10           *ments under the Dietary Supplement Health and Edu-*  
11           *cation Act of 1994 (Public Law 103–417).*

12   **SEC. 307. INSPECTION OF FOREIGN FOOD FACILITIES.**

13           *Chapter VIII (21 U.S.C. 381 et seq.), as amended by*  
14           *section 305, is amended by inserting at the end the fol-*  
15           *lowing:*

16   **“SEC. 808. INSPECTION OF FOREIGN FOOD FACILITIES.**

17           **“(a) INSPECTION.**—*The Secretary—*

18                   **“(1)** *may enter into arrangements and agree-*  
19                   *ments with foreign governments to facilitate the in-*  
20                   *spection of foreign facilities registered under section*  
21                   **415; and**

22                   **“(2)** *shall direct resources to inspections of for-*  
23                   *ign facilities, suppliers, and food types, especially*  
24                   *such facilities, suppliers, and food types that present*  
25                   *a high risk (as identified by the Secretary), to help*



1           “(2) *AUDIT AGENT.*—*The term ‘audit agent’*  
2           *means an individual who is qualified to conduct food*  
3           *safety audits, and who may be an employee or an*  
4           *agent of a third-party auditor.*

5           “(3) *ACCREDITATION BODY.*—*The term ‘accredi-*  
6           *tation body’ means a recognized authority that per-*  
7           *forms accreditation of third-party auditors and audit*  
8           *agents.*

9           “(4) *ACCREDITED THIRD-PARTY AUDITOR.*—*The*  
10           *term ‘accredited third-party auditor’ means a third-*  
11           *party auditor accredited by an accreditation body*  
12           *under this section.*

13           “(5) *CONSULTATIVE AUDIT.*—*The term ‘consult-*  
14           *ative audit’ means an audit of an eligible entity—*

15                   “(A) *to determine whether such entity is in*  
16                   *compliance with the provisions of this Act and*  
17                   *with applicable industry standards and prac-*  
18                   *tices; and*

19                   “(B) *the results of which are for internal fa-*  
20                   *cility purposes only.*

21           “(6) *ELIGIBLE ENTITY.*—*The term ‘eligible enti-*  
22           *ty’ means a foreign entity, including a foreign facil-*  
23           *ity registered under section 415, in the food import*  
24           *supply chain that chooses to be audited by an accred-*  
25           *ited third-party auditor or audit agent.*

1           “(7) *REGULATORY AUDIT.*—The term ‘regulatory  
2     *audit*’ means an audit of an eligible entity—

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

5           “(B) the results of which determine—

6           “(i) whether an entity is eligible to re-  
7     ceive a certification under section 801(q);  
8     and

9           “(ii) whether the entity is eligible to  
10    participate in the voluntary qualified im-  
11    porter program under section 806.

12          “(8) *THIRD-PARTY AUDITOR.*—The term ‘third-  
13     party auditor’ means a foreign government, foreign  
14     cooperative, or any other qualified third party, as the  
15     Secretary determines appropriate, that conducts au-  
16     dits of eligible entities to certify that such eligible en-  
17     tities meet the applicable requirements of this section.

18          “(b) *ACCREDITATION SYSTEM.*—

19           “(1) *ACCREDITATION BODIES.*—

20           “(A) *RECOGNITION OF ACCREDITATION BOD-*  
21     *IES.*—

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

1           *recognition of accreditation bodies that ac-*  
2           *credit third-party auditors and audit*  
3           *agents to certify that eligible entities meet*  
4           *the applicable requirements of this Act.*

5           “(ii) *DIRECT ACCREDITATION.*—*If, by*  
6           *the date that is 1 year after the date of es-*  
7           *tablishment of the system described in*  
8           *clause (i), the Secretary has not identified*  
9           *and recognized an accreditation body to*  
10          *meet the requirements of this section, the*  
11          *Secretary may directly accredit third-party*  
12          *auditors and audit agents.*

13          “(B) *NOTIFICATION.*—*Each accreditation*  
14          *body recognized by the Secretary shall submit to*  
15          *the Secretary a list of all accredited third-party*  
16          *auditors and audit agents accredited by such*  
17          *body.*

18          “(C) *REVOCATION OF RECOGNITION AS AN*  
19          *ACCREDITATION BODY.*—*The Secretary shall*  
20          *promptly revoke the recognition of any accredita-*  
21          *tion body found not to be in compliance with the*  
22          *requirements of this section.*

23          “(2) *MODEL ACCREDITATION STANDARDS.*—*The*  
24          *Secretary shall develop model standards, including*  
25          *audit report requirements, and each recognized ac-*

1        *creditation body shall ensure that third-party audi-*  
2        *tors and audit agents meet such standards in order*  
3        *to qualify as an accredited third-party auditor or*  
4        *audit agent under this section. In developing the*  
5        *model standards, the Secretary shall look to standards*  
6        *in place on the date of the enactment of this section*  
7        *for guidance, to avoid unnecessary duplication of ef-*  
8        *forts and costs.*

9        “(c) *THIRD-PARTY AUDITORS AND AUDIT AGEN-*  
10       *CIES.—*

11                “(1) *REQUIREMENTS FOR ACCREDITATION AS A*  
12        *THIRD-PARTY AUDITOR OR AUDIT AGENT.—*

13                        “(A) *FOREIGN GOVERNMENTS.—*Prior to ac-  
14        *crediting a foreign government as an accredited*  
15        *third-party auditor, the accreditation body (or,*  
16        *in the case of direct accreditation under sub-*  
17        *section (b)(1)(A)(ii), the Secretary) shall perform*  
18        *such reviews and audits of food safety programs,*  
19        *systems, and standards of the government as the*  
20        *Secretary deems necessary to determine that the*  
21        *foreign government is capable of adequately en-*  
22        *sureing that eligible entities certified by such gov-*  
23        *ernment meet the requirements of this Act with*  
24        *respect to food manufactured, processed, packed,*  
25        *or held for import into the United States.*

1           “(B) *FOREIGN COOPERATIVES AND OTHER*  
2           *THIRD PARTIES.*—Prior to accrediting a foreign  
3           cooperative that aggregates the products of grow-  
4           ers or processors, or any other third party that  
5           the Secretary determines appropriate to be an  
6           accredited third-party auditor or audit agent,  
7           the accreditation body (or, in the case of direct  
8           accreditation under subsection (b)(1)(A)(ii), the  
9           Secretary) shall perform such reviews and audits  
10          of the training and qualifications of auditors  
11          used by that cooperative or party and conduct  
12          such reviews of internal systems and such other  
13          investigation of the cooperative or party as the  
14          Secretary deems necessary to determine that each  
15          eligible entity certified by the cooperative or  
16          party has systems and standards in use to en-  
17          sure that such entity meets the requirements of  
18          this Act.

19          “(2) *REQUIREMENT TO ISSUE CERTIFICATION OF*  
20          *ELIGIBLE ENTITIES.*—

21                 “(A) *IN GENERAL.*—An accreditation body  
22                 (or, in the case of direct accreditation under sub-  
23                 section (b)(1)(A)(ii), the Secretary) may not ac-  
24                 credit a third-party auditor or audit agent un-  
25                 less such third-party auditor or audit agent



1           *agrees to issue a written and electronic certifi-*  
2           *cation to accompany each food shipment for im-*  
3           *port into the United States from an eligible enti-*  
4           *ty certified by the third-party auditor or audit*  
5           *agent, subject to requirements set forth by the*  
6           *Secretary. Such written certification may be in-*  
7           *cluded with other documentation regarding such*  
8           *food shipment. The Secretary shall consider such*  
9           *certificates when targeting inspection resources*  
10          *under section 421.*

11           “(B) *PURPOSE OF CERTIFICATION.*—*The*  
12          *Secretary shall use evidence of certification pro-*  
13          *vided by accredited third-party auditors and*  
14          *audit agents to—*

15                   “(i) *determine the eligibility of an im-*  
16                   *porter to receive a certification under sec-*  
17                   *tion 801(q); and*

18                   “(ii) *determine the eligibility of an im-*  
19                   *porter to participate in the voluntary quali-*  
20                   *fied importer program under section 806.*

21          “(3) *AUDIT REPORT REQUIREMENTS.*—

22                   “(A) *REQUIREMENTS IN GENERAL.*—*As a*  
23          *condition of accreditation, an accredited third-*  
24          *party auditor or audit agent shall prepare the*  
25          *audit report for an audit, in a form and manner*

1           *designated by the Secretary, which shall in-*  
2           *clude—*

3                   “(i) *the identity of the persons at the*  
4                   *audited eligible entity responsible for com-*  
5                   *pliance with food safety requirements;*

6                   “(ii) *the dates of the audit;*

7                   “(iii) *the scope of the audit; and*

8                   “(iv) *any other information required*  
9                   *by the Secretary that relate to or may influ-*  
10                   *ence an assessment of compliance with this*  
11                   *Act.*

12                   “(B) *SUBMISSION OF REPORTS TO THE SEC-*  
13                   *RETARY.—*

14                   “(i) *IN GENERAL.—Following any ac-*  
15                   *creditation of a third-party auditor or*  
16                   *audit agent, the Secretary may, at any*  
17                   *time, require the accredited third-party*  
18                   *auditor or audit agent to submit to the Sec-*  
19                   *retary an onsite audit report and such other*  
20                   *reports or documents required as part of the*  
21                   *audit process, for any eligible entity cer-*  
22                   *tified by the third-party auditor or audit*  
23                   *agent. Such report may include documenta-*  
24                   *tion that the eligible entity is in compliance*

1           with any applicable registration require-  
2           ments.

3           “(ii) *LIMITATION.*—The requirement  
4           under clause (i) shall not include any re-  
5           port or other documents resulting from a  
6           consultative audit by the accredited third-  
7           party auditor or audit agent, except that  
8           the Secretary may access the results of a  
9           consultative audit in accordance with sec-  
10          tion 414.

11          “(4) *REQUIREMENTS OF AUDIT AGENTS.*—

12           “(A) *RISKS TO PUBLIC HEALTH.*—If, at  
13           any time during an audit, an accredited audit  
14           agent discovers a condition that could cause or  
15           contribute to a serious risk to the public health,  
16           the audit agent shall immediately notify the Sec-  
17           retary of—

18                   “(i) the identification of the eligible en-  
19                   tity subject to the audit; and

20                   “(ii) such condition.

21           “(B) *TYPES OF AUDITS.*—An accredited  
22           audit agent may perform consultative and regu-  
23           latory audits of eligible entities.

24           “(C) *LIMITATIONS.*—An accredited audit  
25           agent may not perform a regulatory audit of an

1           *eligible entity if such agent has performed a con-*  
2           *sultative audit or a regulatory audit of such eli-*  
3           *gible entity during the previous 24-month pe-*  
4           *riod.*

5           “(5) *CONFLICTS OF INTEREST.*—

6                   “(A) *THIRD-PARTY AUDITORS.*—*An accred-*  
7                   *ited third-party auditor shall—*

8                           “(i) *not be owned, managed, or con-*  
9                           *trolled by any person that owns or operates*  
10                           *an eligible entity to be certified by such*  
11                           *auditor;*

12                           “(ii) *in carrying out audits of eligible*  
13                           *entities under this section, have procedures*  
14                           *to ensure against the use of any officer or*  
15                           *employee of such auditor that has a finan-*  
16                           *cial conflict of interest regarding an eligible*  
17                           *entity to be certified by such auditor; and*

18                           “(iii) *annually make available to the*  
19                           *Secretary disclosures of the extent to which*  
20                           *such auditor and the officers and employees*  
21                           *of such auditor have maintained compliance*  
22                           *with clauses (i) and (ii) relating to finan-*  
23                           *cial conflicts of interest.*

24                   “(B) *AUDIT AGENTS.*—*An accredited audit*  
25                   *agent shall—*

1           “(i) not own or operate an eligible en-  
2           tity to be certified by such agent;

3           “(ii) in carrying out audits of eligible  
4           entities under this section, have procedures  
5           to ensure that such agent does not have a fi-  
6           nancial conflict of interest regarding an eli-  
7           gible entity to be certified by such agent;  
8           and

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

14          “(C) REGULATIONS.—The Secretary shall  
15          promulgate regulations not later than 18 months  
16          after the date of enactment of the FDA Food  
17          Safety Modernization Act to ensure that there  
18          are protections against conflicts of interest be-  
19          tween an accredited third-party auditor or audit  
20          agent and the eligible entity to be certified by  
21          such auditor or audit agent. Such regulations  
22          shall include—

23                 “(i) requiring that audits performed  
24                 under this section be unannounced;

1           “(ii) a structure to decrease the poten-  
2           tial for conflicts of interest, including tim-  
3           ing and public disclosure, for fees paid by  
4           eligible entities to accredited third-party  
5           auditors or audit agents; and

6           “(iii) appropriate limits on financial  
7           affiliations between an accredited third-  
8           party auditor or audit agent and any per-  
9           son that owns or operates an eligible entity  
10          to be certified by such auditor or audit  
11          agent.

12          “(6) *WITHDRAWAL OF ACCREDITATION.*—*The*  
13          *Secretary shall withdraw accreditation from an ac-*  
14          *credited third-party auditor or audit agent—*

15               “(A) *if food from an eligible entity certified*  
16               *by such third-party auditor or audit agent is*  
17               *linked to an outbreak of human or animal ill-*  
18               *ness;*

19               “(B) *following a performance audit and*  
20               *finding by the Secretary that the third-party*  
21               *auditor or audit agent no longer meets the re-*  
22               *quirements for accreditation; or*

23               “(C) *following a refusal to allow United*  
24               *States officials to conduct such audits and inves-*  
25               *tigations as may be necessary to ensure contin-*

1            *ued compliance with the requirements set forth*  
2            *in this section.*

3            “(7) *NEUTRALIZING COSTS.*—*The Secretary shall*  
4            *establish a method, similar to the method used by the*  
5            *Department of Agriculture, by which accredited third-*  
6            *party auditors and audit agents reimburse the Food*  
7            *and Drug Administration for the work performed to*  
8            *establish and administer the accreditation system*  
9            *under this section. The Secretary shall make oper-*  
10           *ating this program revenue-neutral and shall not gen-*  
11           *erate surplus revenue from such a reimbursement*  
12           *mechanism.*

13           “(d) *RECERTIFICATION OF ELIGIBLE ENTITIES.*—*An*  
14           *eligible entity shall apply for annual recertification by an*  
15           *accredited third-party auditor or audit agent if such enti-*  
16           *ty—*

17                  *“(1) intends to participate in voluntary quali-*  
18                  *fied importer program under section 806; or*

19                  *“(2) must provide to the Secretary a certification*  
20                  *under section 801(q) for any food from such entity.*

21           “(e) *FALSE STATEMENTS.*—*Any statement or rep-*  
22           *resentation made—*

23                  *“(1) by an employee or agent of an eligible enti-*  
24                  *ty to an accredited third-party auditor or audit*  
25                  *agent; or*

1           “(2) by an accredited third-party auditor or an  
2           audit agent to the Secretary,  
3 shall be subject to section 1001 of title 18, United States  
4 Code.

5           “(f) MONITORING.—To ensure compliance with the re-  
6 quirements of this section, the Secretary shall—

7           “(1) periodically, or at least once every 4 years,  
8           reevaluate the accreditation bodies described in sub-  
9           section (b)(1);

10           “(2) periodically, or at least once every 4 years,  
11           audit the performance of each accredited third-party  
12           auditor and audit agent, through the review of audit  
13           reports by such auditors and audit agents, the com-  
14           pliance history as available of eligible entities cer-  
15           tified by such auditors and audit agents, and any  
16           other measures deemed necessary by the Secretary;

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

21           “(4) take any other measures deemed necessary  
22           by the Secretary.

23           “(g) PUBLICLY AVAILABLE REGISTRY.—The Secretary  
24 shall establish a publicly available registry of accreditation  
25 bodies and of accredited third-party auditors and audit



1 *agents, including the name of, contact information for, and*  
2 *other information deemed necessary by the Secretary about*  
3 *such bodies, auditors, and agents.*

4 “(h) *LIMITATIONS.—*

5 “(1) *NO EFFECT ON SECTION 704 INSPECTIONS.—*

6 *The audits performed under this section shall not be*  
7 *considered inspections under section 704.*

8 “(2) *NO EFFECT ON INSPECTION AUTHORITY.—*

9 *Nothing in this section affects the authority of the*  
10 *Secretary to inspect any eligible entity pursuant to*  
11 *this Act.”.*

12 **SEC. 309. FOREIGN OFFICES OF THE FOOD AND DRUG AD-**  
13 **MINISTRATION.**

14 (a) *IN GENERAL.—The Secretary shall establish offices*  
15 *of the Food and Drug Administration in foreign countries*  
16 *selected by the Secretary, to provide assistance to the appro-*  
17 *priate governmental entities of such countries with respect*  
18 *to measures to provide for the safety of articles of food and*  
19 *other products regulated by the Food and Drug Administra-*  
20 *tion exported by such country to the United States, includ-*  
21 *ing by directly conducting risk-based inspections of such ar-*  
22 *ticles and supporting such inspections by such govern-*  
23 *mental entity.*

24 (b) *CONSULTATION.—In establishing the foreign offices*  
25 *described in subsection (a), the Secretary shall consult with*

1 *the Secretary of State and the United States Trade Rep-*  
2 *resentative.*

3       (c) *REPORT.*—*Not later than October 1, 2011, the Sec-*  
4 *retary shall submit to Congress a report on the basis for*  
5 *the selection by the Secretary of the foreign countries in*  
6 *which the Secretary established offices, the progress which*  
7 *such offices have made with respect to assisting the govern-*  
8 *ments of such countries in providing for the safety of arti-*  
9 *cles of food and other products regulated by the Food and*  
10 *Drug Administration exported to the United States, and*  
11 *the plans of the Secretary for establishing additional foreign*  
12 *offices of the Food and Drug Administration, as appro-*  
13 *priate.*

14 **SEC. 310. SMUGGLED FOOD.**

15       (a) *IN GENERAL.*—*Not later than 180 days after the*  
16 *enactment of this Act, the Secretary shall, in consultation*  
17 *with the Secretary of Homeland Security, the Commissioner*  
18 *of Customs and Border Patrol, and the Assistant Secretary*  
19 *for Immigration and Customs Enforcement, develop and*  
20 *implement a strategy to better identify smuggled food and*  
21 *prevent entry of such food into the United States.*

22       (b) *NOTIFICATION TO HOMELAND SECURITY.*—*Not*  
23 *later than 10 days after the Secretary identifies a smuggled*  
24 *food that the Secretary believes would cause serious adverse*  
25 *health consequences or death to humans or animals, the Sec-*

1 *retary shall provide to the Secretary of Homeland Security*  
2 *a notification under section 417(k) of the Federal Food,*  
3 *Drug, and Cosmetic Act (21 U.S.C. 350f(k)) describing the*  
4 *smuggled food and, if available, the names of the individ-*  
5 *uals or entities that attempted to import such food into the*  
6 *United States.*

7 *(c) PUBLIC NOTIFICATION.—If the Secretary—*

8 *(1) identifies a smuggled food;*

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

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

14 *the Secretary shall promptly issue a press release describing*  
15 *that food and shall use other emergency communication or*  
16 *recall networks, as appropriate, to warn consumers and*  
17 *vendors about the potential threat.*

18 *(d) DEFINITION.—In this subsection, the term “smug-*  
19 *gled food” means any food that a person introduces into*  
20 *the United States through fraudulent means or with the in-*  
21 *tent to defraud or mislead.*

1           **TITLE IV—MISCELLANEOUS**  
 2                           **PROVISIONS**

3   **SEC. 401. FUNDING FOR FOOD SAFETY.**

4           (a) *IN GENERAL.*—*There are authorized to be appro-*  
 5 *priated to carry out the activities of the Center for Food*  
 6 *Safety and Applied Nutrition, the Center for Veterinary*  
 7 *Medicine, and related field activities in the Office of Regu-*  
 8 *latory Affairs of the Food and Drug Administration—*

9                   (1) *\$825,000,000 for fiscal year 2010; and*

10                   (2) *such sums as may be necessary for fiscal*  
 11 *years 2011 through 2014.*

12           (b) *INCREASED NUMBER OF FIELD STAFF.*—

13                   (1) *IN GENERAL.*—*To carry out the activities of*  
 14 *the Center for Food Safety and Applied Nutrition, the*  
 15 *Center for Veterinary Medicine, and related field ac-*  
 16 *tivities of the Office of Regulatory Affairs of the Food*  
 17 *and Drug Administration, the Secretary of Health*  
 18 *and Human Services shall increase the field staff of*  
 19 *such Centers and Office with a goal of not fewer*  
 20 *than—*

21                           (A) *3,800 staff members in fiscal year 2010;*

22                           (B) *4,000 staff members in fiscal year 2011;*

23                           (C) *4,200 staff members in fiscal year 2012;*

24                           (D) *4,600 staff members in fiscal year 2013;*

25                           *and*

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

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

5                   (A) provide additional detection of and re-  
6                   sponse to food defense threats; and

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

9   **SEC. 402. WHISTLEBLOWER PROTECTIONS.**

10           Chapter X of the Federal Food, Drug, and Cosmetic  
11   Act (21 U.S.C. 391 et seq.), as amended by section 210,  
12   is further amended by adding at the end the following:

13   **“SEC. 1012. WHISTLEBLOWER PROTECTIONS.**

14           “(a) *IN GENERAL*.—No entity engaged in the manu-  
15   facture, processing, packing, transporting, distribution, re-  
16   ception, holding, or importation of food may discharge an  
17   employee or otherwise discriminate against an employee  
18   with respect to compensation, terms, conditions, or privi-  
19   leges of employment because the employee, whether at the  
20   employee’s initiative or in the ordinary course of the em-  
21   ployee’s duties (or any person acting pursuant to a request  
22   of the employee)—

23                   “(1) provided, caused to be provided, or is about  
24                   to provide or cause to be provided to the employer, the  
25                   Federal Government, or the attorney general of a

1       *State information relating to any violation of, or any*  
2       *act or omission the employee reasonably believes to be*  
3       *a violation of any provision of this Act or any order,*  
4       *rule, regulation, standard, or ban under this Act, or*  
5       *any order, rule, regulation, standard, or ban under*  
6       *this Act;*

7               “(2) *testified or is about to testify in a pro-*  
8       *ceeding concerning such violation;*

9               “(3) *assisted or participated or is about to assist*  
10       *or participate in such a proceeding; or*

11               “(4) *objected to, or refused to participate in, any*  
12       *activity, policy, practice, or assigned task that the*  
13       *employee (or other such person) reasonably believed to*  
14       *be in violation of any provision of this Act, or any*  
15       *order, rule, regulation, standard, or ban under this*  
16       *Act.*

17       “(b) *PROCESS.—*

18               “(1) *IN GENERAL.—A person who believes that*  
19       *he or she has been discharged or otherwise discrimi-*  
20       *nated against by any person in violation of sub-*  
21       *section (a) may, not later than 180 days after the*  
22       *date on which such violation occurs, file (or have any*  
23       *person file on his or her behalf) a complaint with the*  
24       *Secretary of Labor (referred to in this section as the*  
25       *‘Secretary’) alleging such discharge or discrimination*

1 *and identifying the person responsible for such act.*  
2 *Upon receipt of such a complaint, the Secretary shall*  
3 *notify, in writing, the person named in the complaint*  
4 *of the filing of the complaint, of the allegations con-*  
5 *tained in the complaint, of the substance of evidence*  
6 *supporting the complaint, and of the opportunities*  
7 *that will be afforded to such person under paragraph*  
8 *(2).*

9 “(2) *INVESTIGATION.—*

10 “(A) *IN GENERAL.—Not later than 60 days*  
11 *after the date of receipt of a complaint filed*  
12 *under paragraph (1) and after affording the*  
13 *complainant and the person named in the com-*  
14 *plaint an opportunity to submit to the Secretary*  
15 *a written response to the complaint and an op-*  
16 *portunity to meet with a representative of the*  
17 *Secretary to present statements from witnesses,*  
18 *the Secretary shall initiate an investigation and*  
19 *determine whether there is reasonable cause to*  
20 *believe that the complaint has merit and notify,*  
21 *in writing, the complainant and the person al-*  
22 *leged to have committed a violation of subsection*  
23 *(a) of the Secretary’s findings.*

24 “(B) *REASONABLE CAUSE FOUND; PRELIMI-*  
25 *NARY ORDER.—If the Secretary concludes that*

1           *there is reasonable cause to believe that a viola-*  
2           *tion of subsection (a) has occurred, the Secretary*  
3           *shall accompany the Secretary's findings with a*  
4           *preliminary order providing the relief prescribed*  
5           *by paragraph (3)(B). Not later than 30 days*  
6           *after the date of notification of findings under*  
7           *this paragraph, the person alleged to have com-*  
8           *mitted the violation or the complainant may file*  
9           *objections to the findings or preliminary order,*  
10          *or both, and request a hearing on the record. The*  
11          *filing of such objections shall not operate to stay*  
12          *any reinstatement remedy contained in the pre-*  
13          *liminary order. Any such hearing shall be con-*  
14          *ducted expeditiously. If a hearing is not re-*  
15          *quested in such 30-day period, the preliminary*  
16          *order shall be deemed a final order that is not*  
17          *subject to judicial review.*

18                   “(C) *DISMISSAL OF COMPLAINT.—*

19                           “(i) *STANDARD FOR COMPLAINANT.—*

20                           *The Secretary shall dismiss a complaint*  
21                           *filed under this subsection and shall not*  
22                           *conduct an investigation otherwise required*  
23                           *under subparagraph (A) unless the com-*  
24                           *plainant makes a prima facie showing that*  
25                           *any behavior described in paragraphs (1)*



1 through (4) of subsection (a) was a contrib-  
2 uting factor in the unfavorable personnel  
3 action alleged in the complaint.

4 “(ii) *STANDARD FOR EMPLOYER.*—Not-  
5 withstanding a finding by the Secretary  
6 that the complainant has made the showing  
7 required under clause (i), no investigation  
8 otherwise required under subparagraph (A)  
9 shall be conducted if the employer dem-  
10 onstrates, by clear and convincing evidence,  
11 that the employer would have taken the  
12 same unfavorable personnel action in the  
13 absence of that behavior.

14 “(iii) *VIOLATION STANDARD.*—The Sec-  
15 retary may determine that a violation of  
16 subsection (a) has occurred only if the com-  
17 plainant demonstrates that any behavior  
18 described in paragraphs (1) through (4) of  
19 subsection (a) was a contributing factor in  
20 the unfavorable personnel action alleged in  
21 the complaint.

22 “(iv) *RELIEF STANDARD.*—Relief may  
23 not be ordered under subparagraph (A) if  
24 the employer demonstrates by clear and con-  
25 vincing evidence that the employer would

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

3           “(3) *FINAL ORDER.*—

4           “(A) *IN GENERAL.*—*Not later than 120*  
5           *days after the date of conclusion of any hearing*  
6           *under paragraph (2), the Secretary shall issue a*  
7           *final order providing the relief prescribed by this*  
8           *paragraph or denying the complaint. At any*  
9           *time before issuance of a final order, a pro-*  
10           *ceeding under this subsection may be terminated*  
11           *on the basis of a settlement agreement entered*  
12           *into by the Secretary, the complainant, and the*  
13           *person alleged to have committed the violation.*

14           “(B) *CONTENT OF ORDER.*—*If, in response*  
15           *to a complaint filed under paragraph (1), the*  
16           *Secretary determines that a violation of sub-*  
17           *section (a) has occurred, the Secretary shall*  
18           *order the person who committed such violation—*

19                   “(i) *to take affirmative action to abate*  
20                   *the violation;*

21                   “(ii) *to reinstate the complainant to*  
22                   *his or her former position together with*  
23                   *compensation (including back pay) and re-*  
24                   *store the terms, conditions, and privileges*  
25                   *associated with his or her employment; and*

1                   “(iii) to provide compensatory dam-  
2                   ages to the complainant.

3                   “(C) *PENALTY.*—If such an order is issued  
4                   under this paragraph, the Secretary, at the re-  
5                   quest of the complainant, shall assess against the  
6                   person against whom the order is issued a sum  
7                   equal to the aggregate amount of all costs and  
8                   expenses (including attorneys’ and expert witness  
9                   fees) reasonably incurred, as determined by the  
10                  Secretary, by the complainant for, or in connec-  
11                  tion with, the bringing of the complaint upon  
12                  which the order was issued.

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

19                  “(4) *ACTION IN COURT.*—

20                  “(A) *IN GENERAL.*—If the Secretary has not  
21                  issued a final decision within 210 days after the  
22                  filing of the complaint, or within 90 days after  
23                  receiving a written determination, the complain-  
24                  ant may bring an action at law or equity for de  
25                  novo review in the appropriate district court of

1           *the United States with jurisdiction, which shall*  
2           *have jurisdiction over such an action without re-*  
3           *gard to the amount in controversy, and which*  
4           *action shall, at the request of either party to such*  
5           *action, be tried by the court with a jury. The*  
6           *proceedings shall be governed by the same legal*  
7           *burdens of proof specified in paragraph (2)(C).*

8           “(B) *RELIEF.*—*The court shall have juris-*  
9           *isdiction to grant all relief necessary to make the*  
10           *employee whole, including injunctive relief and*  
11           *compensatory damages, including—*

12                   “(i) *reinstatement with the same se-*  
13                   *niority status that the employee would have*  
14                   *had, but for the discharge or discrimina-*  
15                   *tion;*

16                   “(ii) *the amount of back pay, with in-*  
17                   *terest; and*

18                   “(iii) *compensation for any special*  
19                   *damages sustained as a result of the dis-*  
20                   *charge or discrimination, including litiga-*  
21                   *tion costs, expert witness fees, and reason-*  
22                   *able attorney’s fees.*

23           “(5) *REVIEW.*—

24                   “(A) *IN GENERAL.*—*Unless the complainant*  
25           *brings an action under paragraph (4), any per-*

1        *son adversely affected or aggrieved by a final*  
2        *order issued under paragraph (3) may obtain re-*  
3        *view of the order in the United States Court of*  
4        *Appeals for the circuit in which the violation,*  
5        *with respect to which the order was issued, alleg-*  
6        *edly occurred or the circuit in which the com-*  
7        *plainant resided on the date of such violation.*  
8        *The petition for review must be filed not later*  
9        *than 60 days after the date of the issuance of the*  
10       *final order of the Secretary. Review shall con-*  
11       *form to chapter 7 of title 5, United States Code.*  
12       *The commencement of proceedings under this*  
13       *subparagraph shall not, unless ordered by the*  
14       *court, operate as a stay of the order.*

15                *“(B) NO JUDICIAL REVIEW.—An order of*  
16        *the Secretary with respect to which review could*  
17        *have been obtained under subparagraph (A) shall*  
18        *not be subject to judicial review in any criminal*  
19        *or other civil proceeding.*

20                *“(6) FAILURE TO COMPLY WITH ORDER.—When-*  
21        *ever any person has failed to comply with an order*  
22        *issued under paragraph (3), the Secretary may file a*  
23        *civil action in the United States district court for the*  
24        *district in which the violation was found to occur, or*  
25        *in the United States district court for the District of*

1        *Columbia, to enforce such order. In actions brought*  
2        *under this paragraph, the district courts shall have*  
3        *jurisdiction to grant all appropriate relief including,*  
4        *but not limited to, injunctive relief and compensatory*  
5        *damages.*

6            “(7) *CIVIL ACTION TO REQUIRE COMPLIANCE.—*

7            “(A) *IN GENERAL.—A person on whose be-*  
8        *half an order was issued under paragraph (3)*  
9        *may commence a civil action against the person*  
10       *to whom such order was issued to require com-*  
11       *pliance with such order. The appropriate United*  
12       *States district court shall have jurisdiction,*  
13       *without regard to the amount in controversy or*  
14       *the citizenship of the parties, to enforce such*  
15       *order.*

16           “(B) *AWARD.—The court, in issuing any*  
17       *final order under this paragraph, may award*  
18       *costs of litigation (including reasonable attor-*  
19       *neys’ and expert witness fees) to any party*  
20       *whenever the court determines such award is ap-*  
21       *propriate.*

22           “(c) *EFFECT OF SECTION.—*

23           “(1) *OTHER LAWS.—Nothing in this section pre-*  
24       *empts or diminishes any other safeguards against dis-*  
25       *crimination, demotion, discharge, suspension, threats,*

1        *harassment, reprimand, retaliation, or any other*  
 2        *manner of discrimination provided by Federal or*  
 3        *State law.*

4            “(2) *RIGHTS OF EMPLOYEES.*—*Nothing in this*  
 5        *section shall be construed to diminish the rights,*  
 6        *privileges, or remedies of any employee under any*  
 7        *Federal or State law or under any collective bar-*  
 8        *gaining agreement. The rights and remedies in this*  
 9        *section may not be waived by any agreement, policy,*  
 10       *form, or condition of employment.*

11          “(d) *ENFORCEMENT.*—*Any nondiscretionary duty im-*  
 12       *posed by this section shall be enforceable in a mandamus*  
 13       *proceeding brought under section 1361 of title 28, United*  
 14       *States Code.*

15          “(e) *LIMITATION.*—*Subsection (a) shall not apply with*  
 16       *respect to an employee of an entity engaged in the manufac-*  
 17       *ture, processing, packing, transporting, distribution, recep-*  
 18       *tion, holding, or importation of food who, acting without*  
 19       *direction from such entity (or such entity’s agent), delib-*  
 20       *erately causes a violation of any requirement relating to*  
 21       *any violation or alleged violation of any order, rule, regula-*  
 22       *tion, standard, or ban under this Act.”.*

23        **SEC. 403. JURISDICTION; AUTHORITIES.**

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

1           (1) *alter the jurisdiction between the Secretary of*  
2 *Agriculture and the Secretary of Health and Human*  
3 *Services, under applicable statutes, regulations, or*  
4 *agreements regarding products eligible for voluntary*  
5 *inspection under the Agricultural Marketing Act (7*  
6 *U.S.C. 1621 et seq.);*

7           (2) *alter the jurisdiction between the Adminis-*  
8 *tration of the Alcohol and Tobacco Tax and Trade*  
9 *Bureau and the Secretary of Health and Human*  
10 *Services, under applicable statutes and regulations;*

11           (3) *limit the authority of the Secretary of Health*  
12 *and Human Services to issue regulations related to*  
13 *the safety of food under—*

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

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

20           (4) *impede, minimize, or affect the authority of*  
21 *the Secretary of Agriculture to prevent, control, or*  
22 *mitigate a plant or animal health emergency, or a*  
23 *food emergency or foodborne illness outbreak involving*  
24 *products regulated under the Federal Meat Inspection*  
25 *Act, the Poultry Products Inspection Act, the Egg*



1 *Products Inspection Act, or agreements regarding vol-*  
2 *untary inspection under the Agricultural Marketing*  
3 *Act (7 U.S.C. 1621 et seq.).*

4 **SEC. 404. COMPLIANCE WITH INTERNATIONAL AGREE-**  
5 **MENTS.**

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

11 **SEC. 405. UPDATING GUIDANCE RELATING TO FISH AND**  
12 **FISHERIES PRODUCTS HAZARDS AND CON-**  
13 **TROLS.**

14 *The Secretary shall, not later than 180 days after the*  
15 *date of enactment of this Act, update the Fish and Fisheries*  
16 *Products Hazards and Control Guidance to take into ac-*  
17 *count advances in technology that have occurred since the*  
18 *previous publication of such Guidance by the Secretary.*

19 **SEC. 406. FOOD TRANSPORTATION STUDY.**

20 *The Secretary of Health and Human Services, acting*  
21 *through the Commissioner of Food and Drugs, shall conduct*  
22 *a study of the transportation of food for consumption in*  
23 *the United States, including transportation by air, that in-*  
24 *cludes an examination of the unique needs of rural and*  
25 *frontier areas with regard to the delivery of safe food.*

Calendar No. 247

111<sup>TH</sup> CONGRESS  
1<sup>ST</sup> Session

**S. 510**

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**A BILL**

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

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DECEMBER 18, 2009

Reported with an amendment